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Global Economic Impact of Missing and Low Pesticide Maximum Residue Levels, Vol. 1

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United States International Trade Commission

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Abbreviations and Acronyms

Term	Definition
ABC	Almond Board of California
ADI	acceptable daily intake
AFBF	American Farm Bureau Federation
AIR	Annex I Review program
AMS	Agriculture Marketing Service, USDA
ANVISA	Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency), Brazil
ANZFRMC	Australian New Zealand Food Regulation Ministerial Council
ANZFSC	Australia New Zealand Food Standards Code
AOEL	acceptable operator exposure levels
APC	American Peanut Council
APEC	Asia-Pacific Economic Cooperation
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQSIQ	General Administration of Quality Supervision, Inspection, and Quarantine, China
ARfD	acute reference dose
AS	active substance
ASEAN	Association of Southeast Asian Nations
ASOEX	Fruit Exporters Association of Chile
ASPMI	American Sweet Potato Marketing Institute
AWRI	Australian Wine Research Institute
BCI	Bryant Christie Inc.
BMP	Better Management Practices
BSMI	Bureau of Standards, Metrology, and Inspection, Taiwan
CAA	Consumer Affairs Agency, Japan
CAC	Codex Alimentarius Commission
CAWG	California Association of Winegrape Growers
CCAE	Council of the Codex Alimentarius Europaeus
CCAJ	Chocolate and Cocoa Association of Japan
CCB	California Cherry Board
CCPR	Codex Committee on Pesticide Residues
CCQC	California Citrus Quality Council
CETA	Canada-EU Comprehensive Economic Trade Agreement
CFFA	California Fresh Fruit Association
CI	Cranberry Institute
CIMMYT	International Maize and Wheat Improvement Centre
COA	Council of Agriculture, Taiwan
CRC	California Rice Commission
CRD	Chemicals Regulation Directorate, United Kingdom
CTGC	California Table Grape Commission
CXL	Codex Maximum Residue Level
DDT	dichlorodiphenyltrichloroethane
EAC	East African Community
EC	European Commission
EEAS	European Union External Action Service
EFSA	European Food Safety Authority
EP	European Parliament
EPA	U.S. Environmental Protection Agency
EPRS	European Parliamentary Research Service
EU	European Union

Term	Definition
EWG	Expert Working Group
FAMIC	Food and Agricultural Materials Inspection Center, Japan
FAO	Food and Agricultural Organization of the United Nations
FAS	Foreign Agricultural Service, USDA
FDA	U.S. Food and Drug Administration
FIPMCC	Federal IPM Coordinating Committee (United States)
FSANZ	Food Standards Australia and New Zealand
FSC	Food Safety Commission, Japan
FSSA	Food Safety and Sanitation Act of 2014, Taiwan
GAP	good agricultural practice
GEMS	Global Environment Monitoring System
GJRs	Global Joint Reviews
GM	genetically modified (crops)
GTAP	Global Trade Analysis Project
HCD	Horticultural Crops Directorate, Kenya
HHS	U.S. Department of Health and Human Services
IBAMA	Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis (Brazilian Institute of the Environment and Renewable National Resources), Brazil
ICAMA	Institute for the Control of Agrochemicals, Ministry of Agriculture, China
IPCS	International Programme on Chemical Safety
IPM	integrated pest management
IPM IL	Innovation Lab for Integrated Pest Management
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint Meeting on Pesticide Residues (FAO and WHO)
KEBS	Kenya Bureau of Standards
KEPHIS	Kenya Plant Health Inspectorate Service
LOD	Limit of determination
LOQ	Limit of quantification
MAFF	Ministry of Agriculture, Forestry and Fisheries, Japan
MAPA	Ministério da Agricultura, Pecuária e Abastecimento (Ministry of Agriculture, Livestock, and Supply), Brazil
MARKUP	Market Access Upgrade Programme, EU
MFDS	Ministry of Food and Drug Safety, South Korea
MHLW	Ministry of Health, Labour and Welfare, Japan
MOHW	Ministry of Health and Welfare, Taiwan
MRL	maximum residue limit
NABC	North American Blueberry Council
NAFTA	North American Free Trade Act
NCGA	National Corn Growers Association
NHC	Northwest Horticultural Council
NOEL	no-observed-effect level
NPC	National Potato Council
NRCS	Natural Resources Conservation Service, USDA
NTM	nontariff measure
OECD	Organisation for Economic Co-operation and Development
PAC	Pesticides Advisory Committee, Taiwan
PAFF	European Standing Committee on Plants, Animals, Food, and Feed
PBT	persistent, bioaccumulative, and toxic
PCPA	Pest Control Products Act, Canada
PCPB	Pest Control Products Board, Kenya

Term	Definition
PHI	pre-harvest interval
PIP	Pesticide Initiative Programme, EU
PMRA	Pest Management Regulatory Agency, Canada
POP	persistent organic pollutant
PPC	Pesticide Policy Coalition
ppm	parts per million
PPPs	plant protection products
RASFF	Rapid Alert System for Food and Feed, EU
RMS	Rapporteur Member State
SDA	Secretariat of Agricultural Protection, Brazil
SENASA	National Agricultural and Phytosanitary Service, Peru
SFE	State Phytosanitary Service, Costa Rica
SPS	sanitary and phytosanitary
SSA	Sub-Saharan Africa
TACTRI	Taiwan Agricultural Chemicals and Toxic Substances Research Institute
TBTs	technical barriers to trade
TFDA	Taiwan Food and Drug Administration
TMDI	theoretical maximum daily intake
UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
UN DESA	United Nations Department of Economic and Social Affairs
UNECE	United Nations Economic Commission for Europe
UNEP	United Nations Environment Programme
USAID	U.S. Agency for International Development
USDA	U.S. Department of Agriculture
USGC	U.S. Grains Council
USHIPPC	U.S. Hop Industry Plant Protection Committee
USITC	U.S. International Trade Commission
USSEC	U.S. Soybean Export Council
USTR	U.S. Trade Representative
USW	U.S. Wheat Associates
vPvB	very persistent and very bioaccumulative
WHO	World Health Organization
WI	Wine Institute
WTO	World Trade Organization

Executive Summary

Overview

Plant protection products, including pesticides, are important to agricultural producers working to ensure crop production for growing populations. The use of these pesticides, which include insecticides, fungicides, rodenticides, and herbicides, can leave residues on crops and food products.

Governments seek to regulate pesticide residues to ensure that agricultural products are safe to consume and are not harmful to human, animal, or plant life or health. They require that a pesticide or the active substance in a pesticide be approved for use before establishing a maximum residue level (MRL) for each specific pesticide/crop combination. An MRL is the highest level of a given pesticide's residue on a given crop that is legally tolerated in a government's jurisdiction.[1] Tens of thousands of MRLs exist worldwide, since each MRL is specific to a pesticide/crop combination.

Establishing MRLs is a highly complex and costly endeavor. It involves collecting and evaluating large amounts of crop field and other data in order to perform scientific risk assessments for active substances or ingredients in the pesticides used on specific crops. In light of this, international standard-setting bodies, such as the Codex Alimentarius Commission, establish voluntary MRLs for global use. Governments can choose to adopt these international standard MRLs, in the cases where they exist, or to establish MRLs on their own. Regardless of the method a government uses to establish its MRLs, they generally apply to both domestically produced products and imported ones. In some cases when an MRL does not exist regulators can establish an "import tolerance" by creating an MRL that applies only to imports. In other cases, when an MRL is lower than that of the growing/producing market, regulators may raise existing MRLs to match foreign use patterns. Established MRLs on the same pesticide/crop combinations frequently vary widely from country to country. Moreover, not all pesticide/crop combinations are covered by an established MRL in every market; these never-established MRLs are sometimes referred to as "missing" MRLs.

According to many agricultural exporters in the United States and worldwide, pesticide-related policies in some countries are creating significant challenges to agricultural trade. Farmers are increasingly adjusting production practices in response to evolving policies and regulations governing maximum residue levels of pesticide on agricultural products. These policy and regulatory changes, and the associated uncertainty, can negatively affect farmers' costs as well as their ability to access export markets, which may affect their income.

Stakeholders throughout the world's agricultural supply chains are concerned with the differences in MRLs across markets, including when they are missing or low. However, what constitutes a "missing" or "low" MRL is not strictly defined by the agricultural trade community. Generally, agricultural exporters consider MRLs to be "missing" when a market to which they wish to export does not have an MRL for

[1] This MRL definition is used by Codex Alimentarius (an international standard-setting body discussed later in this chapter) and major agricultural markets, including the United States and the European Union. EPA, "About Pesticide Tolerances," September 16, 2016; Codex, "Maximum Residue Limits (MRLs)," 2018; European Commission, "Maximum Residue Levels" (accessed February 20, 2020).

the pesticide/crop combination that they use/produce. There are several reasons why MRLs may be missing in a particular importing market: for example, a particular pesticide may not be registered in the market for use on any crops, or if the pesticide is registered for use, it may not have established an MRL for a specific crop, or the market may not have adopted an existing Codex MRL for a pesticide/crop combination.

Agricultural exporters may also consider some MRLs to be “low” in destination markets. No specific numerical pesticide residue level cutoff defines what constitutes a low MRL; instead, a “low MRL” is generally understood to be a relative term. Broadly, exporters consider an export market MRL to be low if it is lower than in their home market, lower relative to another export market, or lower relative to Codex. Exporters may also consider an export market MRL to be low if it has been lowered from a previous level or set to a default, which for many markets is set at the analytical limit of quantification (also referred to as the lowest limit of analytical determination). Many participants in global agricultural supply chains report that the MRLs for a number of pesticides that they rely on have been lowered, sometimes sharply and sometimes within a relatively short time period, in a way that may make it difficult for them to continue to produce and supply their goods to consumers abroad.

Differences among MRLs, including when MRLs are missing and low, as well as differences among MRL policies are increasingly affecting trade in a number of ways. Agricultural exporters may not be able to sell their crops to markets where an MRL is set lower than in their domestic market, particularly if the MRL is so low that it is difficult for producers to meet while still protecting their crops from harmful pests and diseases. A missing MRL for a pesticide/crop combination in a given market can mean the pesticide is automatically prohibited for use on a certain crop; the missing MRL can prevent exporters elsewhere from shipping the crop to that market. Finally, shifting or unclear policies in importing markets complicate production and export decisions of farmers who rely on transparency and predictability in the trading system. Exporters and other stakeholders in the agricultural trade community are concerned about a number of aspects of these policies, including the increased activity of global regulators in establishing their own MRL systems; variation in the international and country-specific frameworks guiding the regulation of certain pesticides and the establishment of MRLs; and the resulting differences in MRLs across markets.

The impacts from missing or low MRLs can vary by country and may be particularly problematic for farmers exporting minor or specialty crops, which have fewer existing MRLs. Producers in tropical countries, who face greater pest pressure, may also be particularly affected by these factors. In lower-income countries, producers typically have fewer resources available for addressing these challenges. In addition to the challenges posed by missing and low MRLs, farmers around the world are dealing with the problems of changing pest pressures stemming from pests evolving resistance to pesticides and shifting climate patterns that can increase pest pressures and allow pests to impact new growing areas.

The U.S. Trade Representative (USTR) requested the U.S. International Trade Commission (USITC or Commission) to conduct an investigation and prepare a two-volume report on the global economic impact of pesticide MRLs on farmers around the world. The scope of this investigation is limited to pesticide and MRL policies related to food crops. This first volume of the report includes a broad description of the approaches taken by national and international bodies in setting MRLs. The report then describes regulations and practices governing the use of pesticides and the setting of MRLs in major U.S. agricultural export markets. It further discusses the challenges and concerns faced by industry stakeholders across the agricultural supply chain in meeting export market MRLs, such as when MRLs are missing or low.

Through case studies, this report next examines the costs and effects of MRL compliance and noncompliance for producers in countries representing a range of income classifications, including those in tropical climates where farms are subject to high levels of pest and disease pressure. In response to the USTR's request, the report also includes information on the costs and effects of adopting new pesticides, as well as costs and effects of setting, modifying, or testing for new or existing MRLs in export markets. Finally, the report reviews the costs and effects of missing and low MRLs as assessed in the economic literature. Case studies of U.S. farmers as well as a quantitative analysis of the impact of MRLs on international trade will be presented in the second volume of the study.

The regulation of pesticide residues can be a sensitive subject. It is therefore important to place our findings in this report in context. The United States has long and consistently recognized the right of nations to regulate to protect human, animal, and plant life and health, as well as the environment.[2] In the text of its trade agreements, for example, the United States has recognized as a general objective that each party should determine for itself what level of protection is appropriate for its own people.[3] At the same time, it has also made clear that each party should avoid creating "unnecessary obstacles to trade," should base its decisions on science, and should regulate transparently and in accordance with good regulatory practices.[4]

Pursuant to the USTR's request, this report examines the many challenges and concerns exporting countries face in complying with MRLs, and the costs agricultural producers incur as a result of low and missing MRLs. The Commission was not asked to determine whether various MRLs around the world are science-based, are developed transparently and in accordance with good regulatory practices, or create "unnecessary obstacles" to international trade. Instead, our report is best viewed as helping to answer the relatively more straightforward part of a more difficult question: putting aside whether they are necessary or unnecessary, what kind of "obstacles" (challenges and costs) do missing and low MRLs create, and what is the magnitude of those costs? Thus, this report does not undertake a critique of stringent pesticide regulations. Rather, as requested, it assesses and describes the economic costs and trade effects associated with those regulations. Understanding those costs and effects is important as governments develop and implement the pesticide regulations they consider appropriate to protect human health and the environment.

Maximum Residue Level Policy Approaches

While there is widespread agreement internationally about the importance of protecting both consumer health and the environment, the approaches and policies employed to regulate pesticide use and determine pesticide MRLs on food crops are globally inconsistent. As the needs and expectations of growers, who use pesticides, and consumers, who purchase agricultural products, continue to evolve—in many cases at a faster rate than consensus-based international organizations can accommodate—

[2] See e.g., WTO SPS Agreement, Art. 2; USMCA, Preamble; USMCA, art. 9.3.1(a); The USMCA is the most recently concluded U.S. trade agreement.
[3] See, e.g., USMCA, art. 9.6.4(a).
[4] See, e.g., USMCA, Preamble; USMCA, art. 9.3.1; USMCA, art. 9.6.

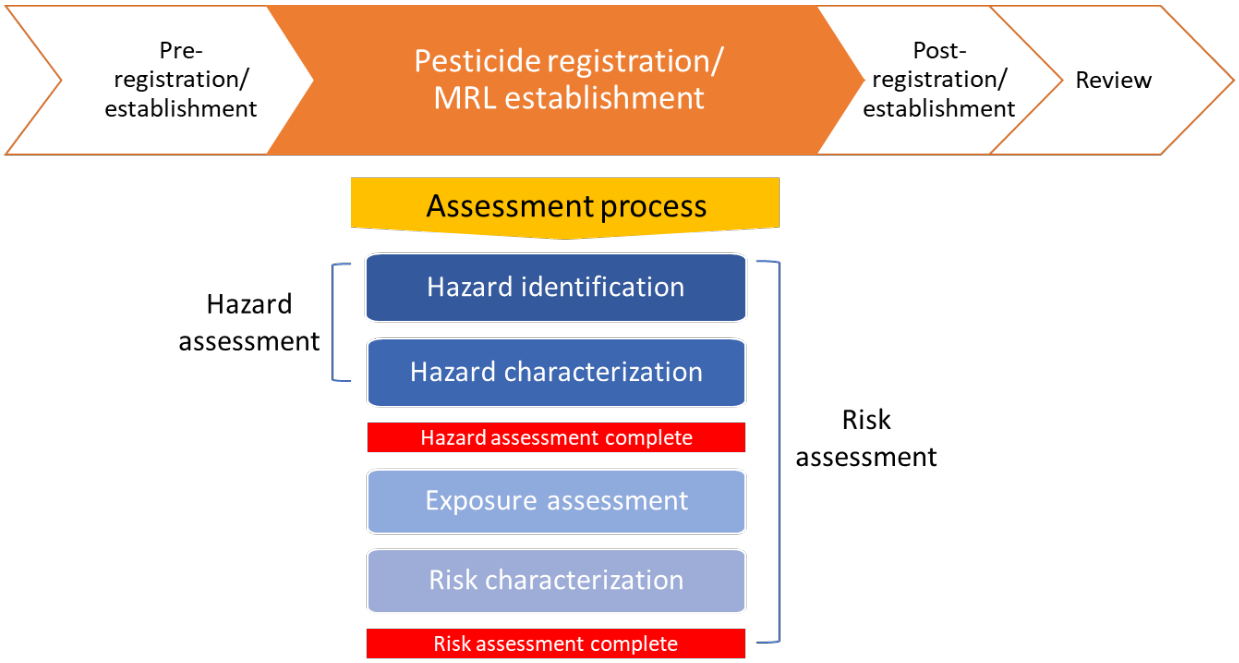
pesticide regulation and MRLs are diverging and becoming more localized. Differences in the way regulators in various countries use a range of criteria to assess the impact of pesticides on human health, animal health, and the environment have led to increasing divergence of MRLs globally over time.

Hazard and risk. In order to determine whether a chemical in a pesticide is safe to use, in what doses, and for which uses, regulators consider the hazard and risk its use may pose to public health and to the environment. Hazard is the intrinsic potential of a substance to cause harm, whereas risk is the probability of harm occurring based on the expected level of exposure. Government authorities register pesticides and establish MRLs through what is called risk analysis. Risk analysis is the process for controlling situations where an organism, system, or (sub)population could be exposed to a hazard. Risk analysis consists of three components: risk assessment, risk management, and risk communication.[5] The first two of these components will be discussed in this section. Risk communication, which is omitted for brevity, is the interactive exchange of information about risks (health and environmental) among risk assessors, risk managers, and the public.

Risk assessment is a science-based process and consists of the four steps shown in figure ES.1 below: (1) hazard identification, (2) hazard characterization, (3) exposure assessment, and (4) risk characterization. A complete risk assessment, therefore, includes an assessment of both hazard and risk. The scientific risk assessment process is the model used by the Codex Alimentarius Commission and its subsidiary organizations, as well as authorities in markets that establish their own positive list systems for MRLs. Risk assessment bodies or organizations are composed of scientists and industry professionals who evaluate assumptions underlying a risk assessment, such as various exposure scenarios. Risk management, on the other hand, may consider not only risk assessment results but also, for example, economic cost-benefit analyses and the feasibility of various options in developing a policy outcome, in consultation with a range of stakeholders.[6] Risk management in food safety is the process of considering different policy options to address the outcomes of risk assessment, with the objective of protecting the consumer.

[5] IPCS, *IPCS Risk Assessment Terminology*, 2004, 12–14.
[6] Codex, *Procedural Manual*, *26th ed*., 2018, 129, 131.

Figure ES.1 Stages of hazard assessments and risk assessments



Source: Compiled by USITC, based on IPCS, *Principles and Methods for the Risk Assessment of Chemicals in Food*, 2009, and FAO, Pesticide Registration Toolkit (accessed March 15, 2020).

Policy approaches to risk management of pesticides. Stakeholders at times use the terms "hazard-based" and "risk-based" to describe risk management approaches to pesticide policies that affect pesticide registrations and MRLs. While there is no standard definition of a "hazard-based policy approach," various characterizations of hazard-based approaches are consistent. Academic studies, for instance, define a "hazard-based" approach as one where the presence of a potentially harmful agent at a detectable level in food is used as the primary basis for risk management action, including regulation.[7] The "hazard-based" approach has also been linked to broader policy approaches such as the "precautionary principle," which can lead to regulatory action in situations of scientific uncertainty to avoid adverse impacts to human health or the environment.[8] A "risk-based" policy approach, on the other hand, is generally understood to consider both a pesticide's potential to cause harm and the degree of risk of exposure to pesticide residues. In other words, basing risk management policy decisions on all four steps of the risk assessment process, including identification and characterization of hazard and assessment of exposure has typically been characterized as following a "risk-based approach."

National regulatory processes are typically nuanced and complicated. Most authorities and regulatory agencies rely on considerations that relate to both hazard and risk when managing pesticide policy. The application of different risk management approaches to pesticide policy has practical implications for the availability and levels of MRLs. Internationally agreed-upon processes require that all four steps of the risk assessment—hazard identification, hazard characterization, exposure assessment, and risk

[7] Barlow et al., "The Role of Hazard- and Risk-Based Approaches," December 2015, 176.
[8] EPRS, "The Precautionary Principle," February 2016, 6–7.

characterization—be completed in establishing MRLs; they consider a hazard assessment by itself as insufficient for setting an MRL.

Codex and other international efforts related to MRLs. A number of international efforts to harmonize MRLs, as well as the policies and practices for setting and reviewing MRLs, are currently underway. The Codex Alimentarius ("Codex") is one of the most widely recognized global efforts to harmonize MRLs and related policies. Codex refers to the collective standards and related documents (guidelines and codes of practice) published by the Codex Alimentarius Commission (CAC), an international standard-setting body jointly overseen by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). The CAC is open to all member nations and associate members of FAO and meets annually with delegations that often include representatives of nations' food industries, consumer organizations, and academic institutions.

Codex has thus become an important international reference point for the establishment of mandatory and voluntary food standards. Codex aims to update its standards, guidelines, and codes of practice regularly to ensure they are consistent with current scientific knowledge. Codex MRLs exist both to protect consumer health and to facilitate international trade. Codex standards are also meant to ensure the use of globally accepted practices in the international trade of foods.

To be binding and fully effective, Codex standards, guidelines, and codes of practice, including MRLs, must be adopted into national legislation or regulations.[9] A number of countries officially default to Codex MRLs in some or all instances where they have not established their own MRLs, and many consider and incorporate Codex standards when establishing their own MRLs. Several industry representatives, however, have expressed concern that countries are increasingly diverging from Codex standards in establishing their own MRLs.

The two primary subsidiary bodies involved in establishing Codex MRLs are the Codex Committee on Pesticide Residues (CCPR) and the Joint Meeting on Pesticide Residues (JMPR). The CCPR consists of representatives of national governments and acts as Codex's risk management body. The CCPR is primarily responsible for recommending MRLs for adoption by the CAC. As the risk assessment body of Codex, the JMPR provides scientific advice to the FAO, the WHO, and the CCPR, and is made up of independent FAO and WHO scientific experts. The JMPR has no approval or registration functions but recommends suitable standards for pesticide residues in food commodities based on internationally recognized scientific risk assessment practices.

The Codex process for setting MRLs has been successful in many respects, and various industry representatives consider Codex MRLs to be valuable. While not all stakeholders agree with the MRLs set by Codex, others have expressed their respect for the scientific process and their support for global harmonization at Codex levels. The inclusivity and open nature of Codex has also been lauded as beneficial to developing countries. At the same time, stakeholders recognize that the Codex MRL-setting process faces challenges as well. The biggest challenge is the length of time that the CAC process requires to set or revise standards, as it can take several years—even though, in part, this is because the process is well defined, open, and transparent. The lack of capacity and resources at JMPR is also a key challenge that has been identified by industry groups.

[9] FAO and WHO, *Codex Alimentarius: Understanding Codex,* 2016, 7, 13, 22.

Other international efforts to harmonize MRLs exist as well. Regional organizations such as the Asia-Pacific Economic Cooperation (APEC), the Association of Southeast Asian Nations (ASEAN), and the East African Community (EAC), as well as international organizations such as the Organisation for Economic Co-operation and Development (OECD), have all devoted effort and resources to harmonize MRLs between their member countries. In particular, a program developed by the OECD, the OECD MRL Calculator, aims to harmonize the way MRL calculations are made across countries by providing a suggested MRL based on the residue data from field trials as input by risk assessors. This tool helps harmonize the calculations used by markets to determine MRLs after field trial data are submitted. The OECD calculator has been used to develop some MRLs in Codex, the European Union (EU), the United States, and Canada, among others.

Another international effort that affects MRLs is the promotion of lower- or reduced-risk pesticides. Scientific advancement in the field of pesticides has led to the development of lower- or reduced-risk pesticides that break down quickly after application and have lower toxicity to nontarget organisms. The United States government has promoted the use of such pesticides around the world through various programs. For instance, the U.S.- funded Interregional Research Project No. 4 (IR-4) project supports the registration of newer, often reduced-risk pesticides in the United States and in developing countries by conducting pesticide studies required for registering pesticides. Through the U.S. Agency for International Development and U.S. Department of Agriculture, the United States also globally promotes the adoption of integrated pest management practices, which emphasize the use of lower-risk pest control methods.

Maximum Residue Level Practices in Major U.S. Export Markets

Many countries—including key U.S. export markets for agricultural goods—have moved away from deferring to the Codex system and have instead developed “positive list” systems, in which governments establish their own independent lists of MRLs for pesticide/crop combinations. In developing these positive lists, regulators may to varying degrees consider and incorporate Codex standards. This section examines the MRL-setting process for several major markets for U.S. agricultural exports, including Australia, Brazil, Canada, China, the EU, Japan, South Korea, and Taiwan. Coinciding with the development of their positive list systems, regulators in these markets have developed regulations, requirements, practices, processes, and timelines for the approval and registration of active substances used in pesticides, as well as for establishing MRLs and import tolerances. Each of these systems is complex, and though they have much in common, none is identical to or completely harmonized with the others.

Australia has operated its current MRL system for nearly 30 years and has some unique characteristics that distinguish it from other major U.S. agricultural export markets. One is that two countries—Australia and New Zealand—share some MRL regulatory responsibilities in certain instances that facilitate MRL processes and bilateral trade. Another is that certain aspects of Australia’s MRL process, such as yearly updates to its MRLs, ease the process for both growers and pesticide manufacturers and facilitate global agricultural exports to Australia. Industry representatives, growers, and third-country government officials often point to Australia’s system as one that facilitates agricultural production and trade.

Brazil’s MRL regulatory system has been in place for more than 30 years. The overlap of regulatory agencies in Brazil, however, has been reported to complicate the MRL-setting process there, and registering a pesticide can take up to six years. Of the major markets presented in this chapter, Brazil is the only market identified as regularly deferring to Codex MRLs where it has not set its own MRL. This is particularly important since industry representatives report that in practice, Brazil does not have an effective system in place to request import tolerances.

Canada’s MRL system has operated in its current framework for 14 years and is characterized by extensive collaboration with the United States due to longstanding trade ties. Industry representatives have commented positively on the straightforward nature of Canada’s MRL-setting process. This is reportedly a result of a series of regulatory reforms which enabled a faster approval process for establishing MRLs in Canada, with a consequent increase in MRLs. In addition, industry representatives have praised Canada’s default MRL, which is 0.1 ppm, as facilitating agricultural trade flows with Canada. In comparison, most other markets have a numerical default of 0.01 ppm, or do not set any default level (effectively prohibiting imports with residues of the pesticide involved).

China’s current MRL system is relatively new, with substantial changes made to its regulatory framework in 2017. Large tranches of new MRLs have been established by the relevant Chinese regulatory agencies in the past three years, and the Chinese government has indicated an interest in setting up to 10,000 MRLs by the end of 2020. Industry representatives have noted concerns about the perceived opacity of the regulatory approval process for MRLs in China and about requirements to conduct pesticide residue trials in China rather than in the producing market. Industry representatives also note that there is uncertainty regarding the extent to which China defers to Codex MRLs in the absence of existing Chinese MRLs. Multiple industry representatives have also noted that it is not possible to secure an MRL in China solely for an import tolerance.

The **European Union** has maintained a harmonized MRL system throughout the European single market since 2008, and EU MRLs apply to over 400 pesticides. Several components of the EU MRL-setting system are different from those in many other countries. For example, a 2018 European Parliament report identified the European MRL process as the world’s most “stringent” regulatory system for approving pesticides, and some industry representatives suggest the process is “more complex than anywhere else.”[10]

In addition, the EU’s MRL system includes hazard-based cutoff criteria in its approach to identifying the impact on human and ecological health and in approving an active substance. The cutoff criteria define the human health and environmental effects that must be ruled out in order for an active substance to be approved for use in the EU.[11] The EU’s inclusion of the cutoff criteria in its assessment of pesticides used in agricultural production is cited by multiple industry representatives as creating uncertainty and potentially increasing costs for registrants and growers.[12]

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[10] EP, *Report on the Union’s Authorisation Procedure for Pesticides*, December 18, 2018, 7, 17.
[11] European Commission, “Regulation (EC) 1107/2009,” Annex II, 2009.
[12] Industry representatives, interview by USITC staff, March 5, 2020; industry representative, interview by USITC staff, March 10, 2020.

Another notable feature of the EU's system is that the final step in the approval of active substances and the setting of MRLs involves voting by bodies made up of member state representatives, including the European Commission's Standing Committee on Plants, Animals, Food, and Feed (PAFF) and the European Parliament. In many other markets, a final decision is made by a government regulatory body and elected representatives have no active role in the approval of active substances or MRLs.[13]

Japan's current positive list system has been in place since 2006, when it transitioned to the current system following a series of food scares in the early 2000s. During the transition, Japan worked with domestic and foreign industry representatives in establishing MRLs for a variety of pesticide/crop combinations, and as part of this process, Japan adopted a number of Codex MRLs. Several industry representatives mentioned Japan's practice of launching the evaluation of a pesticide for MRLs at the same time as the required evaluation in the pesticide manufacturer's home country, describing this time-saving approach as facilitating trade.

South Korea transitioned to a positive list system, with a staggered implementation process based on crop types, in 2016 and 2019. South Korea also conducted extensive outreach to industry representatives when setting its new MRLs and incorporated some Codex MRLs into its domestic regulations. Some industry representatives fear that many of the temporary MRLs set up to facilitate the transition to the positive list system may not be made permanent by the time the temporary MRLs expire in December 2021. They reported that this could result in potential trade disruptions if these MRLs are set to South Korea's default of 0.01 ppm.

Taiwan began to develop its positive list system in 1999 and was one of the first markets to adopt such a system. Like Australia and the United States (among other markets), Taiwan does not provide a numerical default in its MRL regulations (such as Canada's 0.1 ppm or the more common 0.01 ppm set by Japan and the EU), though it appears to frequently set MRLs to a 0.01 ppm default. While industry representatives have praised the collaborative framework set up by Taiwan's MRL regulatory authorities, they have also expressed concern that the efficacy requirements for pesticides registered for import MRLs, as well as domestic testing requirements for both efficacy and residue testing, could represent a barrier to trade for treated agricultural products. Following industry feedback, in February 2020, Taiwan's Ministry of Health and Welfare removed the efficacy requirement for setting import tolerances.

Challenges in Establishing and Complying with Maximum Residue Levels

Greater fragmentation and divergence in MRL policies around the world, coupled with evolving technological capacity that increases testing precision, often translates into elevated costs and market impacts throughout the agricultural supply chain. Industry representatives across the supply chain, including growers and processors, pesticide manufacturers, exporters, importers, and regulatory authorities, have pointed out numerous challenges to trade throughout the pesticide and MRL

[13] Industry representatives, interview by USITC staff, February 13, 2020; ASA and USSEC, written submission to USITC, December 13, 2019, 5; U.S. Grains Council, National Corn Growers Association, and MAIZALL, written submission to USITC, December 13, 2019, 23; industry representatives, interview by USITC staff, March 5, 2020; industry representative, interview by USITC staff, March 10, 2020.

regulatory process. Registration of the pesticide or the active substances in a pesticide is typically required before establishment of an MRL. While the costs of registering a pesticide or an active substance are often borne by pesticide manufacturers, the entirety of the agricultural supply chain is impacted by different markets' policies for registering pesticides and setting MRLs. Growers are generally reliant on pesticide manufacturers to register active substances in pesticides and seek MRLs, and when MRLs are low or missing for the specific pesticide/crop combinations they need, growers can incur increased costs, face a number of production challenges, or lose market access.

Table ES.1 highlights the major challenges and concerns faced by stakeholders at each step in the pesticide registration and MRL establishment process, as well as the costs of compliance and noncompliance with existing MRLs. It also provides examples of issues that illustrate these challenges and concerns in terms of specific processes, practices, and other select issues as well as their impacts.

Table ES.1 Challenges and concerns related to establishing and complying with MRLs

Issues	Challenges and concerns	Examples of issues
Approving/renewing active substances and establishing MRLs	Complex and costly data requirements increase costs and may limit pesticide availability for growers.	• Testing and data collection • Minor crops and crop groupings • Generic pesticides
	Unclear regulations and lack of predictability create uncertainty and may limit pesticide availability for growers.	• Hazard-based approach for registration of active substances • Guidance documents • Emergency use of pesticides • Pesticide bans • Inability to secure an import tolerance
MRL-related challenges in the agricultural supply chain	Varying MRL policies affecting growers and exporters can complicate regulatory compliance and threaten market access.	• Default MRL policies • Transition periods for new MRLs • MRL exemption policy disharmony
	MRL changes in key markets can lead to increased costs and may limit growers' ability to deal with pest challenges.	• Finding alternate markets • Finding alternative pesticide products and use patterns
Cost of compliance with MRLs	Compliance with MRLs impacts producers and other stakeholders in the supply chain, particularly in developing countries.	• Segregating crops or growing to meet the lowest MRL • Pre-export testing and MRL monitoring costs • Government support to ensure MRL compliance • Support from importing countries and related benefits
Costs of an MRL violation	Violations impact producers along the supply chain and can extend to other agricultural sectors.	• Loss of agricultural commodity revenue and redirected shipments • Increased testing • Reputational impact of an MRL violation

Source: Compiled by USITC.

Complex and costly data requirements for approving/renewing active substances and establishing MRLs. In the absence of globally consistent pesticide and MRL policies and requirements, complying with differing requirements on a market-by-market basis is costly. Pesticide manufacturers make significant investments to support pesticide registrations (active substance approval/renewal) and to establish MRLs in each market. The data requirements for pesticide registration and obtaining MRLs can be the largest single expense in bringing a pesticide to market.[14] Given the close relationship between pesticide registration and establishing MRLs, particularly with respect to the data collection and testing requirements, challenges for stakeholders at these two stages often overlap.

Some of the most significant challenges pesticide manufacturers experience across markets are the costs and increasing complexities of the tests and trials required for risk assessments. Many of these challenges involve assessments for metabolites—chemical substances produced as a pesticide breaks down during use. Difficulties include the high cost of testing metabolites, the lack of global agreement among regulators about the specific metabolites that ought to be assessed, uncertainty about the scope and complexity of metabolite data required by regulators at the beginning of the application process, and the increasing ability to detect low quantities of these substances. In addition to metabolite testing, other trial and testing requirements, such as crop field trial requirements, pose challenges for pesticide manufacturers and the growers that rely on them to secure MRLs.

Registrants also face challenges associated with the costs and lack of economic incentives to pursue MRLs on minor crops and generic pesticides (the latter are discussed further below). Minor crops, which include specialty crops such as fruits, vegetables, nuts, and coffee, are typically grown in small volumes relative to major crops (like grains and soybeans) but can be very important cash crops for some farmers. Many of the challenges routinely associated with securing MRLs are compounded for minor crops and can have a disproportionate impact on growers of minor crops.

Because of these challenges, especially the increasingly costly data requirements, manufacturers of pesticides used on minor crops are likely to see lower expected economic returns relative to the costs of securing an MRL. This situation may lead them not to apply for MRLs for pesticide/crop combinations in a number of potential export markets. As a result, growers of minor crops often have only a small number of pesticides available for their use; and when export market MRLs change, they are particularly vulnerable to any loss of the few tools they have to address pest pressure.

If no pesticide manufacturer is willing to apply for a registration or MRL, growers are left to carry out the complex task for themselves. In response, some governments have provided support to efforts to establish MRLs for minor crop pesticides. In addition, international efforts have led to the adoption of crop groupings to simplify the process. In markets that recognize crop groupings—e.g., leafy greens—an MRL for one crop within a grouping will apply to other members of the grouping. While these efforts have been somewhat successful, limited funding and a lack of full harmonization of crop groupings leave many gaps in minor crop MRLs.

Maintaining or establishing MRLs for generic pesticides (i.e., those no longer covered by a patent) presents particular challenges for both pesticide manufacturers and growers. Once a product is no longer under patent, a generic version of the original pesticide can continue to be produced by the original manufacturer, or a number of other firms may also begin producing generic versions. In either case, producers of generic pesticides face challenges in renewing registrations and submitting MRL

[14] Industry representative, interview by USITC staff, December 12, 2019; industry representative, interview by USITC staff February 13, 2020.

applications, which is particularly challenging for older active substances. Some of these difficulties are due to the evolution of testing and data requirements, which may require additional and costly data collection. As a result of all these factors, growers may lose MRLs for generic pesticides in some markets even though these pesticides are still in use and are still effective, limiting growers' access to affordable pesticides. This can have a disproportionate impact on growers in developing countries, as newer pesticides might not be registered or available in those markets or may be too expensive for those growers. As with minor crops, in cases where pesticide manufacturers do not pursue renewals or MRLs, grower groups themselves may decide to face the complexities and bear the costs of pursuing the renewal of a registration or the establishment of a new MRL.[15] Similarly, growers may benefit from some government support in dealing with this challenge.

Unclear regulations and lack of predictability in approving/renewing active substances and establishing MRLs. In addition to the high costs associated with complying with data and testing requirements, pesticide manufacturers seeking approval for active substances and MRLs often encounter a lack of regulatory clarity and unpredictability in the application process. This unpredictability leads to increased costs, can limit availability of pesticides for growers, and can impede innovation and the potential development of new pesticides to address ongoing and emerging pest pressures. While these issues are reported in all markets, industry representatives state that they are particularly problematic in the EU. Reasons include its large market size, the structure and complexity of its regulatory process, the volume of active substances that are being reviewed, and the impact that EU regulatory decisions have on other markets.

While all regulators may establish criteria to limit the use of active substances that they deem hazardous, stakeholders report that the EU's implementation of its hazard-based criteria and the complexity of its process for evaluating active substances are of particular concern. This is principally because the EU's implementation of the hazard-based approach and the precautionary principle differ from that of most other major markets.[16] Industry representatives report that these approaches, including the cutoff criteria, have contributed to non-approvals (and non-renewals) of active substances in the EU. This, in turn, affects the global use of certain pesticides by growers seeking to export to the EU and reportedly to other markets as well. Furthermore, these representatives have expressed concern about the potential to lose more pesticides, especially as other markets may begin to adopt the same hazard-based approaches.

While EU regulations have not changed significantly since the issuance of Regulation (EC) No 396/2005 and Regulation (EC) 1107/2009, industry representatives have noted that the EU's issuance of numerous and frequently updated guidance documents has created challenges for registrants in registering/ renewing pesticides and securing MRLs. A number of stakeholders report that EU guidance documents are published frequently and often overlap, adding complexity and uncertainty to the process of registering an active substance and securing an MRL. Further, they express concern that certain guidance found in these documents, such as the guidance on endocrine disruptors, is so broad as to create more confusion than clarity.

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[15] CRC, written submission to the USITC, December 13, 2019, 6; Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 75.
[16] Industry representatives, interview by USITC staff, March 5, 2020.

Industry representatives are also concerned that use of "emergency use" provisions in the EU, as well as bans of pesticides by certain member states, may undermine the competitiveness of imported agricultural products. In some cases, the EU's emergency use provisions allow member states to make limited use of pesticides containing active substances that have been removed from the EU market, but only in short-term, urgent situations. Industry representatives suggest that the increasing use of these provisions has allowed growers in certain member states to effectively opt out of complying with the EU's pesticide restrictions while exporters and growers in other member states must comply with the pesticide restrictions or with low or missing MRLs. Pesticide manufacturers and growers also noted that some EU member states' recent pesticide bans and proposals for bans have introduced uncertainty about the legal use of pesticides within the EU and the EU's importation of crops treated with those pesticides. Two recent bans in particular—one in France on dimethoate, and a proposed ban in Austria on the use of the herbicide glyphosate—are concerning to both growers and pesticide manufacturers.

MRL-related challenges in the agricultural supply chain. When growers face different MRLs for the same pesticide/crop combination in different markets, including when an MRL is low or missing in a key market, a variety of challenges can emerge in attempting to comply with them. While these challenges may affect many participants in the supply chain, including processors, exporters, and governments, many of the costs are incurred by the growers. The three major challenges producers identified with respect to low or missing MRLs were differences in MRLs, including in the use of default MRLs; short transition periods when MRLs are lowered; and disharmony in the list of products that are exempt from MRL requirements.

When an MRL has not been established, different markets have differing default policies in place. There is no global standard for a default value in the event an MRL is not granted or has not yet been considered in a market. Markets may defer to MRLs established by Codex or by other markets, or they may establish their own numerical default. However, some markets may effectively have zero tolerance for pesticide residues in the absence of an MRL, rather than set a specific default. As a result, default MRLs can be set at differing values for the same pesticide/crop combination around the world, limiting the use of these pesticides by growers internationally.

When an MRL is lowered in an import market, national authorities in the import market set a transition period to give producers time to adjust. While these transition times are of varying lengths, some can be as short as a few months. Transition periods that are shorter than growing seasons or are implemented too late in the growing season to make meaningful adjustments in production practices are particularly problematic for growers. Further, short transition periods do not account for the time that agricultural products spend in processing, in transit, and on store shelves. Short transition periods can be particularly challenging for processed products that remain in storage for longer periods, such as wine and nuts.

In many of the United States' major agricultural export markets, certain pesticides may be "exempt" from MRL requirements (i.e., their residue levels are not subject to regulatory limits). This practice can be helpful because it allows growers to use these exempt pesticides when MRLs for alternative conventional pesticides are missing, lowered, or set to a low default. However, because markets do not consistently exempt the same pesticides, exporting growers must still be careful in using exempt pesticides.

Responses to MRL Changes in Key Markets. When national authorities lower pesticide MRLs on a crop, growers and exporters respond by either finding alternate markets for their crop or adapting their growing practices to meet the new MRL. Otherwise, they risk an MRL violation in the export market. If neither of these solutions is practicable, farmers may have to shift to producing other crops entirely. The first two choices mentioned involve complexities of their own. Finding an alternate market can be a short-term adjustment, adopted while growers adapt their practices to comply with a lower MRL, or it can be longer term or even permanent solution if it is not possible to alter farming practices to comply with the change. Regardless of the duration, having to switch markets can be difficult and costly for producers.

Alternatively, growers must use different pesticides, change farming practices, or switch their use pattern to stay below the MRL. But adopting any of these changes can also add to growers' costs. In many cases, these additional costs can be particularly damaging to growers as meeting lower MRL requirements does not usually result in price premiums for farmers, so the cost cannot be recouped. In some cases, there are no or few alternative pesticides available. The inability to use a pesticide in order to meet export market MRLs may also lead to crop loss, lower yields, a lower-quality crop (potentially bringing down prices), or higher costs of production due to the costs of changing production methods or the use of less effective means of addressing pests.

Costs of Compliance with MRLs. If growers and exporters choose to ship agricultural products to markets with low or missing MRLs, costs of MRL compliance are borne by growers as well as additional participants in the supply chain, such as aggregators, packers, and processors. Stakeholders have identified some of the most significant costs associated with complying with low MRLs. One possible response is for stakeholders to segregate agricultural products throughout the supply chain or for growers to produce all of their crops to suit their export market with the lowest MRL, but this is often costly and sometimes impossible to do. Pre-export testing to ensure compliance can prevent the larger losses triggered by MRL violations, but these programs are costly, and the cost is often borne by the processor/exporter.

Developing countries are also reportedly more likely to be seriously impacted by MRL compliance costs, given their limited resources and technical capacity to ensure that their farm products are in compliance before they are shipped. Some suggest that changes in MRLs in developed countries can erode agricultural development and even food security in developing countries. In some cases, governments sometimes provide support in various ways to ensure their growers' and exporters' ability to comply with MRLs, but this is on a case-by-case basis and cannot cover all instances where that support is needed.

Costs of an MRL Violation. Exceeding MRLs set by regulators in import markets is considered an MRL violation and imposes costs along the supply chain, particularly for farmers and exporters. The cost of a rejected shipment is the most visible and direct effect of an MRL violation. Agricultural products that exceed MRLs in the destination market may be returned, sent to an alternate export market, destroyed, or released for non-human consumption (e.g., livestock feed or composting). In addition, the shipper is still responsible for the sales contract and must replace the product at additional cost.

A single MRL violation can result in higher inspection rates on the agricultural commodity from the offending exporting market. The rise in inspection rates increases costs and causes delays along the supply chain, which can lower quality and shorten shelf life for perishable crops. Growers and exporters may experience not only lost sales but also damage to their reputation in that market. Importers may switch to other suppliers because of the perceived risk of additional MRL violations, which could disrupt the importer's supply and increase their costs as well.

Costs and Effects of Missing and Low Maximum Residue Levels: Producer Case Studies

The case studies in this report describe costs and effects that growers and exporters face as a result of missing and low MRLs and illustrate the ways that compliance and noncompliance with export market MRLs affect farmers in countries representing a range of income classifications. These costs and effects are wide-ranging and often vary, depending on whether or not producers can comply with missing and low MRLs. The case studies provide examples of growers producing different types of crops in different regions around the world and demonstrate that farmers could be forced to accept yield losses, ship products with defects in quality, or to use less effective or more costly methods of controlling pests, if they cannot use certain key pesticides. Numerous factors affect farmers' MRL responses, including degree of pest pressure, climate conditions, ability to adapt growing practices to changing conditions (e.g., availability of substitutes and alternatives), shipping distance to key markets, and other supplier requirements. The case studies presented in this report primarily focus on costs and effects of MRLs in the EU and Japan, although MRLs in other markets, including Taiwan and South Korea, are also of concern to exporters. Since the topics of these case studies were selected based on the results of the Commission's public hearing and comment process as well as field research by staff, the Commission believes they are representative of the challenges and concerns posed by missing and low MRLs.

Fresh bananas/Costa Rica. Several recent EU decisions to lower MRLs on important pesticides used in the fresh banana industry caused significant concern to Costa Rican growers. The EU is Costa Rica's most important export market. These pending changes will eliminate the use of several fungicides that are alternatives for one another, as well as two insecticides that are important to modern pest-management practices in the banana industry. If the MRLs for all these fungicides and insecticides are lowered before additional alternatives can be developed, the industry cautions that banana production in Costa Rica may no longer be feasible.

Banana producers in Costa Rica offered numerous examples of the potential effects of low MRLs on their industries, including declines in yield that would raise unit costs for producers. Although export levels have so far remained stable, reportedly the reason for this is that producers have decided to take on the increased costs to maintain market share. Since import markets will not accept major price increases, increased costs of production cannot be passed on to the consumer, so these costs are largely borne by farmers. However, there exist concerns that short-term measures taken to maintain production levels may not be sustainable over the longer term, especially as pests become resistant to the limited number of pesticides available or new pest threats emerge.

French beans/Kenya. The EU is the primary export market for the Kenyan French bean industry, which is export oriented and dominated by thousands of small shareholder farmers. Kenya's historical ties to European markets, as well as its relative geographic proximity and long growing season, contribute to close trade relationships. As a result, Kenya closely follows changes in the status of active substances in the EU as well as their related MRLs, and often removes pesticides from the domestic market in line with the EU market requirements. EU MRLs that are lowered to the lowest limit of analytical determination (0.01 ppm) are perceived as restrictive and generally result in the inability to use the related pesticide. This reduces the already limited registered pesticides options available to farmers growing French beans, which is a minor crop. Smallholder farmers are impacted the most, with past MRL rejections causing many farmers to go out of business. Other players along the supply chain are also affected, including aggregators, packers, exporters, and importers. This case study uses past instances of EU MRL violations to illustrate their effects along the French bean value chain in Kenya.

Mangoes/Peru. While the case study focuses primarily on producers in Peru, comparisons to other producing countries in tropical regions demonstrate that the effects of changes in MRLs may differ based on the unique characteristics of various producing countries. Mangoes are a highly perishable and important export specialty crop for many developing countries and are vulnerable to a variety of fungal and pest pressures. Limiting the number of pesticides that can be rotated within a producer's pest management system increases insect resistance, resulting in damaged fruit and higher yield losses for mango growers.

Mango growers in Peru and Brazil are concerned about the lowering of MRLs for important mango plant protection products, as well as the lack of harmonized MRLs among major export markets, both of which could have a significant impact on production yields and costs. Because MRLs differ among their major export markets, certain Peruvian producers have had to segregate mango production by export market, which raises operational costs; the difficulty of keeping fruit segregated increases the chances of an accidental MRL exceedance and consequently a rejected shipment. In such a case, that supplier would incur significant costs associated with destroying or re-shipping the product, and the incident could damage the supplier's reputation, potentially leading to lost future sales.

Avocados/Peru and Chile. Several recent decisions to lower MRLs, as well as missing and diverging MRLs for key pesticides, have had a major impact on Peruvian and Chilean avocado growers. Growers in Peru are segregating crops to ensure compliance with varying MRLs in different export markets, which raises their costs. Missing and low MRLs have prevented them from using new, higher-performing pesticides that are similar in price to older formulations. Since growers in Chile find it more difficult to segregate their crops by market, they have chosen instead to ensure that all avocado production meets the lowest MRLs of all their export markets.

Table Grapes/Peru and Chile. Recent and planned future reductions in EU MRLs affect access to important pesticides used in the table (fresh) grape industry. Table grape producers, trade associations, and government representatives in Peru and Chile are concerned about the lowering of MRLs for important plant protection products. The recent reduction in the EU's MRL for a pesticide to the lowest limit of analytical determination (0.01 ppm) could seriously depress Peruvian exports and may exert significant pressure on growers. Chilean industry representatives are concerned that when the registration for these products comes up for review, the EU could reduce MRLs to the lowest limit of analytical determination for three insecticides as well as for an important fungicide. As a result, Chilean growers may no longer be able to use these plant protection products for table grapes bound for the EU. If they cannot replace them, they could lose access to the EU market, which is their third-largest market after the United States and China.

Coffee/Global Producers. Compliance and noncompliance with low MRLs, particularly in Japan, have raised costs for coffee growers and exporters. In Japan, a significant global coffee importer, MRLs for numerous pesticides are set to the limit of determination. These MRLs have various effects on producers depending on the size of the coffee farms involved, the level of reliance on and knowledge of the

Japanese market, and the specific pesticides used in each country. Information about problems experienced by exporters in Kenya illustrated the effects of noncompliance with Japan's MRLs, with the costs of rejected shipments reaching up to half of the value of the shipment itself. Exporters in Colombia and Jamaica also described the costs of complying with Japan's coffee MRLs—including costs for pre-export testing, which they see as necessary but expensive. Adding to the challenges is that in all three countries, coffee from many farmers is often combined into one lot for sale. This increases the risk of cross-contamination, makes producer-specific testing cost- and time-prohibitive, and prevents traceability back to the source of a possible MRL violation.

Grains and Oilseeds/Global Producers. This case study examines the future impact of changing MRL policies on growers of major row crops that are leading agricultural export commodities of the United States, as well as other countries such as Argentina and Brazil. Unlike minor crops, grains or oilseeds from one farm are typically sold in bulk and blended at points along the supply chain with product from other farms before reaching final export markets. The diverse farms involved may apply different pre- or post-harvest treatments to control their pests. Because of this supply chain structure, farmers generally do not know which export markets their crops will be shipped to, and importers are unable to trace product—and an MRL violation—back to an individual farm.

As a result, growers often must ensure that their product meets the lowest MRLs found anywhere in their export markets. Several grain groups shared increasing concerns about future changes in MRL policies, including the lowering of MRLs, bans on the use of certain pesticides, and diverging MRLs among major export markets. According to representatives of these groups, the changes could pose significant challenges to growers, resulting in higher costs, yield losses, and rejected shipments. Changing MRL policies, particularly in the EU, will have a direct impact on the production and supply chain for grains and oilseeds, and these impacts could reportedly intensify if other export markets choose to align their own import tolerances with those of the EU.

Effects of MRL Policies from the Economic Literature

MRLs are a type of nontariff measure (NTM) affecting agricultural goods, and have the potential to affect trade as well as prices, production, and income in exporting countries. By definition, low MRLs, including missing MRLs that result in low default MRLs being applied, in import markets impose stricter standards on agricultural products being exported to those destinations. Most studies that have examined the effects of MRLs conclude that, for the products within the markets examined, low MRLs or those that differ between exporter and importer pairs (i.e., are more heterogenous) deter or reduce trade; however, some studies conclude that low or differing MRLs on balance have trade-enhancing effects. Studies have generally posited that trade-reducing effects are linked to inherent costs borne by growers and exporters in complying with these policies, and that trade-enhancing effects are linked to increased demand due to consumer preferences for products with lower pesticide residues. Most studies have found that, regardless of findings of trade-reducing or trade-enhancing effects of MRLs, the effects are not uniform across countries. Frequently, studies have found that lower-income exporting countries bear heavier costs of compliance associated with low MRLs and face more significant trade-reducing effects.

Studies focusing on MRLs have generally not examined the effects of these policies on production, prices, or income. However, other studies related to agricultural NTMs provide insight into the potential implications of MRLs for these indicators. Several of these studies have found that certain agricultural NTMs contribute to higher prices for imported agricultural products. These studies have found that in certain cases, exporting producers may benefit if they can afford to spend what is needed to meet more stringent NTMs while maintaining output levels. On the other hand, producers who are unable to comply may experience reduced production, loss of income, and in some cases, lower product quality and prices.

Beyond the literature on NTMs are studies on the benefits and costs of pesticide use. One group of studies has found that appropriate pesticide use reduces the amount of crop output that is lost to pests and increases perceived crop quality. Some other studies have identified harmful effects related to pesticide use and overuse in terms of both lessened agricultural productivity and broader societal and environmental problems. Still others have concluded that long-term and gradual reduction of pesticide use, combined with the adoption of other crop protection practices, is possible without sacrificing productivity or income.

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Chapter 1 Introduction

Overview

Plant protection products, including pesticides, are important to agricultural producers around the world working to ensure crop production for growing populations. However, according to many agricultural exporters in the United States and worldwide, pesticide-related policies in some countries are creating significant challenges to agricultural trade.[17] Farmers are increasingly adjusting production practices in response to evolving policies and regulations governing the levels of pesticide residues on agricultural products. Global differences in MRLs, including when MRLs are missing and low, as well as changing MRL policies in major agricultural export markets, can negatively affect farmers' costs as well as their ability to access export markets, which may affect their income.

Pesticides encompass a broad range of chemicals used to more efficiently produce and safeguard crops and include insecticides, fungicides, rodenticides, and herbicides. These important tools help farmers prepare fields for planting, combat harmful pests and diseases during crop production, and protect harvested crops in storage and transit. Strategic pesticide use is an integral part of modern farming, frequently as part of an integrated pest management system.[18] However, the use of pesticides can leave residues on crops and food products.

Governments seek to regulate pesticide residues to ensure that agricultural products are safe to consume and are not harmful to human, animal or plant life or health.[19] Once a government approves a pesticide for use, it establishes a maximum residue level (MRL) for each specific combination of a pesticide with a crop. An MRL is the highest level of a given pesticide's residue that is legally tolerated for a given crop in that government's jurisdiction.[20] Treated crops or crop products must comply with established (or default) MRLs in order to be sold or imported to a market. If there is no MRL for a specific pesticide/crop pair, an agricultural product using that pesticide cannot be sold or imported to a market. Since each MRL is specific to a pesticide/crop combination, tens of thousands of MRLs exist worldwide.

Establishing MRLs is a highly complex and costly endeavor. It involves collecting and evaluating large amounts of crop field data and other data in order to perform thousands of scientific risk assessments

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[17] The USITC received numerous submissions related to this factfinding report, including U.S. industry groups, U.S. exporters, foreign governments, and foreign exporters. A full list can be found in appendix D of this report.

[18] Integrated pest management practices can include using biological controls (e.g., beneficial insects), chemical controls (pesticides), mechanical controls (e.g., use of row covers), and cultural controls (that is, controls related to cultivation—e.g., drainage and plant spacing).

[19] The WTO, for example, has recognized that WTO members have a right to regulate pesticides to protect "human, animal and plant life or health." WTO SPS Agreement, Art. 2.

[20] This MRL definition is used by Codex Alimentarius (an international standard-setting body discussed later in this chapter) and major agricultural markets, including the United States and the European Union. EPA, "About Pesticide Tolerances," September 16, 2016; Codex, "Maximum Residue Limits (MRLs)," 2018; European Commission, "Maximum Residue Levels" (accessed February 20, 2020).

for each active substance in the pesticides on each of the specific crops they may be applied to. In light of this, international standard-setting bodies, such as the Codex Alimentarius Commission, establish voluntary MRLs for global use. Governments can choose to adopt these international standard MRLs, in the limited cases where they exist, or to establish MRLs on their own.[21] Regardless of the method a government uses to establish its MRLs, they generally apply to both domestically produced products and imported ones. From country to country, however, the established MRLs on the same pesticide/crop combinations frequently vary. Moreover, not all pesticide/crop combinations are covered by the MRLs established or adopted by regulators in their domestic markets; these never-established MRLs are sometimes referred to as “missing” MRLs.

Shifting MRL policies and differences in MRLs globally are increasingly affecting trade in a number of ways. Agricultural exporters may not be able to sell their crops to markets where an MRL is set lower than in their domestic market, particularly if the MRL is so low that it is difficult for producers to meet while still protecting their crops from harmful pests. A missing MRL for a pesticide/crop combination in a given market can mean the pesticide is automatically prohibited for use on a certain crop; the missing MRL can prevent exporters elsewhere from shipping the crop to that market. Finally, shifting policies in importing markets complicate production and export decisions of farmers who rely on transparency and predictability in the trading system. Exporters and other stakeholders in the agricultural trade community are concerned about a number of aspects of these shifts, including the increased activity of government regulators in establishing their own MRL systems; variation in the international and country-specific frameworks guiding the regulation of certain pesticides and the establishment of MRLs; and the resulting differences in MRLs across markets.

There are several factors contributing to global differences in MRLs. The regulatory processes and practices for registering new pesticides and establishing MRLs vary from one market to the next—whether regarding data requirements, testing requirements, or methodological approaches—and can lead to different assessments of the hazards and risks associated with the same residues. In addition, scientific advances in detecting residue levels and in analyzing the effects of chemical substances on human health and the environment give regulators in some markets increasingly precise tools with which to assess pesticides and set MRLs at levels that they consider safe. These changes affect both new and existing pesticides, as well as their associated MRLs. When registered pesticides and established MRLs undergo periodic reviews by regulatory bodies, such changes in technology and in regulators’ evaluation practices may contribute to the nonrenewal of certain pesticides and the subsequent reduction or elimination of their associated MRLs. Moreover, these changes in MRLs are sometimes implemented with brief transition periods, making it difficult for exporters to adapt their production practices in time.

Many of the costs and effects of divergent or low and missing MRLs are borne not only by growers, but also by other participants throughout the agricultural supply chain—such as processors, aggregators,

[21] Codex Alimentarius Commission has established more than 4,800 Codex MRLs for a variety of specific pesticide/crop or pesticide/crop-grouping combinations. However, these represent a relatively limited number of MRLs relative to the number of MRLs needed by growers, given that each MRL represents a unique pesticide/crop combination.

exporters, retailers, and even pesticide manufacturers—in different ways.[22] These costs and effects confront growers in a broad range of countries, from upper-income countries like the United States to lower-middle-income countries in Africa, Asia-Pacific, and Latin America. Growers who attempt to comply with low or missing MRLs by reducing or eliminating the use of certain pesticides may incur costs in the form of production and yield losses or through the need to develop alternative pest management strategies that may be more costly. Growers are also generally reliant on pesticide manufacturers to register pesticides and to seek MRLs, but these costly and time-intensive processes entail a significant investment by these firms. Pesticide manufacturers can spend years and hundreds of millions of dollars researching and developing a single new pesticide, registering pesticides for use in multiple markets, and seeking MRLs for a variety of crops.[23] Growers constrained by missing or low MRLs and who have no access to alternative pesticides potentially may lose access to lucrative export markets.

Scope

The U.S. Trade Representative (USTR) asked the U. S. International Trade Commission (USITC or Commission) to conduct an investigation and provide a report on global economic impacts of missing and low pesticide maximum residue levels.[24] The USTR asked that the report include information and analysis about the impact of pesticide MRLs on farmers in countries representing a range of income classifications, including the United States. The USTR also stated that the report should cover the years 2016–19, but may, where appropriate, examine longer-term trends.

The USTR asked that the Commission's report be delivered in two volumes, with the first volume due on June 30, 2020. Volume 1 of this report (the present report) is to contain the following components, as described in the request letter:

1. An overview of the role of plant protection products and their MRLs in relation to global production, international trade, and food safety for consumers. Describe the current and expected challenges to global agricultural production, including the impact of evolving pest and diseases pressures in differing regions and climates.
2. A broad description of the approaches taken in setting national and international MRLs for crops. Describe the risk-based approach to setting MRLs in the context of agricultural trade, including the guidelines and principles of the Codex Alimentarius (Codex). Describe the procedures in the Codex for setting pesticide MRLs, including the role of the Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) Joint Meeting on Pesticide Residues (JMPR) in conducting risk assessments. Compare this risk-based approach to a hazard-based approach. Describe U.S. efforts to advance the use of lower-risk pesticides globally.

[22] USHIPPC, written submission to USITC, December 10, 2019, 4; NPC, written submission to USITC, December 10, 2019, 3; Wine Institute and CAWG, written submission to USITC, December 13, 2019, 4; CFFA, written submission to USITC, December 10, 2019, 2; Cranberry Institute, written submission to USITC, December 11, 2019, 1; NHC, written submission to USITC, December 13, 2019, 3; ABC, written submission to USITC, December 13, 2019, 2.
[23] Further information on the costs borne by pesticide manufacturers in researching and registering pesticides for crop use can be found in chapter 4 of this report.
[24] Appendix A contains a copy of the request letter and appendix B contains the *Federal Register* notices associated with this investigation.

3. A description of how MRLs for plant protection products are developed and administered in major markets for U.S. agricultural exports. Describe the specific regulations, processes, practices, and timelines in these major markets for establishing, modifying, and administering MRLs. Describe specific MRL enforcement practices and processes, including practices and procedures for addressing noncompliant imported plant products. Provide examples of how Codex MRLs are adopted into national legislation or regulation. Identify trade-facilitative practices and processes.
4. A description of challenges and concerns faced by exporting countries in meeting importing country pesticide MRLs, such as when MRLs are missing or low. Explain the reasons for missing and low MRLs.
5. Through case studies, describe the costs and effects of MRL compliance and noncompliance for producers in countries representing a range of income classifications, such as uncertainty in planting decisions, segregation of products, crop protection costs, yield implications, storage issues, product losses, and consequences of MRL violations. Include information on costs of adopting new plant protection products or those related to establishing, modifying, or testing for new or existing MRLs in export markets. To the extent possible, include effects on producers in countries with tropical climates where products are subject to high levels of pest and disease pressure.
6. A review of the economic literature that assesses both qualitatively and quantitatively how missing and low MRLs affect countries representing a range of income classifications, particularly low-income countries, with regard to production, exports, farmer income, and prices.

Volume 2 of this report, to be delivered to USTR by January 31, 2021, will provide the following, as stated in the request letter:

7. Case studies, which describe the costs and effects of MRL compliance and noncompliance for U.S. producers, such as uncertainty in planting decisions, segregation of products, crop protection costs, yield implications, storage issues, product losses, and consequences of MRL violations. They are to include information on costs of adopting new plant protection products or those related to establishing, modifying, or testing for new or existing MRLs in export markets. To the extent possible, include effects on U.S. producers of specialty crops.
8. To the extent possible, quantitative and qualitative assessments that discuss how missing and low MRLs affect production, exports, farmer income, and prices, both on the national level and, to the extent possible, for small and medium-sized farms.

In response to the USTR's request, this report focuses on the policy approaches and regulations governing the use of plant protection products (referred to in this report as pesticides) and MRLs, including their impact on international trade and agricultural production both in the United States and in countries around the world. The scope of this report is limited to pesticide and MRL policies related to crops and plant protection products. The pesticides covered in this report include insecticides, fungicides, herbicides, and rodenticides.

Organization

The first volume of this report is divided into six chapters, each aligned with the numbered list of the request letter. After introducing the purpose of the report, the first chapter provides an overview of technical terms and basic concepts related to pesticides and the process of establishing MRLs. It then provides related background information about MRLs, including an explanation of the reasons why MRLs may be missing and low. It follows with an overview of MRLs, giving a broad outline of the processes used by regulators to evaluate and set MRLs, and the role pesticides and MRLs play in agricultural production, trade, and food safety for consumers.

The second chapter explores policy approaches to setting MRLs, including the use of hazard and risk assessments; describes the procedures and processes used in the Codex Alimentarius for setting pesticide MRLs; and summarizes other international efforts to harmonize MRLs and promote the use of lower-risk pesticides. Chapter 3 describes MRL-related regulations, policies (including relevant timelines), and practices in key U.S. agricultural export markets. Chapter 4 describes the concerns and challenges of stakeholders addressing import market MRL policies. Chapter 5 presents case studies that explore the impacts of missing and low MRLs on agricultural value chains in countries around the world. It also discusses effects on producers in countries representing a range of incomes, including effects on producers in countries with tropical climates, where products face high levels of pest and disease pressure. Chapter 6 presents a review of economic literature on the impacts missing and low MRLs have on trade, farmer income, production, and prices.

Approach

The Commission report focuses primarily on the years 2016–19, the latest three years for which data are available. However, it examines longer-term trends where appropriate. Commission staff conducted desk research and interviewed government officials, grower organizations, research and extension service groups, pesticide manufacturers and associations, and industry representatives, including farmers, exporters, importers, and retailers. Commission staff also conducted extensive fieldwork with producers in Costa Rica, Peru, and Kenya, as well as with EU officials and industry groups in Brussels, Belgium. In addition, the Commission used information obtained at its public hearing held on October 29, 2019, as well as from briefs and other written submissions received in connection with the hearing and in response to the Commission's notice of investigation published in the *Federal Register* on September 27, 2019.[25]

Overview of Key Terms and Concepts

Establishing MRLs is a complex process taken on by regulatory authorities around the world. Typically, regulatory authorities evaluate the chemical compounds in pesticides and assess the effects of pesticide residues on agricultural products before establishing MRLs for each pesticide/crop combination. This complex process involves collecting and analyzing large amounts of detailed scientific data on the active

[25] See appendix C for the calendar of witnesses at the USITC public hearing, and appendix D for summaries of views of interested parties.

substances in pesticides, pesticide usage, and the residues of pesticides left in or on crops. The following technical terms and concepts associated with registering active substances, regulating pesticide use, and establishing MRLs are used throughout the report to describe these processes and their associated challenges.

Pesticide: For purposes of this report, pesticides are defined as plant protection products containing chemical compounds that act to control the target pest (e.g., insects and diseases) and include fungicides, herbicides, rodenticides, and insecticides. The term “pesticide” can refer to the active substance or a marketed product that can include a combination of active substances in addition to inert ingredients.[26]

Pesticide registration: Farmers may not use pesticides unless the active substances that they contain are approved for use in their domestic markets. The process by which regulatory bodies approve active substances and pesticides for “domestic use” is commonly referred to as “pesticide registration.” The “registrant” —the entity seeking regulatory approval to register an active substance or pesticide—is typically the pesticide manufacturer. To register an active substance or pesticide for domestic use, regulators require registrants to submit an application or dossier including information on the pesticide’s efficacy (i.e., effectiveness at controlling the target pest), its impact on the environment, its toxicology,[27] and its breakdown products, as well as the exposure to humans and the environment with prescribed use (included in the pesticide label, see below). While pesticide registration allows use of the pesticide in the relevant jurisdiction, crops generally may not be imported or sold in that jurisdiction unless an established (or default) MRL is in place for the particular pesticide/crop combination.

Pesticide Registration and MRL Establishment: The establishment of an MRL typically hinges upon the registration of an active substance or pesticide for domestic use, with the exception of import tolerances, which are described in greater detail below. An MRL may be established for a particular market only if the active substance (or pesticide) is first registered in that market; if a pesticide is not registered in a market, MRLs cannot be established. While pesticide registration allows use of the pesticide in the relevant jurisdiction, an MRL is still needed to define the maximum concentration of a pesticide residue legally permitted on or in food commodities and animal feeds.

MRLs based on pesticide registration for domestic use in a specific market reflect the growing conditions, pest and disease pressures, and crops grown in that market and apply to both imported and domestic products. MRLs for pesticides that are not registered in a particular market may be considered missing in that market. The steps involved in registering a pesticide are presented in chapter 2 of this report.

Active substances: Active substances (also called active ingredients in some markets) are the chemicals in the pesticide that act to control the target pest or disease. Active substances exclude solvents, preservatives, or other adjuvants that modulate the performance or application of the pesticide.[28]

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[26] EPA, “Basic Information about Pesticide Ingredients,” July 15, 2019. Inert ingredients may or may not be toxic. Inert ingredients are defined by the U.S. Environmental Protection Agency (EPA) as any component of a pesticide formulation that is not an active substance. These may include solvents, preservatives, or other adjuvants that modulate or enhance the performance or application of the pesticide.

[27] The measurement and analysis of potential toxins.

[28] EPA, “Basic Information about Pesticide Ingredients,” July 15, 2019.

Metabolites: After a pesticide is applied, the active substance(s) in the product break down and change over time. These downstream chemicals of an active substance are referred to as “metabolites” and “degradates.” Metabolites are the breakdown products found in humans, animals, or plants; degradates, in the environment. These are often collectively called “metabolites” and for purposes of this report will be referred to as such.[29] In order to ensure that a pesticide is safe for use throughout its life cycle, regulatory bodies assess the safety of not just the active substance but also the metabolites that are produced when that active substance begins to break down. Challenges with performing risk assessments for metabolites are presented in chapter 4 of this report.

Pesticide residue: According to the Organisation for Economic Cooperation and Development (OECD), a pesticide residue is “the combination of the pesticide and its metabolites, degradates, and other transformation products on human foods, livestock feeds, and/or drinking water.”[30] Regulators establish the residue definition for each pesticide in order to establish and enforce a maximum residue level. For purposes of establishing and enforcing MRLs, the residue analysis focuses on the breakdown products that “can be detected and measured by a broad base of national laboratories.”[31]

Regulatory authorities around the world have the latitude to define what each pesticide residue includes, and at times they may define residues differently. Because regulators may choose to define the pesticide residue as a parent compound alone, or as a combination of a parent compound and some metabolites, pesticide residue definitions can vary by market for the same active substance. This can contribute to the lack of global MRL harmonization.

Crop field trials: Pesticide residue data used by regulatory authorities to conduct risk assessments to establish MRLs are collected from national or regional crop field trials (also referred to as supervised residue trials). The primary objective of field trials is to collect various data, including actual residue levels under actual growing conditions for various pesticide/crop combinations. The trials are also used to establish maximum treatment levels under Good Agricultural Practices associated with various residue levels. In order to generate the required data for their application to secure an MRL, registrants must conduct a wide range of crop field trials for each pesticide/crop combination in actual growing conditions.

Regulatory authorities often require that crop field trials be conducted inside their geographic boundaries so that the trials can represent the production of the crop in their country or region. Since MRLs are based on residue findings from crop field trials, varying requirements for crop field trial locations and other parameters can impact the data generated for the MRL application and contribute to differences in MRL levels globally. Chapter 3 of this report describes crop field trial requirements by market, and chapter 4 of this report describes the challenges that testing requirements present to exporters.

Risk assessment: A risk assessment is a scientifically based process used to evaluate active substances as well as their metabolites, based on the hazard and risk presented by that chemical. **Hazard** is the intrinsic potential of a substance to cause harm, while **risk** is the likely level of exposure and the probability of harm occurring at that level of exposure. Further discussion of hazard and risk, as well as

[29] OECD, *Guidance Document on the Definition of Residue*, 2009, 20.
[30] OECD, *Guidance Document on the Definition of Residue*, 2009, 20.
[31] OECD, *Guidance Document on the Definition of Residue*, 2009, 20.

the role that risk assessments play in pesticide registration and the establishment of MRLs, is presented in chapter 2 of this report. Risk assessment procedures for several countries are presented in chapter 3 of this report.

Maximum residue levels: The Codex Alimentarius Commission ("Codex"), an international organization that sets MRLs for crops, defines MRLs as "the maximum concentration of a pesticide residue recommended to be legally permitted on or in food commodities and animal feeds. MRLs are based on Good Agricultural Practice (GAP) data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable."[32] According to the Food and Agriculture Organization (FAO), "GAP includes the nationally authorized safe uses of pesticides under actual conditions necessary for effective and reliable pest control."[33]

An MRL is the highest level of a given pesticide's residue that is legally tolerated for a given crop in a government's jurisdiction. Governments establish MRLs to ensure that any pesticide residues left on food crops are at levels that are safe for human consumption and not harmful to the environment. MRLs apply to a specific pesticide/crop combination and are typically measured in terms of milligrams per kilogram (mg/kg) or parts per million (ppm). In some markets (such as the United States), MRLs may also be referred to as "tolerances." Table 1.1 below presents a sample of MRLs established by Codex for a fungicide, chlorothalonil, in combination with various specialty crops.[34]

Table 1.1 Codex MRLs for chlorothalonil for selected crops

Crop	MRL	Year of adoption
Asparagus	0.01 ppm	2016
Banana	15 ppm	2013
Grapes	3 ppm	2011
Leek	40 ppm	2011

Source: Codex Pesticide Database (accessed March 2, 2020).

Establishing MRLs: Registering pesticides and establishing MRLs are two distinct processes carried out by regulatory authorities. Although the timing of the two processes may overlap, before an MRL can be established for a specific pesticide/crop combination, the pesticide must first be registered in the domestic market. Regulatory authorities often require the submission of similar data for both processes, including (1) information on the toxicity of the pesticide and its metabolites (breakdown compounds), (2) the amount of the pesticide used and the frequency of use, (3) how much pesticide residue remains in or on a fresh food at final sale or after processing, and (4) information about pesticide exposure. However, to establish MRLs, regulators typically also conduct a dietary risk assessment and combine

[32] Codex, "Codex Maximum Residue Limits for Pesticides" (accessed March 2, 2020).

[33] Further, according to the FAO, GAP "encompasses a range of levels of pesticide applications up to the highest authorized use, applied in a manner which leaves a residue which is the smallest amount practicable. Authorized safe uses are determined at the national level and include nationally registered or recommended uses, which take into account public and occupational health and environmental safety considerations. Actual conditions include any stage in the production, storage, transport, distribution and processing of food commodities and animal feed." Codex, "Codex Maximum Residue Limits for Pesticides" (accessed March 2, 2020).

[34] The United States defines specialty crops as "fruits and vegetables, tree nuts, dried fruits, horticulture, and nursery crops (including floriculture)" and include plants that are "cultivated or managed and used by people for food, medicinal purposes, and/or aesthetic gratification." Specialty Crop Competitiveness Act of 2004, Pub. L. No. 108-465, § 3 (2004); USDA AMS, "What Is a Specialty Crop?" (accessed February 25, 2020).

information about pesticide exposure with information about toxicity to determine the potential health risks posed by the pesticide residues.

There are three main ways a government may establish an MRL:

- Establish its own MRL through its regulatory processes for pesticide registration and MRLs, which may include basing the MRL on the relevant Codex MRL.
- Defer to an existing MRL (often a Codex MRL or an MRL established by another regulatory authority in another country).
- Establish an MRL based on an import tolerance application (see discussion below).

Positive list system: A positive list system is one where the market has a list of active substances/pesticides that are allowed; anything not on the list is not allowed for use in the market. Government authorities generally create a positive list system when they develop their own independent regulatory frameworks and processes to establish their own MRLs. Some of the major global import markets for agricultural goods, such as the United States, Canada, China, the European Union (EU), Hong Kong, South Korea, Taiwan, Japan, and Russia, establish MRLs based on a positive list system.

Codex MRLs: Codex establishes MRLs (referred to as Codex MRLs or “CXLs”) intended to serve as international standards. The majority of countries worldwide depend on these voluntary Codex MRLs, which provide a degree of global harmonization and transparency in MRL setting. Governments may use Codex MRLs either by deferring to them or by taking Codex MRLs into consideration when establishing their own MRLs. Chapter 2 of this report describes the approaches, methods, and procedures used by Codex to establish its MRLs.

Import tolerance: An import tolerance is used by exporters to fill a “missing” MRL that does not exist for their particular pesticide/crop combination in the market to which a crop is exported or where the MRL exists but is lower than that of the producing country. In some cases, the import tolerance is sought because the pesticide is not registered in the import market at all. In other cases, an “import tolerance” might be sought for an imported crop because, while the pesticide is registered for use in the import market, the existing MRL is insufficient to meet a foreign use pattern. In those cases, the existing MRL might be raised.

For example, countries may establish MRLs based on import tolerance applications for pesticides that are not commonly used in that market; e.g., a country in a temperate zone may establish an import tolerance MRL for a pesticide that is normally for tropical crop use. Or they may do so for a pesticide that is used domestically on different crops than the imported crop—e.g., an import market may have established an MRL for chlorothalonil on cherries but not for chlorothalonil on carambola (star fruit). Challenges that agricultural exporters face securing import tolerances in some markets are discussed in chapters 4 of this report.

Default MRLs: When a country has not established an MRL for a specific pesticide/crop combination, regulators may elect to apply a “default” MRL to imported crops treated with this pesticide. Regulators may choose among several options in determining the default they will apply, including deferring to a Codex MRL or another country’s MRL or using a numerical default level (a preset level not determined through an evaluation of the pesticide residue). Some markets elect to adopt a combination of these types of default options for different pesticide/crop combinations.

For markets that elect to use their own numerical default, such as South Korea and the EU, the default MRL can be set near the "lowest limit of analytical determination." Many of these markets use a numerical level of 0.01 ppm for their "limit of determination/quantification" default. However, while numerical defaults for MRLs are typically intended to be very low, they vary by market, ranging from a low of 0.01 ppm to a high of 0.1 ppm.[35] In some instances a numerical default MRL can effectively block market access.

In the absence of a default, some markets, such as the United States and China, may have zero tolerance for residues. That is, if no MRL has been set for a particular pesticide, then a crop with any detectable residue of that pesticide is not permitted. This practice effectively blocks market access for imported crops treated by a pesticide for which an MRL does not exist in the import market.

Pesticide label ("label"): Pesticide labels refer to not only the actual labeling on pesticide packaging, but also the entirety of information on how to handle and use each pesticide.[36] The label includes ways to safely apply and legally manage the use of pesticides, following the regulator-approved practices that consider various risks, such as daily consumption and exposure. In many markets, labels are legally enforceable, must be approved by regulators, and must be closely monitored. In addition, they govern only the domestic use of the pesticide. Hence, a label created in one market may not match the label of a trading partner, even though the pesticide and active substance are identical.

Minor Crops and Crop Groupings: Minor crops are a particular issue when it comes to setting MRLs. Although there is no standard definition of a minor crop, they are often high-value specialty crops with relatively low production levels.[37] The small scales at which minor crops are produced may limit economic incentives for pesticide companies to register pesticides for use on those crops. This can lead to MRLs not being established for pesticide/minor crop combinations.

In response, many governments and Codex cluster similar crops into "crop groupings." For instance, mustard greens might be a member of a "leafy greens" crop grouping. This approach allows data gathered from crop trials for one crop within a grouping to be used for the entire crop grouping. Along with increasing the size of the market for the pesticide, this helps strengthen the economic incentive for pesticide companies to register pesticides for minor crops.

[35] The "lowest limit of analytical determination" is often referred to as "the limit of determination" and is often used synonymously with the "the limit of quantification." These terms refer to the lowest amount of a substance that is quantifiable, within a margin of error. The "limit/level of detection" is sometimes used instead of these terms, although this term is defined as the lowest quantity at which a substance can be detected, even if the amount present cannot be quantified. Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 85; European Commission, "How Are EU MRLs Set?" (accessed February 20, 2020); industry representatives, interview by USITC staff, March 5, 2020. IUPAC, *Compendium of Chemical Terminology* (accessed March 26, 2020).
[36] U.S. EPA, "Introduction to Pesticide Labels" (accessed March 23, 2020).
[37] The term "minor use crops" may be used interchangeably with "minor crops." The EPA defines minor use crops as those having less than 300,000 acres of growing area. OECD, *Guidance Document on Regulatory Incentives for the Registration of Pesticide Minor Uses*, June 23, 2011, 12; EPA, "Minor Uses and Grower Resources," August 2, 2019; OECD, "Minor Uses of Pesticides," 2019.

Missing and Low MRLs

Stakeholders throughout the world's agricultural supply chains are concerned with the differences in MRLs across markets, including when they are missing or low. Moreover, the request from the USTR specifically asks for a report on global economic impacts of missing and low MRLs. However, what constitutes a "missing" or "low" MRL is not strictly defined by the agricultural trade community. A summary of how stakeholders generally interpret these terms is provided below, based on the literature and interested parties that provided information for this investigation.

Missing MRLs

Agricultural exporters consider MRLs to be "missing" when a market to which they wish to export (import market) does not have an MRL for the pesticide/crop combination that they use or produce. There are several reasons why MRLs may be missing in a particular market. Table 1.2 presents several examples of missing MRLs.

Table 1.2 Examples of missing MRLs

Missing MRLs	Examples of reasons that MRLs may be missing in import markets
The market to which farmers export does not have an MRL in place for the pesticide/crop that they use/produce.	• No MRLs for pesticide X **have been established** in Japan because **pesticide X is not registered** for use in Japan. • No MRL for pesticide X/crop Y **has been established in Japan** because although **Japanese farmers use pesticide X, they do not use it on crop Y or produce crop Y**. • A pesticide manufacturer **has not applied for an import tolerance** (MRL) to be set for a certain pesticide/crop combination in South Korea, because it is a specialty crop produced in small volumes which do not justify the expense of conducting the field trials and generating the data required to support the MRL application. • A pesticide manufacturer **has applied for an import tolerance** (MRL) to be set for a certain pesticide/crop combination in Taiwan; however, the submitted **application/dossier was deemed insufficient/unacceptable** by the regulatory authority and rejected. • Although there is a Codex MRL for this pesticide/crop combination, **the importing regulatory authority has not adopted** the Codex MRL or established its own MRL. • Although an importing country generally adopts Codex MRLs, **there is no Codex MRL** for this pesticide/crop combination. • In the absence of an MRL in place, the regulatory authority has not set a default level, implying a **zero-residue tolerance** for that pesticide, i.e., no trace residue levels are permitted on imported crops in that country.

Source: Compiled by USITC.

Low MRLs

Agricultural exporters consider some MRLs to be "low" in destination markets. No specific numerical pesticide residue level cutoff defines what constitutes a low MRL; instead, a "low MRL" is generally understood to be a relative term. Broadly, exporters consider an export market MRL to be low if it is lower than in their home market, lower relative to another export market, or lower relative to Codex. Exporters may also consider an export market MRL to be low if it has been lowered from a previous level or set to a default at the analytical limit of quantification (also referred to as the lowest limit of analytical determination). Table 1.3 illustrates some ways in which an MRL may be considered low by agricultural exporters.

Table 1.3 Examples of low MRLs

Low MRLs	Examples of reasons that MRLs may be considered low in import markets
An import MRL faced by an exporter **is lower** than the MRL permitted in the home market.	• A U.S. exporter faces an MRL of 2 parts per million (ppm) in Australia, while the MRL in the United States is 4 ppm.
An existing import MRL faced by an exporter **is reduced** to a lower level and this level is lower than the MRL permitted in the home market.	• In the process of reviewing existing pesticide registrations, the regulator reviews data and recommends lowering the MRL from 5 ppm to 2 ppm. • South Korea previously had adopted Codex MRLs but is developing a positive list system. As part of the process of establishing its own MRLs, South Korea reduces an MRL from 5ppm (under Codex) to 3 ppm. • In the process of reviewing existing pesticide registrations, the EU does not renew a certain pesticide and revokes the existing 2 ppm MRL for that pesticide. This process results in a change in the MRL from 2 ppm to a default of 0.01 ppm.
An import MRL faced by an exporter **is lower than or is changed to a lower level than** an international standard like Codex.	• A U.S. exporter faces a 3 ppm MRL in Japan, while the Codex MRL is 5 ppm.
An import MRL faced by an exporter is **lower in one export market than in another export market.**	• A U.S. exporter ships apples to the EU and Japan. As a result of these markets' separate processes for establishing MRLs, the MRL for a certain pesticide used on apples is 3 ppm in the EU and 2 ppm in Japan.
An MRL faced by an exporter is **considered by farmers to be too low** to use the pesticide according to the pesticide label approved for use in the home market.	• A U.S. grower complies with a 5 ppm MRL in its home market. However, the same MRL in its main export market is 3 ppm. The U.S. grower is able to meet this lower MRL by adjusting use of the pesticide so that residue levels meet the 3 ppm limit. Later, the MRL in the export market is reviewed and lowered to a default of 0.01 ppm (the limit of determination/quantification). The U.S. grower is unable to adjust pesticide use to meet this extremely low MRL. However, a grower in a different country facing less pest pressure may still be able to meet this default level MRL.

Source: Compiled by USITC.

MRLs and Challenges in Global Agriculture

Pesticides and their corresponding MRLs play a key role in global agricultural production, trade, and food safety. As noted above, policies for establishing MRLs are intertwined with those for registering pesticide use. In setting both policies for using pesticides and policies for deciding the legally tolerable level of pesticide residue left on food crops, regulators take into account some of the same considerations, such as weighing the efficacy of pesticides against their inherent risks.

Food Safety

There is global recognition about the importance of evaluating pesticides to ensure food safety. Regulators around the world seek to ensure that pesticides are available for use generally only after exposure to those pesticides is judged to have negligible adverse effects on human and animal health and the environment. As described in chapter 2, national regulatory bodies have established systems to evaluate the safety of pesticides, regulate pesticide usage, evaluate pesticide residues, and monitor compliance with these regulations. These regulations often evolve over time in response to further scientific research or changing attitudes about acceptable levels of risk. (See also box 2.1**,** "The Evolution of Pesticide Regulations: The Case of DDT.") After evaluating a pesticide for efficacy and possible adverse effects, regulatory bodies generally set MRLs based on the exposure levels at which possible adverse effects from these pesticides may occur. To establish a level of exposure unlikely to cause harm to humans, regulatory bodies evaluate actual pesticide residues in the context of dietary intake and other exposure, and establish MRLs on pesticide/crop combinations accordingly. MRLs allow regulatory bodies to ensure that both domestic and imported agricultural products are safe to consume and that growers have used pesticides correctly. Pesticides' negative effects on human health can be both acute and chronic, and they may have varying impacts on certain groups,[38] such as infants and children. These factors are taken into account during the risk assessments, which consider these human health impacts when evaluating pesticides and MRLs. MRLs are set at use patterns under GAP to ensure the protection of health and the environment.

Trade

Differences in MRLs, including when MRLs are missing and low, as well as differences in MRL policies are increasingly affecting trade in a number of ways. As described in detail in chapters 4, 5, and 6, these effects can ripple through the agricultural value chain and ultimately have consequences on production, prices, and farmer income. The impacts from missing or low MRLs can vary by country and may be particularly problematic for farmers exporting minor or specialty crops, which have fewer existing MRLs. Producers in tropical countries, who face greater pest pressure, may also be particularly affected by these factors.[39] In low-income countries, producers typically have fewer resources available for addressing these challenges.

Agricultural Production and Pesticides

Farmers worldwide depend on pesticides for a variety of reasons, including to obtain higher yields, minimize operating costs, and reduce post-harvest losses. Pesticide use has noneconomic benefits as well. For example, it supports conservation tillage practices that improve the sustainability of agriculture and help meet growing demand for food.

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[38] Delaplane, "Pesticide Usage in the United States," March 1996; Food and Agriculture Organization (FAO), *International Code of Conduct on the Distribution and Use of Pesticides,* 2010.
[39] National Research Council, *Sustainable Agriculture and the Environment*, 1993, 53.

Although beyond the scope of this study, commentators and scientists have also noted some negative impacts of pesticide use.[40] In addition to the potential negative effects on human health noted above, negative environmental impacts may include water and soil contamination, toxicity to wildlife and the loss of biodiversity, and decreases in beneficial insect populations, in particular bees and other pollinators.[41]

Improving Yield

The active substances in pesticides protect crops against insects, weeds, fungi, and other pests, boosting yields in farm output globally.[42] One study estimated that without the more than 1,000 pesticides used in agricultural production around the world, crop losses globally for five major crops would range between 40 percent and 62 percent, depending on the crop.[43] These improvements to yields make pesticides important tools in feeding a growing population and achieving global food security.[44] The increase in agricultural yields boosted by pesticide use can reduce the land required to produce the same amount of food.[45] This can have a positive impact on the environment by preserving habitat and biodiversity.[46]

Sustainable Practices

Pesticides also contribute to sustainable farming practices, such as conservation tillage, which limits disturbance to the soil. Conservation tillage systems are used in the United States for 67 percent of soybeans, corn, and wheat production.[47] Conservation tillage, unlike mechanical soil tillage, reduces soil erosion by up to 90 percent, reducing runoff that pollutes waterways, and increases the amount of carbon that soil can store.[48] This practice often involves the use of herbicides to kill the "cover crop,"

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[40] Sexton, Lei, and Zilberman, "The Economics of Pesticides and Pest Control," September 17, 2007, 279–80; Food and Agriculture Organization (FAO), *International Code of Conduct on the Distribution and Use of Pesticides,* 2010; Bylemans, De Coninck, and Keulemans, *Farming without Plant Protection Products*, June 12, 2019.

[41] Food and Agriculture Organization (FAO), *International Code of Conduct on the Distribution and Use of Pesticides,* 2010.

[42] It is estimated that 35 percent of potential yields around the world are lost due to pest pressure, with an estimated value of $200 billion in annual losses. Popp, Pető, and Nagy, "Pesticide Productivity and Food Security," January 2013; CLA and CLI, written submission to USITC, December 13, 2019.

[43] The study estimated losses for wheat (40 percent), rice (62 percent), maize (55 percent), potatoes (60 percent), and soybeans (48 percent). Bylemans, De Coninck, and Keulemans, *Farming without Plant Protection Products*, June 12, 2019; Lexagri International, Homologa database (accessed February 6, 2020).

[44] Currently, an estimated 820 million people around the world do not have enough food to eat, and food demand is expected to increase 70 percent by 2050. This increase stems from an expected 27 percent increase in world population (with much of that growth in low-income countries), combined with an increasingly wealthy population shifting towards more resource-intensive diets. FAO et al., *The State of Food Security and Nutrition*, 2019; UN DESA, "World Population Prospects 2019: Highlights," June 2019; FAO, "Feeding the World in 2050," November 16, 2009.

[45] Bylemans, De Coninck, and Keulemans, *Farming without Plant Protection Products*, June 12, 2019.

[46] McDougall, "Evolution of the Crop Protection Industry since 1960," November 2018; CropLife International, "Fact Sheet: Biodiversity and Pesticides," April 2009.

[47] Claassen et al., "Tillage Intensity and Conservation Cropping in the United States," September 2018, 27.

[48] Nunes et al., "*No-till and Cropping System Diversification,*" October 2018; USDA, NRCS, "Benefits of Conservation Tillage" (accessed January 27, 2020).

which is planted to maintain soil moisture and nutrients between plantings, before planting the main crop. Planting the main crop is done by drilling the seed into the untilled soil beneath the stubble of the cover crop, eliminating the need to mechanically till the soil at any point. Crop seed genetically engineered to be resistant to herbicides is often used in conservation tillage systems because it allows the grower to use herbicides on these crops to remove cover crops and control weeds, reducing labor and fuel costs.

Post-harvest Loss

Pesticides also play an important role in preventing post-harvest food loss and waste.[49] Fungicides are particularly important in preserving the quality of crops after harvest.[50] For instance, pome and stone fruits, such as apples and cherries, are susceptible to common post-harvest diseases such as bulls-eye rot and blue and gray molds that are controlled using fungicides.[51] The use of post-harvest fungicides not only allows perishable products to maintain quality throughout the supply chain, but also helps producers access long-distance markets. For example, according to one government official, without the ability to apply the fungicide thiabendazole after harvest, Brazilian mangoes would rot over the 20 days it takes to transport them by ship to the EU.[52] Instead, they would have to be airfreighted to markets in the EU at reportedly 10 times the cost.[53] Post-harvest applications of fungicides are also used to control the fungi that produce mycotoxins and aflatoxins, which have serious impacts on food safety.[54] Case studies illustrating the importance of fungicides for producers of highly perishable crops are provided in chapter 5.

Changing Pest Pressures

Despite the benefits of pesticide use, over time the pests that they control can develop resistance to pesticides and can take advantage of shifting weather and climate patterns as well. For farmers globally, evolving pest resistance to pesticides is a growing concern that highlights the need for the proper application of pesticides and for access to a range of pesticide options. Pest and disease pressure can vary within a given growing region, and from season to season. In addition, different growing regions experience different pest pressures,[55] with tropical regions generally facing higher pressure than temperate regions do. Changes in climates are shifting pest ranges, which exposes producers to invasive pest species. Regions faced with novel invasive pests often lack existing natural predators and diseases that can play a role in controlling pests. Also, farmers often need to develop new pest management strategies to control novel pests. This variability in pest pressure across seasons and climatic regions,

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[49] PPC, written submission to USITC, December 13, 2019; IR-4, written submission to USITC, December 13, 2019; CLA and CLI, written submission to USITC, December 13, 2019; NHC, written submission to USITC, December 13, 2019.
[50] Maitree, "Prevention and Control of Mycotoxins," 1991.
[51] NHC, written submission to USITC, December 13, 2019.
[52] Foreign government official, telephone interview by USITC staff, October 22, 2019.
[53] Foreign government official, telephone interview by USITC staff, October 22, 2019.
[54] Maitree, "Prevention and Control of Mycotoxins," 1991; NHC, written submission to USITC, December 13, 2019.
[55] For instance, the pest pressures on rice production in the United States vary by region. While California reportedly is the state most impacted by weeds, it faces only minor pressure from insects and diseases, whereas rice-producing states in the southern United States face heightened pressure from all types of pests due to a warm, humid climate. USA Rice, written submission to USITC, December 13, 2019.

combined with invasive pest species driven by changing climates, illustrates that the importance of pesticides is not constant and uniform.

Pest Resistance

Resistance to pesticides is a major concern for agriculture producers globally.[56] According to one study, weed species have evolved resistance to all 12 classes of herbicide, while no new mode of action for chemical weed control has been developed in over three decades. Similarly, since 1984, 550 species of arthropods (e.g., insects and mites) have become resistant to at least one insecticide, a 23 percent increase.[57] The use of pesticides puts selective pressure on pest species such that the individual pests that are able to survive the application of pesticides are the ones that can then reproduce. This causes pests to evolve resistance over time. Many pests can grow and reproduce faster in warmer climates, shortening the time between generations, which can speed up the evolution of resistance to pesticide products.[58] Moreover, resistance has knock-on effects on cropping systems that can impact a number of stakeholders, including growers and input suppliers. For instance, more than 40 weed species have developed resistance to the herbicide glyphosate, making glyphosate-resistant crop seeds less useful.[59] Reportedly, resistance to pesticides increases annual costs incurred by the U.S. agricultural sector by $10 billion.[60]

There are several ways to avoid pest resistance. One is having multiple pesticide products available for farmers to use.[61] This allows them to rotate the use of different products so that pests are less likely to develop resistance to any one pesticide. Another general way of preventing pest resistance to pesticides is to apply pesticides properly as part of an overall integrated pest management (IPM) strategy.[62] IPM principles involve preventing, identifying, and monitoring pest populations, and then tailoring management techniques to the level of the threat, to help reduce resistance. Minor pest damage may be better managed by introducing beneficial insects, employing biopesticides such as pheromones, or removing and destroying diseased plants.[63] Under an IPM strategy, if pesticides are needed, they are applied according to their label instructions, and the application of the pesticide is timed to maximize its impact while avoiding overuse. This strategic use of pesticides can also help reduce their harm to beneficial insect species.

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[56] NHC, written submission to USITC, December 13, 2019; ABC, written submission to USITC, December 13, 2019; NABC, written submission to USITC, December 13, 2019.
[57] The class into which an herbicide falls is defined by the mode of action of its active substance. Gould, Brown, and Kuzma, “Wicked Evolution,” May 18, 2018; Lingenfelter and Hartwig, “Introduction to Weeds and Herbicides,” 2013; Georghiou, “Overview of Insecticide Resistance,” 1990.
[58] FAO, *The Future of Food and Agriculture*, 2017.
[59] Gould, Brown, and Kuzma, “Wicked Evolution,” May 18, 2018.
[60] This value is based on an estimate that 10 percent of crop damage caused by pests results from resistant pests. Gould, Brown, and Kuzma, “Wicked Evolution,” May 18, 2018; Palumbi, “Humans as the World’s Greatest Evolutionary Force,” September 7, 2001.
[61] EPA, “Slowing and Combating Pest Resistance to Pesticides,” August 2, 2019; NHC, written submission to USITC, December 13, 2019; CLA and CLI, written submission to USITC, December 13, 2019.
[62] EPA, “Slowing and Combating Pest Resistance to Pesticides,” August 2, 2019.
[63] Beneficial insects can be any insect that provides a benefit to agricultural production, such as pollination or preying on pest species. They can be either naturally occurring or introduced by the farmer.

Weather and Climate Impacts on Pesticide Use

Weather conditions and climate patterns in agricultural production regions can have major impacts on pesticide use. Many pests and diseases—such as aphids, downy mildew, and *Stemphylium* leaf blight—thrive in hot, humid, or wet conditions.[64] In temperate climates, changes in weather patterns within and across growing seasons can cause variations in pest pressures. Tropical climates have higher humidity and warmer temperatures and lack hard winter freezes to break pest life cycles. As a result, they often face higher pest and disease pressure than other climatic regions. In some tropical climates, organic production is not commercially practical for a number of crops (for more information on production in tropical climates, see the case studies in chapter 5 of this report). This makes pesticides integral to agricultural production in these climates.

As climate patterns shift, pest pressure on agricultural production is also expected to grow.[65] For example, it is expected that for every 1 degree Celsius (1.8 degrees Fahrenheit) that mean global average temperatures increase, crop yield losses will rise by 10–25 percent, partially due to additional pest and disease pressure.[66] One reason for the rise in pest pressure is that the added heat may increase the reproductive and metabolic rates of pests, resulting in higher populations of hungrier pests.[67] Moreover, when climates shift, pests can survive and cause crop damage in new agricultural areas, leading to an increase in the incidence of pest invasions.[68] For example, the desert locust infestation that began in East Africa in 2019 was partially caused by abnormally wet weather, reportedly linked to climate change, that produced vegetation that sustained desert locusts and allowed them to spread.[69] This outbreak has damaged tens of thousands of acres of croplands and pasture in Kenya, Ethiopia, and Somalia, and threatens South Sudan and Uganda.[70] In one day, a swarm of locusts that is one square kilometer in size can eat as much food as 35,000 people.[71] Kenya has been particularly affected; large swarms up to 40–60 km wide had damaged crops and pastureland in 13 counties as of the end of January 2020.[72] One of the main control methods for desert locusts is through the application of pesticides, often using airplanes.[73]

These pest impacts from shifting climate patterns are amplified as growers lose the option to use certain pesticides due to diverging MRL policies. Industry representatives note that the true impact from the inability to use pesticides may not be felt immediately but will be seen in upcoming years. Some state that "[a]s more and more challenges emerge due to more dramatic weather events and changing

[64] Burt, "Weather and Pests," May 2002; Hausbeck, "Wet, Humid Weather Challenges Vegetable Disease Management," June 24, 2019.
[65] FAO, *The Future of Food and Agriculture,* 2017.
[66] CLA and CLI, written submission to USITC, December 13, 2019; Bylemans, De Coninck, and Keulemans, *Farming without Plant Protection Products*, June 12, 2019.
[67] Deutsch et al., "Increase in Crop Losses to Insect Pests in a Warming Climate," August 31, 2018: 916–19.
[68] CLA and CLI, written submission to USITC, December 13, 2019.
[69] Stokstad, Erik, "In Somalia, an Unprecedented Effort," February 12, 2020; UNEP, "Locust Swarms and Climate Change," February 6, 2020.
[70] FAO, "Alarm over Desert Locusts Increases," January 29, 2020; FAO, "FAO Appeals for Urgent Support," January 30, 2020.
[71] FAO, "Alarm over Desert Locusts Increases," January 29, 2020.
[72] FAO, "FAO Appeals for Urgent Support," January 30, 2020.
[73] Stokstad, Erik, "In Somalia, an Unprecedented Effort," February 12, 2020.

climatic patterns, it has never been more important to have all of the tools available for safe and efficient agricultural production."[74] For example, the sweet potato industry noted that one pesticide (a premix of propiconazole and fludioxonil) was effective in reducing threats to sweet potato crops from black rot, which has been occurring more frequently following hurricanes. However, the absence of an EU MRL for this pesticide/crop combination effectively limits the ability of growers to use this product in cases of extreme weather conditions.[75]

Pesticides and Invasive Pests: Fall Armyworm

Recent experience with the fall armyworm (*Spodoptera frugiperda*), an invasive pest threatening staple crops in a number of developing countries, illustrates the challenges posed by invasive pests and the importance of access to pesticides to overcome evolving pest pressures. The fall armyworm is an invasive or "transboundary" pest that has caused extensive damage to agricultural production in sub-Saharan Africa (SSA) and Asia since 2016. The fall armyworm is native to tropical and subtropical regions in the Americas and feeds mostly on corn, but also on other major staple crops like rice, sorghum, and millet.[76] Given its short life cycle of about a month, two or three generations of the pest can infest and damage a single crop.[77] The pest was first identified in SSA in 2016 and by 2018 had spread to India.[78] In July 2019, it had reached Japan.[79] By 2019, reports were made of global yield losses of upwards of 40 percent. Experts estimated that the cost of damage to corn production alone could reach more than $4.8 billion, potentially leaving over 300 million people food insecure.[80]

In the early days of the outbreak, the fall armyworm presence in SSA was compounded by the limited number of pest control methods available to local farmers. By contrast, in the United States and Brazil, fall armyworm is effectively controlled with a combination of approaches. These include the planting of Bt corn (containing genes from *Bacillus thuringiensis*, which produces proteins that are toxic to many insects), combined with biocontrol methods (such as the predatory wasp *Trichogramma*), biopesticides (such as neem oil), and low-risk chemical pesticides; examples of the latter include indoxacarb for control at the early larval stage and novaluron for control at the late larval stage.[81]

In most SSA countries, however, neither Bt corn nor many newer, lower-risk biologic and synthetic pesticides are approved for use by local farmers.[82] Also, generally missing across the region are biocontrol methods, such as predatory insects, which require local industries to grow and distribute the

[74] ASA and USSEC, written submission to USITC, December 13, 2019, 6.
[75] ASPMI and U.S. Sweet Potato Council, written submission to the USITC, December 13, 2019, 3.
[76] In 2015, rice production in California was impacted for the first time by a fall armyworm infestation following a severe, long-term drought. California Rice, written submission to USITC, December 13, 2019; FAO, "Fall Armyworm" (accessed January 18, 2020).
[77] Tanakasempipat and Thukral, "Fall Armyworm Invades Crops across Asia," June 20, 2019.
[78] FAO, "Fall Armyworm" (accessed January 18, 2020).
[79] FAO, "Fall Armyworm" (accessed January 18, 2020).
[80] Tanakasempipat and Thukral, "Fall Armyworm Invades Crops across Asia," June 20, 2019; FAO, "Five Things to Know," February 27, 2018.
[81] USAID, "Technologies for Managing Fall Armyworm," August 22, 2018; Dively, "Management of Fall Armyworm," 2018; EPA, "Pesticide Fact Sheet: Indoxacarb," October 30, 2000; EPA, "Pesticide Fact Sheet: Novaluron," September 24, 2001.
[82] Dively, "Management of Fall Armyworm," 2018; USAID, "Technologies for Managing Fall Armyworm," August 22, 2018; Prasanna et al., *Fall Armyworm in Africa: A Guide*, 2018.

relevant organisms.[83] Generally, SSA farmers have been able to access only those pesticides registered for use in their countries, which tend to be older, generic versions of broad-spectrum pesticides. These pesticides, which are toxic to a wide range of organisms, are less expensive but also considered more hazardous to human and/or environmental health than newer, reduced-risk pesticides.[84] Moreover, broad-spectrum pesticides are not tailored for use on fall armyworm, and therefore provided limited control.

However, the broad-spectrum pesticides were distributed by SSA governments at low or no cost to farmers who had little training in their safe and effective use.[85] This weakened the demand for better, lower-risk methods, and led to the heavy and unsafe use of outdated hazardous pesticides that did not effectively control the fall armyworm, which ultimately developed resistance to many of these products.[86] Once fall armyworm gets established in a new location, it is nearly impossible to eradicate.[87] Because the expected crop loss was so high, some countries, such as Kenya, have allowed emergency authorizations for farmers to use previously unavailable pesticides to treat fall armyworm.[88]

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[83] USAID, "Technologies for Managing Fall Armyworm," August 22, 2018; Prasanna et al., *Fall Armyworm in Africa: A Guide*, 2018; Dively, "Management of Fall Armyworm," 2018.
[84] U.S. government official, telephone interview by USITC staff, January 17, 2020; USAID, "Technologies for Managing Fall Armyworm: Lessons from Brazil" August 22, 2018; Prasanna et al., *Fall Armyworm in Africa: A Guide for Integrated Pest Management*, 2018.
[85] U.S. government official, telephone interview by USITC staff, January 17, 2020.
[86] U.S. government official, telephone interview by USITC staff, January 17, 2020; Prasanna et al., *Fall Armyworm in Africa: A Guide for Integrated Pest Management*, 2018; USAID, "Technologies for Managing Fall Armyworm: Lessons from Brazil," August 22, 2018.
[87] FAO, "Fall Armyworm (FAW) Q&A," 2017.
[88] Industry representatives, interview by USITC staff, Nairobi, Kenya, December 2, 2019.

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Chapter 2
Maximum Residue Level Policy Approaches

Introduction

While there is widespread agreement internationally about the importance of protecting both consumer health and the environment, the approaches and policies employed to regulate pesticide use and determine pesticide maximum residue levels (MRLs) on food crops are globally inconsistent. Regional and international organizations have developed guidelines and standards to promote the use of harmonized MRLs. However, as the needs and expectations of growers, who use pesticides, and consumers, who purchase agricultural products, continue to evolve—in many cases at a faster rate than consensus-based international organizations can accommodate—pesticide regulation and MRLs are diverging and becoming more localized. A number of stakeholders reported concerns that the approaches taken by some policy makers and regulators in registering pesticides and setting MRLs may be susceptible to political and socioeconomic considerations and influences attenuated from the underlying scientific findings on pesticides and associated risks.[89] Stakeholders are also concerned that divergent MRLs and the use of non-risk-based assessments to reject the registration or re-registration of pesticides will affect MRLs and impact trade of agricultural and food products globally.[90] Numerous challenges and concerns associated with meeting missing or low MRLs in major agricultural export markets are further discussed in chapter 4 of this report.

The objective of this chapter is to lay out a common context within which to understand regulations and policies governing pesticides and MRLs.[91] To meet this objective, this chapter outlines key concepts and internationally recognized steps for risk assessment which are used in registering pesticides and establishing MRLs.[92] Next, this chapter gives an overview of the steps and practices used by the Codex Alimentarius Commission ("Codex"), an international standard-setting body, focusing on the roles and responsibilities of the Codex Committee on Pesticide Residue (CCPR) and the Joint Meeting on Pesticide Residue (JMPR), the two Codex subsidiary groups primarily responsible for establishing Codex MRLs.[93] This chapter also describes other international efforts affecting MRL-setting policy, including MRL initiatives organized by the member states in the Asia-Pacific Economic Cooperation (APEC) forum and the Association of Southeast Asian Nations (ASEAN), as well as work by the Organisation for Economic

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[89] WTO, "Minutes of the Meeting of the Council for Trade in Goods," October 30, 2019, 18–31; WTO, "EU—Implementation of Non-Tariff Barriers on Agricultural Products," July 4, 2019, September 2, 2019, and November 1, 2019; ACP, "Letter to the Chair of the Committee on Trade in Goods," July 8, 2019.
[90] Lantz, "EU Endocrine Disruptors," November 2017.
[91] Market-specific regulations in key agricultural markets are presented in chapter 3 of this report.
[92] The term MRL is used generically and applies to any situation where a maximum residue level may be established, including import tolerances. See chapter 1 for an overview of terms.
[93] The Codex Alimentarius Commission, the organization, and the *Codex Alimentarius*, the set of standards that are agreed upon and published, are both commonly referred to as "Codex," and the two meanings are used interchangeably throughout this report.

Co-operation and Development (OECD) to harmonize pesticide registration and the MRL-setting processes. Finally, this chapter discusses the development of lower- or reduced-risk pesticides and integrated pest management practices, as well as the international efforts to promote their use in countries at various levels of income.

Regulation of Pesticides and MRLs

Differences in the way regulators in various countries use a range of criteria to assess the impact of pesticides on human health, animal health, and the environment have led to increasing divergence of MRLs globally over time.[94] How different authorities weigh the benefits and possible harm of chemicals—as seen with DDT (box 2.1)—can affect how they regulate pesticides and MRLs. In all markets, regulatory authorities assess pesticides and MRLs using the principles of both hazard and risk in most circumstances. Hazard is the intrinsic potential of a substance to cause harm, whereas risk is the probability of harm occurring based on the expected level of exposure.[95] Governments consider the potential for both hazard and risk when conducting risk assessments to evaluate active substances for registration, for renewal of existing registrations, or for establishment of MRLs (whether based on domestic registrations or import tolerance applications). Regulators factor risk assessment results into their risk management decisions. However, policy makers and regulators in certain markets, in certain circumstances, reportedly focus on hazard assessment when making risk management decisions; some have policies in place that prescribe the use of hazard-based criteria in certain limited circumstances without completing a full risk assessment.[96]

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[94] USITC, hearing transcript, October 29, 2020, 17, 39, 53, 64 (testimony of Alinne Oliveira, Bryant Christie), 23–27, 66 (testimony of David Epstein, Northwest Horticultural Council), and 125–26 (testimony of Christopher Novak, CropLife America).

[95] IPCS, *IPCS Risk Assessment Terminology,* 2004, 12. A useful discussion is found in Barlow et al. 2015 (see below). This widely cited article summarizes a December 2014 workshop sponsored by the International Life Sciences Institute Europe, "Hazard vs. Risk Based Approaches in Food Safety Assessment," at which participants discussed both risk-based and hazard-based approaches in food safety assessment. In lieu of proceedings, the main issues were summarized in a journal article in *Trends in Food Science and Technology*. Barlow et al., "The Role of Hazard- and Risk-Based Approaches in Ensuring Food Safety," December 2015.

[96] USITC, hearing transcript, October 29, 2020, 8–11 (testimony of Luis González Fernández, Republic of Paraguay), 17, 39, 53, 64 (testimony of Alinne Oliveira, Bryant Christie), 23–27, 66 (testimony of David Epstein, Northwest Horticultural Council), and 125–26 (testimony of Christopher Novak, CropLife America).

Box 2.1 The Evolution of Pesticide Regulations: The Case of DDT

During the 20th century, synthetic chemicals increasingly found their way into pesticides—and while they made pesticides highly effective in controlling pests and plant diseases, some chemicals also adversely affected the environment and human health. During and shortly after World War II, the development and use of chemical pesticides expanded as farmers found that they greatly improved crop quality and yields.[a] At that time, residue-based pesticide regulations were lacking. As use of these pesticides increased, some pests developed resistance; non-target plants and animals were harmed; and pesticide residues appeared in unexpected places.[b] These negative effects led to tightened food safety regulations, and some chemicals that were found to be highly toxic were prohibited or severely restricted.[c] In addition, to protect consumer safety and address environmental exposure, pesticide residue regulations, testing requirements, and enforcement mechanisms were implemented.

The need for policy approaches that allow national and international policy makers and regulators to balance a pesticide's toxicity with its benefits is illustrated by the example of DDT. In 1939, Paul Hermann Müller discovered the insecticidal properties of dichlorodiphenyltrichloroethane, commonly known as DDT. DDT was initially used extensively during World War II to control insects that spread malaria, typhus, and other insect-borne human diseases of serious concern to both the military and civilian populations. DDT's use was then expanded to include insect control in crop production. Because of its effectiveness, agricultural use spread widely throughout developed countries.[d]

As DDT's use increased around the world, so did evidence of its negative environmental and toxicological effects.[e] Increased regulation and prohibitions followed. By 1972, the U.S. Environmental Protection Agency (EPA) issued the final cancellation order for all remaining crop uses of DDT.[f] In 2001, the Stockholm Convention listed DDT as a persistent organic pollutant (POP), prohibiting its use as an agricultural chemical globally. This action did make one exception, permitting production and use limited to disease vector (mosquito) control.[g] Similarly, in 2006 the World Health Organization supported the indoor use of DDT to help combat malaria in countries where malaria remains a major health concern because it considered its use as a pesticide in combating malarial mosquitos to outweigh its health and environmental risks.[h]

[a] CDPR, "A Brief History of Pesticide Regulation," February 2017, 3–4.
[b] Delaplane, "Pesticide Usage in the United States," March 1996.
[c] CDPR, "A Brief History of Pesticide Regulation," February 2017, 3–4.
[d] CDPR, "A Brief History of Pesticide Regulation," February 2017, 3.
[e] Negative effects of DDT have been shown to include (1) decreased reproductive rate in birds because of eggshell thinning and embryo deaths; (2) high toxicity to aquatic animals and fish; (3) high persistence in the environment with soil half-life of up to 15 years and an aquatic half-life of 150 years; (4) accumulation in fatty tissues of animals and humans; and (5) carcinogenic effects (DDT is now classified as a B2 carcinogen). NPIC, "DDT: General Fact Sheet," 1999.
[f] In the United States, the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") requires all pesticides sold or distributed in the United States to be registered. Section 6(b) of FIFRA authorizes EPA to take the initiative to cancel a pesticide registration when existing risks related to the use of the pesticide are unacceptable, and registrants either have not made, or cannot make, necessary changes to the terms and conditions of the registration to address the unacceptable risks. EPA, "Pesticide Cancellation," n.d.
[g] UN, "The 12 Initial POPs," n.d. (accessed March 26, 2020).
[h] EPA, "DDT—A Brief History and Status," n.d. (accessed March 26, 2020).

Hazard and Risk

In order to determine whether a chemical in a pesticide is safe to use, in which doses, and in which uses, regulators consider the hazard and risk inherent in its use to public health and to the environment. The general concepts of hazard and risk, both introduced in chapter 1 and detailed below, play an important role in how pesticides are registered and how MRLs are established.

The International Programme on Chemical Safety (IPCS) defines a hazard as the "inherent property of an agent or situation having the potential to cause adverse effects when an organism, system, or (sub) population is exposed to that agent."[97] The presence of a hazard or a potentially harmful agent (in this discussion, any pesticide residue on plant-based agricultural products) at a detectable level in food is a basis for regulations and/or other risk management actions.

Risk is the probability of harm occurring at a given level of exposure. The IPCS defines risk as "the probability of an adverse effect in an organism, system, or (sub) population caused under specified circumstances by exposure to an agent."[98] Exposure estimates are compared with the health-based guidance values to determine if there is an unacceptable risk to health and whether regulation and/or risk management actions to limit exposure are required.[99]

While the differences between the terms "hazard" and "risk" are well understood within the scientific risk management community, research shows that the public does not generally distinguish the two concepts.[100] However, widely varying perceptions by the general public about risk in the food supply chain may create contradictory demands on risk management professionals regarding food safety policies.[101]

Although hazard and risk are separate concepts, they may also work together. A hazard assessment can be a stand-alone process and can be completed independently of a risk assessment. A hazard assessment, however, is also a sub-process of a risk assessment. A risk assessment, therefore, cannot be completed without a hazard assessment.

Risk Analysis

The IPCS defines risk analysis as the process for controlling situations where an organism, system, or (sub)population could be exposed to a hazard. Risk analysis consists of three components: risk assessment, risk management, and risk communication.[102] Risk assessment and risk management are discussed in detail below. Risk communication is the interactive exchange of information about risks (health and environmental) among risk assessors, risk managers, news media, interested groups, and the general public.

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[97] IPCS, *IPCS Risk Assessment Terminology*, 2004, 12.
[98] Barlow et al., "The Role of Hazard- and Risk-Based Approaches in Ensuring Food Safety," December 2015; IPCS, *IPCS Risk Assessment Terminology*, 2004, 13.
[99] In general, health-based guidance values are calculated using various measures of human exposure to chemicals. These measures include concepts such as acceptable daily intake, tolerable daily intake, acute reference dose, and acceptable operator exposure levels. IPCS*, Principles and Methods for the Risk Assessment of Chemicals in Food*, 2008.
[100] Barlow et al., "The Role of Hazard- and Risk-Based Approaches in Ensuring Food Safety," December 2015, 177.
[101] One illustration of the difference between a hazard and a risk is that of a lion in the zoo: a lion is a hazard; however, a lion in a zoo poses no risk. USITC, hearing transcript, October 29, 2029, 22–23, 39 (testimony of David Epstein, Northwest Horticultural Council).
[102] IPCS, *IPCS Risk Assessment Terminology*, 2004, 13–14.

Risk Assessment

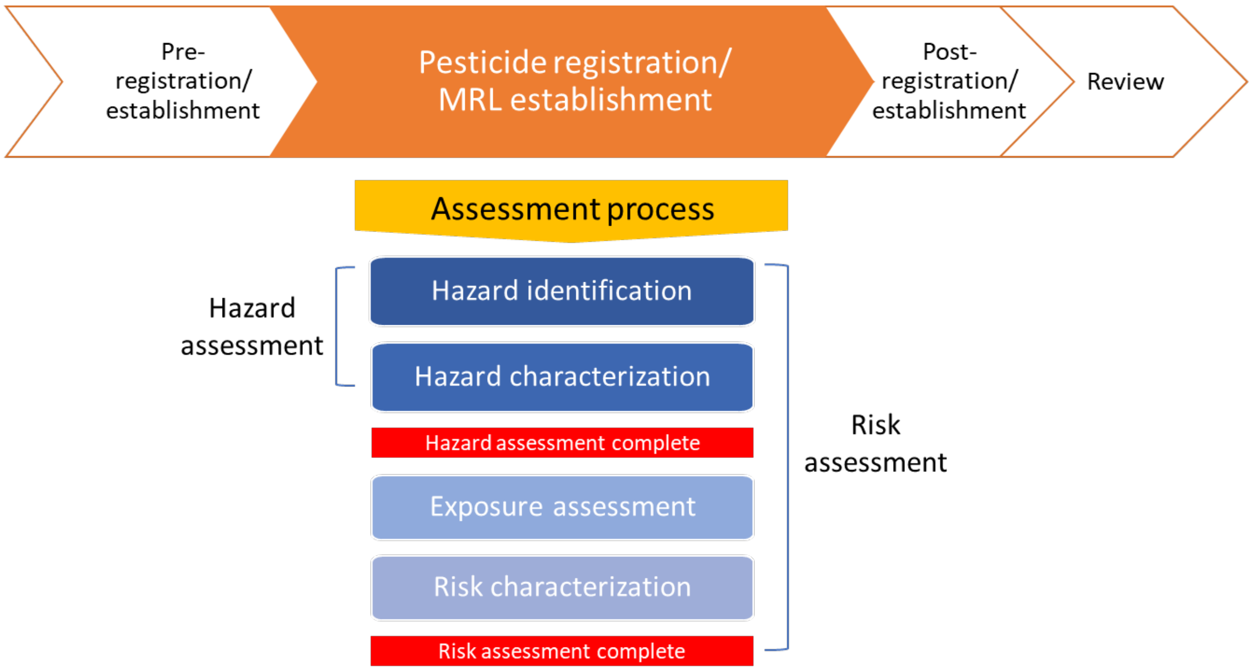
Risk assessment is a science-based process that consists of the four steps shown in figure 2.1 below: (1) hazard identification, (2) hazard characterization, (3) exposure assessment, and (4) risk characterization.[103] A complete risk assessment, therefore, includes an assessment of both hazard and risk. The scientific risk assessment process is the model used by the Codex Alimentarius Commission and its subsidiary organizations, discussed in detail below, as well as authorities in markets that establish their own positive list systems for MRLs.[104] Risk assessment bodies or organizations are composed of scientists and industry professionals who evaluate assumptions underlying a risk assessment, such as various exposure scenarios.

The pesticide registration process considers effects of active substances used in pesticides on human health, animal health, and the environment, under Good Agricultural Practices (GAP). The establishment of MRLs, on the other hand, focuses on risks posed by consumption and exposure. It looks at pesticides' residue—both from active substances and from their by-products, caused by degradation and metabolism—and considers how they affect the health of humans, animals, and other systems, including the environment.

[103] In 1995, the FAO and the World Health Organization (WHO) convened a meeting of experts on the application of risk and risk analysis to food standards issues. At this meeting, the FAO and the WHO adopted the four steps of risk assessment. The main objective was to provide the FAO, the WHO, and the Codex Alimentarius Commission (CAC), as well as member countries, advice on practical approaches for the application of risk analysis to food standards. WHO, "Application of Risk Analysis to Food Standards Issues," March 1995. Thus, as a scientific field, risk assessment is relatively young; scientific journals, papers, and conferences covering the fundamental ideas and principles of risk assessment are generally not more than 30 to 40 years old. Aven, "Risk Assessment and Risk Management: Review of Recent Advances on Their Foundation," August 2016, 1.

[104] Codex, *Procedural Manual, 26th ed.*, 2018, 131.

Figure 2.1 The assessment of hazard and risk during registration phase of pesticides and establishment of MRLs



Source: Compiled by USITC, based on IPCS, *Principles and Methods for the Risk Assessment of Chemicals in Food*, 2009, and FAO, Pesticide Registration Toolkit (accessed March 15, 2020).

Hazard assessment, as noted earlier, is designed to determine the possible adverse effects of an agent or situation to which an organism, a system (including an environmental system), or a population could be exposed.[105] Any hazard assessment focuses on the inherent properties that make an agent or substance hazardous. It consists of two steps: (1) hazard identification and (2) hazard characterization.[106]

Hazard Identification: This step identifies the type and nature of adverse effects that an agent (in this case, a pesticide) has an inherent capacity to cause in an organism, system, or population (humans and animals).[107] In the context of assessing pesticide residue levels and their effects on food safety, a hazard is seen as an inherent property of a pesticide that has the potential to cause adverse effects when consumed by humans or animals.

Hazard Characterization: This step is a qualitative, and when possible quantitative, description (characterization) of the inherent property of the pesticide that has the potential to cause adverse effects on organisms, systems, and populations.[108] Where possible, this step should include a dose-

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[105] IPCS, *IPCS Risk Assessment Terminology*, 2004, 10–15.
[106] Barlow et al., “The Role of Hazard- and Risk-Based Approaches in Ensuring Food Safety,” December 2015, 177–78; IPCS, *IPCS Risk Assessment Terminology*, 2004, 10–15.
[107] Barlow et al., “The Role of Hazard- and Risk-Based Approaches in Ensuring Food Safety,” December 2015, 177–78; IPCS, *IPCS Risk Assessment Terminology*, 2004, 10–15.
[108] Barlow et al., “The Role of Hazard- and Risk-Based Approaches in Ensuring Food Safety,” December 2015, 177–78; IPCS, *IPCS Risk Assessment Terminology*, 2004, 10–15.

response assessment,[109] which quantifies the hazards identified in the hazard identification step. In particular, the dose-response assessment portion of the hazard characterization step determines the relationship between a dose of the pesticide and the incidence of effects on organisms, systems, and populations—and in the case of MRLs, on humans in particular.[110]

After the hazard assessment (i.e., identification and characterization), the risk assessment continues by calculating or estimating the risk to a given target organism, system, or population, including identifying uncertainties,[111] following exposure to a hazardous agent (i.e., pesticide). The risk assessment considers the inherent characteristics of the pesticide, as well as the characteristics of the specific target organism, system, or population. The risk assessment, therefore, includes two additional steps: exposure assessment and risk characterization.

Exposure Assessment: Exposure assessment gauges the exposure of an organism, system, or population to a pesticide (including chemicals derived when the parent chemical breaks down via degradation or metabolism).[112] Common sources of exposure to pesticides for the general population include residues in food and drinking water. Pesticide exposure assessments also consider the risks to certain populations, such as infants, children, and pregnant women, which may have unique characteristics.

Risk Characterization: The final step in a risk assessment is risk characterization. The goal of risk characterization is to provide scientific information about the type and magnitude of an adverse effect that a chemical could cause under specific circumstances.[113] In this last step, the assessor combines the information from the exposure assessment stage with the dose-response information from the hazard characterization stage. The assessor also includes qualitative and, wherever possible, quantitative determinations of the probability of occurrence of known and potential adverse effects of a pesticide in a given organism, system, or population under defined exposure conditions.[114] The analysis of uncertainty is an important aspect of risk characterization, and the final determination should include a range of uncertainty (safety factor).[115] In the case of MRLs, the internationally adopted practice is to

[109] Dose-response assessments involve calculating the amount of a substance a person is exposed to and its effects. EPA, "Assessing Human Health Risk from Pesticides," 2019; Barlow et al., "The Role of Hazard- and Risk-Based Approaches in Ensuring Food Safety," December 2015, 177. It also takes into account its attendant uncertainties. The IPCS defines dose-response assessment as an analysis of the relationship between the total amount of an agent administered, taken up by, or absorbed by an organism, system, or (sub)population and the changes developed in that organism, system, or (sub) population in reaction to that agent, and inferences derived from such an analysis with respect to the entire population. Dose-response assessments also apply to systems and thus to the environment. IPCS, *IPCS Risk Assessment Terminology*, 2004, 10–15, 23.
[110] HHH, NIH, and NLM, "Risk Assessment" (accessed March 16, 2020).
[111] "Uncertainty factors used in the estimation of subthreshold doses are necessary reductions to account for the lack of data and inherent uncertainty in these extrapolations. For example, when human data are not available, many subthreshold doses are based upon the results of toxicity studies in experimental animals." Dourson et al., "Evolution of Science-based Uncertainty Factors in Noncancer Risk Assessment," October 1996, 108.
[112] Barlow et al., "The Role of Hazard- and Risk-Based Approaches in Ensuring Food Safety," December 2015, 177–78; IPCS, *IPCS Risk Assessment Terminology*, 2004, 10–15.
[113] Barlow et al., "The Role of Hazard- and Risk-Based Approaches in Ensuring Food Safety," December 2015, 177–78; IPCS, *IPCS Risk Assessment Terminology*, 2004, 10–15.
[114] Barlow et al., "The Role of Hazard- and Risk-Based Approaches in Ensuring Food Safety," December 2015 177–78; IPCS, *IPCS Risk Assessment Terminology*, 2004, 10–15.
[115] Barlow et al., "The Role of Hazard- and Risk-Based Approaches in Ensuring Food Safety," December 2015, 177–78; IPCS, *IPCS Risk Assessment Terminology*, 2004, 10–15.

apply a default safety factor of 100.[116] The result of the risk assessment is then ultimately communicated to risk managers.

Risk Management

Risk assessment and risk management are important but different processes that are part of pesticide registration and MRL establishment. Risk assessment is a scientific process based on the analysis of extensive test and crop field trial data to gauge risk, as described above. Risk management, on the other hand, is a decision-making process that considers the results of risk assessment among other factors in evaluating and selecting policy outcomes.[117]

Risk management in food safety is the process of considering different policy options to address the outcomes of risk assessment, with the objective of protecting the consumer. Risk management may consider economic cost-benefit analyses and the feasibility of various options, in consultation with various stakeholders, along with risk assessment results, in developing a policy outcome.[118]

These two steps—risk assessment and risk management—are rarely conducted by the same entity. In Japan, for example, the risk assessment body is the Food Safety Commission, while the risk management body is the Ministry of Health, Labor, and Welfare. While both are part of the Japanese government and are key agencies involved in establishing MRLs in Japan, the specific roles that the two bodies play are very different.[119] Further details on country-specific bodies that conduct risk assessment and risk management, including those in Japan, can be found in chapter 3 of this report.

Policy Approaches to Risk Management of Pesticides

National regulatory processes are typically nuanced and complicated. Most authorities and regulatory agencies rely on considerations that relate to both hazard and risk when managing pesticide policy.[120] Stakeholders at times use the terms "hazard-based" and "risk-based" to describe risk management approaches to pesticide policy that affect pesticide registrations and MRLs.[121] These concepts, as used

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[116] An overall uncertainty factor of 100 is extensively used to assess the risk posed to human health by pesticide residues. In other words, regulators determine a level at which the risks associated with a certain level of exposure are not likely to occur, and that level of exposure of that pesticide is then divided by 100 to assure minimal risks of exposure. This factor is derived from an underlying assumption that an average human is 10 times more sensitive than an average animal and the most sensitive human is 10 times more sensitive than the average human. These factors are multiplied together to produce a factor of 100. CRD, "Investigation of the State of the Art," 2013, 5–6, 10–11.
[117] FAO and WHO, *Updating the Principles and Methods of Risk Assessment,* 2016, 13.
[118] Codex, *Procedural Manual*, 26th ed., 2018, 129.
[119] For instance, the Food Safety Commission primarily focuses on the hazard classification and risk characterization based on the estimated average daily intake for the pesticide/crop combination under consideration. The risk management bodies, including the Ministry of Health, Labor, and Welfare, as well as the Ministry of Agriculture, Forestry, and Fisheries and the Ministry of Energy, focus on creating peripheral regulations such as Good Agricultural Practices and ecological toxicity tests.
[120] Industry representative, telephone interview by USITC staff, October 18, 2019.
[121] USSEC, written submission to USITC, December 13, 2019, 5; ABC, written submission to USITC, December 13, 2019, 5; CRC, written submission to USITC, December 13, 2019, 3; CLA, written submission to USITC, December 13, 2019, 22; NPC, written submission to USITC, December 13, 2019, 13; Barlow et al., "The Role of Hazard- and Risk-Based Approaches in Ensuring Food Safety," December 2015.

by stakeholders, are described below. The application of different risk management approaches to pesticide policy has practical implications for the availability and levels of MRLs.

"Hazard-based Approach"

While there is no standard definition of a "hazard-based policy approach," the characterization of hazard-based approaches by stakeholders is generally consistent.[122] Academic studies have defined a hazard-based approach as one in which the presence of a potentially harmful agent at a detectable level in food is used as the primary basis for risk management action, including regulation.[123] The European Commission has recognized that a hazard-based approach regulates substances on the basis of their intrinsic properties, without taking account of the extent to which consumers may be exposed to the substance.[124]

This use of the hazard-based approach has been linked to broader policy approaches such as the "precautionary principle,"[125] which can lead to regulatory action in situations of scientific uncertainty to avoid adverse impacts to human health or the environment.[126] Industry representatives have stated that in practice, hazard-based approaches result in regulations set solely on the basis of intrinsic properties of a substance, regardless of potential exposure.[127] For example, if a pesticide is shown to have specific, demonstrated harmful effects, such as carcinogenicity, a hazard-based policy approach may be to ban the pesticide's use without regard to the risk of exposure. In other words, where policy decisions have been primarily based only on the first two steps of the risk assessment process outlined above, i.e., a hazard assessment, the policy-setting process has typically been characterized as a "hazard-based approach."

[122] In this context, "standard definition" refers to published definitions as adopted by various United Nations organizations, including the FAO, WHO, and IPSC; e.g. see IPCS, *IPCS Risk Assessment Terminology*, 2004. These organizations have not adopted standard language to define what is a "risk-based approach" or a "hazard-based approach."
[123] Barlow et al. compared hazard- and risk-based approaches as they specifically applied to food safety and did not address environmental issues. Barlow et al., "The Role of Hazard- and Risk-Based Approaches in Ensuring Food Safety," December 2015, 176.
[124] Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 20.
[125] EPRS, "The Precautionary Principle," February 2016, 6–7. Industry representatives also link hazard-based approaches to the precautionary principle. USITC, hearing transcript, October 29, 2019, 126 (testimony of Christopher Novak, CropLife America), and 80 (testimony of David Epstein, Northwest Horticultural Council); European Commission, "Communication from the Commission on the Precautionary Principle," February 2, 2000, 8.
[126] The European Union's "cut-off criteria" for pesticide registration, in which the evaluation process ends at the hazard identification stage without a full risk assessment, is often cited as an example of a hazard-based approach applying the precautionary principle. Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 179–80. EPRS, "Regulation (EC) 1107/2009," April 2018, 21–22, 43.
[127] Northwest Horticultural Council, written submission to USITC, December 13, 2019, 5; USITC, hearing transcript, October 29, 2019, 17, 39, 53, 64 (testimony of Alinne Oliveira, Bryant Christie), 23–27, 66 (testimony of David Epstein, Northwest Horticultural Council), 125–26 (testimony of Christopher Novak, CropLife America); Barlow et al., "The Role of Hazard- and Risk-Based Approaches in Ensuring Food Safety," December 2015, 176; Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 20.

"Risk-based Approach"

A "risk-based policy approach" is generally characterized as the adoption of regulations that require a risk assessment using toxicology data to establish health-based guidance values for human and animal exposure.[128] It is generally understood that risk-based approaches consider not only a pesticide's innate potential to cause harm but also the risk of exposure and the potential harm of that exposure. Academic studies indicate that risk-based approaches compare exposure estimates to health-based guidance values to assess if there may be an unacceptable risk to health and whether risk management action is needed.[129] Industry representatives' statements concur that, in practice, risk-based approaches consider exposure in addition to hazard.[130] In other words, basing policy decisions on all four steps of the risk assessment process, including identification and characterization of hazard and assessment of exposure, as discussed above, has typically been characterized as following a "risk-based approach."

Using a risk-based approach, policy makers and regulators generally consider several factors in addition to the pesticide's inherent toxicity or intrinsic potential to cause harm.[131] In particular, they examine its proposed or approved uses, how much residue may be expected, and—given those proposed or approved uses—how much exposure would likely result under various production and consumption conditions, including environmental exposure. Thus, the focus is not only on the hazardousness or danger of exposure, but also the likelihood and degree of exposures and the harm resulting from that exposure.[132]

Perspectives on Hazard- and Risk-based Approaches

Within the United States, a number of U.S. stakeholders have characterized hazard-based approaches as placing more weight on social demand for preemptive or precautionary regulatory action.[133] In this characterization, regulators may apply provisional measures to protect human health, pending further scientific information, up to and including banning the use of a pesticide.[134] Provisional measures are intended to be temporary; however, the collection of further scientific information and additional risk assessment may take extensive periods of time or may not happen at all, leaving provisional measures in place for longer periods of time. Hazard-based approaches have been described as being inconsistent

[128] Barlow et al., "The Role of Hazard- and Risk-Based Approaches in Ensuring Food Safety," December 2015, 176; USITC, hearing transcript, October 29, 2019, 19 (testimony of Alinne Oliveira, Bryant Christie), and 22–23, 39 (testimony of David Epstein, Northwest Horticultural Council).
[129] *See, e.g.,* Barlow et al., "The Role of Hazard- and Risk-Based Approaches in Ensuring Food Safety," December 2015, 176.
[130] USITC, hearing transcript, October 29, 2019, 19 (testimony of Alinne Oliveira, Bryant Christie), and 39 (testimony of David Epstein, Northwest Horticultural Council).
[131] USITC, hearing transcript, October 29, 2019, 17, 39, 53, 64 (testimony of Alinne Oliveira, Bryant Christie) 23–27, 66 (testimony of David Epstein, Northwest Horticultural Council), and 125–26 (testimony of Christopher Novak, CropLife America).
[132] Barlow et al., "The Role of Hazard- and Risk-Based Approaches in Ensuring Food Safety," December 2015; IPCS, *IPCS Risk Assessment Terminology*, 2004.
[133] Barlow et al., "The Role of Hazard- and Risk-Based Approaches in Ensuring Food Safety," December 2015, 178; USITC, hearing transcript, October 29, 2019, 53 (testimony of Alinne Oliveira, Bryant Christie, Inc.), 80 (testimony of David Epstein, Northwest Horticultural Council), and 125–26 (testimony of Christopher Novak, CropLife America); U.S. Hop Industry Plant Protection Committee, written submission to USITC, December 10, 2019, 5.
[134] Barlow et al., "The Role of Hazard- and Risk-Based Approaches in Ensuring Food Safety," December 2015.

with risk-based approaches.[135] Moreover, some industry stakeholders believe that this approach truncates the scientific process, while being no more protective than the risk-based approach.[136] Other industry stakeholders have expressed concern that this approach is resulting in several potentially hard-to-replace chemical compounds and pesticides being revoked for use.[137]

Some U.S. stakeholders believe that more preemptive or precautionary regulatory action is required, suggesting that risk-based approaches may be insufficient in addressing increasingly unknown hazards of certain pesticides on human health and the environment. One environmental group suggests that the reliance on chemical pesticides promoted by the current pesticide regulatory environment insufficiently protects farmworkers and their families.[138] Another group asserts that U.S. agencies approve chemicals before a full evaluation of health and environmental impacts has been completed.[139] This group advocates banning the use of neonicotinoids to protect honeybees, birds, and human health until a thorough assessment is conducted,[140] as well as a removal of many organophosphates.[141]

Public debate on the use of risk-based and hazard-based approaches also continues in other countries, including major markets such as the EU. Certain environmental and nongovernment organizations oppose risk-based approaches.[142] Some critics argue that risk-based approaches, though logical in theory, are complex in practice and require a considerable amount of data that may not be available.[143] The same critics also argue that decisions based on risk assessments tend to take considerable time and resources, yet their outcomes often still hold uncertainties. Therefore, in this view, because scientists can analyze data and test results differently and come to different reasoned conclusions, ultimately the decision to use a chemical is also often a policy decision, rather than a single science-based outcome.[144]

On the other hand, critics of hazard-based approaches argue that they allow regulators and policy makers to decide to ban certain chemicals or other substances on the assumption that they are hazardous without testing whether this is actually the case.[145] They point out the risk to human health caused by higher doses of a chemical may be drastically different than any harm to human health caused by much smaller doses.[146] Thus, when evaluating residues of pesticides on food crops, they state that it is necessary to examine the likelihood and degree of exposure and harms associated with such exposure to understand whether the pesticide may be safely used and determine an appropriate MRL. Some also assert that hazard-based approaches can facilitate arbitrary decisions by risk managers, who they maintain can arbitrarily choose a risk or hazard classification of products and/or activities according to political expediency and public opinion. They state that this process can result in passing of bans,

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[135] Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, vii.
[136] NHC, written submission to USITC, December 13, 2019, 5; USITC, hearing transcript, October 29, 2019, 17, 39, 53, 64 (testimony of Alinne Oliveira, Bryant Christie), 23–27, 66 (testimony of David Epstein, Northwest Horticultural Council), and 125–26 (testimony of Christopher Novak, CropLife America).
[137] USHIPPC, written submission to USITC, December 10, 2019, 5.
[138] Ferguson, "Pesticides, Heat, and the People Who Feed Us," December 9, 2019.
[139] NRDC, "Ban Dangerous Pesticides" (accessed May 30, 2020).
[140] NRDC, "NRDC Report Reveals Rampant Contamination," January 22, 2020.
[141] NRDC, "Protecting Against Chemicals Designed to Kill," November 2011, 1-2.
[142] Lofstedt, "Risk versus Hazard," June 2011, 151.
[143] ChemSec, "Hazard versus Risk," January 2017.
[144] ChemSec, "Hazard versus Risk," January 2017.
[145] Chakraborty, "The Risk versus Hazard Debate," 2012, 5.
[146] Lofstedt, "Risk versus Hazard," June 2011, 151.

directives, or other regulations that are at times hazard-based and other times risk-based, contributing to uncertainty for various stakeholders in the agricultural supply chain.[147]

Concerns about the application of hazard-based approaches to pesticide approval and MRLs, including import tolerances, are shared by a broad group of countries from a variety of economic development levels.[148] These nations state that application of hazard-based approaches to pesticide approval and renewal effectively prohibits exporting countries from using these substances, diverging from the principle of evidence and science-based risk assessments meant to ensure that such measures are not more trade-restrictive than necessary. As a result, these nations claim that application of a hazard-based approach by a regulatory authority in an importing country essentially imposes that regulatory approach on its export trading partners.

Key Stages of Pesticide Registration and MRL Establishment

As noted above, regulatory authorities may take varying approaches to the consideration of hazard and risk in pesticide registration and MRL policies. However, the processes for registering pesticides and establishing MRLs for most regulatory authorities and international bodies include many of the same steps, and many, if not all, of the data submitted for registration purposes are also used during the risk assessment to establish MRLs.[149] As discussed below, pesticide registration involves four key stages, and generally the pesticide registration process must be completed and the pesticide registered for specific uses before an MRL for that pesticide/crop combination can be established. The steps for MRL establishment are similar to those of pesticide registration, although the two processes are fundamentally separate.

Pesticide Registration[150]

To be legally used in a jurisdiction, pesticides are required to go through a thorough, and often lengthy and expensive,[151] registration process overseen by regulatory authorities.[152] Many of the steps and actions involved in pesticide registration are common across countries, although the registration

[147] Chakraborty, "The Risk versus Hazard Debate," 2012, 5.
[148] WTO, "Implementation of Non-Tariff Barriers on Agricultural Products," July 4, 2019.
[149] Country-specific processes and practices are presented in chapter 3 of this report.
[150] This section is generally based on the FAO Pesticide Registration Toolkit. The FAO describes pesticide registration as "the process whereby the responsible national government or regional authority approves the sale and use of a pesticide following evaluation of comprehensive scientific data demonstrating that the product is effective for its intended purpose and does not pose an unacceptable risk to human or animal health or to the environment." FAO, Pesticide Registration Toolkit, 2020.
[151] Industry representatives have suggested that the development cost for a new crop protection compound, including costs directly and indirectly related to registration, can approach $250 million. Industry representatives, interviews by USITC staff (February 13, 2020, December 12, 2019). A detailed discussion is presented in box 4.1 (chapter 4).
[152] Import tolerances, as described in chapter 1 and further detailed in chapter 4, are a notable exception to local registration of chemicals.

packages differ from country to country.[153] The Pesticide Registration Toolkit provided by the Food and Agriculture Organization of the United Nations (FAO) divides the pesticide registration process into four key phases, shown below. These phases closely mirror those for setting an MRL.

Pre-registration: The pre-registration phase typically consists of a pre-application meeting between the applicant and the registration authority to identify what information and data will be required for the application, also commonly referred to as a “dossier.”[154] This step can pinpoint whether additional local studies are required,[155] or whether it is permissible for the applicant to submit a pre-application dossier to obtain guidance on whether the pesticide can be registered.[156]

Registration: The registration phase begins when the full application is submitted to the appropriate domestic regulatory authority. Evaluation of the dossier is the main step in the registration phase and includes the risk assessment of the pesticide. To increase the process’s efficiency, registration authorities are increasingly applying tiered or stepwise approaches to evaluation and data requirements.[157] Based on the evaluation of the data and other information collected, the pesticide may then be authorized for use according to domestic Good Agricultural Practices (GAP). These practices are described in what is commonly referred to as the pesticide “label,” as mentioned in chapter 1. As noted above, while pesticide registration allows use of the pesticide in the relevant jurisdiction, crops generally may not be imported or sold in that jurisdiction unless an established (or default) MRL is in place for the particular pesticide/crop combination.

Post-registration: Once a pesticide or active substance has been approved, monitoring and evaluation takes place to measure the effectiveness of the registration process, update information on efficacy and

[153] The entirety of the documentation required to register a pesticide and establish an MRL or import tolerance goes by various names depending on the jurisdiction. The most common names are the “dossier” or the “application.” Data requirements vary based on the pesticide group (e.g., chemical or microbial), pesticide type (e.g., insecticide, herbicide, fungicide), the intended use (e.g., on field crops for human consumption or on bed nets for disease vector control), and the type of registration (e.g., new product formulation, new active substance, or extension of an existing registration). Regulators require registrants to generate many types of data, such as the substance’s identity and composition, physical and chemical properties, proposed application methods, residues, exposure, classification, labeling, and packaging. FAO, Pesticide Registration Toolkit, 2020.

[154] Applicants can range from pesticide manufacturers to growers and to exporters. For more information, see chapters 3 and 4 of this report.

[155] Local studies collect data through biological efficacy trials and residue studies on local commodities. Conducting local trials may require an experimental permit to import the pesticide being registered.

[156] At this stage, some application authorities may inform the applicant that the pesticide under consideration may not fulfill minimum criteria for registration. Minimum criteria may be based on experience, or on certain basic criteria such as those used in hazard assessments, where pesticides of a certain toxicity class (e.g., carcinogens) may not be permitted for specific uses or may be completely banned from use. This is important because the decision whether a pesticide can be registered affects the decision whether an MRL may be established. Further details for each country can be found in chapter 3 of this report.

[157] In a tiered approach, the registration authority may require only a limited set of information and data; if this limited data shows that the pesticide meets efficacy, residue, and human and environmental risk requirements, no further data need be submitted. If the limited dataset is insufficient, more data will be required. While this tiered approach may reduce data requirements and thus costs of an application, ineffective communication between registration authorities and applicants may result in delays and additional costs. FAO, Pesticide Registration Toolkit, 2020.

safety, monitor for non-adherence to restrictions, and use this information to take corrective actions if necessary.

Review: Existing pesticides undergo reviews, either periodic or unscheduled, to ensure that authorities consider and assess new information on product performance and risks. These reviews may result in re-registration of the pesticide, with or without new restrictions, or in cancellation of the registration.

Applying for and Establishing an MRL

Like the pesticide registration process, the process for establishing an MRL, whether overseen by an international body such as Codex or by regulators in an individual country, serves to determine an acceptable pesticide residue level for a specific pesticide/crop combination. First, there is a pre-application stage where applicants prepare their dossier, similar to the pre-registration stage of a pesticide registration. During the second stage of establishing an MRL, which is akin to the registration stage of a pesticide, applicants submit a dossier (application) including key information that was generated for the pesticide registration process but also information concerning consumption and exposure data specific to the pesticide/crop combination under consideration. The dossier is then evaluated by scientific experts, and the regulatory body either approves the application and establishes an MRL or rejects the application. After the MRL is established, the impacts of the pesticide for which the MRL was granted are monitored and evaluated. Finally, reviews and renewals of MRLs may be conducted periodically.

There are two key ways in which applying for an MRL is different from registering a pesticide. First, in most cases, a pesticide must be registered for domestic use for an MRL to be obtained.[158] Practically, a large share of the extensive scientific data needed for an MRL application are generated for the pesticide registration process. And legally, most regulators require pesticide registration prior to establishment of an MRL. Thus, in principle, an MRL application typically starts after a pesticide registration, although some steps necessary to establish MRLs may begin before a pesticide registration is complete.[159] Second, unlike a pesticide that can be registered for use on multiple crops, an MRL is established for a specific pesticide/crop combination, making applications more complex, and making each individual MRL application more detailed and potentially more costly.

International Efforts Related to MRLs

Harmonization Efforts

A number of international efforts to harmonize MRLs, as well as the policies and practices for setting and reviewing MRL policies and practices, are currently underway. The first part of this section focuses

[158] An important exception to this is for import tolerances that are established when the pesticide used in the exporting country is not registered for use in the importing market. Securing an import tolerance does not require domestic registration of the pesticide before importing treated crops for domestic consumption. Some countries have established processes for requesting import tolerances, while others do not. National import tolerance processes and practices are described in chapter 3 of this report.
[159] In practice, MRL applications are often concurrent with or start even before completion of pesticide registration. See chapters 1 and 3 of this report for further details.

on Codex Alimentarius, which is leading one of the most widely recognized global efforts to harmonize MRLs and related policies. Other international and regional efforts are also described in this section.

Codex Alimentarius Committee and Codex Alimentarius

After World War II, political leaders and economists, especially in Europe, were convinced that improved agricultural trade would be essential to ensuring the world's ability to feed its people.[160] By 1950, however, the Joint FAO/World Health Organization (WHO) Expert Committee on Nutrition found that food additive standards might be deterring international trade.[161] Thus, increasing concerns from global food regulators, traders, and consumers led international organizations to create guidance for drawing up food standards and regulations that would simultaneously facilitate trade and protect consumers.[162] In the early 1960s, with the support of four major international bodies—the WHO, the United Nations Economic Council for Europe (UNECE), the OECD, and the Council of the Codex Alimentarius Europaeus,[163]—the FAO established the Codex Alimentarius and the Codex Alimentarius Commission (CAC).[164]

The CAC is an international standard-setting body jointly overseen by the FAO and the WHO; it administers standards, guidelines, and codes of practice related to traded food and agricultural products.[165] CAC membership is open to all member nations and associate members of the FAO, with currently 189 members.[166] The CAC meets annually, and such meetings typically include more than 600 delegates representing member governments and observer organizations. Delegations to the sessions are organized on a national basis and are led by senior officials appointed by their governments. These delegations often include representatives of nations' food industries, consumer organizations, and academic institutions.[167]

The Objective of Codex

The objective of the CAC is to study, develop, and publish a wide variety of voluntary food health and safety standards. These standards include MRLs, but also encompass other standards and guidelines related to food hygiene, food additives, labeling and presentation, and analytical and sampling methods used in food testing. The standards and related documents (guidelines and codes of practice) published by the CAC are collectively known as the Codex Alimentarius. Codex has become an important

[160] Randall, "Codex Alimentarius: How It All Began," 1995.
[161] Randall, "Codex Alimentarius: How It All Began," 1995.
[162] FAO and WHO, *Codex Alimentarius: Understanding Codex,* 2016, 3.
[163] Codex Alimentarius Austriacus was a collection of food standards and descriptions created between 1897 and 1911 by the Austro-Hungarian Empire. The Council of the Codex Alimentarius Europaeus was established in June 1958 to create a European-wide food code like the Codex Alimentarius Austriacus. Results fell short of the need, so in 1960, the council proposed an association with the WHO, which eventually resulted in formation of the FAO/WHO Codex Alimentarius. Randall, "Codex Alimentarius: How It All Began," 1995.
[164] In 1963, the World Health Assembly approved establishment of the Joint FAO/WHO Food Standards Program and adopted the Statutes of the CAC, which held its inaugural meeting in Rome. FAO and WHO, *Codex Alimentarius: Understanding Codex,* 2016, 5.
[165] FAO and WHO, *Codex Alimentarius: Understanding Codex,* 2016, 10.
[166] The members consist of 188 countries and 1 member organization (the EU).
[167] FAO and WHO, *Codex Alimentarius: Understanding Codex,* 2016, 20–21.

international reference point for the establishment of mandatory and voluntary food standards.[168] Codex aims to update its standards, guidelines, and codes of practice regularly to ensure they are consistent with current scientific knowledge.[169]

Codex MRLs exist both to protect consumer health and to facilitate international trade.[170] To facilitate trade, the CAC's mission includes collaborating with member states, establishing harmonized definitions and standards for foods and pesticides, and promoting global uniformity and certainty for farmers, pesticide manufacturers, and consumers.[171] In line with this mission, the CAC has established more than 4,800 Codex MRLs for a variety of specific pesticide/crop or pesticide/crop-grouping combinations.[172]

Besides setting MRLs, Codex[173] also works on a variety of initiatives to support the harmonization of MRL policies across member states. U.S. officials interviewed consider Codex to be a useful forum for discussing the harmonization of best practices in setting MRLs, and a variety of member states have used Codex to propose best practices to others.[174] For example, Codex member states have used Codex as a forum to discuss crop groupings for the MRL-setting process, and member states have described efforts to harmonize crop groupings as a success of Codex.[175]

Codex standards are also meant to ensure the use of globally accepted practices in the international trade of foods. The World Trade Organization (WTO) Agreement on Sanitary and Phytosanitary measures (the SPS Agreement) recognizes the important role of Codex in international food trade—in particular, the standards, guidelines, and recommendations established by the CAC regarding pesticide residues and associated practices for registering pesticides and setting MRLs. The SPS Agreement considers analytical and sampling methods, as well as MRLs, based on Codex standards to be scientifically justified and requires that members use Codex standards as the basis for their MRLs unless specifically permitted otherwise under the SPS Agreement—for example, where pursuant to a risk assessment a member determines a lower MRL is required to protect public health.[176]

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[168] FAO and WHO, *Codex Alimentarius: Understanding Codex,* 2016, 7.
[169] FAO and WHO, *Codex Alimentarius: Understanding Codex,* 2016, 22.
[170] FAO, *Codex Alimentarius Commission Procedural Manual*, 2016, 25.
[171] FAO and WHO, "About Codex Alimentarius" (accessed December 10, 2019).
[172] In comparison, it is estimated that the U.S. EPA has established MRLs (called tolerances in the United States) for over 50,000 pesticide/crop combinations. Lexagri International, Homologa database (accessed February 6, 2020). Specifically, the U.S. has established tolerances for more than 600 substances, each having MRLs for one or more specific substance/crop combinations. One example is malathion, which has tolerances for more than 100 specific crops or crop groupings. See Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 C.F.R. § 180. In comparison, South Korea has 7,629 MRLs for 262 agricultural commodities and 462 pesticides. Kim, "Pesticide MRL Setting and PLS Progress in Korea," 2017.
[173] In line with the common use among industry representatives, the term Codex refers to both the Codex Alimentarius Commission and the Codex Alimentarius in this chapter, unless specified.
[174] U.S. government representative, interview by USITC staff, December 4, 2019.
[175] U.S. government representative, interview by USITC staff, December 4, 2019. A general description of crop groupings can be found in chapter 1. Crop grouping harmonization can be useful for registrants and growers to ensure an even regulatory process when setting MRLs across multiple jurisdictions and may prevent duplicative testing and potentially divergent testing standards and requirements. Harmonized crop groupings can be particularly important for minor or specialty crops, which often rely on testing from representative crops within their crop groupings in order to set their own MRLs. Lunn, "Crop Grouping and Residue Extrapolation" (accessed November 27, 2019).
[176] WTO SPS Agreement, Arts. 3 and 5; Codex Alimentarius, "About Codex," 2016, 43 (accessed January 6, 2020).

To be binding and fully effective, Codex standards, guidelines, and codes of practice, including MRLs, must be translated and enacted into national legislation or regulations.[177] Codex MRLs are applicable only when countries specifically reference them in their own legislation or regulations. A number of countries, including Argentina, Egypt, the Philippines, Thailand, and Vietnam, officially default to Codex MRLs in some or all instances where they have not established their own MRLs.[178] Some MRL-setting authorities, such as in the United States, Canada, and European Union (EU), may consider Codex MRLs in addition to a variety of other variables when setting their own MRLs. It is EU policy to align its MRLs with Codex MRLs provided three specific conditions are met. In the interest of transparency and predictability, it has expressed reservations at CCPR and CAC meetings when a Codex MRL does not meet the third of the three conditions required by the EU.[179] Some countries, such as Japan and South Korea, have incorporated multiple Codex MRLs into their positive MRL lists.

Several industry representatives, however, have expressed concern that countries are increasingly diverging from Codex standards by establishing their own MRL approval processes that allow only approved pesticide/crop MRLs in that market.[180] Increasing adoption of positive list systems has multiplied the number of different MRLs for the same pesticide/crop combinations, and as result, has reportedly made global trade of agricultural products more costly and difficult in terms of compliance.[181] Examples of markets shifting to positive list systems include Japan, South Korea, Hong Kong, and the countries of ASEAN, all major trading partners for U.S. exports.[182]

Key Codex MRL-setting Bodies[183]

The two primary subsidiary bodies involved in establishing Codex MRLs are the CCPR and the JMPR. The CCPR consists of representatives of national governments and acts as Codex's risk management body. Much of the framework for calculating pesticide MRLs is mandated by the CCPR, either through historical tradition or specific directives.[184] The CCPR, in cooperation with the JMPR, sets the schedule of

[177] FAO and WHO, *Codex Alimentarius: Understanding Codex,* 2016, 13.
[178] Berry, "Codex MRLs—Use and Trends," October 2016.
[179] The EU will align its MRLs with Codex MRLs subject to these three conditions: (1) the EU already sets MRLs for the commodity under consideration; (2) the existing EU MRL is lower than the Codex MRL; and (3) the Codex MRL is acceptable to the EU with respect to areas such as consumer protection, sufficient supporting data, and extrapolations. The EU expresses reservations about Codex MRLs if condition 3 is not met. European Commission, written submission to USITC, December 13, 2019, 18.
[180] U.S. Grains Council, National Corn Growers Association, and MAIZALL, written submission to USITC, December 13, 2019, 19; NPC, written submission to USITC, December 10, 2019, 5; ABC, written submission to USITC, December 13, 2019; 2.
[181] USGC, NCGA, and MAIZALL, written submission to USITC, December 13, 2019; NPC, written submission to USITC, December 10, 2019, 2; ASA and USSEC, written submission to USITC, December 13, 2019, 4; industry representative, interview by USITC staff, December 12, 2019.
[182] According to the California Cherry Board, when Hong Kong established its national positive MRL list in 2014, it sought feedback from the U.S. cherry industry in the development of its cherry MRLs. However, Hong Kong has not updated its list of MRLs since then, and multiple U.S. industries have expressed concern at the lack of MRL development in Hong Kong since 2014. Northwest Horticultural Council, written submission to USITC, December 13, 2019, 8; CCB, written submission to USITC, December 11, 2019; CFFA, written submission to USITC, December 12, 2019.
[183] This section is based on the following documents: FAO and WHO, *Updating the Principles and Methods of Risk Assessment,* 2016, and FAO, *Codex Alimentarius Commission Procedural Manual*, 2016.
[184] FAO and WHO, *Updating the Principles and Methods of Risk Assessment*, 2016.

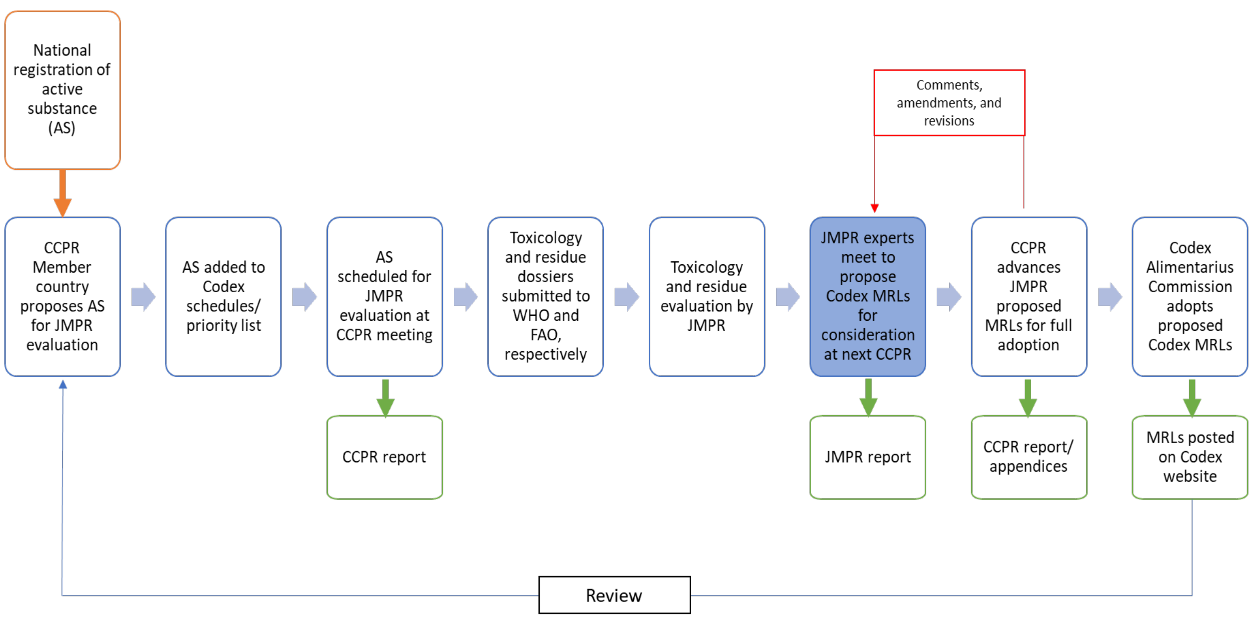
JMPR evaluations of Codex MRL proposals for the year and accepts member comments before finalizing the list.[185]

As the risk assessment body of Codex, the JMPR provides scientific advice to the FAO, the WHO, and the CCPR, and is made up of independent FAO and WHO scientific experts. The JMPR consists of a group of scientists, rather than government representatives, that are invited to participate in order to provide the technical expertise necessary to consider MRL proposals as well as ensure independence from political influence.[186] The JMPR has no approval or registration functions but recommends suitable standards for pesticide residues in food commodities based on internationally recognized scientific risk assessment practices.[187] Detailed discussion on the role of each body is presented below.

Codex MRL-setting Process

Although complex, the dual roles of CCPR/JMPR are designed to ensure that a thorough scientific review and analysis has been completed in setting MRLs. It also gives member countries time to study the JMPR recommendation and provide comments. The general Codex process for establishing an MRL is summarized in figure 2.2.

Figure 2.2 Codex MRL-setting procedure



Source: Compiled by USITC, based on Crop Life America, "Challenges to Establishing Harmonized Maximum Residue Levels," August 2014
Note: AS may represent either first-time uses or new uses for an already established AS.

[185] FAO, *Codex Alimentarius Commission Procedural Manual*, 2016, 171–73.
[186] Hamilton et al., "Evaluation of Pesticide Residues by FAO/WHO JMPR," 2017, 117.
[187] Approval and registration functions are under the purview of national pesticide authorities. FAO and WHO, *Updating the Principles and Methods of Risk Assessment*, 2006.

Preparing for a Codex MRL proposal

Unlike a national pesticide registration or an MRL application, for which the pesticide manufacturer (registrant) generally initiates the registration process, the Codex MRL process must be initiated by a Codex member, or observer (see figure 2.2). The proposal should list data-gathering and testing requirements such as hazard and risk assessments, field trials, and toxicology studies.[188] For an MRL proposal to be approved and included in the Codex review schedule, the nominating member must declare its intent to register the pesticide for use in its domestic market, and commit to providing the supporting data for the pesticide review throughout the full Codex process.[189] Approved proposals are prioritized and assigned to the JMPR to complete risk assessment and the CCPR to complete risk management.[190]

Proposing and post-proposal of Codex MRLs

In order to be scheduled for JMPR evaluation, the pesticide must have a registered use in the territory of the member making the proposal.[191] In addition, the member must also submit a working paper to the JMPR that summarizes the results of field trials and the conclusions of its own national investigations, in addition to any original reports that may have been provided by registrants.[192] JMPR's risk assessments are based on the data submitted for national registrations of pesticides worldwide as well as scientific studies published in peer-reviewed journals. After assessing the level of risk presented by the pesticide, the JMPR establishes limits for safe intake to ensure that the amount of pesticide residue to which people are exposed over their lifetime will not adversely affect their health.

JMPR's risk assessment evaluation and MRL recommendations are sent to the CCPR for primary review.[193] All of JMPR's recommendations are considered in one regular session per year, but additional sessions can be held if Codex member states agree.[194] The Codex process is intended to minimize trade-restrictive actions and to consider the economic consequences as well as the feasibility of all risk management options.[195]

As part of the review process, the Secretariat distributes JMPR's recommended MRLs to the members of the Codex Alimentarius Commission and "interested international organizations" for comment. The Secretariat sends any comments it receives to the JMPR for consideration and follow-up. This feedback loop between the CCPR and JMPR is shown highlighted in red in figure 2.2. Once all comments have been addressed, the proposed MRL is submitted to the Executive Committee for critical review and then to the Commission for adoption. Timing considerations related to Committee and CAC meeting

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188 FAO and WHO, *Updating the Principles and Methods of Risk Assessment,* 2016.
189 FAO, *Codex Alimentarius Commission Procedural Manual*, 2016, 173.
190 FAO and WHO, *Updating the Principles and Methods of Risk Assessment,* 2016.
191 FAO, *Codex Alimentarius Commission Procedural Manual*, 2016, 174. As mentioned, "labels" refer to the domestically authorized use of pesticides under Good Agricultural Practices.
192 FAO, "Submission and Evaluation of Pesticide Residues Data," 2016, 13.
193 FAO, *Codex Alimentarius Commission Procedural Manual*, 2016, 170.
194 FAO, *Codex Alimentarius Commission Procedural Manual*, 2016, 12.
195 FAO, *Codex Alimentarius Commission Procedural Manual*, 2016, 129.

schedules may cause draft MRLs to be sent to governments earlier. Once accepted by the CCPR, the suggested/amended MRLs are submitted to the CAC for adoption as Codex MRLs.[196]

Role of the JMPR in Risk Assessment

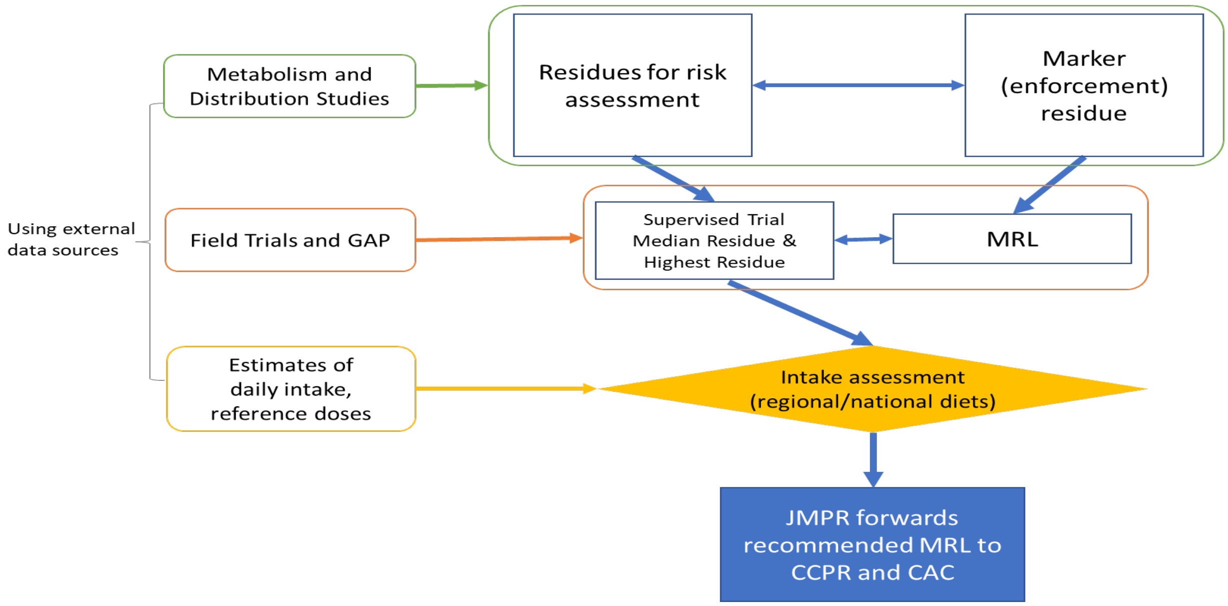
As mentioned, the JMPR is one of the subsidiary bodies that conduct risk assessment and is a key part of the Codex MRL process. This section provides a more detailed explanation of the JMPR risk assessment process, represented by the blue highlighted box in figure 2.2.

The JMPR comprises the WHO Core Assessment Group and the FAO Panel of Experts on Pesticide Residues in Food and the Environment. Its primary responsibility is performing risk assessments and recommending MRLs to the CCPR and ultimately the CAC. The JMPR's risk assessment process includes all four components of risk assessment, described above, as defined by the CAC: (1) hazard identification, (2) hazard characterization, (3) exposure assessment, and (4) risk characterization. The JMPR also reports possible sources of uncertainty to the CCPR.

The JMPR, through the WHO Core Assessment Group, is responsible for evaluating exposure to pesticides in light of dietary intake and the toxicity of the active substance and its metabolites.[197] Using pesticide data, the JMPR estimates the "no observed adverse effect level" of a pesticide,[198] sets the acceptable daily intake[199] of the pesticide's residues in food for humans, estimates the acute reference doses,[200] and characterizes other toxicological criteria such as non-dietary exposure.[201] Figure 2.3 depicts the JMPR's evaluation process and the contributing individual elements.

[196] FAO, *Codex Alimentarius Commission Procedural Manual*, 2016, 164.
[197] FAO, "Submission and Evaluation of Pesticide Residues Data," 2016, 3.
[198] The "no observed adverse effect level" or NOAEL of a pesticide is the highest dose of a substance that causes no changes distinguishable from changes in normal (control) animals. FAO and WHO, *Updating the Principles and Methods of Risk Assessment*, 2006, 42.
[199] The acceptable daily Intake of a chemical is the estimate of the amount of a substance in food or drinking water, expressed on a body-weight basis, that can be ingested daily over a lifetime without appreciable health risk to the consumer on the basis of all the known facts at the time of the evaluation. It is expressed in milligrams of the chemical per kilogram of body weight. FAO and WHO, *Updating the Principles and Methods of Risk Assessment*, 2006, 42.
[200] The acute reference dose of a chemical is the estimate of the amount of a substance in food or drinking water, expressed on a body-weight basis, that can be ingested in a period of 24 hours or less, without appreciable health risk to the consumer on the basis of all the known facts at the time of evaluation. It is expressed in milligrams of the chemical per kilogram of body weight. FAO and WHO, *Updating the Principles and Methods of Risk Assessment*, 2006, 42.
[201] FAO, "Submission and Evaluation of Pesticide Residues Data," 2016, 3.

Figure 2.3 JMPR Evaluation of residue data and recommendation of MRLs



Source: USITC, based on FAO and WHO, *Updating the Principles and Methods for Risk Assessment: MRLs for Pesticides and Veterinary Drugs*, 2006.

The FAO Panel within the JMPR reviews GAP, which include pesticide usage patterns,[202] the chemistry of the pesticides, the "environmental fate" of pesticides[203] (as it impacts residues in food or feed commodities), how the pesticides are metabolized in animals and crops, and methods of analysis of pesticide residues.[204] The FAO Panel is responsible for proposing residue definitions and calculating MRLs, highest residues,[205] and using crop field trial results to evaluate median residue values of pesticides in food and feed.[206] The FAO Panel also considers whether the toxicity of the active substance may cause any public health concerns.[207] The JMPR reviews certain topics itself, including, but not

[202] Good Agricultural Practices (GAP) includes the nationally authorized safe uses of pesticides, as reflected in the approved pesticide "label," under actual conditions necessary for effective and reliable pest control. It encompasses a range of levels of pesticide applications up to the highest authorized use, applied in a way that leaves a residue that is the smallest amount practicable. Authorized safe uses are determined at the national level and include nationally registered or recommended uses, which take into account public and occupational health and environmental safety considerations. Actual conditions include any stage in the production, storage, transport, distribution, and processing of food commodities and animal feed. FAO and WHO, *Updating the Principles and Methods of Risk Assessment*, 2006, 27.
[203] Environmental fate refers to how a pesticide, its active substance, or metabolites degrade or persist in soil and water. It also considers how persistence in soil affects subsequent crops in rotation. FAO and WHO, *Updating the Principles and Methods of Risk Assessment*, 2006, 14.
[204] FAO, "Submission and Evaluation of Pesticide Residues Data," 2016, 3.
[205] The Highest Residue (HR) is the highest residue level (ppm) in a composite sample of the edible portion of a food commodity when a pesticide has been used according to the maximum GAP conditions. FAO, "Updating the Principles and Methods of Risk Assessment," 41.
[206] FAO, "Submission and Evaluation of Pesticide Residues Data," 2016, 3.
[207] FAO, "Submission and Evaluation of Pesticide Residues Data," 2016, 3.

limited to, metabolism and environmental fate; use patterns; and residues resulting from supervised field trials, and in food in commerce or at consumption.[208]

The JMPR's risk assessment is meant to incorporate data from various regions of the world, including developing countries. The JMPR estimates Codex MRLs based on its assessment of toxicological information (metabolism and distribution studies, figure 2.3) and its assessment of pesticide and residue information (field trials and GAPs, figure 2.3). When these data are not available, the CCPR may ask the JMPR to request additional information.[209] Risk assessments must be based on "realistic exposure scenarios, with consideration of different situations," and acute, chronic, cumulative, and combined health effects must be considered.[210] These processes take into account a number of estimates of residue intake in the diet as well as the acceptable daily intake, with the end goal of setting Codex MRLs at a level that is safe for human consumption globally.[211]

For its exposure assessment, the JMPR uses global dietary information taken from the Global Environment Monitoring System (GEMS)/Food database. These data on diets and other elements are used to inform assessments of chronic exposure risks and acute exposure calculations, such as acute reference doses and international estimates of short-term intake.[212] JMPR may also use consumption monitoring data and exposure studies from sources outside the GEMS/Food data system.[213]

The data submissions required for this complex evaluation process are quite sizable. Often small agricultural industries, such as those that produce minor crops, are not able to compile these data. The pesticide manufacturers of pesticides used on minor crops may hesitate to invest in so much data collection for pesticides used by such a small group of growers. To help with data submissions related to minor crops, Codex may require fewer field trials of these crops, allow the use of different forms of data and information in these cases, or allow residue trials from different regions that do not collectively represent worldwide use.[214]

Role of the Codex Committee on Pesticide Residues in Risk Management Decisions[215]

As Codex's main risk management body, the CCPR is primarily responsible for recommending MRLs for adoption by the CAC. The CCPR bases its recommendations on JMPR's risk assessments of the pesticide, and where appropriate, on other factors important for consumers' health protection and for the promotion of free trade.[216] If the CCPR determines that additional scientific guidance is necessary, it

[208] FAO, "Submission and Evaluation of Pesticide Residues Data," 2016, 11.
[209] FAO, *Codex Alimentarius Commission Procedural Manual*, 2016, 127.
[210] FAO, *Codex Alimentarius Commission Procedural Manual*, 2016, 127.
[211] FAO, *Codex Alimentarius Commission Procedural Manual*, 2016, 25.
[212] JMPR compares the acute reference dose to the international estimate of short-term intake, both of which are measures of acute intake, to determine if the chemical is an acute intake concern. FAO and WHO, *Updating the Principles and Methods of Risk Assessment*, 2006, 11; FAO, *Codex Alimentarius Commission Procedural Manual*, 2016, 145, 153–55.
[213] FAO, *Codex Alimentarius Commission Procedural Manual*, 2016, 153.
[214] FAO, *Codex Alimentarius Commission Procedural Manual*, 2016, 188-189.
[215] FAO and WHO, *Updating the Principles and Methods of Risk Assessment,* 2016, 4; FAO and WHO, *Food Safety Risk Analysis*, 2006, 7; FAO, *Codex Alimentarius Commission Procedural Manual*, 2015, 149.
[216] FAO, *Codex Alimentarius Commission Procedural Manual*, 2015, 127, 149.

may make a specific request that the JMPR provide such guidance. The CCPR must also consider the relevant uncertainties as described by the JMPR. The CCPR may consider only MRLs recommended by the JMPR.

The CCPR is required to base its recommendations on the GEMS/Food diets used by JMPR to identify consumption patterns and assess the risk of chronic exposure. Acute exposure calculations by JMPR are not based on the GEMS diets, but rather on consumption data provided by CAC members and compiled by GEMS/Food. If no validated methods of analysis are available for setting an MRL for a specific pesticide, the CCPR is precluded from establishing an MRL.[217]

Periodic Review of Codex MRLs

Pesticides that have been previously approved for an MRL are subject to periodic reviews and can also be subject to "normal re-evaluation" when additional information has been made available to the JMPR.[218] This is equivalent to the "renewal" stage in national/market-led establishment of MRLs, the fourth step in the process presented above.[219] In the case of revising an MRL, only new supporting studies are required. Re-submission of prior studies is not necessary.[220]

When a pesticide is no longer supported by a pesticide manufacturer, as is common for older active substances, the responsibility for providing the data and other information required for the reapproval falls on the requesting country instead.[221] The JMPR may use studies without the accompanying raw data when those data are not available.[222] When there are limitations on data availability, the JMPR may still proceed with reviewing the reapproval request. However, they will use conservative assumptions when addressing any information gaps.[223]

A pesticide that has not been reviewed for more than 15 years, or that has not had a significant review of its Codex MRL for 15 years, will be included in a priority list ("Table 2B of Schedules and Priority Lists"), and a member can nominate it to be moved to a higher priority list ("Table 2A") for a periodic review if there are concerns. If a pesticide has not been reviewed for 25 years, it may be transferred to Table 2A without a member concern being submitted. Members with public health concerns may submit concerns and nominate a pesticide for inclusion on Table 2A even if the pesticide has been reviewed in the last 15 years.[224] Codex MRLs are proposed for revocation if they have not been reviewed for more than 25 years and are not supported by any members or observers.[225]

[217] FAO, *Codex Alimentarius Commission Procedural Manual*, 2015, 127, 149.
[218] FAO, "Submission and Evaluation of Pesticide Residues Data," 2016, 8–10.
[219] To avoid confusion with the term "review," which is also used to refer to risk assessment, the term "reapproval" is used in this subsection.
[220] FAO, "Submission and Evaluation of Pesticide Residues Data," 2016, 13.
[221] FAO, "Submission and Evaluation of Pesticide Residues Data," 2016, 7.
[222] FAO, "Submission and Evaluation of Pesticide Residues Data," 2016, 7.
[223] FAO, "Submission and Evaluation of Pesticide Residues Data," 2016, 8.
[224] FAO, *Codex Alimentarius Commission Procedural Manual*, 2016, 176.
[225] FAO, *Codex Alimentarius Commission Procedural Manual*, 2016, 179.

Challenges for Codex

The Codex process for setting MRLs has been successful in many respects, and various industry representatives consider Codex MRLs to be valuable.[226] While not all industry stakeholders agree with the MRLs set by Codex, others have expressed their respect for the scientific process and their support for global harmonization at Codex levels.[227] The inclusivity and open nature of Codex has also been lauded as beneficial to developing countries.[228]

At the same time, industry stakeholders recognize that the Codex MRL-setting process faces challenges as well. The biggest challenge is the length of time that the CAC process requires to set or revise standards, particularly the process for setting Codex MRLs, which has been sharply criticized.[229] The process of developing and approving a Codex MRL can take several years. In part, this is because while the process is well defined, open, and transparent, it was specifically designed to accommodate all members' concerns and emphasizes reaching consensus at each stage of the process.[230] As a result, the comment and revision steps may allow various issues to slow the process, thus increasing the cost and time for approval.[231] An industry representative suggested that requests in the CCPR for additional analysis, additional questions, and reevaluation (shown as the red feedback loop in figure 2.2) have slowed establishment of Codex MRLs.[232] The lack of capacity and resources at JMPR is also a key challenge that has been raised by industry groups.[233]

To speed the adoption of MRLs, members of the CCPR have asserted that acceptance of the JMPR risk assessment should be sufficient to proceed, as long as the JMPR is using the same data to evaluate risk as individual members.[234] Thus, comments are increasingly being limited for various standards, including JMPR-proposed MRLs, which has accelerated the approval process.[235]

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[226] CCB, written submission to USITC, December 11, 2019, 7; CTGC, written submission to USITC, November 15, 2019, 2; USHIPPC, written submission to USITC, December 10, 2019, 8; NPC, written submission to USITC, December 10, 2019, 11; CI, written submission to USITC, December 11, 2019, 10.
[227] USA Rice, written submission to USITC, December 10, 2019, 2; NWC, written submission to USITC, December 13, 2019, 7.
[228] Industry representative, interview by USITC staff, January 2020.
[229] FAO and WHO, *Updating the Principles and Methods of Risk Assessment,* 2016, 7.
[230] The procedures for establishing MRLs are published in the procedural manual of the Codex Alimentarius Commission. Codex Secretariat*, Procedure Manual*, 2018.
[231] The CAC makes every effort to reach agreement on adoption or amendment of standards by consensus. Decisions to adopt or amend standards may be taken by voting only if efforts to reach consensus fail. Codex Secretariat*, Procedure Manual*, 2018. Halabi interpreted CAC procedures to mean that consensus does not require unanimity, but rather a standard less than unanimity but more than a supermajority. Halabi, "The Codex Alimentarius Commission," 2015; USGC, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 17; ABC, written submission to USITC, December 13, 2019, 3.
[232] The industry representative confirmed that certain member countries were increasingly using the comment and review process to slow MRL approvals. Industry representative, interview by USITC staff, November 26, 2019. *Understanding Codex* and the *Procedural Manual* discuss bypassing steps to speed up the approval process; this is referred to as the 5/8 Process. FAO and WHO, *Codex Alimentarius: Understanding Codex*, 2016, 23; FAO and WHO, *Procedural Manual*, 182.
[233] Bayer, written submission to USITC, December 13, 2019, 2; ABC, written submission to USITC, December 13, 2019, 4.
[234] Industry representative, interview by USITC staff, November 26, 2019.
[235] FAO and WHO, *Updating the Principles and Methods of Risk Assessment*, 2016, 23.

Other Harmonization Efforts

In addition to Codex, there are a number of regional efforts to harmonize the analytical approach to MRLs, with some establishing harmonized MRLs. Many of these efforts seek to facilitate trade and to address the issues that limit the number of MRLs established for use on minor crops. Other efforts aim to advance the use of reduced-risk pesticides. A number of such regional and global efforts are described below.

APEC Import MRL Guideline for Pesticides

The APEC forum's member economies[236] have increasingly recognized the importance of MRL harmonization. Working with the APEC Sub-Committee on Standards and Conformance and through the APEC Food Safety Cooperation Forum, APEC members and others are collaborating on developing shared standards for the regulation of MRLs.[237]

The main MRL framework for APEC is the *APEC Import MRL Guideline for Pesticides.* The Australian government in particular has highlighted the work of APEC and the APEC import guideline, noting "[Australia] has supported strong collaboration between economies and raised the profile of the benefits of harmonized systems. Further advocacy of this work will benefit the global community and provide an avenue to effectively and efficiently address the challenge of missing MRLs."[238] In addition to Australia, South Korea was identified as using the APEC import MRL guideline when it developed its positive list system.[239]

The APEC guideline provides a sequential timeline of the MRL regulatory process, with information at each stage noting recognized shared practices.[240] It also lays out a series of regulatory approval paths based on practices from APEC and other countries.[241] The guideline encourages collaboration between regulatory authorities and registrants, in particular before the formal MRL regulatory process begins, and discusses the use of crop groupings in setting MRLs. It also lays out the practices countries can use if there are data gaps, or if Codex MRLs already exist, and gives guidance on average daily intake and acute reference doses.[242] In addition, the guideline drew up an import MRL application template that gives minimum data requirements for registrants and that facilitates the harmonization of data collection for major economies in the Pacific Rim.[243] The guideline has been agreed to by all APEC economies, and new initiatives to support widespread implementation, including workshops and translations, are underway.[244]

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[236] APEC member economies include Australia; Brunei Darussalam; Canada; Chile; China; Hong Kong, China; Indonesia; Japan; South Korea; Malaysia; Mexico; New Zealand; Papua New Guinea; Peru; the Philippines; Russia; Singapore; Taiwan; Thailand; the United States; and Vietnam. Asia-Pacific Economic Cooperation, "Member Economies," n.d. (accessed December 13, 2019).
[237] Government of Australia, written submission to USITC, December 13, 2019, 6.
[238] Government of Australia, written submission to USITC, December 13, 2019, 2.
[239] Government of Australia, written submission to USITC, December 13, 2019, 6.
[240] APEC, "Import MRL Guideline for Pesticides," July 2016.
[241] APEC, "Import MRL Guideline for Pesticides," July 2016.
[242] APEC, "Import MRL Guideline for Pesticides," July 2016.
[243] Government of Australia, written submission to USITC, December 13, 2019, 6.
[244] Crossley, "APEC Import MRL Guideline for Pesticides," October 2016.

ASEAN

ASEAN[245] establishes ASEAN Harmonized MRLs through its Expert Working Group on MRLs (EWG-MRL) in an effort to facilitate inter-ASEAN trade.[246] Using consensus of the regulatory authorities from member states, harmonized ASEAN MRLs can be adopted from Codex MRLs, extrapolated from similar crops, and supported using pesticide residue trials that follow Codex procedures.[247] This reduces the burden of pesticide registration, since the ASEAN Harmonized MRLs can be calculated from regionally generated field trials and residue data rather than separately for each ASEAN member state.[248] As of 2019, ASEAN had established more than 850 MRLs involving around 70 pesticides for numerous vegetables and fruits.[249] ASEAN's EWG-MRL also facilitates the establishment of pesticide MRLs for minor crops by using a commodity group MRL and by extrapolation from a relevant major crop.[250] One industry representative, however, expressed the opinion that ASEAN's work to establish a regionally harmonized MRL system would represent "a step backward from global harmonization" in that it would add unpredictability to the market.[251]

EAC

The East African Community (EAC) is making efforts to harmonize pesticide regulatory systems among member countries in an attempt to facilitate trade and leverage regulatory resources so that growers can have more tools for pest control and can access newer products faster.[252] The EAC is working to establish a common data package for pesticide registrations that includes mutual recognition of efficacy data from joint trials. This could cut the number of trials needed from 16 to just 3 or 4, which would substantially lower costs.[253] It has the goal of a single-submission registration process, which would reduce the burden to those registering pesticides for use in the EAC region.[254] These efforts have led to a regional effort to harmonize MRLs to facilitate trade.[255] Expert working group meetings were held beginning in 2016, and by their third meeting in 2018 had completed work on harmonizing the application form, pesticide label requirements, and guideline documents for registration and for efficacy and residue data requirements.[256] Harmonized EAC guidelines for efficacy and residue trials and registration requirements were endorsed by the EAC's Council of Ministers in 2019 and are slated for domestic adoption in the first half of 2020.[257]

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245 ASEAN member states include Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Burma (Myanmar), the Philippines, Singapore, Thailand, and Vietnam. ASEAN, "ASEAN Member States," n.d. (accessed February 27, 2020).
246 Ngan, "ASEAN Harmonized MRLs," May 29–30, 2019, 3–4, 11. ASEAN, "ASEAN Maximum Residue Levels," October 2015 (accessed February 25, 2020).
247 Rahim, "Expert Working Group on Harmonization," May 12, 2017, 8.
248 Ngan, "ASEAN Harmonized MRLs," May 29–30, 2019, 5.
249 ASEAN, "ASEAN Maximum Residue Levels," October 2015 (accessed February 25, 2020).
250 Rahim, "Expert Working Group on Harmonization," May 12, 2017, 24–25.
251 NWHC, written submission to USITC, December 13, 2019.
252 The East African Community includes Burundi, Kenya, Rwanda, South Sudan, Tanzania, and Uganda. Sandahl, "East African Community Efforts," June 13–14, 2018, 2–3.
253 Sandahl, "East African Community Efforts," June 13–14, 2018, 5.
254 Sandahl, "East African Community Efforts," June 13–14, 2018, 7.
255 Odong, "Regional Initiative to Harmonize Pesticide MRLs," October 2016.
256 Sandahl, "East African Community Efforts," June 13–14, 2018, 9.
257 Wafukho, "CropLife Africa Middle East Attends EAC Harmonisation Meeting," March 2019, 7.

OECD

The OECD offers countries a wide range of tools and forums for harmonizing MRLs. Its Agricultural Pesticides Programme was created in 1992 to better harmonize the processes used in developing pesticide regulations.[258] As part of these efforts, the OECD has developed a series of guidance documents on the testing of chemicals, residue definitions, and selecting toxicologically relevant metabolites, in order to minimize the variability of outcomes from the risk assessment of the same data package.[259] In addition, the OECD offers forums where scientists and regulators can discuss best practices, methodologies, and other topics related to pesticide regulation.[260] In the mid-2000s, OECD members also began conducting Global Joint Reviews (GJRs) for new pesticides. These GJRs offer countries the opportunity to share the relevant data and other scientific information used to evaluate specific pesticide registration applications, thereby expediting the approval of substances and the establishment of MRLs. Although countries participating in one of these reviews are not obliged to reach the same decisions based on the shared data package, these types of reviews often lead to harmonized MRLs. While use of GJRs is limited and has declined in recent years, most major markets have participated in at least one of them.[261]

OECD Calculator

In 2008, to address varying analytical methods for calculating MRLs among countries, an expert group was formed to develop what became known as the OECD calculator.[262] The OECD calculator aims to harmonize the way MRL calculations are made across countries by providing a suggested MRL based on the residue data from field trials as input by risk assessors. Use of this calculator is intended to minimize differences in how countries decide on an MRL once data are submitted; industry representatives report that such differences can be substantial.[263] The calculator does not address the number of trials, or the geographic distribution and type of residue field trials, but it is designed to accommodate most of the residue data sets submitted.[264] The OECD calculator has been used to develop MRLs in Codex, the EU, the United States, and Canada, among other countries.[265]

International Efforts to Advance Lower-risk or Reduced-risk Pesticides

Another international effort that affects MRLs is the promotion of lower-risk or reduced-risk pesticides. Scientific advances in the field of pesticides have led to the development of pesticides that break down quickly after application and have less-toxic effects on non-target organisms. The United States has promoted the use of such lower- or reduced-risk pesticides around the world through various projects.

[258] OECD, "Agricultural Pesticides Programme" (accessed December 16, 2019).
[259] Solecki et al., "OECD Guidance Documents and Test Guidelines," 30–31.
[260] OECD, "Pesticides Publications" (accessed February 26, 2020).
[261] Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 107–8.
[262] OECD, *OECD MRL Calculator: Statistical White Paper*, 2011, 13.
[263] Industry representative, phone interview with USITC staff, November 6, 2019.
[264] OECD, *OECD MRL Calculator: Statistical White Paper*, 2011, 14.
[265] Industry representative, interview by USITC staff, December 12, 2019. For more information on the structure of the OECD calculator, please consult OECD, *OECD, MRL Calculator: Statistical White Paper*, 2011.

For instance, the U.S.-funded Interregional Research Project No. 4 (IR-4) supports the registration of newer, often reduced-risk, pesticides in the United States and in developing countries by conducting the pesticide studies needed for their registration. Through the U.S. Agency for International Development (USAID) and U.S. Department of Agriculture (USDA), the United States also globally promotes the adoption of integrated pest management (IPM) practices, which emphasize the use of lower-risk pest control methods.

Recent Developments in Pesticides

Recent developments in pesticides have led to lower overall toxicity levels, despite increased usage stemming from the proliferation of herbicide-resistant crops.[266] The first synthetic pesticides developed in the late 1930s were generally broad spectrum, meaning they affected both the intended pest and other species. Many of these pesticides did not readily break down after application and lingered in the environment.[267] In order to reduce these impacts and offer farmers a wider range of pest management options, pesticides have become more tailored to specific pests through the development of new active substances that have a narrow mode of action unique to the targeted pest. Furthermore, newer pesticides tend to break down rapidly after application, limiting the time during which they can pose environmental and health issues.[268] In addition, the efficacy of pesticides has increased. As a result, average application rates today are about 5 percent of what they were in the 1950s.[269]

Alongside these developments in synthetic pesticides, there has been a major increase in the number of biopesticides derived from naturally occurring substances.[270] This was driven by a combination of interest in IPM practices, farmer demand for more pest control options, and the lower regulatory burden biopesticides face. All of these factors have led to the development and use of lower-risk plant protection methods.

The IR-4 Project

IR-4 is a U.S. government-funded effort that supports the use of lower- and reduced-risk pesticides. IR-4, which estimated its total annual direct funding and in-kind support to exceed $46 million in 2018, partners with various U.S. federal agencies such as USDA and EPA.[271] It works with non-federal stakeholders as well, such as state agricultural experiment stations, the agrochemical industry, and producer groups and growers. IR-4 is internationally recognized as a model for other countries seeking

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[266] Kniss, "Long-term Trends," 2017.
[267] Industry representative, telephone interview by USITC staff, November 6, 2019; World Health Organization, "Pesticide Residues in Food," February 19, 2018.
[268] Industry representative, telephone interview by USITC staff, November 6, 2019.
[269] According to Phillips McDougal, average application rates, measured in terms of grams of active substance applied per hectare, for fungicides, insecticides and herbicides were 1,200, 1,700, and 2,400 g/ha respectively in the 1950s, compared with 100, 40, and 75 g/ha today. Phillips McDougall, *Evolution of the Crop Protection Industry since 1960*, 2018, 6.
[270] Phillips McDougall, *Evolution of the Crop Protection Industry since 1960*, 2018, 5–6.
[271] Baron et al., "The IR-4 Project over 50 Years," February 2016; In 2018, the IR-4 project received more than $17 million in direct funding from various sources. In addition, it received in-kind contributions valued at $6.0 million from state agricultural experiment stations and land grant universities, $6.0 million in EPA fee waivers, 1:1 matching from the crop protection industry valued at $17 million, and $750,000 from the government of Canada. The IR-4 Project, "2018 Annual Report," 10–11.

guidance on the development of programs and processes of identifying, prioritizing, and generating data for pesticide registrations on minor-use crops.[272]

Since 1963, the IR-4 project has aided specialty crop production in the United States by supporting over 46,000 specialty-crop use tolerances (the U.S. term for MRLs), 50 percent of which are minor use registrations. In its 2006–08 strategic plan, the IR-4 project first included an initiative to pursue global harmonization of specialty crop MRLs. The goal was to combine U.S. and international data on new minor use pesticides to meet the requirements for Codex MRL minor use pesticide/specialty crop combinations.[273]

Developing pesticides for specialty crops and minor uses may not always be economically viable for registrants.[274] As a result, IR-4's efforts to facilitate registration of sustainable pest management technology, including pesticides, for specialty crops and minor uses may place newer and potentially lower-risk pesticides within reach of growers that would not have access to them otherwise.[275] In addition, IR-4 works to increase the availability of newer pesticides—often lower- or reduced-risk—around the world by building capacity in developing countries to conduct pesticide trials.[276] The IR-4 project also supports work on biopesticides and organic production, which indirectly advances lower- and reduced-risk pesticides.

Integrated Pest Management (IPM)

Since the advent of synthetic pesticides, efforts have been made to avoid their overuse while still producing healthy and abundant crops.[277] Similar efforts today have come to be known as IPM, a concept supported by a wide range of stakeholders within the agricultural community.[278] IPM indirectly leads to lower use of pesticides, as well as use of reduced-risk pesticides. The principles of IPM include preventing pest outbreaks through tailor-made approaches, such as rotating crops, monitoring pest populations, and controlling pests using methods that balance their effectiveness with their associated risks.[279]

[272] OECD, *Guidance Document on Regulatory Incentives*, 2011, 21.
[273] Industry representative, telephone interview by USITC staff, October 3, 2019.
[274] EPA, "Minor Uses and Grower Resources" (accessed March 26, 2020). A detailed discussion of minor crops is presented in chapter 4 of this report.
[275] Minor crops (or "minor use crops"), which are often specialty crops, have relatively small production. The low output limits economic incentives for pesticide companies to register pesticides for use on those crops. The EPA defines minor use crops as those having less than 300,000 acres in growing area. A minor use pesticide is a pesticide registered for use on minor use crops. EPA, "Minor Uses and Grower Resources" (accessed August 2, 2019); OECD, "Minor Uses of Pesticides" (accessed April 24, 2020).
[276] Industry representative, telephone interview by USITC staff, October 3, 2019.
[277] Smith, "Supervised Control of Insects," 1949, 2; FAO, "AGP—Integrated Pest Management" (accessed January 15, 2020).
[278] FAO, "AGP—Integrated Pest Management" (accessed January 15, 2020)**;** EPA, "Integrated Pest Management (IPM) Principles," April 11, 2019.
[279] For instance, a mild pest outbreak may be controlled effectively using pheromones (a naturally occurring chemical) that disrupt the mating cycle of the pest, while for moderate pest pressure, an application of a pesticide that is targeted at that specific pest may be used. EPA, "Integrated Pest Management (IPM) Principles," April 11, 2019.

When applying these principles, growers have several categories of pest control methods to choose from, including biological controls (e.g., beneficial insects), "cultural" (cultivation-related) controls (e.g., choosing crop varieties that are resistant to pests), and chemical controls (e.g., pesticides). In practice, broadcast spraying of a broad-spectrum, non-targeted pesticide would be used only for the most severe outbreaks after other control methods were exhausted.[280] Reportedly, many growers in the United States, and an increasing number around the world, are using some degree of IPM techniques in order to apply pesticides more effectively while lessening any negative health and environmental impact.[281]

USAID and USDA support IPM development and adoption through a number of programs.[282] In 1990, USAID requested a series of studies of IPM, which led to what is now Feed the Future Innovation Lab for Integrated Pest Management at Virginia Tech University (IPM IL). IPM IL is funded by USAID to address health, environment, and economic issues through integrated pest technologies, partnering with USDA in these efforts.[283] Examples of IPM IL activities include identifying and containing the papaya mealybug in India in 2008 and monitoring the invasion of the tomato leafminer *Tuta absoluta* in several areas during the past decade. Since 1993, IPM IL has operated in nearly 30 countries.

IPM IL was also involved in the global response to the infestation of fall armyworm in sub-Saharan Africa (SSA) beginning in 2016. As noted in chapter 1 of this report, this invasive pest poses a severe threat to agricultural production and food security across SSA. In response to the outbreak, a U.S. government interagency Task Force on Fall Armyworm, led by USAID, was created to promote the use of lower-risk pest control methods within an IPM framework to contain the new threat.[284] A major output of the Task Force was a comprehensive manual, developed in partnership with the FAO and the International Maize and Wheat Improvement Centre (CIMMYT), on the use of IPM, including these improved pest control methods, in combating fall armyworm.[285] In addition, the task force worked with regional governments and key stakeholders to speed up the approval and availability of lower-risk pesticides in SSA.[286]

Beyond improving pest management and the response to emerging pest outbreaks, these efforts to promote IPM have had positive impacts in agricultural trade by helping farmers to lower pesticide residues on their crops. For example, USAID efforts contributed to Vietnamese exports of mangoes,

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[280] EPA, "Integrated Pest Management (IPM) Principles," April 11, 2019 (accessed February 11, 2020).
[281] EPA, "Integrated Pest Management (IPM) Principles," April 11, 2019 (accessed February 11, 2020); NHC, written submission to USITC, December 13, 2019; ABC, written submission to USITC, December 13, 2019; CI, written submission to USITC, December 11, 2019; CFFA, written submission to USITC, December 13, 2019; NABC, written submission to USITC, December 9, 2019; WI and CAWG, written submission to USITC, December 13, 2019; ASA and USSEC, written submission to USITC, December 13, 2019; USHIPPC, submission to USITC, December 10, 2019; CCQC, written submission to USITC, December 10, 2019.
[282] U.S. federal government investment for IPM-related research was about $180 million in 1973 and grew to $204.9 million in 1996. In 2001, the Federal IPM Coordinating Committee (FIPMCC) was established to "provide interagency guidance on IPM policies, programs and budgets." It comprises all federal agencies that are involved in IPM, including USDA, EPA, and USAID. In 2018, USDA updated the National Roadmap for Integrated Pest Management after a yearlong review by FIPMCC. USDA, "USDA Announces Update to National Road Map," October 24, 2018, revised September 21, 2018, 10; Jacobsen, "USDA Integrated Pest Management Initiative," 1996.
[283] IPM Innovation Lab, "Partnerships" (accessed January 13, 2020).
[284] U.S. government representative, telephone interview by USITC staff, January 17, 2020.
[285] U.S. government representative, telephone interview by USITC staff, January 17, 2020; Prasanna et al., *Fall Armyworm in Africa,* 2018.
[286] U.S. government representative, telephone interview by USITC staff, January 17, 2020.

dragon fruit, lychee, and longan fruit to the United States.[287] Around 2012, a number of Vietnamese shipments of these tropical products were impacted by pesticide residue detections at U.S. ports.[288] To address this, IPM IL implemented a five-year project to strengthen the production and export potential of Vietnamese tropical fruits through the adoption of IPM techniques by growers. Using IPM, Vietnamese growers were able to produce more fruit of higher quality and to gain access to high-value export markets as a result of this USAID-based investment.[289]

[287] IPM Innovation Lab, "IPM for Exportable Fruit Crops in Vietnam," 2019.
[288] U.S. government representative, telephone interview by USITC staff, January 17, 2020.
[289] U.S. government representative, telephone interview by USITC staff, January 17, 2020. IPM Innovation Lab, "IPM for Exportable Fruit Crops in Vietnam," 2019.

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Chapter 3
MRL Practices in Major U.S. Export Markets

Introduction

As noted in chapter 2, some markets have moved away from deferring to the Codex Alimentarius (Codex) system and have instead developed positive list systems, in which governments establish their own independent lists of maximum residue levels (MRLs) for pesticides that may to varying degrees incorporate Codex standards. Coinciding with the development of positive list systems, regulators in these major markets have also created regulations, requirements, practices, processes, and timelines for the approval and registration of active substances, as well as for establishing MRLs and import tolerances.[290] Though they have much in common, none are identical or completely harmonized.

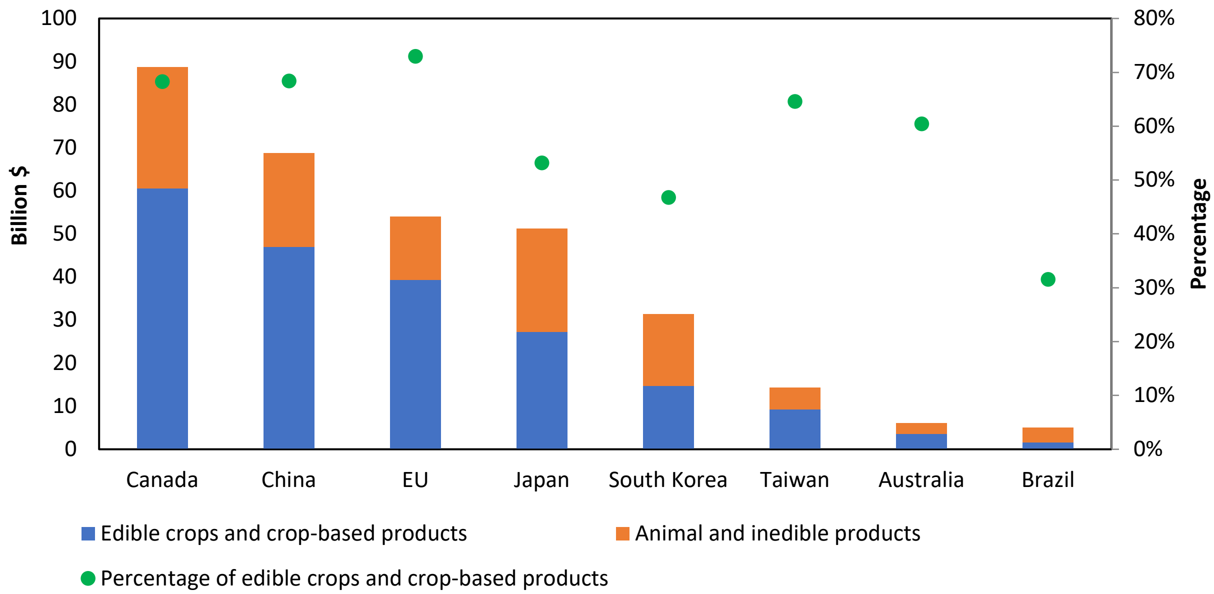
In all of these markets, substantial data and resources are needed to complete an application (dossier), as required by regulators to register active substances and establish MRLs. Applications typically require the submission of multiple years' worth of data, including the results of efficacy testing, environmental studies, human toxicology studies, and exposure studies, and often can be tens of thousands of pages long and cost millions of dollars to compile, according to industry representatives.[291] Even small differences in risk assessment processes between individual countries can significantly increase the overall costs for multiple applications.[292] Regardless of how much information is gathered and submitted to regulators, and even though scientists often use internationally accepted methodologies to conduct their risk assessments, regulators looking at the same application data can still draw different conclusions about an active substance and/or the MRL.[293]

[290] For purposes of this chapter, an MRL is defined as the highest level of a given pesticide's residue on a given crop that is legally tolerated in a government's jurisdiction. This type of MRL is applicable for both domestically produced and imported crops.
[291] Industry representative, interview by USITC staff, December 12, 2019; U.S. government representative, interview by USITC staff, December 30, 2019; industry representative, interview by USITC staff, January 7, 2020; industry representative, interview by USITC staff, February 13, 2020. Efficacy testing determines whether application of a pesticide on a crop in a manner suggested by the pesticide manufacturer actually addresses the pest issue it is designed to address. Environmental studies (sometimes referred to as studies of "environmental fate" or "environmental toxicity") are conducted to establish the environmental impact of a proposed pesticide use on a crop, and frequently include water, air, and soil assessments. Other environmental tests can include assessments on aquatic life, birds, bees, and biodiversity. Toxicology testing for pesticides determines whether the exposure of a pesticide residue that would result from its use, as laid out in the crop field trials, would cause negative human or environmental effects. These effects often include both short-term and long-term effect analyses. Exposure studies determine the likely level of exposure that can be expected from the application and resulting residue of a pesticide on humans upon consumption of a crop treated with the pesticide. Purdue Extension, "Pesticide Toxicology, PPP-40" (accessed February 18, 2020).
[292] Industry representative, interview by USITC staff, February 13, 2020.
[293] Industry representative, interview by USITC staff, November 26, 2019; U.S. government representative, interview by USITC staff, December 30, 2019.

This chapter describes pesticide registration and MRL policies in several important U.S. agricultural export markets that establish and maintain their own MRL lists. These include Australia, Brazil, Canada, China, the European Union (EU), Japan, South Korea, and Taiwan.[294] These markets were chosen for a variety of reasons, including the size of the export market for U.S. and other major agricultural exporters, any significant changes to MRL policies in export markets, and the extent to which these markets may reflect broader developments in global MRL regulations. Figure 3.1 shows average U.S. agricultural exports from 2016 to 2019 to these markets and divides agricultural exports into two groups: (1) edible crops and crop-based products and (2) animal and inedible products. [295] Edible crops and crop-based products, which are highlighted in this report, include fresh, frozen, and prepared products of vegetables, fruits, and grain.[296] On average, 60 percent of all U.S. agricultural exports are edible crops and crop-based products, and this trend is consistent across major U.S. export markets other than Brazil, a major importer of U.S. undenatured alcohol, and South Korea, a major importer of U.S. beef products. The remaining 40 percent of global U.S. agricultural exports are of animal and inedible products. This category covers edible meat and dairy products, including beef, pork, poultry, and fish, and inedible products such as tobacco, hides and skins, and cotton; these products are not the focus of this report.

[294] Mexico is not covered in this chapter. Mexico is the United States' second-largest export market for agricultural products. Mexico often harmonizes its MRLs with U.S. MRLs. Multiple industry representatives noted that Mexico appears to accept U.S. MRLs on imported foods from the United States, meaning that bilateral trade disruptions between the United States and Mexico over MRLs would be unlikely and that this unofficial arrangement facilitates bilateral trade. One industry association wrote that while Mexico maintains a positive list, the MRLs on this list are associated with domestic labels. This association also notes that "unofficially, in practice, Mexico accepts U.S. MRLs for imported products from the United States." Cranberry Institute, written submission to USITC, December 11, 2019, 9; ABC, written submission to USITC, December 13, 2019, 7; CFFA, written submission to USITC, December 12, 2019, 3; APC, written submission to USITC, December 6, 2019, 2; U.S. government official, interview by USITC staff, December 9, 2019.
[295] Categorization is based on USITC digests. Edible crops and crop-based products include AG017 to AG042. AG001 to AG016 and AG043 to AG050 are categorized as animal and inedible products. For further information on commodity digests, see https://www.usitc.gov/data/index.htm.
[296] The category of edible crops and crop-based products also includes other edible products such as pasta and bakery goods, juices, and wines and spirits.

Figure 3.1 U.S. agricultural exports to selected key markets, 2016–19 average



Source: USITC/USDOC DataWeb (accessed February 24, 2020).
Note: For China, dollar amounts and percentages do not include exports to Hong Kong.

This chapter describes the specific regulations, processes, practices, and timelines for establishing, modifying, and enforcing MRLs for each of these key U.S. export markets. It also covers relevant MRL enforcement practices and processes, including practices and procedures for addressing noncompliant imported plant products. Each market-specific section below identifies the processes of registering an active substance, securing an MRL/import tolerance, complying with default policies when an MRL has not yet been set, and enforcement of MRLs. Each section concludes with a summary of any important regulatory developments, trade-facilitative practices, or unique characteristics that impact MRLs in that market (table 3.1).

Table 3.1 Summary table of MRL policies for key U.S. agricultural export markets

Export market	Main MRL agency	Default MRL	Number of field trials required for an MRL	Time required to approve MRL application	Other notable features
Australia	Australian Pesticides and Veterinary Medicines Authority (APVMA)	None. (no detectable level allowed)	2 to 6 for minor crops, 6 to 12 for major crops	12 months	Extensive collaboration with New Zealand on MRL issues, yearly open period to adjust MRLs is viewed by grower groups as trade facilitative.
Brazil	National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária, ANVISA)	Defer to Codex Alimentarius (Codex); no detectable level allowed otherwise	4, but expected to grow to 8	Unclear	Firms have indicated difficulty in securing import tolerances for Brazil, opting to seek MRLs instead. Brazil may rely on other countries' MRLs to fill gaps, but firms report this is uncertain.
Canada	Pest Management Regulatory Agency, under Health Canada	0.1 parts per million (ppm)	1–5 for minor crops, 8–16 for major crops	15–23 months	Extensive collaboration with U.S. regulators to support harmonization, and the 0.1 ppm default is viewed by industry representatives as trade facilitative.
China	Institute for the Control of Agrochemicals, under Ministry of Agriculture and Rural Affairs	None. (no detectable level allowed)	Up to 12 trials required	Unclear	Local field trial requirements, unclear environment for requesting MRLs or import tolerances.
EU	European Food Safety Authority (EFSA), European Commission (EC), and the EC Standing Committee on Plants, Animals, Food, and Feed (PAFF)	0.01 ppm	4 for minor crops, 8 for major crops for active substances.	2.5–3.5 years	New food law and controls regulation may impact MRL setting and enforcement; use of cutoff criteria may lead to non-approval of active substances based on hazard assessment; member states separately authorize the use of the pesticide containing active substances approved at the EU level.
Japan	Ministry of Health, Labour, and Welfare (MHLW)	0.01 ppm	3 for minor crops, 6 for major crops	12 months	Certain post-harvest fungicides are classified as food additives; concurrent evaluation of MRL application with producer market is viewed as trade facilitative by reducing wait times to export treated agricultural products.

Export market	Main MRL agency	Default MRL	Number of field trials required for an MRL	Time required to approve MRL application	Other notable features
South Korea	Korean Ministry of Food and Drug Safety (MFDS)	0.01 ppm	3 for minor crops, 6 for major crops	12 months	Among the more recent markets transitioning to an MRL system, have been working with industry and grower groups to set permanent MRLs; transitional MRLs, operative during South Korea's transition to its positive list system, will expire in 2021.
Taiwan	Food and Drug Administration (TFDA), under Department of Health and Welfare (DOHW)	None. (no detectable level allowed)[a]	1 for minor crops, 3 for major crops	12–24 months	Local field trial requirements.

Source: Compiled by USITC.
[a] Taiwan has noted that it does not characterize its default as zero tolerance because it leads to confusion. Rather, "in practice, the determination of pesticide residues is based on the limit of quantification Taiwan has published for the detection of pesticide residue, and only the number higher than the limit of quantification will be recognized." TECRO, written submission to USITC, December 13, 2019, 38–39.

Major U.S. Export Markets

Australia

Australia is the United States' 15th-largest agricultural export destination, with an average of $1.51 billion in annual exports from 2016 to 2019. Sixty percent of these exports were of edible crops and crop-based products. However, two of the three largest export groups are animal products: swine and pork ($194 million) and dairy products ($148 million). Among edible crops and crop-based products, certain edible preparations ($166 million) is the largest export group, followed by distilled spirits ($118 million) and edible nuts ($93 million).[297]

Australia has had its MRL system in place for nearly 30 years, and industry representatives, growers, and third-country government officials regard the Australian system as one that facilitates agricultural production and trade.[298] Australia's system has some unique characteristics that distinguish it from other major U.S. agricultural export markets. One is that two countries—Australia and New Zealand—share regulatory responsibilities in some instances that facilitate MRL processes and bilateral trade. Another is that certain aspects of Australia's MRL process, such as yearly updates to its MRLs, facilitate

[297] USITC DataWeb/USDOC (accessed January 24, 2020). Please see figure 3.1 for further information.
[298] NABC, written submission to USITC, December 9, 2019, 4–5; ABC, written submission to USITC, December 13, 2019, 8; industry representative, interview by USITC staff, October 7, 2019; industry representative, interview by USITC staff, November 21, 2019; USITC, hearing transcript, October 29, 2019, 33 (testimony of Terry Humfeld, Cranberry Institute).

the process for both growers and pesticide manufacturers and facilitates global agricultural exports to Australia.[299]

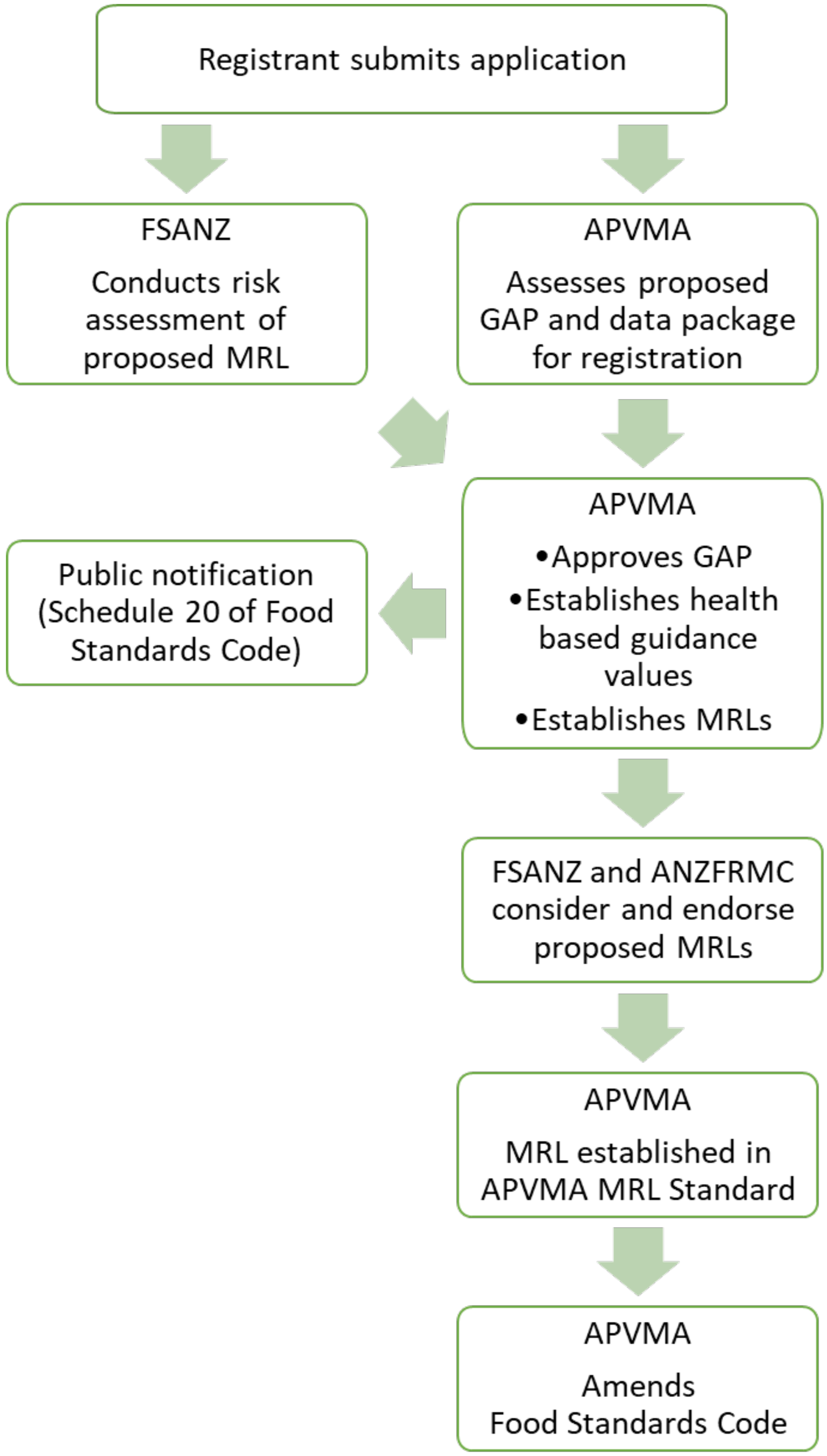
Active Substance Registration and MRL Regulations and Processes

Registering a pesticide: Australia requires that a pesticide be registered and approved for use within the country before establishing an MRL. Australia's Agricultural and Veterinary Chemicals Act 1992 and the Agricultural and Veterinary Chemicals Code Act 1994 establish the authority of the Australian Pesticides and Veterinary Medicines Authority (APVMA) to approve and register "active constituents" (active substances).[300] The application to register a pesticide must include information to allow APVMA to assess the active substance according to safety, efficacy, trade, and labeling criteria.[301] In order to conduct its risk assessment, Australia, like the other markets discussed in this chapter, requires that a number of studies be conducted. These studies must contain data on toxicology, metabolites, impacts on the environment, efficacy, and safety, among other information.[302] The Australian government estimates that the process of registering a new pesticide takes about 18–25 months and costs about $100,000.[303]

Securing an MRL: After a pesticide has been registered for use in Australia, an interested party (which is usually the original registration applicant) can apply for an MRL for a pesticide/crop combination (figure 3.2). Australia has two standards under which it establishes MRLs: the APVMA MRL Standard, which is used for domestic use, and Schedule 20 of the Australia New Zealand Food Standards Code (the Code), which includes import tolerances.[304] MRLs are set according to Good Agricultural Practice (GAP) after making a risk assessment and noting use patterns in other countries.[305] APVMA establishes MRLs for both imported and domestically produced agricultural products, with support from Food Standards Australia New Zealand (FSANZ). APVMA (and its predecessor, the National Registration Authority) has established MRLs in Australia since 1993.[306] Typically, APVMA proposes MRLs and then FSANZ is responsible for conducting the risk assessment, including the chemical residue effects of proposed

[299] NPC, written submission to USITC, December 10, 2019, 9; industry representative, interview by USITC staff, October 7, 2019.
[300] Under Part 2 (Establishment, Functions and Powers of APVMA), the Agricultural and Veterinary Chemicals (Administration) Act 1992 provides APVMA the authority to "assess the suitability for sale in Australia of active constituents for proposed or existing chemical products." Government of Australia, "Agricultural and Veterinary Chemicals (Administration) Act 1992," Federal Register of Legislation, 1992.
[301] Government of Australia, APVMA, "What to Include in Your Application" (accessed January 29, 2020).
[302] Government of Australia, APVMA, "Toxicology (Part 3)" (accessed January 29, 2020); Government of Australia, APVMA, "Metabolism and Kinetics (Part 4)" (accessed January 29, 2010); Government of Australia, APVMA "Environment (Part 7)" (accessed January 29, 2020); Government of Australia, APVMA, "Pesticides Efficacy and Crop Safety General Guideline (Part 8)" (accessed January 29, 2020).
[303] Government of Australia, APVMA "Timeframe and Fees" (accessed February 19, 2020).
[304] Under this framework, Australia can set both a domestic MRL and an import tolerance for the same pesticide/crop combination. In certain instances, this means import tolerances may be set at levels higher than the domestic MRLs for those pesticide/crop combinations. Government of Australia, ANZFSC, "Australia New Zealand Food Standards Code—Schedule 20—Maximum residue limits," June 2, 2020; Government of Australia, APVMA, "Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019," July 9, 2020; Deller, "MRL Establishment in Australia," APVMA, 2017.
[305] Government of Australia, written submission to USITC, December 13, 2019, 3.
[306] Government of Australia, APVMA, "Pesticides and Veterinary Residues" (accessed November 18, 2019).

Figure 3.2 Australia's MRL-setting process



Source: USITC, based on Deller, "MRL Establishment in Australia," APVMA, 2017; FSANZ, "Maximum Residue Limits—Variations," April 2019; Government of Australia, APVMA, "Residue and Residue Testing," n.d. (accessed February 20, 2020).
Note: APVMA = Australia Pesticides and Veterinary Medicine Authority; FSANZ = Food Standards-Australia New Zealand; ANZFRMC = Australia New Zealand Food Regulation Ministerial Council.

substances in Australian diets.[307] FSANZ also reviews new MRLs established by APVMA; FSANZ and the Australian New Zealand Food Regulation Ministerial Council will evaluate proposed MRLs, and following their endorsement, the MRLs are adopted into the Code.[308]

The APVMA will consider a variety of factors in accessing MRL applications. Like other major markets, APVMA establishes MRLs in Australia such that when pesticides are used on crops, the pesticides are "used at the minimum effective level and using GAP and after an assessment of the potential risk to public health and safety at that level."[309] APVMA is also tasked with taking into consideration acceptable daily intake (ADI) determinations. For minor crops, APVMA suggests between 2 and 6 residue trials in order to establish the data necessary for MRLs, and for major crops they suggest between 6 and 12 trials, depending on the commodity.[310]

A notable feature of the Australian system is that in establishing an MRL, APVMA considers other countries' MRLs to determine whether their own MRLs may conflict with others for export purposes. In considering the potential impact of a new MRL, APVMA "is obliged under the Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code) to be satisfied that the use of the pesticide according to the registered use pattern would not unduly prejudice trade or commerce between Australia and other countries."[311] Additionally, the APVMA may take into consideration the MRLs and use patterns of other countries for pesticide/crop combinations that are not used in Australia for agricultural production.[312] FSANZ and APVMA are also required to consider Codex MRLs when setting Australian MRLs, but they are not bound by them and may set MRLs distinct from Codex MRLs.[313]

Import tolerances: Exporters and pesticide manufacturers can apply for an import tolerance in Australia if there is no MRL for the specific pesticide/crop combination or if the existing MRL is lower than that of the exporting market. According to the Asia-Pacific Economic Cooperation (APEC)**,** the average time required to secure an import tolerance in Australia is approximately 12 months from submission of the application to the final decision.[314] As in most other markets, an application for an import tolerance requires that the registrant include information on crop residues, downstream residues for animals if applicable (for example, feed crops that might be then consumed by livestock), pesticide residues in the product following any relevant storage, processing or cooking, and information on MRLs set in other countries and by Codex (in addition to the applicant's proposed MRL).[315]

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[307] Government of Australia, FSANZ, "Maximum Residue Limits—Variations," April 2019.
[308] Government of Australia, Department of Agriculture, Water and the Environment, "Residue and Residue Testing" (accessed February 20, 2020).
[309] Government of Australia, "Australia New Zealand Food Standards Code: Standard 1.4.2.—Agvet Chemicals" (accessed November 18, 2019).
[310] Government of Australia, APVMA, "Residue Trials to Obtain Permanent Maximum Residue Limits for Crops," 2014.
[311] Government of Australia, APVMA, "Overseas Trade" (accessed January 16, 2020); AWRI, "Maximum Residue Limits (MRLs)" (accessed November 18, 2019).
[312] Government of Australia, written submission to USITC, December 13, 2019, 3.
[313] Government of Australia, APVMA, "Overseas Trade" (accessed January 16, 2020).
[314] APEC, "APEC Compendium of Government Administration in Setting Maximum Residue Limits for Pesticides," June 2019, 6–9.
[315] Government of Australia, APVMA, "Residues (5A)" (accessed January 16, 2020).

Default MRLs: In the event that no MRL has been set for a pesticide/crop combination, Australia does not allow any detectible level of that pesticide residue to remain on the specific crop in the Australian market.[316] In some instances, after a risk assessment has been conducted, Australia may set an MRL to the "limit of analytical quantification," the lowest point at which a given pesticide may be detected for that specific agricultural product.[317] This limit can vary by pesticide and crop.[318] Similar to many other major markets, in the event the APVMA proposes a change to any MRLs under Schedule 20, it will release a call for public comment, where industry and the public can weigh in on potential changes.[319]

Enforcement

Enforcement of MRLs in Australia is carried out at both the national and state/territory level. Food regulatory agencies are required to monitor and enforce the Food Standards Code (which includes MRLs) at the state level.[320] At the national level, the Australian Department of Agriculture inspects foods imported into Australia to ensure MRL compliance.[321] In addition, FSANZ also monitors chemical residues in Australian food as part of a yearly dietary study, referred to as the Australian Total Diet Study.[322]

In addition, agricultural products imported into Australia are classified either as "risk food" or "surveillance food." Risk foods are agriculture products that are identified as having a medium to high risk to human health and safety (examples include meat, eggs, dairy, and cut fruit and vegetables),[323] are covered by the *Imported Food Control Order 2019*, and are subject to inspection. Surveillance foods, or food viewed as having lower risks to public health and safety (like nuts, uncut fruits and vegetables, and legumes),[324] are randomly referred and inspected for MRLs and other food regulations at a rate of 5 percent of shipments.[325] In the event an agricultural product exceeds any MRL covering any of the more than 100 pesticide residues tested, the product must either be re-exported or destroyed by the importer.[326]

[316] Luo, "Australia Sets new MRL for 19 AgVet Chemicals," January 2017.
[317] For example, for the active substance abamectin, the Australian MRLs for adzuki beans, almonds, blueberries, navy beans, cotton seeds, and macadamia nuts are all set at the limit of determination for those individual products (which are respectively, in ppm, 0.002, 0.01, 0.02, 0.002, 0.01, and 0.01). The limit of analytical quantification is also sometimes referred to as the "limit of analytical determination." Government of Australia, OPC, "Schedule 20: Maximum residue limits" (accessed November 18, 2019).
[318] Government of Australia, APVMA, "Maximum Residue Limit Proposals at or about the Limit of Analytical Quantitation," June 29, 2018.
[319] Government of Australia, FSANZ, "Maximum Residue Limits—Variations," April 2019.
[320] BCI, "Australia Pesticide MRLs Market Information Report," March 2019.
[321] Government of Australia, FSANZ, "Chemicals in Food—Maximum Residue Limits," April 2018.
[322] Government of Australia, FSANZ, "Australian Total Diet Study," June 2019.
[323] Williams, "What Are the High Risk Foods?" Food Safety Australia, June 21, 2019.
[324] Government of Australia, Department of Agriculture, Water, and the Environment, "Imported Food Inspection Scheme" (accessed February 18, 2020).
[325] Risk foods are subject to additional testing to identify instances of microorganism content, bovine spongiform encephalopathy, caffeine content, or other issues. Government of Australia, Department of Agriculture, "Tests Applied to Risk Food" (accessed January 16, 2020); Government of Australia, written submission to USITC, December 13, 2019, 5.
[326] Government of Australia, written submission to USITC, December 13, 2019, 5.

Bilateral Recognition of MRLs

Australia maintains a partially shared MRL regulatory and enforcement framework with New Zealand, under which each country recognizes the MRL system of the other as equivalent for the purpose of supporting bilateral exports of agricultural products between the two countries, notwithstanding the fact that each country maintains its own MRL system.[327] So long as a New Zealand agricultural export to Australia complies with New Zealand's own MRLs, it is viewed by the Australian government as compliant with Australian MRL regulatory requirements.[328] Additionally, Australian exports of agricultural products to New Zealand qualify for the New Zealand market if they comply with New Zealand MRLs, follow standard 1.4.2 of the Australia New Zealand Food Standards 3 (Australian MRLs), or follow a Codex MRL.[329] Finally, food standards in Australia and New Zealand are both governed by FSANZ.[330]

Trade Facilitative Practices

Industry representatives and third countries have identified a number of MRL-related practices in Australia as facilitating agricultural production and trade.[331] Each spring, the Australian government under FSANZ conducts a yearly assessment of the harmonization of MRLs, and opens a comment period for interested parties to offer suggestions to change MRLs.[332] During this period, FSANZ prepares an MRL harmonization proposal to consider requests from interested parties who wish Australia's government to revise its MRLs to harmonize either with international Codex standards or the MRLs of the country from which the Australian agricultural import is sourced.[333] In order to submit a harmonization request to FSANZ, an interested party must submit relevant information regarding the MRL, with possible follow-up from FSANZ. The information applicants submit is similar to the information required to request a new MRL from Australian regulatory authorities.[334]

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327 MRLs in Australia are governed under Schedule 20 of the *Australia New Zealand Food Standards Code*, while New Zealand MRLs are governed by the Ministry of Primary Industries under the *Food Act 2014.* Government of Australia, "Australia New Zealand Food Standards Code: Standard 1.4.2.—Agvet Chemicals" (accessed November 18, 2019).

328 Government of New Zealand, "Pesticide Maximum Residue Levels," November 7, 2019.

329 Government of New Zealand, "Pesticide Maximum Residue Levels," November 7, 2019.

330 Government of Australia, FSANZ, "Food Standards" (accessed March 17, 2020).

331 NABC, written submission to USITC, December 9, 2019, 4–5; ABC, written submission to USITC, December 13, 2019, 8–9; industry representative, interview by USITC staff, October 7, 2019; industry representative, interview by USITC staff, November 21, 2019; USITC, hearing transcript, October 29, 2019, 33 (testimony of Terry Humfeld, Cranberry Institute).

332 Government of Australia, FSANZ, "MRL Proposals," April 2018; NABC, written submission to USITC, December 9, 2019, 4–5; ABC, written submission to USITC, December 13, 2019, 8–9.

333 Government of Australia, FSANZ, "MRL Proposals," April 2018; NABC, written submission to USITC, December 9, 2019, 4–5; Government of Australia, FSANZ, "Maximum Residue Limits—Variations," April 2019.

334 FSANZ requires the following information: "Information about the agvet chemical to be considered, including the relevant health-based guidance values; a description of the food commodity as described by Codex and/or the Code; the specific MRL you are seeking and a reference to the legislation where the MRL is published; information on the food commodity or commodities that are intended to be imported using this MRL; and evidence that the food is to be imported into Australia including volumes imported from the country with the source MRL, details on

Following receipt of this information, FSANZ will investigate the safety, legitimacy, and justification of the MRL proposal. Notably, FSANZ also considers the market significance of an existing and reportedly inadequate MRL in this process. FSANZ will also evaluate whether the source country has equivalent permissions for use and subsequent standards.[335] FSANZ will then submit its report to the ADVMA, which will make a determination as to whether to harmonize the proposed MRL changes with international or other country MRLs.[336] Some industry representatives have characterized the Australian regulatory process for establishing MRLs as "the most efficient in the world," and have stated that its petitioning process is "particularly effective."[337]

Brazil

Brazil is the United States' second-largest market for U.S. agricultural products in Latin America,[338] with an average of $1.25 billion in annual exports from 2016 to 2019. Thirty-two percent of these exports were of edible crop and products. Ethyl alcohol for non-beverage purposes, part of the animal and inedible products group, recorded the largest exports at $627 million. Among edible crops and crop-based products, cereals ($131 million) and certain edible preparations ($84 million) were the largest.[339]

Brazil's MRL regulatory system has been in place for more than 30 years. The overlap of regulatory agencies in Brazil, however, has been noted to complicate the MRL-setting process there, and registering a pesticide can take up to six years.[340] Of the major markets presented in this chapter, Brazil is the only market identified as regularly deferring to Codex MRLs where it has not set its own, which is particularly important since industry representatives report that in practice Brazil does not have an effective system in place to request import tolerances. Additionally, Brazil's cutoff criteria for active ingredients (as laid out in the 1989 law that regulates pesticide use in Brazil) and its reported reexamination of approvals when pesticides are not renewed in the European Union have been noted by industry representatives as contributing to the uncertainty about Brazil's regulation of pesticide approvals and MRLs.[341]

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the size and nature of the Australian market, and cost impacts in the absence of a harmonized MRL, if available." Government of Australia, FSANZ, "Maximum Residue Limits—Variations," April 2019.

[335] Government of Australia, FSANZ, "Maximum Residue Limits—Variations," April 2019.

[336] Government of Australia, FSANZ, "Maximum Residue Limits—Variations," April 2019.

[337] NPC, written submission to USITC, December 10, 2019, 9.

[338] As discussed above, Mexico is the United States' largest export market for agricultural products in Latin America, and often harmonizes its MRLs with U.S. MRLs.

[339] USITC DataWeb/USDOC (accessed January 24, 2020).

[340] Fang, "Brazilian Pesticide Regulation Overview," March 13, 2017.

[341] The 1989 law was noted, in a comparative analysis of MRL regulations in Brazil and the United States, as "incorporating hazard assessment by banning the registration of pesticides that are carcinogenic, teratogenic, mutagenic or hormone disruptors. The law also allows for product registrations to be challenged or cancelled at the request of representative civil society organizations (Law 7802 1989, article 5)." Additionally, pesticides are not registered in Brazil if "Brazil does not have methods for deactivation or its components, for which there is no antidote of effective treatment . . . [or they are] more dangerous to humans than lab tests on animals have been able to show, according to updated scientific and technical criteria," in addition to the traditional cutoff criteria of a product being judged to be carcinogenic, mutagenic, teratogenic, or reprotoxic. Government of Brazil, MAPA, "Brazil MRL Update," June 2016, 31. One industry representative noted that, "if a chemical is deemed to be

Active Substance Registration and MRL Regulations and Processes

Registering a pesticide: Brazil requires that a pesticide be registered and approved for use within the country before establishing an MRL. The registration of a pesticide in Brazil is carried out by the Ministry of Agriculture, Livestock, and Supply (MAPA). Analysis of the pesticide registration application is jointly conducted by the National Health Surveillance Agency (ANVISA), the Brazilian Institute of the Environment and Renewable National Resources (IBAMA), and MAPA.[342] The registration process is governed principally by the 1989 statute Law 7802 (as is the overall system for MRLs) followed by subsequent decrees and regulatory ordinances. Law 7802 lays out requirements regarding the registration of pesticides, the registration of component inert ingredients and additives, use and disposal of pesticides, and the marketing requirements for pesticides proposed for use in the Brazilian market.[343]

Pesticide registration applications must contain significant data to fulfill Brazilian regulatory requirements. Applicant submissions must include information on the purpose and use of the pesticide as well as methods used by the applicant in conducting the analysis to register the pesticide. For purposes of completing a risk assessment, applications must also include crop and residue trial data on efficacy, general toxicity, and toxic effects on the skin and eyes, in addition to eco-toxicology data on impacts to organisms and plants, as well as any carcinogenicity, neurotoxicity, or hormonal impacts.[344] MAPA governs the efficacy evaluation of products and issues the certificate of registration to use the product, ANVISA conducts the toxicological assessment and classification of active ingredients and establishes MRLs, and IBAMA conducts the environmental assessment and classification of environmental hazards of active ingredient registrations (figure 3.3).[345] An industry publication has noted that a possible overlap of regulatory duties across agencies could complicate the pesticide registration process. Another source states that registering a pesticide in Brazil can often take three years, but may take up to six.[346]

carcinogenic or genotoxic, it could not be approved. But since they have not defined what is carcinogenic, genotoxic, for instance, Anvisa does a full risk assessment in order to establish MRLs." USITC, hearing transcript, October 29, 2019, 64 (testimony of Alinne Oliveira, representing USHIPPC). Pelaez, Rodrigues da Silva, and Borges Araújo, "Regulation of Pesticides: A Comparative Analysis," October 2013, 649; industry representative, interview by USITC staff, December 12, 2019; Government of Brazil, MAPA, "Brazil MRL Update," June 2016, 26.

[342] Government of Brazil, MAPA, "Brazil MRL Update," June 2016, 29–30.

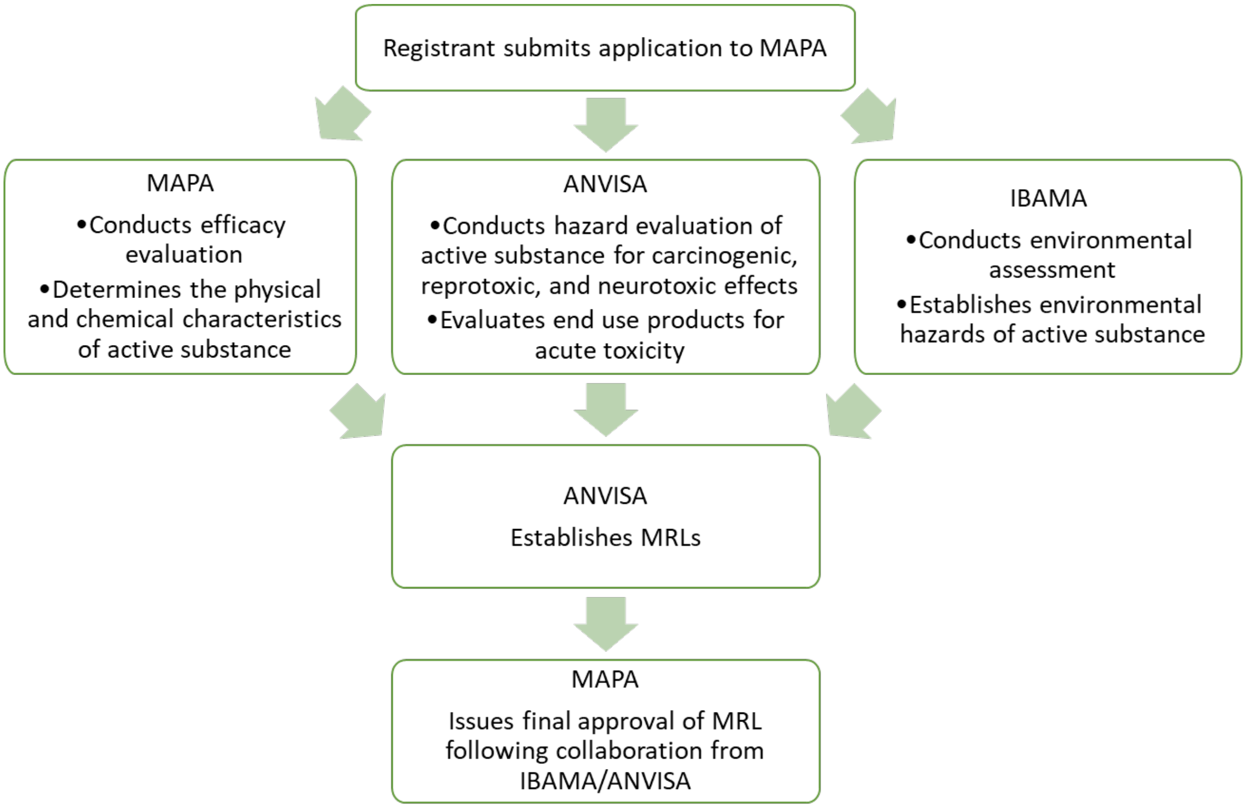
[343] Fang, "Brazilian Pesticide Regulation Overview," March 13, 2017; Government of Brazil, MAPA, "Brazil MRL Update," June 2016, 26.

[344] Fang, "Brazilian Pesticide Regulation Overview," March 13, 2017.

[345] Government of Brazil, MAPA, "Brazil MRL Update," June 2016, 30.

[346] Leonard Gianessi and Ashley Williams, "Fungicides Prevent Massive Losses of Soybeans in Brazil," November 2011 (CLA submission); Fang, "Brazilian Pesticide Regulation Overview," March 13, 2017.

Figure 3.3 Brazil's MRL-setting process



Source: USITC, based on Government of Brazil, MAPA, "Brazil MRL Update," 2016, 29–34; USDA, FAS, *Brazil: Food and Agricultural Import Regulations and Standards Report 2018*, March 11, 2019.

Securing an MRL: After a pesticide has been registered for use in Brazil, an interested party (which is usually the original registration applicant) can apply for an MRL for a pesticide/crop combination. As noted above, MRL policy in Brazil is governed under the 1989 Law 7802.[347] The principal agency responsible for setting MRLs in Brazil is ANVISA.[348] ANVISA also works in conjunction with MAPA, which registers pesticides for use in the Brazilian market.[349] Finally, IBAMA conducts the environmental assessments in the setting of MRLs.[350] Four crop trials for residue data must be conducted in order to provide the appropriate level of scientific data to establish the human health and environmental impact

[347] Government of Brazil, "Act No. 7.802 concerning research, production, labelling, packaging, exploitation, classification, use, etc. of pesticides," 1989.
[348] Government of Brazil, ANVISA, "Pesticides" (accessed January 16, 2020); BCI, "Brazil Pesticide MRLs Market Information Report," July 2018.
[349] Government of Brazil, ANVISA, "Pesticides" (accessed January 16, 2020); BCI, "Brazil Pesticide MRLs Market Information Report," July 2018.
[350] Government of Brazil, ANVISA, "Pesticides" (accessed January 16, 2020); BCI, "Brazil Pesticide MRLs Market Information Report," July 2018.

of the proposed MRL, though industry representatives say the number of required crop trials may rise to eight in the future.[351]

Import tolerances: Industry representatives report that in practice, Brazil does not have a system to request import tolerances.[352] Despite this reported gap, imports of agricultural commodities to Brazil may not be significantly impacted because Brazil usually sets import tolerances to Codex MRLs when there are relevant Codex MRLs and no Brazilian MRLs.[353] Additionally, industry representatives also report that Brazil will often unofficially accept an exporting market's MRL in the event that neither Brazil nor Codex has an MRL for that pesticide/crop combination.[354]

Default MRLs: In instances where Brazil has not established its own national MRL, Brazil will usually default to Codex MRLs.[355] However, there is uncertainty whether this applies to pesticides that have not yet been registered for domestic use.[356] When there is no applicable Codex MRL for a pesticide/crop combination, Brazil does not have a policy of setting a numerical default MRL. Consequently, in the absence of a national or Codex MRL, the MRL level may effectively be zero.[357]

Enforcement

Enforcement and monitoring of Brazilian MRLs falls under the Secretariat of Agricultural Protection (SDA),[358] which is tasked with preparing and executing Brazil's *National Plan for the Control of Residues and Contaminants*.[359] Testing is carried out by a variety of agencies and organizations, principally the National Agricultural and Livestock Laboratories, as well as by accredited public and private laboratories.[360] The level of testing for imported agricultural products is conducted in accordance with a

[351] This development, if it occurs, would be in line with several other countries that have recently decided to increase the number of trials required to establish that the appropriate residue data has been collected prior to setting an import tolerance. Further information on these developments can be seen in section "Divergence in Testing and Analysis" in chapter 4. Industry representative, interview by USITC staff, December 12, 2019.
[352] USHIPPC, written submission to USITC, December 10, 2019, 8; industry representative, interview by USITC staff, March 5, 2020.
[353] Government of Brazil, MAPA, "Brazil MRL Update," June 2016, 36.
[354] Industry representatives, interview by USITC staff, March 5, 2020.
[355] In some instances, pesticides for which Codex has established MRLs are banned for use in Brazil; in those cases, Brazil will not accept Codex MRLs for those active substances. This coincides with the cutoff principle set out in the original 1989 legislation for the legal use of pesticides and subsequent MRLs in Brazil, noted by MAPA. A list of banned active substances can be viewed at Government of Brazil, ANVISA, Regularização de Produtos—Agrotóxicos (Regulation of Products—Pesticides) (accessed February 18, 2020). For several of these active substances, Codex MRLs exist (for example, heptachlor and prochloraz each have multiple Codex MRLs, but are banned for use in Brazil and no Brazilian MRLs are available for them). Codex Alimentarius, "Pesticide Index," (accessed March 7, 2020). Government of Brazil, MAPA, "Brazil MRL Update," June 2016, 31; Gonzales, "Brazil's Fundamental Pesticide Law Under Attack," February 20, 2018.
[356] It is uncertain whether Brazil's default policy of using Codex MRLs only occurs for pesticides which have already been registered for use in Brazil, or all pesticides. According to one industry representative: "Brazil does not recognize Codex MRLs for pesticides which have not been registered in Brazil." USW, "Comments Regarding Foreign Trade Barriers to U.S. Exports for 2019 Reporting USTR-2018-0029," October 30, 2018, 5.
[357] BCI, "Brazil Pesticide MRLs Market Information Report," July 2018.
[358] BCI, "Brazil Pesticide MRLs Market Information Report," July 2018.
[359] BCI, "Brazil Pesticide MRLs Market Information Report," July 2018.
[360] BCI, "Brazil Pesticide MRLs Market Information Report," July 2018.

variety of factors; testing may occur randomly, may be based on whether previous violations had been identified, or may vary if the product represents an important part of the Brazilian diet.[361] In instances where a violation is identified, the SDA conducts additional tests of subsequent batches from that producer.[362]

Canada

Canada is the United States' largest agricultural export destination, with an average of $22.16 billion in annual exports during 2016–19. Sixty-eight percent of these exports were of edible crop and crop-based products. Among these exports, the biggest product group is pasta, cereals, and other bakery goods ($2.15 billion), closely followed by fresh, chilled, or frozen vegetables ($1.88 billion) and certain edible preparations ($1.58 billion). Among animal and inedible products, animal feeds ($1.51 billion) accounted for the largest exports.[363]

Canada's MRL system has operated in its current framework for 14 years and is characterized by extensive collaboration with the United States due to long-standing trade ties.[364] Industry representatives have commented positively on the straightforward nature of Canada's MRL-setting process.[365] One industry source reports that this is a result of a series of regulatory reforms which allowed for a faster approval process to establish MRLs in Canada, with a subsequent increase in the number of MRLs.[366] In addition, industry representatives have praised Canada's default MRL, which is 0.1 ppm, as facilitating agricultural trade flows with Canada.[367] In comparison, most other markets have a numerical default of 0.01 ppm, or do not set a default level which effectively prohibits imports with residues of the particular pesticide (table 3.1).

Active Substance Registration and MRL Regulations and Processes

Registering a pesticide: Canada requires that a pesticide be registered and approved for use within the country before establishing an MRL. The Pest Management Regulatory Agency (PMRA), a division of the Canadian health ministry (Health Canada), is responsible for the registration of pesticides. The PMRA requires that health and environmental trials be conducted before pesticide registration takes place, as well as a demonstration of the pesticide's value (which in other markets is referred to as an efficacy test). Required testing includes environmental impact and toxicity testing, as well as a health evaluation of the product. In registering a product, Canadian regulators may consult with U.S. and European regulators to determine if other evaluations reached the same conclusions.[368]

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[361] BCI, "Brazil Pesticide MRLs Market Information Report," July 2018.
[362] BCI, "Brazil Pesticide MRLs Market Information Report," July 2018.
[363] USITC DataWeb/USDOC (accessed January 24, 2020). Please see figure 3.1 for further information.
[364] Government of Canada, written submission to USITC, December 13, 2019, 4.
[365] Industry representative, interview by USITC staff, November 29, 2019; Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 4.
[366] Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 4.
[367] APC, written submission to USITC, December 6, 2019; CFFA, written submission to USITC, December 12, 2019, 3; CCB, written submission to USITC, December 11, 2019, 6; industry representative, interview by USITC staff, November 29, 2019.
[368] Government of Canada, Health Canada, "Pesticide Registration Process," June 3, 2004.

Securing an MRL: After a pesticide has been registered for use in Canada, an interested party (which is usually the original registration applicant) can apply for an MRL for a pesticide/crop combination. This process is regulated in Canada under the *Pest Control Products Act* (PCPA). The act was approved in December 2002 and implemented in 2006. The act has been amended several times to implement international and bilateral trade agreements.[369]

The authority to establish MRLs in Canada, as well as to enforce them, falls under the purview of the PMRA.[370] When an MRL is determined, it is published in a public MRL database.[371] In submitting an application to receive an MRL for a pesticide/crop combination, a registrant is required to submit a cover letter that includes a brief description of the submission; statement of product specification; authorization to share data as necessary; scientific data supporting the safety and effectiveness of the product; foreign reviews of submitted data; and any requests for waivers.[372]

Like many other markets discussed in this chapter, Canadian MRLs are also subject to periodic review. In Canada, MRLs are reviewed in a 15-year cycle (though MRLs may be revoked in the event of a public health concern before the 15-year review date). In addition to health reviews, Canada's PMRA also considers Codex MRLs as well as U.S. MRLs in determining the designation or revocation of its own MRLs for agricultural products.[373] In several instances when a U.S. MRL has been revoked, the PMRA has also proposed revocation of that MRL in Canada's market.[374]

Import tolerance: Exporters and pesticide manufacturers can apply for an import tolerance in Canada if there is no MRL for the specific pesticide/crop combination or if the existing MRL is lower than that of the exporting market. Applications for a new import tolerance in Canada typically take 15–23 months from submission of the import tolerance application to the final decision, according to APEC.[375] Import tolerance applications require very similar information to that required to establish domestic MRLs and follow similar processes.[376]

The PMRA has regularly encouraged pre-submission consultations between registrants and the PMRA before the registrant submits an import tolerance application. Pre-submission may be particularly useful

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[369] The PCPA was amended to allow Canada to implement the World Trade Organization (WTO) Trade Facilitation Agreement as well as the Canada-EU Comprehensive Economic Trade Agreement (CETA). The PCPA has also been amended for labelling purposes, for agricultural products not intended for domestic market consumption, and for protection of proprietary test data. Government of Canada, Health Canada, "Pest Control Products (Pesticides) Acts and Regulations" (accessed November 13, 2019).
[370] Government of Canada, Health Canada, "Pest Control Products (Pesticides) Acts and Regulations," updated July 3, 2019. USDA, FAS, *Canada: Pesticides and MRLs in Canada*, August 7, 2015, 2-4.
[371] The Canadian MRL database can be accessed here: https://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php
[372] The MRL application is governed by the *Pest Management Regulatory Agency's Regulatory Directive 2003-01 for Organizing and Formatting a Complete Submission for Pest Control Products*. Government of Canada, PMRA, "Residue Chemistry Guidelines," 2003.
[373] While the U.S. and Canadian MRLs are often characterized as harmonized to a great extent, some Canadian MRLs are higher or lower than U.S. MRLs, and some MRLs for each market are missing. Government of Canada, Health Canada, "Proposed Maximum Residue Limit PMRL2018-44," 2018.
[374] Government of Canada, Health Canada, "Proposed Maximum Residue Limit PMRL2018-44," 2018.
[375] APEC, "APEC Compendium of Government Administration in Setting Maximum Residue Limits for Pesticides," June 2019, 14–17.
[376] Health Canada and U.S. EPA, "NAFTA Guidance Document on Data Requirements for Tolerances in Imported Commodities in the United States and Canada," December 2005, 3.

if the registrant has limited experience in the system, the active substance may qualify as low risk, or the active substances are under re-evaluation.[377] In their evaluation, Canada may consult Codex MRLs, in addition to the MRLs of other countries.[378]

Default MRLs: Unlike most other major markets, default MRLs in Canada are set at 0.1 ppm, which is considered to be less restrictive than the default level of 0.01 ppm that is established by several other major U.S. export markets.[379] Several industry representatives have indicated that Canada's default level of 0.1 ppm helps to facilitate trade.[380]

Enforcement

The PMRA imposes administrative monetary penalties under the *Agriculture and Agri-Food Administrative Monetary Penalties Act*, which acts as a mechanism to enforce compliance with the PCPA. MRL enforcement is shared between the PMRA and Canadian Food Inspection Agency, which is responsible for surveillance of MRLs in food products manufactured domestically in Canada and imported from abroad.[381]

In instances of MRL noncompliance, fines and additional shipment testing can result.[382] In addition to monetary fines for noncompliance, any shipment determined to have violated MRLs can be detained and destroyed under order of the PMRA. The recipient of the notice of noncompliance is responsible for the cost of disposal for shipments violating the MRLs.[383] In the event of an MRL violation, the next

15 shipments of that product from that source are either subject to intensified testing by the Canadian health ministry or must obtain pre-certification from a recognized laboratory that meets Canadian regulatory standards.[384]

[377] Consultations are required for microbial applications and joint review requests. Government of Canada, "Pre-submission Consultations," 2016.
[378] USDA, FAS, *Canada: Pesticides and MRLs in Canada*, August 7, 2015, 2–4.
[379] Industry representative, telephone interview by USITC staff, October 24, 2019; CFFA, written submission to USITC, December 12, 2019, 3.
[380] NPC, written submission to USITC, December 10, 2019, 11; CCB, written submission to USITC, December 11, 2019, 6; CFFA, written submission to USITC, December 12, 2019, 3; ABC, written submission to USITC, December 13, 2019, 6; APC, written submission to USITC, December 6, 2019. The Canadian MRL database can be accessed at Government of Canada, Health Canada, "Maximum Residue Limits for Pesticides database" (accessed November 13, 2019). NHC, "Export Manual: Canada" (accessed November 13, 2019).
[381] Government of Canada, written submission to USITC, December 13, 2019, 2.
[382] Fines are divided between nonbusiness and business classifications and vary from $CAN 500 ($354) to $CAN 1,300 ($920) for nonbusinesses and $CAN 1,300 ($920) to $CAN 10,000 ($7,079) for businesses. The gravity of the violation is determined with consideration to whether there are prior violation/offenses, the degree of intent or negligence, and the level of harm that could have been caused by the violation. Government of Canada, Health Canada, "Administrative Monetary Penalties," 2019.
[383] Government of Canada, Health Canada, "Administrative Monetary Penalties," 2019.
[384] NHC, "Export Manual: Canada" (accessed November 13, 2019).

Trade Facilitative Practices: U.S. and Canadian Cooperation on MRLs

As noted above, Canada and the United States collaborate on several components of the MRL regulatory process, thereby facilitating trade in agricultural goods between these two markets. For example, the two countries maintain a harmonized crop grouping system, which ensures that farmers and pesticide producers operate from a similar position in the Canadian and U.S. markets with respect to crop groupings and subsequent testing needs.[385] (For further information on crop grouping issues, see the section "Minor Crops and Crop Groupings" of chapter 4 of this report.) Canada and the United States also allow for some zonal overlap in crop trials (if a crop trial conducted in a zone in Canada has a sufficiently similar geographical makeup to one in the United States, it will be viewed as equivalent by both countries).[386] Additionally, Canada encourages applicants to consider the MRLs set by the United States (as well as Codex and Mexican MRLs) when proposing MRLs for the Canadian market.[387] On occasion, regulatory officials in either Canada or the United States may also consider renewal applications for MRLs earlier than their own market's expiration date in order to align with renewal testing requirements in the other market.[388]

In addition, Canada and the United States have also worked together with other APEC member states to develop the *APEC Import MRL Guideline for Pesticides*, which was published in 2016 (more information on MRL efforts in APEC are presented in chapter 2 of this report).[389] The two countries also collaborate on pesticide regulations through the North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticides, as well as in Codex and the World Trade Organization (WTO).[390] This cross-market collaboration has been described as trade facilitative by multiple industry representatives: one noted that Canadian MRLs are "largely harmonized with U.S. MRLs . . . and allow trade without any issue."[391]

China

China is the United States' third-largest agricultural export destination, with an average of $17.18 billion in annual exports during 2016–19. Sixty-eight percent of U.S. agricultural exports to China are edible crops and crop-based products, led by oilseeds ($9.39 billion) and distantly followed by cereals ($904 million). Among animal and inedible products, hides, skins, and leather is the largest category ($903 million).[392]

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[385] Government of Canada, PMRA, *Residue Chemistry Guidelines*, Dir 98-02, June 1, 1998, 15-2; U.S. government official, interview by USITC staff, December 4, 2019.
[386] Government of Canada, PMRA, *Residue Chemistry Guidelines*, Dir 98-02, June 1, 1998, 2.
[387] Government of Canada, PMRA, *Residue Chemistry Guidelines*, Dir 98-02, June 1, 1998, 11-3.
[388] U.S. government official, interview by USITC staff, December 4, 2019.
[389] APEC, "Import MRL Guideline for Pesticides," July 2016.
[390] Government of Canada, written submission to USITC, December 13, 2019, 1.
[391] CFFA, written submission to USITC, December 12, 2019, 3. This view is not universally held, however; the U.S. blueberry industry noted, for example, that the Canadian MRL for captan on blueberries (5 ppm) is not harmonized with the less restrictive U.S. and Codex MRLs (20 ppm). This reportedly limits the ability of U.S. berry growers to manage gray mold for blueberries exported to Canada. NABC, written submission to USITC, December 9, 2019, 2.
[392] USITC DataWeb/USDOC (accessed January 24, 2020). Please see figure 3.1 for further information.

China's current MRL system is relatively new, with substantial changes made to its regulatory framework in 2017. Large tranches of new MRLs have been established by the relevant Chinese regulatory agencies in the past three years, and the Chinese government has indicated an interest in setting up to 10,000 MRLs by the end of 2020.[393] Industry representatives have noted concerns about the perceived opacity of the regulatory approval process for MRLs in China and about requirements to conduct pesticide residue trials in China rather than in the producing market.[394] Industry representatives also note that it is unclear to what extent China defers to Codex MRLs in the absence of existing Chinese MRLs.[395] Multiple industry representatives have also noted that it is not possible to secure an import tolerance in China.[396]

Active Substance Registration and MRL Regulations and Processes

Registering a pesticide: China requires that a pesticide be registered and approved for use within the country before establishing an MRL. The registration of pesticides in China falls under the Ministry of Agriculture and Rural Affairs, according to the *GB 2763-2016 National Food Safety Standard—Maximum Residue Limits for Pesticide in Food*. This regulation sets out the rules for the registration, study, production, and marketing of pesticides in China. Many of the registration requirements mirror other major markets: registrants must submit residue data, toxicity for humans (including carcinogenicity), environmental impact, and efficacy trials.[397] However, an aspect unique to China is a requirement that the regulatory studies conducted within China should be approved by the Ministry of Agriculture or provincial agricultural departments before testing in China, requiring collaboration between government agencies and manufacturers before the application is even submitted.[398]

Securing an MRL: After a pesticide has been registered for use in China, an interested party (which is usually the original registration applicant) can apply for an MRL for a pesticide/crop combination. The main agency responsible for the setting and enforcement of MRLs in China is the Institute for the Control of Agrochemicals, Ministry of Agriculture (ICAMA).[399] Each of the pesticide risk assessments that

[393] Fang, "Pesticide Dietary/Residue Risk Assessment and MRL Development in China," September 11, 2019.
[394] According to the Almond Board of California, "China has its own national MRL list, and it does not defer to Codex or other markets," while the Cranberry Institute indicated that "in practice, it appears that China will use a Codex MRL if it is established for a compound it is reviewing." ABC, written submission to USITC, December 13, 2019, 7; CI, written submission to USITC, December 11, 2019, 8. Other industry representatives have indicated they believe China defers to Codex MRLs in many instances. Industry representative, interview by USITC staff, November 26, 2019; industry representative, interview by USITC staff, December 12, 2019; industry representative, interview by USITC staff, March 5, 2020.
[395] Industry representative, interview by USITC staff, November 21, 2020; industry representative, interview by USITC staff, March 5, 2020.
[396] Industry representative, interview by USITC staff, December 12, 2019; industry representative, interview by USITC staff, February 13, 2020; industry representative, interview by USITC staff, March 5, 2020; APC, written submission to USITC, December 6, 2019, 4; Cranberry Institute, written submission to USITC, December 11, 2019, 8.
[397] Efficacy tests in China are defined under a broader "substitutability and benefit" analysis that explores the impact of a new pesticide in the context of substitutable products. Fang, "Overview of China's New Pesticide Regulations," October 9, 2019.
[398] Fang, "Overview of China's New Pesticide Regulations," October 9, 2019.
[399] Prior to the 2009 Food Sanitation Act, MRLs in China were developed by the health ministry. Fang, "Pesticide Dietary/Residue Risk Assessment and MRL Development in China," September 11, 2019.

fall under the larger risk assessment for an MRL must contain four elements: hazard identification, hazard characterization, exposure assessment, and risk characterization (these elements are common for many MRL regulatory frameworks).[400] In setting MRLs, the ICAMA may look to Codex regulations, but it is not bound by them.[401] After an established MRL is set, it will remain valid for 15 years; temporary MRLs are set for 5 years.[402] A temporary MRL may be set for a pesticide when there are not yet sufficient dietary data, when testing methods are unavailable, or when the pesticide or its use on a specific crop is not yet registered in China and is for import inspection only.

Pesticide MRLs in China are governed by a series of regulations, principally standard *GB-2763-2016*, which has been updated several times.[403] In 2017, China added to its MRL regulatory framework with *NYT 3094-2017*, which adopted new Chinese MRLs and introduced three types of mandatory risk assessment reports for the overall assessment and designation of MRLs: a dietary/residue analysis of the pesticide/crop combination, a health analysis of the proposed MRL, and an environmental analysis.[404] Additional MRLs for more pesticides and crops were also added in 2018.[405] The most recent list of MRLs from China was published by China in August 2019, adding 2,967 and establishing a total of at least 7,000 MRLs for more than 450 pesticides and 250 foods.[406] These MRLs were implemented in February 2020.[407]

Import tolerances: Despite published measures regarding testing and data requirements for MRLs generally, several industry groups have indicated that no formal process is currently in place for potential registrants to obtain import tolerances for the Chinese market.[408] Multiple industry representatives noted specifically that it was not possible to secure an MRL in China solely through an import tolerance.[409] Firms' expectations for the publication of an import tolerance framework vary:

[400] In the dietary/residue risk assessment, there must also be a toxicological assessment, residue chemistry assessment, and a dietary intake assessment. Fang, "Pesticide Dietary/Residue Risk Assessment and MRL Development in China," September 11, 2019.
[401] In developing 10,000 MRLs by 2020, it is estimated that as many as 2,700 MRLs may be set from the Codex Alimentarius MRLs, assuming the risk assessment on Chinese dietary patterns and monitoring of residues meets regulatory thresholds. Fang, "Pesticide Dietary/Residue Risk Assessment and MRL Development in China," September 11, 2019.
[402] Fang, "Pesticide Dietary/Residue Risk Assessment and MRL Development in China," September 11, 2019.
[403] Under *GB 2763-2016*, there are 4,150 national MRLs covering 433 pesticides in 286 crops. Fang, "Pesticide Dietary/Residue Risk Assessment and MRL Development in China," September 11, 2019; BCI, "China Pesticide MRLs Market Information Report," July 2018.
[404] Fang, "Pesticide Dietary/Residue Risk Assessment and MRL Development in China," September 11, 2019.
[405] This was published under *GB 2763.1-2018.* USDA, FAS, *National Food Safety Standard Maximum Residue Limits for Pesticides in Foods: China-People's Republic of*, May 28, 2019.
[406] Government of China, *GB 2763-2019*, August 2019; USDA, FAS, *China-People's Republic of: National Food Safety Standard Maximum Residue Limits for Pesticides in Foods*, November 18, 2019, 2.
[407] Fang, "Pesticide Dietary/Residue Risk Assessment and MRL Development in China," September 11, 2019.
[408] CFFA, written submission to USITC, December 12, 2019, 5; APC, written submission to USITC, December 6, 2019, 4; Cranberry Institute, written submission to USITC, December 11, 2019, 8; ABC, written submission to USITC, December 13, 2019, 7; industry representative, interview by USITC staff, October 23, 2019; CCB, written submission to USITC, December 11, 2019, 5; industry representative, interview by USITC staff, November 26, 2019; industry representative, interview by USITC staff, March 5, 2020.
[409] Industry representative, interview by USITC staff, October 23, 2019; industry representative, interview by USITC staff, March 5, 2020; APC, written submission to USITC, December 6, 2019, 4; Cranberry Institute, written submission to USITC, December 11, 2019, 8.

some firms have noted that China is reportedly expected to release a process for import tolerance applications in the near future, potentially in 2020 or 2021, while others are uncertain of the timeline.[410] Regardless of when the process is in place, some suggest that it will take several years for import tolerances to be established. However, because China has occasionally expanded its MRLs to include Codex MRLs, firms continue to be able to offer agricultural goods in the Chinese market despite not being able to secure an MRL solely for an import tolerance.[411] Industry representatives also note that China will sometimes defer to the exporting market's MRL in the event that China or Codex does not have one (similar to Brazil), creating an informal import tolerance for exporting markets with their own relevant MRLs.[412]

Default MRLs: Reportedly, China does not have a default in the event that no MRL has yet been determined for a pesticide/crop combination. This means that instead of a numerical default MRL, China effectively would not allow any detectible level of that pesticide residue to remain on the specific crop in its market.[413] As a result, agricultural products treated with a pesticide without a relevant MRL would not be permitted to be imported into China. As noted above, however, industry representatives have indicated that in some instances, China may defer to an exporting market's MRL when no MRL exists.[414]

Enforcement

Enforcement of China's MRLs is governed by the General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ) and is conducted by the General Administration of Customs.[415] In instances where shipments are found to exceed China's MRLs, firms are usually subject to fines.[416] However, in instances of significant violation or multiple violations, regulators are authorized to revoke business licenses, order an importing business closed, or detain individuals.[417]

Updates to Testing Requirements

Industry representatives have noted concerns about planned updates to testing requirements for pesticides in China, which would require that data used in setting MRLs in China must be gathered in China.[418] While China provides an exemption for residue trials carried out in countries with bilateral mutual recognition agreements, it is not clear if any country currently meets those exemption

[410] ABC, written submission to USITC, December 13, 2019, 7; CI, written submission to USITC, December 11, 2019, 5–6; CFFA, written submission to USITC, December 12, 2019, 5; industry representative, interview by USITC staff, March 5, 2020; NPC, written submission to USITC, December 10, 9.
[411] NPC, written submission to USITC, December 13, 2019, 9; CCB, written submission to USITC, December 11, 2019, 5.
[412] Industry representative, interview by USITC staff, March 5, 2020.
[413] APC, written submission to USITC, December 6, 2019, 4; ABC, written submission to USITC, December 13, 2019, 7.
[414] Industry representative, interview by USITC staff, March 5, 2020.
[415] Industry representative, interview by USITC staff, December 13, 2019.
[416] Fang, "Pesticide Dietary/Residue Risk Assessment and MRL Development in China," September 11, 2019.
[417] BCI, "China Pesticide MRLs Market Information Report," July 2018.
[418] Industry representative, interview by USITC staff, December 12, 2019; industry representative, interview by USITC staff, December 18, 2019.

requirements.[419] An exemption would allow registrants to submit data from the producing market, which is a standard practice in many other markets.[420]

One industry representative noted that they would not be able submit applications for new MRLs in China due to this new requirement, mainly because duplicating testing and trials would be prohibitively expensive and time consuming.[421] Others also note that China currently does not appear to have the capacity to conduct the necessary testing for all the pesticide/crop combinations for the Chinese market.[422]

European Union

The European Union (EU) is the United States' fourth-largest agricultural export destination, with an average of $13.48 billion in annual exports during 2016–19. Seventy-three percent of these exports were of edible crops and crop-based products. The biggest export groups are edible nuts ($2.96 billion) and oilseeds ($2.18 billion), followed by certain edible preparations ($802 million). Among animal and inedible products, fresh and frozen fish ($766 million) and animal feeds ($749 million) accounted for the largest exports.[423] In addition to importing approximately 10 percent of U.S. agricultural exports, the EU is an especially important market for many exporters in different regions of the world, particularly those of specialty crops in Africa and in Central and South America.

The EU has maintained a harmonized MRL system throughout the European single market since 2008, and EU MRLs apply to over 400 pesticides.[424] Previously, individual European member states set their own MRLs, which had created a patchwork of MRL regulations across Europe with uneven harmonization among member states.[425] While nearly all pesticide/crop MRLs are now harmonized across the EU, MRLs for fish and products used exclusively for animal feed are not.[426]

The EU MRL system governs one of the world's largest global consumer (and producer) markets for agricultural products and is currently in the midst of a large-scale review of existing MRLs.[427] Given the large size of the EU market, EU MRLs can have a substantial impact on agricultural production and trade globally. Due to the difficulty of producing agricultural crops to meet different pesticide residue limits in different markets, EU MRLs affect production decisions of exporting producers for whom the EU is one

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419 Industry representative, interview by USITC staff, December 12, 2019.
420 Industry representative, interview by USITC staff, December 12, 2019.
421 Industry representative, interview by USITC staff, December 12, 2019.
422 Industry representative, interview by USITC staff, December 18, 2019.
423 USITC DataWeb/USDOC (accessed January 24, 2020). Please see figure 3.1 for further information.
424 European Commission, "EU legislation on MRLs" (accessed March 7, 2020).
425 For example, under the previous member-state system, the MRL for prochloraz used in avocados was set at 5ppm in Belgium, Germany, the United Kingdom, and Portugal; 0.3ppm in France; and 0.05ppm in the Netherlands, Italy, Spain, Switzerland, and Greece. The current EU-wide MRL for prochloraz in avocados is 5 ppm. Scheepers, Jooste, and Alemu, "Quantifying the Impact of Phytosanitary Standards," 2007; Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 3, 12.
426 European Commission, written submission to USITC, December 13, 2019, 5.
427 European Commission, "Renewal of Approval" (accessed February 20, 2020); USITC DataWeb/USDOC (accessed January 24, 2020).

of several large export markets.[428] See chapter 5 for a case study discussion on the effects of segregating banana crops and shipments to the EU, United States, and Japan, to account for different MRLs.

EU MRLs can be particularly significant for producing countries that are highly dependent on the EU market for their exports.[429] EU MRLs are also important because certain countries formally defer to EU MRLs in the absence of their own domestic MRLs.[430] Industry representatives have also noted that some countries may informally follow or take into account EU decisions when establishing their own MRLs. The deferral to EU MRLs amplifies the importance of EU pesticide and MRL policy decisions in a "ripple effect."[431]

Several components of the EU MRL-setting system are different from those in many other countries. A 2018 European Parliament report identified the European MRL process as "one of the most stringent in the world," and some industry representatives suggest the process is "more complex than anywhere else."[432] The EU MRL system includes separate hazard-based cutoff criteria in its approach to identifying the impact of an active substance on human and ecological health and approving (registering) that active substance. According to EU regulations, the EU will not approve the active substance if it triggers the cutoff criteria.[433] The EU's hazard-based approach to assessment of pesticide use in agricultural production is cited by multiple industry representatives as creating uncertainty and potentially increasing costs for registrants and growers.[434] Another notable feature of the EU's system is that the final step in the approval of active substances and in setting MRLs involves voting by bodies made up of member states' representatives, including the technical experts on the European Commission's Standing Committee on Plants, Animals, Food, and Feed (PAFF). The European Parliament also has a role in approving the establishment of MRLs.[435] In many other markets, a final decision is made by a

[428] See chapters 4 and 5 for more information.
[429] Industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019; industry representative, interview by USITC staff, San Jose, Costa Rica, December 5, 2019; industry representative, interview by USITC staff, November 26, 2019; Costa Rican government official, interview by USITC staff, San Jose, Costa Rica, December 6, 2019; Peruvian government representative, email to USITC staff, December 27, 2019.
[430] Prologica has identified Costa Rica, Egypt, Switzerland, and Uruguay as countries which defer to EU MRLs in some or all instances.
[431] U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 9; industry representative, interview by USITC staff, January 8, 2020; industry representative, interview by USITC staff, January 10, 2020; industry representative, interview by USITC staff, February 19, 2020.
[432] EP, *Report on the Union's Authorisation Procedure for Pesticides*, December 18, 2018, 7, 17; industry representative, interview by USITC staff, October 3, 2019. One EU official noted in a committee hearing to the European Parliament's PEST Committee that "To help achieve these goals [of food safety, protecting citizens and animal health], the European Union has the most stringent regulatory system of pesticides in the world." European Parliament, hearing transcript, June 19, 2018, 3 (testimony of Vytenis Povilas Andriukaitis, Member of the Commission).
[433] European Commission, "Regulation (EC) 1107/2009," Annex II, 2009.
[434] ABC, written submission to USITC, December 13, 2019, 4; industry representative, interview by USITC staff, January 8, 2020; industry representative, interview by USITC staff, February 13, 2020; industry representatives, interview by USITC staff, March 5, 2020.
[435] See below for more details on EU procedures for approving active substances and setting MRLs, including the role of the European Parliament. Several industry representatives noted their understanding that the role of the European Parliament in its votes on proposed MRLs and active substance designations by the European Commission, for example, is binding for the setting of MRLs but advisory in the approval of active substances.

government regulatory body, and elected representatives have no active role in the approval of active substances or MRLs. Further information on this topic is presented in chapter 4.

Active Substance Registration and MRL Regulations and Processes

This section describes the regulatory process to secure an MRL in the EU, beginning with active substance registration, establishing an MRL or import tolerance, and applying for renewal of an existing MRL. It also includes an explanation of MRL enforcement measures in the EU and concludes with a brief discussion of the implementation of two regulations related to the MRL enforcement and the process for setting and enforcing MRLs.

In order to create consistency across the single market, two regulations, Regulation (EC) No 396/2005 and Regulation (EC) No 1107/2009, principally govern the EU's harmonized MRL system, as well as the structure of the approval of pesticides for EU food consumption.[436] Regulation (EC) No 396/2005 provides the framework for the approval of MRLs on food and feed, while Regulation (EC) No 1107/2009 ("Plant Protection Product Regulation") lays out the requirements for the approval of active substances and the authorization of pesticides for use.[437] These regulations also set out the conditions for the renewal of MRLs, the conditions for member states to grant emergency authorizations for the use of pesticides and other member state powers, how to apply for changes to MRLs, and regulations for pesticide/crop combinations for which MRLs do not currently exist.[438] Additionally, EU Directive 2009/128/EC sets EU-wide rules for the sustainable use of pesticides to reduce public health and environmental risks.[439]

In the EU, the process to apply for the approval for domestic use of an active substance in a pesticide is different from the process to authorize a specific pesticide for use in each member state.[440] EU-wide regulatory authorities have the sole authority to approve an active substance (for example, glyphosate) for use across the EU.[441] However, once an active substance is approved by the EU, each member state must then separately authorize the use of the pesticide containing the approved active substance (e.g.,

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Industry representatives, interview by USITC staff, February 13, 2020; ASA and USSEC, written submission to USITC, December 13, 2019, 5; U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 23; industry representatives, interview by USITC staff, March 5, 2020; industry representative, interview by USITC staff, March 10, 2020.

[436] These EU regulations are binding legislative acts that are applied in their entirety across the EU. Regulations adopted after December 1, 2009, when the Treaty of Lisbon entered into force, include EU in their titles, while earlier regulations (such as Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005) are denoted by (EC). European Commission, Treaty on the Functioning of the European Union, Chapter 2, Section 1, articles 288–296, 2012.

[437] European Commission, written submission to USITC, December 13, 2019, 7.

[438] In addition to setting emergency authorizations for the use of pesticides, the regulations authorize member states to set residue levels for active substances in post-harvest treatment for a fumigant in their own territory, provided the food is not intended for immediate consumption, with consumer controls, and with member states and the EC informed. The member states are also required to collect and submit annual data on retailers, traders, and producers that exceed MRLs (which is submitted to the European Food Safety Authority). Regulation (EC) No 1107/2009, articles 18, 26, 30, and 31.

[439] European Commission, written submission to USITC, December 13, 2019, 8.

[440] European Commission, written answers to PEST Committee preparatory questions for the June 19, 2018 meeting, 21, 24.

[441] European Commission, written submission to USITC, December 13, 2019, 7.

while the EU approves glyphosate, member states would separately authorize the use of Roundup™, a pesticide containing glyphosate). Only EU member states have the authority to authorize the domestic use of a pesticide, and they cannot authorize the use of a pesticide if the active substance has not been approved (registered) by the EU.[442]

Registering an active substance/pesticide: Before securing an MRL, the active substance in the relevant pesticide must be approved for use in the EU.[443] According to the European Commission, this approval process takes approximately two and a half to three and a half years and requires several steps.[444] First, an interested party—this is generally the chemical company (registrant), but it could also be an importer or an agricultural producer—must submit an application for approval of a new active substance to an EU member state.[445] For a new approval, an applicant selects the member state that will evaluate its dossier (application) and submits the dossier and its evaluation to the European Food Safety Authority (EFSA).[446] Next, the selected member state, known as the Rapporteur Member State (RMS), is responsible for interacting with the applicant and ensuring the completeness of the dossier.[447] The RMS also represents the applicant's dossier before EU-level regulatory authorities.[448] This initial step is meant to take approximately one year in the total 2.5–3.5 year process, but often takes longer—reportedly 20 months on average—as this is the main period when applicants can submit additional data that have been requested by the RMS.[449]

Following the conclusion of the RMS evaluation, the RMS will send its report to the European Commission and EFSA. EFSA, which is composed of scientific experts appointed by member states, carries out the risk assessment, conducts a review of the active substance application, and submits its risk assessment to the European Commission.[450] The European Commission reports that this process

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[442] European Commission, written answers to PEST Committee preparatory questions for the June 19, 2018 meeting 24; European Commission, "Communication from the Commission on the European Citizens' Initiative 'Ban Glyphosate and Protect People and the Environment from Toxic Pesticides,'" C (2017) 8414, December 12, 2017, 3–4.
[443] European Commission, Regulation (EC) No 1107/2009.
[444] European Commission, "Approval of Active Substances" (accessed November 8, 2019).
[445] Given the nature of the European single market, an interested party only has to submit one application to one EU member state. If approved, the active substance would be applied to the entire European single market. European Commission, "Regulation (EC) 396/2005," 2005. Industry representatives have cited several factors in determining which EU member state to select as the RMS for a pesticide application. One registrant indicated that the regulatory capacity of the EU member state to process a highly complex active substance registration application was an important factor in the member state selection process. France, the Netherlands, and Austria (as well as the United Kingdom before its withdrawal from the European Union in 2019) received the most active substance applications from 2011 to 2018. Industry representative, interview by USITC staff, October 23, 2019; Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 213.
[446] The European Food Safety Authority (EFSA) is a quasi-independent government agency under the European Commission's Directorate General for Health and Food Safety. In addition to its mandate to process and analyze MRL requests, EFSA also compiles an annual public report on pesticide residues for the EC. EFSA, "About EFSA," (accessed February 20, 2020).
[447] European Commission, "Regulation (EC) 396/2005," 2005.
[448] European Commission, "Approval of Active Substances" (accessed November 8, 2019).
[449] Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 123.
[450] European Commission, "Technical Guidelines," SANTE/2015/10595 Rev. 5.4, November 27, 2018, 6.

typically takes between three and six months and is followed by a one-month period to allow the applicant to submit additional data.[451]

Upon completion of the risk assessment by EFSA, the process moves to the European Commission and the PAFF. First, the European Commission drafts a proposal on the approval or non-approval of the substance, which is based on EFSA's report. This phase takes approximately three months.[452] The European Commission's draft proposal then moves to the PAFF, which is composed of scientific experts from EU member states and is chaired by the European Commission. If the PAFF Committee approves the draft proposal, the European Commission will adopt the proposal as a regulation and the active substance will be approved for use in the EU.[453] The European Parliament can also cast a vote on any proposed approval or non-approval of an active substance, but that vote is regarded as non-binding or advisory.[454]

The European Union's evaluation of an active substance application requires significant analysis of the substance's hazard and risk potential for human health and the environment, and efficacy data. Under Regulation (EC) 1107/2009, EFSA is required to determine whether any active substance can cause substantial health impacts. This determination is based on a number of factors, and includes the cutoff criteria. If an active substance meets these select criteria, the regulations require the non-approval of the substance, except in the limited instances noted below. This effectively cuts the substance off from legal use throughout the European Union, curtailing producers' ability to use it on crops in the European single market.[455] These cutoff criteria include substances determined to be:

- carcinogenic, mutagenic, and reprotoxic (collectively referred to as CMR) categories 1A or 1B according to the European Regulation on Classification, Labelling, and Packaging of chemical substances and mixtures;[456]

[451] European Commission, "Technical Guidelines," SANTE/2015/10595 Rev. 5.4, November 27, 2018, 25.
[452] EFSA, "Pesticides" (accessed November 6, 2019).
[453] European Commission, "Approval of Active Substances" (accessed January 21, 2020).
[454] In the EU, active substances are approved in the form of an "implementing act" or "implementing regulation." In the EU, this form of regulation allows the European Parliament an opportunity to review a proposed implementing regulation but not to veto it. European Commission, Commission Implementing Regulation (EU) …/... concerning the non-renewal of approval of the active substance thiacloprid, January 13, 2020. See Europa/Eur-Lex Home accessible at: https://eur-lex.europa.eu/summary/glossary/implementing_acts.html; see also industry representative, interview by USITC staff, February 13, 2020; ASA and USSEC, written submission to USITC, December 13, 2019, 5; U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 23; industry representative, interview by USITC staff, March 10, 2020.
[455] European Commission, Regulation (EC) No 1107/2009, Annex II, 2009.
[456] Carcinogens are defined as "substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence." Mutagens are "substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce heritable genetic defects or increase their incidence." Finally, reprotoxins are defined as, "substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may produce or increase the incidence of non-heritable adverse effects in the progeny and/or an impairment of male or female reproductive functions or capacity." Government of France, "Carcinogenic, Mutagenic and Reprotoxic Substances," September 22, 2016. Information on the EU CLP regulation can be found in European Commission, "Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008," December 16, 2008.

- endocrine disruptors;[457]
- persistent, bioaccumulative, and toxic (PBT); or
- very persistent and very bioaccumulative (vPvB).[458]

This portion of the process is often referred to as part of the EU's "hazard-based" approach to the approval of active substances and the subsequent setting of MRLs. In practice, because there are exceptions (referred to as "derogations") to this approach, risk-based assessments are often also conducted even if the active substance is determined to meet the cutoff criteria. However, in instances where an active substance triggers the cutoff criteria, the EU allows for the non-approval of an active substance regardless of the risk of exposure; reportedly, MRLs and import tolerances for pesticides containing the active substance will be reduced to the default.[459] While a number of substances submitted for approval have been classified as falling within the cutoff categories and non-approved for use, the European Commission maintains that no substance has been non-approved based solely on the human health cutoff criteria, as risk-based assessments also contributed to these non-approvals.[460]

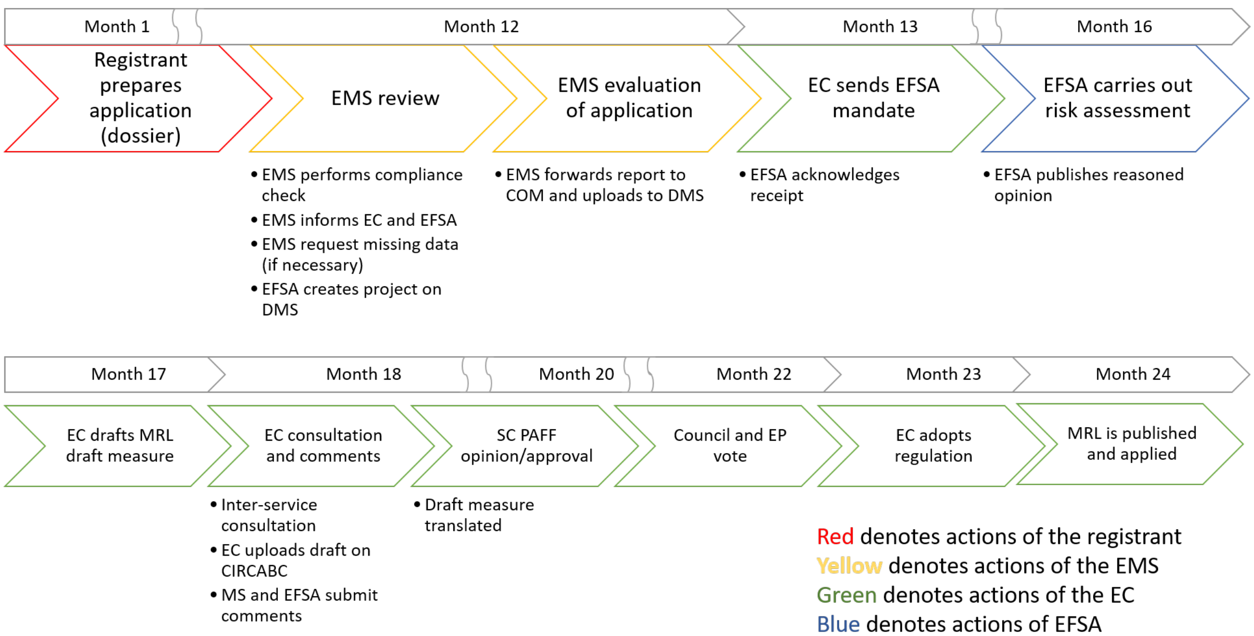
After an active substance has been approved by EU authorities, in order for pesticides containing the active substance to be used in an EU member state, it must be individually authorized by the member state.[461] If a pesticide is not approved for domestic use by a member state, growers in that member state are not legally permitted to use that pesticide. While these non-approvals do not impact the ability to export treated crops with a non-approved pesticide to an EU country (provided it has EU MRLs), this would limit the ability to market that pesticide for use in the EU.

Securing an MRL: After an active substance has been registered for use in the EU, an interested party (which is usually the original registration applicant) can apply for an MRL for a pesticide/crop combination (figure 3.4) with respect to pesticides that use that active ingredient. The approval process to secure an MRL for the EU market is similar to the approval process for active substance registration and typically takes about two years.[462] In general, the MRL is set at the same time as the approval or renewal of the active substance, so the processes tend to be concurrent.[463] An applicant is required to submit an application to the RMS, which conducts an evaluation of the likely health and environmental

[457] Endocrine disruptors are defined as "chemicals which under certain conductions can have an impact on the hormonal system of humans and animals." European Commission, "Endocrine Disruptors" (accessed February 19, 2020).
[458] PBT and vPvB substances are defined as substances which can decay in the environment only over an extended period of time, bioaccumulate in the environment or in organisms, or are toxic to organisms. The full definition of these terms can be found in Regulation (EC) 1107/2009 in Chapter 3.7.
[459] The U.S. Grains Council noted "a May 2018 EC policy document (endorsed by the Standing Committee of Member States representatives in June 2019) stating that when an active substance is not renewed because it triggered the hazard-based cut-off criteria, the existing MRL will be reduced to the default of 0.01 ppm or to a lower LOD." Article 17 of Regulation (EC) No 396/2005 is the basis for this regulatory decision. U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 22.
[460] European Commission government representative, email to USITC staff, April 28, 2020; industry representative, interview by USITC staff, January 8, 2020; industry representative, interview by USITC staff, February 13, 2020; industry representative, interview by USITC staff, March 10, 2020.
[461] EC, written submission to USITC, December 13, 2019, 7.
[462] Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 124.
[463] European Commission, DG SANTE, "Technical Guidelines," SANTE/2015/10595 Rev. 5.4, November 27, 2018, 16–17.

impact of the proposed MRL.[464] The RMS then completes a comprehensive report on the likely impacts of the proposed MRL and provides it to the European Commission and EFSA.[465] EFSA then conducts its own risk assessment to determine the likely impact of the MRL, including setting a residue definition[466] and setting the ADI and other key health and environmental calculations. EFSA then submits its report to the European Commission.[467]

Figure 3.4 The EU's MRL-setting process



Source: European Commission, DG SANTE, *Technical Guidelines: MRL Setting Procedure*, November 27, 2018, 25–26. (Timelines are approximate.)
Note: EMS is the European Member State (or Rapporteur Member State), EC is European Commission, EFSA is the European Food Safety Authority, SC PAFF is the Standing Committee on Plants, Animals, Food, and Feed, Council is the European Council, and EP is the European Parliament.

The European Commission reviews both the EFSA proposal and RMS report and drafts a proposed MRL (the registrant will have proposed an MRL in its application, which EFSA may consider). The proposed MRL regulation is then notified, as required, to the WTO through the WTO/SPS (sanitary/phytosanitary) secretariat; this is a common practice for countries that add to or update their MRLs. As when other countries add or update MRLs, WTO member states then have 60 calendar days to issue comments on

[464] European Commission, DG SANTE, "Technical Guidelines," SANTE/2015/10595 Rev. 5.4, November 27, 2018, 6–9.
[465] European Commission, DG SANTE, "Technical Guidelines," SANTE/2015/10595 Rev. 5.4, November 27, 2018, 6–9.
[466] The "residue definition" is the residue of the active substance that has been selected to be used for testing purpose in order to confirm that the active substance has been used according to the label, which has been written according to good agricultural practices (GAPs).
[467] European Commission, DG SANTE, "Technical Guidelines," SANTE/2015/10595 Rev. 5.4, November 27, 2018, 6–9.

draft regulations proposed by the European Commission.[468] Following this period, the proposed MRL is sent to the PAFF, which considers the proposed regulation and any comments from WTO members.[469] After PAFF's approval, the European Parliament and Council have two months to review and object to the draft regulation setting out the MRL. In the event that neither the Council nor European Parliament objects, the European Commission then publishes the regulation.[470] The European Commission may also change the draft MRL proposal to accommodate European Parliament or Council concerns.[471] If the proposal for an MRL is rejected, the MRL will remain at the default for EU MRLs of 0.01 ppm, or the lowest limit of analytical determination (LOD).[472]

The EU has indicated its policy is to "regularly and systematically" align EU MRLs with Codex MRLs, in instances where (1) the EU sets MRLs for the commodity in question, (2) the existing EU MRL is lower than the Codex MRL, and (3) the Codex MRL meets EU consumer protection requirements and sufficient data have been gathered to meet EU data requirements.[473] If no MRL exists in the EU and the EU chooses not to align with the Codex MRL because the Codex does not meet the third condition (or if there is no Codex MRL), applicants may request that the EU establish an import tolerance.

Securing an Import Tolerance: Exporters and pesticide manufacturers can apply for an import tolerance in EU if there is no MRL for the specific pesticide/crop combination or if the existing MRL is lower than that of the exporting market. This process is similar to that of applying for an MRL, with Regulation (EC) 2006/395 noting that "it is appropriate that MRLs are set for imported products that take these uses [in the market of the exporting country] and the resulting residues into account provided that the safety of the products can be demonstrated using the same criteria as for domestic production."[474] According to the European Commission, from 2008 to 2019, 94 applications for import tolerances were submitted to the EU. Of those, 85 percent (80 applications) were approved, 10 percent (9 applications) were disapproved, and 5 applications are currently being analyzed.[475] Some pesticide manufacturers and grower groups have expressed concern that notwithstanding the EU's import tolerance regulations, substances that fail to receive approval due to the EU's cutoff criteria factors may not be able to secure import tolerances for those substances (this issue is discussed in greater detail in chapter 4).

Renewing EU Active Substances and MRLs: While many markets periodically review existing active substance approvals and their associated MRLs (usually between 10 and 15 years), the EU's approvals of active substances and MRLs expire and must be renewed. Depending on the active substance, typically

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[468] European Commission, written submission to USITC, December 13, 2019, 12.
[469] European Commission, written submission to USITC, December 13, 2019, 12.
[470] European Commission, DG SANTE, Technical Guidelines: MRL Setting Procedure, November 27, 2018, 11–12.
[471] European Commission, DG SANTE, "Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals – Residues, 13 - 14 June 2019," 12–13; see also industry representative, interview by USITC staff, November 26, 2019; industry representatives, interviews by USITC staff, January 8, 2020; industry representative, interview by USITC staff, February 13, 2020; industry representative, interview by USITC staff, March 10, 2020; European Commission, written submission to USITC, December 13, 2019, 12.
[472] European Commission, written submission to USITC, December 13, 2019, 6; EC, "How Are EU MRLs Set?" (accessed February 20, 2020).
[473] European Commission, written submission to USITC, December 13, 2019, 18.
[474] European Commission, "Regulation (EC) NO 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC," Paragraph 26, February 23, 2005.
[475] European Commission, written submission to USITC, December 13, 2019, 17.

an initial approval of an MRL can last for up to 10 years and renewal of an MRL for up to 15 years. Certain active substances, however, can have shorter renewal periods, ranging between 7 and 15 years.[476] Upon adoption of the current active substance regulation in 2009, the EU noted it would consider renewals of active substances and associated MRLs in tranches which is currently underway.[477]

The process to renew an EU active substance and its associated MRL is similar to the process to obtain approval of a new active substance and MRL, with a few distinctions around the selection of the RMS and the role of the European Parliament and the Council.[478] Similar to the approval process for new MRLs, an interested party (often the firm that applied for the initial MRL) will submit an application for reapproval. In the case of renewals, however, the European Commission will assign a RMS and a co-RMS (or in some cases, multiple RMSs) to produce a renewal assessment report rather than permit a registrant to select an RMS.[479] The renewal assessment report will then be submitted to EFSA (which prepares its own report) and the European Commission.[480] When the European Commission receives the EFSA and member state reports, it will issue its draft proposal. The European Commission may elect to reapprove the existing active substance and its MRLs, revise the authorizations, or not renew an active substance approval. In the latter case, the pesticide/crop combinations would be subject to a default MRL of 0.01 ppm or the lowest limit of analytical determination.[481]

In instances where the European Commission suggests renewing or amending an existing MRL, the draft regulation will be notified to WTO members, with a 60-day comment period for draft regulations (similar to an original MRL).[482] After the 60-day period, the PAFF Committee, composed of EU member states and chaired by the European Commission, reviews the draft and may consider feedback from the WTO SPS process. If the PAFF Committee then approves the draft regulation, the European Parliament and Council of the European Union will then have two months to review and object to the draft regulation. In the event that neither the Council nor European Parliament objects, the European Commission will adopt the MRL renewal regulation.[483] On average, this process takes approximately two years, though the EU has noted this overall timespan "varies widely based on the complexity of each case" and requests submission of applications for renewal three years before the expiration date of the approval.[484] While generally the European Parliament has voted in support of the recommendations from EFSA and European Commission there has been at least one instance where the European Parliament has voted against such a recommendation.[485]

If an MRL is lowered or removed, the EU process provides for a transition period to allow third countries, growers, and pesticide manufacturers to adjust to the new MRL regulatory framework. According to the EU, such reductions or removals of MRLs typically "become applicable 6 months and

[476] European Commission, Regulation (EC) 1107/2009, 2009, articles 5, 14, 22, and 24.
[477] European Commission, "Renewal of Approval" (accessed February 20, 2020).
[478] BCI, "EU Early Alert, Pesticide Review," August 15, 2019.
[479] EFSA, "Pesticide Evaluations: Overview and Procedure" (accessed March 17, 2020).
[480] Information regarding the renewal process and requirements can be found in Regulation (EC) 1107/2009.
[481] European Commission, written submission to USITC, December 13, 2019, 5.
[482] European Commission, written submission to USITC, December 13, 2019, 12.
[483] European Commission, written submission to USITC, December 13, 2019, 13.
[484] European Commission, written submission to USITC, December 13, 2019, 13.
[485] In 2019, the European Parliament voted against renewing an import tolerance for clothianidin. European Parliament, "Motion for a Resolution on the draft Commission regulation amending Annexes II, III and IV to Regulation (EC) No 396/2005," February 21, 2019.

20 days after the publication of the Regulation modifying the MRLs." The EU has acknowledged, however, that in some cases this timeframe has been truncated, stating that "only on rare occasions motivated by exceptionally strong concerns for human health is the deferral of the application date shorter than the above-mentioned period." In the review process for MRLs for chlorpyrifos, for example, the transition period was limited to three months.[486]

Default MRLs: In instances where an EU MRL/import tolerance has not already been set, the default level is 0.01 ppm or, in some cases, to the lowest limit of analytical determination. For substances identified with "exceptionally high toxicity, where the default value of 0.01 ppm is not sufficiently protective for consumers," MRLs in the EU can be set below 0.01 ppm.[487]

Enforcement

While the creation and reapproval of MRLs reflects the shared responsibilities of the EU member states, the European Commission, and EFSA, the enforcement of MRLs at ports is largely handled by individual member states. EU member states are required to ensure that shipments entering their respective ports of entry are MRL-compliant before these goods can be introduced to the European single market.[488] As such, member states carry out inspections of goods and set their own regulations for products that fail to meet MRL requirements.[489] The EU has indicated that a variety of options exist for noncompliant shipments, including shipment destruction, dispatch of the product outside the EU, or allocation of the shipment for purposes other than for what it was intended.[490]

Violations for exceeding MRLs in the EU are infrequent. In its 2018 report on 2016 MRL violations, EFSA concluded that out of 11 major categories of agricultural products,[491] only 1.7 percent of samples were found to exceed MRL requirements.[492] According to industry representatives, exporters are likely overly cautious when exporting to the EU market due to the costly consequences of noncompliance.[493] To avoid exceedances, shipments are frequently subjected to pre-export checks to ensure they are compliant with import market MRLs.[494]

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[486] European Commission, written submission to USITC, December 13, 2019, 14–15; Dahllof and Horel, "Pesticide chlorpyrifos banned by EU," EU Observer, December 9, 2019.
[487] European Commission, written submission to USITC, December 13, 2019, 6; EC, "How Are EU MRLs Set?" (accessed February 20, 2020).
[488] European Commission, written submission to USITC, December 13, 2019, 20–22.
[489] European Commission, written submission to USITC, December 13, 2019, 20–22.
[490] Treatment of goods is generally not available for MRL exceedances but applies to exceedances of contaminants. European Commission, written submission to USITC, December 13, 2019, 24.
[491] The 11 products for testing included apples, head cabbage, leeks, lettuce, peaches, strawberries, tomatoes, rye, wine, cow's milk, and swine fat. EFSA, "The 2016 European Union Report on Pesticide Residues in Food," July 25, 2018, 6.
[492] Additionally, this same report found that of a sample of 84,657 observations across EU member states, only one sample was identified as noncompliant having originated from the United States. EFSA, "The 2016 European Union Report on Pesticide Residues in Food," July 25, 2018, 3.
[493] For more information on exporters' experiences with import market MRL compliance, see chapters 4 and 5 of this report. Industry representative, telephone interview by USITC staff, November 26, 2019; industry representative, interview by USITC staff, San Jose, Costa Rica, December 5, 2019; industry representative, interview by USITC staff, Lima, Peru, December 11, 2019.
[494] For further information, see chapter 4.

In instances where an MRL exceedance is detected in a shipment sample, EU member states are able to inform one another and the European Commission through the Rapid Alert System for Food and Feed (RASFF). RASFF is a communication network between EU member states and the European Commission that covers a variety of food and feed issues, including MRL violations. RASFF is designed to ensure member states are kept aware of food health and safety developments.[495] In addition, RASFF can be used by exporting countries or businesses to inform the EU of likely MRL violations for shipments prior to testing at port.[496]

Official Controls Regulation Sets Updated Standards for MRL Enforcement

The Official Controls Regulation (Regulation (EU) 2017/625) came into force in December 2019. It lays out a series of regulations governing the authorities that verify food safety compliance, including MRL compliance.[497] This regulation in particular introduces "official controls and other official activities performed to ensure application of food and feed law, rules on animal health and welfare, and plant health and plant protection products." The regulation also provides a degree of flexibility governing laboratory testing for compliance with food safety regulations; it allows some labs to carry out analysis in certain circumstances before formal accreditation, which may ease MRL compliance challenges.[498]

General Food Law Regulation Reportedly Creates Concerns with Intellectual Property Protection in Pesticide Registration

Regulation (EU) 2019/1381 of the European Parliament and of the Council, known as the General Food Law, was published in September 2019, with an implementation date of March 27, 2021.[499] This law has been identified by industry representatives as potentially impacting the application process for approving active substances and setting MRLs in the EU market.[500] In part, as a result of concerns about the potential health impacts of glyphosate among EU consumers, this regulation extended transparency provisions of risk assessments for pesticides.[501] Regulation (EU) 2019/1381 states that "all scientific data

[495] For example, in the European Commission's 2018 report on RASFF, a member state identified important quantities of eggs as having quantifiable residues from fipronil; the member state then communicated that finding to the rest of the EU. As a result, the eggs were withdrawn from circulation in the EU market (the MRL for fipronil in eggs is set to 0.005 ppm). European Commission, *The Rapid Alert System for Food and Feed: 2017 Annual Report*, 2018, 24.
[496] For example, in 2017 Chile notified RASFF member states that four shipments of agricultural products with illegal residues of oxytetracycline had been sent from Chile to the EU market. Those shipments were then traced and removed from the European Union. European Commission, *The Rapid Alert System for Food and Feed: 2017 Annual Report*, 2018.
[497] European Commission, "Official Controls and Enforcement: Food" (accessed December 14, 2019).
[498] Appels and Kooijmans, "New EU Official Controls Regulation," March 11, 2019.
[499] EU, "Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019," September 6, 2019.
[500] Industry representative, interview by USITC staff, December 12, 2019; industry representative, interview by USITC staff, December 18, 2019.
[501] European Commission, "Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain," September 6, 2019, 5; Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 171.

and information supporting requests for authorizations or for approvals . . . as well as other requests for scientific output should be made publicly available."

Firms have expressed mixed reactions to the potential intellectual property implications of this regulation: some noted concern, while others indicated this is not a particularly significant issue.[502] Although the regulation notes the importance of protecting intellectual property rights, one industry representative expressed concern that as written, implementation of this regulation would require pesticide patent holders to disclose sensitive testing data, which may lead to a degradation of intellectual property protection in the EU.[503] Another firm noted that it could be costly to carry out the added work needed to justify designating as a company secret the individual components of an active substance submitted for registration.[504]

Japan

Japan is the United States' fifth-largest agricultural export destination, with an average of $12.80 billion in annual exports during 2016–19. Fifty-three percent of these exports were of edible crop and crop-based products. Among exports under that group, the biggest product group is cereals ($3.23 billion). The second- and third-largest product groups were of animal and inedible products: cattle and beef ($1.85 billion) and swine and pork ($1.52 billion). [505]

Japan's current positive list system has been in place since 2006, following a series of food safety concerns in the early 2000s (before the transition, foods found to contain chemicals without MRLs were "not enjoined from distribution").[506] During the transition, Japan worked with domestic and foreign industry representatives in establishing MRLs for a variety of pesticide/crop combinations, and as part of this process, adopted a number of Codex MRLs. Several industry representatives identified Japan's practice of initiating evaluations of pesticides for MRLs concurrently with the manufacturer's home country evaluation as a trade-facilitative practice in the MRL-setting process for imported products.[507]

Active Substance Registration and MRL Regulations and Processes

Registering a pesticide: Japan requires that a pesticide be registered and approved for use within the country before establishing an MRL. The registration of pesticides falls under the authority of the Ministry of Agriculture, Forestry, and Fisheries (MAFF) and is governed by the *Agricultural Chemical Control Act*, which governs the registration of agricultural chemicals, appropriate language for labelling,

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[502] Industry representative, interview by USITC staff, December 12, 2019; industry representative, interview by USITC staff, December 18, 2019; industry representative, interview by USITC staff, January 8, 2020.
[503] Industry representative, interview by USITC staff, December 12, 2019.
[504] Industry representative, interview by USITC staff, December 18, 2019.
[505] USITC DataWeb/USDOC (accessed January 24, 2020). Please see table 3.1 for further information.
[506] Specifically, during 2001–02, the use of unregistered crop protection products and MRLs in imported crops became a significant public concern in Japan. Yokota, "Establishment of MRLs in Japan," 2018, 9; Government of Japan, MHLW, "Introduction of the Positive List System for Agricultural Chemical Residues in Foods," June 2006; ABC, written submission to USITC, December 13, 2019, 6; Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 4.
[507] USHIPPC, written submission to USITC, December 10, 2019, 6; Cranberry Institute, written submission to USITC, December 11, 2019, 7; NPC, written submission to USITC, December 10, 2019, 5–6.

training and penalty regulations, and distributor responsibilities.[508] In order to register a pesticide, applicants must include with their application extensive information regarding efficacy, toxicity in humans (including information on mutagenicity, neurotoxicity, and carcinogenicity), environmental fate, residue analysis, and metabolism testing in animals, plants, and livestock.[509]

However, several types of substances are exempt from Japan's MRL regulatory framework. These include agricultural chemicals determined not to pose adverse health effects, specified agricultural chemicals listed under the *Agricultural Chemicals Regulation Law*, or chemicals which are determined not to require any MRL in foreign markets.[510] Exporters do not need to secure MRLs or import tolerances for these chemicals to be legally used in the Japanese market or be exported to Japan. (This practice of exempting certain chemicals from MRLs is common across many major markets and is discussed in greater detail in chapter 4.)[511]

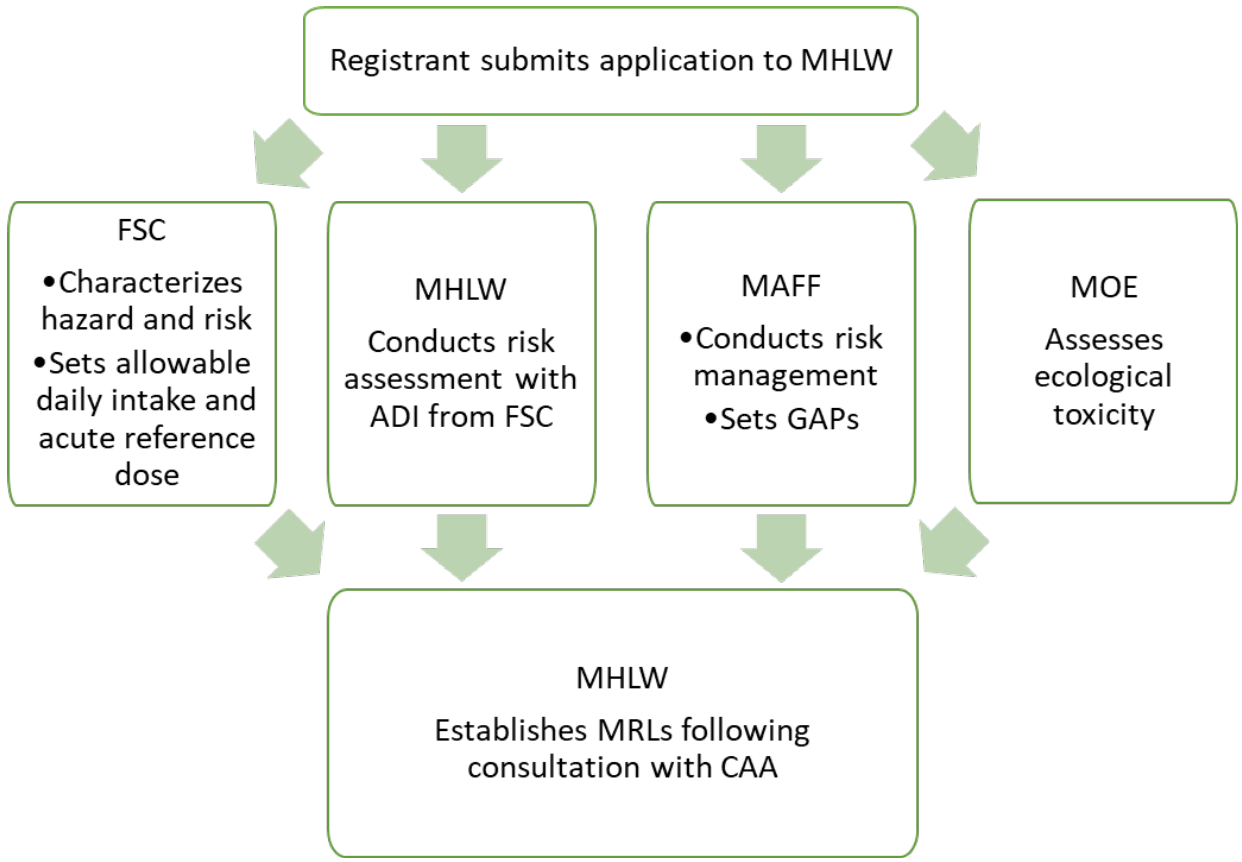
Securing an MRL: After a pesticide has been registered for use in Japan, an interested party (which is usually the original registration applicant) can apply for an MRL for a pesticide/crop combination.[512] Before the regulatory process to set MRLs begins, an applicant must submit data regarding the toxicity of the pesticide and must conduct residue data trials to provide the appropriate likely impacts of the pesticide use on human health and the environment.[513] Japan administers its pesticide authorizations and MRLs under the Ministry of Health, Labour and Welfare (MHLW).[514] Japan adopted a positive list system when it enacted its *Law to Partially Revise the Food Sanitation Law* ("Food Sanitation Law," Law No. 55, 2003); the new system took effect in May 2006.[515]

After an applicant has gathered the necessary information to complete the MRL data package, the applicant submits the package to the MHLW, which accepts applications and also has the final authority to set MRLs (figure 3.5). [516] As part of the evaluation process, applications are transmitted to several regulatory agencies which have shared authority in the evaluation, setting, and enforcement of MRLs. The first step, assessing likely risk of a potential MRL, falls under the independent Food Safety Commission (FSC). The FSC evaluates the application and sets the ADI and acute reference dose (ARfD) for pesticide/crop combinations and recommends the risk management implementation of the

[508] Yokota, "Establishment of MRLs in Japan," 2018, 11.
[509] Government of Japan, FAMIC, "Data Requirements, Test Guidelines, and Data Submission for Registration of an Agricultural Chemical," 2019.
[510] Yamada, "Japan's So-called 'Positive List,'" MAFF, 2013, 6.
[511] Yamada, "Japan's So-called 'Positive List,'" MAFF, 2013, 6.
[512] While the executive summary for an MRL application must be in Japanese, accompanying application materials may be in English. Japan Food Chemical Research Foundation, "Guideline for Establishment of MRLs" (accessed February 20, 2020).
[513] Japan Food Chemical Research Foundation, "Guideline for Establishment of MRLs" (accessed February 20, 2020).
[514] Japan Food Chemical Research Foundation, "Guideline for Establishment of MRLs" (accessed February 20, 2020). A list of current MRLs in Japan can be found at Japan Food Chemical Research Foundation, "Maximum Residue Limits List of Agricultural Chemicals in Foods" (accessed November 12, 2019).
[515] Government of Japan, MHLW, "Introduction of the Positive List System for Agricultural Chemical Residues in Foods," June 2006.
[516] Yokota, "Establishment of MRLs in Japan," 2018, 11–13.

proposed MRLs.[517] The FSC also analyzes domestic and international information on food safety, and manages total risk communication with relevant agencies.[518]

Figure 3.5 Japan's MRL-setting process



Source: Yamada, "Japan's So-called 'Positive List,'" MAFF, 2013, 2.

Following the conclusion of the risk assessment for the potential MRL, risk management for MRLs is then overseen in Japan by the MHLW and MAFF. MHLW oversees the monitoring of pesticide residues, and MAFF conducts risk management for agriculture and livestock production and sets GAP.[519] If the risk assessment and risk management evaluations are acceptable to the MHLW, the MRL application is accepted.[520]

Other authorities in Japan are involved in certain components of the MRL regulatory process. For example, the Japanese Consumer Affairs Agency (CAA) is consulted on the establishment of MRLs, and the Food and Agricultural Materials Inspection Center (FAMIC) is tasked with the reception of application forms and data for registration of active substances and evaluates submitted data.[521]

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[517] CLA and CLI, written submission to USITC, "Japan MRLs + Import Tolerances," 2017, 1.
[518] Yokota, "Establishment of MRLs in Japan," 2018, 11–13.
[519] Yokota, "Establishment of MRLs in Japan," Japan Crop Protection Association, 2018, 11–13.
[520] Yamada, "Japan's So-called 'Positive List,'" MAFF, 2013, 2.
[521] Yokota, "Establishment of MRLs in Japan," Japan Crop Protection Association, 2018, 18.

One characteristic that distinguishes Japan's regulatory system for pesticide MRLs from other major markets in this study is that post-harvest fungicides are classified as food additives. Japan regulates post-harvest fungicides outside the MRL regulatory system for pesticides used for pre-harvest fungicides, insecticides, or other products.[522] According to the U.S. Department of Agriculture, at least five substances—imazalil, o-phenylphenol, sodium o-phenylphenate, tiabendazole, and fludioxonil—have been governed under this separate regulatory structure.[523]

Import tolerances: Exporters and pesticide manufacturers can apply for an import tolerance in Japan if there is no MRL for the specific pesticide/crop combination or if the existing MRL is lower than that of the exporting market. According to a 2019 APEC report, an application for a new import tolerance in Japan typically takes about 12 months to complete from the time the application is submitted to the time when Japanese authorities make their final decision.[524] The steps required to set an import tolerance mirror those listed above in the setting of an MRL: relevant information on toxicity and environmental impact must be submitted, and the application goes through a parallel process in Japanese agencies.[525]

In certain circumstances, Japan may lower or revoke Japanese import tolerances or MRLs. For example, Japan may lower or revoke an MRL when a corresponding Codex MRL is lowered or revoked, or to reflect MRL changes made in other markets.[526] If Japan lowers or revokes an MRL, the changes generally become effective six months after publication of notice in Japan's official registrar of regulation.[527] According to one industry representative, if the EU finds that an active substance is hazardous to public health under the EU's cutoff criteria, that finding may trigger a special investigation in Japan.[528]

Default MRLs: Japan has set the default for MRLs at 0.01 ppm (this default is also referred to as the "uniform limit" in Japan).[529] This default MRL mirrors that of the EU, whose MRL regulations were specifically cited by Japan as a reasonable limit for their regulatory purposes. The MHLW indicates that this limit is set specifically to ensure that when the MRL is applied, consumption of the residue does not exceed .0015 mg/day, calculated based on "the food consumption of the Japanese population."[530]

Despite Japan's numerical MRL default of 0.01ppm, there are some circumstances when Japan will set a lower default. For example, Japan may set a pesticide's MRL to a "not-detected level" if the Joint FAO/WHO Expert Committee on Food Additives (JECFA) or JMPR sets a low limit on acceptable exposure

[522] ABC, written submission to USITC, December 13, 2019, 6; CCFA, written submission to USITC, December 12, 2019, 2.
[523] USDA, FAS, "Guide to Japanese Labeling Requirements for Post-harvest Fungicide," August 17, 2012, 1.
[524] APEC, "APEC Compendium of Government Administration in Setting Maximum Residue Limits for Pesticides," June 2019, 38–41.
[525] Yamada, "Japan's So-called 'Positive List,'" MAFF, 2013, 21.
[526] Yokota, "Establishment of MRLs in Japan," 2018, 29.
[527] Yokota, "Establishment of MRLs in Japan," 2018, 30.
[528] Industry representative, interview by USITC staff, December 12, 2019.
[529] Government of Japan, MHLW, "Introduction of the Positive List System for Agricultural Chemical Residues in Foods," June 2006.
[530] Government of Japan, MHLW, "Introduction of the Positive List System for Agricultural Chemical Residues in Foods," June 2006.

for that pesticide."[531] Additionally, if a chemical is determined to be carcinogenic by the MHLW, it will receive an MRL at a "not-detected level."[532]

Enforcement

Enforcement of MRLs for treated agricultural products exported to Japan is carried out by port authorities. If a product is shipped to Japan and exceeds Japan's MRLs, the product is not allowed to enter the Japanese market. Instead, it is re-shipped or destroyed. If it has already entered the Japanese market, it is removed from the domestic market.[533]

Both pesticide manufacturers as well as growers have noted Japan has a particularly strong enforcement structure. Japan has noted it reserves the right to increase testing on all shipments of a particular treated commodity following two residue violations.[534] When imported agricultural products are found to exceed Japanese MRLs, subsequent shipments generally are subject to increased inspection, though reports of the degree of increased inspection varies. Industry sources have indicated that Japan will not return to a regular level of monitoring until after 60 consecutive shipments have cleared inspection.[535] In August 2019, as a result of MRL exceedances, U.S. celery shipments to Japan became subject to "enhanced monitoring," where 30 percent of shipments were tested.[536] For repeated violations, entire classes of agricultural goods from that country or origin reportedly may be tested and held at port.[537] Often agricultural shipments will be tested by exporters before shipment to prevent an MRL exceedance in the Japanese market, a practice common for exporters sending treated crops to markets that have strong enforcement.[538]

Japan's Pre-registration of MRLs

One feature unique to Japan is that since 2013, Japan has allowed MRL applications from registrants to be submitted before the pesticide is formally approved for use in the producing market. This allows for the concurrent evaluation of MRL applications both in the producing market for a pesticide and in Japan.[539] Although Japan will not grant a formal registration or MRL without the necessary testing and

[531] Government of Japan, MHLW, "Introduction of the Positive List System for Agricultural Chemical Residues in Foods," June 2006.
[532] Government of Japan, MHLW, "Introduction of the Positive List System for Agricultural Chemical Residues in Foods," June 2006.
[533] Fussell, "An Overview of Regulation and Control of Pesticide Residues in Food," 2016, 15–16.
[534] Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 6; U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 19; NHC, "Export Manual: Japan" (accessed February 18, 2020).
[535] APC, written submission to USITC, December 6, 2019, 2; U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 19.
[536] Chow, "U.S. Celery Export Violations Found in Japan," August 6, 2019.
[537] APC, written submission to USITC, December 6, 2019, 4; Chow, "U.S. Celery Export Violations Found in Japan," August 6, 2019.
[538] Fussell, "An Overview of Regulation and Control of Pesticide Residues in Food," 2016, 15–16; NHC, "Export Manual: Japan" (accessed February 18, 2020); U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 19.
[539] Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 96; CLA and CLI, written submission to USITC, "Japan MRLs + Import Tolerances," 2018.

labeling in the market where the product is grown and processed, initiating the process earlier and working concurrently with other regulatory authorities reportedly has helped to reduce delays.[540] The (U.S.) Cranberry Institute stated that the industry was able to begin the process of setting its MRLs for Japan the while the U.S. MRL process was ongoing. The Cranberry Institute indicated that this allowed it to introduce treated cranberries to the Japanese market one year earlier than it could have otherwise, and helped support cranberry exports to the Japanese market.[541] Representatives from other industries indicated that they had a similar experience,[542] and that pursuing a concurrent approval process reduces the time required to receive the necessary approvals to enter a market.[543]

Japan's Transition to the Positive List System

Grower groups noted that Japan's regulatory authorities conducted extensive research and outreach to support a smoother transition from Japan's prior MRL system to its current structure.[544] The California Cherry Board stated that the transition was "handled transparently and avoided trade disruptions," and that transitional measures allowed for smooth trade. The U.S. Grains Council noted that "during the process of establishing their Positive List System, the Japanese and U.S. governments collaborated closely and held ongoing consultations with U.S. industry to address areas of concern."[545] Provisional MRLs were established by referencing Codex MRLs, and in instances where a Codex MRL had been established and Japan had yet not registered the pesticide/crop combination, it would typically align Japanese MRLs with Codex MRLs. (In instances where the active substance had been registered in Japan, it would opt either for the provisional Japanese MRL or the Codex MRL.)[546] In other instances, Japanese regulatory authorities would consider MRLs set by the EU, the United States, Canada, Australia, and New Zealand.[547]

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[540] Cranberry Institute, written submission to USITC, December 11, 2019, 7; USHIPPC, written submission to USITC, December 10, 2019, 6.
[541] Cranberry Institute, written submission to USITC, December 11, 2019, 7.
[542] In addition to the cranberry industry, the U.S. hop industry also noted the time savings that resulted from the application process change and expressed a favorable view of Japan's transition to its positive list system. USHIPPC, written submission to USITC, December 10, 2019, 6.
[543] The National Potato Council (NPC) noted, "now registrations can initiate an application in Japan [for an MRL] while the product is being reviewed in another market. Japan will not establish the MRL until a label is submitted and approved, but it will begin its evaluation, which can cut up to a year off the review process." NPC, written submission to USITC, December 10, 2019, 6.
[544] NPC, written submission to USITC, December 10, 2019, 5; CCB, written submission to USITC, December 11, 2019, 5; U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 9.
[545] Additionally, the National Potato Council noted that Japan's transition "was largely effective in avoiding trade issues. In the three years before the transition, Japan solicited needed MRLs from all stakeholders." NPC, written submission to USITC, December 10, 2019, 5; CCB, written submission to USITC, December 11, 2019, 5; U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 9.
[546] Yokota, "Establishment of MRLs in Japan," Japan Crop Protection Association, 2018, 29–30.
[547] Japan regulatory authorities would look to these five markets' MRL regulations in instances where MRLs had not been established by Codex. In instances where the active substance was registered in Japan and MRLs had been established in those markets, it would either consider its pre-established MRL or MRLs in those markets. It would also look to those markets when Codex MRLs had not been set and the pesticide/crop combinations had not yet been registered in Japan, but those markets had set their own MRLs. These provisional MRLs applied to approximately 758 active substances. Yokota, "Establishment of MRLs in Japan," 2018, 13.

Industry representatives have publicly noted the importance of the transparency of the transition process as well as praised Japan's outreach to industry prior to its transition to the positive list system. For example, in the cocoa bean industry, the Chocolate and Cocoa Association of Japan (CCAJ) conducted extensive outreach between cocoa-producing countries and relevant Japanese regulatory authorities in establishing appropriate MRLs for the industry.[548] This outreach included visiting farmers, warehouses, and chemical firms to determine the on-the-ground conditions at each step of the supply chain, as well as conducting residue analysis before shipments in order to reduce regulatory compliance challenges. When exploring the CCAJ regulatory challenges in Japan, the CCAJ noted its major challenge was the absence of harmonization in MRLs between Japan and the EU.[549]

South Korea

South Korea is the United States' sixth-largest agricultural export destination, with an average of $7.85 billion in annual exports during 2016–19; 47 percent of exports are edible crops and crop-based products. Cereals ($1.24 billion) is the largest among edible crops and crop-based products and second overall. Three of the top four product groups in exports to South Korea are animal and inedible products, led by cattle and beef ($1.46 billion, largest overall), animal feeds ($658 million, third overall), and swine and pork ($486 million, fourth overall).[550]

South Korea transitioned to a positive list system in two phases, in 2016 and 2019. During this process, South Korea also conducted extensive outreach to industry representatives when setting its new MRLs and incorporated some Codex MRLs into its domestic regulations. Some industry representatives, however, have noted concern that many of the temporary MRLs set up to facilitate the transition to the positive list system (which will expire in December 2021) may not be made permanent in time, and reported that this could result in trade disruptions if these MRLs are set to South Korea's default of 0.01 ppm.

Active Substance Registration and MRL Regulations and Processes

Active substances and MRLs are principally regulated in South Korea under the Food Sanitation Act.[551] In 2016, the government of South Korea announced it would shift its designation of MRLs to a positive list system, with an implementation date of December 2016 for seed and nut products and tropical fruits.[552] In January 2019, this system was extended to all agricultural commodities.[553] Before the positive list system was adopted, South Korean MRLs had been designated under a complex process that included

[548] Kaminaga, "The Positive List System in Japan and Our Approach to the Issues of Pesticide Residues in Cocoa," January 2011, 5.
[549] The CCAJ noted that EU-Japan MRL harmonization was difficult due to an absence of sufficient scientific data that back up the EU MRLs. Kaminaga "The Positive List System in Japan and Our Approach to the Issues of Pesticide Residues in Cocoa," January 2011, 5.
[550] USITC DataWeb/USDOC (accessed January 24, 2020).
[551] USDA, FAS, *Republic of Korea: Food and Agricultural Import Regulations and Standards Report*, March 22, 2019, 4.
[552] Lantz, "The Coming MRL Challenge in Korea," July 2016.
[553] Lantz, "The Coming MRL Challenge in Korea," July 2016.

deferral to Codex MRLs as one aspect.[554] In addition to Codex deferral, South Korea formally had a policy where the lowest MRLs for an agricultural commodity in a crop group could be applied to other crops in that grouping that did not have established MRLs. [555]

In 2019, South Korea implemented its full positive list system, with a 0.01 ppm default MRL for pesticide/crop combinations without an established MRL.[556] To limit disruptions to trade during the transition, the South Korean Ministry of Food and Drug Safety (MFDS) took several measures to ameliorate the impact of a transition to a 0.01 ppm default: Codex, the U.S. Environmental Protection Agency (EPA), and EU evaluation reports for generic compounds were accepted up to late 2018; the MFDS extended 2,500 MRLs that were scheduled to expire during the transition period to the end of 2021; and it established 3,342 temporary MRLs until the end of 2021.[557]

Industry groups and firms interviewed expressed the view that the South Korean transition to the positive list system has been largely cooperative and transparent. For example, one industry representative stated that the relevant South Korea regulatory bodies worked with agricultural exporters and pesticide producers in setting MRLs prior to the introduction of the positive list system.[558] An industry group said that "[South] Korea's implementation of its Positive List System included a multi-year process of ongoing consultations between government and industry . . . many of the U.S. grain industry's trade risk issues were resolved before the system went into effect."[559] Another industry representative noted that South Korea's transition to a positive list system was characterized by "its transparency and flexibility."[560]

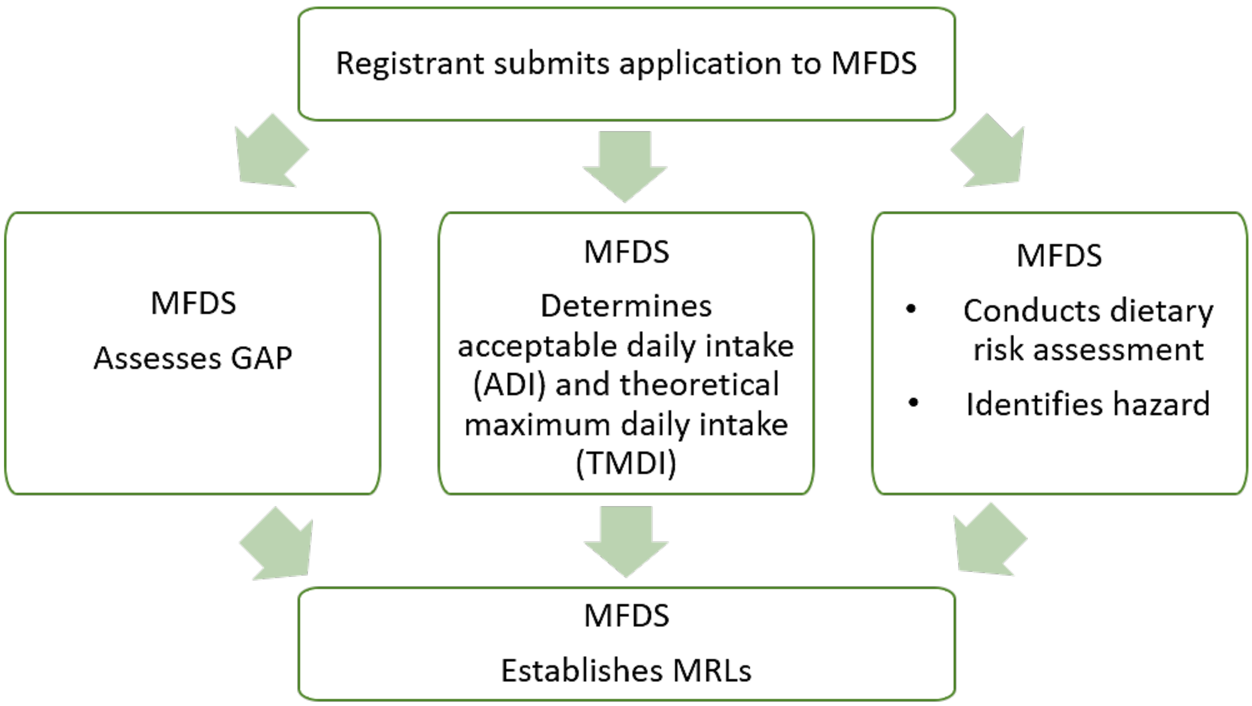
Registering a pesticide: South Korea requires that a pesticide be registered and approved for use within the country before establishing an MRL. The registration of pesticides in South Korea is governed under the Ministry of Agriculture, Food, and Rural Affairs, and the pesticide must be registered with the Ministry's Rural Development Administration. Data requirements include information regarding toxicity in animals and humans, carcinogenicity of the pesticide, and environmental impacts of the product.[561]

Securing an MRL: After a pesticide has been registered for use in South Korea, an interested party (which is usually the original registration applicant) can apply for an MRL for a pesticide/crop combination. Applicants are required to provide data on the toxicity of a residue on humans from both short-term (acute) and long-term (chronic) perspectives, on genetic or carcinogenic effects of the proposed pesticide residue on humans, and on environmental impacts, as well as data on residual trials conducted according to GAP. When those data have been submitted to the South Korea MFDS, it conducts its evaluation of the proposed MRL (figure 3.6). This includes determining an ADI of that

[554] The prior system applied a national South Korean MRL if it existed, or commodity-specific Codex MRL (and if no Codex MRL existed, a South Korean MRL would have been established using a similar crop as guidance). Lantz, "The Coming MRL Challenge in Korea," July 2016.
[555] USDA, FAS, *Republic of Korea: Implementation of Positive List System for Maximum Residue Limits*, November 29, 2018, 2.
[556] NABC, written submission to USITC, December 9, 2019, 3.
[557] USDA, FAS, *Republic of Korea: Implementation of Positive List System for Maximum Residue Limits*, November 29, 2018, 2.
[558] Industry representative, interview by USITC staff, November 21, 2019.
[559] U.S. Grains Council, NCGO, and MAIZALL, written submission to the USITC, December 13, 2019, 19.
[560] NPC, written submission to the USITC, December 10, 2019, 6.
[561] Choi, "Commentary Open Access Limitations of the Pesticide Management Regulation in Korea," 2016, 1–2.

pesticide, followed by a dietary risk assessment.[562] This assessment also includes a theoretical maximum daily intake (TMDI), an estimate of the likely consumption of that pesticide by a South Korean consumer with the proposed MRLs, accounting for an average domestic consumer's diet. When the TMDI is determined, the MFDS will set an MRL if the TMDI is at or lower than 80 percent of the acceptable daily intake.[563] If it exceeds 80 percent of the ADI, the MFDS conducts a new risk assessment prior to accepting the MRL application.[564]

Figure 3.6 Regulatory process to set MRLs in South Korea



Source: Kim, "Pesticide MRL Setting and PLS Progress in Korea," May 31, 2017, 16.
Note: MFDS (Ministry of Food and Drug Safety)

Import tolerances: Exporters and pesticide manufacturers can apply for an import tolerance in South Korea if there is no MRL for the specific pesticide/crop combination or if the existing MRL is lower than that of the exporting market. Aside from the initial registration of the product, the process for securing an import tolerance is comparable to an MRL: an import tolerance applicant's data must include the toxicology as well the residue trial data according to GAP and environmental impacts. The MFDS then follows that same dietary risk assessment, acceptable daily intake, and theoretical maximum daily intake policies as in the case of MRLs.

The process for granting an import tolerance in South Korea typically takes 12 months from the submission of the application to the issuance of a decision. In order to facilitate the transition from the prior system to South Korea's current positive list system, the MFDS has offered accommodations to

[562] Kim, "Pesticide MRL Setting and PLS Progress in Korea," May 31, 2017, 16.
[563] Kim, "Pesticide MRL Setting and PLS Progress in Korea," May 31, 2017, 16.
[564] Kim, "Pesticide MRL Setting and PLS Progress in Korea," May 31, 2017, 16.

those seeking import tolerances.[565] During the transition period for South Korea's positive list system (which will end in December 2021, when transition MRLs must either secure permanent MRLs or default to 0.01 ppm), the MFDS announced it would offer an expedited review of import tolerance applications.[566] Practically, this has meant the review process from receipt of application took 5 months, less than the typical 12 months it normally would have taken in South Korea—and many other markets—to issue a final decision on an application.[567] Additionally, and as mentioned above, the South Korean government indicated that it would accept Codex, EPA, and EU evaluation reports for registrants of generic compounds seeking import tolerances.[568]

Default MRLs: South Korea has established a 0.01 ppm default MRL for pesticide/crop combinations that have no established MRLs.[569] This replaced the prior system, which defaulted to Codex in instances when there were no established South Korean MRLs; and when no Codex MRL existed, the default was for the lowest MRL for the same crop group and that pesticide.[570]

Enforcement

In South Korea, enforcement of MRLs is carried out by the MFDS, which conducts testing of shipments entering the South Korean market.[571] Industry representatives have noted that in instances where shipments exceed MRLs, substantial follow-up testing will be triggered for future shipments. In the instance of a violation, South Korean regulatory authorities are reportedly authorized to test that commodity for up to five years if there is a violation.[572] U.S. industry groups noted testing can pose particular problems in the case of a highly perishable good. One industry group wrote that after a shipment in 2010 was found to exceed a South Korean MRL, South Korea altered its testing requirements for that product from "preferred" to "normal" and continued to require additional testing for multiple years. The U.S. industry group reported that this made it difficult for the industry to sell in the South Korean market, as the product was highly perishable.[573] Another industry group stated that shipments tested are also held before release into the South Korean market, which particularly affects their products that are highly perishable.[574]

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[565] APEC, "APEC Compendium of Government Administration in Setting Maximum Residue Limits for Pesticides," June 2019, 66–69.
[566] USDA, FAS, *Republic of Korea: Implementation of Positive List System for Maximum Residue Limits*, November 29, 2018, 2.
[567] USDA, FAS, *Republic of Korea: Implementation of Positive List System for Maximum Residue Limits*, November 29, 2018, 2.
[568] Kim, "Pesticide MRL Setting and PLS Progress in Korea," May 31, 2017, 14.
[569] USDA, FAS, *Korea: Implementation of Positive List System for Maximum Residue Limits*, November 29, 2018, 1.
[570] USDA, FAS, *Korea: Implementation of Positive List System for Maximum Residue Limits*, November 29, 2018, 1.
[571] The South Korean Ministry of Food and Drug Safety conducts testing of 370 compounds randomly. In addition to a quarterly test of 10 to 12 other chemicals not covered by the multi-residue test, which receive single-residue testing. The Ministry does not reveal which 10 to 12 chemicals, nor which crops, will be tested. NHC, "Export Manual: Korea," 2019.
[572] Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 6.
[573] CCB, written submission to USITC, December 11, 2019, 3–4.
[574] NHC, "Export Manual: Korea," 2019.

Ending Temporary MRLs in South Korea

One point of concern raised by registrants and growers exporting to the South Korean market is the phasing out of certain temporary MRLs as of December 31, 2021, that had been put in place during the country's transition to a positive list system. As of that date, all temporary MRLs in South Korea which have not received a permanent MRL will default to 0.01 ppm.[575] Registrants are currently applying for import tolerances for many of the compounds with temporary MRLs in South Korea (many of which had been set to Codex MRLs).[576]

While many of the major crops are expected to receive the necessary import tolerances before the transition to default MRLs, one industry representative expressed concern that smaller, specialty, and minor crops may not be able to justify the cost of completing the testing and field trials necessary to receive active substance and MRL designations for the South Korean market.[577] Another firm noted that in allocating resources for MRLs across multiple jurisdictions, it may be difficult to justify the resources necessary to secure all the MRLs currently used by their firm in South Korea's market.[578] Several industry representatives have expressed concern that the temporary MRLs covering their products may not be available in permanent status by 2022.[579]

Taiwan

Taiwan is the United States' eighth-largest agricultural export destination, with an average of $3.57 billion in annual exports during 2016–19. Sixty-five percent of these exports were of edible crops and crop-based products, led by cereals ($742 million) and oilseeds ($675 million). Cattle and beef ($473 million) is the largest group of exports among the category of animal and inedible products and is the third-largest overall. [580]

Taiwan began to develop its positive list system in 1999–2000. At this time, it announced that it would only accept imported agricultural products for which MRLs had been established in Taiwan.[581] Its current framework was introduced in the 2008 *Standards for Pesticide Residue Limits in Foods*. This was followed in 2014 with the designation of the Taiwan Ministry of Health and Welfare (MOHW) as the central authority on food safety, which occurred under the 2014 Food Safety and Sanitation Act (FSSA).[582] Additionally, the Agro-Pesticide Management Act governs the test items and guidance for

[575] Industry representative, interview by USITC staff, December 12, 2019.
[576] Industry representative, interview by USITC staff, December 12, 2019.
[577] Industry representative, interview by USITC staff, December 12, 2019.
[578] Industry representative, telephone interview by USITC staff, December 18, 2019.
[579] For example, the California Cherry Board noted that the setting of the temporary South Korean MRLs for methyl bromide was important for the $100 million U.S. cherry export market to South Korea. CCB, written submission to USITC, December 11, 2019, 4.
[580] USITC DataWeb/USDOC (accessed January 24, 2020). Please see figure 3.1 for further information.
[581] One source noted that "in 1999, Taiwan announced that it would establish its own positive MRL list and imports would need to meet those standards to enter the market." Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 4; Government of Taiwan, Food and Drug Administration, "Pesticide Residue Limits in Foods," November 6, 2019.
[582] Liao, "Pesticide Regulation and MRL Establishment in Taiwan," TFDA, May 29, 2019, 5.
CFFA, written submission to USITC, December 12, 2019, 3; Government of Taiwan, Food and Drug Administration, "Pesticide Residue Limits in Foods," November 6, 2019.

registration of pesticides in Taiwan.[583] Similar to Australia and the United States (among other markets), Taiwan does not have a numerical default provided in its MRL regulations (such as Canada's 0.1 ppm or the 0.01 ppm set by Japan and the EU), though it appears to frequently set MRLs to a 0.01 ppm default.[584] While industry representatives have praised the collaborative framework set up by Taiwan's MRL regulatory authorities, they have also expressed concern that the efficacy requirements for pesticides registered for import MRLs, as well as domestic testing requirements for both efficacy and residue testing, could represent barriers to trade for treated agricultural products.[585] Following industry feedback, in February 2020, Taiwan's Ministry of Health and Welfare removed the efficacy data requirement for setting import tolerances.[586]

Active Substance Registration and MRL Regulations and Processes

Registering a pesticide: Taiwan requires that a pesticide be registered and approved for use within the country before establishing an MRL. Taiwan registers pesticides under the Taiwan Agricultural Chemicals and Toxic Substances Research Institute (TACTRI) within the Council of Agriculture (COA). The COA also manages pesticide use in farms, issues permits for pesticide use, and conducts research and development of pesticides.[587] In registering a pesticide for domestic use, a registrant must describe the physical characteristics of a pesticide and its intended use, and must provide a toxicology study for impacts on skin, mouth, eyes, and lungs. In addition, bird, honeybee, and aquatic toxicity tests are required. Finally, efficacy trials and crop safety trials are required.[588]

Securing an MRL: After a pesticide has been registered for use in Taiwan, an interested party (which is usually the original registration applicant) can apply for an MRL for a pesticide/crop combination. In Taiwan's initial transition to a positive list, it reportedly temporarily deferred to Codex MRLs if none had been established in Taiwan, thereby preventing substantial trade disruptions.[589] MRLs are set in Taiwan under the Standards for Pesticide Residue Limits in Foods (Standards), which contains MRLs for both domestic and imported agricultural products.[590] This regulation, first set in 2008, originally contained more than 300 pesticide MRLs in more than 20 food categories, and has been amended to add, delete, or change MRLs many times (the most recent change to MRLs in Taiwan occurred November 6, 2019).[591] In addition to listing Taiwan MRLs, this regulation also includes pesticides characterized as "highly safe," which are thus exempt from MRL requirements, as well as pesticides explicitly banned for use. (Both exempted and banned lists are typical in many MRL regulatory structures, and are discussed in further detail in chapter 4 of this report.)[592] Although in its initial transition to its positive list system Taiwan

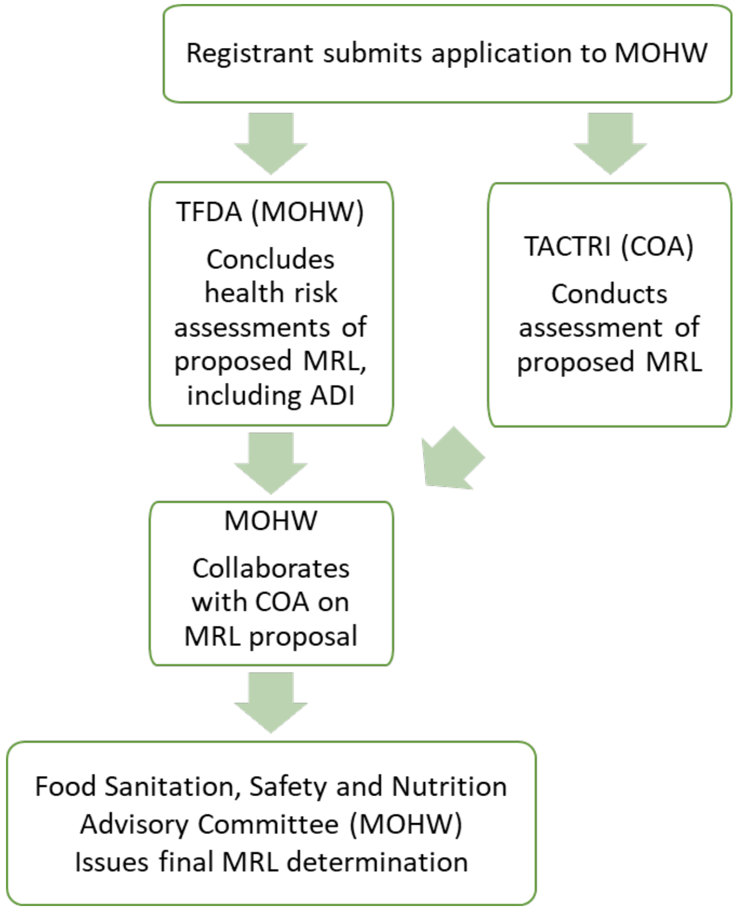
[583] USITC, hearing transcript, October 29, 2019, 12 (testimony of James Tsai, TECRO).
[584] USDA, FAS, *Taiwan: Pesticide Import Tolerance Application Process*, April 10, 2019, 1.
[585] Industry representative, interview by USITC staff, October 3, 2019; industry representative, interview by USITC staff, December 12, 2019.
[586] Taiwan government official, email message to USITC staff, April 30, 2020.
[587] TECRO, written submission to USITC, December 13, 2019, 2.
[588] TACTRI, "Summary of Requirements for Pesticide Registration: Microbial Pesticides," July 5, 2019.
[589] CFFA, written submission to USITC, December 12, 2019, 3–4.
[590] TECRO, written submission to USITC, December 13, 2019, 9.
[591] Government of Taiwan, Food and Drug Administration, "Standards for Pesticide Residue Limits in Foods" (accessed November 14, 2019).
[592] Government of Taiwan, Food and Drug Administration, "Standards for Pesticide Residue Limits in Foods" (accessed November 14, 2019).

adopted Codex MRLs as a transition measure, currently Taiwan is not bound by Codex MRLs. Taiwan may, however, consider them when setting its own.[593]

Any party interested in securing an MRL in Taiwan is required to submit an application to the MOHW's Food and Drug Administration (TFDA) (figure 3.7). TFDA works on establishing and enforcing MRLs with other government agencies in Taiwan. These include the COA and the Pesticides Advisory Committee (PAC).[594] In assessing an MRL application, TFDA takes into consideration Codex standards, makes health assessments relative to the consumers' dietary intake trends, conduct reviews with an expert committee, and collaborates with the COA.[595] It also submits the application to the TACTRI within the COA, to conduct an assessment of the proposed MRLs.[596]

[593] Government of Taiwan, Food and Drug Administration, "Standards for Pesticide Residue Limits in Foods" (accessed November 14, 2019).
[594] Taiwan's Pesticides Advisory Committee sets the regulations governing the testing methods, standards, and specifications in setting MRLs and import tolerances, as well as reviews methods and scope of pesticide application in farms and understanding pesticide technology issues. The Pesticides Technical Advisory Committee consists of representatives from the MOHW, TFDA, the Environmental Protection Administration, the Toxic Chemical Substances Bureau, the Agriculture and Food Agency, and the Occupational Safety and Health Administration. The PAC holds plenary meetings every three months and extraordinary and intergroup meets also sometimes occur. In addition, all information for MRL applications is required to be presented to the PAC for technical review. TECRO, written submission to USITC, December 13, 2019, 2, 5, 13.
[595] Government of Taiwan, Ministry of Health and Welfare, "Modified MRLs for pesticides announced," January 11, 2017.
[596] TECRO, written submission to USITC, December 13, 2019, 2.

Figure 3.7 Taiwan's MRL-setting process



Source: USDA, FAS, *Taiwan: Pesticide Import Tolerance Application Process*, April 10, 2019, 5; USITC, hearing transcript, October 29, 2019, 12 (testimony of James Tsai, TECRO). Note: TFDA (Taiwan Food and Drug Administration), TACTRI (Taiwan Agricultural Chemical and Toxic Substances Research Institute), MOHW (Ministry of Health and Welfare).

TFDA also provides a 60-day public comment period to allow interested parties to offer submissions in connection with potential MRLs.[597] Upon conclusion of the appropriate tests for toxicology, public health, and environmental fate, the proposed MRL is then submitted to the Food Sanitation, Safety, and Nutrition Advisory Committee of MOHW, which makes a final determination on whether to grant an MRL for a pesticide/crop combination.[598] Similar to South Korea, if the TMDI of a pesticide residue based on a proposed MRL exceeds 80 percent of the acceptable daily intake overall or for any age group, the MRL will be adjusted until it falls below that threshold for all age groups.[599] If MOHW ultimately agrees with the application, the MRL will be accepted for use in Taiwan.

[597] In previous instances, public comments have often suggested MRLs for pesticides be aligned with international standards, and that strict standards or inadequate standards for products like tea, sesame, spices, and herbs be brought into closer harmony with EU or Japanese standards. TECRO, written submission to USITC, December 13, 2019, 5, 37; Taiwan Ministry of Health and Welfare, "Modified MRLs for Pesticides Announced," January 11, 2017.
[598] TECRO, written submission to USITC, December 13, 2019, 5
[599] TECRO, written submission to USITC, December 13, 2019, 5.

Import tolerances: Exporters and pesticide manufacturers can apply for an import tolerance in Taiwan if there is no MRL for the specific pesticide/crop combination or if the existing MRL is lower than that of the exporting market. A substantial portion of Taiwan's MRLs are established through import tolerance applications, making this process important to exporters to Taiwan's market.[600] The regulatory structure for import tolerances mirrors that set for domestic use MRLs, with the exception that the COA proposes MRLs for domestically registered products, while for import tolerances the MOHW will evaluate the MRLs proposed by the interested party.[601]

According to TECRO, a new import tolerance in Taiwan typically takes between 12 and 24 months to process, from initial submission of the application to the final decision from the MOHW.[602] Industry representatives, however, indicate that the process for receiving import tolerances in Taiwan appears to be slower now than it was during 2000–2010; one report noted that setting import tolerances can take "several years" in certain circumstances.[603] Additionally, industry representatives have expressed concern about the requirement that residue trials be conducted within Taiwan, even if the pesticide is not intended for domestic use, in order to set an import tolerance.[604]

Default MRLs: In the event that a Taiwan MRL/import tolerance has not been assigned or an MRL/import tolerance application has not been accepted, there is no provision in Taiwan's regulations for a default MRL,[605] so a pesticide must not be detectable in an imported agricultural commodity for domestic consumption.[606] However, in some instances, it has been reported that Taiwan may also set a default of 0.01 ppm for some pesticide/crop combinations.[607]

Enforcement

The Ministry of Health and Welfare (MOHW) of Taiwan works with the Bureau of Standards, Metrology, and Inspection (BSMI, under the Ministry of Economic Affairs), to conduct MRL inspections and enforce

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[600] Industry representative, email to USITC staff, April 30, 2020.
[601] Liao, "Pesticide Regulation and MRL Establishment in Taiwan," May 29, 2019, 25.
[602] Taiwan's submission indicated that an application typically takes one year to review and assess, but that the total administrative review process (including preparing the implementing regulation and setting it into force) takes from one to two years. In an example provided in its submission from Bayer, regarding trifloxystrobin in artichokes, Taiwan noted that the entire process took two and a half years. TECRO, written submission to USITC, December 13, 2019, 9.
[603] NPC, written submission to USITC, December 10, 2019, 8; APEC, "APEC Compendium of Government Administration in Setting Maximum Residue Limits for Pesticides," June 2019, 26–29; CLA, written submission to USITC, "Taiwan MRLs + Import Tolerances," 2017.
[604] Industry representative, interview by USITC staff, December 12, 2019.
[605] Taiwan's submission noted: "the term 'zero tolerance' is misleading and will no longer be used in Taiwan. The issue of zero tolerance of imported agricultural commodities in Taiwan was brought up in a report presented by a TFDA officer at the MRL Workshop held in California May 29– 30, 2019. The so-called 'zero-tolerance' shown in the presentation referred to Taiwan not yet having a default limit of 0.01 ppm. In practice, the determination of pesticide residues is based on the limit of quantification Taiwan has published for the detection of pesticide residue, and only the number higher than the limit of quantification will be recognized." TECRO, written submission to USITC, December 13, 2019, 38–39. NABC, written submission to USITC, December 9, 2019, 5; CLA, written submission to USITC, "Taiwan MRLs + Import Tolerances," 2017.
[606] USA Rice, written submission to USITC, December 10, 2019, 5; USDA, FAS, *Taiwan: Food and Agricultural Import Regulations and Standards-Narrative*, December 10, 2015, 1–2.
[607] USDA FAS, *Taiwan: Pesticide Import Tolerance Application Process*, April 10, 2019, 1–2.

MRL regulations.[608] Upon inspection, the BSMI will issue a Federal Phytosanitary Certificate, which confirms the inspection has been completed. If a shipment is identified as exceeding an MRL, the TFDA has the authority to order the suspension of operations, the cessation of sales of that shipment, and the sealing of shipment produce to prevent exposure.[609] Depending on the scale of the MRL violation and the category of a food business, assets or property interests may also be seized, and fines may be issued.[610]

Additionally, when authorities find that a shipment has failed to comply with Taiwan's MRLs, they subject the next five shipments from the same origin, brand name, or importer to mandatory testing (and such shipments will not be released until the testing is complete).[611] According to industry representatives, TFDA said that in the event of two violations in a six-month period, the particular exporter would be subject to a 100 percent "batch-by-batch" inspection at port.[612] This mirrors Taiwan's stated policy that if one violation is detected, imports of that commodity will be tested at a 20–50 percent inspection rate, up from the typical 2–10 percent. And after two consecutive violations, the rate of inspections will increase from 20–50 percent of shipments to 100 percent batch by batch for each shipment.[613] For a product shipment that exceeds Taiwan's MRLs, Taiwan's regulations require that the product either be returned to its country of origin or destroyed.[614] Additionally, Taiwan publishes MRL violations (other markets, including the EU, sometimes do this).[615]

Testing requirements to determine proper enforcement of Taiwan's MRLs are set by two regulations: The *Standards for Pesticide Residue Limits in Foods* and the *Method of Test for Pesticide Residues in Foods: Multiresidue Analysis*. According to one industry representative operating in Taiwan, standards for compliance differ between the two regulations with respect to whether a shipment is compliant, based on whether imported products are (1) "at or below the MRL" (applicable to the *Standards* regulation) or (2) "below the MRL" (applicable to the *Method* regulation). In one instance, import inspectors reportedly relied on the "below" standard as the measure under the *Method of Test* regulation rather than selecting the "at or below" standard under the *Standards for Pesticide Residue* regulation. When Taiwan import inspectors chose the "below" standard, this led to a shipment being considered in violation of the regulation. As a result, the shipment was rejected and had to be diverted.[616]

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[608] USDA, FAS, *Taiwan Agricultural Situation: Taiwan Changes Labeling and Import Regulations 2007*, 2007, 1–2.
[609] Taiwan, "Act Governing Food Safety and Sanitation," 2008.
[610] Firms can be fined between NT$60,000 ($1,964) and NT$200,000,000 ($6.5 million). Taiwan, "Act Governing Food Safety and Sanitation," 2008.
[611] USDA, FAS, *Taiwan Agricultural Situation: Taiwan Changes Labeling and Import Regulations 2007*, 2007, 1–2.
[612] According to the Cranberry Institute, "Taiwan tests for pesticide residues and the consequences for a violation can be significant. Other industries have faced media coverage and elevated testing, even stretching into the following year," though they also noted, "the U.S. cranberry industry has had no issues to date in Taiwan." Cranberry Institute, written submission to USITC, December 11, 2019, 8; NHC, written submission to USITC, December 13, 2019, 31.
[613] Liao, "Pesticide Regulation and MRL Establishment in Taiwan," TFDA, May 29, 2019, 25.
[614] TECRO, written submission to USITC, December 13, 2019, 10.
[615] USDA, FAS, "Taiwan 2019 Import Violations Report," January 21, 2020, 1–3.
[616] NABC, written submission to USITC, December 9, 2019, 5–6.

Testing Requirements for Efficacy and Residue Data

Industry representatives have expressed concern about two testing requirements in Taiwan. The first issue concerns a requirement (now revoked) that efficacy data be submitted even for import tolerance applications. Because such data are typically not required as part of the application process for an import tolerance, according to industry representatives Taiwan's requirement to conduct efficacy testing imposed higher costs relative to other markets.[617] Some industry representatives believe that this requirement was intended to incentivize registrants to register active substances in Taiwan rather than to apply for import tolerances.[618] In response to industry concerns, in February 2020 the Taiwan Ministry of Health and Welfare removed the efficacy data requirement for import tolerances.[619]

The second issue identified by industry representatives is a proposal to increase the number of crop field trials required in order to establish MRLs in Taiwan.[620] Should this proposal be enacted, the number of field trials for major crops for Taiwan MRLs would be increased from three to five.[621] Increasing the number of crop field trials would add to the cost of compiling the necessary data to submit an application for an import tolerance or MRL (further information on data testing requirement challenges are discussed in chapter 4).[622] Industry representatives have also reported that a portion of the crop field trial requirement must currently be conducted in Taiwan, creating concerns about Taiwan's testing capacity as well as increasing costs for registrants.[623]

[617] Industry representative, interview by USITC staff, October 3, 2019; industry representative, telephone interview by USITC staff, December 12, 2019.
[618] Industry representative, interview by USITC staff, December 12, 2019; industry representative, interview by USITC staff, December 18, 2019.
[619] Taiwan government representative, email to USITC staff, April 30, 2020.
[620] Industry representative, interview by USITC staff, December 12, 2019.
[621] Industry representative, interview by USITC staff, December 12, 2019.
[622] TECRO, written submission to USITC, December 13, 2019, 38–39.
[623] Industry representative, interview by USITC staff, December 12, 2019.

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Chapter 4
Challenges Associated with MRLs

Introduction

A growing trend of missing and low pesticide maximum residue levels (MRLs) is affecting growers and exporters of agricultural products, as well as other stakeholders.[624] Greater fragmentation and divergence in MRL policies around the world is an important reason for this development, along with other, non-regulatory factors. Regulatory structures and procedures for registering active substances and for establishing MRLs and import tolerances are becoming more complex. Simultaneously, testing procedures are increasingly sophisticated, while technological advances enable regulatory authorities to test pesticide and residue data with more precision and at lower levels. These factors can often lead to low or missing MRLs across markets.

While the costs of registering an active substance are often borne by pesticide manufacturers, the entirety of the agricultural supply chain is impacted by different markets' policies for registering pesticides and setting MRLs, especially when this leads to low or missing MRLs. Growers are generally reliant on pesticide manufacturers to seek MRLs, and when MRLs are low or missing for the specific pesticide/crop combinations they need, growers can incur higher costs, face production challenges, or lose market access. Growers and processors, agricultural exporters and importers, pesticide manufacturers, and regulatory authorities have identified numerous challenges to trade throughout the pesticide and MRL regulatory process.

This chapter first describes the challenges associated with registering an active substance and securing an MRL. In particular, this section focuses on complex and costly data requirements as well as unclear regulations and a lack of predictability in some markets. The chapter then describes the challenges presented by different MRL-setting policies, including default MRL policies, short transition periods when an MRL is lowered, and disharmony across markets on exemptions from MRL requirements. Next, it addresses how growers, processers, and exporters respond to changes in MRLs, including the need to find other markets, use alternate pesticides, or adjust farming practices. The chapter then explores general issues growers face with MRL compliance strategies, including segregating crops, growing to the lowest global MRL, and pre-testing treated agricultural products. It also examines costs and pitfalls of governments' attempts to support growers' compliance with foreign MRLs. The final section of the chapter describes the impact of MRL violations, including loss of revenue through destruction or redirection of an agricultural commodity shipment, increased testing requirements, and reputational damage.

Table 4.1 highlights the major challenges and concerns faced by industry stakeholders at each stage in the pesticide registration and MRL establishment process, as well as the costs of compliance and noncompliance with existing MRLs. It also lists issues that illustrate these challenges and concerns, as well as their impacts.

[624] A description of missing and low MRLs is discussed in chapter 1.

Table 4.1 Challenges and concerns related to pesticide registration and MRL establishment

Issues	Challenges and concerns	Examples of issues
Approving/renewing active substances and establishing MRLs	Complex and costly data requirements increase costs and may limit pesticide availability for growers.	• Testing and data collection • Minor crops and crop groupings • Generic pesticides
	Unclear regulations and lack of predictability create uncertainty and may limit pesticide availability for growers.	• Hazard-based approach for registration of active substances • Guidance documents • Emergency use of pesticides • Pesticide bans • Inability to secure an import tolerance
MRL-related challenges in the agricultural supply chain	Varying MRL policies affecting growers and exporters can complicate regulatory compliance and threaten market access.	• Default MRL policies • Transition periods for new MRLs • MRL exemption policy disharmony
	MRL changes in key markets can lead to increased costs and may limit growers' ability to deal with pest challenges.	• Finding alternate markets • Finding alternative pesticide products and use patterns
Cost of compliance with MRLs	Compliance with MRLs impacts producers and other stakeholders in the supply chain, particularly in developing countries.	• Segregating crops or growing to meet the lowest MRL • Pre-export testing and MRL monitoring costs • Government support to ensure MRL compliance • Support from importing countries and related benefits
Costs of an MRL violation	Violations impact producers along the supply chain and can extend to other agricultural sectors.	• Loss of agricultural commodity revenue and redirected shipments • Increased testing • Reputational impact of an MRL violation

Source: Compiled by USITC.

Challenges with Approving/Renewing Active Substances and Establishing MRLs

In order to establish an MRL for specific pesticide/crop combinations, the active substance (active ingredient) in the pesticide must be registered for domestic use. This is an extensive regulatory process that requires evaluating the efficacy (the effectiveness) of the substance and its potential risks to human health and the environment. According to industry representatives, this evaluation process creates several challenges that can reduce the likelihood of securing an MRL. These challenges fall into two broad categories: (1) complex and costly requirements for registrants, and (2) unclear regulations and lack of predictability in the regulatory process. Given the close relationship between a government's approving an active substance and establishing MRLs for it, particularly with respect to the data collection and testing requirements, challenges for stakeholders at these two stages often overlap. This section will explore several of the important challenges and concerns that have emerged in registering an active substance, renewing a registration, and securing MRLs.

Complex and Costly Data Requirements

Pesticide manufacturers must make a significant investment to support the registration of an active substance or pesticide in a market and to establish its MRLs in that market. Generating the data required to register a pesticide and obtain MRLs for it can be a registrant's largest single expense in bringing a pesticide to market. Some of the most significant challenges pesticide manufacturers experience across markets are the costs and increasing complexities of the tests and trials required for risk assessments, including for metabolite assessments. Registrants pursuing MRLs on minor crops and generic pesticides face additional challenges, including increased costs and economic disincentives.[625]

Because pesticide manufacturers face uncertainty about whether a pesticide or active substance will ultimately be approved for use in a market, or whether they will secure an MRL, they must weigh several factors in deciding whether the financial returns are worth the cost of complying with each market's regulatory requirements.[626] One major factor in this decision is the relative importance of a crop on a global basis and the expected pesticide sales to growers (e.g., whether it is a major crop like corn, for which pesticide sales could be substantial, or a minor crop like mangoes, for which pesticide sales are likely lower).[627] In addition, the size of domestic production of the crop, or of a likely import market, may also be a factor for manufacturers. They may also take into account any unique characteristics of the pesticide (for example, if a pesticide's active substance breaks down into any potentially toxic metabolites).[628] Increasingly costly data requirements may result in a manufacturer's decision not to register a pesticide or active substance, seek an MRL, or support renewal of a pesticide in a given market. This reportedly may also undermine innovation and the development of new pesticides, all of which ultimately limit pesticide availability to growers and exporters.[629]

Testing and Data Collection Requirements

Extensive, time-consuming, and costly testing and data collection requirements for active substance (or pesticide) registrations and renewals, as well for MRL establishment, pose multiple challenges for industry stakeholders. Testing requirements for pesticide registration and MRL establishment can constitute a substantial portion of the overall cost of bringing a pesticide to market—one firm reported that this may account for about 40 percent (or up to $100 million) of the cost to bring an average pesticide to market (box 4.1).[630] In addition to the monetary cost of collecting and analyzing the

[625] Industry representative, interview by USITC staff, December 12, 2019; industry representative, interview by USITC staff, February 13, 2020.
[626] Industry representative, interview by USITC staff, February 13, 2020.
[627] As noted previously, there is no standard definition for major and minor crops and different markets may define them according to their own preferences. Major crops are generally understood to be grown on a larger scale; minor crops, often high-value specialty crops, are generally associated with relatively low production levels. OECD, *OECD Guidance Document on Defining Minor Uses of Pesticides*, October 23, 2009, 15. Industry representative, interview by USITC staff, February 13, 2020.
[628] Industry representative, interview by USITC staff, October 3, 2019; industry representative, interview by USITC staff, December 12, 2019; industry representative, interview by USITC staff, February 13, 2020.
[629] Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 153; EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, I-131; foreign government official, interview by USITC staff, January 8, 2020; industry representative, interview by USITC staff, October 24, 2019.
[630] Industry representative, interview by USITC staff, December 12, 2019.

required data, the risk assessment process can often take years.[631] Stakeholders have noted that the time required for this testing reduces the expected returns and profitability of patent-protected pesticides by effectively reducing the patent protection period.[632]

Despite the existence of common, internationally recognized approaches to registering pesticides and setting MRLs, risk assessment and management processes and requirements can vary by market.[633] While regulators typically request data on the pesticide's efficacy as well as its environmental, animal, and human health impacts, some markets may require unique tests or stipulate different conditions for data collection. For example, differences in the number of crop field trials required, as well as the data required on different metabolites, reportedly have led to costly or duplicative testing.[634] Such differences between markets contribute to globally unharmonized regulation.

Box 4.1 Costs of Developing and Registering a Pesticide

The cost of developing a pesticide is very high, and the process takes many years. A number of sources have estimated these costs, based on input from pesticide manufacturers and regulatory authorities. One study that surveyed major pesticide manufacturers estimates that, on average, the total cost from discovery (including R&D) to bringing a pesticide to market has increased from $152 million in 1995 to $286 million in the 2010–14 period.[a] The average number of years it takes to develop and launch a new pesticide has reportedly increased as well, from 8.3 years in 1995 to 11.3 years in the 2010–14 period.[b] While research accounted for 38 percent of the total costs of bringing a pesticide to market during this period, the development cycle (which includes the costs of field trials, toxicology, chemistry, and environmental chemistry studies) accounted for 51 percent.[c] In addition, the combined costs to register a new pesticide in the United States and the European Union (EU) were reportedly $33 million (or 12 percent of this total cost) in the 2010–14 period, up from $13 million (or 9 percent of total costs) in 1995.[d]

Reports indicate that, on average, more than 150 to 200 studies are carried out to register a single new active substance.[e] According to the European Commission, each of these individual studies to register or renew an active substance can cost "between several thousands to several million euro."[f] In the case of renewals, although the active substance has previously been approved, additional testing is often required.[g] One source estimates that the overall costs for additional studies for renewals in the EU varies based on the substance, but can range between $5 and $15 million.[h]

[631] Crop field trials, for example, must be conducted over consecutive harvests.
[632] Industry representative, interview by USITC staff, December 12, 2019.
[633] These internationally agreed-upon approaches include standards and guidance documents issued by international organizations such as the Organisation for Economic Co-operation and Development (OECD), Codex, and the Food and Agriculture Organization of the United Nations (FAO).
[634] Industry representative, interview by USITC staff, December 12, 2019.

As a result of the costs and the time required to launch a new pesticide, it is often not possible to immediately or quickly provide growers with a new alternative when a pesticide has been removed from use. For example, through its $5 billion research effort to find new weed control products, Bayer recently announced the development of a new chemical molecule effective against grasses that are resistant to existing herbicides.[i] Bayer states that this is the first new product of its kind in 30 years. However, given the standard development and regulatory processes required, the new chemical is not anticipated to reach the market for approximately 10 years.[j]

[a] The costs cited are an average of estimates collected over a number of years and do not account for inflation.
[b] Phillips McDougall, *The Cost of New Agrochemical Product Discovery,* March 2016, 3–4; industry representative, interview by USITC staff, December 12, 2019.
[c] Phillips McDougall, *The Cost of New Agrochemical Product Discovery,* March 2016, 3.
[d] This report defines registration costs as including the preparation and submission of data dossiers to, and subsequent negotiations with, registration authorities. Other studies on the costs of registering an active substance in the EU have reported figures slightly higher. Phillips McDougall, *The Cost of New Agrochemical Product Discovery,* March 2016, 3,7; Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 146.
[e] Phillips McDougall, *Evolution of the Crop Protection Industry since 1960*, November 2018, 7; EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, II-32.
[f] European Commission, "Questions and Answers: Commission Replies," December 12, 2017.
[g] ECPA, answers to written questions for the PEST Committee hearing of May 15, 2018, 7, 11 (accessed March 18, 2020).
[h] ECPA, answers to written questions for the PEST Committee hearing of May 15, 2018, 7 (accessed March 18, 2020).
[i] Industry representative, interview by USITC staff, February 19, 2019; Bayer, "Bayer Driving Agricultural Innovation and Sustainability," February 13, 2020.
[j] Bayer, "Bayer Driving Agricultural Innovation and Sustainability," February 13, 2020; Bayer, "Delivering World Class Innovation," February 13, 2020, 12.

Metabolites

Registrants and growers face multiple challenges related to metabolites, the molecules that active substances break down into. Most of these challenges stem from the high cost of testing metabolites, the lack of global agreement among regulators about the specific metabolites that ought to be assessed, uncertainty about the scope of metabolite data required by regulators at the beginning of the application process, and increasingly sophisticated testing equipment and data requirements for these substances. As discussed in further detail below, this is particularly challenging in the European Union (EU), where stakeholders report greater uncertainty about the outcomes of active substance registration/renewal and associated MRLs in part due to the EU's use of the hazard-based criteria.

Regulators scrutinize metabolites, in part, because as an active substance breaks down over its life cycle, its metabolites may persist and may have negative impacts on the environment or human health.[635] As technology and methods to detect metabolites improve, regulators are becoming aware of many more metabolites and increasingly require that their effects on human health and the environment be examined.[636] For risk assessment purposes, metabolites are broadly characterized as major, minor, or

[635] FAO, *Submission and Evaluation of Pesticide Residues Data*, 2016, 15, 18; industry representative, interview by USITC staff, November 26, 2019; U.S. government official, interview by USITC staff, December 30, 2019.
[636] FAO, *Submission and Evaluation of Pesticide Residues Data*, 2016, 15, 18; industry representative, interview by USITC staff, February 13, 2020.

theoretical, based on the degree to which they are present.[637] In general, regulators agree that most major metabolites, and any metabolites that are equal to or more toxic than the parent substance, must be included in the risk assessment. However, they generally do not specify exactly which metabolites should be evaluated.[638]

Unfortunately, simply identifying a metabolite's presence does not necessarily tell how toxic it is, and toxicity can be difficult and costly to determine for each metabolite.[639] According to the Organisation for Economic Co-operation and Development (OECD), while the goal in metabolite analysis is to "predict" whether its toxicity is lower than, equal to, or higher than that of the parent compound, it will not be technically possible to do so in every case.[640] Since there is no regulatory consensus globally on which of the many minor and theoretical metabolites that originate from an active substance should be evaluated for their potential toxicity, it is difficult for registrants to correctly determine which metabolites might be of concern to regulators.[641]

The process of determining and evaluating a myriad of metabolites is expensive and time consuming for pesticide manufacturers, and regulatory uncertainty both before and during the registration process adds more costs. According to industry representatives, the cost of evaluating a single metabolite can range from $50,000 and $100,000, and typically multiple metabolites must be evaluated. Given the high cost of metabolite testing, registrants must be selective in choosing the metabolites they will test before submitting their application, without being able to confirm with regulators that these are the metabolites of concern.[642] Moreover, regulatory bodies may request additional information on metabolites after the registrant has submitted the application. This can be particularly challenging for renewals of the active substances of older pesticides that are nearing the end of patent protection; the costs for registrants to conduct testing on extra metabolites may exceed the expected benefits of supporting the renewal.[643] (For further information on issues affecting generic pesticides, see "Generic Pesticides" later in this chapter.)

Industry representatives further report that regulators' access to increasingly precise testing equipment and analytical methods creates an added challenge in this process, particularly with regard to renewing

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[637] Major metabolites are defined in international guidelines as those which contribute to 10 percent more of the quantity of the total residue; minor metabolites are those that make up less than 10 percent of the residue; and theoretical metabolites are those that may not have been found in empirical studies but are theoretically possible. OECD, *Guidance Document on the Definition of Residue*, 2009, 23–24.
[638] Industry representative, interview by USITC staff, November 26, 2019; industry representative, interview by USITC staff, December 12, 2019; U.S. government official, interview by USITC staff, December 30, 2019; industry representative, interview by USITC staff, February 13, 2020.
[639] OECD, *Guidance Document on the Definition of Residue*, 2009, 20–28; industry representative, interview by USITC staff, December 12, 2019.
[640] OECD, *Guidance Document on the Definition of Residue*, 2009, 24.
[641] Industry representative, interview by USITC staff, November 26, 2019; industry representative, interview by USITC staff, December 12, 2019; U.S. government official, interview by USITC staff, December 30, 2019; industry representative, interview by USITC staff, January 8, 2020; industry representative, interview by USITC staff, January 10, 2020.
[642] Industry representative, interview by USITC staff, December 12, 2019; U.S. government representative, interview by USITC staff, December 30, 2019; industry representative, interview by USITC staff, January 10, 2020; industry representatives, interview by USITC staff, March 5, 2020.
[643] Industry representative, interview by USITC staff, November 21, 2019; industry representative, interview by USITC staff, February 13, 2020.

active substances. Reportedly, this disproportionately impacts active substance renewals because technical and technological advances made between the original registration and the renewal application allow regulators to detect more metabolites, and at lower levels, than were included in the original risk assessments.[644]

EU-specific concerns. Industry representatives report that the growing data requirements for metabolites in the risk assessment process are particularly challenging in the EU.[645] Pesticide manufacturers and grower groups state that over the past several years, rather than determine the level of risk based on exposure, the EU has applied hazard-based criteria that increasingly require registrants to establish the safety of not only the active substances in pesticides but also their metabolites. Firms report that this has resulted in requests for additional data on the safety of more metabolites and that meeting such requests would require further costly and time-consuming testing. Further, given that EU regulations do not allow registrants to add data outside the limited windows provided, this additional testing is not generally possible within the timelines for submitting data in support of an application. This has created uncertainty and contributed to non-approvals/nonrenewals of active substances.[646]

The increased scrutiny of minor metabolites in the EU has also reportedly resulted in delays of the approval of MRLs and import tolerances. One pesticide manufacturer noted that in attempting to establish an import tolerance for an active substance in the EU, the approval process was extended due to requests for information on one of the metabolites in the pesticide, even though the metabolite was not detected on the agricultural product.[647] Another grower group noted that additional data requirements for certain metabolites have contributed to the length of their 12-year-long attempt to secure an MRL in the EU, and that this process is still ongoing.[648] As a result of the increased focus on metabolites in the EU regulatory process, registrants may no longer find it cost-effective to register or renew certain pesticides or to seek import tolerances in the EU.[649]

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[644] Industry representative, interview by USITC staff, November 21, 2019.
[645] Industry representative, interview by USITC staff, December 12, 2019; Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 44.
[646] USITC, hearing transcript, 53–54 (testimony of Alinne Oliviera); industry representative, interview by USITC staff, October 23, 2019; industry representative, interview by USITC staff, January 8, 2020; foreign government official, interview by USITC staff, January 8, 2020; industry representative, interview by USITC staff, January 10, 2020; industry representative, interview by USITC staff, March 5, 2020.
[647] This firm noted that after initially submitting its request for the tolerance, additional information on residue processing, hydrolysis tests, and metabolite issues was subsequently requested. According to the firm, nearly ten years later it had yet to receive a decision on the import tolerance for this product. Industry representative, interview by USITC staff, December 13, 2019.
[648] In its submission, the Cranberry Institute noted: "For a decade, the cranberry industry has sought a MRL for an important herbicide. Efforts to date to obtain that MRL have proven fruitless. The cranberry industry has obtained multiple USDA TASC grants, conducted residue field trials, and put together applications, but the EU rejected the findings over concern regarding a metabolite (a breakdown product). It was highly unlikely the product even appeared in cranberry, but the EU would not change its position. . . . Now a new application must be generated and submitted." CI, written submission to USITC, December 11, 2019, 6.
[649] IR-4, written submission to USITC, December 11, 2019, 2; industry representative, interview by USITC staff, December 12, 2019; industry representative, interview by USITC staff, January 8, 2020.

Crop Field Trial Requirements

In addition to metabolite testing, other trial and testing requirements, such as crop field trial requirements, pose challenges for pesticide manufacturers and the growers that rely on them to secure MRLs. Differences in crop field trial requirements across markets are reportedly a concern because of the expense of conducting field trials (which cost about $20,000 each) and the time that it takes to complete them, given that they often require multiple growing cycles. The cumulative costs in money and time required to meet crop field trial requirements can be substantial, particularly when registrants intend to pursue the establishment of MRLs for a pesticide in multiple markets with differing crop field trial requirements. These added costs may erode the economic incentives for pesticide manufacturers to register an active substance (or pesticide) or apply for an import tolerance.[650]

Crop field trials, which are required for deriving and establishing MRLs, are conducted over multiple harvest periods in actual growing conditions. Field trials are conducted to generate the data needed to determine the amount of pesticide residues that remain on crops when pesticides are used according to the heaviest use patterns possible under Good Agricultural Practices (GAP).[651] Because of differences in climate, pest pressures, and consequent pesticide use patterns, crop field trials must be undertaken in each market to establish an MRL. Moreover, the number of trials often varies from one market to the next. For example, for major crops like wheat, as many as 12 trials may be required in Australia, 16 in Canada, and 8 in the EU (table 4.2). This has a cumulative effect on the costs of registering a product and securing an MRL in multiple markets. For example, one industry representative indicated that in order to secure an MRL in the EU, the United States, and China for a pesticide used on one crop, a combined 36 crop trials would need to be conducted to meet the trial thresholds necessary for the regulatory purposes of each jurisdiction.[652]

Table 4.2 Minimum number of trials required for major and minor crops in selected markets

	Australia[a]	Brazil[b]	Canada[c]	China	Codex	EU	Japan	South Korea	Taiwan
Major crops	6–12	4	8–16	12	8	8	6	6	3
Minor crops	2–6	4	1–5	Unclear	4–5	4	3	3	1

Source: Compiled by USITC from information presented below.
Note: “Major” and “minor” crops are not specifically defined internationally. “Major” crops are generally understood to be grown on a larger scale; they are often bulk crops like wheat, corn, rice, and soy. “Minor” crops, on the other hand, are generally understood to be specialty crops like blueberries, pistachios, and eggplants that are grown on a smaller scale. OECD, *OECD Guidance Document on Defining Minor Uses of Pesticides*, October 23, 2009, 15.
[a] In Australia, the number of crop trials varies by pesticide and depends on a number of factors, including the timing of the application of the pesticide on the crop, how often the pesticide is applied to the crop, the persistence of the pesticide after applications, and other factors. APVMA, “Residue Trials to Obtain Permanent Maximum Residue Limits” (accessed February 12, 2020).
[b] According to an industry representative, Brazil is expected to raise its required number of crop trials for major crops from 4 to 8. Industry representative, interview by USITC staff, December 12, 2019.
[c] Canada does not issue residue trial guidance based on a major/minor crop distinction, but rather on the total area of land a crop is grown on. Government of Canada, “Joint Canada/United States Field Trial Requirements,” 2017.

[650] Industry representative, interview by USITC staff, December 12, 2019.
[651] GAP has been defined by the FAO as a “collection of principles to apply for on-farm production and postproduction processes, resulting in safe and healthy food and non-food agriculture products, while taking into account economic, social and environmental sustainability.” FAO, *A Scheme and Training Manual on Good Agricultural Practices*, 2016, 1. FAO, “Residue Estimates—Crops,” n.d. (accessed March 26, 2020); OECD, *Guidance Document on Crop Field Trials*, September 7, 2016, 8.
[652] Industry representative, interview by USITC staff, December 12, 2019.

Recently, several countries have increased the number of field trials necessary for the collection of residue data, adding to the already large number of crop field trials required to register an active substance and secure an MRL. For instance, the number of crop trials needed in order to secure an MRL for Brazil is expected to rise for major crops from 4 to 8, while the number of trials required for major crops in South Korea and Japan recently rose in both countries from 3 to 6.[653]

One reason the number of trial requirements can differ is that markets often define major and minor crops differently. This inconsistency presents challenges to registrants seeking MRLs for crops that are designated as minor crops in one jurisdiction but as major crops in another. Pesticides designed for uses on minor crops may have to undergo as many (or almost as many) trials as major crops, which are grown in larger volumes and are therefore more commercially profitable for pesticide manufacturers. (See "Minor Crops and Crop Groupings" below.)[654]

Minor Crops and Crop Groupings

Growers of minor crops often face missing MRLs and encounter challenges in securing these MRLs in their export markets. Minor crops, which include specialty crops such as fruits, vegetables, nuts, and coffee, are typically grown in small volumes relative to "major crops" (like grains and soybeans) but can be very important cash crops for some farmers.[655] Pesticides used on minor crops may offer lower expected economic returns relative to the costs of securing the MRL, creating a disincentive for manufacturers to apply for MRLs for these pesticide/crop combinations in a number of potential export markets. As discussed in more detail below, if a manufacturer does not apply for an MRL on a given combination, growers are left to apply themselves and to take on the challenge of gathering the data needed to support an MRL application.[656] In response, some governments have provided support for establishing MRLs on minor crops. In addition, international efforts have resulted in the adoption of crop groupings to simplify the process of establishing these MRLs. While these efforts have been somewhat

[653] Industry representative, interview by USITC staff, December 12, 2019.
[654] As previously noted, there is no standard definition for major and minor crops; different markets may define them according to their own preferences, which can include production area. For example, the EU criteria for a major crop (requiring the highest number of crop trials) state that such a crop either (1) makes a contribution to daily dietary intake of 0.125 g/kg bw/day (grams per kilogram of body weight per day) or (2) has a cultivation area larger than 20,000 hectares (approximately 50,000 acres) and production exceeding 400 million kilograms per year. By contrast, Canada's top bracket for crop trial requirements encompasses crops with more than 4 million hectares of cultivated production. Industry representative, interview by USITC staff, December 12, 2019; Government of Canada, "Joint Canada/United States Field Trial Requirements," 2017; EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, 54–55; OECD, *OECD Guidance Document on Defining Minor Uses*, October 23, 2009, 17.
[655] OECD, *Guidance Document on the Exchange and Use of International Efficacy*, January 15, 2020, 8–9; OECD, *Guidance Document on Regulatory Incentives*, June 23, 2011, 12.
[656] OECD, *Guidance Document on Regulatory Incentives*, June 23, 2011, 12; industry representative, interview by USITC staff, October 24, 2019; industry representative, interview by USITC staff, January 6, 2020; CI, written submission to USITC, December 11, 2019, 1; NABC, written submission to USITC, December 9, 2019, 2; NHC, written submission to USITC, December 13, 2019, 14–15; USHIPPC, written submission to the USITC, December 13, 2019, 4.

successful, limited funding and lack of full harmonization of crop groupings leave many gaps in minor crop MRLs.[657]

In choosing whether to apply for an MRL, pesticide manufacturers weigh the expected profitability of the pesticide's use on a crop against other factors. These factors include the cost of registration,[658] the directing of limited resources to establish that MRL rather than an MRL on a more profitable crop, the limited period of patent protection, and the risk that the MRL may not be approved.[659] As a result, when the market for the pesticide is not large enough and the expected profitability is low, a pesticide manufacturer may decide not to apply for an MRL. When trial data must be conducted in multiple regions within a market, the difficulty and cost to apply for an MRL also increases.[660] This is particularly problematic for growers in smaller, developing markets, because pesticide sales there often do not provide large enough economic returns for the manufacturers to take on the costs and risks of the application process. Foreign government representatives have noted that smaller producing markets find it difficult to persuade pesticide manufacturers to seek MRLs in additional export markets unless larger producing markets also need those MRLs.[661]

In some cases, grower groups collect and generate the required data and submit an MRL application. However, in so doing, they incur the associated high costs, which can limit the number of MRLs they can pursue.[662] As a result, in order to support the position of growers, governments have taken steps to mitigate these costs by providing technical assistance and funding to gather data, as is the case with the Interregional Research Project #4 (IR-4) project. (For information on the IR-4 project and its work on

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[657] CI, written submission to USITC, December 11, 2019, 4; Government of Australia, written submission to USITC, December 13, 2019, 4; industry representative, interview by USITC staff, October 23, 2019; industry representative, interview by USITC staff, October 24, 2019; industry representative, interview by USITC staff, February 19, 2020; NHC, written submission to USITC, December 13, 2019, 15.

[658] The cost of establishing an MRL for a pesticide for use on minor crops, estimated at over $500,000 each, is high compared to such a pesticide's limited sales potential. OECD, *Guidance Document on Regulatory Incentives*, June 23, 2011, 18; industry representatives, interview by USITC staff, October 24, 2019.

[659] According to the OECD, other issues include "the potential economic liability from a use should there be problems with lack of efficacy or perhaps more concerning crop safety/damage following the use of a product. In cases where problems arise, liability costs in compensation cases can far outweigh the likely returns." One firm noted that given the limited duration of patent protection for pesticides, manufacturers may determine that the multiyear process of seeking an MRL in many export markets is difficult to justify for smaller crops. OECD, *Guidance Document on Regulatory Incentives*, 2011, 22; industry representative, interview by USITC staff, December 12, 2019; industry representative, interview by USITC staff, October 24, 2019; industry representative, interview by USITC staff, November 6, 2019; industry representative, interview by USITC staff, February 13, 2020; CRC, written submission to USITC, December 13, 2019, 6–7; OECD, *OECD Guidance Document on Defining Minor Uses of Pesticides*, October 23, 2009, 15.

[660] Industry representative, interview by USITC staff, November 6, 2019; industry representatives, interview by USITC staff, December 12, 2019; industry representatives, interview by USITC staff, October 24, 2019; industry representative, interview by USITC staff, February 13, 2020; industry representative, interview by USITC staff, February 19, 2020; NABC, written submission to USITC, December 9, 2019, 2.

[661] Industry representative, interview by USITC staff, October 24, 2019; industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019; foreign government officials, interview by USITC staff, January 8, 2020; industry representative, interview by USITC staff, February 19, 2020.

[662] CI, written submission to USITC, December 11, 2019, 4; OECD, *Guidance Document on Regulatory Incentives*, 2011, 21; USHIPPC, written submission to the USITC, December 13, 2019, 4.

minor crops, please see chapter 2 of this report.)[663] According to the OECD, these programs are considered "critical and in some cases may be the only mechanism to drive solutions for many minor uses that are not economically attractive to registrants."[664] Government programs have been used by grower groups both in the United States and abroad. For example, the National Horticultural Council in the United States recently received a U.S. government grant that will cover up to $163,000 of their costs for applying for 11 MRLs in South Korea for pesticides used on sweet cherries.[665] In another case, the U.S. hop industry has secured a $240,000 three-year state block grant to secure up to 12 permanent hop MRLs in South Korea and is working with registrants to apply for the remainder of the 38 temporary hop MRLs.[666]

Another way to address the challenges of establishing MRLs on minor crops is to group them into larger "baskets" called crop groupings.[667] Crop groupings, which are used by Codex and a number of country governments, extend MRLs established on selected representative crops to a number of crops that are botanically related.[668] For example, in the U.S. crop groupings, an MRL established based on trials for dry peas can be applied to lentils and chickpeas.[669] This allows the data collected for similar crops to be used in lieu of gathering data for each crop separately, reducing the overall data collection burden for multiple applications and ultimately increasing the number of MRLs for minor crops.[670]

The development of crop groupings, while helpful, has not been without challenges. Because of differences between local agricultural practices and patterns, there is no universally accepted definition of either minor crops or the larger crop groupings they may fall under.[671] Hence regulators select the agricultural commodities they wish to include in specific crop groupings according to their own preferences, resulting in crop groupings of minor crops that can vary by market. An example of this classification disharmony for two minor crops, pistachios and sweet potatoes, is presented in table 4.3. This variation renders the crop groupings less useful in terms of streamlining data collection for MRLs for the same pesticide/crop combinations in multiple markets.[672]

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[663] Government of Australia, written submission to USITC, December 13, 2019, 4.
[664] OECD, *Guidance Document on Regulatory Incentives*, 2011, 21.
[665] NHC, written submission to USITC, December 13, 2019, 14–15.
[666] USHIPPC, written submission to the USITC, December 13, 2019, 6.
[667] OECD, *Guidance Document on Regulatory Incentives*, 2011, 19.
[668] EPA, "Pesticide Tolerance Crop Grouping Revisions," n.d. (accessed March 26, 2020); Bayer, written submission to USITC, December 13, 2019, 3.
[669] USITC, hearing transcript, October 29, 2019, 118 (testimony of Dale Thorenson, USA Pea and Lentil Council).
[670] For example, Australian regulatory authority APVMA "supports use patterns that span crops grouped through similarities in their botanical classification, morphology, growth habit, the portion of the commodity harvested and/or consumed." They noted that this approach "is particularly important for the establishment of MRLs for minor crops." Government of Australia, written submission to USITC, December 13, 2019, 4. See EPA, "Pesticide Tolerance Crop Grouping Revisions," n.d. (accessed March 26, 2020); Bayer, written submission to USITC, December 13, 2019, 3; USITC, hearing transcript, October 29, 2019, 118 (testimony of Dale Thorenson, USA Pea and Lentil Council); industry representative, interview by USITC staff, October 24, 2019.
[671] FAO, "Residue Estimates—Crops," n.d. (accessed March 26, 2020).
[672] Bayer, written submission to USITC, December 13, 2019, 3; industry representatives, interview by USITC staff, October 24, 2019; U.S. government official, interview by USITC staff, December 4, 2019.

Table 4.3 Crop grouping inconsistencies: Classification of pistachios and sweet potatoes in select markets

	Australia	European Union	South Korea	Japan	Taiwan
Pistachios	Tree nuts	Tree nuts	Peanuts or nuts (includes gingko nuts)	Other nuts	Tree nuts (includes coconut)
Sweet potatoes	Root and tuber vegetables	Tropical roots and tuber vegetables	Potatoes	Potatoes	Root, bulb, and tuber vegetables

Source: European Commission, "EU Pesticide Databases: Search Products" (accessed November 27, 2019); Japan Food Chemical Research Foundation, "Maximum Residue Limits (MRLs): Food Types," (accessed November 27, 2019); Food Safety Korea, "Pesticides and Veterinary Drugs Information," (accessed November 27, 2019); TECRO, written submission to USITC, December 13, 2019, 28.

Generic Pesticides

Maintaining or establishing MRLs for generic pesticides (i.e., those no longer covered by a patent) presents particular challenges for both pesticide manufacturers and growers. Once a product is no longer under patent, an off-patent version can be produced by any number of firms, potentially limiting profits and the economic incentive of manufacturers to renew registrations and support MRLs. Manufactures seeking to renew off-patent active substances (those used in generic pesticides) may also face issues due to changes in data requirements and standards from when the substance was first registered. In cases where generic manufacturers do not pursue renewals or MRLs, grower groups themselves can pursue a renewal/MRL, which can be a costly and complicated process. As a result of all these factors, growers may lose MRLs for generic pesticides in some markets even though these pesticides are still in use and are still effective, limiting growers' access to affordable pesticides.[673]

Generic pesticide manufacturers face these additional challenges in renewing MRLs or securing new ones because the pesticides are usually based on older active substances, some originally registered decades ago under different processes and testing requirements and using older technologies. As a result of technological advances and changes in regulatory processes, older active substances that are up for revaluation and renewal are subject to new and more complex criteria than when they were originally registered. Consequently, applications to support generic versions of these older substances can require new data for the risk assessment. Additionally, because many generic pesticides were developed using older approaches, they might have a more significant environmental impact than newer pesticides still under patent. This increases the risk of a non-renewal or rejection of an MRL application.[674]

When a pesticide is no longer covered by a patent, the market conditions for the manufacture and sale of that product typically change, as do the incentives for the original patent holder to seek MRLs. Although generic pesticides constitute a large portion of the total pesticide market—about 45 percent of the total market value of global agricultural chemicals—if the price of a pesticide declines once it is off patent, the original producer may see limited profit potential in that product. This is especially true if multiple generic manufacturers begin to produce pesticides with the same active substance, limiting

[673] CRC, written submission to USITC, December 13, 2019, 6; Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 75–77; USA Rice, written submission to USITC, December 10, 2019, 4; industry representative, interview by USITC staff, May 6, 2020.
[674] Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 75–77; ECPA, answers to written questions from the PEST Committee for the May 15, 2018 hearing, n.d., 11 (accessed March 18, 2020).

market share for each firm. The combination of the costs of additional testing, potentially lower profitability of the product, and the higher risk of non-approval may lead the original manufacturer to choose not to support the application.[675]

If the original manufacturer does not support the application, generic manufacturers can step in. But they can face additional challenges in gathering data that can prevent them from renewing or securing an MRL. A generic manufacturer would have to absorb the costs of any new testing, but in addition, it also frequently has difficulty accessing the original data.[676] This may occur if, for example, the original patent holder that prepared the proprietary data for the initial registration no longer exists or does not wish to sell the data.[677] If a generic manufacturer cannot access preexisting data, it will have to incur the costs of collecting the original data anew, along with any new data that might be required.[678] When multiple manufacturers are producing pesticides with these active substances, the economic incentive for any one firm to support an application shrink still further.[679]

Given these market factors, if pesticide manufacturers choose not to renew registrations and MRLs for older active substances, grower groups may be forced to become involved in order to prevent the loss of important crop protection tools. Some grower groups noted that to continue to use certain generic pesticides on their crops, they have had to organize a task force in a particular market to coordinate the submission of applications and pull together the funds to pay the requisite fees.[680] In another instance, after Japan's proposal to review and reduce its MRL on the off-patent active substance propanil, California Rice and USA Rice noted they face a complicated data-gathering effort because propanil is now produced by a secondary manufacturer. They note that without assistance, the registrant would not have access to the necessary data to support the MRL and a failure to renew the MRL for propanil on rice could significantly lessen rice quality and yields and impact trade.[681]

These challenges are further exacerbated when governments change or update their regulatory processes. For example, one firm noted that South Korea's transition to a positive list system could present particular problems involving MRLs on generic pesticides. Because the temporary MRLs established to facilitate the transition will expire in 2021, grower groups and pesticide manufacturers must scramble to secure permanent MRLs before the temporary MRLs expire. To do so, they must submit applications for these MRLs. Given the high cost of collecting data and submitting MRL applications for generic pesticides relative to the expected economic benefits, pesticide manufacturers may prioritize patented pesticide applications over those for generics, potentially leading to missing

[675] Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 75–77.
[676] Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 7–8, 75–77; industry representative, interview by USITC staff, May 6, 2020.
[677] Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 75–77.
[678] Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 75–77.
[679] Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 77; industry representative, interview by USITC staff, May 6, 2020.
[680] NABC, written submission to USITC, December 9, 2019, 4; ABC, written submission to USITC, December 13, 2019, 7.
[681] CRC, written submission to USITC, December 13, 2019, 7; USA Rice, written submission to USITC, December 10, 2019, 4.

MRLs for generic pesticides unless growers themselves pursue renewal of the pesticide.[682] As more markets make significant changes to their MRL systems or transition to positive lists, and more pesticides come off patent, these challenges will likely increase.

Unclear Regulations and Lack of Predictability

In addition to the high costs associated with complying with data and testing requirements, pesticide manufacturers seeking approval for active substances and MRLs often encounter a lack of clarity in the regulations and unpredictability in the application process. This situation reportedly increases costs, limits availability of pesticides for growers, and can impede innovation and the potential development of new pesticides to address ongoing and emerging pest pressures.[683] While these issues are reported in all markets, industry representatives state that they are particularly problematic in the EU. This is due to the structure and complexity of its regulatory process, the volume of active substances that are being reviewed, the EU's large market size, and the impact that EU regulatory decisions have on other markets.[684]

Hazard-based Approach for Registration of Active Substances in the EU

Stakeholders recognize that regulators have the right to establish criteria to limit the use of active substances (or pesticides) that they deem hazardous. They report, however, that the EU's implementation of its hazard-based criteria and the complexity of its process for evaluating active substances is of particular concern. This is principally because the EU's implementation of the hazard-based approach and the precautionary principle differs from the approaches used in most other major markets.[685] Industry representatives report that this approach has contributed to non-approvals (and non-renewals) of some active substances in the EU that have been considered acceptable in other major markets. This has, in turn, reportedly affected the global use of certain pesticides by growers (see "Finding Alternative Pesticide Products and Use Patterns" below and case studies in chapter 5).

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[682] This representative noted that "applications are difficult to draft and older generics often do not have a registrant willing to support the [costs necessary to file the] application." The South Korean regulatory authorities have responded in part by allowing applicants to use U.S. or Codex JMPR evaluations for generic pesticides instead of original residue data, recognizing that it may be difficult to gather updated data for generic pesticides before the 2021 deadline. CI, written submission to USITC, December 11, 2019, 7; CLA and CLI, written submission to USITC, "Korea MRLs + Import Tolerances," 2017.
[683] Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, vi; foreign government official, interview by USITC staff, January 8, 2020. In one study of industry representatives, a majority of pesticide manufacturers surveyed indicated that the costs act as a barrier to development of new pesticides. EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018 I-123, I-131.
[684] USITC, hearing transcript, October 29, 2019, 128 (testimony of Christopher Novak, CropLife America); industry representative, interview by USITC staff, October 24, 2019; foreign government representative, interview by USITC staff, January 8, 2020; industry representative, interview by USITC staff, January 8, 2020.
[685] Industry representative, interview by USITC staff, January 8, 2020; industry representative, interview by USITC staff, January 10, 2020; industry representatives, interview by USITC staff, March 5, 2020; CWC, written submission to USITC, December 12, 2019, 2; NPC, written submission to USITC, December 10, 2019, 5.

Furthermore, they have expressed concern that they may effectively lose the ability to use more pesticides and that other markets may begin to adopt the same hazard-based approaches.[686]

As a result of the EU's application of the hazard-based criteria and the precautionary principle, the burden of proof of establishing the absence of harm reportedly falls on the registrant.[687] One aspect of this hazard-based approach is the potential use of cutoff criteria. As established under Regulation (EC) 1107/2009, the EU will approve an active substance for domestic use only if it is determined not to have carcinogenic, mutagenic, reproductive, or endocrine disrupting properties and that it is not a persistent organic pollutant. As a result, registrants are required to definitively prove that their pesticides do not meet any of the cutoff criteria, regardless of the level of exposure a consumer may face from the application of that pesticide on a treated crop (which may be minimal).[688] With very limited exceptions, if a pesticide cannot be proven not to be carcinogenic, mutagenic, toxic to human reproductive systems, endocrine-disrupting, or persistent in the environment, the associated MRLs will be lowered to the default.[689]

In spite of industry representatives' reports that the hazard-based approach and the cutoff criteria have reduced the number of pesticides available to EU growers and exporters to the EU market, the European Commission reports that no active substance has failed to secure approval based on the human health-related cutoff criteria alone.[690] The European Commission and some EU member state authorities, further, report that in all but one instance where the cutoff criteria were triggered, a risk assessment was still completed and EFSA determined that there were other risks—for example, to human health,

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[686] NPC, written submission to USITC, December 10, 2019, 5; CCQC, written submission to USITC, December 10, 2019, 4; U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 21; USHIPPC, written submission to the USITC, December 13, 2019, 5.

[687] The EU's hazard-based approach to the registration of pesticides is said to be underpinned by the precautionary principle (which the European Commission reports is laid down in Article 191 TFEU and has been recognized by the European Courts as a general principle of Union law). The precautionary principle was implemented in Article 1(4) of Regulation 1107/2009. EC, answers to questions from the PEST Committee hearing on April 12, 2018, 15; EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, 21–22, 39–40, II-34. The EU's regulatory assessment reportedly "relies on 'industry-supplied evidence'. The rationale for this provision lies in the logic of the precautionary principle, that puts the burden of proof on applicants. It means that manufacturers who are interested in marketing their plant protection products in Europe have to provide evidence about the safety of active substances contained in them." EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, II-34, II-92. See USITC, hearing transcript, October 29, 2019, 53–54 (testimony of Alinne Oliviera, USHIPPC); industry representative, interview by USITC staff, October 23, 2019; industry representative, interview by USITC staff, November 26, 2019; foreign government representative, interview by USITC staff, January 8, 2020; industry representative, interview by USITC staff, March 5, 2020.

[688] Before the adoption of Regulation 1107/2009, the EU reportedly operated with a risk-based approach, under Directive 414/1991. EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, II-21, II-92; industry representatives, interview by USITC staff, March 5, 2020; Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 20.

[689] Bryant Christie, *Estimation of Potentially Affected Agricultural Imports*, October 2017, 2; industry representative, interview by USITC staff, October 24, 2019; industry representative, interview by USITC staff, February 13, 2020; Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 20; EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, II-92.

[690] There has been one instance when an active substance was non-approved because it met environmental, hazard-based criteria. European Commission government official, email to USITC staff, April 28, 2020.

plants, animals, or the environment.[691] However, several industry representatives have suggested that the application of hazard-based criteria and the precautionary principle was a significant contributing factor to the nonrenewal of some substances. They report that in these instances EFSA has not identified significant risks, but rather reported that the safety of an active substance could not be confirmed due to insufficient data.[692] Industry representatives report that if active substance applications are denied based on the cutoff criteria, the MRL is generally set at 0.01 ppm, potentially limiting pesticide availability.[693]

A number of studies have estimated the number of pesticides that might be removed from the EU market as a result of the cutoff criteria and the impact this would have on agricultural production. While one report estimated that 5 percent of active substances could be expected to trigger cutoff criteria and be removed from the market, several member states and other reports estimated that much higher shares of pesticides could be impacted.[694] One 2017 study concluded that the cutoff criteria could affect as many as 58 current active substances covering nearly $80 billion (€70 billion) worth of agricultural products. This could represent as much as 60 percent of the total value of EU agricultural imports.[695] This study listed Central and South America and Africa as the regions most likely to be significantly impacted by the removal of certain EU MRLs under the cutoff criteria.[696] This is partly due to the large volume of agricultural trade between these markets and the EU, as well as the limited number of alternative export markets.[697]

In addition to losing authorization to use an active substance in the EU, industry representatives have expressed concern that it may not be possible to secure an import tolerance if the pesticide involved triggers the cutoff criteria.[698] Although triggering the cutoff criteria in the EU does not automatically cancel or preclude the establishment of associated import tolerances, their status may be uncertain in part because there have been indications that these pesticides will be considered on a case-by-case basis. It has also been reported that import tolerances for pesticides that triggered the EU's cutoff

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[691] European Commission government official, email to USITC staff, April 28, 2020; EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, II-27.
[692] Industry representative, interview by USITC staff, October 23, 2019; industry representative, interview by USITC staff, October 24, 2019; industry representative, interview by USITC staff, October 30, 2019; industry representative, interview by USITC staff, November 26, 2019; industry representative, interview by USITC staff, January 8, 2020; industry representative, interview by USITC staff, February 13, 2020; U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 21–22.
[693] Industry representative, interview by USITC staff, January 7, 2020; industry representative, interview by USITC staff, February 13, 2020; U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 22.
[694] EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, II-25–II-27.
[695] Bryant Christie, *Estimation of Potentially Affected Agricultural Imports*, October 2017, 7–8.
[696] Bryant Christie, *Estimation of Potentially Affected Agricultural Imports*, October 2017, 7–12.
[697] Nearly half of the value of the agricultural products covered by these potential MRL reviews are fruit and nuts, groundnuts, and oilseeds. Bryant Christie, *Estimation of Potentially Affected Agricultural Imports*, October 2017, 7–12.
[698] Industry representative, interview by USITC staff, October 24, 2019; industry representative, interview by USITC staff, January 7, 2020; industry representative, interview by USITC staff, January 8, 2020; industry representative, interview by USITC staff, March 10, 2020; USITC, hearing transcript, October 29, 2019, 127 (testimony of Christopher Novak, CropLife America); U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 22.

criteria have recently been reduced to the default MRL.[699] (See "Inability to Secure an Import Tolerance" below.) Without an import tolerance for many of these pesticides, the already limited access of growers (particularly in developing-country markets) to the crop protection tools needed to alleviate pest pressures for crops exported to the EU market would shrink even further. (See "MRL-related Challenges in the Agricultural Supply Chain," below.)[700]

Guidance Documents in the EU

While EU regulations themselves have not changed significantly since Regulation (EC) No 396/2005 and Regulation (EC) 1107/2009 were issued over a decade ago, industry representatives have noted that the EU's issuance of numerous and frequently updated guidance documents has created a number of challenges for registering/renewing active substances (or pesticides) and securing MRLs.[701] The EU has dozens of technical and procedural guidance documents that provide guidelines on complying with the 2005 and 2009 regulations related to registration/renewal of active substances and establishing MRLs.[702] Some guidance documents elaborate on information in previous regulations, such as how environmental impact assessments apply to organisms like bees.[703] Others clarify data requirements in dossiers, such as what data are needed to assess potential "endocrine disruptors" for purposes of meeting the cutoff criteria in an application (see box 4.2).[704]

A number of stakeholders report that EU guidance documents create confusion and uncertainty and add complexity to the process of registering an active substance and securing an MRL because they can be overly broad, often overlap, and are published frequently.[705] Registrants have noted that the nature and the frequency of the updated guidance in many cases has created uncertainty about what data to collect to support their application, what information to submit, and even whether there is sufficient economic incentive to submit an application.[706] Additionally, the timing of the publication of certain guidance

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[699] Industry representative, interview by USITC staff, October 24, 2019; industry representatives, interview by USITC staff, January 7, 2020; industry representative, interview by USITC staff, January 8, 2020; industry representative, interview by USITC staff, January 10, 2020; U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 22; ASA and USSEC, written submission to USITC, December 13, 2019, 5.
[700] Industry representative, interview by USITC staff, December 2, 2019; industry representative, interview by USITC staff, February 19, 2020.
[701] Industry representative, interview by USITC staff, January 7, 2020; industry representative, interview by USITC staff, January 8, 2020; EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, II-33.
[702] A number of guidance documents and standards are used in the EU. The European Commission and EFSA are among the bodies responsible for developing these documents, but some guidance documents published by international organization, such as the OECD, are also used in the EU processes. Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 173.
[703] In 2013, the European Commission requested that EFSA create a guidance document highlighting the environmental risk of active substances on bees. This guidance document now serves as guidance for future registrants in identifying any particular harm to bees which may occur in the application of pesticides to crops. This guidance was later updated in 2014. EFSA, "Guidance on the Risk Assessment," July 4, 2013.
[704] Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 193–95.
[705] Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 172; EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, 45–46, II-33; industry representative, interview by USITC staff, January 7, 2020.
[706] Industry representative, interview by USITC staff, January 7, 2020; industry representative, interview by USITC staff, February 13, 2020.

documents has also caused concern.[707] The European Commission has indicated that a guidance document published after a dossier has been submitted will not apply to that dossier; however, in practice, EFSA might note on an application that certain aspects do not meet the updated guidance document requirements.[708]

In response to these and other industry concerns, the European Commission has indicated that it considers guidance documents to be part of its ongoing efforts to improve transparency and adapt to advances in technology and analysis.[709] The European Commission also asserts that it seeks and incorporates input from all stakeholders when developing these documents.[710] Further, they note that they make use of international forums when appropriate to attempt to reach agreement on processes and requirements internationally.[711]

Box 4.2 Endocrine Disruptors

One recent guidance document of particular concern to both pesticide manufacturers and growers pertains to the ongoing debate about endocrine disruptors, which are included among the EU's cutoff criteria.[a] Generally, endocrine disruptors are chemicals which, under certain conditions, can impact the endocrine (hormonal) system of humans and animals.[b] As established under Regulation (EC) 1107/2009, the EU will approve an active substance for domestic use only if it is determined not to have carcinogenic, mutagenic, reproductive, or endocrine disrupting properties and that it is not a persistent organic pollutant. However, the criteria for how to define an endocrine disruptor were not provided in the regulation. In 2017 the European Commission adopted criteria that tasked EFSA and ECHA with defining what constitutes an endocrine disruptor.[c] In June 2018, following consultation with the public and stakeholders, a guidance document was released to address endocrine disruptors in both biocides (poisons for non-agricultural use) and pesticides.[d]

Industry representatives have stated that this 2018 guidance provides an overly broad definition of what constitutes an endocrine disruptor, as experts are still deeply divided over the definition. Since endocrine disruptors are among the EU's cutoff criteria, industry representatives fear that the expansive definition outlined in the guidance document could trigger the non-approval or nonrenewal of many active substances, with some suggesting that hundreds of substances could potentially be phased out.[e] Firms that had already submitted active substance applications or renewals for approval when the document was released have been given a 30-month "stop the clock" step in the regulatory process so they can gather enough data about the potential endocrine-disrupting qualities in the active substances for the EU authorities to come to a decision about them.[f] However, industry representatives believe that

[707] Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 173–74; EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, II-33; industry representative, interview by USITC staff, January 7, 2020; industry representative, interview by USITC staff, January 8, 2020.
[708] EFSA, written responses to the PEST committee's preparatory questions for the April 12, 2018, hearing, 6 (accessed March 9, 2020); industry representative, interview by USITC staff, January 7, 2020; industry representative, interview by USITC staff, January 8, 2020.
[709] European Commission, responses to the PEST Committee's preparatory questions for the June 19, 2018, hearing, n.d., 4–5 (accessed March 9, 2020).
[710] European Commission, responses to the PEST Committee's preparatory questions for the June 19, 2018, hearing, 4 (accessed March 9, 2020); EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, II-6.
[711] European Commission government representative, email to USITC staff, April 28, 2020.

EFSA will likely need extra time to conduct its own assessments using the new endocrine disruptor guidance, extending the approval process further.[g]

The European Commission acknowledges that endocrine disruption is a fairly new way of looking at the toxicity of pesticides, and also states that, in general, they continually work to clarify definitions and requirements while also considering established health requirements.[h] Nonetheless, stakeholders are concerned that the broadness of the definition of "endocrine disruptors" might lead to the removal of a number of important pesticides from the market and that this additional criterion will further delay an already long approval process.[i]

[a] Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 193–194; EPRS, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market, April 2018, I-14; industry representative, interview by USITC staff, February 13, 2020.
[b] OECD, "OECD Work Related to Endocrine Disruptors," 6–9 (accessed May 1, 2020); European Commission, "Endocrine Disruptors" (accessed March 20, 2020).
[c] European Commission, "Endocrine Disruptors," (accessed March 20, 2020); EFSA, "Guidance on Identifying Endocrine Disruptors Published," June 7, 2018.
[d] EFSA, "Guidance for the Identification of Endocrine Disruptors," June 2018; European Commission, responses to the PEST Committee's preparatory questions for the June 19, 2018, hearing, 4 (accessed March 9, 2020).
[e] EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, II-45; industry representative, interview by USITC staff, January 7, 2020; industry representative, interview by USITC staff, February 13, 2020.
[f] Industry representative, interview by USITC staff, January 8, 2020; industry representative, interview by USITC staff, February 13, 2020.
[g] Industry representative, interview by USITC staff, January 8, 2020; industry representative, interview by USITC staff, February 13, 2020.
[h] European Commission, "Endocrine Disruptors: Overview" (accessed April 6, 2020); European Commission, responses to the PEST Committee's preparatory questions for the June 19, 2018, hearing, 4–5 (accessed March 9, 2020).
[i] Industry representative, interview by USITC staff, January 8, 2020; industry representative, interview by USITC staff, February 13, 2020; industry representative, interview by USITC staff, February 19, 2020.

The Emergency Use of Pesticides in the EU

In certain circumstances, some national authorities (or sometimes jurisdictions within countries) may allow domestic growers to use pesticides that are otherwise prohibited for use, while not permitting imports of agricultural products treated with that pesticide. While emergency use provisions are common in most markets, (see box 4.3), the way they are implemented in the EU is of concern to exporters. Industry representatives are particularly concerned that such emergency use provisions in the EU may undercut the competitiveness of imported agricultural products. Industry representatives also believe that the increasing use of these provisions by EU member states is a result of the removal of certain active substances from the EU market. In those cases, some stakeholders suggest that these provisions enable growers in certain member states to effectively opt out of complying with the EU's pesticide restrictions, giving domestic growers an advantage over foreign suppliers of affected crops.[712]

[712] Industry representative, interview by USITC staff, November 26, 2019; industry representative, interview by USITC staff, January 7, 2020; industry representative, interview by USITC staff, March 5, 2020; industry representative, interview by USITC staff, March 10, 2020.

Box 4.3 Examples of Emergency Use Provisions in Practice

Typically, authorities approve the emergency use of unapproved or unregistered pesticides in circumstances where a pest outbreak has been detected that could cause substantial harm to an agricultural commodity. An emergency use provision is generally regarded as a safety valve to prevent widespread agricultural crop or environmental damage. These provisions can also cover cases where an MRL exists for some pesticide/crop combinations but not others, and a pest outbreak targeting a non-covered pesticide/crop combination poses immediate threats to the environment, economy, or human health. For example, Canada permits the temporary emergency use of pesticides on a specific crop in Canada as long as the active substances are registered for use on other crops in Canada. These emergency uses cannot exceed one year and cannot be renewed.[a] Recent examples include using *Bacillus thuringiensis* in Ontario for an outbreak of box tree moth on boxwood trees, flonicamid for lygus bugs on peppers, and mancozeb in several Canadian provinces on Christmas trees.[b]

[a] Government of Canada, "Registration of Pesticides for Emergency Use" (accessed January 30, 2020).
[b] Government of Ontario (Canada), Ministry of Agriculture, Food, and Rural Affairs, "Emergency Use Registrations" (accessed January 16, 2020).

In the EU, member states are allowed to grant emergency use of pesticides that either are not authorized for use in that country or include active substances not approved for use in the EU, while imports of crops on which those pesticides have been used may not be permitted.[713] In the EU, member states have employed emergency-use provisions with increasing frequency in recent years (figure 4.2): there were approximately 200 authorizations in 2011, 680 authorizations in 2018, and 513 authorizations in 2019 .[714] Industry stakeholders suggest that the increasing number of emergency-use authorizations may be due to the loss of adequate pesticides in the EU market due to their nonrenewal, which often results in the MRLs being lowered to default levels.[715]

For example, in 2010, the pesticide 1,3-dichloropropene (a pre-plant fumigant) was not renewed and a subsequent 2013 report from EFSA noted that there were no EU MRLs or import tolerances for this substance.[716] Since then, 1, 3-dichloropropene has been authorized for emergency use more than 40 times in Portugal, Greece, Italy, Spain, Malta, Cyprus, and France. As a result, a diverse array of crops, including strawberries, tomatoes, eggplants, peppers, watermelons, lettuce, broccoli, carrots, and

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[713] Industry representative, interview by USITC staff, October 3, 2019; industry representative, interview by USITC staff, March 5, 2020. The ability to grant emergency use of pesticides by member states in the EU is governed by article 53 of Regulation (EC) 1107/2009. EC, Regulation (EC) No 1107/2009, article 53, 2009.
[714] EU member states have the authority to designate the use of pesticides for emergency use in their own country only. This authorization is only for a period of no more than 120 days/year. This can mean a 120-day fixed period, or 120 days split over growing periods. This regulation is set out in Article 53 of Regulation (EC) 1107/2009. EU Pesticides Database, "Search for Emergency Authorisations," European Commission (accessed February 14, 2020); EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, 52.
[715] EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, I-36; Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 47; industry representative, interview by USITC staff, January 7, 2020; industry representative, interview by USITC staff, March 10, 2020.
[716] The report states: "Considering that this active substance is no longer authorized within the European Union, [and] that no MRLs are established by the Codex Alimentarius Commission, . . . residues of 1,3-dichloropropene are not expected to occur in any plant or animal commodity. " The report also noted that "the default MRL of 0.01 ppm, as defined by Regulation (EC) No 396/2005, provides a satisfactory level of protection for the European consumer." EFSA, "Reasoned Opinion on the Review of the Existing Maximum Residue Levels (MRLs) for 1,3-Dichloropropene," 2013, 1–3.

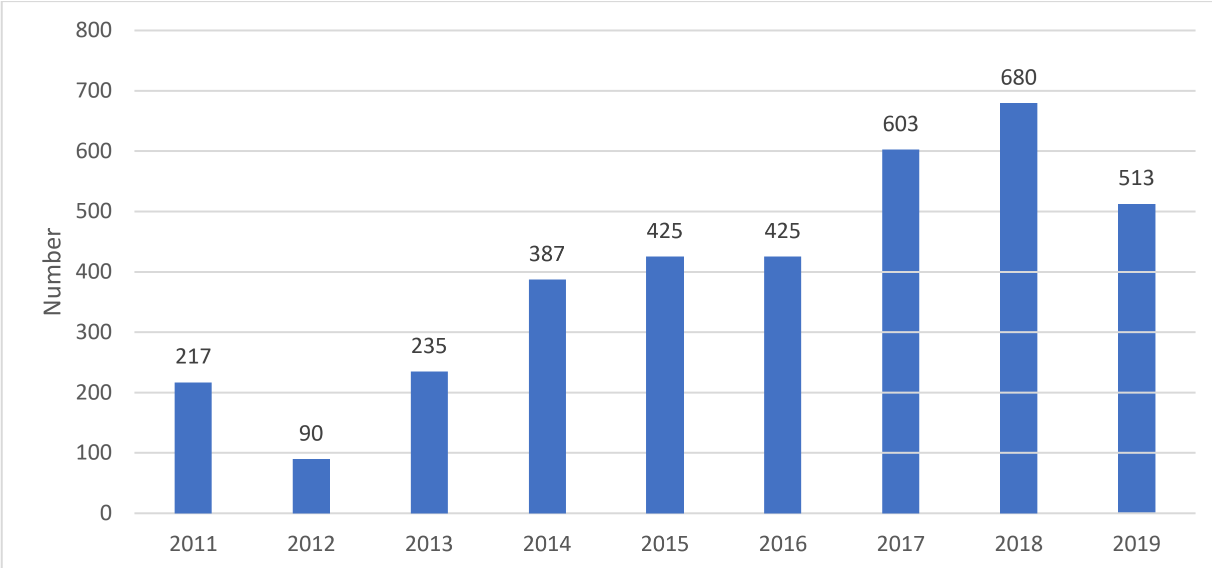
potatoes, have been grown in certain member states using pesticides that are unavailable to their foreign competitors.[717] According to the European Commission, crops treated with a pesticide resulting from emergency use may not leave the member state in which they were grown. However, industry representatives suggest that there is no means by which the EU can restrict the movement of these agricultural goods across EU borders. In contrast, non-EU imports of these crops can more easily be restricted.[718]

The European Commission has taken steps to examine domestic emergency use authorizations and has issued warnings to member states about their potential abuse. Various sources report that most of these authorizations are for pesticides containing active substances that are approved by the EU but where the pesticide lacks member state authorization or authorization for minor uses.[719] The European Commission itself has estimated that these constitute up to 90 percent of EU emergency-use authorizations.[720]

However, at least some of these emergency authorizations have been for pesticides containing active substances that are not approved for use in the EU.[721] In 2017, the European Commission asked EFSA to assess the emergency authorizations for pesticides containing clothianidin, imidacloprid, and thiamethoxam to determine if there were no suitable alternatives, as required for the emergency authorizations.[722] In February 2019, as a result of this review, the European Commission sent a warning to two EU member states, Lithuania and Romania, over potential abuse of emergency authorizations for these pesticides.[723] The European Commission subsequently drafted a decision which would legally prevent member states from granting emergency authorizations to use these specific pesticides in their domestic crops, and in February 2020, it instructed Lithuania and Romania to halt the emergency use of these pesticides on their crops.[724]

[717] EU Pesticides Database, "Search for Emergency Authorisations" (accessed February 14, 2020); EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, I-42–I-46.
[718] European Commission government official, email to USITC staff, April 28, 2020; industry representative, interview by USITC staff, November 26, 2019; foreign government representative, interview by USITC staff, January 8, 2020.
[719] EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, 10, 58, I-9, I-36; Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 46–47; European Commission, answers to questions from the PEST Committee hearing on April 12, 2018, 11–12.
[720] EU Pesticides Database, "Search for Emergency Authorisations" (accessed February 14, 2020).
[721] EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, 10, 57–58.
[722] European Commission, DG SANTE, "Commission Implementing Decision (EU) 2020/153 of 3 February 2020," February 3, 2020.
[723] Stam, "EU Commission to Crack Down," February 26, 2019; European Commission, DG SANTE, "Commission Implementing Decision (EU) 2020/153 of 3 February 2020," February 3, 2020; European Commission, DG SANTE, "Commission Implementing Decision (EU) 2020/152 of 3 February 2020," February 3, 2020.
[724] Stam, "EU Commission to Crack Down," February 26, 2019; ENDS Europe, "Romania and Lithuania Ordered to Cease," February 3, 2020; European Commission, DG SANTE, "Commission Implementing Decision (EU) 2020/153 of 3 February 2020," February 3, 2020; European Commission, DG SANTE, "Commission Implementing Decision (EU) 2020/152 of 3 February 2020," February 3, 2020.

Figure 4.1 Emergency use authorizations of pesticides by EU member states, 2011–19



Source: Data for 2011–16 from Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 24. Data for 2017–19 from EU Pesticides Database, "Search for Emergency Authorisations" (accessed February 14, 2020). Data for 2012 may be incomplete.

Bans of Pesticides by EU Member States

Governments may ban the use of an active substance (or pesticide) for a variety of health and environmental concerns, often in the framework of international agreements like the Rotterdam Convention and the Stockholm Convention on Persistent Organic Pollutants. However, pesticide manufacturers and growers have noted that some EU member states' recent pesticide bans and their proposals for bans despite EU-wide approval have introduced uncertainty about whether agricultural goods treated with these pesticides can be imported and whether the active substances in those pesticides will eventually be banned in the EU. Although these member state pesticide bans are meant to apply only to domestic use, manufacturers and growers exporting to the EU have pointed to recent developments which suggest that these bans may in fact impact exported crops bound for EU member state markets.

Two recent bans in particular—one in France on dimethoate, and a proposed ban in Austria on the use of the herbicide glyphosate—are concerning to both growers and pesticide manufacturers. In 2016, France banned the domestic use of the insecticide dimethoate, but in April 2019, France expanded its ban to halt imports of agricultural products that contained dimethoate (despite an existing EU MRL for dimethoate at the time).[725] The French ban negatively affected exports of products, including U.S. cherries, to the French market, raising questions about the legality of single member states banning agricultural products treated with EU-approved active substances.[726] While dimethoate was not renewed in the EU in May 2019, eliminating the discrepancy between EU approval of the active substance and France's ban on pesticides containing it, growers remain concerned about the possibility

[725] USDA, FAS, *France: France Continues Ban on U.S. Cherries*, May 8, 2019.
[726] CCB, written submission to USITC, December 11, 2019, 6; industry representative, interview by USITC staff, March 10, 2020.

of future bans by individual states that are inconsistent with EU approvals of active substances and the impacts they might have on product imports into the EU.[727]

In April 2019, Austria's parliament passed legislation proposing to end the use of pesticides containing glyphosate in Austria's market, despite the EU's 2017 renewal of the active substance.[728] Glyphosate is a major crop protection chemical for a number of globally important export crops, including soybeans, cotton, alfalfa, and sugar beets. A ban on glyphosate use would represent a substantial challenge for all growers in these sectors in addition to those who export to the EU, as glyphosate is one of the most widely-used pesticides globally.[729] Although this ban has not been adopted, some stakeholders have raised questions about whether Austria's proposed ban is legal under EU regulations for both active substances and MRLs.[730] Glyphosate has received an extension for use until 2022 in the EU, and a four-country consortium (France, the Netherlands, Hungary, and Sweden) is currently evaluating an application to reapprove glyphosate in the EU market, which will then move to EFSA for evaluation.[731]

Inability to Secure an Import Tolerance

Import tolerances are sometimes used to help mitigate trade problems that can occur when an import market does not have an MRL in place for a pesticide/crop combination needed by exporting growers or when the existing MRL is lower than that of the exporting market.[732] These can be particularly important if an importing market does not grow the crop or use the pesticide. Import tolerances facilitate trade in agricultural products because the application process for them is easier and less costly than the alternative, which is to register a pesticide for use within each export market. However, in some major markets, pesticide manufacturers and growers report that it is either not possible to secure an import tolerance or that uncertainty in the import tolerance process can pose a risk. Brazil and China are two examples of major markets where it is reportedly not possible to secure import tolerances.[733] In the EU, stakeholders have expressed concern about the fact that existing import tolerances for pesticides that lose their registration in the EU may be canceled, and MRLs may thereafter be set at the default level. Stakeholders have reported that in these instances, growers may be left with few available pesticides to

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[727] European Commission, DG SANTE, "Final Review Report for the Active Substance Dimethoate," May 21, 2019, 1–2.
[728] Tidey, "Austrian MPs Vote to Completely Ban Glyphosate," April 7, 2019; EC, DG SANTE, "Final Review report for the active substance glyphosate," November 9, 2017, 4-5.
[729] Benbrook, "Trends in Glyphosate Herbicide Use," 2016.
[730] Michalopoulos, "Farmers Hope EU Commission Will Block Austria's Glyphosate Ban," July 11, 2019; industry representative, interview by USITC staff, March 10, 2020.
[731] Michalopoulos, "Farmers Hope EU Commission Will Block Austria's Glyphosate Ban," July 11, 2019.
[732] Only a limited number of markets have a formal regulatory procedure for establishing import tolerances. These include Australia, Canada, the EU, Hong Kong, Japan, Russia, South Korea, Taiwan, and the United States. CLA, "Challenges to Establishing Harmonized Maximum Residue Levels," August 2014, 14. California Table Grape Commission, written submission to USITC, November 15, 2019, 15; U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 17.
[733] Industry representative, interview by USITC staff, March 5, 2020; APC, written submission to the USITC, December 6, 2019, 4; Cranberry Institute, written submission to the USITC, December 11, 2019, 8; USHIPPC, written submission to the USITC, December 13, 2019, 8; U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 17; CCB, written submission to USITC, December 11, 2019, 5.

use and the uncertainty about whether pesticide manufacturers will seek to secure import tolerances to replace those MRLs.[734]

When there is no effective process for securing an import tolerance, the alternative is to secure an MRL based on domestic use in the target market, even if the pesticide is not intended to be used in that market.[735] Some industry representatives, including those in the U.S. cranberry industry, have indicated that this is a problem in China.[736] For example, even though China has limited domestic cranberry production, an exporter would need to register a pesticide and secure an MRL in China in order to export cranberries treated with that pesticide to China. This would entail gathering data to support a pesticide registration in compliance with Chinese requirements, as well as conducting crop field trials in China to support an MRL application. These complex and expensive steps are not incurred when requesting an import tolerance.[737] Further, according to the Cranberry Institute, due to the limited production of cranberries in China, conducting these tests would be at least difficult and potentially impossible.[738]

In some markets where there are no effective processes to secure import tolerances, some alternatives to registering a pesticide and applying for a domestic use MRL may exist in practice. For instance, Brazil's agricultural ministry has noted that in the absence of a relevant MRL, a Codex MRL may be incorporated or accepted as an import tolerance.[739] China reportedly may also accept a Codex MRL as an import tolerance in the absence of an MRL of their own.[740] Additionally, industry representatives report that both Brazil and China have unofficially indicated that they may accept the producing country's MRL as an import tolerance in the absence of their own MRL or a Codex MRL. In spite of this, industry representatives have highlighted that there is uncertainty about the lack of processes to secure import tolerances in both of these markets and that this has created challenges for pesticide manufacturers and exporters in the past and may continue to do so further in the future.[741]

Exporters to the EU face different challenges related to import tolerances. Several industry representatives have noted that the EU processes are not clear about whether import tolerances will

[734] Foreign government representative, interview by USITC staff, October 22, 2019; industry representative, interview by USITC staff, February 13, 2020.
[735] CFFA, written submission to USITC, December 12, 2019, 5; NPC, written submission to USITC, December 10, 2019, 9.
[736] Industry representative, interviews by USITC staff, March 5, 2020; Cranberry Institute, written submission to USITC, December 11, 2019, 8; NPC, written submission to USITC, December 10, 2019, 9; CFFA, written submission to USITC, December 12, 2019, 5; CCB, written submission to USITC, December 11, 2019, 6; ABC, written submission to USITC, December 13, 2019, 7.
[737] Industry representatives, interviews by USITC staff, February 13, 2020; USITC, hearing transcript, October 29, 2019, 93 (testimony of Terry Humfeld, Cranberry Institute); CFFA, written submission to USITC, December 12, 2019, 5; NPC, written submission to USITC, December 10, 2019, 9.
[738] USITC, hearing transcript, October 29, 2019, 93–94 (testimony of Terry Humfeld, Cranberry Institute).
[739] Government of Brazil, MAPA, "Brazil MRL Update," June 2016, 36.
[740] USITC, hearing transcript, October 29, 2019, 94 (testimony of Terry Humfeld, Cranberry Institute); industry representative, interview by USITC staff, March 5, 2020; CFFA, written submission to USITC, December 12, 2019, 5.
[741] Industry representative, interview by USITC staff, March 5, 2020.

remain in place if the registration for an active substance is not renewed (box 4.4).[742] Exporters to the EU note that a 2018 European Commission document states that while import tolerance applications will not be automatically rejected in these instances, they will be granted only on a case-by-case basis; the EU's decision may also take into account "other legitimate factors," as well as the precautionary principle.[743] Exporters also note that "other legitimate factors" have not been defined in the legislation and suggest that this stipulation leaves much room for interpretation.[744] Finally, industry representatives have expressed concern that when an active substance is not approved for domestic use in the European Union or an existing MRL has been lowered, they may not be able to secure an import tolerance.[745] However, the European Commission has noted that an import tolerance is not automatically denied as a result of actions taken on an active substance.[746]

Box 4.4 Uncertainty in Securing Import Tolerances in the EU and the Role of the European Parliament

A number of factors reportedly contribute to stakeholders' uncertainty about securing an import tolerance in the EU. In particular, the role of the European Parliament and the political pressures EU stakeholders may exert on the process are ongoing sources of concern for pesticide manufacturers and growers globally.[a]

While the EU processes for registering pesticides and for securing MRLs or import tolerances are similar (see chapter 3), the role of the European Parliament differs between the two.[b] Notably, the Parliament's vote on the approval or non-approval of registration for active substances is advisory and non-binding, though it is taken into account. In contrast, the Parliament's vote on the European Commission's recommendation for an MRL or an import tolerance is binding, and the proposed MRL or import tolerance cannot be established if the Parliament rejects it.[c]

The European Parliament first exercised this discretionary authority over import tolerances in March 2019, when it voted not to approve an import tolerance for clothianidin used on potatoes from Canada.[d] Clothianidin, a neonicotinoid which was already banned in the EU for domestic use, is widely used on corn, soybeans, leafy greens, and fruits to control thrips, aphids, and beetles.[e] Clothianidin was banned for use in the EU in 2018 due to concerns about environmental impacts, namely its effects on bees.[f] Industry representatives report that while these types of environmental impacts are part of the risk assessment for registering an active substance for domestic use in each market, they

[742] ASA and USSEC, written submission to USITC, December 13, 2019, 5; USITC, hearing transcript, October 29, 2019, 67–68 (testimony of Terry Humfeld, Cranberry Institute); industry representative, interview by USITC staff, January 7, 2020; industry representative, interview by USITC staff, January 10, 2020; industry representative, interview by USITC staff, March 10, 2020; U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 22; industry representative interview by USITC staff, October 24, 2019; industry representative, interview by USITC staff, January 7, 2020.
[743] ASA and USSEC, written submission to USITC, December 13, 2019, 5; ABC, written submission to USITC, December 13, 2019, 5; U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 22.
[744] ASA and USSEC, written submission to USITC, December 13, 2019, 5; U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 22.
[745] U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 22; industry representative, interview by USITC staff, October 24, 2019; industry representative, interview by USITC staff, January 7, 2020; industry representative, interview by USITC staff, January 10, 2020; industry representative, interview by USITC staff, March 10, 2020.
[746] European Commission, written submission to USITC, December 13, 2019, 17, 29.

are not a part of the risk assessment for import tolerances. This is because when governments assess proposed import tolerances, their evaluation is typically based on the human health impacts of predicted pesticide residues. Assessment of an import tolerance does not envision the production and the use of the pesticide, or the environmental impacts of such activities, in the evaluating government's own market.[g]

The European Parliament's resolution, however, noted concerns about the impact of clothianidin on pollinators on a global scale, which industry representatives suggest is unprecedented.[h] Industry representatives are concerned that Parliament might vote again in the future against the Commission's recommendations to approve an import tolerance. Such a pattern, given the large size of the EU market, would effectively mandate limits on pesticide use globally, according to stakeholders.[i]

[a] ASA and USSEC, written submission to USITC, December 13, 2019, 5; U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 23; USITC, hearing transcript, October 29, 2019, 127–8 (testimony of Christopher Novak, CLA); industry representative, interview by USITC staff, January 8, 2020; foreign government official, interview by USITC staff, January 8, 2020.
[b] Industry representative, interview by USITC staff, February 13, 2020.
[c] Because the EU's regulations on establishing MRLs and import tolerances were passed before its regulations approving active substances, the Parliament's role is slightly different in each. Industry representative, interview by USITC staff, February 13, 2020; EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, 19.
[d] European Parliament, "Objection to an implementing act: Maximum residue levels for several substances including clothianidin," March 13, 2019; ASA and USSEC, written submission to USITC, December 13, 2019, 5.
[e] Minnesota Department of Health, "Clothianidin and Drinking Water," May 2016.
[f] European Commission, DG SANTE, "Addendum to the Review Report for the Active Substance Clothianidin," April 27, 2018.
[g] Industry representative, interview by USITC staff, February 13, 2020.
[h] Industry representative, interview by USITC staff, November 26, 2019; industry representative, interview by USITC staff, January 8, 2020; foreign government representative, interview by USITC staff, January 8, 2020; industry representative, interview by USITC staff, February 13, 2020.
[i] Foreign government representative, interview by USITC staff, October 22, 2019; industry representative, interview by USITC staff, October 23, 2019; industry representative, interview by USITC staff, January 8, 2020.

MRL-related Challenges in the Agricultural Supply Chain

Growers increasingly face different MRLs for the same pesticide/crop combination in different markets, including when an MRL is low or missing in a key market. These situations can pose a variety of challenges for producers, who must minimize or eliminate the use of a pesticide on agricultural commodities shipped to those export markets. While these challenges may affect many participants in the supply chain, including processors, exporters, and governments, much of the cost is incurred by the growers. Growers of crops in certain sectors that are relatively organized are more likely to be able to adjust to changes in MRLs without trade disruption than are growers in less well-organized sectors.[747] With greater organizational capacity, crop sector representatives can inform growers of changes to MRLs and of the availability of alternative pesticides and practices. In some instances, they can also work with registrants or regulatory bodies to secure MRLs or new registrations for alternative pesticides.[748]

[747] Foreign government representative, interview by USITC staff, January 8, 2020.
[748] Foreign government representative, interview by USITC staff, January 8, 2020.

This section will explore several of the diverse challenges growers experience and how they react when MRLs in their key export markets change. The first part of this section will describe challenges associated with different MRL-setting policies, including divergence in market defaults in cases where an MRL is missing; transition periods when MRLs are changed; and disharmony in MRL exemptions. The second part of this section will describe responses to the challenges growers and exporters face when an MRL is lowered or eliminated in a key export market. In these instances, growers and exporters must either identify alternate markets for their agricultural production or identify and use alternative pesticides that will ensure compliance with the new MRL. The third part of the section describes the general costs of compliance with MRLs. The fourth part describes the high costs that can result from an MRL violation.

Varying MRL Policies

Because of the differences in MRL-setting policies described above, producers often note that the resulting variation among export markets creates challenges for them. The three major challenges producers identified in this area were differences in default MRLs, short transition periods for MRL changes, and disharmony in the list of products that are exempt from MRL requirements.

Default MRL Policies

As described in chapter 1, many export markets have default MRL policies in place to accommodate instances when an MRL has not been established. Markets may use default MRLs that defer to Codex MRLs, or to MRLs in other markets, or to a numerical default. Some default policies are easier for growers to comply with than others, depending on how the policies relate to growing conditions and pest pressures for a particular crop. A number of growers and pesticide manufacturers have expressed a preference for MRL policies that set a numerical default rather than markets that do not, since the latter effectively establish a default of zero (i.e., create a zero tolerance for a pesticide on that particular crop) and can impact trade to a greater extent.[749]

Growers may prefer a numerical default MRL instead of a zero tolerance because a default value greater than zero can accommodate some limited use of the pesticide in certain cases. Industry representatives have noted that a numerical default, even if extremely low, may allow them to adjust use patterns (for example, by using the pesticide in lower quantities or at earlier stages in the growing process). In this way some growers can still use the pesticide to resolve pest issues while complying with MRLs in the export market. For other exporters, other crops, or for other uses, however, a low numerical default may be too restrictive to allow for exports.

If there is zero-tolerance for residues, any detected level of an unapproved active substance could lead to a rejected shipment. Consequently, in these markets, the number of existing MRLs and the ease with which stakeholders can apply for import tolerances is particularly important. For examples of how default policies affect crop exports, chapter 5 of this report explores the effects of default policies on avocado and mango exports.

[749] Industry representative, interview by USITC staff, December 12, 2019; Yeung et al., *Declining International Cooperation on Pesticide Regulation,* 2017, 21–22.

Transition Periods for New MRLs

When MRLs are lowered in an import market, national authorities in the import market set transition periods of varying lengths to give producers time to adjust. Growers report that some transition periods are too short to allow them time to comply—in some cases, they are as short as a few months. Growers particularly report concerns when transition periods are shorter than growing seasons or are implemented too late in the growing season for meaningful adjustments in production practices to be made. Short transition periods are also problematic because they do not account for the time that agricultural products spend in processing, in transit, and on store shelves. These short transition periods affect both fresh and processed products, with particular challenges for processed products that remain in storage for longer periods.

One example of how brief MRL transition periods can affect fresh produce occurred in the Asian banana market. The Philippine banana industry, which supplies 97 percent of the South Korean market, would have been negatively impacted by changes in South Korea's MRLs in 2014, when South Korea lowered its MRL for iprodione on bananas from 5 to 0.02 ppm with a very short transition time. Philippine banana growers cautioned that if a longer transition period to find alternatives was not granted, this abrupt change could cause a major trade disruption, with short supply and high prices in the South Korean market. In the end, the South Korean government granted several import tolerances for bananas that allowed Philippine exports to continue.[750]

For agricultural products with a longer shelf life, a short transition period to a lower MRL can have an even greater impact on agricultural trade.[751] Examples include commodities that are dried (like figs), that have a long shelf life naturally (like nuts), or that are further processed (like wine), as well as those that can be frozen for long periods.[752] Sometimes MRL changes can occur after crops have been harvested for foreign markets but before they are exported. Additionally, the treatment of goods that have been imported into a market but held in storage is reportedly unclear.[753]

For instance, the California Association of Winegrape Growers and the Wine Institute noted that the elimination of MRLs can create imbalances between domestically produced wines in foreign markets and U.S. wine exports to those markets. Wines in the EU are considered exempt from new MRL standards if they have already been "placed in market" before the change. Industry representatives report that shelf life regulations can allow wines produced in the EU to be identified as "placed in market" even if they are simply resting in EU warehouses. However, according to these representatives, wines produced in foreign markets may be considered "placed in market" only upon import. Because wines are not released for export until they have aged a certain period of time, it is possible that wines produced in a foreign market and ones produced in the EU with the same originally legal pesticide use

[750] Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 62–63.
[751] Foreign government representative, interview by USITC staff, January 8, 2020; ABC, written submission to USITC, December 13, 2020, 5; Wine Institute and CAWG, written submission to USITC, December 13, 2019, 5.
[752] NPC, written submission to USITC, December 10, 2019, 4; ABC, written submission to USITC, December 13, 2020, 5; Wine Institute and CAWG, written submission to USITC, December 13, 2019, 5.
[753] AFBF, written submission to USITC, December 13, 2019, 2–3; USHIPPC, written submission to USITC, December 13, 2019, 5.

would be subject to different MRL standards, based on the time they are considered to have been "placed in market."[754]

This is also an area of concern for exporters of many edible nuts, including peanuts and almonds, as those products can remain in the "channels of trade," the route from producer to final consumer, for several years.[755] Some growers, particularly those with these longer shelf life products, will phase out the use of pesticides that will lose their relevant MRLs well in advance in order to avoid potential future violations.[756] Further, some representatives note that for products that are produced in the EU, the effective dates for MRLs are applied differently than for imported products, possibly placing imports of these types of long shelf life products at a disadvantage.[757]

This potential issue has also been noted by U.S. hops growers, who face a similar challenge. According to the U.S. Hop Industry Plant Protection Committee, hops are usually converted into pellets or oils for storage and future usage and can remain stored safely for several years.[758] The committee noted that "there is significant concern in the hop industry that a product that was imported into the EU and stored in the EU can be legal one day and then suddenly illegal the next because of an MRL change."[759]

MRL Exemption Policy Disharmony

In many of the United States' major export markets, certain pesticides may be granted exemptions from MRL requirements (i.e., their residue levels are not subject to regulatory limits). Usually, producers, growers, exporters, and importers are not required to seek import tolerances or MRLs for pesticides with MRL exemptions.[760] In order to have a product designated as an exempted pesticide, generally registrants are required to submit the same or similar information as that needed in order to secure an MRL—toxicity data and residue data—as well as evaluations of exemptions from other countries.[761]

This practice can be helpful to growers in certain situations because it allows them to use these exempt pesticides when MRLs for alternative conventional pesticides are missing, lowered, or set to a low default.[762] A pesticide is typically exempted from MRL requirements following an assessment that it does not represent a likely significant health or environmental risk to consumers; in many instances, this

[754] Wine Institute and CAWG, written submission to USITC, December 13, 2019, 5.
[755] ABC, written submission to USITC, December 13, 2019, 5; APC, written submission to USITC, December 6, 2019, 3.
[756] USITC, hearing transcript, October 29, 2019, 96 (testimony of Terry Humfeld, Cranberry Institute); USITC, hearing transcript, October 29, 2019, 18 (testimony of Alinne Oliviera, USHIPPC).
[757] APC, written submission to USITC, December 6, 2019, 3; ABC, written submission to USITC, December 13, 2019, 5.
[758] USHIPPC, written submission to USITC, December 13, 2019, 5; USITC, hearing transcript, October 29, 2019, 18 (testimony of Alinne Oliviera, USHIPPC).
[759] USHIPPC, written submission to USITC, December 13, 2019, 5.
[760] In other instances, there may be markets where certain compounds are used more frequently in domestic production, and those will receive MRL exemptions while other markets maintain MRLs on the same compound. Japan, for example, exempts shiitake mycelia extracts (a type of pesticide which helps break down plant matter) from MRL requirements, while no other market studied for this report offers similar treatment to this product. Government of Japan, Ministry of Health, Labour, and Welfare, "Notification No. 498," 2019, 1.
[761] Kim, "Pesticide MRL Setting and PLS Progress in Korea," May 31, 2017, 43.
[762] Kynetec, *Value of Mancozeb If EU MRLs Are Revoked*, October 18, 2019, 28.

may be due to either its low toxicity or the low exposure risk it poses to crop producers or consumers with normal use.[763]

However, because markets do not consistently exempt the same pesticides, exporting growers must still be careful in using exempt pesticides. For example, oxytetracycline can be used as an organic pesticide on some crops, and in Taiwan it is classified as exempt, meaning that no MRL is required for agricultural crops treated with oxytetracycline. However, in the EU, oxytetracycline is not exempt and its MRLs are set to the default.[764] Consequently, growers using oxytetracycline on crops exported to both these markets could face MRL violations in the EU but successfully export to Taiwan.

Responses to MRL Changes in Key Markets

When national authorities lower pesticide MRLs, growers and exporters respond by either finding alternate markets for their crops or adapting growing practices to meet the new MRL. Otherwise, they risk an MRL violation in the export market. This section describes the challenges associated with finding new markets and with adapting growing practices, usually by finding alternative pesticides.

Finding Alternate Markets

Farmers and exporters who cannot comply with a new export-market MRL may need to find an alternate market for their products. This can be a short-term solution, adopted while growers adapt their practices to comply with a lower MRL, or it can be longer term if it is not possible to alter farming practices to comply with the change. Regardless of the duration, having to switch markets can be difficult and costly for producers, and growers who cannot find alternative markets have to switch products or stop production altogether.

Potential alternate export markets may offer lower prices or have insufficient demand, especially if other producers are also seeking to ship to that market. For example, banana exporters to the EU report that the European market prefers smaller bananas. If there is a situation in which exporters have to ship their smaller bananas to an alternate market that prefers bigger bananas due to the EU’s lowering of MRLs, they will receive lower prices for them.[765] Similarly, some producers cannot sell their crops in their own domestic markets as an alternative to exporting, because of either low domestic consumer demand or domestic prices that are too low to cover their costs. This is often the case with developing-country producers, but such a situation could affect smaller growers in all markets.[766]

A number of industry representatives have expressed concerns that certain potential MRL changes would lead to an inability to sell to the market proposing the change. For example, the U.S. rice industry writes that if Japan’s MRL on propanil were to be lowered, as Japan’s Ministry of Health Labor and

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[763] U.S. government official, interview by USITC staff, December 9, 2019; industry representative, interview by USITC staff, March 5, 2020.
[764] Taiwan Ministry of Health and Welfare, “List of Pesticide MRLs Omitted,” August 2, 2019; European Commission, “EU Pesticides Database: Oxytetracycline,” n.d. (accessed December 9, 2019).
[765] Industry representative, interview by USITC staff, Costa Rica, December 10, 2019.
[766] Industry representative, interview by USITC staff, Costa Rica, December 10, 2019; USITC, hearing transcript, October 29, 2019, 110 (testimony of Kay Rentzel, U.S. Sweet Potato Council); industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019; ASPMI and U.S. Sweet Potato Council, written submission to USITC, December 13, 2019, 4.

Welfare has proposed, it would result in MRL violations by U.S rice exporters or in a loss of the Japanese market altogether.[767] The U.S. Wheat Association writes that the EU is reviewing the pesticide malathion, and if its MRLs were reduced, combined with the already-announced reduction of the MRL on chlorpyrifos-methyl in 2020, it would be difficult for U.S. wheat producers to meet the new lower levels.[768] At the same time, importing markets may face shortages of supply if exporters choose to ship to other markets rather than comply with the MRL. Importing markets may also have less access to out-of-season produce or face less diverse product options.[769]

Finding Alternative Pesticide Products and Use Patterns

If an active substance fails to secure an MRL, loses it, or faces a reduced MRL in a market, growers must use different pesticides, change farming practices, or switch their use pattern to stay below the MRL. In some cases, there are no or few alternative pesticides available. Even if there are alternate conventional pesticides, alternate products such as biopesticides, or alternative farming practices available, adopting any of these changes can add to growers' costs. In many cases, these added costs can be particularly damaging to growers because meeting lower MRL requirements does not necessarily result in price premiums for farmers. The inability to use a pesticide in order to meet export market MRLs may also lead to crop loss, lower yields, a lower-quality crop (potentially bringing down prices), or higher costs of production due to switching costs or the use of these less effective means of addressing pests.[770] The section that follows will examine these additional costs in more detail.

Growers may not have access to alternative pesticides or may have limited information about alternatives. When growers lose access to a pesticide, they may not know whether alternative pesticides are available for their crops, if alternative pesticides can be used under the conditions they are growing in, or if alternative pesticides will be effective.

For instance, to take a U.S. domestic example, growers reportedly have difficulty finding alternatives to chlorpyrifos now that substance is removed from the California market.[771] Despite the fact that the state of California incurred the expense of engaging consultants to find and provide information on alternative products to growers, no list had yet been released as of April 2020.[772] Separately, one study of selected EU member states found that for one-sixth of the uses of a banned neonicotinoid, there was

[767] USA Rice, written submission to USITC, December 10, 2019, 4–5.
[768] USW, written submission to USITC, December 12, 2019, 3.
[769] Industry representative, interview by USITC staff, January 6, 2020.
[770] Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 163.
[771] The California Environmental Protection Agency announced that all sales of chlorpyrifos products would end on February 6, 2020 and farmers would no longer be allowed to use it after December 31, 2020. CalEPA, "Agreement Reached to End Sale of Chlorpyrifos," October 9, 2019; Hooker, "Chlorpyrifos Workshops Reach Beyond One Pesticide," January 22, 2020.
[772] Grettenberger, Long, and Putnam, "The End of Chlorpyrifos in California," October 11, 2019; Hooker, "Chlorpyrifos Workshops Reach Beyond One Pesticide," January 22, 2020.

no reliable alternative available.[773] The lack of alternatives may be more pronounced in developing countries, where fewer active substances tend to be authorized.[774]

Further, when pesticides become unavailable for use on specialty or minor crops, MRLs for some effective alternatives on the market may not have been established. Either growers must work with the pesticide manufacturer to ask them to submit applications for an MRL, or they must take on the costs of doing so themselves.[775] In either event, growers will not have an equally effective alternative available in the short term and will face future growing seasons with uncertainty about their ability to control pest pressures.[776]

Adopting alternatives may be more costly. Growers have reported that using alternative pesticides may be more expensive, particularly if there are few alternatives available.[777] For example, sweet potato producers have indicated that because dicloran cannot be used on products exported to the EU, fludioxonil is the only fungicide available for use to control *Rhizopus*.[778] They suggest that because it is the sole product still available, the price is higher than it would be otherwise and higher than dicloran would be.[779] As another example, the California Rice Commission reports that one foreign market is considering removing approval for three pesticides used on rice, and while there are alternatives, they are more expensive.[780]

Switching products or methods is frequently accompanied by additional costs, including those that result from conversion to new farming practices or training for new practices or new pesticide use.[781] Often training is important to ensure that pesticides are being applied properly. Some pesticides require applicator training and certification, while others have complex label and application instructions for which training may be needed.[782] This training can be done by larger grower groups or can be supported by government agencies, as described below.

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[773] EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018 I-40.
[774] Industry representative, interview by USITC staff, October 3, 2019; foreign government representative, interview by USITC staff, October 22, 2019; industry representative, interview by USITC staff, November 6, 2019; foreign government representative, interview by USITC staff, January 8, 2020; industry representative, interview by USITC staff, February 19, 2020.
[775] AFBF, written submission to USITC, December 13, 2019, 2.
[776] Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 163; foreign government representative, interview by USITC staff, October 22, 2019.
[777] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019; Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 163; USITC, hearing transcript, October 29, 2019, 45–46 (testimony of Terry Humfeld, Cranberry Institute); Kynetec, *Value of Mancozeb If EU MRLs Are Revoked*, October 18, 2019, 25; CRC, written submission to USITC, December 13, 2019, 7; CI, written submission to USITC, December 11, 2019, 6.
[778] ASPMI and U.S. Sweet Potato Council, written submission to USITC, December 13, 2019, 2; USITC, hearing transcript, October 29, 2019, 112–13 (testimony of Kay Rentzel, ASPMI and U.S. Sweet Potato Council).
[779] ASPMI and U.S. Sweet Potato Council, written submission to USITC, December 13, 2019, 2.
[780] CRC, written submission to USITC, December 13, 2019, 7.
[781] Industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019; Costa Rican government representative, interview by USITC staff, San José, Costa Rica, December 6, 2019; industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019; EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, I-40.
[782] ASA and USSEC, written submission to USITC, December 13, 2019, 3; industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019.

Other changes in practice can be more costly or damaging to the crops. For example, mango exporters in India report that two alternatives to using pesticides on the fruit include netting the fruit or treating it with hot water. Because netting is more costly than the hot water treatment, growers often prefer the latter, even though it might damage the quality of some of the thinner-skinned mango varieties grown in India. Further, because the hot water treatment shortens their shelf life, those mangoes need to be transported by air freight, significantly increasing costs.[783]

Growers may not have immediate access to alternative pesticides. Industry representatives also report that even though a pesticide might be available on the domestic market, growers might refrain from using it until it has secured an MRL or import tolerance in certain export markets.[784] As noted above, the time and resources required to develop a new pesticide are extensive (box 4.1), and registering these products in other markets or securing import tolerances in other markets takes additional time. This limits the availability of some newer, lower-risk pesticides that are available in the domestic market for use in exported crops. Industry representatives report being unable to use these products until the approval and MRL process has been completed in their export markets.[785]

For example, it has been reported that a pesticide that was approved for use on grain in the United States in 2007 was not approved for use in the EU and Japan until 2012. Because of the nature of grain exports (see box 4.5, "Export of Blended Crops"), growers were not able to use this pesticide until it was approved in its major export markets, including the EU and Japan. As a result, the registrant reportedly did not market the pesticide in the United States until it was approved in other markets. This issue is not limited to new pesticides but may also occur with new uses for older pesticides.[786] In 2015, Canadian canola producers faced this situation with quinclorac and two of their large trading partners: China, which imported one-third of Canada's canola, and Japan. Although quinclorac was approved for domestic use and Japan established an MRL for it in late 2015, the Canola Council of Canada advised growers not to use the pesticide because there were no China or Codex MRLs.[787] In 2015, the pesticide manufacturer submitted the documentation to Codex to support the establishment of an MRL for quinclorac on canola, and Codex adopted the MRL in 2018. But the product was not introduced into the Canadian canola market until the 2019 growing season, and the delay is estimated to have caused yield losses of $390 million.[788]

Alternatives may be less effective, contributing to income loss for growers through lower crop yields and quality. Industry representatives report that in some cases, when an MRL for a product is removed or if no MRL for a pesticide exists in the export market, they are forced to use an alternate product that

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[783] Mukherjee, et al., SPS Barriers to India's Agriculture Export, 2019, 40–41.
[784] Industry representative, interview by USITC staff, October 3, 2019; industry representative, interview by USITC staff, November 26, 2019; industry representative, interview by USITC staff, December 12, 2019; USITC, hearing transcript, October 29, 2019, 16–17 (testimony of Alinne Oliviera, USHIPPC); USW, written submission to USITC, December 12, 2019, 3; NPC, written submission to USITC, December 10, 2019, 3.
[785] Murray et al., "An Integrated Pest Management Strategic Plan," July 2018; IR-4, written submission to USITC, December 11, 2019, 1–2; USITC, hearing transcript, 17, 48 (testimony of Alinne Oliveira, USHIPPC); NPC, written submission to USITC, December 10, 2019, 3; USW, written submission to USITC, December 12, 2019, 3.
[786] USW, written submission to USITC, December 12, 2019, 3.
[787] CCC, "Canola Council Advises against Using Quinclorac in 2016," January 11, 2016.
[788] Roberts, "Quinclorac MRL Approval Marks Collaborative Win," August 29, 2018; BASF, "New BASF Tool to Control Cleavers in Canola," August 13, 2018; USDA, et al., "A Trade Facilitative Approach to Pesticide MRL Compliance," December 3, 2018, 4.

is less effective, and this may also exacerbate issues with pest resistance.[789] This situation can increase the grower's labor and input costs, since a less effective alternative may require more applications or more labor-intensive methods of application. It may also reduce yields if the product is less effective.[790] All of this can negatively impact growers and their competitiveness.[791] Additionally, industry representatives report that in some cases the alternative product might have a greater environmental impact than the previously used pesticide.[792]

Growers provide examples of lower yields or lower-quality products that can result from the use of less effective alternatives.[793] For instance, the California Rice Commission notes that if the California rice industry were to lose the MRL for propanil in Japan, there would be no alternative to use as a "clean-up herbicide," and the resulting weeds in fields would lead to lower yields and quality.[794] The U.S. cranberry industry contends that the loss of the chlorothalonil MRL in the EU will raise costs, lower quality, and increase risk of pest resistance. They express additional concern that the EU MRL for one of the main fungicides that is an alternative to chlorothalonil might also not be renewed, exacerbating the effects of the removal of chlorothalonil as an option and potentially costing growers millions of dollars in lost revenue.[795] Others, however, contend the impact of the loss of active substances on production may be overstated.[796]

For many agricultural goods, producers earn the highest prices for products that can be sold on the fresh market. Pesticides are an important tool that is used to prevent pest or fungal pressures that can damage the appearance of a product. When the ability to use these pesticides is limited, products that do not meet the standards of the fresh market must be sold either for processing or in a different market that offers a lower price to the producer. U.S. sweet potato producers indicate that without access to bifenthrin, wireworm and rootworm larvae would lead to damage in sweet potatoes that would prevent them from being sold in the fresh market.[797]

Determining alternative usage can be costly. If an MRL is lowered in an export market, growers in the producing market may not be able to find out whether and how to change their use of the product to

[789] Ecorys, *Study Supporting the REFIT Evaluation*, October 10, 2018, 163; USITC, hearing transcript, October 29, 2019, 46, 30–31 (testimony of Terry Humfeld, Cranberry Institute); USITC, hearing transcript, October 29, 2019, 159–60 (testimony of Dale Thorenson, USA Dry Pea & Lentil Council); CI, written submission to USITC, December 11, 2019, 6; NABC, written submission to USITC, December 9, 2019, 2.
[790] NABC, written submission to USITC, December 9, 2019, 2; USITC, hearing transcript, 17, 48 (testimony of Alinne Oliveira, USHIPPC); USITC, hearing transcript, October 29, 2019, 30 (testimony of Terry Humfeld, Cranberry Institute); USITC, hearing transcript, October 29, 2019, 159–60 (testimony of Dale Thorenson, USA Dry Pea & Lentil Council); CRC, written submission to USITC, December 13, 2019, 7.
[791] EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, I-96.
[792] EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, I-40; ABC, written submission to USITC, December 13, 2019, 1.
[793] CRC, written submission to USITC, December 13, 2019, 7; Mukherjee, et al., *SPS Barriers to India's Agriculture Export*, 2019, 37.
[794] CRC, written submission to USITC, December 13, 2019, 7.
[795] CI, written submission to USITC, December 11, 2019, 5–6; USITC, hearing transcript, October 29, 2019, 49–50 (testimony of Terry Humfeld, Cranberry Institute).
[796] EPRS, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market*, April 2018, I-39.
[797] ASPMI and U.S. Sweet Potato Council, written submission to USITC, December 13, 2019, 3.

comply with the change in the MRL.[798] While growers know that applying a pesticide according to the label will generally allow them to meet their domestic MRLs, when the foreign MRL is lower, they do not know how and to what degree to adjust their use to comply with the lower MRLs.[799] Pesticide manufacturers report working with industry associations when MRLs are lowered to help growers learn how to change their use of the pesticides to comply.[800] Finding an appropriate alternative usage pattern and rate can be time consuming and costly, and while registrants may support these efforts, growers nevertheless bear some of this expense. For example, the grower-supported Washington Tree Fruit Research Commission has been studying residues from different pesticides and uses to advise growers on how to lower residues to meet foreign MRLs. They estimate that the cost of this program since 2011 has been approximately $200,000.[801]

This uncertainty can also affect the use of new pesticides. U.S. sweet potato growers have indicated that a new product that has become available has proven to be effective, but growers are unsure if using the product according to the U.S. label will generate residue levels that comply with EU MRLs. As a result, the relevant association is seeking testing from a residue lab to ensure that growers will be able to use the product as indicated on the label and still export to the EU.[802]

Cost of Compliance with MRLs

If growers and exporters choose to ship agricultural products to markets with low or missing MRLs, costs of MRL compliance may be seen throughout the supply chain, where they are borne in various ways by numerous stakeholders.[803] Pesticide manufacturers often pay to conduct outreach with growers and agricultural industry associations to ensure that their products are used according to label instructions. In some instances, pesticide manufacturers inform growers of alternative measures that can be used if an MRL has been lowered.[804] Growers, for their part, often bear higher production costs or lower profits. Supply chain participants in developing countries are also reportedly more likely to be disproportionately impacted by MRL compliance costs than those elsewhere, given their limited resources and technical capacity to ensure that their farm products are in compliance before they are

[798] Industry representative, interview by USITC staff, November 6, 2019; industry representative, interview by USITC staff, February 13, 2020; industry representative, interview by USITC staff, February 19, 2020; USITC, hearing transcript, October 29, 2019, 37 (testimony of David Epstein, NHC).
[799] NHC, written submission to USITC, December 13, 2019, 12; USITC, hearing transcript, October 29, 2019, 37 (testimony of David Epstein, NHC).
[800] Industry representative, interview by USITC staff, February 13, 2020; industry representative, interview by USITC staff, May 6, 2020.
[801] Industry representative, interview by USITC staff, February 13, 2020; industry representative, interview by USITC staff, February 19, 2020; NHC, written submission to USITC, December 13, 2019, 13–14.
[802] ASPMI and U.S. Sweet Potato Council, written submission to USITC, December 13, 2019, 3.
[803] For example, one study on the impact of the possible loss of selected pesticides in the United Kingdom suggested that yields would decrease by 4–50 percent, varying by product, and that total farming profit in the country's agrifood sector would decline, with overall losses at over 35,000 jobs and billions of pounds. Andersons, *Crop Production Technology*, October 2014, i–ii.
[804] Industry representative, interview by USITC staff, February 13, 2020.

shipped.[805] Some suggest that changes in MRLs in developed countries can impact agricultural development and even food security in developing countries.[806]

This section describes methods producers use to comply with existing, established MRLs in key export markets (as distinct from their responses to MRL changes, which are described above). These include segregating crops by market destination, growing crops to meet the lowest import market MRLs, and conducting pre-export testing of agricultural products for MRL compliance. In addition, in some markets, governments will provide support to address the costs of MRL compliance and subsequent challenges. This is discussed at the conclusion of this section.

Segregating Crops or Growing to Meet the Lowest MRLs

In order to comply with various MRLs, growers report that they often must choose to either segregate their crops or to produce all of their crops to suit their export market with the lowest MRL. The choice of whether to segregate crops or produce to the lowest MRL depends on many factors that can make one or the other more cost-effective, including pest and climate pressures in the growing region, the degree of vertical integration of the industry, the number of export markets an industry ships to, and whether crops from multiple farms are combined before export. The choice to segregate or standardize production affects the entire supply chain, from the growing and harvest process to processing, packing, and shipping, and either decision can increase costs throughout.

Depending on the variability of MRLs for major export markets and the feasibility of doing so, growers and exporters may segregate crops by export market destination. In this way they can ensure compliance with differing MRLs throughout the growing and harvest process, though this increases production costs.[807] Peruvian mango growers, for example, will often segregate their mangoes to the United States and the EU based on the differing MRLs.[808] This practice, however, often differs by crop and country depending on the unique pest pressures in a region, as described in chapter 5.

Segregating crops requires the involvement and investment of intermediaries in the agricultural export industry, such as aggregators, packers, and processors, to separate agricultural products throughout the supply chain in order to avoid cross-contamination. This practice is costly and sometimes impossible to implement, and so is often avoided.[809] The U.S. sweet potato industry notes that in order to ensure no cross-contamination, the storage/packing/shipping facilities used would require separate storage areas before and after the packing process, which would require significant investment.[810] If segregating crops

[805] Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 79.

[806] Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 80; industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019; industry representative, interview by USITC staff, February 19, 2020.

[807] NABC, written submission to USITC, December 9, 2019, 2; NHC, written submission to USITC, December 13, 2019, 12.

[808] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019; industry representative, interview by USITC staff, Lima, Peru, December 11, 2019.

[809] NHC, written submission to USITC, December 13, 2019, 13; USITC, hearing transcript, October 29, 2019, 40 (testimony of David Epstein, NHC).

[810] ASPMI and U.S. Sweet Potato Council, written submission to USITC, December 13, 2019, 4.

is prohibitively costly or difficult, growers will often produce to the lowest MRL in their export markets. This can often occur when growers do not know the ultimate destination of their crop, or when their crops are blended and sent to multiple markets (box 4.5).[811] In some cases, when producing according to the lowest MRL, processors will indicate to growers that certain pesticides cannot be used.[812] U.S. peanut shellers that contract with peanut growers may restrict the use of certain pesticides to prevent violations in export markets.[813] The National Potato Council also indicates that the costs of MRL violations are so high that U.S. potato processors specify in their contracts which pesticides growers can apply to their crops.[814] Adjusting most or all production to the lowest MRL, however, may involve using less-effective pesticides that can impact the quality and appearance of the crop, potentially lowering prices for products.[815]

Box 4.5 MRLs and Blended Crops

Some crops and related agricultural products are blended before they are shipped, increasing the difficulty of tracing exports to their final destinations. These types of agricultural goods include bulk crops, such as corn or wheat, as well as other horticultural goods and associated products, such as coffee, nuts, and wine. Grain, for example, travels through on-farm or local storage to larger elevators where grain from multiple growing seasons, multiple farms, and often more than one country are mixed, or "bulked and blended."[a] Similarly, tree nuts from various farms are gathered by handlers after hulling and shelling to be sorted by size and quality, combining nuts from multiple orchards.[b] Coffee follows a similar pattern, as described in chapter 5.

Processed agricultural goods are also impacted by blending. For example, most of the U.S. wine made for export is sourced from multiple growers and sold in bulk form.[c] Because of these processes, such bulk or blended agricultural goods often cannot be traced back to their source.[d] In addition, since these products are blended without foreknowledge of the export destination, the use of pesticides cannot necessarily be tailored to individual export market MRL regulations; the crop must be grown to comply with all major market MRLs.[e]

However, some observers have noted that blending can reduce the likelihood of an MRL violation due to the dilution of some small shipments that may violate an MRL into a larger shipment that does not. For example, U.S. wheat growers noted that they typically do not experience MRL violations for this reason.[f]

[811] ASPMI and U.S. Sweet Potato Council, written submission to USITC, December 13, 2019, 3; NHC, written submission to USITC, December 13, 2019, 13; Wine Institute and CAWG, written submission to USITC, December 13, 2019, 4.
[812] USITC, hearing transcript, October 29, 2019, 62 (testimony of Terry Humfeld, Cranberry Institute); USITC, hearing transcript, October 29, 2019, 16–17 (testimony of Alinne Oliveira, USHIPPC); APC, written submission to USITC, December 6, 2019, 2; NPC, written submission to USITC, December 10, 2019, 3; USHIPPC, written submission to the USITC, December 13, 2019, 4.
[813] APC, written submission to USITC, December 6, 2019, 2.
[814] NPC, written submission to USITC, December 10, 2019, 1.
[815] NHC, written submission to USITC, December 13, 2019, 4; USHIPPC, written submission to the USITC, December 13, 2019, 4.

[a] U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 7–8; USW, written submission to the USITC, December 12, 2019, 1.
[b] ABC, written submission to USITC, December 13, 2019, 2.
[c] Wine Institute and CAWG, written submission to USITC, December 13, 2019, 4.
[d] U.S. Grains Council, NCGA, and MAIZALL, written submission to USITC, December 13, 2019, 8; Wine Institute and CAWG, written submission to USITC, December 13, 2019, 4; USW, written submission to the USITC, December 12, 2019, 1.
[e] ABC, written submission to USITC, December 13, 2019, 2; Wine Institute and CAWG, written submission to USITC, December 13, 2019, 4.
[f] USW, written submission to the USITC, December 12, 2019, 1.

Pre-export Testing and MRL Monitoring Costs

To avoid the costs and consequences of an MRL violation, many exporters test their products for MRL compliance prior to shipping them to their market destinations.[816] These compliance checks are conducted either before export or at the point of import, often as a condition of contracts between the seller and the buyer. Although such testing can prevent the larger losses triggered by MRL violations, these programs are costly, and the cost is often borne by the processor/exporter. In some developing countries, limited laboratory capacity may prevent this type of testing.[817] Further, investing in pre-export testing does not necessarily ensure compliance with MRLs. In surveys of the mango and rice sectors in India, it was noted that because testing procedures in India and the EU are often different, they may yield different results. In some cases, tests in India showed compliance but the products ultimately exceeded EU MRLs.[818] The coffee case study in chapter 5 contrasts the testing programs implemented by exporters in Colombia, Jamaica, and Kenya to ensure compliance with Japan’s MRLs.

Other examples of the cost of pre-export testing were provided by U.S. nut- and fruit-growing industries. The Almond Board of California reports that the laboratory fees alone for their industry-wide testing program cost over $150,000 annually; the total cost, including costs of gathering and evaluating the residue samples, is higher.[819] The U.S. peanut industry noted that it would be cost prohibitive to test all shipments before export and that it must rely on representative sampling instead.[820] One fruit company that operates 12 farms in Washington state reports that its pre-export residue testing program costs, on average, $18,000 annually for the lab analyses alone. This does not include the labor costs on the farms and within the company to oversee these programs and ensure that products meet different markets’ MRLs.[821] Other industry groups, such as the U.S. wheat industry, note that the structure of their industry and the nature of the agricultural product does not allow for sampling and testing prior to vessel loading. In those cases, pre-export testing may occur as the product is shipped so that results are

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[816] IR-4, written submission to USITC, December 11, 2019, 3; USITC, hearing transcript, October 29, 2019, 62 (testimony of Terry Humfeld, Cranberry Institute); industry representative, interview by USITC staff, October 24, 2019; industry representative, interview by USITC staff, February 21, 2020.
[817] Mukherjee, et al., *SPS Barriers to India’s Agriculture Export*, 2019, 75–76; CRC, written submission to USITC, December 13, 2019, 5.
[818] Mukherjee, et al., *SPS Barriers to India’s Agriculture Export*, 2019, 35, 75.
[819] ABC, written submission to USITC, December 13, 2019.
[820] APC, written submission to USITC, December 6, 2019, 2.
[821] NHC, written submission to USITC, December 13, 2019, 14.

received while the vessel is in transit, as redirection during transit is less costly than a rejected shipment.[822]

In addition to pre-export testing, industry representatives report that monitoring MRL developments and dealing with MRL issues imposes additional costs.[823] The U.S. hop industry reports that it spends over $150,000 annually on consultants and travel associated with MRL work.[824] The Northwest Horticulture Council reports that MRL compliance in the U.S. Pacific Northwest tree fruit sector requires the efforts of over 500 people at warehouses, shipping facilities, and packinghouses, as well as in the field. These efforts include not only pre-export testing for MRLs, but also making pesticide spray recommendations, collecting spray records, and undertaking pesticide residue research.[825]

Government Support to Ensure MRL Compliance

In some cases, governments provide support in various ways to ensure their growers' and exporters' ability to comply with MRLs. This support can include investing in pre-testing technology for growers to test their product before shipment, developing infrastructure and supporting education for growers on MRL compliance and proper pesticide usage, providing funding to support the securing of MRLs for minor crops or generic pesticides, and sometimes giving direct support to farmers. An example of direct government support to address growers' financial losses from MRL compliance challenges occurred in Kenya, where the Kenyan government gave temporary support to growers who lost their main market after the EU stopped some of its imports of Kenyan French beans and snow peas due to MRL violations.[826]

Though some larger industries are able to implement their own pre-export testing programs, as noted above, in some instances the government of the exporting industry manages these tests as well. These programs can be costly, particularly for developing countries, and cannot always prevent violations. For example, cocoa is Ghana's largest agricultural export, and because Japan has the most stringent MRLs of any of Ghana's major export markets, the government of Ghana adopted Japan's pesticide residue analysis methodology during 2008–10 to ensure MRL compliance.[827] However, because Japan continuously updated their testing methodology and instruments during this time, testing in Ghana and Japan diverged. As a result, despite Ghana's efforts to meet Japan's MRLs, there were 113 violations of Japanese MRLs on cocoa from Ghana over the period.[828] Even if they had been aware of the ongoing changes in Japan, analysts comment that to continuously upgrade would have been very costly for Ghana or other developing economies, and potentially prohibitive.[829]

[822] USW, written submission to USITC, December 12, 2019, 1–2.
[823] Industry representative, interview by USITC staff, November 21, 2019.
[824] USHIPPC, written submission to USITC, December 10, 2019, 4.
[825] NHC, written submission to USITC, December 13, 2019, 11–12.
[826] Additional detail is provided in the French beans case study in chapter 5.
[827] Industry representative, interview by USITC staff, February 19, 2020; Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 65–66.
[828] Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 65–66.
[829] Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 65–66.

Support from Importing Countries and Related Benefits

Financial and technical support for MRL compliance can also come from the importing country and may have positive spillover effects into the exporters' domestic markets. The EU recognizes that exporters, especially from lower income economies, may have difficulties in meeting lowered MRLs.[830] To help enable producers and exporters to meet new MRLs and maintain market access, the EU has funded several programs, such as the Pesticide Initiative Programme (PIP), to provide training to producers and exporters.[831] Between 2004 and 2006, the PIP's collective training programs trained over 130 consultant trainers in around 15 countries in the African, Caribbean, Pacific (ACP) region.[832] Additionally, more than 700 participants took part in training sessions on the themes of safe pesticide use, crop protection, crop hygiene, and traceability.[833] Currently, the EU's Market Access Upgrade Programme (MARKUP) is providing support to small and medium sized enterprises in the East African Community (EAC) region to increase access for agribusiness and horticultural exports to the EU market.[834] As part of the MARKUP, Kenya will receive €3.7 million (about $4.4 million) to support agricultural exports to the EU.[835] The program seeks to enhance the competitiveness and market access for Kenyan agricultural exports through capacity building among small scale farmers and strengthening related services provided by national institutions, including the Horticultural Crops Directorate (HCD), the Kenya Plant Health Inspectorate Service (KEPHIS), and the Kenya Bureau of Standards (KEBS).[836]

These programs can also increase industry organization and coordination, leading to a better managed value chain, and possibly have positive effects in the overall domestic market as farmers learn and practice improved chemical handling and production practices and as product aggregators and shippers increase the safety of product handling procedures. Importer efforts to support improvements in the supply chain have improved traceability. Programs that provide training to farmers, who produce for both the export and domestic market, reportedly could have positive spillover effects if good agronomic practices are applied to crops grown for the domestic market.[837]

Costs of an MRL Violation

Exceeding MRLs set by regulators in import markets is considered an MRL violation. Addressing violations and avoiding potential violations imposes high costs along the supply chain, particularly for farmers and exporters. Violations can occur when routine efforts to comply with MRLs, described above, are unsuccessful. They may be more likely to occur when an MRL is lowered in an export market, as

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[830] Industry representative, interview with USITC staff, February 19, 2020.
[831] Industry representative, interview with USITC staff, February 19, 2020.
[832] Schiffers et al., "The PIP Training Programme: Building of ACP Experts Capacities," 2006, 39.
[833] Schiffers et al., "The PIP Training Programme: Building of ACP Experts Capacities," 2006, 39, 46.
[834] EU-EAC Market Access Upgrade Programme (MARKUP), "Overview" (accessed May 1, 2020).
[835] European Union External Action Service (EEAS), "Kenya Signs 3.7m Euro Trade Deal to Boost Agricultural Exports," September 2, 2019; World Bank, Data, Official Exchange Rate (LCU per US$), Euro Area (accessed May 1, 2020).
[836] European Union External Action Service (EEAS), "Kenya Signs 3.7m Euro Trade Deal to Boost Agricultural Exports," September 2, 2019.
[837] Industry representative, interview with USITC staff, February 19, 2020.

described earlier in this section. These costs include revenue loss from a rejected shipment that cannot be sold in its original market and is redirected or destroyed instead; increased testing of commodities mandated by the export market; and reputational impacts that can affect sales and market access.

When violations do occur, they can be costly not only for the exporter but for the whole sector, and sometimes extend to related agricultural export products. An importing market that finds a producer has exceeded an MRL may impose costly penalties on the producer and even on the entire product sector in the form of fines and increased testing at port (a particular challenge for perishable products with limited shelf life, like cherries). Sometimes products from violating exporters, or even the whole sector, are banned until corrective actions are taken.

Loss of Agricultural Commodity Revenue and Redirected Shipments

The cost of a rejected shipment is the most visible and direct effect of an MRL violation.[838] Because there are reportedly no, or limited, insurance options for the these types of losses, various industries have indicated that costs for exceeding MRLs are very high for both the shipper and the entire industry, but they bear them to avoid a rejected shipment.[839] Agricultural products that exceed MRLs in the destination market are not released to buyers or consumers in that market and may instead be returned, sent to an alternate export market, or destroyed.[840] In some instances, rejected shipments are released for non-human consumption (e.g., livestock feed or composting), if the MRL for those uses is met, but usually receive lower prices. In addition, the shipper often has the responsibility to honor the sales contract and find replacement product at additional cost.

Rejected shipments can lead to substantial losses in the producing market that affect not only the exporters of the rejected product, but also the broader sector.[841] In 2010, when table grapes from India were rejected in the EU, it reportedly cost the industry €33.3 million. Lower prices were paid to those growers in the next harvest and the incident led to a two-year slowdown in business in India for processors and exporters.[842] Further problems may arise when exporters must replace the product to

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[838] It is difficult to determine the exact number of rejected shipments globally as different markets have different reporting and publication requirements on rejected shipments.

[839] While some sectors report that there are no insurance options, others suggest there may be some. According to U.S. Wheat Associates (USW), in noting challenges complying with Japanese MRLs, “initially both importing groups tried to get guarantees from U.S. exporters that shipments would meet all pesticide MRLs, but they were unsuccessful. The Japanese trading companies subsequently worked with insurance companies to provide insurance coverage against the risk of violative residues in shipments. That system continues to be used, but no claims have ever been filed.” USW, written submission to USITC, December 12, 2019, 2; APC, written submission to USITC, December 6, 2019, 2; NHC, written submission to USITC, December 13, 2019, 13; CRC, written submission to USITC, December 13, 2019, 8.

[840] CFFA, written submission to USITC, December 12, 2019, 2–3; industry representative, interview by USITC staff, January 6, 2020; foreign government official, interview by USITC staff, January 8, 2020; NPC, written submission to USITC, December 10, 2019, 13.

[841] Industry representative, interview by USITC staff, January 6, 2020; industry representative, interview by USITC staff, January 8, 2020; industry representative, interview by USITC staff, February 19, 2020; NPC, written submission to USITC, December 10, 2019, 13; CRC, written submission to USITC, December 13, 2019, 8; CCB, written submission to USITC, December 11, 2019, 4; APC, written submission to USITC, December 6, 2019, 2.

[842] Mukherjee, et al., *SPS Barriers to India’s Agriculture Export*, 2019, 55.

honor the contract and prevent added costs from breach of contract. Doing so can come at an additional cost to the exporters, particularly if they originally obtained their agricultural products under contract but must buy the replacement product on the spot market.[843]

Even if the rejected product can be redirected and sold in an alternate market, there are significant costs associated with this. For example, the Almond Board reports that the average cost of redirecting a rejected shipment would be over $10,000 for logistics and transportation alone.[844] Other costs and losses from redirecting goods including the payment of port fees to hold and redirect the product and the loss of quality and value when perishable goods are delayed on their way to market.[845] Some estimates put the average cost of rerouting a container at $20,000, and the Northwest Horticultural Council reports that each load of fruit that is rejected can cost between $30,000 to $40,000, depending on whether the product can be redirected, what market it can be redirected to, and how long this has delayed the product.[846]

Increased Testing

A single MRL violation can result in the importing market imposing higher inspection rates on the agricultural commodity from the offending exporting market. The rise in inspection rates increases costs and causes delays along the supply chain. Inspection delays can lower quality and shorten shelf life for perishable crops.[847]

After MRL violations, some countries combine significant increases in inspection rates—up to 100 percent—with the potential for a temporary ban. Increased inspection rates can cause costly delays and encourage importers to change sourcing. Costs of delays at a port for testing alone are reported to be thousands of dollars per day.[848] For example, Taiwan—which reportedly has missing MRLs that increase the risk of violations—responds to MRL violations using a tiered additional inspection regime.[849] As explained in the Taiwan section of chapter 3, in the absence of a violation, random testing of agricultural commodities is conducted on between 2 and 10 percent of shipments. After one violation, that testing increases to between 20 and 50 percent of shipments of the violating commodity. After a second consecutive violation, testing is increased to a 100 percent “batch-by-batch” testing regime.[850] In 2016, Taiwan reportedly imposed an increased inspection rate on all imports of U.S. cherries following 16 MRL

[843] Industry representative, interview by USITC staff, Nairobi, Kenya, December 4, 2019.
[844] ABC, written submission to USITC, December 13, 2019, 2.
[845] USITC, hearing transcript, October 29, 2019, 51 (testimony of David Epstein, NHC); industry representatives, interview by USITC staff, January 6, 2020; industry representative, interview by USITC staff, February 19, 2020; NHC, written submission to USITC, December 13, 2019, 13; CRC, written submission to USITC, December 13, 2019, 8; CFFA, written submission to USITC, December 12, 2019, 3.
[846] Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 80–81; NHC, written submission to USITC, December 13, 2019, 13.
[847] Industry representative, interview by USITC staff, February 19, 2020; CCB, written submission to USITC, December 11, 2019, 3–4; NHC, “Export Manual: Korea,” 2019.
[848] CRC, written submission to USITC, December 13, 2019, 8.
[849] Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 67–69; NHC, written submission to USITC, December 13, 2019, 31.
[850] Liao, “Pesticide Regulation and MRL Establishment in Taiwan,” May 29, 2019, 9.

violations in 2015.[851] Increased inspections from MRL violations may have been responsible for declines in Taiwan's imports of U.S. cherries.[852]

Reputational Impact of an MRL Violation

After an MRL violation, growers and exporters may experience not just lost sales but also damage to their reputation in that market. In some instances, exporters might temporarily lose export licenses, and importers may switch to other suppliers because of the perceived risk of additional MRL violations. This in turn could potentially disrupt the importer's supply.[853]

Many countries provide public notification when an MRL violation occurs, alerting importers and the general public to potential risks. These notifications are monitored by importers, who consider the risk of MRL violations in making their purchasing decisions. For example, as noted above, industry representatives stated that since the EU intercepted one shipment of French beans from Kenya that exceeded MRLs, there have been negative effects on the demand for all beans from Kenya.[854] In the past, when there were MRL violations and increased inspection rates, importers quickly shifted orders from Kenya to other countries, therefore impacting all farmers in the country.[855]

Recognizing the reputational risks of a violation, some governments have increased oversight of farms to ensure compliance with export market MRLs. To lessen the risk of a single MRL violation causing enhanced inspections and costs to an entire industry, local governments in Australia are working with growers and handlers to ensure that pesticides are being used correctly.[856]

[851] According to industry representatives, at that time Taiwan had proposed MRLs for 15 of the 16 violations, and permanent MRLs were in place weeks after the violations. Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 67–68.
[852] Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 67–68.
[853] Industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019; industry representative, interview by USITC staff, February 19, 2020.
[854] Industry representatives, interview by USITC staff, Nairobi, Kenya, December 5, 2019.
[855] Industry representatives, interview by USITC staff, February 19, 2020.
[856] Heard, "CBH Gets Tough on Chemical Maximum Residue Limits," October 9, 2017.

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Chapter 5
Costs and Effects of Missing and Low MRLs: Producer Case Studies

The case studies presented in this chapter describe costs and effects associated with missing and low maximum residue levels (MRLs).[857] They illustrate how compliance and noncompliance with export-market MRLs affect farmers in countries representing a range of income classifications. These costs and effects vary widely, depending in part on whether producers choose to bear the costs of complying with missing and low MRLs or instead seek alternate export markets. Numerous factors affect this decision. Some of the most important factors identified in the case studies that follow are presented in table 5.1. The table describes each factor, gives an example of it, and references the case studies that examine each in more detail.

The case studies provide examples of growers who are addressing missing and low MRLs in key export markets in different ways depending on specific factors described in the table. The case studies represent producers from countries in a range of income classifications, from different regions around the world, shipping to various key export markets, and producing diverse types of crops. When asked about MRL-related challenges in major export markets, growers frequently mentioned missing and low MRLs in the EU. They emphasized that their focus on the EU is due to both the size of that market (it was the first or second leading export destination for most of the producers described below) and the recent non-approvals and non-renewals of active substances in the EU, as described in chapter 4. As a result, many of the case studies focus at least in part on the EU market, though other export markets (such as Japan) are also described where relevant. In all of the case studies, producers' examples show how they could be forced to accept yield losses, to ship products with defects in quality, to cease exporting to the market, or to mitigate losses through the use of less effective or more labor-intensive pesticide alternatives, if they cannot use certain key pesticides.

The case studies describe the effects of missing and low MRLs on exporting producers of a variety of crops, with a particular focus on highly perishable minor crops. The first two case studies describe in detail the challenges presented by low MRLs to banana producers in Costa Rica and French bean producers in Kenya. The next three case studies present more briefly some of the effects from missing and low MRLs in three fruit-growing industries—mangoes, avocados, and table grapes. Finally, two additional case studies profile MRL-related challenges for less perishable crops that are blended and sold in bulk. The first of these covers coffee; the second, grains and oilseeds. Around the world, many of these crops are grown in different tropical regions, including in Africa and the Americas, that have relatively high and evolving pest and disease pressure. These farmers are more reliant on pesticides in part because their growing regions lack a cold season, which naturally reduces pest and disease pressure in more temperate regions. The case studies also illustrate how export market MRLs may present different kinds of challenges based on supply chain conditions. The unique effects of MRLs on sectors dominated by small shareholder farms, as well as on sectors that include large, multinational firms, are also examined.

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[857] Missing and low MRLs are defined in chapter 1.

Table 5.1 Factors contributing to growers' ability to bear the costs of complying with missing and low MRLs

Factor	Description	Example	Case study discussion
Degree of pest pressure naturally present in growing region	Growing regions that face fewer pest pressures may be better able to cope with low or missing MRLs in export markets.	Avocado growers in Peru face fewer pest pressures than avocado growers in Chile. Because fewer pesticide applications are needed, Peruvian growers can take advantage of markets that have a default MRL, even if it is very low, while Chilean growers find very low MRLs unworkable.	Bananas, avocados, mangoes, table grapes
Changes in climate conditions	Many growers report that pest pressures are increasing as climate factors create conditions more favorable to pests. Low or missing MRLs may reduce the number of pesticides available for addressing these new challenges.	Banana growers in Costa Rica face a higher incidence of fungal disease than in other countries, and fungal disease is on the rise due to changes in climate patterns. This makes it more important to have a wide variety of fungicides available, but MRLs for several key fungicides have been lowered in the European Union (EU).	Bananas, French beans, mangoes, grains and oilseeds
Ability to adapt growing practices to changing MRLs	The cost of educating growers about the changes in agricultural practices needed to achieve MRL compliance can be considerable. These costs may be borne by crop buyers (such as exporting firms, which may be vertically integrated with growers) or by government.	After Kenyan French bean producers faced problems with exceeding the EU's MRLs, an industry-led effort to educate farmers about proper pesticide use was conducted, at a cost of about $300,000.	French beans, mangoes, coffee
Effectiveness of other parts of the integrated pest management (IPM) system or alternative products to substitute for conventional pesticides	Depending on the particular pest pressures growers need to manage, they may be more or less able to substitute other parts of their IPM practices (such as pruning) or alternative products (such as biopesticides) for pesticides affected by low or missing MRLs.	Producers have tested targeted deleafing of banana plants to reduce pressure from fungus and the use of biopesticides as fungicides, as well as grapefruit oil as a postharvest fungicide for mango. But these alternatives may not have an established record of effectiveness, and they may require more costly application methods than their conventional counterparts.	Bananas, avocados, mangoes, coffee, grains and oilseeds

Factor	Description	Example	Case study discussion
Availability of alternative pesticides suited to a particular use	Some pesticides for which MRLs are low or missing may have few alternatives available, particularly for minor crops. In some cases, major markets may lower MRLs for several pesticides that substitute for one another, all in close succession. A lack of alternatives that can be used in rotation also increases the risk of pest resistance to pesticides.	Postharvest fungicides are a category of pesticides for which the EU has lowered MRLs for several products that are alternatives for one another. As a result, growers report that they are running out of options.	Bananas, French beans, mangoes
Reliance on pesticide registrants to obtain MRLs and bring alternative pesticides to market	Growers of minor and specialty crops are relatively few, and markets for their products are small compared to those for commodities like grains and oilseeds. As a result, it can be difficult for them to enlist the support of pesticide registrants in developing alternative pesticides and working with regulators.	After the MRL was lowered for one postharvest fungicide, an industry association worked with a pesticide registrant to get an alternative product approved for use on mango imports in the EU. However, this was reportedly a difficult process, and the alternative became available to growers only at the last possible opportunity before they would have had to go through a growing season without any alternative postharvest fungicide.	French beans, mangoes
Domestic approvals of new pesticides in exporting country	Any pesticide that a grower would like to use needs approval for use from relevant domestic authorities. If the system of pesticide registration is slow or if it is difficult to get approval for new active substances, this limits the alternative pesticides available to growers when export markets lower MRLs.	All of the industry representatives and producers interviewed in Costa Rica stated that the lack of domestic approvals for new active substances limits their ability to respond to lower MRLs in the EU, and that they would like to have access to the newer pesticides that are available in some competing producing countries.	Bananas, French beans
Ability to maintain segregated growing areas for different markets based on MRLs	Some growing regions and industry structures are able to segregate production and adapt pesticide use to individual markets in order to comply with MRLs. Countries and crops where production is consolidated and vertically integrated can more easily do this than where production is mostly by smaller growers. However, even some large, integrated producers are unable to segregate production due to climate conditions, close proximity of farms, or other factors.	Avocado and mango growers in Peru are able to segregate farms by destination market due to a high degree of vertical integration and relatively low pest pressure. However, major banana growers in Costa Rica report that farm-level segregation is unfeasible due to high pest pressure and a close proximity of fields that raises the risk of cross-contamination. For crops in regions that cannot be segregated, growers must produce to the strictest MRL among their major export markets.	Bananas, avocados, mangoes, table grapes

Factor	Description	Example	Case study discussion
Ability to maintain segregated packing facilities after harvest	For some crops, it is possible to segregate post-harvest packing by market based on MRLs, while for others, crops from many farms are bulked for export and cannot be segregated based on pesticide use.	For bananas and mangoes, post-harvest segregation is possible, but carries high costs and risks of mistakes that result in an MRL violation. For coffee and grains, post-harvest segregation is impossible because the produce of many farms is often bulked and blended for export.	Bananas, mangoes, coffee, grains and oilseeds
Shipping time in relation to postharvest pest pressure	There is a risk of product losses to postharvest diseases and to pests during transit, but MRL compliance may require shippers to reduce the use of important postharvest pesticides.	After the MRL for the main postharvest fungicide used by Brazilian mango growers was lowered and the fungicide could no longer be used, the industry temporarily had to ship product by air at greatly increased cost in order to provide the mangoes with any shelf life.	Bananas, mangoes
Transition time needed to comply with MRL changes	In some cases, the speed of MRL changes does not seem to take into account the length of the growing cycle. If a pesticide has already been applied and then producers find out that the crop will not be eligible for export to a key market, the costs can be high due to the resulting oversupply and need to find alternate markets.	The EU completed its review of the renewal of the pesticide chlorpyrifos in mid-2019, determined that it would withdraw its authorization in December 2019, and directed EU member states to end the grace period for transition to the new MRL at the limit of determination (0.01 ppm) by April 2020. Industry representatives noted that they were seeking alternatives as quickly as possible, but it was proving very difficult for growers to find them on the timeline that was given by the EU.	Bananas, mangoes, coffee, grains and oilseeds
Inability to pass increased costs of production on to buyers	For some products, markets will not pay the additional cost of the measures growers must take to comply with MRLs.	Retail prices for bananas and French beans have been stable for years, limiting the ability of producers to receive higher prices when costs rise.	Bananas, French beans
Private standards and supplier requirements that amplify the effects of low MRLs	Retail buyers may require third-party certifications that set limits on pesticide usage (e.g., Rainforest Alliance). Or, particularly in the EU, retail buyers may also set their own standards for pesticide use and acceptable residue levels that are stricter than legal MRLs.	Some buyers require that a banana cannot have residues of more than 3 to 5 different pesticides. Buyers may also set overall caps that combine official MRLs into one total allowance for all residues that cannot be exceeded. Larger exporters that sell to a number of different buyers may face different requirements from each buyer.	Bananas, avocados, coffee

Source: Compiled by USITC.

Case Study: Bananas from Costa Rica and Other Countries in the Americas

This case study examines the effects of several recent EU decisions to lower MRLs on important pesticides used in the fresh banana industry. Bananas are fast-growing, perishable specialty products that are vulnerable to a number of diseases and pest infestations, since they are typically grown in the tropics, where hot growing conditions can increase pest pressure. The EU is Costa Rica's most important export market. The case study focuses primarily on producers in Costa Rica because pest pressures there make the challenges presented by low MRLs particularly acute, but comparisons to other producing countries in the Americas are presented throughout in order to demonstrate that effects differ based on the unique characteristics of various producing countries. Costa Rican banana producers face potentially major effects from pending changes in EU MRLs that will eliminate the use of several fungicides that are alternatives for one another, as well as two insecticides that are important to modern pest-management practices in the banana industry. The industry cautions that if the MRLs for all these fungicides and insecticides are lowered before additional alternatives can be developed, banana farming in Costa Rica may not be feasible because yield losses will be so high as to make production in the country cost prohibitive. Potential effects on yields and exports are described below.

Banana Trade Overview

Bananas are an important export crop for many tropical countries in Latin America, the Caribbean, Africa, and Asia. In 2018, global banana exports (fresh or dried) totaled $11.3 billion (22.5 million metric tons), led by Ecuador, the Philippines, Colombia, Guatemala, and Costa Rica.[858] The EU, the United States, Russia, Japan, and China were the leading global banana importers due to limited domestic production and consistent consumer demand.

Given the EU's generally temperate climate, European banana production is limited, and most production is in subtropical islands that are not part of continental Europe. Bananas grown in the EU and its territories accounted for about 11 percent of EU consumption in 2014.[859] The EU sources most of its bananas from Colombia, Ecuador, and Costa Rica. Exports from Latin America have benefited from a gradual reduction in EU banana tariffs that has been phased in since 2009, and Colombia and Ecuador (as well as Peru, which is a smaller banana exporter) have received additional tariff benefits for bananas as a result of the EU-Andean Community Trade Agreement.[860] Ecuador also benefits from having a higher than average share of its banana-growing area (about 7 percent)[861] in organic production, which is in higher demand in the EU than in other export markets.

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[858] The relevant subheading of the international Harmonized Commodity Description and Coding System (Harmonized System or HS), 0803.90, covers fresh and dried bananas, but dried bananas account for only a small share of global trade. This case study focuses on fresh banana trade. IHS Markit, Global Trade Atlas database (accessed December 20, 2019).
[859] *Eurofresh Distribution*, "Bananas," April 29, 2016.
[860] FAO, *Banana Market Review*, 2018.
[861] Lernoud et al., *The State of Sustainable Markets*, 2018, 145.

Likewise, there is limited domestic banana production in the United States, which imports bananas mostly from Guatemala, Costa Rica, and Ecuador. U.S. banana imports are duty free under normal trade relations, so the top suppliers are generally the largest banana-producing countries in the Americas, with Central America having a slight geographic advantage. Russia also gets most of its supply from Central and South America. The Philippines is the top supplier to both Japan and China, since it is geographically closer to Asian markets. In summary, banana trade is regionalized, with Central and South American countries supplying the United States, EU, and Russia, while the Philippines is the major supplier in Asian markets.

Costa Rica Overview

Costa Rica is classified by the World Bank as an upper-middle-income country with a gross national income (GNI) per capita of $11,520 in 2018.[862] It has benefited from greater political stability and lower rates of poverty than many of its regional neighbors.[863] Costa Rica has tropical and subtropical climate areas, and the terrain features two coastal plains separated by a mountainous region. Since the 1990s, the share of agriculture in the country's GDP has fallen from 13.7 to 5.6 percent, and the share of the labor market employed in agriculture has fallen from 21.4 to 12.7 percent.[864] However, agricultural production of tropical crops such as bananas remains an important source of rural employment, particularly in areas of Costa Rica where there are fewer other industries.[865]

Costa Rica's export-oriented agricultural products include traditional crops such as bananas and coffee, as well as nontraditional crops such as pineapples and palm oil. Production of nontraditional crops has grown rapidly since the 1990s, while production of traditional crops has remained stable.[866] Bananas made up 18 percent of the value of Costa Rica's agricultural sector in 2013–15, down from 25 percent in 1995–97.[867] Banana farms are mostly located in the eastern portion of the country, which is poorer than other regions.[868] Costa Rica is unique among the selected case study countries in that it has prominently emphasized the importance of environmental policies (driven in part by its reliance on ecotourism) and has actively promoted various conservancy efforts, some of which also affect its agricultural policies, as described below.

Costa Rica's Pesticide and MRL Policies

Registration of new active substances in Costa Rica is managed by the Ministry of Agriculture and Livestock's State Phytosanitary Service (SFE, for the Spanish acronym). SFE consults with the Ministry of Health and the Ministry of Environment and Energy on applications for new active substances and takes their views into consideration in determining whether to approve an agrichemical.

[862] World Bank, "Country and Lending Groups" (accessed January 20, 2020).
[863] OECD, *Agricultural Policies in Costa Rica*, 2017, 20.
[864] OECD, *Agricultural Policies in Costa Rica*, 2017, 21.
[865] CropLife International, "Bananas in Costa Rica" (accessed April 15, 2020).
[866] OECD, *Agricultural Policies in Costa Rica*, 2017, 57.
[867] OECD, *Agricultural Policies in Costa Rica*, 2017, 58.
[868] Industry representative, interview by USITC staff, Costa Rica, December 5, 2019.

SFE also maintains the list of Costa Rican MRLs. Costa Rica uses a positive list: it defers first to Codex in the absence of an established national MRL, and when there is no established national or Codex MRL, U.S. and EU MRLs are compared and the highest (least restrictive) MRL is applied (see box 5.1).[869] Costa Rica does not apply a default value if an MRL is not established through this system, so if an MRL is missing for a pesticide/crop combination, the pesticide cannot be used on that crop.[870] SFE is also responsible for enforcing MRLs. It runs a laboratory that tests for pesticide residues on agricultural products for the domestic market and for export, as well as on imported products.[871]

Costa Rican Industry Structure and Production System

In Costa Rica, about 2.5 million metric tons of bananas per year are grown on about 107,500 acres, and banana exports are worth about $1 billion annually.[872] About half of the banana crop is grown by independent growers, and the other half on farms owned by major international companies such as Dole, Del Monte, and Chiquita. About 86 percent of production comes from large farms (over 250 acres).[873] Around 40,000 people are directly employed in the industry, which is mostly located in the eastern part of the country, and most bananas are shipped by boat out of the port of Limón on the Caribbean Sea. Once shipped, it typically takes 10 days for bananas to reach the United States, 14 to reach the EU, and 25 to reach China, and bananas must be protected from postharvest diseases during this transit time.[874]

The major markets for Costa Rican bananas are the EU and the United States. Relatively small amounts are also shipped to Ukraine, Turkey, Norway, and Russia, and to markets in East Asia, most notably China. In recent years, the industry has looked to develop the markets in Japan, Russia, and South Korea in order to further diversify its export destinations.[875] Prices are reportedly similar in the EU and the United States, and either may offer a slightly higher price at any given time.[876]

In Costa Rica, banana production is vertically integrated and is not segregated by market. Instead, producers follow the MRLs and other requirements of the most restrictive major export market. The EU market accounts for about 55 percent of the global banana market and its banana MRLs are considered by banana industry representatives to be the most restrictive in terms of the pesticides that can be used, so most Costa Rican banana production is structured to conform to EU MRLs.[877] Major banana-producing companies typically test for pesticide residues at the point of import (prior to official entry at the border) so that any MRL exceedances can be discovered before the bananas enter the market.[878]

[869] Bryant Christie, "Costa Rica Pesticide MRLs Market Information Report," August 2018.
[870] Bryant Christie, "Costa Rica Pesticide MRLs Market Information Report," August 2018.
[871] Costa Rican government official, interview by USITC staff, San José, Costa Rica, December 6, 2019.
[872] CORBANA, *Estadísticas de Exportación Bananera 2018* (Banana export statistics), May 2019, 10.
[873] OECD, *Agricultural Policies in Costa Rica*, 2017, 65.
[874] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[875] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[876] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[877] Industry representative, telephone interview by USITC staff, November 26, 2019.
[878] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.

Pest Pressures and Pesticide Use

Bananas are a fast-growing tropical crop that face high pest pressures. Mealybugs, scale insects, nematodes, and a fungal disease called black sigatoka are the main pests threatening bananas in Costa Rica and throughout the Americas.[879] Because of these high pest pressures and because bananas grow quickly and are harvested frequently, it is challenging for growers to meet low MRLs in export markets.

In growing bananas to meet MRLs, farmers typically apply pesticides based on certain preharvest intervals (PHIs). A PHI is the minimum time between the last application of the pesticide and the harvest of the crop and is used to set a withholding period during which pesticides are not used in order to comply with an MRL. As a result of the short growing period for bananas, it is not feasible to use some pesticides for which MRLs are low in destination markets because the PHI for bananas is too brief. According to an industry representative, this makes adjusting to low MRLs more challenging for bananas than for some other fruits with longer growing cycles, such as pineapples. Since pineapples grow much more slowly, it is possible to observe a longer preharvest interval in which pesticides are not applied, without risking damage to the fruit during key periods of growth.[880]

Mealybugs and scale insects represent a direct threat to banana yields because they damage the skin of the fruit, making the bananas unacceptable to customers. In particular, mealybugs attract sooty mold that feeds on their feces, damaging the skin of the banana. Scale insects suck on the fruit, and as the fruit ripens, cause green spots that buyers in import markets will not accept. Nematodes (roundworms) and black sigatoka (a fungal disease), by contrast, have indirect effects on yields. Nematodes feed through banana tree roots, causing yield reductions and smaller average fruit size. The total yield loss caused by nematodes may be up to 50 percent.[881]

Fungicides are the most important category of plant protection products for bananas in Costa Rica. This is largely due to the presence of black sigatoka, which is the most damaging and difficult fungal pressure in the Costa Rican banana industry. Black sigatoka causes leaves to die, which causes premature ripening in bananas. As growers are forced to harvest bananas earlier, this in turn reduces the number of bananas harvested.[882] Fungicides are typically applied once a week to control this disease,[883] and they account for 71 percent of the total banana crop protection market by value.[884] Fungicides are also particularly expensive compared to other pesticides used on bananas.[885]

Pest pressures in the banana industry are also increasing. A harmful fungal disease that affects bananas was recently detected for the first time in the Americas, in Colombia. The disease, known as TR-4 or fusarium wilt, is a soil-borne fungus that has the potential to greatly damage the banana crop throughout the Americas. This fungus has already infested banana plantations in Southeast Asia, Africa, and Australia and is a growing concern to exporting producers, as it infects and destroys Cavendish banana plants, which make up virtually all banana exports and which are the most widely cultivated variety in the world,

[879] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[880] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[881] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[882] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[883] Kynetec, *Report: Value of Mancozeb If EU MRLs Are Revoked*, October 18, 2019, 19.
[884] Kynetec, *Report: Value of Mancozeb If EU MRLs Are Revoked*, October 18, 2019, 18.
[885] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.

particularly in the Americas. The disease is particularly troubling because it can remain dormant in the soil for years, causes significant crop damage, and cannot currently be controlled by any plant protection product.[886]

Climate Effects on Pest Pressures

According to industry representatives, climate pressures have increased pest threats to the banana industry in recent years. For example, one grower reported that black sigatoka has become more prevalent because changing rain patterns have created more favorable conditions for this fungus.[887] Mealybug and scale insect populations have also reportedly risen as temperatures have become hotter and more favorable to their growth.[888] These threats are most difficult for banana growers in Costa Rica and other Central American countries, which generally face greater pest pressure than growers in South America. Pest pressures generally increase with heat, while humidity can increase some pest pressures while decreasing others. For example, Honduras is the hottest and driest banana-producing country and, as a result, faces the highest insect pressure.[889] On the other hand, with respect to fungal disease, banana-producing countries that receive less rain have lower fungal pressure than wetter countries. One industry representative noted that Guatemala has a lower incidence of fungal diseases than Costa Rica because it is drier.[890]

Costs and Effects of Missing and Low MRLs on the Banana Industry

Banana producers in Costa Rica offered numerous examples of negative effects from low MRLs on their industries, listed in table 5.2 below. Most of these effects were observed as a decline in yield that increased costs per unit for producers. Because EU MRL changes affecting the banana industry are either recent or still pending, export levels have so far remained stable. Producers and other industry observers emphasized that this is because in the short run, producers will try alternative pesticides, increase land use, or take other steps to maintain a constant level of production.[891] However, this reduces banana growers' margins because markets will not accept major price increases, so increased costs of production cannot be passed on to the consumer. One industry representative remarked that retail prices of bananas in the United States had not risen for nearly 20 years.[892] In addition, the short-term measures taken to maintain production levels may not be sustainable over the longer term, as pests become resistant to the limited number of pesticides available or new pest threats emerge, as described below.

Table 5.2 presents the MRLs for several plant protection products for bananas in Costa Rica's top banana export markets of the EU and the United States, plus Canada (an import market discussed elsewhere in this case study), and Codex. These products, described in detail below, include key insecticides

[886] FAO, World Banana Forum, "Fusarium Tropical Race 4 (TR4)" (accessed April 7, 2020).
[887] Industry representative, telephone interview by USITC staff, November 26, 2019.
[888] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[889] Industry representative, telephone interview by USITC staff, November 26, 2019.
[890] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[891] Costa Rican government representative, interview by USITC staff, San José, Costa Rica, December 6, 2019; industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[892] Industry representative, telephone interview by USITC staff, November 26, 2019.

(buprofezin and chlorpyrifos) and fungicides (chlorothalonil, imazalil, and mancozeb) that are of critical importance to the banana sector. Three of the five have had recent or pending MRL changes in the EU, and one will face a pesticide registration review in January 2021. In 2017, the EU MRL for buprofezin was lowered to the default after the pesticide approval was amended to include only use on non-edible crops. The EU did not renew its approval of chlorpyrifos and chlorothalonil, and these MRLs defaulted to the limit of determination of 0.01 ppm in early 2020. EU approval for mancozeb expires in January 2021, and banana industry representatives are concerned that it may not be renewed. Finally, the EU began a review of imazalil in 2017 and concluded that the MRL should be lowered to the limit of determination. However, in 2019 the EU agreed to a three-year phase-in period before the lower limit was implemented. Colombia, Costa Rica, the Dominican Republic, Ecuador, and Côte d'Ivoire have raised a concern at the WTO's Sanitary and Phytosanitary (SPS) Committee over the EU amendments of MRLs for imazalil.[893]

Table 5.2 MRLs for key pesticides used in the banana industry (ppm)

Active ingredient	Pesticide type	Codex	Canada	United States	EU	Recent Changes (EU)
Buprofezin	Insecticide	0.3	0.3	0.2	0.01	In 2017, approval was amended to include only use on non-edible crops. In January 2019, MRLs for buprofezin on most edible crops defaulted to 0.01 ppm (previous level was 0.5 ppm).
Chlorpyrifos	Insecticide	2	0.1	0.1	0.01	Approval not renewed as of December 2019. EU member states' grace periods ended by April 2020, after which MRLs defaulted to 0.01 ppm (previous level was 4 ppm).
Chlorothalonil	Fungicide	15	0.1	0.5	15	Approval not renewed as of March 2019. Grace period ends May 2020—after this, MRL will default to 0.01 ppm.
Mancozeb	Fungicide	2	0.1	2	2	Next review by January 2021.
Imazalil	Fungicide	3	0.01	3	2	Next review by December 2024.

Source: Bryant Christie Global, Pesticide MRLs database for active substances shown (accessed December 20, 2019); European Commission, EU Pesticides Database for active substances shown (accessed January 22, 2020); WTO SPS Committee, "Summary of the Meeting of 21-22 March 2019," June 27, 2019.

Insecticides

Buprofezin and chlorpyrifos are the major insecticides used in the banana industry for which EU MRLs have been or will soon be lowered. Buprofezin is an insecticide used to control scale insects and mealybugs in bananas. Chlorpyrifos is an insecticide that is used as an alternative to buprofezin. It is particularly important in controlling mealybugs because there are no alternatives to control them at present, now that buprofezin can no longer be used because of its reduced MRL.[894]

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[893] WTO, "EU Amendments of MRLs for Imazalil," (accessed December 17, 2019).
[894] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.

In 2019, the EU lowered the MRL for buprofezin from 0.5 ppm to the limit of determination (0.01 ppm). According to industry representatives, the EU justified this change based on concerns about a metabolite known as aniline, which is produced when buprofezin is heated to high temperatures. The U.S. Environmental Protection Agency (EPA) classifies aniline as a probable carcinogen, although both the EPA and industry representatives point out that aniline is naturally present in small amounts in many types of fruits and vegetables.[895] However, according to industry representatives, in testing, aniline was produced only when buprofezin reached temperatures over 350 degrees Fahrenheit, and they state that this would never happen during normal shipment and use of a fresh banana.[896] Opportunities to provide input to the relevant EU authorities about normal use of buprofezin and whether it was likely that aniline would be produced during normal use were reportedly limited.[897] Industry representatives in Costa Rica worry about not being able to use this insecticide because it was very important in responding to an outbreak of scale insects in 2013.[898]

Both buprofezin and chlorpyrifos are applied to banana bunches using plastic bags (called treebags) that are impregnated with the insecticide and then placed around the bunch. Industry representatives consider this to be the best practice for applying insecticide to bananas because it reduces risks to workers and the environment, as compared with other methods of application such as spraying.[899] Alternative insecticides that can be applied via impregnated plastic bags are bifenthrin and pyriproxyfen. Pyriproxyfen is not approved by the Costa Rican government and therefore cannot be used by banana growers there, but it is starting to be used in Honduras (see box 5.1).[900] A combination of these insecticides is typically used in order to avoid insects developing resistance to them. Outside of those four insecticides, alternatives usually have to be sprayed by plane, which comes with increased environmental and worker health risks.[901]

One industry representative reported yield losses from experiments in which mealybugs were not controlled with any insecticides. Losses to mealybugs were less than 1 percent with a pyriproxyfen treebag, compared with 12 percent with no treatment. Examples of yield losses that could result from lack of access to insecticides come not only from experiments, but also from real outbreaks: particularly hot weather in 2019 resulted in increased pest pressure from mealybugs, which threatened to reduce yields by up to 7 percent. The outbreak was controlled by using chlorpyrifos, which brought the yield loss down to 1 percent. As a result, the industry is particularly concerned about losing access to this product.[902]

Another industry representative estimated that the loss of access to chlorpyrifos would result in yield losses of up to 30 percent, and that based on this yield loss, the cost of producing bananas would rise by $1.50 per 18-kilogram box.[903] The price of bananas fluctuates, but this generally reflects a more than

[895] EPA, “Aniline” (accessed November 26, 2019); industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[896] Industry representative, telephone interview by USITC staff, November 26, 2019.
[897] Industry representative, telephone interview by USITC staff, November 26, 2019.
[898] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[899] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[900] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[901] Industry representative, telephone interview by USITC staff, November 26, 2019.
[902] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[903] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.

10 percent increase in cost. The overall economic impact on Costa Rican producers in this case would be $180 million.[904] In this analysis, the producer also found that the lower yields would result in some farms producing less than 2,000 boxes per hectare. At this level of production, a farm generally has to close, so some smallholder farms would be unable to remain in operation.[905]

Box 5.1 Costa Rican Pesticide Approvals

The costs and effects of low MRLs in key export markets for Costa Rican producers are compounded by the fact that registering new pesticides in Costa Rica is very difficult, owing both to the complexity of the bureaucratic process and the political strength of environmental concerns in the Costa Rican system. This lack of domestic pesticide approvals limits the availability of alternative pesticides for banana growers and makes it difficult for companies that have growing operations throughout Latin America to use a regional approach to pest management, since they are unable to use agrichemicals in Costa Rica that they can use in other countries. In the past 15 years, Costa Rica has only approved a handful of new active substances, according to many industry representatives. One banana producer stated that registration of a new active substance can take as many as 10 years in Costa Rica. In a 2017 assessment of the Costa Rican agricultural system, the Organisation for Economic Co-operation and Development (OECD) found that since 2009, Costa Rica had approved just 8 of 170 new active substances and 8 of 178 formulated pesticides, and that the process regularly takes more than four years, as compared with two years in other Latin American countries. The analysis also found that this lack of access to new products increases Costa Rican producers' reliance on older compounds and leads to pesticide overuse.

Source: Industry representatives, interviews by USITC staff, San José, Costa Rica, December 4 and 5, 2019; OECD, *Agricultural Policies in Costa Rica*, 2017, 73–74.

Nematocides

In the Costa Rican banana industry, nematocides are a particularly important type of pesticide because Costa Rica is especially susceptible to nematodes compared to other banana-producing countries due to its soil conditions and the faster-reproducing strains of nematodes that are found there. [906] Left untreated, nematode damage to banana production in Costa Rica is significant. There are five main pesticides (nematocides) that can be used to control nematodes in Costa Rican bananas. One banana producer conducted field trials in Costa Rica with no products applied to control nematodes and the result was a 45 percent loss of yield. In trials conducted in other banana-growing countries (Honduras, Ecuador, and Colombia), crop losses were 10–14 percent.[907]

Of the five nematocides available to banana producers in Costa Rica, only two are approved for use in the EU. The other three are not approved in the EU and thus have default MRLs of 0.01 ppm. One of these pesticides, ethoprophos, lost its EU approval very recently; its approval was not renewed in the EU in 2019 and the grace period ended in March 2020, so producers are still adjusting to this change. Of the two nematocides still EU-approved for use on bananas, one is listed as a candidate for substitution, meaning that it may lose approval in the future. The other compound that has EU approval contains a

[904] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[905] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[906] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[907] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.

newer active substance called fluopyram, which is somewhat less effective than the other four.[908] Since the banana industry in Costa Rica does not segregate production by export market, nematode treatment in Costa Rica will be limited to the use of this less effective product if producers cannot use the others due to lower EU MRLs.

Fungicides

Banana producers are concerned about two key fungicides, chlorothalonil and mancozeb, for which MRLs are expected to be reduced in the EU in 2020 and 2021. Chlorothalonil is a fungicide used in rotation with other fungicides, such as mancozeb, to control black sigatoka. Use of chlorothalonil in the Costa Rican banana industry increased steadily between 1996 and 2018.[909] The EU approval for chlorothalonil was not renewed in 2019, the grace period on its use ended in May 2020, and the MRL defaulted to the limit of determination (0.01 ppm).

Mancozeb is a fungicide that is up for renewal in the EU in 2021. It is used for largely the same purposes as chlorothanonil, and the two are considered substitutes for one another. Mancozeb has a lower cost than alternatives, and generic versions of this product are available. If it were not available and growers had to rely on alternative fungicides, total fungicide costs on Costa Rican banana farms would rise by 10 percent, according to an analysis by Kynetec, an agricultural market research firm. This analysis found that the loss of access to mancozeb by Costa Rican banana growers would reduce yield by 6.3 percent and increase farm costs by 3.5 percent, resulting in an overall 10.5 percent reduction in farm income.[910] Modeling conducted by Kynetec found that this could lead to a short-term 4 percent decrease in the quantity of bananas exported from Costa Rica and the possibility that smaller growers who are less able to adapt would be absorbed by larger growers.[911] However, in the long run, production and exports would recover as alternative fungicides are developed.[912]

Alternatives to chlorothalonil and mancozeb are limited. Among them are fenpropimorph and difenoconazole, which have less environmental impact but are less effective for the control of black sigatoka.[913] Biopesticides, such as *Bacillus subtilis* and *Melaleuca alternifolia* (tea tree oil), are additional alternatives being tested. But the cost of using them is higher, especially given that the same equipment cannot be used to apply conventional pesticides and biopesticides.[914]

The loss of approved fungicide products would mean that black sigatoka could become devastating to many growers in Central and South America. Industry representatives report that they are very concerned that the entire family of fungicide products that control black sigatoka is listed for possible nonrenewal in the EU.[915] Based on experience, one major banana grower believes that the yield loss from black sigatoka with no fungicides whatsoever would be about 75 percent in Costa Rica, 50 percent in

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[908] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[909] Kynetec, *Report: Value of Mancozeb If EU MRLs Are Revoked*, October 18, 2019, 19.
[910] Kynetec, *Report: Value of Mancozeb If EU MRLs Are Revoked*, October 18, 2019, 10.
[911] Kynetec, *Report: Value of Mancozeb If EU MRLs Are Revoked*, October 18, 2019, 24–25.
[912] The report findings do not specify exactly how long it might take for these alternatives to become widely available, but interviews with industry representatives indicate that it would likely take several years. Kynetec, *Report: Value of Mancozeb If EU MRLs Are Revoked*, October 18, 2019, 25.
[913] Kynetec, *Report: Value of Mancozeb If EU MRLs Are Revoked*, October 18, 2019, 10.
[914] Kynetec, *Report: Value of Mancozeb If EU MRLs Are Revoked*, October 18, 2019, 28.
[915] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.

Ecuador, Guatemala, and Honduras, and 25 percent in Colombia.[916] Similarly, another industry representative stated that in a worst-case scenario if no fungicides at all were available, it would not be economically feasible to grow bananas in Costa Rica.[917]

While a worst-case scenario for growers is that many fungicides lose approval over a short period of time, a more likely scenario is that decreases in export market MRLs cause fungicides to be phased out one by one. Even in this case, however, the yield loss could eventually build to the same level as seen in experiments using no fungicides, as overuse of the remaining fungicides could lead black sigatoka to develop resistance over time.[918] For example, if chlorothalonil and mancozeb are both taken out of use, there is an increased likelihood of black sigatoka becoming resistant to the remaining fungicides, as black sigatoka is a type of fungus that is particularly apt to develop resistance.[919]

Postharvest Fungicides

Postharvest fungicides are important tools that extend the shelf life of a banana by protecting banana exports from crown rot and other postharvest fungal diseases. There are several factors that affect growers' selection of postharvest fungicides for bananas, including cost, effectiveness, and MRLs in key markets. An additional factor is the need to avoid developing resistance. If the mode of action by which the postharvest fungicide works is the same as that of the other fungicides used in the field, fungal diseases may develop resistance to the postharvest treatment. This happened in the 1980s, when postharvest fungal diseases in bananas developed resistance to thiabendazole, which was also being used in the field to control sigatoka. (More information on thiabendazole is provided in the mango case study.)[920] If this resistance emerges, it limits the number of alternative products that can be used postharvest.

In recent years, the most commonly chosen postharvest fungicide used on bananas has been imazalil. However, as described above, the EU is in the process of phasing in a lowering of the imazalil MRL from 2 ppm to 0.01 ppm. The main alternative to imazalil for postharvest treatment of bananas against fungus is azoxystrobin, which is reportedly more expensive.[921] In addition, one study of postharvest fungicides for bananas grown in Côte d'Ivoire found azoxystrobin to be less effective than imazalil. A Costa Rican government representative stated that as imazalil falls out of use, it is likely that more banana shipments will be rejected at the border due to outbreaks of fungal disease in the shipping containers. As a result, banana producers around the world have joined together to express concern about the loss of imazalil.[922]

Unlike the situation when bananas are still growing in the field, some segregation of the banana crop by destination market is possible during the postharvest stage, so producers may choose to use different postharvest treatments for different markets. However, producers reported that this is very costly and increases the risk of making a mistake that can lead to an MRL exceedance.[923] One industry

[916] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[917] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[918] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[919] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[920] Lassois et al., "Crown Rot of Bananas," 2010.
[921] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[922] Costa Rican government representative, interview by USITC staff, San José, Costa Rica, December 6, 2019.
[923] Industry representative, telephone interview by USITC staff, November 26, 2019.

representative stated that banana buyers in Japan and South Korea are more reluctant to accept the use of postharvest fungicides and that they have experimented with not using any postharvest fungicides for these markets, but that this raised costs significantly.[924] Similarly, two different industry representatives reported that Canada maintains a low MRL for imazalil—0.1 ppm, compared with 3 ppm in the United States (as shown in table 5.2)—and that some shipments of bananas to the United States are not treated with imazalil because of the risk that bananas may end up being shipped through the United States to the Canadian market.[925] Both emphasized that this lack of harmonization was costly.

Industry Responses to Changing MRLs for Bananas

Industry representatives are concerned that over the next three to four years, the backbone of integrated pest management for bananas could be wiped away by changing MRLs in the EU.[926] In general, these industry representatives and some government officials in tropical countries believe that the EU MRLs for tropical fruits are a form of indirect discrimination. As noted above, these observers contend that the EU is more likely to lower or eliminate MRLs on crops that are not produced within the EU region; moreover, they state that the EU MRL-setting process does not take into account the unique pest pressures of a tropical environment.[927] Industry representatives also report that the deadlines imposed during EU reviews and changes to MRLs do not give producers enough time to test alternative plant protection products that could replace those for which MRLs are being lowered or eliminated.[928]

There is also concern that the EU's banana MRLs will be adopted by other countries. One observer expressed frustration that importing countries often believe that if producers can comply with a very low MRL or pesticide ban in one market, they should be able to do it for all others, without realizing that the short-term measures that producers take to comply with newly lowered MRLs may present long-term risks and increased costs to the production system.[929] This observer reported that South Korea had adopted some EU MRLs for bananas, and that concern about chlorpyrifos seemed to be spreading from the EU to certain parts of the U.S. market.[930]

If MRLs in key export markets continue to diverge, one possible response would be increased segregation of the banana crop by market. However, for many banana growers in Latin America, it would not be possible to segregate banana production by end market at the farm level, for the reasons described above. According to industry representatives, it would be impossible to do so in Costa Rica partly because farms are in close proximity to one another and partly because climate and pest pressures are high, making segregation cost prohibitive.[931] In Ecuador, it would be possible because climate and pest pressures are a bit more manageable, meaning there are more options for use of alternative pest

[924] Industry representative, telephone interview by USITC staff, November 26, 2019.
[925] Industry representative, telephone interview by USITC staff, November 26, 2019; industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[926] Industry representative, telephone interview by USITC staff, November 26, 2019.
[927] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019; foreign government representatives, interview by USITC staff, Belgium, January 8, 2020.
[928] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[929] Costa Rican government representative, interview by USITC staff, San José, Costa Rica, December 6, 2019.
[930] Costa Rican government representative, interview by USITC staff, San José, Costa Rica, December 6, 2019.
[931] Industry representatives, interviews by USITC staff, San José, Costa Rica, December 5, 2019.

management strategies. However, use of these alternatives would raise costs by 30 to 40 percent.[932] To the extent segregation were possible, it would likely be at the country level rather than by farm or region. This country-level segregation has already happened in one instance due to an insect outbreak in Guatemala and Honduras. In that case, growers in the affected countries decided to use buprofezin and forego sales to the EU market. This was costly, however, because the EU market prefers smaller bananas than other markets, and producers had grown bananas to conform to that market preference. Selling these smaller bananas in alternate markets that allow the use of buprofezin results in lower prices.[933]

If many of the pesticides used in the banana industry cannot be used in the EU market, another response would be to increase the percentage of production that is certified organic, so the MRL changes may favor organic banana growers. However, large-scale organic banana production in Costa Rica is not feasible due to pest pressures, so this would favor growers in Colombia, Ecuador, or Peru.[934] One government official stated that organic production is more land-intensive than conventional production and observed that Panama had cut down rainforest land in order to put in organic banana farms.[935] As a result, a shift to more organic production may have unintended environmental consequences.

Case Study: French Beans from Kenya and East African Countries

This case study focuses on the effects of missing and low MRLs in the EU on Kenyan exports of French beans to the EU.[936] Kenya considers it important to maintain access to its primary French bean export market, the EU, and when active substances lose their MRLs in the EU, Kenya often cancels pesticide use registrations for the domestic market as well. This results in even fewer registered pesticides being available for French beans in Kenya, which as a minor crop already have a limited number of Codex MRLs.[937] This case study analyzes past instances of EU MRL violations to illustrate their effects along the French bean supply chain in Kenya, including costs to Kenyan smallholder farmers, exporters, EU importers, the Kenyan government, and pesticide manufacturers. It also looks at actions taken by the Kenyan government and industry in response to EU audits related to MRL violations in 2012–13. These actions resulted in some benefits, such as strengthened industry structures and extension outreach that improved productivity and quality.

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[932] Industry representative, telephone interview by USITC staff, November 26, 2019.
[933] Industry representative, interview by USITC staff, San José, Costa Rica, December 5, 2019.
[934] Industry representative, telephone interview by USITC staff, November 26, 2019.
[935] Costa Rican government representative, interview by USITC staff, San José, Costa Rica, December 6, 2019.
[936] French beans, also known as haricots verts, are slender, delicate green beans with tiny seeds. There are different grades, including extra fine and fine. The extra fine beans are mostly for export, while there are sales of some fine and regular beans to the domestic market. Industry representative, interview by USITC staff, Nairobi, Kenya, December 3, 2019.
[937] Minor crops (also called "minor use crops"), often specialty crops, are crops with relatively small production, limiting economic incentives for pesticide companies to register pesticides for use on them. EPA defines minor use crops as those having less than 300,000 acres in growing area. EPA, "Minor Uses and Grower Resources," August 2, 2019; OECD, "Minor Uses of Pesticides," 2019.

French Bean Trade Overview

French beans are an important export crop for several African, North American, and Central American countries. In 2018, the leading French bean exporters were Morocco, Mexico, Guatemala, the United States, and Kenya.[938] This case study focuses on producers in Kenya, but also includes some examples from other countries when possible, particularly African countries.

The EU is the world's largest importer of French beans, with imports of $540.7 million (215,317 metric tons) in 2018.[939] The United States was the second largest, with $152.9 million (95,686 metric tons), and Canada was third with $67.0 million (29,543 metric tons).[940] Imports are often driven by seasonality and shipping advantages, with countries importing from nearby countries that have warmer, longer growing seasons; the EU from Africa, the United States from Mexico and Central America, and Canada from the United States, Mexico, and Central America.[941]

The EU's leading French bean import suppliers are all lower-middle-income economies.[942] The top four, Morocco, Kenya, Egypt, and Senegal, accounted for 59 percent, 21 percent, 9 percent, and 5 percent of EU French bean imports, respectively, in 2018.[943] These countries are able to export French beans to the EU year round, including in the off-season of EU's domestic bean production.[944]

Kenya Overview

Kenya is a sub-Saharan African country with a GNI per capita of $1,620 in 2018.[945] Agriculture is an important component of the Kenyan economy and contributes about one-third of Kenya's total gross domestic product.[946] Around 75 percent of Kenyans rely on agriculture for at least part of their income.[947] Approximately 20 percent of Kenya's land, a mixture of primarily arid and semi-arid regions, is suitable for farming.[948] Because Kenya typically does not experience freezing temperatures that would break the pest life cycle, Kenya has greater pest pressures than countries with more temperate climates and freezing winters.

Agricultural exports are Kenya's largest single export category. In 2018, primary agricultural export products were tea ($1,359.7 million); cut flowers ($570.5 million); fresh vegetables, roots, and tubers

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938 IHS Markit, Global Trade Atlas database, HS subheading 0708.20 (accessed January 22, 2020).
939 IHS Markit, Global Trade Atlas database, EU HTS subheading 0708.2000 (accessed January 10, 2020).
940 IHS Markit, Global Trade Atlas database, HS subheading 0708.20 (accessed January 20, 2020).
941 IHS Markit, Global Trade Atlas database, HS subheading 0708.20 (accessed January 20, 2020).
942 The World Bank defines lower-middle-income economies as those with per capita GNIs between $1,026 and $3,995. World Bank, "World Bank Country and Lending Groups" (accessed January 10, 2020).
943 IHS Markit, Global Trade Atlas database, EU HTS subheading HTS 0708.2000 (accessed January 10, 2020).
944 EU green bean production in 2018 was nearly 1.1 million metric tons. Eurostat, "Crop Production in National Humidity," Fresh Beans, Harvested Production (accessed January 20, 2020).
945 World Bank, "World Bank Country and Lending Groups" (accessed November 8, 2019); World Bank, Data, GNI per capita, atlas method (current US$) (accessed November 8, 2019); World Bank, Data, "Population, Total—Kenya" (accessed November 22, 2019).
946 Government of Kenya, MOALF&I, *Agricultural Sector Transformation and Growth Strategy*, 2019, 23–24.
947 USAID, "Agriculture and Food Security" (accessed November 22, 2019).
948 USAID, "Agriculture and Food Security" (accessed November 22, 2019); Oluoch-Kosura, "Performance of Kenya's Agriculture: A Macro-Economic Perspective" (accessed February 24, 2020).

($248.3 million); coffee ($230.4 million); and fresh fruits ($142.7 million).[949] French beans alone accounted for 1.5 percent of total annual Kenyan exports.[950]

Kenya Industry Structure and Production System

Kenya produced an estimated 62,000 metric tons of French beans on 18,533 acres of land in 2017.[951] French bean production is virtually all open-air, irrigated production, and is largely centered around the Mount Kenya area.[952] Around 60 percent of the French beans are grown by smallholder farmers, most with less than 5 acres of land dedicated to a mix of crops, including French beans.[953] The French bean industry employs around 52,000 smallholder farmers and an estimated 40,000 to 70,000 hired workers on farms and in factories (handling, cleaning, packaging, and some canning).[954] Smallholder farms can be part of cooperatives, growing crops under contract for larger farms or under agreements with aggregators who collect produce from multiple farms for the export market. The share of Kenya's output produced by smallholder farms has fallen over the past five years as MRLs have affected exporter sourcing decisions and profits have been squeezed.[955] Average annual prices have declined in real terms, while complying with numerous quality, environmental, social, and health and safety standards is increasingly costly, especially to smallholder farmers.[956]

In Kenya, French beans are primarily grown for the export market, which offers a premium price compared to the domestic market.[957] Kenya's exports are competitive in the EU French bean market because of Kenya's geographic and climatic advantages, investments in certification programs and marketing, and value-added packaging and market segmentation focusing on sales to higher-value portions of the European French bean market.[958] Kenya is heavily reliant upon the EU market, which accounted for 91 percent (by value) of Kenyan French bean exports in 2018.[959] The remainder of Kenyan

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[949] IHS Markit, Global Trade Atlas database, HS subheading 0902 (tea), HS subheading 0603 (cut flowers), HS chapter 07 (fresh vegetables, roots, and tubers), HS subheading 0803, 0804, 0805, 0806, 0807, 0809, and 0810 (fresh fruits), and HS subheading 0901 (coffee) (accessed January 10, 2020).

[950] EuropeAid, DEVCO, "Green Beans Value Chain Analysis in Kenya," February 2018, 3.

[951] EuropeAid, DEVCO, "Green Beans Value Chain Analysis in Kenya," February 2018, 3.

[952] Primary growing areas are Embu, Kirinyaga, Machakos, Murang'a, Naivasha, Nyeri, and Thika. M-Farm, "Growing French Beans in Kenya," January 16, 2015; industry representative, interview by USITC staff, Nairobi, Kenya, December 5, 2019.

[953] A smallholder farmer is a small-scale farmer. Although a universal definition of a small-scale farm does not exist, the one used in this case study is consistent with that given in the Netherlands Development Organization's *The Beans Value Chain in Kenya* (August 2012): less than 5 hectares, potentially including up to 10 to 20 head of livestock, and possibly employing a mixture of commercial and subsistence farming, with much of the labor supplied by the family. Netherlands Development Organization, *The Beans Value Chain in Kenya*, August 2012, i.

[954] EuropeAid, DEVCO, "Green Beans Value Chain Analysis in Kenya," February 2018, 3.

[955] EuropeAid, DEVCO, "Green Beans Value Chain Analysis in Kenya," February 2018, 2; industry representative, interview by USITC staff, Nairobi, Kenya, December 3, 2019.

[956] EuropeAid, DEVCO, "Green Beans Value Chain Analysis in Kenya," February 2018, 2; industry representative, interview by USITC staff, Nairobi, Kenya, December 3, 2019.

[957] Industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019; industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019; industry representative, interview by USITC staff, Nairobi, Kenya, December 6, 2019; EuropeAid, DEVCO, "Green Beans Value Chain Analysis in Kenya," February 2018, 1.

[958] EuropeAid, DEVCO, "Green Beans Value Chain Analysis in Kenya," February 2018, 1.

[959] IHS Markit, Global Trade Atlas database, HS subheading 0708.20 (accessed January 10, 2020).

French bean exports go primarily to the United Arab Emirates, Hong Kong, and Switzerland.[960] Although French beans are rarely used in local cuisine, the substantial quantity of beans that do not meet export standards are typically sold at lower prices in the domestic market, largely split among the household, hotel, and restaurant markets, with some sold for animal feed or compost.[961]

Kenya's Pesticide and MRL Policies

Kenya uses a risk-based approach for pesticide registration and MRL assessment based on Codex MRL standards.[962] Kenya also takes into consideration MRL changes in important export markets, which can prompt re-evaluations of Kenya's registrations and MRLs.[963] Kenya's Pest Control Products Board (PCPB) is the governmental body that regulates pesticide registration, trade, production, distribution, and usage in Kenya. PCPB works together with the Kenya Plant Health Inspectorate Service (KEPHIS), which is responsible for monitoring pesticide residues on plant-origin foods.[964] KEPHIS also issues export certificates, which are required for a firm to export products, and provides outreach to producers and exporters. Kenya's Department of Health is responsible for domestic monitoring and enforcement of pesticide use and food safety. Kenyan farmers cannot legally use a pesticide on a crop before it has been registered for use in Kenya, which requires that efficacy trials be conducted in Kenya.[965]

Pest Pressures and Pesticide Use

French bean farmers face high and growing pest pressures in Kenya, particularly when wet seasons are prolonged. There are typically two wet seasons in Kenya, a more intense rainy period lasting from April to May and a milder one from October to early December. Major pests include white flies, thrips, mites, pod borer, rust, blight, and anthracnose.[966] There is also the potential for greater future pest pressure tied to climate change and invasive pests, as has happened to other crops in Kenya (box 5.2). At the same time, a limited number of pest-management products are available for use on French beans.[967]

Box 5.2 Climate and Invasive Species Effects on Pest Pressures in Kenya

Kenya is seeing stronger pest pressures tied to climate effects and an increase of invasive species.[a] Recently, extreme pest pressures have illustrated the importance and need for more pesticide registrations and more MRLs in Kenya. The sequence of invasive pests in recent years has affected a number of Kenya's crops beyond French beans. These instances have driven up Kenyan pesticide imports, some purchased as emergency measures by the Kenyan government in response to concerns about yield losses to maize, Kenya's major food crop. For example, in 2011, Kenya was confronted with maize lethal necrosis, a combination of two viruses that can wipe out an entire crop.[b] This was followed in 2014 by the

[960] IHS Markit, Global Trade Atlas database, HS subheading 0708.20 (accessed January 10, 2020).
[961] EuropeAid, DEVCO, "Green Beans Value Chain Analysis in Kenya," February 2018, 2.
[962] Kenyan government representative, interview by USITC staff, Nairobi, Kenya, December 4, 2019.
[963] For example, Kenya has reviewed and changed registrations for pesticides following EU changes, such as Kenya's banning the use of dimethoate on French beans after the EU lowered the MRL.
[964] Bryant Christie Inc., "Kenya Pesticide MRLs Market Information Report," August 2018, 1.
[965] Kenyan government representative, interview by USITC staff, Nairobi, Kenya, December 4, 2019.
[966] Industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019; industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019.
[967] Kenyan government representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019.

spread of the tomato leafminer or *Tuta absoluta*, which affects tomatoes (and is also capable of causing complete losses if left unchecked), as well as potatoes and eggplants. Pest control for *Tuta absoluta* is challenging because of the pest's ability to rapidly develop insecticide resistance and the nature of the crop damage it causes.[d] In 2016, fall armyworm appeared, and by 2018 it was present in one-fourth of Kenya's maize acreage.[e] The threat of crop loss due to fall armyworm was so extreme that the Kenyan government intervened and allowed the use of emergency pesticide approvals to give maize farmers tools to fight this invasive insect.[f]

Source: Industry representative, interview by USITC staff, Nairobi, Kenya, December 5, 2019; FAO, Food Security and Nutrition Working Group, "Maize Lethal Necrosis Disease (MLND)—A Snapshot," June 2013; Infonet Biovision, "Tuta Absoluta (Tomato Leaf Miner)" (accessed December 18, 2019); Greenlife Crop Protection Africa, "Tuta Absoluta" (accessed December 18, 2019); and FAO, "FAO Trains Farmers in Kenya to Save Crops," November 19, 2018.
[a] Industry representative, interview by USITC staff, Nairobi, Kenya, December 5, 2019.
[b] FAO, Food Security and Nutrition Working Group, "Maize Lethal Necrosis Disease (MLND)—A Snapshot," June 2013.
[c] Infonet Biovision, "Tuta Absoluta (Tomato Leaf Miner)" (accessed December 18, 2019).
[d] Greenlife Crop Protection Africa, "Tuta Absoluta" (accessed December 18, 2019).
[e] FAO, "FAO Trains Farmers in Kenya to Save Crops," November 19, 2018.
[f] Industry representatives, interview by USITC staff, Nairobi, Kenya, December 2, 2019.

Factors Limiting Substitute Pesticide Registrations

Farmers face higher costs from the lowering of MRLs when there are limited substitute pesticides registered for use, leaving farmers with fewer and less cost-effective alternatives to control specific pests and exposing their crops to greater risk of pest resistance. This problem is worse for specialty crops for which relatively few pesticides are available, and becomes even more challenging in markets where it is difficult to register new pesticides. For example, Kenyan industry and government representatives expressed concerns that if Kenyan authorities continue to cancel pesticide registrations in response to EU non-approvals or nonrenewals, Kenyan French bean farmers will be left without adequate cost-effective pest control options.[968] These representatives also identified several factors that could tend to limit Kenyan pesticide registrations and MRLs for French beans and other specialty crops, including (1) the high cost of establishing an MRL compared to potential returns, and (2) the intellectual property rights concerns of pesticide manufacturers.[969]

One reason so few actively registered pesticides are available to growers for use in Kenya is the cost and difficulty of conducting efficacy trials required for pesticide registration in Kenya, which can cost around $30,000 and take from 1.5 to 5 years, depending on the crop characteristics. [970] These must be completed for each pesticide on individual crops in Kenya for the pesticide to be registered for use by producers.[971] The economic incentives for registrants to pay for and conduct such trials in Kenya, and separately in

[968] Kenyan government representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019; industry representative, interview by USITC staff, Nairobi, Kenya, December 3, 2019; industry representative, telephone interview by USITC staff, January 30, 2020; Kenyan government representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019.
[969] Kenyan government representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019.
[970] Industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019; industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019; Kenyan government representative, interview by USITC staff, Nairobi, Kenya, December 4, 2019.
[971] Kenyan government representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019; Kenyan industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019; Kenyan government representative, interview by USITC staff, Nairobi, Kenya, December 4, 2019.

other African countries, are limited, especially because many crops (such as French beans) are "minor" crops for which the market size is fairly small.[972] There are some programs and funding available to assist industry and government groups with registration costs, such as the Interregional Research Project No. 4 (IR-4) that facilitates registrations of pesticides on specialty food crops (see chapter 2) and EU-funded programs which help pay for efficacy trials.[973] Also, EAC task forces are working with different government agencies and industry associations in multiple countries to develop policies within the EAC to facilitate pesticide registrations and recognize the results of efficacy trials across East African countries.[974]

Another potential limit to the registration of new pesticides across Africa is concern about intellectual property rights protection.[975] As part of the registration process for domestic use, a pesticide manufacturer must submit detailed information about the formulation and ingredients in a particular pesticide, as well as a massive amount of information about its toxicological effects and residue data.[976] In general, manufacturers are concerned that revealing so much technical information about a pesticide may leave them vulnerable to intellectual property infringement. [977] Industry representatives have noted that this is a major concern inhibiting their submission of registration packets for new plant protection products.[978] As a result, growers in many developing countries, such as Kenya and other African countries, that lose access to existing pesticides through cancellations or non-renewals may find manufacturers of new pesticides reluctant to seek their registration in key export markets, leaving growers to choose among a much more limited number of possible pesticides which are generally older, generic, and more broad-spectrum; conversely, fewer of the newer, reduced-risk, targeted pesticides are available.[979]

Farmers in Kenya also tend to rely heavily on older, generic formulations because they know how to use them. For smallholder farmers in particular, it can be difficult learning how to properly use a new product, given sometimes limited access to information and limited capital resources.[980] Moreover, the older formulations are established and known to be effective, as well as often being lower in cost.[981] Because generic formulations may be similar but not identical to the original patented plant protection product and use different components (e.g., surfactants and solvents), they may work slightly differently.[982] Kenyan farmers struggle with the additional problem of counterfeit, sometimes adulterated, pesticides and products which, even if applied by the farmer according to instructions, could result in MRL violations.[983]

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[972] Kenyan industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019.
[973] Kenyan government representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019; Kenyan industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019; industry representative, telephone interview by USITC staff, February 19, 2020.
[974] Kenyan government representative, interview by USITC staff, Nairobi, Kenya, December 4, 2019.
[975] Industry representative, interview by USITC staff, Nairobi, Kenya, December 5, 2019.
[976] Kenyan government representative, interview by USITC staff, Nairobi, Kenya, December 4, 2019.
[977] Industry representative, telephone interview by USITC staff, December 18, 2019.
[978] Industry representative, interview by USITC staff, Nairobi, Kenya, December 5, 2019.
[979] Industry representative, interview by USITC staff, Nairobi, Kenya, December 5, 2019.
[980] Kenyan industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019; Kenyan industry representative, interview by USITC staff, Nairobi, Kenya, December 5, 2019.
[981] Industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019.
[982] Jones, "Fungicide and Fallow Management: 3 Tips for Planting in 2018," January 19, 2018.
[983] Rading, "15 Percent of Pesticide Products in Kenya Are Fake," August 9, 2018.

Costs and Effects of Missing and Low MRLs on the French Bean Industry

Missing and low MRLs have costs and effects along the value chain for Kenyan French bean exporters and affect a wide array of stakeholders, from farmers, aggregators, and exporters to importers and consumers, as well as government regulators and the crop protection industry. Kenyan smallholder farmers face some of the most drastic effects among distribution chain participants, with MRL rejections capable of causing farmers to go out of business.[984] Like other Kenyan horticultural exports, the Kenyan French bean industry is heavily reliant upon exports to the EU and must adjust production practices to meet that market's requirements for access.[985] When the EU lowers a pesticide MRL and the MRL cannot be met using label instructions, Kenyan's PCPB often removes registration for that product for use on French beans in Kenya.[986] An added challenge is the difficulty and cost of educating so many smallholder farmers about changes to MRLs to ensure compliance with new required production practices.

Table 5.3 presents the MRLs for several compounds used in Kenya, major French bean-importing markets, and Codex. These pesticides are highlighted because they were identified by government representatives and industry experts as important compounds for Kenyan French bean growers that either (1) were the source of MRL violations in 2013 (see discussion below) or (2) are currently important to growers and could potentially face lower future MRLs. The pesticides include key insecticides (dimethoate, chlorpyrifos, and acephate) and fungicides (tebuconazole and mancozeb) that either used to be or still are important to the Kenyan French bean industry. Of the five pesticide products, the EU MRLs for dimethoate, acephate, chlorpyrifos, and tebuconazole have already been lowered (table 5.3), the effects of which are described later in this section. As shown in table 5.3, chlorpyrifos is about to lose its EU approval, and the Kenyan vegetable industry is concerned about mancozeb, whose approval is slated to expire in January 2021. Kenya is among the numerous countries that have voiced concerns at the WTO SPS Committee over EU policies to assess, classify, and regulate endocrine disrupters, with Kenya noting that under the EU's proposed regulations, many plant protection products that have no existing alternatives would be banned.[987]

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[984] Industry representative, interview by USITC staff, Nairobi, Kenya, December 6, 2019.
[985] Kenyan government representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019; industry representative, interview by USITC staff, Nairobi, Kenya, December 3, 2019.
[986] Kenyan industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019.
[987] WTO, "European Union Legislation on Endocrine Disruptors," updated December 6, 2019.

Table 5.3 MRLs for key pesticides used in the French bean industry (ppm)

Active substance	Pesticide Type	Codex	Kenya	Canada	United States[a]	EU	Recent changes (EU)
Acephate	Insecticide	5	5	1	3	0.01	
Chlorpyrifos	Insecticide	0.01	0.01	0.1	0.05	0.01	Approval not renewed as of December 2019. EU member states' grace periods ended by April 2020, after which MRLs defaulted to 0.01 ppm (previous level was 0.05 ppm).
Dimethoate	Insecticide	Missing	Missing	1	2		
Mancozeb	Fungicide	Missing	Missing	0.1	Missing	0.1	Approval expires January 2021.
Tebuconazole	Fungicide	3	3	0.1	0.1	2	

Sources: Bryant Christie Global, Pesticide MRLs database (accessed January 28, 2020); European Commission, EU Pesticide Database (accessed multiple dates).
Note: "Missing" indicates that there is no MRL for this product on French beans.
[a] United States MRLs are for the succulent bean group.

Insecticides

Insecticides were the type of pesticide that industry experts most often discussed when asked about the costs and effects of missing and low MRLs. The three insecticides discussed here were each important, widely used insecticides for Kenyan French bean growers before changes in EU MRLs led to Kenyan changes to pesticide registrations. As registrations for these insecticides were removed or approved uses were modified, Kenyan growers switched to less cost-effective alternative insecticides. Dimethoate was a popular broad-spectrum insecticide once used by an estimated 90 percent of Kenyan farmers to controls thrips, mites, white flies, and aphids.[988] Kenyan farmers could eliminate all pests with one application.[989] The EU banned the use of dimethoate in the EU in 2009, and after an import tolerance request to the EU for dimethoate was rejected in 2012, the EU lowered the MRL from 0.2 ppm to 0.02 ppm (the limit of determination at that point in time).[990] The use of dimethoate was not a problem for Kenyan farmers when the MRL was 0.2 ppm, but farmers were no longer able to use dimethoate when the MRL was lowered to 0.02 ppm.[991] Kenya's agrochemical companies were also affected, with sales of dimethoate falling from 400,000 liters a year to 30,000 liters when the registration was removed.[992]

[988] Industry representative, interview by USITC staff, Nairobi, Kenya, December 5, 2019.
[989] Industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019.
[990] Munen, "EU Rejects French Beans over Use of Banned Spray," February 23, 2013; industry representative, interview by USITC staff, Nairobi, Kenya, December 5, 2019.
[991] Industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019. The EU MRL for dimethoate used on beans in pods was set to 0.02 on June 7, 2010. It was lowered to the current limit of determination, 0.01 ppm, on January 17, 2018. EC, EU Pesticide Database, "0260010: Beans (with pods), Dimethoate" (accessed January 6, 2020).
[992] Industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019.

At about the same time, the EU lowered its MRLs for chlorpyrifos and acephate, two other insecticides that were important for Kenyan French bean farmers.[993] Chlorpyrifos was used to control thrips and white flies, but is no longer permitted for post-emergence use on French beans or other fruits and vegetables in Kenya.[994] Acephate is currently registered for use in Kenya on French beans to control aphids, thrips, cutworms, and white flies.[995] Beginning in 2013, the EU lowered the MRLs for these products on French beans to the limit of determination—again, a very low level that required either ending use of the product or significantly changing previous agricultural practices.[996]

Between 2012 and 2014, the years surrounding the EU MRL changes described above, the EU found numerous insecticide MRL violations on imports of French beans from Kenya. These violations seriously impacted Kenyan exporters and farmers, as described below in the section on "Effects along the Supply Chain and Industry Structure."[997]

Fungicides

Although effects from insecticides MRLs are the primary focus of this case study, there are several fungicides that are important for the French bean industry in Kenya. Tebuconazole is a fungicide that treats rust, anthracnose, and angular leaf spot on French beans. In 2012 the Kenyan French bean industry decided to try to establish a Codex MRL for tebuconazole.[998] The Kenyan industry worked with the Europe-Africa-Caribbean-Pacific Liaison Committee (COLEACP) to generate a data package and label for the product with Kenya and Senegal.[999] In 2018 Codex adopted an MRL of 3 ppm, and EFSA proposed the same MRL as Codex after reviewing the data package, but the EU did not raise its MRL to the Codex level.[1000] Despite EFSA's 2017 conclusion that there was sufficient information to support an MRL of 3 ppm for beans with pods, higher than the EU's existing MRL of 2 ppm, and that the MRL was unlikely to present a risk to consumer health, it was not approved for final EU implementation because the assessment did not include a risk assessment of certain metabolites.[1001] In December 2019, the EU was reported to be examining tebuconazole more critically, reviewing metabolites and considering policy changes arousing concern in Kenya.[1002] Kenyan vegetable producers reportedly are also concerned about

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[993] Chlorpyrifos was one of the active substances for which there were French bean MRL violations in 2012 and 2013.
[994] Government of Kenya, PCPB, Registered Products by Crop (accessed February 20, 2020).
[995] Government of Kenya, PCPB, Registered Products by Crop (accessed February 20, 2020).
[996] In 2003, the EC mandated the banning of plant protection products containing acephate within 18 months. Industry representative, interview by USITC staff, Nairobi, Kenya, December 5, 2019; EFSA, "Review of the Existing Maximum Residue Levels for Chlorpyrifos," 2017, 25; EC, 2003/219/EC: Commission Decision of 25 March 2003 concerning the non-inclusion of acephate in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance (Text with EEA relevance) (notified under document number C(2003) 868), http://data.europa.eu/eli/dec/2003/219/oj.
[997] Munen, "EU Rejects French Beans over Use of Banned Spray," February 23, 2013.
[998] Kenyan government representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019.
[999] Kenyan government representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019; COLEACP, *Annual Report 2014*, n.d., 12.
[1000] Kenyan government representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019; Codex Alimentarius, "Pesticide Database Search," "Tebuconazole" (accessed April 30, 2020).
[1001] Brancato et al., "Modification of the Existing Maximum Residue Level for Tebuconazole," June 2017, 1, 3–4.
[1002] Kenyan government representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019.

mancozeb, which is up for review by the EU and is used to control fungal and bacterial infections on French beans and blight on over 300 crops in Kenya.[1003]

Effects Along the Supply Chain

Complying with MRLs creates costs for farmers, importers, exporters, and regulatory agencies throughout the supply chain. One industry expert estimated the cost of traceability and MRL compliance efforts as 20 percent of the cost of production.[1004] Noncompliance with import market MRLs, however, can trigger even higher costs, such as when Kenyan French beans from a number of suppliers were temporarily banned from the EU in 2013. This ban cost smallholder farmers up to $1,000 each, which is more than the annual income of the average smallholder farmer.[1005] Related increases in EU inspection rates for imports from Kenya also raised costs throughout the supply chain.[1006] The effects specific to past instances of MRL violations for insecticide residues on Kenyan crops, and the yield implications from adapting production practices to meet lower insecticide MRLs, along with other general effects from missing and low MRLs, are discussed later in this section. They are organized by the type of cost or effect and what portion of the supply chain is affected.

Kenyan Regulatory Capacity

The Kenyan regulatory agencies mentioned earlier, KEPHIS and PCPB, have also seen effects from missing and low MRLs. KEPHIS has both incurred costs and received benefits related to compliance with lower EU MRLs. For example, as the limit of determination for the EU's pesticide MRLs fell to lower levels, more modern, sophisticated equipment was required. KEPHIS had to buy two testing machines, each costing $500,000, that could perform tests to the lower limit of determination. Staff training was also needed to learn the new approach for testing and to assure compliance with the EU standards in other ways. KEPHIS sent staff to the EU reference lab for training, and then EU trainers from those labs went to Kenya to conduct training on site in Kenya's labs, both substantial expenses. KEPHIS also invested in training farmers in proper pesticide use and continues to incur significant costs to register exporters as eligible to export, including sampling and testing horticultural products.

Compliance with MRLs has also resulted in some benefits to KEPHIS. KEPHIS received funding for two testing machines (in addition to the ones that KEPHIS purchased themselves) from the EU and USAID. Additionally, there are EU capacity-building funds to assist KEPHIS in ensuring MRL compliance though

[1003] Industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019.
[1004] Industry representative, interview by USITC staff, Nairobi, Kenya, December 5, 2019.
[1005] Munen, "EU Rejects French Beans over Use of Banned Spray," February 23, 2013; Netherlands Development Organization, *The Beans Value Chain in Kenya*, August 2012; World Bank, Data, Official Exchange Rate (LCU per US$), Kenya (accessed January 23, 2020); U.S. Bureau of Labor Statistics, Databases, Tables and Calculators, "CPI Inflation Calculator" (accessed January 23, 2020).
[1006] The EU increased inspection rates on imports of French beans and peas in pods from Kenya to 10 percent beginning January 1, 2013. Inspection rates for beans returned to normal levels of 2 percent on July 1, 2015. Inspection rates for peas in pods were lowered to 5 percent on July 1, 2017, and to the normal rate of 2 percent in July 2018. European Union, Commission Implementing Regulation (EU) No 1235/2012, December 19, 2012; European Union, Commission Implementing Regulation (EU) 2015/1012, June 23, 2015; European Union, Implementing Regulation (EU) 2017/1142, June 27, 2017; European Union, Commission Implementing Regulation (EU) 2018/941, July 2, 2018.

staff and industry training. EU audits of the Kenyan system and corrective actions resulted in increased long-term efficiency and greater capacity.

Farmers

There are multiple examples of the effects that MRL noncompliance can have on farmers. For example, in 2013, farmers in the Kangai Tisa Horticultural Farmers group were affected by the EU's detection of excess residues of dimethoate and other organophosphate chemicals on export crops.[1007] Over 1,000 farmers faced losses from their inability to export 12 metric tons of French beans.[1008] There were reports of unpicked produce rotting in fields and individual farmer losses of up to 70,000 or 80,000 Kenyan shillings (approximately $900 to $1,000 in real terms), compared to a typical smallholder farmer's annual profit of only 60,000 Kenyan shillings.[1009] The rate at which the EU inspected Kenyan French beans rose as well, imposing additional costs; it took until 2015 for the inspection rates to go back down to 2 percent.[1010] Overall impacts included job losses and businesses collapsing, from handlers and packers all the way to the farmer.[1011]

This example also demonstrates how time and producer education are needed for producers of a given commodity to be able to transition production practices to meet changed MRLs. Despite the Kenyan ban on dimethoate, which followed the EU's lowering of the MRL, a survey by the *Daily Nation* newspaper found that at the time of the market disruptions in 2013, the chemical was still being sold at trading centers in Kirinyaga County.[1012] Following the incident, multiple efforts were undertaken to educate farmers about proper pesticide use, with the cost of one industry-led effort estimated at around $30 to $40 per farmer for an effort reaching 8,000 farmers.[1013]

More recently, in 2019, there were reports of three large Kenyan companies with shipments rejected at the EU border because of products exceeding MRLs.[1014] This led to increased EU inspection rates of all French bean imports from Kenya.[1015] Further, the companies were banned from exporting to the EU by KEPHIS but are reportedly still purchasing products from the farmers they maintain contracts with in order to preserve their supply chain, and redirecting or disposing of the product.[1016] The companies reportedly will be given time to take corrective actions, and then will be reevaluated by KEPHIS to

[1007] Munen, "EU Rejects French Beans over Use of Banned Spray," February 23, 2013.
[1008] Munen, "EU Rejects French Beans over Use of Banned Spray," February 23, 2013.
[1009] Munen, "EU Rejects French Beans over Use of Banned Spray," February 23, 2013.; Netherlands Development Organization, *The Beans Value Chain in Kenya*, August 2012, i; World Bank, Data, Official Exchange Rate (LCU per US$), Kenya (accessed January 23, 2020); U.S. Bureau of Labor Statistics, Databases, Tables and Calculators, "CPI Inflation Calculator" (accessed January 23, 2020).
[1010] Industry representative, interview by USITC staff, Nairobi, Kenya, December 5, 2019.
[1011] Industry representative, interview by USITC staff, Nairobi, Kenya, December 5, 2019.
[1012] Munen, "EU Rejects French Beans over Use of Banned Spray," February 23, 2013.
[1013] Industry representative, interview by USITC staff, Nairobi, Kenya, December 5, 2019.
[1014] Industry representative, interview by USITC staff, Nairobi, Kenya, December 5, 2019.
[1015] The EU increased inspection rates of imports of French beans from Kenya from the standard 2 percent to 5 percent in early 2019, and these rates remain in effect as of March 2020. European Union, Commission Implementing Regulation (EU) 2019/35 of 8 January 2019; European Union, Commission Implementing Regulation (EU) 2019/1793, October 22, 2019 (in force as of March 30, 2020).
[1016] Industry representative, interview by USITC staff, Nairobi, Kenya, December 5, 2019.

determine whether they are eligible to be relisted.[1017] Each delisted exporting company is charged by KEPHIS for expenses related to the audit, testing, and relisting.[1018]

In cases where an individual container of produce does not comply with import market MRLs, the crop may be disposed of, resulting in a complete loss to the farmer, who is not paid.[1019] In instances when a crop is not destroyed, rerouting the container from a market where it has been rejected to another market costs on average $20,000.[1020] Exporters often implicitly pass these costs down to the farmers through lower prices. For example, one French bean exporter calculated the drop in the price it was willing to pay to farmers to equal the cost of rejected shipments, cutting the farmer price more than 50 percent.[1021] There are also costs to farmers when MRL noncompliance is detected before export. Under some contracts or informal agreements with buyers, if the beans and peas from a grower do not comply with EU MRLs, the grower won't be paid, and all costs incurred by the grower are lost.[1022]

Compliance with the EU's insecticide MRLs also has costs associated with yield implications for farmers. Farmers face a tradeoff between quality or an MRL violation, as they are not able to both control pests and meet MRLs.[1023] For example, farmers reported ending pesticide applications more days before harvest than specified by the approved pesticide application instructions, resulting in additional days of exposure to white fly and thrip damage. Even one to three days of additional insect damage can mean that a larger portion of the French beans do not meet strict export quality requirements because of spots on the beans and receive half the price. However, the costs of losing a few kilograms of exportable produce is much less than the potential cost of an MRL violation, which could mean being banned from the export channel and going out of business.[1024]

Importers and Exporters

Produce exporters and importers also face costs from MRL compliance and noncompliance. For Kenyan exporters, costs related to the enhanced inspections and delisting from the 2013 disruption were high enough that between April and November of that year, a number of French bean exporters went out of business. Additionally, at least six changed their business, leaving bean and pea exports and shifting to exporting other products or selling to local markets. Exporters reported cost increases during this period of 25.8 percent on average.[1025]

Importers have also been affected, albeit in different ways. For example, in 2013, the enhanced inspection rates for UK imports of Kenyan French beans and peas raised costs to both UK importers and Kenyan exporters. In a report, the Fresh Produce Consortium estimated that in April 2013 additional

[1017] Industry representative, interview by USITC staff, Nairobi, Kenya, December 5, 2019.
[1018] Industry representative, telephone interview by USITC staff, February 4, 2020.
[1019] Kenyan government representative, telephone interview by USITC staff, October 16, 2019.
[1020] Yeung et al., "Case Studies of Trade Problems Related to MRLs," 2017, 81.
[1021] Industry representative, interview by USITC staff, Nairobi, Kenya, December 5, 2019.
[1022] Industry representative, interview by USITC staff, Nairobi, Kenya, December 6, 2019.
[1023] Industry representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019.
[1024] Industry representative, interview by USITC staff, Nairobi, Kenya, December 6, 2019.
[1025] Government of the United Kingdom (UK), Department for Business Innovation & Skills, *FPC Review of Charges for Official Controls*, March 2015, 27–28.

inspections were costing the UK industry at least £80,000 (about $140,000 in real terms) per month.[1026] Companies reported that the annual cost of clearance delays could be as much as £50,000 (about $85,000 in real terms) per company and that the cost of additional pesticide screening could be as much as £280,000 (about $490,000 in real terms) per year.[1027] Since fresh produce is often prepackaged with "sell by" dates, inspection delays can mean wasted products.[1028] There are also reputational risks from inspection delays, with one importer reporting that they can't afford to have a 48-hour delay: retailers remember the delays, and the importer may be subject to penalties or even dropped as a supplier by the retailer.[1029] Such costs from MRL compliance and noncompliance cannot be passed on to consumers, so it must be absorbed by importers and others in the supply chain.[1030]

Exporters also face reputational risks from MRL violations. Noncompliance with MRLs also poses significant marketwide costs. When an MRL violation is reported on Kenyan French beans from one exporter, it lowers the import demand for all Kenyan French beans. Numerous violations can also prompt importers to increase their inspection rates for Kenyan produce—for example, going from 5 percent sampling to 10 percent sampling. This has costs in terms of the amount of product required for testing (which is product that cannot be sold later) and delays at the port where the product is tested, which can prove very costly for perishable products such as French beans. For example, in 2013, when higher EU inspection rates were in place following MRL violations on imported French beans, there were delivery delays of up to 72 hours that significantly shortened product shelf life after the products were delivered to retailers.[1031]

Industry Structure

Lower MRLs and the removal of pesticide registrations affect the size and structure of the French bean industry. Prices have remained steady over the past five years, meaning that they have fallen in real terms. As a result, costs to adjust production practices to meet lower MRLs, such as marginal increases in input costs or slight decreases in yields, create a price squeeze on producers.[1032] French bean farmers are leaving the industry, moving over to avocados or other horticultural crops, including berries.[1033] At the same time, exporters tend to favor larger farmers with more uniform growing practices: the difficulty of ensuring that so many smallholder farmers adapt to new practices and meet new MRL requirements adds to exporters' risks. Larger farmers are also better able to adapt to lower MRLs. They can buy, store, and apply their own chemicals and benefit from scale. If a chemical is phased out, they can use the stores

[1026] Government of the UK, Department for Business Innovation & Skills, *FPC Review of Charges for Official Controls*, March 2015, 27; World Bank, Data, Official Exchange Rate (LCU per US$), United Kingdom (accessed May 1, 2020); U.S. Bureau of Labor Statistics, Databases, Tables and Calculators, "CPI Inflation Calculator" (accessed May 1, 2020).
[1027] Government of the UK, Department for Business Innovation & Skills, *FPC Review of Charges for Official Controls*, March 2015, 3; World Bank, Data, Official Exchange Rate (LCU per US$), United Kingdom (accessed May 1, 2020); U.S. Bureau of Labor Statistics, Databases, Tables and Calculators, "CPI Inflation Calculator" (accessed May 1, 2020).
[1028] Industry representative, interview by USITC staff, London, January 6, 2020.
[1029] Government of the UK, Department for Business Innovation & Skills, *FPC Review of Charges for Official Controls*, March 2015, 12.
[1030] Industry representative, interview by USITC staff, London, January 6, 2020.
[1031] Technical Center for Agricultural and Rural Cooperation, Agritrade, "New EU Maximum Residue Levels Hit Kenyan Vegetable Exports," April 28, 2013.
[1032] Industry representative, interview by USITC staff, Nairobi, Kenya, December 3, 2019.
[1033] Industry representative, interview by USITC staff, Nairobi, Kenya, December 3, 2019.

they have on hand to treat another eligible crop.[1034] As a result, the smallholder farmers' share of French bean production has fallen from about 70 percent to about 60 percent.[1035]

Trade Patterns

Lower MRLs can also alter trade patterns, sometimes to a country's benefit. Strong regulatory capacity and an organized industry able to adapt growing practices to meet new, lower MRLs in one country can allow exporters from that country to take market share from another country unable to adapt to new MRL requirements. For example, Kenya is better situated to adapt to lower MRLs than Uganda, which has less governmental regulatory capacity and less effective industry associations.[1036] Moreover, if shipments of produce from one country are rejected because of MRL restrictions, importers will increase sourcing from other countries to lower their risk of rejected shipments.[1037]

Positive Effects

In some cases, MRL compliance and noncompliance can have positive effects, such as receiving funding from other countries or development organizations for testing equipment, capacity development, educational or extension efforts, and, ultimately, system and food safety improvements resulting from these efforts. For example, the EU has supported a number of programs focused on promoting Kenyan vegetable exports, food safety system improvement, and value chain strengthening (e.g., the Pesticides Initiative Programme and Fit for Market).[1038] MRL violations in 2012 and 2013 led to an audit of the Kenyan French bean value chain that ultimately improved production practices, led to better adherence to GAP, and encouraged stronger industry coordination, which can lead to higher-quality and higher-value products. In addition, further training for farmers on correct application of chemicals may lower the incidence of improper chemical application and exposure.

In some cases, it is difficult to separate the effects of MRL requirements from other importer requirements that put additional pressure on growers. For example, most Kenyan exports of French beans and other horticultural crops to the EU are Global GAP certified. This involves requirements affecting agrochemical application and proper pre-harvest intervals, as well as correct handling of agrochemicals, environmental stewardship, labor relations, and wages.

Case Study: Mangoes from Peru

This case study examines the effects of recent EU decisions to lower the MRLs on important pesticides used in the mango industry. Mango is a highly perishable minor crop, and like other tropical crops, it is vulnerable to pressure from many types of pests, including fungi. Mango growers in Peru and Brazil are concerned about the lowering of MRLs for important mango plant protection products, particularly thiabendazole, chlorpyrifos, and methomyl.

[1034] Industry representative, interview by USITC staff, Nairobi, Kenya, December 5, 2019.
[1035] Kenyan government representative, interview by USITC staff, Nairobi, Kenya, December 2, 2019.
[1036] Industry representative, interview by USITC staff, Nairobi, Kenya, December 5, 2019.
[1037] Industry representative, telephone interview by USITC staff, February 20, 2020.
[1038] EuropeAid, DEVCO, "Green Beans Value Chain Analysis in Kenya," February 2018, 1.

The case study focuses primarily on producers in Peru, but comparisons to other producing countries are presented throughout in order to demonstrate that effects differ depending on producing countries' unique characteristics. In 2018, global mango exports (including guavas, mangoes, and mangosteens, fresh or dried) totaled $2.7 billion. The top exporters were Mexico, the Netherlands (a transit country to other markets in Europe), Thailand, Peru, and Brazil. Top importers were the United States, China, the Netherlands, Germany, and the United Kingdom.

Like trade in bananas, trade in mangoes is regionalized, with Latin American producers supplying markets in North America and Europe, and Asian producers supplying markets in their own area. The United States imports primarily from Mexico, Peru, Ecuador, and Brazil. Major sources for China include Thailand, Indonesia, and Taiwan. Peru and Brazil are the top suppliers to the Netherlands and Germany, while Brazil, Ghana, and Peru are the top suppliers to the United Kingdom.[1039]

Peru Industry Structure and Production System

In Peru, mangoes are grown by both large, vertically integrated exporters with several hundred acres of mango groves, and small, independent farms with less than one hectare of land (less than 2.5 acres).[1040] Larger, vertically integrated firms will often purchase from small independent growers.[1041] Mangoes are grown in the northern regions of Peru close to the border with Ecuador, and south of Lima near the city of Ica. The long mango harvesting season in Peru ensures that growers can supply export markets during times of the year when other mango-producing countries cannot. Due to the length of the harvesting season, post-harvest pest pressures are prevalent, so Peruvian mango growers need access to several post-harvest treatment options for dealing with pests.[1042]

The major markets for Peruvian mangoes are the EU and the United States. Smaller amounts are sent to South Korea, Canada, Chile, and Russia. In recent years, the industry has looked to further develop markets in Asia, particularly in China, in order to diversify its export destinations.[1043]

In Peru, larger, vertically integrated producers are able to segregate mango production by market. They do this largely due to differing MRL requirements in major trade partners, particularly the EU and the United States. [1044] Brazil is also able to do so, though the original reasons are different. Throughout Brazil, there are specific regions of the country that specialize in producing tropical fruits like mangoes for the

[1039] The Netherlands is the largest supplier of mangoes to Germany. This is likely due to the fact that the Netherlands serves as a transit country for other European countries' imports. IHS Markit, Global Trade Atlas database, HS subheading 0804.50 (accessed January 10, 2020).
[1040] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019; industry representative, interview by USITC staff, Lima, Peru, December 12, 2019.
[1041] One vertically integrated firm that grows a variety of fresh fruit indicated that mangoes are the only product that it purchases from independent growers. Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1042] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1043] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1044] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019; industry representative, interview by USITC staff, Lima, Peru, December 11, 2019.

EU market, so those operations are largely segregated from other producers exporting product to other markets.[1045]

Peru's Pesticide and MRL Policies

Peru uses a risk-based system for pesticide registration and MRL assessment (box 5.3).[1046] The Farming, Livestock, and Food Safety Inputs Office of Peru's National Agricultural and Phytosanitary Service (SENASA) is the agency responsible for the registration and monitoring of plant protection products. SENASA maintains a national MRL list and defers to Codex in the absence of an established MRL. If no Codex MRL exists, then the U.S. MRL value is accepted. If neither a Codex nor a U.S. MRL exist, then SENASA defers to the EU MRL value.[1047] SENASA works directly with growers and trade associations to inform them about MRL policy changes in major export markets. It has also established "trade-facilitating" joint MRL recognition and inspection systems with certain partners such as the EU and Indonesia and is pursuing similar agreements with other major trading partners.[1048]

Box 5.3 Pesticide Registration and Cancellation in Peru

In Peru, the process for canceling a plant protection product is similar to that for registering a new one. Plant protection product approvals and cancellations are established by law and undergo a review process by an interagency technical committee that includes SENASA. Product registration cancellations consider whether alternatives to the pesticide are available. The committee takes all characteristics of the alternative product, such as application procedures and efficacy, into consideration before deciding whether it is a viable substitute for the product under review. Three pesticides that are currently under review for potential cancellation in Peru are carbofuran, oxamyl, and methomyl.

Source: Peruvian government representative, interview by USITC staff, Lima, Peru, December 12, 2019; Peruvian government official, email message to USITC staff, February 10, 2020.

Pest Pressures and Pesticide Use

Fungicides

Mangoes face a variety of pest pressures, particularly from fungi and insects. In Latin America, Africa, and other regions where mangoes are commonly grown, the fungus *Colletotrichum gloeosporioides* causes an infection known as anthracnose, which thrives in humid and warm conditions. Anthracnose can destroy mango fruit during both the pre- and post-harvest periods and is a recurring concern for mango production in Peru. Pre-harvest fruit losses occur when the fungus infects and kills flowers before they are pollinated, and infects smaller, immature fruits before they reach full growth. During the post-harvest period, anthracnose can reduce fruit quality by creating dark, sunken lesions that become increasingly visible as the already picked fruit ripens further. This can result in severe losses, because major importing markets prefer unblemished mangoes that meet the cosmetic standards for top-quality fruit.[1049] Latent

[1045] Foreign government representative, telephone interview by USITC staff, October 22, 2019.
[1046] Peruvian government representative, interview by USITC staff, Lima, Peru, December 12, 2019.
[1047] Bryant Christie Inc., "Peru Pesticide MRLs Market Information Report," January 2018, 1.
[1048] Peruvian government representative, interview by USITC staff, Lima, Peru, December 12, 2019.
[1049] Gianessi and Williams, "Fungicides Result in Mangoes Suitable for Export," May 2012.

infections are common and may remain dormant for a period of time, meaning that even if a mango appears healthy, it can still develop anthracnose symptoms as it ripens and makes its way to final markets (i.e., retailers and consumers).[1050] If mangoes are not properly treated during the flowering and fruit development stages, anthracnose can also spread to other plants, further reducing farm yields and overall product quality.[1051] Anthracnose and other fungal diseases become increasingly prevalent if a growing area experiences abnormal or severe weather conditions, such as increased rainfall.[1052]

A common post-harvest fungicide used to treat anthracnose and other fungal diseases in the Americas is thiabendazole, which is registered for use in major mango-producing countries such as Peru and Brazil.[1053] In African mango-producing countries, fungicides such as prochloraz and iprodione have been used more often, although their use is now limited due to EU MRLs.[1054] Other fungicides, such as those that contain copper as an active substance, can be used from the start of the flowering process up until harvest.[1055] One major producer of mangoes in Peru noted that it has been testing different natural extracts as substitutes for thiabendazole. The grower has been able to use a grapefruit extract but noted that thiabendazole is more efficient than the extract at controlling fungal outbreaks that occur after harvest.[1056]

Insecticides

Other pest pressures that mango growers face come from insects, including mealybugs, scale insects, mango tree borers, and mango hoppers, which can cause severe damage to the mango tree. Two common insecticides used to control pests such as mealybugs, scale insects, and mango hoppers include chlorpyrifos and methomyl. One major producer of mangoes in Peru noted that these two insecticides serve similar purposes in the integrated pest management scheme for mangoes, and that growers have few other options for managing these insects.

Pesticide Registrations and MRLs in Major Markets

Thiabendazole is a common post-harvest fungicide registered for use in most countries and has established MRLs in Codex and most major importing markets, including the EU and the United States. Thiabendazole is registered for use within the EU, and its approval has been extended until March 31, 2032; however, while the EU has set a higher MRL for thiabendazole on some fruits, the MRL for the substance on mangoes is set at the limit of determination (0.01 ppm).[1057] It is also registered for use in mango-producing countries such as Brazil and Peru, but not on mangoes grown in Kenya.[1058] As noted,

[1050] Gianessi and Williams, "Fungicides Result in Mangoes Suitable for Export," May 2012.
[1051] *Old Farmer's Almanac*, "Anthracnose" (accessed December 18, 2019); GreenLife Crop Protection Africa, "Mango Anthracnose" (accessed December 18, 2019).
[1052] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1053] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1054] Industry representative, telephone interview by USITC staff, February 19, 2020.
[1055] Loucks, "Fungicide Spray for Mango Trees" (accessed January 23, 2020).
[1056] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1057] EC, EU Pesticides database (accessed December 20, 2019).
[1058] Government of Brazil, Ministério da Agricultura, Pecuária e Abastecimento (Ministry of Agriculture, Livestock, and Supply), "Consulta de Ingrediente Ativo" (Active ingredient consultation), accessed December 20, 2019; foreign

two other postharvest fungicides, prochloraz and iprodione, have historically been used by mango growers in African countries that export to the EU (such as Côte d'Ivoire). These have also been subject to lower EU MRLs recently.[1059]

While chlorpyrifos and methomyl are common insecticides used on a variety of fruits and vegetables, there are no established MRLs for these pesticides used on mangoes in Codex. As described in the banana and French bean sections, the European Commission did not renew the approval for chlorpyrifos, and lowered the MRLs for chlorpyrifos to the limit of determination on February 18, 2020.[1060] The grace period for the use of chlorpyrifos within the limits of the former MRL was expected to end in April 2020. In May 2017, the EU lowered the MRL for methomyl used on mangoes to the limit of determination (0.01 ppm). Other markets, including the United States, China, and Codex, are missing MRLs for at least one of these two products (see table 5.4). These pesticides are discussed in greater detail in the following sections of this case study.

Table 5.4 MRLs for key pesticides used in the mango industry (ppm)

Active substance	Pesticide Type	Codex	China	Canada	South Korea	United States	EU	Recent changes (EU)
Chlorpyrifos	Insecticide	Missing	Missing	0.1	0.4	0.1	0.01	MRL lowered from 0.05 to 0.01 ppm in 2018. Approval not renewed as of December 2019. EU member states' grace periods ended by April 2020.
Methomyl	Insecticide	Missing	0.2	0.01	0.01	Missing	0.01	MRL lowered from 0.02 to 0.01 ppm in 2017.
Prochloraz	Fungicide	7.0	2	0.1	5.0	Missing	5.0	Approval expires in December 2023.
Iprodione	Fungicide	Missing	Missing	0.07	1.5	Missing	0.01	MRL for mango lowered from 0.02 to 0.01 in 2015. In 2017, approval for the active substance was not renewed.
Thiabendazole	Fungicide	5.0	5.0	0.1	10.0	10.0	0.01	MRL lowered from 5.0 to 0.01 in 2017.

Source: Bryant Christie Global, Pesticide MRLs database (accessed December 20, 2019); Codex Alimentarius, Pesticides Database Search (accessed December 20, 2019); European Commission, EU Pesticides database (accessed December 20, 2019); Commission Regulation (EU) 2020/192 of 12 February 2020 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for prochloraz in or on certain products, O.J. (L040), 4.
Note: "Missing" indicates that there is no MRL for this product on mangoes.

Costs and Effects of Missing and Low MRLs on the Mango Industry

Peruvian mango growers noted that missing and low MRLs for products that serve an important role in their integrated pest management systems could have a variety of effects, including yield losses,

government representative, telephone interview by USITC staff, October 22, 2019; industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1059] Industry representative, telephone interview by USITC staff, February 19, 2020.
[1060] EC, "Chlorpyrifos and Chlorpyrifos-methyl" (accessed April 29, 2020).

increased insect and disease resistance, lost sales, rejected shipments, and a rise in prices for retailers and consumers.

Lowering of MRLs for Chlorpyrifos and Methomyl

Chlorpyrifos and methomyl serve similar purposes in the integrated pest management system for mangoes, and growers will often rotate among these products to prevent pests from developing resistance. With the EU MRL on methomyl lowered to 0.01 PPM in 2016, mango growers in Peru have increasingly relied on chlorpyrifos. Industry representatives in Peru indicate that the upcoming lowering of the MRL for chlorpyrifos, combined with the previous changes to the EU MRLs for methomyl, could have a significant impact on certain mango producers, undermining production yields and increasing costs. When the number of pesticides that can be rotated within a producer's pest management system is reduced, insects develop resistance at a faster rate, resulting in damaged fruit and higher yield losses for the grower.[1061] According to one producer of mangoes in Peru, even if alternative products such as biopesticides are available, particularly as substitutes for post-harvest thiabendazole, they are sometimes more expensive and less effective than conventional pesticides.[1062] If this particular mango grower were to lose access to both insecticides, the grower would run out of options for managing certain pests.[1063]

Product Segregation by Market

Due to diverging MRLs in major export markets, certain Peruvian producers have to segregate mango production to ensure that products destined for different markets do not mix. One grower noted that it segregates production for the EU from production for the United States due to differing MRL requirements.[1064] If fruit destined for one market is mixed with fruit destined for another export market that has a lower MRL, this could result in a rejected shipment. Segregation, however, raises operational costs.

One firm noted that in 2014, a supplier was concerned that a shipment of mangoes destined for the EU might have been mixed with mangoes destined for another market that had lower MRLs. Even though the supplier had carefully segregated mango groves and implemented production practices according to the unique MRLs for each market, the supplier had reason to suspect that the mangoes had been commingled at a packaging facility, and that as result, the mangoes would ultimately be rejected for exceeding the EU's MRLs. While the shipment was ultimately intercepted before being shipped to the wrong market, the incident highlighted the risk facing many producers and suppliers. If a supplier has a shipment rejected due to an MRL violation, that supplier would incur significant costs associated with destroying or re-shipping the product. In addition, a rejected shipment could damage the supplier's reputation among importers and retailers, potentially leading to lost future sales.[1065]

[1061] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1062] One producer noted that following the EU's ban on applying thiabendazole as a post-harvest treatment, it replaced it with a grapefruit extract, which is less effective than thiabendazole. Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1063] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1064] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1065] Industry representative, interview by USITC staff, Lima, Peru, December 11, 2019.

Thiabendazole and Brazilian Mango Growers

Brazilian mango industry representatives are concerned that lowering the EU MRL for thiabendazole could have a significant impact on mango growers in Brazil. Mangoes are grown primarily in Brazil's Northeast region, which is susceptible to fungal outbreaks due to its warm and humid climate and its proximity to the Amazon rainforest.[1066] For this reason, mango growers rely heavily on fungicides such as thiabendazole. Brazilian growers indicated that when the EU lowered its MRL for thiabendazole residues on mangoes to the limit of determination, this had a significant impact on costs, as there are a limited number of registered alternative fungicides in Brazil compared to other mango-producing countries.[1067]

Without post-harvest treatment, mangoes have a shelf life of 15–20 days. However, it takes an average of 20 days to transport them (mostly by boat) from Brazilian mango groves to retailers throughout the EU. Brazilian growers noted that if they cannot apply thiabendazole as a post-harvest treatment, the mangoes would likely spoil by the time they reach EU retail stores. One alternative has been to transport produce by air, but this costs approximately 10 times as much as traditional shipping methods and raises prices for retailers and consumers.[1068] In fact, the Netherlands, which is the EU's largest importer of mangoes, attributed a rise in the average unit value of imported mangoes in previous years to a higher share of airfreighted product, as well as fluctuations in availability and new varieties of fruit.[1069] Over the longer term, a rise in the share of Brazilian mangoes transported by airfreight could reduce price competitiveness for Brazilian mangoes compared to those from other suppliers.

Prochloraz, Iprodione, and West African Mango Growers

In West African countries such as Côte d'Ivoire, industry representatives familiar with the mango industry report that they are concerned that growers there will run out of options for postharvest fungicides, explaining that they have worked with pesticide manufacturers to find an alternative product that could be registered. When the EU lowers the MRL for prochloraz on mango to the limit of determination effective September 2020,[1070] these growers will lose an alternative product that they had used in place of iprodione after registration of that fungicide was not renewed by the EU in 2017. Realizing that growers would face a lack of postharvest fungicides, an industry association representing African exporters and European importers worked with a pesticide registrant to get a new substance registered in Côte d'Ivoire. This was reportedly a difficult process because of the minor-crop nature of mango. The registration was only barely completed in time for growers to have an available postharvest fungicide during the 2020 season.[1071]

[1066] Foreign government representative, telephone interview by USITC staff, October 22, 2019.
[1067] Foreign government representative, telephone interview by USITC staff, October 22, 2019.
[1068] Foreign government representative, telephone interview by USITC staff, October 22, 2019.
[1069] CBI, "Exporting Mangoes to Europe," October 24, 2018.
[1070] Commission Regulation (EU) 2020/192 of 12 February 2020 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for prochloraz in or on certain products, O.J. (L040), 4.
[1071] Industry representative, telephone interview by USITC staff, February 19, 2020.

Case Study: Avocados from Peru

This case study examines the effect of several recent decisions to lower the MRLs on important pesticides used in the avocado industry, as well as the effects of missing MRLs for major pesticides that could be used by avocado growers. Growers noted the importance of segregation as a practice used to ensure compliance with MRLs in various export markets. Some growers, such as those in Peru, segregate avocado production by market, while others, such as those in Chile, ensure that all avocado production meets the lowest MRLs of all their export markets. Unlike producers in Mexico and other countries that have humid growing climates, Peru's major avocado producers are concentrated along the country's coastal arid regions. These growers noted that they face fewer pest pressures than growers located in more humid climates, and therefore do not need to apply as many pesticides as other avocado-producing regions of the world. For this reason, Peruvian avocado growers are more concerned with markets that have missing MRLs, where no default limit of determination/quantification is established.

While this case study focuses primarily on producers in Peru, comparisons to other producing countries are presented throughout in order to demonstrate that effects are different, based on the unique characteristics of various producing countries. In 2018, global avocado exports (fresh or dried) totaled $5.8 billion. The top exporters were Mexico, the Netherlands (a transit country for other EU markets), Peru, Chile, and Spain. Top importers were the United States, the Netherlands, France, and Germany. The United States imports primarily from Mexico (which accounted for over 88 percent of avocado imports, by value), Peru, and Chile. Major sources of avocados for the Netherlands include Peru, Chile, and South Africa, while Spain is a major supplier to France and Germany.[1072]

Peru Industry Structure and Production System

In Peru, avocados are grown by large, vertically integrated producers with farms ranging from less than 250 acres to nearly 7,500 acres. Some of the larger producers purchase avocados from independent growers, and they often supply the grower with seeds and pesticides to ensure best practices for controlling pests.[1073] As noted, avocados are grown primarily in arid regions of Peru supplied with water from irrigation canals, so there are fewer pest pressures, particularly from weeds, than in other countries where avocados are grown.[1074] While a smaller portion of Peru's avocados are grown in the northern tropical region of the country, farmers there experience more pest pressures, particularly from weeds, so they have to use at least one application of herbicides such as glyphosate.[1075]

The major markets for Peruvian avocados are the EU and the United States, but exports to Asian markets such as China, Japan, and Hong Kong have risen significantly in recent years. In 2016, China accounted for about 1.2 percent of Peru's avocado exports by value, a figure that rose to 4.1 percent in 2018. One

[1072] The Netherlands is a major transit country for imports of avocados to other EU countries such as Germany. IHS Markit, Global Trade Atlas database, HS subheading 0804.40 (accessed January 10, 2020).
[1073] Industry representatives noted that vertically integrated farms can range from 100 hectares to nearly 3,000 hectares. Industry representative, interview by USITC staff, Trujillo, Peru, December 9, 2019.
[1074] Industry representative, interview by USITC staff, Trujillo, Peru, December 9, 2019; Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1075] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.

major Peruvian producer and exporter of avocados indicated that it was focused on growth in the Chinese market and had received approval to start exporting to China in the past year.[1076]

Pest Pressures and Pesticide Use

Avocado growers around the world face a variety of pest pressures, particularly from insects and fungi, and rely on a variety of pesticides to maintain high product quality and prevent yield losses. Because avocados have high concentrations of natural oils, growers have to be careful when applying lipophilic pesticides because they can become concentrated and remain present in the fruit for a longer period.[1077]

Insecticides

Throughout Central and South America, common insect pests affecting avocado growers include spider mites, bed bugs, scale insects, and various species of moths (*Oiketicus kirbyi and Stenoma catenifer).* Spider mites are present year-round but become an increasing nuisance during the fruit development stage and the harvest season. A type of bed bug known as chinches are present during the flowering season, and if left untreated, can affect the growth of the avocado and result in a misshapen fruit. Two pesticides Peruvian avocado growers apply to address these pests include acetamiprid and etoxazole. As is discussed later in this case study, alternative insecticides are available to growers, but some of these products are missing MRLs in major export markets. If left uncontrolled, spider mites can damage the skin of the fruit through a method known as burning, which reduces quality and prevents certain growers from exporting their product into the fresh avocado market. Fruit that have burned skins are often sold for industrial uses (i.e., as processed foods) and farmers obtain a lower price for these products than for higher-quality fruits that are sold into the fresh market.[1078]

Certain growers also use biopesticides and natural extracts made from cinnamon, garlic, and chili oil for spider mites—all products that reduce the likelihood of an MRL violation.[1079] One producer noted that for several months they had been applying *Bacillus subtilis,* a biopesticide which has been successful in bringing these pests under control. However, the producer noted that it is unable to apply biopesticides to avocados intended for certain export markets, as those products are not registered in those markets.[1080]

Another pest known as thrips is not as common in Peru and certain other avocado-producing countries, but in Mexico thrips are a major nuisance, feeding directly on immature fruit and causing severe scarring, which can reduce the quality of the fruit.[1081] The scarring can also slow and stunt fruit growth, lessening yields.[1082] Abamectin is a common insecticide used to treat avocado thrips.[1083]

[1076] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1077] Lipophilic pesticides are pesticides that dissolve in fat or oil. Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1078] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1079] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1080] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1081] Industry representative, interview by USITC staff, Trujillo, Peru, December 9, 2019.
[1082] University of California Agriculture Statewide IPM Program, "Avocado Thrips" (accessed December 20, 2019).
[1083] University of California Agriculture Statewide IPM Program, "Avocado Thrips" (accessed December 20, 2019).

Fungicides

Fungi and the threat of fungal infection is another major pressure affecting avocado growers. As with mangoes, anthracnose can damage avocado tree leaves, flowers, and fruit, and is prevalent in countries with tropical (i.e., warm and humid) climates. During the pre-harvest period, anthracnose can spread on fruit that has suffered mechanical and insect damage. If the disease spreads, it could eventually cause the fruit to drop prematurely, reducing yields. Avocados are picked green, so after harvest, infections can remain latent until the fruit starts to ripen and makes its way to retailers and consumers, resulting in a lower-quality product.[1084]

Growers use a variety of plant protection products, including copper fungicides, thiram, and thiabendazole, to protect against anthracnose and other fungal diseases.[1085] Thiram is used to protect the seed, to treat the leaves, and to protect harvested crops from developing fungal infections during storage and transport. However, there is no Codex MRL for thiram used on avocados, and the MRLs in markets that have established import tolerances vary to a significant degree (see table 5.5).[1086] Thiabendazole is also used to treat fungal infections in avocados.

Pesticide Registrations and MRLs in Major Markets

Table 5.5 presents the MRLs for several plant protection products in major avocado-importing markets, plus Codex. These products, described in detail below, include key insecticides (acetamiprid, abamectin, etoxazole, and methomyl) and fungicides (thiabendzole and thiram) that are of critical importance to avocado growers. In the EU, MRLs for etoxazole and methomyl were lowered to the limit of determination effective January 19, 2017, and May 17, 2017, respectively, while the MRL for the fungicide thiram was raised from the limit of determination to 10 ppm January 25, 2016.[1087] The insecticide acetamiprid had a missing MRL in the United States until February 14, 2020, when an MRL of 0.5 ppm was established, while the EU MRL for this product was renewed at the limit of determination (0.01 ppm) effective August 13, 2019.[1088] Some of these plant protection products are discussed in greater detail in the following sections of this case study.

[1084] Dev, “Lifecycle of Avocado Anthracnose,” January 13, 2012.
[1085] Industry representative, interview by USITC staff, Trujillo, Peru, December 9, 2019; industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1086] Yeung et al., *Declining International Cooperation on Pesticide Regulation*, 2017, 61; Dev, “Lifecycle of Avocado Anthracnose,” January 13, 2012.
[1087] EC, EU Pesticides database (accessed December 20, 2019).
[1088] EC, EU Pesticides database (accessed December 20, 2019); 85 FR 8433; industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.

Table 5.5 MRLs for key pesticides used in the avocado industry (ppm)

Active substance	Pesticide type	Codex	Canada	Japan	China	United States	EU	Recent changes (EU)
Acetamiprid	Insecticide	Missing	0.1	0.01	2.0	0.5	0.01	Change in August 2019
Abamectin	Insecticide	0.015	0.02	0.02	Missing	0.02	0.01	Approval expires April 2021.
Etoxazole	Insecticide	Missing	0.2	0.01	Missing	0.2	0.01	MRL lowered from 0.02 to 0.01 ppm in 2017. Approval expires July 2020.
Methomyl	Insecticide	Missing	0.01	3.0	0.2	2.0	0.01	MRL lowered from 0.02 to 0.01 ppm in 2017.
Thiabendazole	Fungicide	15.0	0.1	3.0	15.0	10.0	20.0	MRL raised from 15.0 to 20.0 in 2017.
Thiram	Fungicide	Missing	0.1	0.6	Missing	15.0	10.0	MRL raised from 0.1 to 10.0 in 2016.

Source: Bryant Christie Global, Pesticide MRLs database (accessed December 20, 2019); Codex Alimentarius, Pesticides Database Search (accessed December 20, 2019); European Commission, EU Pesticides database (accessed December 20, 2019).
Note: "Missing" indicates that there is no MRL for this product on avocados.

Costs and Effects of Missing and Low MRLs on the Avocado Industry

Missing, low, and diverging MRLs have had a major impact on Peruvian avocado growers, with the primary effect being that growers have to segregate production for each of their major export markets. Segregated production is possible in the Peruvian avocado industry because of lower pest pressure, combined with a high degree of vertical integration in the Peruvian avocado industry compared to other avocado-producing countries. This increases growers' ability to rely on nonchemical pest-management practices and alternative products, such as biopesticides, in addressing pest pressures. One Peruvian grower reported that it segregates avocado production for the EU and the United States due to their diverging MRLs for the pesticide acetamiprid, while another grower also indicated that it has to segregate avocados for various markets, including for recently established export markets in Asia.[1089] Segregating production raises costs, particularly for farms supplying export markets that have lower and missing MRLs.[1090]

Given the unique features of the Peruvian avocado industry, costs of production are generally higher for the U.S. market than the EU market, according to growers. These growers report that this is because they are able to use pesticides for which the EU MRL is set at the limit of determination, as long as they observe a long preharvest interval in which the product is not applied. These long preharvest intervals are possible in Peru without risking damage to the crop due to the relatively low pest pressure there, as

[1089] Industry representative, interview by USITC staff, Trujillo, Peru, December 9, 2019; industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1090] This grower noted that the United States has established a high MRL for acetamiprid for blueberries (1.6 ppm), but there was no established MRL for the same chemical on avocados. Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019. On February 14, 2020, the United States Environmental Protection Agency established an MRL of 0.5 ppm for avocados and other tropical and subtropical fruits in subgroup 24B. 85 Fed. Reg. 8433; Bryant Christie Global, Pesticide MRLs database (accessed March 16, 2020).

described above. However, because some of these pesticides are missing MRLs in the United States, they cannot be used on production intended for the U.S. market at all, and this raises the cost of producing for the U.S. market higher than for the EU. In addition, some growers would prefer to use new, higher-performing chemicals that are similar in price to traditional products, are known to have less of an environmental impact, and are better for the soil, such as emamectin benzoate—a derivative of abamectin. However, MRLs for products like these are missing in major export markets such as the United States and the EU.[1091]

In other countries such as Chile, growers of minor crops like avocado and citrus do not segregate production by market. These products are generally grown on large "macro" farms approximately 1,000 acres in size, and growers have decided that the most effective way to apply pesticides is by meeting the most restrictive MRLs found in all of their export markets. For the Chilean industry, the most restrictive market is usually the EU, according to industry representatives. This means that if one export market has a lower MRL or has not established an MRL for a certain pesticide, the grower would have to limit or omit applications of that pesticide to all products, regardless of export market. This can prevent growers from applying some pesticides that they would otherwise use on products destined for other export markets.[1092]

Peruvian avocado growers also noted that an EU reduction in MRLs for etoxazole and methomyl has impacted their ability to use these products to address pests such as spider mites and bed bugs; the same will soon be true of acetamiprid. One major avocado producer noted that it had to stop using etoxazole to control spider mites during the preharvest stage after the EU lowered the MRL to the limit of determination.[1093] As growers lose access to insecticides like these, pests are likely to develop resistance at a faster rate. The damage these pests cause to avocado fruit has a direct impact on growers due to the fact that damaged fruit cannot be sold into the higher-priced fresh fruit market.[1094]

Private standards also play an important role in determining which pesticides an avocado producer decides to apply. Private standards set by major food retailers can capture a number of different traits, including pesticide usage, among many other requirements. Throughout the EU, various food retailers request that producers ensure their avocados meet a lower MRL than what is already established for the EU. One Peruvian grower and exporter noted that private buyers in Germany often require the producer to meet 33 percent of the official EU MRL for certain pesticides applied to avocados.[1095] Another avocado grower indicated that it produces avocados to meet the strictest private standard of a major German retailer, so all of the grower's general production for the entire EU market meets this standard.[1096] Segregating for individual markets already results in higher costs, so it may not be cost effective for a grower to segregate for an individual retailer. If a grower does in fact decide to have all of their production abide by a stricter private standard, it could limit their ability to rotate pesticides, reducing the efficacy of those products they continue to apply.

[1091] This producer noted that the registrant is working to get MRLs established for this insecticide in major export markets. Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1092] Industry representative, telephone interview by USITC staff, January 16, 2020.
[1093] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1094] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1095] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1096] Industry representative, interview by USITC staff, Trujillo, Peru, December 9, 2019.

Case Study: Table Grapes from Peru and Chile

This case study examines the effects of the recent and future reductions in EU MRLs on important pesticides used in the table (fresh) grape industry. Table grapes are a highly perishable crop and an important export for countries representing a variety of income levels, including Peru (upper-middle income) and Chile (high income). Like other minor crops, table grapes are vulnerable to a variety of pest and fungal pressures. Table grape producers, trade associations, and government representatives in Peru and Chile are concerned about the lowering of MRLs for important plant protection products, including buprofezin, spirodiclofen, indoxacarb, methoxyfenozide, quinoxyfen, and others.

This case study focuses primarily on producers in Peru and Chile to demonstrate the wide impact that changing MRL policies could have on two of the world's largest producers of table grapes. In 2018, worldwide fresh grape exports totaled $8.2 billion. The top exporters were Chile, the Netherlands (a transit country for exports to other European countries), the United States, and Peru. Top importers were the United States, the Netherlands, Germany, and the United Kingdom. Chile and Peru were the largest suppliers of fresh grapes to the United States, China, and Europe.[1097] Producers in Peru noted that exports to China have been growing significantly in recent years, and they are interested in increasing exports to China in the future.[1098]

Peru and Chile Industry Structures and Production Systems

In Peru, table grapes are grown by a few large, vertically integrated producers in the northern tropical regions of the country along the border with Ecuador, as well as south of Lima in the drier Nazca region.[1099] The Peruvian table grape harvest season, which lasts about eight months, is longer than that of other major fresh grape producers such as Chile and the United States.[1100] One major reason why table grape producers were initially attracted to Peru was because of the success that other minor crop producers had had with irrigating their products in a desert climate, which faces fewer pest pressures due to its aridity.[1101] However, because there is a longer growing season in Peru than in other countries where table grapes are grown, producers still need access to a wide variety of plant protection products. Growers also segregate production by export market due to diverging and missing MRLs.[1102]

Table 5.6 presents major pesticides used by Peruvian and Chilean table grape producers. In August 2019, the EU lowered its MRL for the insecticide buprofezin from 1.0 ppm to the limit of determination (0.01 ppm).[1103] On June 27, 2019, the EU withdrew the authorization for quinoxyfen, which is a key plant

[1097] IHS Markit, Global Trade Atlas database, HS heading 0806 (accessed January 10, 2020).
[1098] Industry representative, interview by USITC staff, Lima, Peru, December 11, 2019.
[1099] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019; industry representative, interview by USITC staff, Lima, Peru, December 11, 2019.
[1100] This industry representative expressed the belief that U.S. producers can harvest for only one month of the year.
[1101] Certain producers noted that Chile and Ecuador have more humid climates than Peru, which generally leads to higher pest and fungal pressures. Industry representative, interview by USITC staff, Lima, Peru, December 11, 2019.
[1102] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019.
[1103] EC, EU Pesticides database (accessed February 5, 2020).

protection product for Chilean table grape producers.[1104] Chilean growers expressed concern that this action might be followed by changes to the MRLs for spirodiclofen, indoxacarb, and methoxyfenozide, as the registrations for these products come up for renewal in 2020 (for spirodiclofen and indoxacarb) and 2026 (for methoxyfenozide).

Table 5.6 MRLs for key pesticides used in the table grape industry (ppm)

Active ingredient	Pesticide Type	Codex	China	United States	EU	Recent changes (EU)
					0.01	In 2017, approval was amended to
Spirodiclofen	Insecticide	0.2	2.0	2.0	1.0	Approval expires July 2020.
					0.02	Approval expires October 2020.
Methoxyfenozide	Insecticide	1.0	1.0	1.0	0.01	Approval expires March 2026.
					1.0	Approval not renewed as of October 2018. Member states' grace periods ended by March 2020.

Source: Bryant Christie Global, Pesticide MRLs database (accessed February 5, 2020); Fruit Exporters Association of Chile (ASOEX), written submission to the USITC, February 18, 2020; European Commission, EU Pesticides database (accessed February 5, 2020).

Costs and Effects of Missing and Low MRLs on the Table Grape Industry

Chilean and Peruvian government officials and Chilean fruit industry representatives noted the importance of a variety of pesticides to table grape producers and stated that a reduction in the EU MRLs for these products could have a significant impact on producers (box 5.4). According to one Peruvian government official, the recent reduction in the EU's MRL for buprofezin from 1.0 ppm to 0.01 ppm, which took effect on August 13, 2019, could seriously depress Peruvian exports. The official stated that this development might exert significant pressure on growers, as the 2019/20 growing season was already underway.[1105] Similarly, Chilean industry representatives have expressed concern that the EU could reduce MRLs to the limit of determination for the insecticides spirodiclofen, indoxacarb, and methoxyfenozide, as well as for the fungicide quinoxyfen, when the registration for these products comes up for review. If Chilean growers lose access to these plant protection products, they could lose access to the EU market, which is their third-largest market after the United States and China.[1106]

[1104] EC, EU Pesticides database (accessed February 5, 2020); Fruit Exporters Association of Chile (ASOEX), written submission to USITC, February 18, 2020.
[1105] Peruvian government representative, email message to USITC staff, December 27, 2019; Commission Regulation (EU) 2019/91 of 18 January 2019 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for buprofezin, diflubenzuron, ethoxysulfuron, ioxynil, molinate, picoxystrobin and tepraloxydim in or on certain products, O.J. (L 22).
[1106] Fruit Exporters Association of Chile (ASOEX), written submission to USITC, February 18, 2020.

Peruvian growers noted the importance of segregating product by market in order to avoid potential MRL violations. Larger vertically integrated producers have the resources necessary to do this, but they note that it leads to higher production costs. For example, certain Peruvian growers noted that the cost of producing grapes for the U.S. market, which does not set numerical default MRLs, can be 15–20 percent higher than that in other export markets like the EU.[1107] Even if an export market like the EU reduces its MRLs to the limit of determination/quantification, it is easier for certain growers, to export to these markets than to markets that have missing MRLs; this is especially true of growers that face fewer pest pressures, such as growers in dry areas of Peru.

Box 5.4 Effects of Mancozeb Availability on Grape Growers in India

India was the world's 10th-largest exporter of grapes (fresh) in 2018, by value, with exports rising 35 percent between 2016 and 2018. The European Union is a major market for Indian grapes, and exports to the EU have doubled since 2015. Mancozeb is an important fungicide used in India's grape industry. If mancozeb were not available and growers had to rely on alternative fungicides, total fungicide costs on Indian grape farms would rise by 23.7 percent, according to an analysis by Kynetec, an agricultural market research firm. This analysis found that the loss of access to mancozeb by Indian grape farmers would reduce yield by 9.8 percent and increase farm costs by 3.6 percent, resulting in an overall 20.7 percent reduction in farm income. Modeling conducted by Kynetec found that this could lead to a short-term 10.9 percent decrease in the quantity of grapes exported from India. The loss of mancozeb would have a significant impact on smallholders (about five acres or less), as these growers account for 70 percent of India's grape farms.

Alternatives to mancozeb are limited. Dimethomorph is the most viable substitute for mancozeb used by Indian grape farmers, and even though the product is more expensive, dosage applications are lower than mancozeb, so costs may not differ. Other alternatives include cymoxanil and propineb. However, switching to these fungicides would likely increase treatment costs due to the higher number of required applications.

Source: A 2019 report by Kynetec found that India's exports of grapes to the EU accounted for 4 percent of the country's total production. Kynetec, *Value of Mancozeb: India—Grapes*, October 18, 2019, 10, 14, 15, 18, 21, 24, 25.

Case Study: Effects of Japanese Coffee MRLs on Global Producers

Coffee is a minor crop grown in tropical regions in Africa, the Americas, and Asia, and is vulnerable to various pests and diseases. Like producers of many other minor crops, coffee growers typically have relatively limited pesticide options. And since it is a valuable export crop, it must comply with a variety of global MRLs. Unlike many other minor crops, however, coffee from multiple producers is typically blended and sold in bulk—which is more common with large-volume crops like grains—making MRL compliance a particularly complicated issue for this crop.

This case study examines the costs to coffee growers and exporters of compliance and noncompliance with low MRLs. In Japan, a significant global coffee importer, MRLs for numerous pesticides are set to the

[1107] Industry representative, interview by USITC staff, Trujillo, Peru, December 10, 2019; industry representative, interview by USITC staff, Lima, Peru, December 11, 2019.

"uniform limit" (0.01 ppm). These MRLs have various effects on producers, depending on the size of the coffee farms involved, the level of producers' reliance on and knowledge of the Japanese market, and the specific pesticides used in each country. Kenyan coffee exporters' experience illustrates the effects of noncompliance with Japan's MRLs, with the costs of rejected shipments reaching up to half of the value of the shipment itself.[1108] Exporters in Colombia and Jamaica also experience the costs of complying with Japan's coffee MRLs. These coffee producers generally agree that meeting low MRLs requires pre-export testing, which can be costly, and that there is a risk of cross-contamination when coffee from many farmers is combined into one lot, preventing traceability back to the source of the violation.[1109]

Japanese Coffee Market Overview

This case study primarily focuses on exports of green (unroasted) coffee to Japan. Japan has an important premium coffee market segment and was the world's third-largest coffee importer in 2018, with $1.5 billion of imports.[1110] Most coffee exports to Japan and other leading markets are of green coffee beans, which are then roasted in the importing country. Leading suppliers of green coffee beans to Japan were Brazil, Colombia, and Vietnam, which are also the top 3 exporters to the world.[1111] Of the other exporting countries highlighted in this case study, Costa Rica, Jamaica, and Kenya were the 11th-, 12th-, and 13th-largest suppliers of green coffee to Japan, respectively.[1112] Jamaica is particularly reliant on the Japanese market, sending between 60 and 80 percent of its coffee exports to that market in any given year.[1113] For comparison, Colombia sends about 13 percent of its coffee to the Japanese market.[1114]

According to industry representatives, Japan sets high standards for its coffee imports and conducts more pesticide residue tests on green coffee beans than most other markets.[1115] One industry representative noted that the progressive increases in residue testing levels that Japan imposes in response to violations are particularly stringent. The representative also suggested that, at times, Japan may lower its MRLs as a preemptive or preventative strategy rather than in response to identified risks.[1116]

Coffee Industry Structure and Production System

There are two main coffee varieties grown globally, arabica and robusta. Arabica is generally considered the higher-quality variety and accounts for a slightly larger share of global production. Of the three largest coffee producers, Colombia produces almost exclusively arabica, Vietnam produces almost exclusively robusta, and Brazil produces both types, with the majority being arabica.[1117] The smaller

[1108] Industry representative, interview by USITC staff, Nairobi, Kenya, December 4, 2019.
[1109] Industry representative, interview by USITC staff, Nairobi, Kenya, December 4, 2019; industry representative, telephone interview by USITC staff, January 14, 2020.
[1110] Global coffee imports were $19.1 billion, led by the EU ($8.7 billion) and the United States ($4.5 billion). IHS Global Markit, GTA database, HS subheading 0901.11 and 0901.12 (accessed February 13, 2020).
[1111] IHS Global Markit, GTA database, HS subheading 0901.11 and 0901.12 (accessed February 25, 2020).
[1112] IHS Global Markit, GTA database, HS subheading 0901.11 and 0901.12 (accessed February 25, 2020).
[1113] Industry representative, telephone interview by USITC staff, February 21, 2020.
[1114] Industry representative, email message to USITC staff, March 12, 2020.
[1115] Industry representative, telephone interview by USITC staff, January 14, 2020; industry representative, telephone interview by USITC staff, February 21, 2020.
[1116] Industry representative, email message to USITC staff, March 12, 2020.
[1117] USDA, FAS, *Coffee*, December 2019.

producing countries described in this case study—Costa Rica, Jamaica, and Kenya—all produce mostly arabica coffee and are focused on differentiating their product based on quality.[1118]

Pest Pressures and Pesticide Use

Coffee is susceptible to various pest pressures, which can be intensified by extended wet seasons or dry conditions. However, a somewhat limited number of pest management products are available for use on coffee. Among the most important pesticides in the coffee industry are herbicides, which farmers rely on to control weeds and keep labor costs down, and insecticides to control the coffee berry borer, a harmful pest affecting coffee crops. Growers in Latin America have often used chlorpyrifos to control coffee berry borer, but MRLs for this insecticide have been lowered in both Japan and the EU. In addition, a particularly damaging fungal disease known as coffee rust has become widespread on coffee plantations in Latin America; copper-based fungicides are generally used in combination with nonchemical components of integrated pest management to control it.[1119] Another disease, coffee berry disease, is most prevalent in Africa, and as it, too, is primarily treated with copper-based fungicides, efforts to control it are not affected by low or missing MRLs. Other pests—bacterial blight and scale—require treatment with agrichemicals, although no associated issues from low or missing MRLs were reported.

Table 5.7 presents the MRLs for several plant protection products in major coffee-importing markets, and Codex. MRLs for coffee vary from market to market, and these inconsistencies can cause additional difficulties for coffee exporters. For example, the MRL for one pesticide—2, 4-dichlorophenyl acetic acid (2, 4-D), a pre-emergence broadleaf herbicide registered for use with coffee in Kenya—is 0.01 in Japan but is 0.1 in the EU.

Table 5.7 MRLs for key pesticides used in the coffee industry (ppm)

Active ingredient	Pesticide Type	Codex	Japan	United States	EU	Recent changes
2, 4-dichlorophenyl acetic acid	Herbicide	Missing	0.01	Missing	0.1	
Chlorpyrifos	Insecticide	0.05	0.05	0.10[a]	0.05	EU approval not renewed as of December 2019. EU member states' grace periods ended by April 2020, after which MRLs defaulted to 0.05 ppm.[b] Japan lowered its MRL to 0.05 ppm in 2015.

Sources: Bryant Christie Global, Pesticide MRLs database (accessed February 18, 2020); Colombian government representative, telephone interview by USITC staff, October 9, 2019.
Note: "Exempt" indicates that this product is not subject to an MRL.
[a] Source: International Coffee Organization, "Maximum Residue Limits," September 7, 2018, 2.
[b] The default MRL for coffee (0.05 ppm) is higher than the default level for fresh produce described in other case studies (0.01 ppm).

[1118] USDA, FAS, *Coffee*, December 2019.
[1119] Arneson, "Coffee Rust," updated 2011.

Kenya: Effects of Missing and Low MRLs on Exporters and Producers

Coffee in Kenya is grown by smallholder farmers centered around Mount Kenya and in Western Kenya. Green coffee beans from multiple farmers are combined into lots and sold to exporters on the Nairobi Coffee Exchange. Farmers are paid based on the lot price at the auction. About 85 percent of Kenya's coffee is sold at auction, while the remainder is sold through direct sales from farmers to overseas buyers. Coffee exporters include a mix of small national exporters and large exporters with international backing. The five largest exporters supply more than half of Kenyan coffee exports.

Missing and low MRLs add costs all along the coffee supply chain, but primarily affecting exporters and producers. Kenyan exporters face the gravest effects: the high costs from an MRL rejection and associated product losses have the potential to put small exporters out of business.[1120] Exporters also face costs in complying with low MRLs, including increased testing costs to reduce risk of rejection at the import market. Eventually, these costs reach producers as exporters become less willing to pay good prices for coffee because of possible risks. Moreover, if the risk of facing an MRL violation in an export market is high enough, exporters may stop selling to that market, and producers may lose that entire market.[1121]

Effects of MRL Violations

Rejections of coffee shipments from Kenya by Japanese inspection authorities in 2018 and 2019 illustrate the costs of noncompliance to exporters, which can be half the value of the investment.[1122] In these cases, the shipments were rejected by Japan because inspectors found residues of the herbicide dimethylamine salt of 2, 4-dichlorophenyl acetic acid (2, 4-D) in some Kenyan coffee shipments. In Kenya, this is also registered for use on corn, wheat, and coffee, which could contribute to cross contamination.[1123] In one case, shipments from Kenya had to be rerouted from Japan to the EU market, where they successfully met EU MRL requirements. As a direct result of this episode, exporters bore a threefold burden: they had to pay the additional freight costs to redirect the shipment from Japan to the EU; they received a lower price for the coffee diverted to the EU market; and, since the exporters were still bound by their contracts with Japanese importers, they were required to replace the rejected shipments. Moreover, in this instance, exporters paid a higher price for the replacement coffee because prices at auction had risen.[1124]

[1120] Industry representative, interview by USITC staff, Nairobi, Kenya, December 4, 2019; industry representative, telephone interview by USITC staff, January 14, 2020.
[1121] Industry representative, interview by USITC staff, Nairobi, Kenya, December 4, 2019; industry representative, telephone interview by USITC staff, January 14, 2020.
[1122] Industry representative, telephone interview by USITC staff, January 14, 2020; Government of Japan, Ministry of Health, Labour and Welfare, Imported Foods Inspection Services Home Page, "Recent Cases of Violations," June 2018 and March 2019.
[1123] Government of Kenya, PCPB, "Products for Use in Food Crop Production" database (accessed February 20, 2020).
[1124] Industry representative, interview by USITC staff, Nairobi, Kenya, December 4, 2019.

Multiple MRL violations reported by Japan can add more costs to an industry by triggering increased inspections and actions to investigate the source of MRL violations. Coffee beans from Kenya were subject to enhanced inspection for 2, 4-D under Japan's fiscal year (FY) 2017 Implementation of Inspection Orders, and were again subject to enhanced inspection for 2, 4-D in the FY 2019 plan.[1125] Increased inspection rates raise exporter expenses, because the exporter must supply additional product for testing and because the inspections cause shipping delays. The extra testing also increases the risk of additional violation findings, which could ultimately result in a complete ban of coffee from an exporting country by Japan.

MRL violations detected by one country reportedly can also affect MRL inspection and enforcement practices in markets elsewhere. Kenyan exporters stated that if Japan banned an exporter, certain other markets, including South Korea, Australia, and Taiwan, would reportedly follow suit. The result of MRL violations would thus not only block access to Japan, which has a 2 percent share of Kenya's export market, but would also add another 5 percent loss for the other markets combined.[1126]

Following the MRL violations in Japan, Kenyan regulatory authorities formed a task force to investigate the issue. The task force included the Coffee Directorate of Kenya's Agriculture and Food Authority, the Pest Control Board of Kenya, the Agrochemicals Association of Kenya, and other industry members. This effort required substantial human resources from both the Kenyan government and the private sector, costing staff time and other expenses.[1127]

One way that coffee exporters act to mitigate the risk of MRL violations is via pre-shipment testing. In Kenya, a common practice is to test a composite sample of coffee to be shipped to Japan before export. Tests take 10 days and, in Kenya, can cost from $300 to $500 per contaminant, per sample.[1128] Exporters test only for high-risk contaminants, usually ones that have been detected in the past, although some import markets have up to 100 risk parameters. If the sample is compliant with Japanese MRLs, then the coffee is shipped.[1129]

However, even these measures only lessen the risk faced by exporters, because Japanese authorities test agricultural imports again upon arrival. Accordingly, imported coffee may still be found to be noncompliant and be rejected.[1130] This can occur because only a small sample is tested, and drawing different samples may provide different results. Additionally, when testing for such low MRLs, the degree of accuracy and the amount of rounding used can yield different outcomes between tests. An industry representative stated that accredited pre-shipment testing, rather than testing upon arrival, would greatly reduce risk and cost to exporters, who could cancel and replace a shipment without having to "unscramble the egg" by returning a shipment from the destination and replacing it.[1131]

[1125] Government of Japan, Ministry of Health, Labour, and Welfare, *Results of Imported Foods Monitoring and Guidance Plan for FY 2017*, August 2018, and *Results of Monitoring and Guidance Based on the Imported Foods Monitoring and guidance Plan for FY2017*, n.d. (accessed February 18, 2020); Government of Japan, Ministry of Health, Labour and Welfare, "Implementation of Inspection Orders," appendix 1, last amended January 10, 2020.
[1126] Industry representative, interview by USITC staff, Nairobi, Kenya, December 4, 2019.
[1127] Industry representative, interview by USITC staff, Nairobi, Kenya, December 4, 2019.
[1128] Industry representative, telephone interview by USITC staff, January 14, 2020.
[1129] Industry representative, email message to USITC staff, January 13, 2020.
[1130] Industry representative, email message to USITC staff, January 13, 2020.
[1131] Industry representative, telephone interview by USITC staff, January 14, 2020.

Reducing risks further by testing at the farm level is not a viable option in Kenya for a number of reasons. First, in Kenya, coffee is sold in lots that combine beans from multiple farmers. Exporters purchase the coffee at auction and then aggregate it further, finally exporting large, blended volumes of coffee. Exporters reported to the Commission that one container can combine coffee beans from up to 500 farmers. In addition, testing residue at the farm gate is prohibitively expensive, particularly when a crop is cultivated by a large number of small farmers and many separate tests would be needed. Testing at the lot or farm level also demands too much time, with an industry representative reporting that it takes about 10 days to get test results, while exporters typically only receive samples the week before the relevant auction. Too, this time estimate is for one sample and one contaminant, and if exporters were to test all samples for all contaminants, the laboratories would be overwhelmed.[1132]

Jamaica and Colombia: Costs of Pre-export Testing for MRL Compliance

In interviews, coffee exporters from Jamaica and Colombia generally agreed with their Kenyan counterparts that extensive pre-export testing and farmer education are necessary to avoid problems with MRL compliance in the Japanese market. Jamaican producers rely on a number of measures to ensure compliance, including coordination across the supply chain, extensive farmer education, and access to testing in partnership with a university laboratory, as well as implementation of integrated pest management practices.[1133] Colombian coffee producers are able to comply with MRLs in export markets in part because the government supports investment in the building of capacity for pesticide residue testing.[1134]

As noted above, Jamaican producers rely heavily on the Japanese market and have taken efforts to ensure compliance with what they report is “stricter monitoring” of MRLs at Japanese ports in recent years.[1135] Jamaican industry representatives attribute their ability to comply with Japanese coffee MRLs to several factors. First, pesticide usage in the Jamaican coffee industry is relatively low overall, especially as producers have increasingly looked to nonchemical methods in their integrated pest management systems to manage pest threats in order to comply with Rainforest Alliance certification requirements and other private standards. Second, Jamaican producers and exporters report a high degree of coordination with Japanese buyers and regulatory officials, including annual discussions about pesticide needs and usage with Japanese officials. Third, Jamaica conducts extensive farmer education and pre-export testing to ensure that only compliant product is exported. The country tests one in three shipments of coffee by each exporter through a partnership with a residue laboratory at the University of the West Indies. Tests are for compliance with a single export standard for all export markets based on the lowest applicable MRL; the cost to the exporter is $120 per sample, which is a special price based on an agreement with the university. Coffee that does not meet this standard is not exported. The Jamaican coffee industry is able to comply with the MRLs of its key export market as a result of these measures.[1136]

[1132] Industry representative, email message to USITC staff, January 13, 2020.
[1133] Industry representative, telephone interview by USITC staff, February 21, 2020.
[1134] Colombian government representative, telephone interview by USITC staff, October 9, 2019.
[1135] Coffee Industry Board, “Market Requirements” (accessed February 21, 2020).
[1136] Industry representative, telephone interview by USITC staff, February 21, 2020.

Pre-export testing has also been essential for Colombian producers seeking to export coffee to the Japanese market. Colombian industry representatives gave an example of a temporary trade disruption that resulted when Japan lowered the MRL for chlorpyrifos on coffee in 2015, affecting exports of coffee from Colombia to Japan. The cost of complying with such low MRLs requires significant investments in testing labs and equipment. In response, the Colombian government worked with the coffee industry to implement pre-export testing at 53 national laboratories. The cost to establish testing for chlorpyrifos residues on coffee in these laboratories was reportedly about $5,000 per laboratory, or about $250,000 overall.[1137]

Despite the Colombian investment in testing equipment, Colombian coffee exporters can still incur costs from MRL violations in the Japanese markets. For FY 2017, Colombian coffee beans were transferred to an inspection order (meaning 100 percent of shipments are inspected) after previously being subject to enhanced monitoring inspections for chlorpyrifos.[1138] Still, Japan reported an MRL violation for chlorpyrifos on coffee imports from Colombia in their August 2018 reports on recent cases of violations.[1139] The Colombian industry reports that growers are now observing a 30-day preharvest interval for chlorpyrifos on coffee beans, which they believe should ensure zero residue on exported coffee beans. They report that the reason chlorpyrifos is still in use (with this long preharvest interval) is because alternatives to this insecticide are eight times as expensive, and growers bear most of the costs of complying with MRLs.[1140]

Cost of Alternative Herbicides

Coffee producers in multiple countries expressed concerns about increased costs from the potential lowering of MRLs for key herbicides, such as glyphosate. One medium-sized coffee farmer in Kenya has successfully phased out glyphosate in anticipation that MRLs for it could be lowered, but estimated that not using any herbicides would increase his labor costs by one-third.[1141] Similarly, a coffee industry representative in Costa Rica stated that the industry there has a research program on substitutes for glyphosate; so far, all the alternatives are much more expensive. The representative estimated that without glyphosate, the Costa Rican coffee industry would face 30 percent higher weed control costs.[1142]

Case Study: Future Challenges for Global Grains and Oilseeds Producers

This case study examines the future impact of changing MRL policies on growers of grain and oilseed crops such as corn (maize), soybeans, and wheat (collectively known as row crops), and, to a lesser extent, rice. Unlike minor crops such as French beans and mangoes, grains and oilseeds are often sold in

[1137] Colombian government representative, telephone interview by USITC staff, October 9, 2019.
[1138] Government of Japan, Ministry of Health, Labour, and Welfare, *Results of Imported Foods Monitoring*, August 2018, and *Results of Monitoring and Guidance Based on the Imported Foods Monitoring and Guidance Plan for FY2017* (accessed February 18, 2020).
[1139] Government of Japan, Ministry of Health, Labour and Welfare, "Recent Cases of Violations of the Food Sanitation Law," August 2018.
[1140] Industry representative, email message to USITC staff, March 12, 2020.
[1141] Industry representative, interview by USITC staff, Nairobi, Kenya, December 6, 2019.
[1142] Industry representative, interview by USITC staff, Costa Rica, December 11, 2019.

bulk and blended before reaching final export markets, so it is difficult to trace product back to a specific farm. Because of this, growers often must ensure that their product meets the lowest MRLs of all their export markets; MRL policies in one market may determine which pesticides and production methods are used for all export markets.

While this case study focuses on producers in Argentina, Brazil, and the United States, the examples discussed throughout this case study can be applied to other grain-producing countries, as these are global commodities and producers share many similarities.

Corn: In 2018, global exports of corn were $32.9 billion. The top exporters were the United States, Brazil, Argentina, and Ukraine. Top importers were Japan, Mexico, South Korea, and Spain.[1143]

Soybeans: In 2018, global exports of soybeans totaled $59.1 billion. The top exporters were Brazil, the United States, Paraguay, Canada, and Argentina. Top importers were China (which accounted for 62 percent of global imports by value), Argentina, Mexico, the Netherlands, and Japan.[1144]

Wheat and meslin: In 2018, global exports of wheat and meslin totaled $40.6 billion. The top exporters were Russia, Canada, the United States, and France. Top importers were Indonesia, Italy, Japan, and the Philippines.[1145]

Industry Structure

Unlike the minor/specialty crops addressed in most sections of this chapter, grains and oilseeds such as corn, soybean, and wheat are traded as high-volume global commodities that are sold in bulk and blended together according to certain quality standards. These industry practices, and the MRL challenges farmers face in export markets, are similar across major grain-producing countries.[1146]

Again, in contrast to most minor/specialty crops, which are cultivated on relatively small pieces of land, grain production around the world depends on high-acreage cultivation to harvest large volumes of these crops. Grains are first harvested at the farm level, then sent to elevators or stored onsite, sometimes for several years. Grain elevators often source from multiple farms sited in different regions that have different growing conditions. As grains make their way through the supply chain, they are often mixed with product from other farms that may apply different pre- or post-harvest treatments to control pests.[1147] Because of the structure of the entire supply chain, farmers generally do not know which export markets their crops will be shipped to, and importers are unable to trace product—and an MRL violation—back to an individual farm.[1148]

[1143] IHS Markit, Global Trade Atlas database, HS subheading 1005 (accessed January 10, 2020).
[1144] IHS Markit, Global Trade Atlas database, HS subheading 1201 (accessed January 10, 2020).
[1145] IHS Markit, Global Trade Atlas database, HS subheading 1001 (accessed January 10, 2020).
[1146] U.S. Grains Council, National Corn Growers Association, and MAIZALL, written submission to USITC, December 13, 2019, 9.
[1147] U.S. Grains Council, National Corn Growers Association, and MAIZALL, written submission to USITC, December 13, 2019, 7–9.
[1148] American Soybean Association (ASA) and U.S. Soy Export Council (USSEC), written submission to USITC, December 13, 2019, 2–3; U.S. Wheat Associates, written submission to USITC, December 12, 2019, 1; USA Rice Federation, written submission to USITC, December 10, 2019, 4.

Pest Pressures and Pesticide Use

Major producers of row crops face a variety of pest pressures from weeds, insects, and fungi. Tables 5.8, 5.9, and 5.10 provide a list of common herbicides, insecticides, and fungicides used by wheat, corn, and soybean growers around the world, along with their respective MRLs in major export markets. These products have been identified by growers as being of critical importance to farmers' integrated pest management systems and/or as being substances that are at a near-term risk of MRL policy changes.

Table 5.8 MRLs for key pesticides used in the wheat industry (ppm)

Active substance	Pesticide Type	Codex	Japan	South Korea	Thailand	Philippines	US	EU	Recent Changes (EU and/or Thailand)
Chlorpyrifos	Insecticide	0.5	0.5	0.4	0.5	0.5	0.5	0.5	Approval not renewed as of December 2019. EU member states' grace periods ended by April 2020. Thailand to cancel registration June 2020.
Chlorpyrifos-methyl	Insecticide	3.0	10.0	3.0	3.0	3.0	6.0	0.05	Approval not renewed as of December 2019. EU member states' grace periods ended by April 2020. Thailand to cancel registration June 2020.
Glyphosate	Herbicide	30.0	30.0	5.0	30.0	30.0	30.0	10.0	EU approval expires December 2022.
Paraquat (dichloride)	Herbicide	Missing	0.05	0.1	0.01	Missing	1.1	0.02	No authorization in place in EU. Thailand to cancel registration June 2020.
Spinosad	Insecticide	1.0	2.0	1.0	1.0	1.0	1.5	2.0	EU approval expires April 2021. MRL raised from 1.0 to 2.0 in 2015.

Source: Bryant Christie Global, Pesticide MRLs database (accessed December 26, 2019); European Commission, EU Pesticides database (accessed December 20, 2019); U.S. Wheat Associates, written submission to the USITC, December 12, 2019, 2–4; USDA, FAS, *A December 2 Update on the Ban on Three AIs in Thailand*, December 3, 2019; U.S. Wheat Associates, written submission to USITC, December 12, 2019, 4.
Note: "Missing" indicates that there is no MRL for this product on wheat.

Table 5.9 MRLs for key pesticides used in the corn industry (ppm)

Active substance	Pesticide Type	Codex	Japan	Mexico	South Korea	US	EU	Recent Changes (EU)
Glyphosate	Herbicide	5.0	5.0	1.0	5.0	5.0	1.0	EU approval expires December 2022.
Malathion	Insecticide	0.05	2.0	2.0	2.0	8.0	8.0	Approval expires April 2022.
Propiconazole	Fungicide	0.05	0.2	0.2	0.05	0.2	0.05	EU approval was not renewed as of March 2019. Grace period ended in March 2020.
Glufosinate-ammonium	Herbicide	0.1	0.1	0.2	0.05	0.2	0.1	EU MRL lowered from 0.5 to 0.1 in 2017.

Source: Bryant Christie Global, Pesticide MRLs database (accessed December 26, 2019); European Commission, EU Pesticides database (accessed December 20, 2019); U.S. Grains Council, National Corn Growers Association, and MAIZALL, written submission to the USITC, December 13, 2019, 23–25.

Table 5.10 MRLs for key pesticides used in the soybean industry (ppm)

Active substance	Pesticide Type	Codex	Japan	Mexico	China	Thailand	US	EU	Recent Changes (EU and/or Thailand)
Chlorpyrifos	Insecticide	0.1	0.3	0.3	0.1	0.1	0.3	0.1	EU approval not renewed as of December 2019. EU member states' grace periods ended by April 2020. Thailand to cancel registration June 2020.
Chlorothalonil	Fungicide	1.0	0.2	0.2	0.2	0.2	0.2	0.01	EU approval not renewed as of March 2019. EU member states' grace periods end May 2020.
Glufosinate	Herbicide	2.0	2.0	2.0	2.0	2.0	2.0	2.0	Registrant decided not to renew registration. MRL could be lowered to 0.01 ppm (see discussion in the following section).
Glyphosate	Herbicide	20.0	20.0	20.0	Missing	20.0	20.0	20.0	EU approval expires December 2022.
Mancozeb	Fungicide	Missing	3.0	Missing	Missing	0.1	Missing	0.1	EU approval expires January 2021.
Paraquat	Herbicide	0.5	0.1	0.05	0.5	0.1	0.7	0.02	Thailand to cancel registration June 2020.

Source: Bryant Christie Global, Pesticide MRLs database (accessed January 21, 2020); European Commission, EU Pesticides database (accessed December 20, 2019); Industry representative, telephone interview by USITC staff, Washington, D.C., October 21, 2019; USDA, FAS, *Thailand Notified WTO*, April 2, 2020; USDA, FAS, *A December 2 Update on the Ban on Three AIs in Thailand*, December 3, 2019; U.S. Wheat Associates, written submission to USITC, December 12, 2019, 4.
Note: "Missing" indicates that there is no MRL for this product on soybeans.

Costs and Effects of Missing and Low MRLs on Grain and Oilseed Industries

Several grains producers and relevant trade associations noted that, in the past, growers have not faced significant MRL-related challenges in major export markets. However, there are growing concerns within these industries that future changes in MRL policies, including lowering MRLs and banning the use of certain pesticides, along with differences in MRLs among major export markets, could pose a significant challenge to growers. Possible consequences include yield losses, rejected shipments, and higher costs for producers.[1149] A foreign government representative noted that changing MRL policies, particularly in the EU, will have a direct impact on the production and supply chain for grains and oilseeds, reducing productivity and increasing prices for these commodities.[1150] These impacts could intensify if other export markets choose to align their own import tolerances with those of the EU.[1151]

Mancozeb

Mancozeb is an important fungicide for Brazilian soybean growers and is used largely for the same purposes as chlorothalonil—the two are considered substitutes for one another. If mancozeb were to be banned in the EU when its registration comes up for renewal in 2021 and growers had to rely on alternative fungicides, total fungicide costs for Brazilian soybean farmers would rise by 7.6 percent, according to an analysis by Kynetec, an agricultural market research firm.[1152] This analysis found that the loss of access to mancozeb would reduce yield by 1.3 percent and increase farm costs by 0.6 percent, resulting in an overall 4.7 percent reduction in farm income.[1153] Modeling conducted by Kynetec found that this could lead to a short-term 3.5 percent decrease in the quantity of soybeans exported from Brazil. If growers decided to continue applying mancozeb, their exports to the EU would likely be replaced by U.S. soybeans, as U.S. producers do not apply as much mancozeb. Brazilian exporters could shift their exports to markets such as China and India, as these countries are less restrictive in the use of mancozeb.[1154]

Soybean growers in Brazil are further impacted by the potential loss of a pesticide because alternatives to chlorothalonil and mancozeb are limited. For example, although copper oxychloride is easier for farmers to work with because it comes in a liquid formulation and has less environmental impact, it is more expensive than mancozeb. While the industry is exploring the potential use of organic pesticides, the adoption of these would not be without cost. For example, an organic pesticide such as *Bacillus subtilis* are being tested and are known to have no adverse impact on the environment, but there would be a moderate increase in costs due to the need to acquire and use new technologies to apply the bacillus.[1155]

[1149] Industry representative, telephone interview by USITC staff, October 16, 2019; industry representative, telephone interview by USITC staff, October 21, 2019; industry representative, telephone interview by USITC staff, October 31, 2019.
[1150] USITC, hearing transcript, October 29, 2019, 9–10 (testimony of Luis Gonzalez Fernandez, Embassy of the Republic of Paraguay).
[1151] Industry representative, telephone interview by USITC staff, October 31, 2019.
[1152] As previously stated in the bananas case study, the EU approval for chlorothalonil was not renewed in 2019, and the grace period on its use will end in May of 2020 when the MRL will default to the limit of determination (0.01 ppm).
[1153] Kynetec, *Value of Mancozeb: India—Grapes*, October 18, 2019, 10.
[1154] Kynetec, *Value of Mancozeb: India—Grapes*, October 18, 2019, 24–25.
[1155] Kynetec, *Value of Mancozeb: India—Grapes*, October 18, 2019, 28.

Glyphosate and Glufosinate in the EU

Glyphosate and glufosinate are two very common herbicides applied throughout the world. They serve as important tools in the integrated pest management system for many specialty and row crop growers, including wheat, corn, and soybean farmers. The loss of these products could have a major impact on grain producers around the world and reduce farmers' ability to control weeds.

Glyphosate

In 2017, the EU renewed use of glyphosate for five years, despite concerns raised by officials from some EU member states, including Italy, France, and Germany, all of which have indicated interest in phasing out the use of glyphosate in the coming years.[1156] The current approval is expected to expire on December 15, 2022.[1157] According to certain trade associations, the next five-year renewal for glyphosate in the EU will be particularly challenging in light of recent court cases in the United States and concerns raised by nongovernmental organizations and EU member states during the previous renewal round.[1158] If glyphosate is banned in the EU, this could have a major impact on producers and global trade. Grain producers would have to stop applying glyphosate, regardless of which export market they are shipping to, in order not to risk potential contamination from product commingling during the bulking and blending processes.[1159]

Glufosinate

According to various industry representatives, the registrant of glufosinate—an important tool used by row crop farmers to manage herbicide resistance—chose not to submit an application to renew registration to the EU after it appeared that the request was likely to be denied. This means that the MRL can be lowered to the default of 0.01 ppm without an opinion from the European Food Safety Authority (EFSA). While the European Commission has not yet proposed removing the MRL for glufosinate, many observers contend that the loss of this substance could impact corn and soybean growers around the world, as it will decrease their ability to manage herbicide resistance, which could lead to greater yield losses.[1160] Text box 5.5 highlights the potential impact similar recent pesticide policy changes in Thailand that resulted in losing key pesticides may have on row crop producers.

[1156] Marks, "Glyphosate Is Here to Stay in EU," August 14, 2018.
[1157] Ribeiro, "Glyphosate," December 18, 2019.
[1158] U.S. Grains Council, National Corn Growers Association, and MAIZALL, written submission to USITC, December 13, 2019, 23–24.
[1159] Industry representative, telephone interview by USITC staff, October 21, 2019; industry representative, telephone interview by USITC staff, October 31, 2019.
[1160] U.S. Grains Council, National Corn Growers Association, and MAIZALL, written submission to USITC, December 13, 2019, 25; industry representative, telephone interview by USITC staff, October 21, 2019; industry representative, telephone interview by USITC staff, October 31, 2019.

Box 5.5 Recent Policy Changes in Thailand

Recent changes in Thailand's MRLs for chlorpyrifos, and paraquat could impact soybean and wheat producers around the world. On April 30, 2020, Thailand's National Hazardous Substance Committee agreed on a draft notification to ban paraquat and chlorpyrifos effective June 1, 2020. The change recategorizes these substances under Thailand's domestic pesticide categorization system from category 3 products (allowable but subject to permission) to category 4 products (prohibited for production, importation, exportation, and possession). Effective June 1, 2020, Thailand will then apply a zero-tolerance MRL, which means that residues of these two substances cannot be detected in any shipments of imported food ingredients (e.g., soybeans, wheat).

These chemicals are commonly used in the United States, and one trade association noted that residues of chlorpyrifos are common in the classes of wheat imported by Thailand. If Thailand proceeds with the cancellation of these products on June 1, 2020 (particularly paraquat), this could keep certain U.S. soybean and wheat producers from exporting to the Thai market.

Source: USDA, FAS, *Thailand Moves Forward with Ban on Paraquat and Chlorpyrifos on 1 June 2020, May 1, 2020*; USDA, FAS, *Thailand Notified WTO*, April 2, 2020; USDA, FAS, *A December 2 Update on the Ban on Three AIs in Thailand*, December 3, 2019; U.S. Wheat Associates, written submission to USITC, December 12, 2019, 4.
Note: Thai importers of U.S. wheat and soybeans noted that a ban on paraquat could affect imports as paraquat is widely used by U.S. soybean and wheat growers.

Propanil and Rice

Propanil is a rice-specific herbicide that is registered for use in the United States and most rice-producing countries. Japan set an import tolerance of 0.2 ppm for this pesticide in 2019.[1161] U.S. rice growers noted that rice produced by different growers is often commingled before it is shipped to export markets. This trade association noted that commingling increases the risk of an MRL violation being declared and a shipment being rejected, especially if the MRL is reduced to the limit of determination/quantification. Industry representatives noted that the lowering of the MRL for propanil to 0.2 ppm could result in the loss of the Japanese market for certain producers, or shipments could be held up at port and eventually rejected, resulting in financial losses for growers.[1162]

Climate Change and Sustainable Practices

Like specialty crop growers, many grain producers rely on integrated pest management practices, such as rotating between different crops and pesticides. An integrated pest management system ensures that farmers are able to control and mitigate the effects of pests, including yield losses and reduced product quality. Growers also note that pest outbreaks could intensify due to changing climatic patterns (including severe weather events), stating that the loss of plant protection products could erode their ability to address these future outbreaks. Growers express the belief that together, these factors could reduce yields and place additional stress on their ability to deliver a reliable food supply.[1163]

[1161] Japan Food Chemical Research Foundation, "Propanil" (accessed June 11, 2020)
[1162] USA Rice Federation, written submission to USITC, December 10, 2019, 4–5.
[1163] ASA and USSEC, written submission to USITC, December 13, 2019, 4–6; U.S. Grains Council, National Corn Growers Association, and MAIZALL, written submission to USITC, December 13, 2019, 4–5.

Before the introduction of certain herbicides, corn and other row crop farmers relied on intensive tillage practices to manage weeds. These practices break up carbon that is stored in the soil and release it into the atmosphere in the form of carbon emissions. Herbicides like glyphosate have reduced the need for intensive tillage, so farmers can now engage in conservation tillage, which reduces the number of required trips over the field and lessens soil erosion. Grain industry representatives state that by practicing conservation tillage, farmers are able to reduce their energy consumption and the likelihood that carbon will be released from the soil into the atmosphere. They assert that the loss of glyphosate and other herbicides could result in farmers relying more on traditional tillage practices, which would undermine efforts to reduce carbon emissions.[1164]

[1164] U.S. Grains Council, National Corn Growers Association, and MAIZALL, written submission to USITC, December 13, 2019, 5; industry representative, telephone interview by USITC staff, October 31, 2019.

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Chapter 6
Effects of MRL Policies from the Economic Literature

Key Findings

Maximum residue levels (MRLs) are a type of nontariff measure (NTM) affecting agricultural goods, and have the potential to influence trade as well as prices, production, and income in exporting countries.[1165] By definition, low MRLs, including missing MRLs that result in low default MRLs being applied, in import markets impose stricter standards on agricultural products being exported to those destinations. Most studies that have examined the effects of MRLs conclude that, for the products within the markets examined, low MRLs or those that differ between exporter and importer pairs (i.e., are more heterogenous) deter or reduce trade. However, some studies conclude that low or differing MRLs on balance have trade-enhancing effects. Studies have generally posited that trade-reducing effects are linked to inherent costs borne by growers and exporters in complying with these policies, and that trade-enhancing effects are linked to increased demand due to consumer preferences for products with lower pesticide residues. Most studies have found that, regardless of the findings of trade-reducing or trade-enhancing effects of MRLs, the effects are not uniform across countries. Frequently, studies have found that lower-income exporting countries bear greater costs of compliance associated with low MRLs and face more significant trade-reducing effects.

Studies focusing on MRLs have generally not examined the effects of these policies on production, prices, or income. However, other studies related to agricultural NTMs provide insight into the potential implications of MRLs on these indicators. Several of these studies have found that certain agricultural NTMs contribute to higher prices for imported agricultural products. These studies have found that while exporting producers may benefit if they can afford the costs necessary to meet more stringent NTMs while maintaining output levels in certain cases, producers who are unable to comply may experience reduced production, income, and in some cases lower product quality and prices.

Beyond the literature on NTMs are studies on the benefits and costs of pesticide use. One group of studies has found that appropriate pesticide use reduces the amount of crop output that is lost to pests and increases perceived crop quality. Some other studies have identified harmful effects related to pesticide use and overuse in terms of both lessened agricultural productivity and broader societal and environmental problems. Still others have concluded that long-term and gradual reduction of pesticide use, combined with other crop protection practices, is possible without sacrificing productivity or income.

[1165] The United Nations Conference on Trade and Development (UNCTAD) defines nontariff measures as "policy measures other than ordinary customs tariffs that can potentially have an economic effect on international trade in goods, changing quantities traded, or prices or both." Specifically, UNCTAD classifies MRLs as a type of sanitary and phytosanitary (SPS) measure. UNCTAD, *International Classification of Non-Tariff Measures*, 2019, v, 3.

Introduction

This chapter provides a review of the economic literature that addresses the effects of MRLs on trade, production, farmer income, and prices. The studies summarized within this chapter include analyses focused on countries representing a range of income classifications, including low-income countries, as well as a variety of crop commodities and plant-protection products. Studies focused on the impact of MRLs on trade, referred to as the "core" literature in this chapter, are summarized in the first section of this chapter ("Studies Examining the Trade Effects of MRLs: The Core MRL Literature"). The section begins by describing the common methodological approaches for studying the effects of MRLs on trade. It then summarizes the literature that addresses the effects of MRLs on trade, dividing it into two groups based broadly on author conclusions from study findings. The first group of studies addressed in this section generally conclude that the imposition in import markets of more restrictive MRLs, either in absolute terms or relative to those in effect in the producing market, lead to lower trade volumes within the markets examined. This literature generally theorizes that the reduced trade volumes are due to increased costs of production and trade. The second group of studies in this section generally conclude that lower importer or exporter MRLs increase trade volumes within the markets examined. They attribute this effect to lower MRLs conveying to consumers a perception of higher-quality imported agricultural products, thereby enhancing demand for imports.

None of the studies in the literature that focus specifically on MRLs have analyzed the effects of these regulations on non-trade indicators such as production, farmer income, and prices in exporting countries. This chapter's second section ("Additional Relevant Literature") examines other articles from the economic literature that have presented findings regarding the effects of agricultural NTMs on production, farmer income, and/or prices, in addition to literature that has examined the impacts of pesticide use on agricultural production.

MRLs as Nontariff Measures

Studies that specifically focus on MRLs are a subset of a broader economic literature that has analyzed the effects of NTMs on trade. This broader literature examines the trade effects of technical barriers to trade (TBTs) and sanitary and phytosanitary (SPS) measures. The majority of these studies find a relationship between more stringent measures and lower bilateral trade volumes and infer that such measures have trade-reducing effects. There are studies, however, that find a relationship between stricter measures and higher trade volumes and infer that SPS measures and TBTs are trade enhancing. One recent study provided a meta-analysis of the ways that studies of agrifood trade have assessed the role of NTMs. According to this study, 34 papers have found evidence that NTMs act as barriers and reduce trade, 3 have found that they improve demand and increase trade, and 21 have found evidence of both effects.[1166]

[1166] Santeramo, "On Non-Tariff Measures," April 2019, 15.

Where studies have found trade-increasing effects of NTMs, authors posit that standards[1167] convey information about product quality to consumers.[1168] In an introduction to a broader set of studies that explored methods for measuring the effects of TBTs, Maskus and Wilson included a summary of the potentially commerce-enhancing aspects of standards. The authors noted that because standards impose requirements and specifications on products of a similar type sold in the marketplace, they implicitly improve information flows between suppliers and consumers about the inherent characteristics of products. Such characteristics may be related to actual or perceived quality, desired specifications, or the achievement of a public good such as environmental protection, sanitation, or health during the creation or trade of that product. Because essential characteristics are standardized and quality and performance are "guaranteed," standards can reduce uncertainty costs to consumers and increase substitutability between similar products. As a result, standards can serve to facilitate market transactions, promote integration between global markets, and, potentially, increase trade.[1169]

Studies finding trade-reducing effects of NTMs conclude that these measures impose fixed and recurring costs on exporters as they seek to meet foreign requirements, which in turn causes certain exporters to forego or reduce trade rather than incur the additional costs.[1170] Maskus and Wilson described the inherent costs faced by exporting firms when trading with destination countries that have different or more restrictive product standards. In order to meet a foreign standard, exporters must incur one-time fixed costs related to changing production practices or product specifications, as well as developing the administrative procedures necessary to ensure compliance for future sales to destination markets. In addition, exporters incur recurring costs of maintaining compliance with standards, including quality control, testing, and certification. Both fixed and recurring costs can be trade-limiting: fixed costs can increase market entry barriers, while recurring costs can reduce exporters' ability to compete.

These costs and effects may be compounded to the extent that exporters must diversify production practices in order to meet different requirements in different markets, providing potential advantages to larger firms capable of maintaining differentiated production at the expense of smaller firms that may be less adaptable. Under certain regulatory systems, costs may extend beyond those necessary to meet the technical specifications themselves to include conformity assessment costs—i.e., proving to authorities in destination countries that exports meet the specifications. To the extent that destination country authorities do not recognize the exporters' testing capabilities or declarations of conformity, for example, exporters may face indirect costs such as foreign bureaucratic opacity, border and shipment delays and their effects on products with short life cycles, and uncertainty about whether shipments will ever reach intended recipients.[1171]

[1167] Whereas a "regulation" may be defined as a mandatory requirement imposed by public authorities, and a "standard" may be defined as a voluntary specification driven by private entities, the term "standard" is used by Maskus and Wilson, as well as other authors at times, to refer to both concepts. See Maskus and Wilson, "A Review of Past Attempts and the New Policy Context," 2001, 16.

[1168] For example, within the core MRL literature, see Xiong and Beghin, "Disentangling Demand-enhancing and Trade-Cost Effects," January 2017, 1191, 1197; Foletti and Shingal, "Stricter Regulations Boost Exports," October 1, 2014, 17; Shingal, Ehrich, and Foletti, "Re-estimating the Effect of Stricter Standards," 2017, 24.

[1169] Maskus and Wilson, "A Review of Past Attempts and the New Policy Context," 2001, 17–19.

[1170] For example, within the core MRL literature, see Xiong and Beghin, "Disentangling Demand-enhancing and Trade-Cost Effects," January 2017, 1190–91; Ferro, Otsuki, and Wilson, "The Effect of Product Standards on Agricultural Exports," January 2015, 78; Hejazi, Grant, and Peterson, "Hidden Trade Costs?" June 2018, 30–31.

[1171] Maskus and Wilson, "A Review of Past Attempts and the New Policy Context," 2001, 19–20.

Studies Examining the Trade Effects of MRLs: The Core MRL Literature

Methodological Approaches

This section describes studies that have analyzed the effects of MRLs on trade, most of which have used a gravity model approach. Gravity models are commonly used econometric models that empirically examine international trade patterns as a function of exporter and importer characteristics and the nature of bilateral trading relationships. Gravity models are a particularly useful framework in this context because they are capable of analyzing economic effects of nontariff measures like MRLs that are not themselves direct trade costs (such as tariffs) but that may have important impacts on trade. Because the studies in this section use formal statistical and economic methods associated with gravity models, they are effective at observing the direction and magnitude of trade effects associated with MRLs.

MRL Stringency Versus Heterogeneity

In seeking to develop a variable that can be used within models to meaningfully explain the level of restrictiveness of an importer country's MRLs, studies have assessed the impact of either MRL "stringency" or MRL "heterogeneity." With two exceptions, the studies covered generally chose to assess the impacts of either MRL stringency or MRL heterogeneity.[1172] In general, stringency measures the restrictiveness of MRLs directly, based on (1) their actual levels, with a zero parts per million (ppm) tolerance being the most restrictive and higher ppm being more permissive, or (2) their levels relative to a single international standard, the Codex Alimentarius (Codex). Studies measuring the effects of stringency assume that an importer's MRL has meaningful effects on trade, regardless of how those levels compare to exporters' MRLs. The studies reviewed in this chapter that employ a stringency index are listed in tables 6.1 and 6.3.

By contrast, heterogeneity (also referred to as similarity, dissimilarity, or bilateral stringency) focuses on bilateral country relationships, examining the importer's MRLs relative to the exporter's MRLs. These studies assume that only differences between countries' MRLs affect trade, as countries have fewer problems trading with partners that share similar standards. Expanding on this concept, most recent MRL studies focused on heterogeneity assume that the only differences that affect trade are those where importer MRLs are lower than exporter MRLs, as exporters with lower home-market MRLs will not face added costs meeting higher importer MRLs. The studies reviewed in this chapter that employ a heterogeneity index are listed in tables 6.2 and 6.3.

Tables 6.1, 6.2, and 6.3 include checkmarks to denote where studies have included findings of trade-deterring or trade-enhancing effects of MRLs. These findings were highlighted by the study authors in

[1172] As discussed below, Ferro, Otsuki, and Wilson used stringency and heterogeneity indexes separately in two different groupings of gravity model simulations, while Xiong and Beghin used the two indexes together within the same gravity model. Ferro, Otsuki, and Wilson, "The Effect of Product Standards on Agricultural Exports," January 2015; Xiong and Beghin, "Disentangling Demand-Enhancing and Trade-Cost Effects of Maximum Residue Regulations," July 2014.

the explanation of model results. Studies in tables 6.1 and 6.2 that include findings of both trade-increasing and trade-decreasing effects can reflect varying trade effects for different markets or products analyzed under the same model. Studies in table 6.3 that include findings of both trade-increasing and trade-decreasing effects find these effects concurrently, looking at products and markets in aggregate. In addition to findings of trade effects associated with MRLs observed from the models employed by the authors (which are sometimes mixed), authors generally summarize these findings and reach conclusions in their studies regarding the overall trade effect of MRL stringency and/or heterogeneity (either generally or with respect to the specific markets examined). This chapter organizes the literature into two groups—trade-reducing and trade-enhancing—based on these overall conclusions.[1173]

Table 6.1 Studies analyzing the trade impacts of MRLs using a stringency index

Paper	Study period	Partners (exporter → importer)	Agricultural products	Chemicals	Findings of trade-decreasing effects from lower MRLs	Findings of trade-increasing effects from lower MRLs
Arita, Mitchell, Beckman (2015)	2010–12	United States → European Union (EU)	Fruit, vegetables, nuts	Many (count not available)	✔	
Chen, Yang, and Findlay (2008)	1992–2004	China → Major importers	Vegetables (total and 3 categories)	Chlorpyrifos pesticide	✔	
Kareem, Brummer, and Martinez-Zarzoso (2015)	2008–13	African countries → EU	Tomatoes	468 pesticides	✔	
Scheepers, Joost, Alemu (2007)	unspecified range	South Africa → Europe	Avocados	Prochloraz	✔	
Wei, Huang, and Yang (2012)	1996–2009	China → 31 importers	Tea	Endosulfan, fenvalerate, and flucythrinate	✔	
Wilson and Otsuki (2004)	1997–99	21 developing countries → 11 OECD importers	Bananas	Chlorpyrifos pesticide	✔	
Xiong (2017)	2013–14	Vietnam → TPP and RCEP importers	Tea	All applicable to tea	✔	

1173 The studies grouped in the section entitled “MRLs as Trade-reducing” are Arita, Mitchell, Beckman (2015); Chen, Yang, and Findlay (2008); Kareem, Brummer, and Martinez-Zarzoso (2015); Scheepers, Joost, Alemu (2007); Wei, Huang, and Yang (2012); Wilson and Otsuki (2004); Xiong (2017); Achterbosch et al. (2009); Choi and Yue (2017); Drogué and DeMaria (2012); Hejazi, Grant, and Peterson (2018); Shingal and Ehrich (2018); Winchester et al. (2012); and Ferro, Otsuki, and Wilson (2015). The studies grouped in the section entitled “MRLs as Trade-enhancing” are Xiong and Beghin (2012); Shingal, Ehrich and Folletti (2017); Xiong and Beghin (2014); and Foletti and Shingal (2014).

Paper	Study period	Partners (exporter → importer)	Agricultural products	Chemicals	Findings of trade-decreasing effects from lower MRLs	Findings of trade-increasing effects from lower MRLs
Xiong and Beghin (2012)	2010	60 countries (importing and exporting); focus on United States and Canada	135 plant and animal products	Many (count not available)	✔	✔

Source: Compiled by USITC.
Note: OECD = Organisation for Economic Cooperation and Development, RCEP = Regional Comprehensive Economics Partnership, and TPP = Trans-Pacific Partnership agreement.

Table 6.2 Studies analyzing the trade impacts of MRLs using a heterogeneity index

Paper	Study period	Partners (exporter → importer)	Agricultural products	Chemicals	Findings of trade-decreasing effects from lower/dissimilar MRLs	Findings of trade-increasing effects from lower/dissimilar MRLs
Achterbosch et al. (2009)	1996–2007	Chile → EU	Fruit (6 types)	Up to 48 chemicals for each fruit	✔	
Choi and Yue (2017)	1996–2010	34 major exporters → Japan	Vegetables (total and 4 categories)	Many (count not available)	✔	
Drogué and DeMaria (2012)	2000–09	7 major exporters → 7 major importers	Apples and pears	749 chemicals	✔	
Foletti and Shingal (2014)	2006–12	50 countries (mostly OECD)	118 agricultural products	1,193 pesticides	✔	✔
Hejazi, Grant, and Peterson (2018)	2013–14	United States → 85 countries	51 fruit and vegetable varieties	162 pesticides	✔	✔
Shingal and Ehrich (2018)	2005–14	EU → 53 trading partners	31 agricultural products	Many (count not available)	✔	
Shingal, Ehrich, and Foletti (2017)	2005–14	53 countries (importing and exporting)	31 agricultural products	Many (count not available)		✔
Winchester et al. (2012)	2008–09	EU and 9 other countries (exporting and importing)	11 plant and animal products	Count not available (study looks at standards including MRLs)	✔	

Source: Compiled by USITC.
Note: OECD = Organisation for Economic Cooperation and Development.

Table 6.3 Studies analyzing the trade impacts of MRLs using stringency and heterogeneity indexes

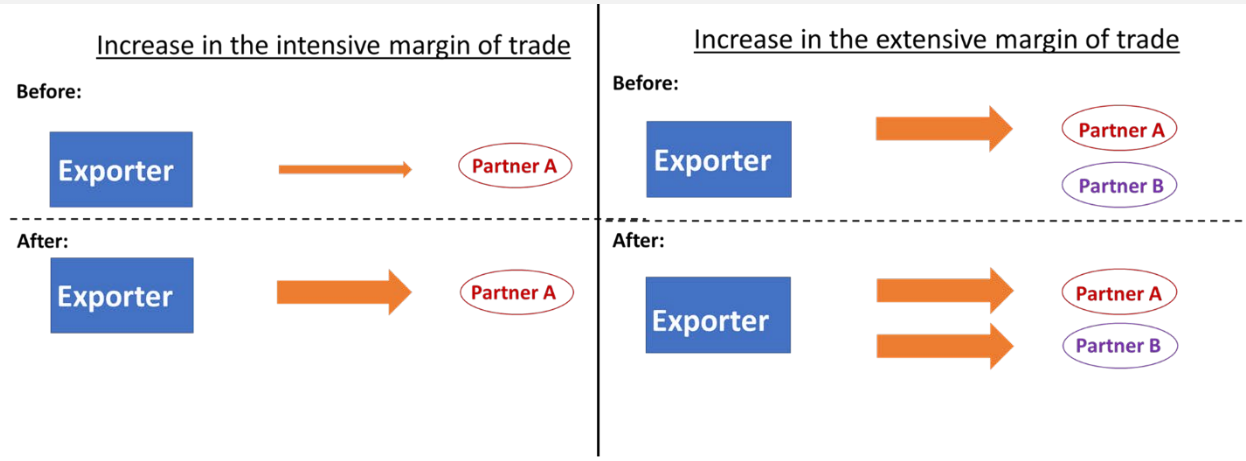
Paper	Study period	Partners (exporter → importer)	Agricultural products	Chemicals	Findings of trade-decreasing effects from lower MRLs	Findings of trade-increasing effects from lower MRLs
Ferro, Otsuki, and Wilson (2015)	2006–11	World → 61 importing countries	66 fruits and vegetables	~1,500 pesticides	✔	✔
Xiong and Beghin (2014)	2008, 2012	61 countries → 20 OECD countries	109 plant products	Many (count not available)	✔	✔

Source: Compiled by USITC.
Note: OECD stands for the Organisation for Economic Cooperation and Development.

Several studies have examined whether MRLs that are either more stringent or heterogeneous influence the volume of agricultural exports not only within existing bilateral trade relationships (i.e., within "the intensive margin of trade") but also even when no bilateral trade relationship previously existed for a given commodity (i.e., on "the extensive margin of trade") (see figure 6.1 for an illustration). Separating out these two effects may be important for understanding how MRLs affect exporter costs. Studies finding that more stringent MRLs affect trade between existing partners, thereby having effects on the intensive margin, have suggested that these policies are imposing variable trade costs.[1174] Studies finding that more stringent MRLs affect the likelihood of trade between countries, thereby having effects on the extensive margin, have suggested that these policies are imposing fixed trade costs.[1175] In terms of statistical significance, direction, and magnitude of trade effects, several of the studies described below have found effects of MRLs at the extensive margin that vary from those they find at the intensive margin.

[1174] See e.g. Hejazi, Grant, and Peterson, "Hidden Trade Costs? Maximum Residual Limits and US Exports of Fresh Fruits and Vegetables," June 2018, 16, 28, 31; Shingal and Ehrich, "Trade Effect of MRL Harmonization in the EU," July 2018, 9.
[1175] See, e.g., Ferro, Otsuki, and Wilson, "The Effect of Product Standards on Agricultural Exports," January 2015, 73–74, 78; Hejazi, Grant, and Peterson, "Hidden Trade Costs? Maximum Residual Limits and US Exports of Fresh Fruits and Vegetables," June 2018, 16, 28, 31; Shingal and Ehrich, "Trade Effect of MRL Harmonization in the EU," July 2018, 9. Although Ferro, Otsuki, and Wilson primarily refer to extensive margin effects in terms of fixed costs, they note that the selection of firms into export markets (whether or not they trade on the extensive margin) is a function of firm-level decisions about the profitability of exporting, which in turn is affected by both fixed and variable costs. Ferro, Otsuki, and Wilson, "The Effect of Product Standards on Agricultural Exports," January 2015, 71.

Figure 6.1 Illustration of extensive and intensive margins of trade



Source: Compiled by USITC.
Note: Arrows represent export flows. Width of arrows is proportionate to trade volume.

Methodological Issues and Limitations

Creating an analytical MRL variable for use in a gravity model in terms of either heterogeneity or stringency presents a challenge, as not all MRLs are included in each market's positive list (or in Codex).[1176] Since MRLs are defined based on a specific crop and pesticide, many are not fully harmonized between trading partners, leading to cases in which an export market has no MRL for a pesticide/crop combination (i.e., the MRL is "missing") even when that combination has an MRL in the producing market.

As described in chapter 5, missing MRLs (or the removal or expiration of MRLs) may have effects on firms that are distinct from low MRLs if they create additional uncertainty for firms engaged in producing and trading agricultural products. The studies in the core MRL literature have not specifically examined the effects of missing MRLs on trade; instead, they have made a variety of methodological judgments to impute or disregard missing MRLs.

The treatment of missing MRLs can lead to significant variation in how MRL indexes are calculated. Some studies include only MRLs that explicitly exist in a country, dropping observations with missing MRLs from their analysis of the effects of MRLs on trade.[1177] Other studies have assigned default values to missing MRLs based on national regulations, or, in the absence of information on regulations, based

[1176] A positive list for MRLs is the result of government authorities in a market developing their own independent regulatory frameworks and processes to establish their own MRLs. If an MRL does not exist for a particular pesticide/crop combination under a positive list system, trade is prohibited unless there are default rules established.
[1177] For example, Achterbosch et al. calculated a heterogeneity index that includes only MRLs implemented in both the importer and exporter countries. Achterbosch et al., "Measure the Measure: The Impact of Differences in Pesticide MRLs on Chilean Fruit Exports to the EU," 2009, 10.

on simplifying assumptions for the purpose of analysis.[1178] The method applied for imputing a level for missing MRLs can change study outcomes. For example, Shingal and Ehrich analyzed the effects of regulatory heterogeneity using three datasets derived from using different treatments of missing MRLs, and found substantially different results for model simulations depending on the missing-MRL adjustment used.[1179]

Another complex aspect of analyzing MRLs within a gravity model relates to the fact that MRLs are set at both the product and pesticide level. As discussed in chapter 1, a market may apply dozens or hundreds of MRLs on individual crops or crop groupings. Of these, only a handful of pesticides may be important to growers in export markets, and this may vary depending on the exporter. Incorporating each of these MRLs as discrete variables together within a single modeling exercise across multiple crops is not practical within a gravity model. For this reason, as discussed below, study authors have used various techniques to incorporate crop-specific MRL variables within their models, all of which have certain analytical tradeoffs. Certain studies have focused only on MRLs for the most important pesticides affecting trade for specific products, but these models may not incorporate the effects of other MRLs affecting those products, particularly if farmers use multiple pesticides or change pesticide inputs in response to MRL changes. Other studies have constructed aggregated crop-specific MRL variables, usually through averaging of MRLs, which may not specifically capture the practical extent of MRL effects based on variation in how pesticides are utilized and valued by farmers.

Although gravity models have been effective tools for analyzing the trade effects associated with MRL stringency and heterogeneity, these models do not themselves identify the actual mechanism by which MRLs drive trade outcomes. While many studies take the additional step of providing a possible reason for observed trade effects, such conclusions are not generally derived from or validated by original analysis or observation. In addition, while gravity models are designed to incorporate multiple factors that could affect trade, they may not sufficiently capture all unobserved or omitted factors that could be driving the size and direction of trade flows.[1180]

[1178] For example, Drogué and DeMaria used national regulations and information from a private database to determine the assignment of specific values to missing MRLs in a variety of importer countries, including defaulting to international Codex levels, defaulting to a zero-tolerance approach (a ban on imports with any discernible pesticide), and defaulting to a very low level (e.g. 0.01 ppm in the EU). Drogué and DeMaria, “Pesticide Residues and Trade, the Apple of Discord?” December 2012, 643.

[1179] In one of these datasets, the only observations included were those where the importer and the exporter had an explicit MRL. In a second dataset, default MRLs were used to replace missing MRLs. In a third dataset, any additional missing MRLs were assigned a level equivalent to the highest MRL for that product. Shingal and Ehrich, “Trade Effect of MRL Harmonization in the EU,” July 2018, 9–10, 15–17.

[1180] As discussed below, Shingal, Ehrich, and Foletti explored methods for analyzing the potential effects of unobserved or omitted variables in their study. Shingal, Ehrich, and Foletti, “Re-estimating the Effect of Stricter Standards,” 2017.

MRLs as Trade-reducing

Studies Finding That Greater Importer MRL Stringency Reduces Trade

Virtually all economic studies focused on MRLs recognize that they are NTMs that can impact trade. For this reason, quantitative analyses of MRLs generally seek to measure the extent to which MRLs affect trade volumes. As mentioned above, one group of studies has focused predominantly on the effects of importer MRL "stringency." These studies observe the trade effects resulting from three types of changes: (1) to MRL levels for individual pesticide/crop combinations, (2) to averaged MRLs for all pesticides across a single crop, or (3) to measures of importer MRL stringency that focus on the number of MRLs or reported concerns related to MRLs.[1181] Applying such MRL stringency indicators directly within the framework of gravity models, several of these studies have found that lower MRLs result in lower bilateral trade volumes for agricultural and food products.

Studies that find smaller trade volumes associated with lower importer MRLs note that these regulations inherently impose stricter requirements, and therefore increase costs necessary to meet those requirements, on exporters seeking to access markets. As noted earlier, such costs can include fixed costs, such as those necessary to change production practices, as well as ongoing additional costs necessary to maintain access to a foreign market with stricter MRLs. These costs may cause exporters to reduce the extent to which they export to countries with low MRLs, or to forego exporting to these markets altogether. For this reason, many studies have examined the effects of MRLs on both the intensive and extensive margins of trade.[1182]

As discussed in chapter 1, MRLs are applied on pesticide/crop combinations, with potentially numerous MRLs available for individual pesticides for each type of imported crop. In practice, however, production in many agricultural industries may rely on a far more limited number of pesticides for individual crops, with sometimes just one key pesticide playing a consistent important role in reducing pest pressures. Many studies have found that lower importer MRLs for specific pesticide/crop combinations had substantial trade-reducing effects on crop exports. Some studies arrived at this conclusion by finding evidence of a symmetric effect: in essence, that higher importer MRLs for specific pesticide/crop combinations increased trade. Several other studies took an additional step and used these derived trade effects to calculate the effects of various MRL harmonization scenarios. These studies found that

[1181] Different studies focusing on stringency or related concepts have used different terms to describe these types of measurements. For example, both Scheepers, Jooste, and Alemu as well as Chen, Yang, and Findlay simply refer to this as the "MRL variable" or "MRL standard," as they apply MRLs directly as variables within their models. Ferro, Otsuki, and Wilson used a "restrictiveness index" to measure stringency, while Li and Beghin calculated "protectionism indices" based on MRL stringency relative to Codex levels. Scheepers, Jooste, and Alemu, "Quantifying the Impact of Phytosanitary Standards with Specific Reference to MRLs," June 2007; Chen, Yang, and Findlay, "Measuring the Effect of Food Safety Standards," April 2008; Ferro, Otsuki, and Wilson, "The Effect of Product Standards on Agricultural Exports," January 2015; Li and Beghin, "Protectionism Indices for Non-Tariff Measures: An Application to Maximum Residue Levels," April 2014.

[1182] See, e.g., Wilson and Otsuki, "To Spray or Not to Spray: Pesticides, Banana Exports, and Food Safety," April 2004, 132; Ferro, Otsuki, and Wilson, "The Effect of Product Standards on Agricultural Exports," January 2015, 78; Xiong and Beghin, "Stringent Maximum Residue Limits, Protectionism, and Competitiveness," October 2012, 1200.

pesticide/crop MRLs were positively correlated with trade; that is, they found that, all other factors being equal, trade would increase overall if importers were to harmonize MRLs for specific pesticide/crop combinations at higher levels and would decrease overall if harmonized at lower levels.

In one of the earliest studies on the economic and trade effects of pesticide MRLs, Wilson and Otsuki found that higher (less restrictive) importer banana/chlorpyrifos MRLs would result in increased exports of bananas by developing countries. This study found that a 1 percent increase in the chlorpyrifos/banana MRL in member countries of the Organisation for Economic Cooperation and Development (OECD) led to a 1.63 percent increase in developing-country banana exports.[1183] After estimating these stringency effects, the study then applied the expected trade effects within several regulatory harmonization scenarios, estimating the effects of harmonizing importer MRLs at four different levels: 0.05 ppm (as applied in practice by most EU countries), 0.1 ppm (United States, Canada, Switzerland), 0.5 ppm (Japan, the Netherlands), and 2.0 ppm (New Zealand, Codex).[1184] Harmonization toward more stringent standards diminished trade overall—for example, harmonization at the lowest EU level of 0.05 ppm resulted in a reduction of exports by 51.2 percent, or $1.88 billion—while harmonization towards less stringent standards increased overall trade. The scenario where all MRLs were changed to the highest Codex level of 2.0 ppm resulted in an increase of exports by 99.1 percent, or $3.64 billion.[1185]

Scheepers, Jooste, and Alemu conducted a similarly targeted analysis, finding that higher avocado/prochloraz MRLs in European countries led to increased South African avocado exports to those countries. At the time of this study, most South African avocado exports were shipped to several European countries that had prochloraz/avocado MRLs falling within a range below and up to Codex levels.[1186] The study found that a 1 percent increase in the MRLs for prochloraz in European countries resulted in a 0.26 percent increase in South African avocado exports to those countries. The study then applied these estimated effects to existing trade values based on a simulation where all European countries increased their MRLs to Codex levels. South African avocado exports to low-MRL countries to

[1183] Wilson and Otsuki, "To Spray or Not to Spray: Pesticides, Banana Exports, and Food Safety," April 2004, 135, 140–41, 144.
[1184] In using this approach, Wilson and Otsuki acknowledged that the trade effects of such adjustments would be overstated due to the unknown extent to which importer MRLs were actually binding on exporters. This was particularly the case given that exporter MRLs (i.e., the regulations applying to exporters within their own domestic markets) were not taken into account within the analysis. In addition, they capped any estimated trade changes at 100 percent of pre-harmonization levels for each importer-exporter pair in order to avoid unrealistic cases. Wilson and Otsuki, "To Spray or Not to Spray: Pesticides, Banana Exports, and Food Safety," April 2004, 141, 143.
[1185] Wilson and Otsuki, "To Spray or Not to Spray: Pesticides, Banana Exports, and Food Safety," April 2004, 142–43. Under this simulation, exporters that served importers undergoing substantial MRL changes experienced significant changes in trade volumes. For example, under a scenario where all destination countries harmonized MRLs at low levels consistent with those of EU importers, countries that already exported predominantly to the EU, such as Cameroon, Côte d'Ivoire, and Morocco, experienced very small trade effects. By contrast, harmonization of Japan's MRLs to EU levels under this scenario resulted in large reductions in exports from countries that predominantly exported to Japan, such as the Philippines. Exporters serving a mixture of EU markets and other countries experienced more moderate effects.
[1186] At the time this study was written, European countries had not yet harmonized to the common MRL levels now shared across the EU. Scheepers, Jooste, and Alemu, "Quantifying the Impact of Phytosanitary Standards with Specific Reference to MRLs," June 2007, 265–66.

which avocados were already being shipped, such as France and the Netherlands, would increase substantially as a result of increasing the MRLs as part of this Codex harmonization exercise.[1187]

Expanding pesticide-specific analysis to focus on a broader variety of crops, Chen, Yang, and Findlay examined the effects of chlorpyrifos MRLs in certain import markets on Chinese exports of vegetables overall as well as on three specific vegetables—garlic, onions, and spinach. They found that lower MRLs were associated with lower trade volumes, such that a 10 percent decrease in an importing country's chlorpyrifos MRL (i.e., the importer's MRL became more restrictive) resulted in a 2.8 percent decrease in Chinese vegetable exports. They also found a variety of effects for the different vegetable categories: a 10 percent decrease in an importing country's chlorpyrifos MRL resulted in a 10.0 percent decrease in spinach exports, compared to a 3.2 percent decrease in garlic exports or a 2.1 percent decrease in onion exports.[1188] The same study also simulated the effects of all importers' harmonization of MRLs around Codex levels. For countries with very low MRLs, particularly Japan, the EU, and Australia, this exercise demonstrated that China's exports of vegetables would substantially increase when the MRLs of these importers increased to Codex levels for the years 2002–05.[1189] The study concluded that higher food safety standards imposed by importing countries had a negative effect on China's exports of agricultural products that was much larger than the effects of import tariffs.[1190]

In contrast to the more targeted studies described above, which focused on individual pesticide/crop combinations, more recent studies have sought to quantify the effects of multiple MRLs on exports of agricultural products. In one early example, Wei, Huang, and Yang expanded the individual pesticide/crop stringency approach by including three measures of MRL stringency in their modeling analysis: one measure for each of three pesticides used in tea production. As with prior studies focused on individual pesticide/crop combinations, they found that for two of the three pesticides, lower MRLs were associated with less trade. Specifically, they found that a 1 percent decrease in an importer's MRL on the pesticide endosulfan resulted in a 0.06 percent decrease in China's tea exports, while a similar reduction in the MRL on the pesticide fenvalerate resulted in a 0.16 percent decrease.[1191]

Several studies have broadened their analysis of MRL stringency even further. These studies have combined individual pesticide/crop-specific MRLs (usually through averaging) to calculate crop-specific MRL stringency indicators, which can in turn be incorporated into a model along with trade data that are gathered on a crop-country-time basis. As with the pesticide/crop-specific analyses described above, these broader studies have also found that greater MRL stringency in importing countries causes reduced exports to those countries.

[1187] Scheepers, Jooste, and Alemu, "Quantifying the Impact of Phytosanitary Standards with Specific Reference to MRLs," June 2007, 270. Specifically, the study found that the increase in MRLs to Codex levels would push up South African exports to France by 313.2 percent; South African exports to the Netherlands, by 2,610.6 percent. Unlike Wilson and Otsuki, described above, the authors did not apply a cap on trade changes to ensure that results fell within a plausible range.
[1188] Chen, Yang, and Findlay, "Measuring the Effect of Food Safety Standards," April 2008, 94–95.
[1189] Chen, Yang, and Findlay, "Measuring the Effect of Food Safety Standards," April 2008, 97–98.
[1190] Chen, Yang, and Findlay, "Measuring the Effect of Food Safety Standards," April 2008, 101.
[1191] Wei, Huang, and Yang, "The Impacts of Food Safety Standards on China's Tea Exports," June 2012, 262–63. They did not find a statistically significant relationship between Chinese exports and importer MRLs for a third pesticide, flucythrinate.

For analysis of certain agricultural products, use of crop-specific measures of MRL stringency may be necessary because production of that crop employs many kinds of pesticides. In one such example, Kareem, Brümmer, and Martinez-Zarzoso examined the effect of the EU's MRL policies on African tomato exports from 2008 to 2013. Because tomatoes retain a high level of pesticide residue and may contain traces of numerous different pesticides, these authors used a stringency index that averaged MRLs for all pesticides used on tomatoes within a gravity model. They found that stricter MRLs in the EU reduced both the extensive and intensive margin of trade occurring between African exporters and EU importers. Results showed that a 1 percent decrease in the MRL stringency index led to a 6.9 percent decrease in Africa's tomato exports at the extensive margin, and a 14.5 percent decrease in Africa's tomato exports at the intensive margin.[1192] The authors attributed these substantial negative trade effects to the heavy use of pesticide in tomato production. Because of this reliance on pesticide, they concluded that small-scale African producers would be forced to sustain higher costs to introduce and maintain the production practices necessary to meet more stringent EU MRLs, and that these costs decreased their sales of tomatoes to EU countries.[1193]

Broader crop-specific measures of MRL stringency have also been used in studies that encompass many agricultural products, exporters, and importers in order to cover a wide range of possible pesticide use. Ferro, Otsuki, and Wilson conducted a study that involved MRL restrictiveness measures for 61 importing countries and that covered a variety of fruits and vegetables. Unlike prior studies that focused solely on individual pesticides, this study constructed MRL restrictiveness measures for all pesticides included within country-year-commodity groupings.[1194] Using these measures within a gravity model, the authors concluded that more restrictive MRLs in destination markets made it less likely that exporters would cover the fixed costs necessary to comply with MRLs in order to trade with those destinations (i.e., less trade at the extensive margin). However, this paper found that the restrictiveness of MRLs had little significant effect on the intensive margin of trade between countries.[1195] This study concluded that an exporter facing two possible destination markets would be more likely to export to the country with less restrictive standards, as they would face fixed costs associated with changing their production practices to comply with stricter standards.[1196]

Without focusing on the actual levels of individual or grouped MRLs, other studies have associated reduced trade with the number of notifications to the WTO regarding MRL-related concerns or the number of MRLs on positive lists in importing countries. These studies assume that a higher number of MRL policies (or concerns related to those policies) translates to greater MRL restrictiveness.

[1192] Kareem, Brümmer, and Martinez-Zarzoso, "The Implication of European Union's Food Regulations on Developing Countries," February 2015, 25.
[1193] Kareem, Brümmer, and Martinez-Zarzoso, "The Implication of European Union's Food Regulations on Developing Countries," February 2015, 27.
[1194] The authors normalized each country's MRL regulation for a pesticide/crop combination in each year to be between zero and one relative to the maximum and minimum MRLs for that same pesticide/crop combination in all other countries. They then took the average of these normalized MRLs across pesticides for each importer-product combination and aggregated them to the importer-product-year level in order to match it to trade data. Ferro, Otsuki, and Wilson, "The Effect of Product Standards on Agricultural Exports," January 2015, 70–71.
[1195] Ferro, Otsuki, and Wilson, "The Effect of Product Standards on Agricultural Exports," January 2015, 73–74.
[1196] Ferro, Otsuki, and Wilson, "The Effect of Product Standards on Agricultural Exports," January 2015, 78.

In order to analyze the effect of MRLs that were explicitly considered to cause trade costs, Arita, Mitchell, and Beckman tracked whether the United States had notified the World Trade Organization (WTO) with concerns about specific MRLs set by the EU. If such concerns had been raised, the authors applied a more restrictive NTM measure for the affected crops.[1197] As a result of this analysis, the authors found that EU MRLs, which were lower than those in the United States, had statistically significant negative effects on U.S. exports to the EU for fruit and vegetables, but not nuts. They calculated that EU MRLs imposed an ad valorem tariff equivalence of between 26 and 40 percent on U.S. fruit exports and between 42 and 53 percent on vegetable exports.[1198] They also found that the value of exports that were foregone in 2011 as a result of EU MRLs equated to $224–$807 million for U.S. fruit exports and $317–$687 million for U.S. vegetable exports.[1199]

In a study that drew an even more explicit linkage between the existence of MRLs and trade-reducing effects, Xiong performed an analysis comparing the number of importers' MRLs to the number of Codex MRLs on tea. The author assumed that a greater number of MRL policies in an importing country's positive list translated to greater overall restrictiveness of these measures on a particular commodity, resulting in a higher ad valorem equivalent attributed to MRLs.[1200] By assuming that a greater number of importer MRLs equated to greater restrictiveness, this study did not take into account that lack of established MRLs in most cases either leads to application of a low default MRL or zero-tolerance which means product may not be imported in the absence of an MRL. The study modeled a number of scenarios in which tea MRLs were harmonized within groups of countries that were negotiating trade agreements.[1201] It found that countries harmonizing MRLs around Codex standards led to a reduction of the ad valorem equivalents of those countries' tea MRLs, given that Codex places fewer MRLs on pesticides used in tea production, and that this change resulted in an increase in Vietnamese tea exports. By contrast, countries harmonizing MRLs around U.S. standards led to higher ad valorem equivalents, given that the United States places more MRLs on pesticides used in tea production than

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[1197] Arita, Mitchell, and Beckman, "Estimating the Effects of Selected Sanitary and Phytosanitary Measures and Technical Barriers to Trade on U.S.-EU Agricultural Trade," November 2015, 3, 15.

[1198] Ad valorem is a rate of duty expressed as a percentage of the appraised customs value of an imported good. When discussing NTMs, ad valorem equivalence is the estimated quantification of the trade costs imposed by these barriers, expressed as percentage of the value of an imported good. Arita, Mitchell, and Beckman, "Estimating the Effects of Selected Sanitary and Phytosanitary Measures and Technical Barriers to Trade on U.S.-EU Agricultural Trade," November 2015, 16–17.

[1199] Arita, Mitchell, and Beckman, "Estimating the Effects of Selected Sanitary and Phytosanitary Measures and Technical Barriers to Trade on U.S.-EU Agricultural Trade," November 2015, 30.

[1200] Xiong, "The Impact of TPP and RCEP on Tea Exports from Vietnam," July 2017, 417. Using ad valorem equivalents of Codex MRLs from previous studies, the authors assumed that if a country imposed a higher number of MRLs on imported goods than Codex did, then the total of that country's MRLs would translate to a proportionately higher ad valorem equivalent than that associated with Codex MRLs. Specifically, this study relied on an assumption derived from Kee et al. (2009) that the ad valorem equivalent rate of Codex's 10 MRLs on tea was equal to 30 percent in one scenario and 50 percent in a second scenario. Because the United States, for example, set MRLs on tea for 28 pesticides, the authors calculated the ad valorem equivalent of U.S. MRLs (in total) as 2.8 (28 ÷ 10) times higher than that of Codex, or 84 percent and 140 percent for the two scenarios (2.8 x 30 percent and 2.8 x 50 percent, respectively).

[1201] Xiong, "The Impact of TPP and RCEP on Tea Exports from Vietnam," July 2017, 417–18. Unlike most other studies mentioned previously in this chapter, which estimate the impact of MRLs on trade using results from the gravity model, this study used an equilibrium displacement model to simulate changes to the world tea market. Xiong, "The Impact of TPP and RCEP on Tea Exports from Vietnam," 2017, 416.

many countries. This change resulted in a decrease in Vietnamese tea exports, unless Vietnamese tea exporters received enough technical assistance to deal successfully with the MRLs.[1202]

Studies Finding That Greater Importer-Exporter MRL Heterogeneity Reduces Trade

In contrast to studies focusing solely on MRL stringency, other studies have examined the trade costs associated with differences in MRLs between exporting and importing markets. Specifically, these studies have focused on "heterogeneity" in MRLs within bilateral trade relationships, assuming trade is affected more by differences in MRLs between partners than by the absolute level of importers' MRLs.[1203] Broadly, these studies can be divided into those that have analyzed MRL heterogeneity regardless of whether the exporter or the importer has a higher standard, and those that have considered MRL heterogeneity to be trade-affecting only when the importer has more stringent standards.

Thus, one group of these studies has measured "regulatory distance" between MRLs regardless of whether the exporter or the importer has the lower MRL. In using this approach, authors have argued that the mere existence of a difference between the regulations applied in partner countries determines the trade impact of these NTMs, regardless of any trade costs or benefits associated with MRLs set at different levels.[1204]

In the first study to analyze heterogeneity in MRL regulations, Achterbosch et al. studied the extent to which differences in MRLs in the EU and Chile affected Chilean exports of fruit to the EU. This study expanded on prior research that sought to identify differences in NTMs between partner countries in order to quantify the NTMs' trade impact.[1205] Unlike earlier studies, which had constructed heterogeneity indexes based on qualitative or binary differences between standards in different countries, the authors took advantage of the numerical nature of MRLs (in which pesticide tolerances are explicitly quantified) to construct a regulatory heterogeneity index—that is, an index which measures differences in the absolute levels of MRLs—as applied in Chile and the EU for six fruit varieties.[1206] In its attempt to capture all differences between regulations within country pairs, this index captured all instances where exporters' MRLs were different (either more or less stringent) than importers' MRLs. Using this index within a model of export demand, the authors determined that Chilean exports to the EU were lower when the differences between EU and Chilean MRLs were more substantial. Results showed that trade was highly sensitive to changes in the heterogeneity index, such

[1202] Xiong, "The Impact of TPP and RCEP on Tea Exports from Vietnam," July 2017, 420–23.
[1203] Different studies focusing on heterogeneity or related concepts have used different terms to describe these types of measurements, such as "relative restrictiveness" (Ferro, Otsuki, and Wilson, "The Effect of Product Standards on Agricultural Exports," January 2015), "bilateral MRL stringency" (Hejazi, Grant, and Peterson, "Hidden Trade Costs? Maximum Residual Limits and US Exports of Fresh Fruits and Vegetables," June 2018), and "similarity" (Drogué and DeMaria, "Pesticide Residues and Trade, the Apple of Discord," December 2012).
[1204] Achterbosch et al., "Measure the Measure: The Impact of Differences in Pesticide MRLs on Chilean Fruit Exports to the EU," 2009, 4.
[1205] Achterbosch et al., "Measure the Measure: The Impact of Differences in Pesticide MRLs on Chilean Fruit Exports to the EU," 2009, 2.
[1206] Achterbosch et al., "Measure the Measure: The Impact of Differences in Pesticide MRLs on Chilean Fruit Exports to the EU," 2009, 8–9.

that a 1 percent increase in the heterogeneity index (reflecting a greater difference between the EU and Chilean MRLs) led to a 7.27–10.98 percent decrease in Chilean exports. Extending this analysis to assess the effects of changes in MRL levels, the authors calculated that a 5 percent decrease in the average pesticide tolerance level for EU MRLs (and a consequent increase in the heterogeneity index) would lead to a 14.8–29.7 percent decrease in Chilean exports, depending on the type of fruit.[1207]

Like Achterbosch et al., Drogué and DeMaria developed a measure of "regulatory distance" to capture instances where exporters' MRLs were different from importers' MRLs, regardless of whether the exporter's MRL was more or less stringent. In measuring differences in MRLs between countries, Drogué and DeMaria expanded on the Achterbosch et al. methodology by incorporating imputed default values for missing MRLs, thereby avoiding exclusion of observed regulatory divergences when MRLs were missing in certain countries for certain products.[1208] This study calculated a similarity index variable for apples and pears and included the variable within a gravity model. Results showed that regulatory distance had a negative effect on trade, with a 1 percent increase in the "similarity" index (where higher values were more dissimilar) translating to a 0.16 percent decrease in the volume of exports. Stated differently, the authors noted that lowering the regulatory distance between countries using their index by 100 percent—full harmonization of MRLs—would result in a 16 percent increase in the volume of trade. However, they also found that differences between MRL regulations only impacted the intensive margin of trade and not the extensive margin of trade between countries.[1209]

Choi and Yue also used a similarity index in order to measure the extent to which various vegetable exporters had MRLs that were at similar levels to those of an importing country, Japan. The approach they used to calculate this index was similar to those of Achterbosch et al. and Drogué and DeMaria (using MRL differences regardless of which partner had the lower MRL). However, based on the authors' observation that Japanese MRLs are generally stricter than those of their trading partners, they assume that greater dissimilarity in MRLs translated to more stringent Japanese MRLs relative to those of exporters. They then used the MRL similarity index to estimate the impacts of Japan's relative MRL stringency on its vegetable imports.[1210] Focusing on a measure of MRL similarity for an aggregation of eight different vegetable products, they found statistically significant trade-increasing effects associated with greater MRL similarity, such that the more similar Japan's MRLs are to those of their trading partners—or, as interpreted by the authors, the less strict Japanese MRLs are for a product category—the greater Japanese imports are for this product category. For more specific groupings of products,

[1207] Achterbosch et al., "Measure the Measure: The Impact of Differences in Pesticide MRLs on Chilean Fruit Exports to the EU," 2009, 12–13.
[1208] Drogué and DeMaria, "Pesticide Residues and Trade, the Apple of Discord," December 2012, 643.
[1209] Drogué and DeMaria, "Pesticide Residues and Trade, the Apple of Discord," December 2012, 646. In addition, Drogué and DeMaria found that these effects were not uniform across all countries. While certain exporters would trade greater volumes as a result of greater global harmonization of MRL regulations (such as Australia, Canada, China, New Zealand, and the EU), others would experience no effects (such as Argentina, Brazil, Chile, South Korea, and South Africa). They further found that the United States and Japan would likely experience lower export volumes as a result of greater regulatory similarity. In explaining this result, the authors concluded that harmonization can be, for certain countries, trade-diverting. They speculated that the United States (which has high food safety standards and also higher production prices) could lose global market share to less costly competitors due regulatory harmonization.
[1210] Choi and Yue, "Investigating the Impact of Maximum Residue Limit Standards on the Vegetable Trade in Japan," February 7, 2017, 161–63.

they also found trade-increasing effects for fruit vegetables (tomatoes and peppers) and leafy vegetables (lettuce and cabbage), but not bulb vegetables (onions and garlic) or root vegetables (carrots and radishes).[1211] The authors concluded that, for vegetables and for certain vegetable groupings in particular, MRL similarity significantly affects trade, such that Japan's relatively stringent MRLs have impeded Japanese imports of these products.

Whereas Achterbosch et al., Drogué and DeMaria, and Choi and Yue analyzed all differences between exporter and importer MRLs (regardless of which country had the more restrictive MRLs), most subsequent studies have concentrated only on such differences when the importer's MRLs are lower (i.e., more restrictive). Under this approach, stringency of importer MRLs does not matter if an exporter already faces similarly stringent MRL regulations in its domestic markets. However, if importers' MRLs are low relative to those in exporters' domestic markets, exporters face costs associated with production changes, compliance, enforcement, and uncertainty.

In a study focusing on index development, Burnquist, Shutes, and Rau adapted the Achterbosch et al. heterogeneity index concept, recognizing that dissimilarity between MRL regulations does not, inherently, result in additional compliance costs to exporters. When exporters face lower MRLs at home than in their destination markets, the regulatory differences are not trade-limiting, as exporters have no difficulty meeting importer MRLs given their domestic market-oriented production processes. In order to avoid overstating the effects of such MRL differences, this paper introduced a heterogeneity index which defined MRLs as "dissimilar" only in circumstances where exporters faced more stringent MRLs in importer markets, but not vice versa.[1212] The study itself, however, did not employ the index developed to evaluate the trade effects of MRLs, though it was used by other authors as noted below.

Winchester et al., in a study of the impacts of NTMs on trade between the EU and nine major trading partners, used the type of heterogeneity index described in Burnquist, Shutes, and Rau.[1213] The authors found that the importer MRLs being lower than exporter MRLs had a substantial adverse effect on trade, such that a 1 percent increase in the heterogeneity index resulted in a 2.8 to 5.0 percent decrease in imports. The authors further found that these effects were driven predominantly by the intensive margin of trade, with no statistically significant effects on the extensive margin.[1214]

Shingal and Ehrich used an index of regulatory heterogeneity[1215] to analyze a dataset of 31 agricultural products traded between 53 importing and exporting countries from 2005 to 2014. The authors observed the impact of the harmonization of MRLs across the EU in 2008, decomposing the impacts of regulatory heterogeneity both within the EU and between the EU and its non-EU trading partners. Results showed that while the relative stringency of MRLs (the distance between exporter and EU importer MRLs) had a negative impact on both the intensive and extensive margins of trade, these

[1211] Choi and Yue, "Investigating the Impact of Maximum Residue Limit Standards on the Vegetable Trade in Japan," February 7, 2017, 166–71.
[1212] Burnquist, Shutes, and Rau, "Heterogeneity Index of Trade and Actual Heterogeneity Index,"2011, 9–10.
[1213] Winchester et al., "The Impact of Regulatory Heterogeneity on Agri-Food Trade," August 2012, 977–78.
[1214] Winchester et al., "The Impact of Regulatory Heterogeneity on Agri-Food Trade," August 2012, 987. The variation in estimated trade effects was due to differences in the statistical estimator used in the analysis.
[1215] This index is similar to those used in Winchester et al., "The Impact of Regulatory Heterogeneity on Agri-Food Trade," August 2012, and Burnquist, Shutes, and Rau, "Heterogeneity Index of Trade and Actual Heterogeneity Index," 2011.

effects were somewhat offset by the positive impact of harmonization over 2009–14.[1216] The authors also found that intra-EU trade increased at the intensive margin following harmonization.[1217] Notwithstanding the overall greater restrictiveness of EU MRLs accompanying harmonization, the authors concluded that the elimination of MRL heterogeneity between EU countries drove these increases in trade.[1218]

In addition to assessing the effects of importers' MRL restrictiveness on trade, as discussed above, Ferro, Otsuki, and Wilson also constructed a measure of relative MRL restrictiveness to account for differences in importer and exporter MRLs. Using this measure, they concluded that the more restrictive an importer's MRLs were relative to an exporter's MRLs, the lower the probability that bilateral trade would occur. In particular, low-income countries were far less likely to export to either high-income or other low-income countries when importer MRLs were more restrictive than exporter MRLs.[1219] Although several exercises in the Ferro, Otsuki, and Wilson study using the relative MRL restrictiveness measure suggested a positive relationship between stricter importer MRLs and the intensity of trade between countries (which they theorize are due to demand-enhancing effects), the authors generally concluded that the effects of relative MRL restrictiveness on the intensity of trade was indistinguishable from zero.[1220]

Hejazi, Grant, and Peterson used a bilateral stringency index (an index of heterogeneity) to measure bilateral differences in MRLs between the United States and a range of export destinations for U.S. fresh fruit and vegetables.[1221] Overall, they found negative trade effects when importer MRLs were lower than exporter MRLs, which they associated with the higher production, testing, and compliance costs to exporters serving international markets with stricter food safety guidelines. These adverse trade effects were particularly substantial when looking at U.S. exports to the EU, where MRLs were more stringent than most other countries.[1222] This study also constructed three separate indexes for herbicides, insecticides, and fungicides in order to determine which measures were responsible for any trade disruptions.[1223] With the exception of one simulation, the model found adverse trade effects when importer MRLs were stricter than exporter MRLs for all three types of pesticides, but particularly for insecticides.[1224] In addition, the study found that adverse trade effects—whether in aggregate, for U.S. exports to the EU specifically, or by pesticide type—occurred at both the extensive and intensive

[1216] Shingal and Ehrich, "Trade Effect of MRL Harmonization in the EU," July 2018, 17.
[1217] Shingal and Ehrich, "Trade Effect of MRL Harmonization in the EU," July 2018, 16.
[1218] Shingal and Ehrich, "Trade Effect of MRL Harmonization in the EU," July 2018, 11, 16.
[1219] High-income exporters, by comparison, were more likely to export to low-income markets when importer MRLs were more restrictive than exporter MRLs—an example of an import demand-enhancing effect discussed in the next section of this chapter. Ferro, Otsuki, and Wilson, "The Effect of Product Standards on Agricultural Exports," January 2015, 75–78.
[1220] Ferro, Otsuki, and Wilson, "The Effect of Product Standards on Agricultural Exports," January 2015, 78.
[1221] As in the Li and Beghin study, this study used a nonlinear index to capture regulatory differences, but it focused on bilateral differences rather than differences from Codex. Hejazi, Grant, and Peterson, "Hidden Trade Costs?" June 2018, 12–13; Li and Beghin, "Protectionism Indices for Non-Tariff Measures: An Application to Maximum Residue Levels," April 2014.
[1222] Hejazi, Grant, and Peterson, "Hidden Trade Costs?" June 2018, 25–26, 39, 44.
[1223] Hejazi, Grant, and Peterson, "Hidden Trade Costs?" June 2018, 15.
[1224] Hejazi, Grant, and Peterson, "Hidden Trade Costs?" June 2018, 26, 45.

margins of trade.[1225] They concluded that more stringent importer MRLs relative to those of exporters imposed both fixed costs, which present market entry barriers, and variable costs, which also have continuing trade-reducing effects.[1226]

MRLs as Trade-enhancing

While the literature generally finds that the application of more stringent or divergent MRL standards diminishes the likelihood or extent of trade through the creation of higher trade costs as reviewed in the studies summarized above, some studies have concluded that stricter MRLs have trade-enhancing effects for certain markets and products. Studies finding trade-enhancing effects from MRLs and SPS and TBT measures have posited these increases are being driven by consumer preferences.[1227] For example, Arita, Mitchell, and Beckman posit that NTMs may represent “unobserved demand-altering characteristics” or communicate information about product quality.[1228] If consumers believe that the imposition or increasing stringency of an MRL improves the quality of a commodity or helps communicate positive information about the good, the MRL may increase overall demand for imports. This demand increase may in turn increase the good’s import volumes even if the good’s production

[1225] However, the authors found that stricter MRLs in importing markets increased U.S. fresh fruit and vegetable exports to trading partners that had signed on to the Trans-Pacific Partnership agreement. This effect appeared to be driven by the effect of stricter TPP-partner herbicide MRLs on U.S. exports, and did not persist when looking at the impact of insecticide or fungicide MRLs on U.S.-TPP trade. Hejazi, Grant, and Peterson, “Hidden Trade Costs?” June 2018, 47.
[1226] Hejazi, Grant, and Peterson, “Hidden Trade Costs?” June 2018, 27–28, 47.
[1227] Disdier, Fontagné, and Mimouni’s 2008 study is one such example. In it, authors looked more generally at SPS and TBT measures, using countries’ WTO notifications of their SPS and TBT measures up to 2004 as a covariate in a gravity model framework. Restricting their sample to 2004 trade with OECD importers, the authors found that SPS and TBT measures had either an insignificant or a negative effect on total bilateral trade flows when measured by an ad valorem equivalent. However, the measures had a significant positive impact on OECD imports for 7 out of 25 Harmonized System (HS2) chapters analyzed, with the largest trade-enhancing effects appearing in the cereals and wool sectors. Eight HS2 chapters showed that SPS and TBT measures had a significant negative impact on trade, while the remaining 10 HS2 chapters showed no significant effect on trade. Disdier, Fontagné, and Mimouni, “The Impact of Regulations on Agricultural Trade: Evidence from the SPS and TBT Agreements,” May 2008.
[1228] Arita, Mitchell, and Beckman, “Estimating the Effects of Selected Sanitary and Phytosanitary Measures and Technical Barriers to Trade on U.S.-EU Agricultural Trade,” November 2015, 6. Information about product characteristics can impact demand when consumers have, and act on, their preferences for certain product attributes—including the presence of pesticide residues. In a separate but related body of literature, researchers have estimated consumer willingness to pay for a reduction in pesticide residues on food products. Early survey research of consumer willingness to pay for pesticide-free fresh fruit and vegetables in Northern Italy found that the majority of customers would pay up to 15 percent more for the assurance. In another study, consumers in metropolitan areas of Vietnam were found to be willing to pay an average of 60 percent more for Chinese mustard that was free of chemical residues. In both studies, income of consumers was positively associated with a greater willingness to pay for pesticide residue-free products. Nonetheless, a meta-analysis of 15 different willingness-to-pay studies of consumers in the United States, United Kingdom, Philippines, Taiwan, and Sri Lanka from the 1990s to the early 2000s found that the income elasticity of reduced risk was not significantly different from zero. The meta-analysis also found that willingness to pay for reduced pesticide risk exposure ranged from 15 to 80 percent, depending on the amount of risk reduction, and found that the design of the survey could drive variation in results as well. Boccaletti and Nardella, “Consumer Willingness to Pay,” 2000; Mergenthaler, Weinberger, and Qaim, “Consumer Valuation of Food Quality,” June 1, 2009; Florax, Travisi, and Nijkamp, “A Meta-Analysis of the Willingness to Pay,” 2005.

and/or trade costs increase.[1229] Examples of the demand-enhancing effect of standards have appeared in some research findings on the trade impact of MRLs which are described below, though these impacts vary depending on the countries and agricultural products analyzed.

Xiong and Beghin found that stricter importer MRLs had an overall demand-enhancing effect on imports of plant products into high-income OECD countries, controlling for other sources of bilateral trade costs using tariff data.[1230] Based on their construction of MRL indexes, the authors were able to distinguish the effect of MRL heterogeneity from the effect of MRL stringency within the same model. Although the effect of MRL heterogeneity was significant and trade-decreasing on the intensive margin of trade for all model results presented, the magnitude of these trade-decreasing effects was outweighed by the trade-increasing effect of MRL stringency, resulting in a net positive effect of stricter importer MRLs on trade overall. This positive effect was statistically significant at the intensive margin of trade, but statistically insignificant at the extensive margin, suggesting that stringent importer MRLs benefit established bilateral trade relationships but do not necessarily create new relationships for specific commodities. From their quantitative results, the researchers concluded that, for the plant products analyzed, the imports of high-income OECD members would decrease by nearly 12 percent if the member countries changed their MRLs, generally by relaxing them, to harmonize to Codex recommendations.[1231]

Shingal, Ehrich, and Folletti used trade data from 53 countries from 2005 to 2014 to find that stricter MRLs facilitated trade, regardless of whether it was the importer or exporter imposing the stricter standards. Importantly, these results were obtained only when the authors imposed controls to account

[1229] See, e.g., Arita, Mitchell, and Beckman, “Estimating the Effects of Selected Sanitary and Phytosanitary Measures and Technical Barriers to Trade on U.S.-EU Agricultural Trade,” November 2015, 6. See also Josling, Roberts, and Orden, “Food Regulation and Trade: Toward a Safe and Open Global System,” 2004; Disdier, Fontagné, and Mimouni, “The Impact of Regulations on Agricultural Trade: Evidence from the SPS and TBT Agreements,” May 2008; and Xiong and Beghin, “Disentangling Demand-Enhancing and Trade-Cost Effects,” July 2014.

[1230] The researchers use a cross-section of bilateral trade data from 2008 and 2012. Importantly, two indexes are included in this study: a MRL stringency index comparing domestic MRLs to Codex standards, developed by Li and Beghin, for each agricultural product analyzed, and a heterogeneity index following Burnquist, Shutes, and Rau and Winchester et al., which compares the trade costs resulting from the regulatory distance between two trading partners. Xiong and Beghin, “Disentangling Demand-Enhancing and Trade-Cost Effects of Maximum Residue Regulations,” July 2014, 1193, 1196; Li and Beghin, “Protectionism Indices for Non-Tariff Measures: An Application to Maximum Residue Levels,” April 2014; Burnquist, Shutes, and Rau, “Heterogeneity Index of Trade and Actual Heterogeneity Index,”2011, 9–10; Winchester et al., “The Impact of Regulatory Heterogeneity on Agri-Food Trade,” August 2012.

[1231] Xiong and Beghin, “Disentangling Demand-Enhancing and Trade-Cost Effects,” July 2014, 1198.

for the endogeneity in the standards-trade relationship.[1232] Before such controls were imposed, the authors found primarily trade-deterring impacts associated with MRLs. However, according to the authors, the failure to control for the possibility that MRLs are more frequently set for products where trading relationships already exist contributed to the finding of trade deterrence resulting from lower MRLs.[1233]

Other studies have focused predominantly on exporters' MRLs. For example, another earlier study by Xiong and Beghin employed data from 2010 and a stringency-index approach to compare the impact of MRLs on U.S. and Canadian trade with the rest of the world. The authors found that stricter domestic MRLs facilitated plant and animal exports to the rest of the world by Canada. This was attributed to the fact that Canadian MRL levels were much lower than the Codex standards adopted by the rest of the world, which the authors theorize differentiated how Canadian exports were perceived in global markets. As a result, the authors concluded Canadian exports gained competitiveness by complying with Canada's stricter domestic MRLs. By contrast, U.S. MRLs were not substantially different from Codex levels. This study did not find a statistically significant trade-facilitating effect for exports from the United States. The authors also found that increases in the stringency of Canadian and U.S. MRLs did not impact each country's imports significantly.[1234]

In another example focused on exporters' MRLs, Foletti and Shingal found a trade-facilitating impact of MRLs only when the exporting country was stricter than the importing country. The authors considered the impact of heterogeneity of MRL regulations on trade using data for 2006–12 from 50 countries. The study found that exporters with stricter MRL standards experienced a significant positive effect at the intensive margin, which they cited as evidence of the trade-enhancing effect of the favorable product information that stricter MRLs convey. This result was consistent across alternative analyses that used different approaches to calculating the heterogeneity index, which were designed to test the robustness of the results. On the other hand, the authors found reductions in the extensive margin of trade when

[1232] Endogeneity occurs when an outcome that a model is trying to predict is correlated with a variable that is not included (because it is unobserved or omitted) in the model. This can lead to inaccurate characterizations about the size and direction of the effects of variables included in the model on the outcome they are trying to predict. The idea that regulatory behavior may be driven by existing trade flows, rather than the reverse being true, is an example of endogeneity. For importers, MRLs will appear in markets where consumers already have a preference for regulation of pesticide residues, so trade flows being attributed to imposition of standards are actually due to unobserved consumer preferences. As Shingal, Ehrich, and Foletti point out, if MRL levels are being set using a risk-based approach, it is likely that policymakers prioritize setting MRLs for the products that are most frequently consumed by their constituents. A similar understanding could motivate exporters' MRL regulations as well, if exporting markets are setting stricter MRLs for products that their producers most frequently export. For example, Li, Xiong, and Beghin find that countries adopt stricter MRLs in sectors where domestic producers are more competitive in the world market. In both cases, there is simultaneity bias: the pre-existing trade relationship informs the imposition of MRLs, rather than the other way around. Li, Xiong, and Beghin, "The Political Economy of Food Standard Determination," January 2017; Shingal, Ehrich, and Foletti, "Re-estimating the Effect of Stricter Standards," 2017.
[1233] The authors use first-difference data and three-way fixed effects—importer-product-time and exporter-product-time—as controls.
[1234] Xiong and Beghin, "Stringent Maximum Residue Limits, Protectionism, and Competitiveness," October 2012, 14–16.

the importer had stricter MRLs, which the authors attributed to high compliance costs in the destination market.[1235]

Box 6.1 Effects of MRLs on Exports from Lower-income Countries

How are lower-income countries different?

In the economic literature, strict importer MRLs have been found to decrease the volume of trade from lower-income countries to higher-income countries.[a] Results from qualitative and quantitative studies suggest that lower-income countries may have a distinct response to other countries' imposition of MRLs for two reasons. First, these countries contain a greater proportion of smallholder farmers. Over 60 percent of farmers in low-income and lower-middle-income countries have farms of less than 1 hectare (less than 2.5 acres), while farms that size only account for around 30 percent of holdings in upper-middle-income and high-income countries.[b] The ability of farmers from lower-income countries to comply with more stringent MRLs depends upon the nature and magnitude of the investments farmers must make to attain compliance. If the fixed cost of compliance is high, smallholders may not be able to meet these costs on their own. Indeed, case studies have shown that size of holdings is a good predictor as to whether farms can meet more stringent standards: in a 2013 study on Chilean raspberry producers, for example, small-scale farmers were found to be less likely to implement food safety and quality standards than large-scale farmers.[c]

Second, on average, the public infrastructure and regulatory environment of lower-income countries is different. Lower-income countries are often characterized by inconsistent electricity and road quality. These factors, combined with the wide geographic dispersion of farmers, can make marketing and transporting agricultural products outside of local markets difficult. Higher-income countries also generally set more and lower MRLs than lower-income countries.[d] This means that lower-income countries will face stricter MRLs than their own in their export destination markets more frequently than their higher-income counterparts. Therefore, the fixed costs necessary to meet lower MRL standards in other countries, combined with other structural barriers not faced by higher-income exporting countries, can produce formidable trade-limiting effects.

How do lower-income countries mitigate trade costs of complying with standards?

Faced with stricter MRLs in their export markets, lower-income countries adjust their production and export strategy to maximize their profits. Some research finds that lower-income countries choose to specialize away from sectors with higher regulatory burdens altogether, avoiding entering new markets in which high technical standards exist.[e] Funga, Chacha, and Tiisekwa find in their survey of 167 small-scale vegetable farmers that over 61 percent of the respondents claimed that they were withdrawing from high-value markets and focusing their production on local spot markets in order to avoid pesticide residue issues.[f] Indeed, several studies have verified pesticide residues in markets in sub-Saharan Africa that are above Codex and EU MRL levels.[g]

If farmers in lower-income countries do choose to attempt compliance with new technical standards, technical assistance has been found to be an effective tool in mitigating trade-deterring effects. Senegalese fruit and vegetable exporters that participated in the EU's Pesticide Initiative Program—a technical assistance effort—saw their sales to the EU increase more than those of exporters that did not

[1235] These alternative analyses included variation in the treatment of missing MRLs, and a restriction of the sample to data where exports were non-zero in the previous year. Foletti and Shingal, "Stricter Regulations Boost Exports," October 1, 2014, 3, 14–16.

participate.[h] In another study, on tea exports from Vietnam, researchers analyzed the role of trade agreements in lowering tariffs and reconciling MRL standards. Whether Vietnamese tea exports declined or grew depended upon both the set of standards (U.S. or Codex) that the trade agreement under analysis would adopt, and the amount of technical assistance that farmers could receive under the agreement to help them comply with the MRLs.[i]

There are also examples in the literature of farmers pooling resources to make the investments necessary to meet export standards. In a study of smallholder farmer involvement in supply chains for high-value vegetable exports in Ethiopia, Kenya, and Zambia, farmers reported using collective action and public-private partnerships to help them maintain participation.[j] Earlier literature provides many examples of the involvement of smallholders in export supply chains as driven by the existence of exporting companies to coordinate production and trade. In a 2004–06 survey of green bean farmers in Madagascar and Senegal, respondents reported that exporting companies offered credit, technical assistance, and other agricultural inputs to those smallholders with whom the companies were contracted.[k] Another study found that contract farming in Kenyan horticulture export chains significantly increased farmer incomes, although smallholder participation in the export supply chain was ultimately determined by farm size and access to irrigation.[l]

Aside from collective or external efforts to encourage exports of agricultural products by smallholders, results from the economic literature also show that the presence of a trade agreement can help facilitate exports of lower-income countries. Murina and Nicita find that developing-country membership in a deep free trade agreement with the EU appears to lessen the compliance burden of SPS measures.[m]

If farmers from lower-income countries are able to address the challenges unique to their situation in covering the costs of complying with MRLs in their export markets, the outcomes for their exports, income, production, and the price of their products should be similar to those presented in the next section of this chapter. Indeed, one study showed that for smallholder farmers in Chile who are able to overcome the barriers to implementing SPS standards, the standards had a positive effect on the quality of the product and net farm income, as the farmers could then supply higher-value market segments both at home and in export markets.[n] This is not the case for all producers in lower-income countries, however. A value chain analysis of table grape exports from South Africa to the United Kingdom from 2000 to 2011 found that the total cost of production (including the cost of pesticides) had risen more rapidly than gains to gross farm income, resulting in a slight decline in net farm returns overall.[o]

[a] See, for example, Ferro, Otsuki, and Wilson, "The Effect of Product Standards on Agricultural Exports." January 2015, 75–78.
[b] Lowder, Skoet, and Raney, "The Number, Size, and Distribution of Farms," November 2016, 24.
[c] Handschuch, Wollini, and Villalobos, "Adoption of Food Safety and Quality Standards among Chilean Raspberry Producers," June 2013.
[d] Foletti and Shingal, "Stricter Regulation Boosts Exports," October 1, 2014, 14–15.
[e] Grundke and Moser, "Hidden Protectionism? Evidence from Non-Tariff Barriers to Trade in the United States," March 2019; Essaji, "Technical Regulations and Specialization in International Trade," December 2008.
[f] Funga, Chacha, and Tiisekwa, "Farm Level Strategic Response to Pesticide Regulations," January 10, 2017, 9.
[g] In Botswana, Ghana, and Zambia. See Machekano et al., "Cabbage or 'Pesticide' on the Platter?" February 2, 2019; Fosu et al., "Surveillance of Pesticide Residues in Fruits and Vegetables from Accra Metropolis Markets, Ghana, 2010–2012," 2017; and Mwanja et al., "Assessment of Pesticide Residue Levels among Locally Produced Fruits and Vegetables in Monze District, Zambia," July 12, 2017, respectively.
[h] Jaud and Cadot, "A Second Look at the Pesticides Initiative Program," July 2012.
[i] Xiong, "The Impact of TPP and RCEP on Tea Exports from Vietnam," July 2017.
[j] Okello, Narrod, and Roy, "Export Standards, Market Institutions and Smallholder Farmer Exclusion," December 2011.
[k] Maertens, Minten, and Swinnen, "Modern Food Supply Chains and Development," July 2012.
[l] McCulloch and Ota, "Export Horticulture and Poverty in Kenya," December 2002.

[m] Murina and Nicita, "Trading with Conditions," January 2017. A deep FTA is a free trade agreement with provisions that extend beyond tariff rates to include "behind-the-border" non-tariff disciplines like harmonization of regulations and dispute settlement processes.
[n] Handschuch, Wollini, and Villalobos, "Adoption of Food Safety and Quality Standards among Chilean Raspberry Producers," June 2013.
[o] Barrientos and Viser, "South African Horticulture," 2012, 18–19.

Additional Relevant Literature

Studies Finding Effects of Agricultural NTMs on Production, Prices, or Farmer Income

Studies focusing on MRLs have generally examined the effects of these policies on trade, with little if any additional analysis on prices, production, and farmer income.[1236] This section therefore considers several studies that have analyzed the effects of other types of agricultural NTMs on these indicators. Several key findings with potential implications for MRL analysis can be observed across these studies.

In general, restrictive NTMs that impose stringent standards may have negative effects on trade, production, prices, and income for firms that are unable or unwilling to incur the additional costs necessary to comply with those importer requirements. This can occur because they lose a preferred market for their sales and are forced to sell at lower prices in other markets or reduce output (for example, dropping a productivity-enhancing production process).[1237] Even when some firms do choose to meet stringent NTMs by changing production practices (for example, when they switch to producing a lower quality product in order to comply with the NTM), they may face adverse economic consequences if their production costs or compliance costs rise faster than their profits from export sales.[1238] However, other firms that are able to incur costs necessary to satisfy a foreign standard without sacrificing quality or productivity may experience increased prices, exports, output, and income. This may occur if there is less competition in foreign markets or if prices increase in those markets for other reasons, such as greater consumer awareness of perceived product quality associated with the stricter standard.[1239]

[1236] In one study, Scheepers, Jooste, and Alemu characterized a reduction in avocado exports caused by stricter importer MRLs as gross losses in avocado producer revenues. They did not, however, assess whether these revenues were recouped elsewhere as a result of new export markets (trade diversion) or increased domestic sales. Scheepers, Jooste, and Alemu, "Quantifying the Impact of Phytosanitary Standards with Specific Reference to MRLs on the Trade Flow of South African Avocados to the EU," June 2007, 269.
[1237] See Anderson and Jackson, "Implications of Genetically Modified Food Technology Policies for Sub-Saharan Africa," September 2004; Van Tongeren et al., "Case Studies of Costs and Benefits of Non-Tariff Measures," July 1, 2010; Beghin et al., "Welfare Costs and Benefits of Non-Tariff Measures in Trade," 2012; Fontagné et al., "Product Standards and Margins of Trade," September 2015.
[1238] See Anderson and Jackson, "Implications of Genetically Modified Food Technology Policies for Sub-Saharan Africa," September 2004, and Van Tongeren et al., "Case Studies of Costs and Benefits of Non-Tariff Measures," July 1, 2010.
[1239] See Anderson and Jackson, "Implications of Genetically Modified Food Technology Policies for Sub-Saharan Africa," September 2004; Van Tongeren et al., "Case Studies of Costs and Benefits of Non-Tariff Measures," July 1, 2010; Beghin et al. "Welfare Costs and Benefits of Non-Tariff Measures in Trade," 2012; Fontagné et al., "Product Standards and Margins of Trade," September 2015; and Cadot and Gourdon, "NTMs, Preferential Trade Agreements, and Prices: New Evidence," February 2015.

Three studies that were reviewed—by Anderson and Jackson, Van Tongeren et al., and Beghin et al.—examined the heterogeneous effects on low-income country exporters of low- or zero-tolerance NTMs imposed by OECD importers. These studies are pertinent for understanding the effects of low- or zero-tolerance MRLs on low-income country exporters, and broader economic welfare considerations. Anderson and Jackson used the model constructed by the Global Trade Analysis Project (GTAP) to explore the effects of EU policies requiring labeling of genetically modified (GM) foods on sub-Saharan African (SSA) countries. The authors assumed that countries adopting GM technologies experienced improved agricultural productivity, while consumers in OECD countries preferred non-GM products to GM products. The study found that in the event of an EU moratorium on imports of GM products, SSA countries as a whole would still benefit more substantially in terms of production and economic welfare if they adopted GM production practices (despite being denied market access in the EU) than if they kept using non-GM production practices.[1240] These increases were driven by increased productivity related to GM production practices. However, the study also found that if only some SSA countries adopted GM production practices, those countries that did not adopt GM production practices would benefit from continued EU market access and improved competitiveness in that market.[1241]

Van Tongeren et al. examined case studies which modeled the effect of agricultural NTMs in OECD countries on production in developing countries. One case study focused on the effects of health and safety standards in OECD countries that banned or otherwise prevented imports of farmed shrimp with prohibited antibiotic and drug residues. Faced with such standards in key import markets, major Asian suppliers of shrimp had incentives to implement Better Management Practices (BMP) programs in their continued production of high-priced shrimp varieties and/or switch production to shrimp varieties that are more disease-resistant, but lower-priced. The study results showed that producers able to afford the higher fixed and variable costs necessary to implement BMP programs while maintaining production of high-priced shrimp varieties would see expanded exports to OECD countries in addition to higher production and gross profits. However, a shift to the production of lower-priced shrimp varieties would lead to overall reductions in production and gross profits. The study concluded by noting that smaller farms not able to meet the OECD country measures could end up being excluded from important export markets, resulting in adverse consequences for smallholders and rural livelihoods.[1242]

Beghin et al. examined various economic welfare implications of agricultural standards by examining EU imports of shrimp. This study used interviews with French citizens to examine changes in their willingness to pay for imported shrimp upon learning of potential health problems stemming from antibiotic use in foreign shrimp aquaculture production. Assuming a scenario where consumers become aware of this factor in foreign shrimp production, the study examined the effects of an EU standard that

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[1240] Anderson and Jackson, "Implications of Genetically Modified Food Technology Policies for Sub-Saharan Africa," September 2004, 8–17.

[1241] Anderson and Jackson, "Implications of Genetically Modified Food Technology Policies for Sub-Saharan Africa," September 2004, 13–14.

[1242] Van Tongeren et al., "Case Studies of Costs and Benefits of Non-Tariff Measures," July 1, 2010, 51–54. Van Tongeren et al. (2010) also contained a case study on EU inspection requirements on cut flower imports, which were designed to reduce the spread of organisms harmful to plants or plant products. This study found that tighter inspection requirements resulted in exporting producers providing fewer exports and receiving less in gross profits. These adverse effects were particularly severe when inspections added to delays of cut flower imports at the border, leading to depreciation of flower value and reduced prices. Van Tongeren et al., "Case Studies of Costs and Benefits of Non-Tariff Measures," July 1, 2010, 72–76.

would require imports to be antibiotic-free. Under this scenario, the study found that foreign producers' cost of production would increase if they chose to produce antibiotic-free shrimp. Such foreign producers would experience reductions in output, while domestic producers in the importing countries would experience increased output (assuming that they have already adopted antibiotic-free production practices). However, foreign producers would still benefit from the standard if consumers were aware of the problems posed by antibiotic use (as described by the author) and were therefore willing to pay a higher price for antibiotic-free shrimp.[1243]

Two other studies identified higher importer prices associated with agricultural NTMs, although they did not draw conclusions about the reasons for these higher prices. Fontagné et al. analyzed how SPS measures affected different-sized French exporters in terms of trade volumes and prices. With respect to changes in trade, the authors found that more stringent importer SPS measures negatively affected both the extensive and intensive margins of trade, with more severe negative effects on smaller exporters. The authors found positive effects on export prices: however, they could not discern if these positive effects came about because the higher production costs resulting from the SPS measures were being passed through to purchasers, because product inputs were being upgraded to meet higher standards, or because competition weakened as exporting firms that could not comply with increasingly stringent standards left the market, allowing the remaining exporting firms to raise prices.[1244]

Cadot and Gourdon examined the effects of NTMs, including both agricultural and nonagricultural NTMs, on trade by estimating their effects on the prices of imported goods. They estimated that SPS measures caused import price increases such that they constituted ad valorem equivalents of 12.9 percent for animal products, 10.3 percent for vegetable products, 6.9 percent for fats and oils, and 8.0 percent for beverages and tobacco. Looking beyond SPS measures to include TBTs and other NTMs, they determined that the ad valorem equivalents of such NTMs were, in total, 26.2 percent for animal products, 19.6 percent for vegetables, 15.2 percent for fats and oils, and 17.3 percent for beverages and tobacco. Despite finding evidence that NTMs led to higher prices in import markets, these authors explicitly did not take a position on whether price effects were a result of higher compliance costs being passed on to the purchaser or demand-enhancing effects.[1245]

Effects of Pesticide Use on Production

Growers for export markets need to ensure that pesticides are used in accordance with practices that avoid violating the MRL policies in key destination markets, which could potentially result in lost shipments and poor reputation in those markets.[1246] When importer MRLs are reduced or shift to

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[1243] Beghin et al., "Welfare Costs and Benefits of Non-Tariff Measures in Trade," 2012, 369–71.

[1244] Fontagné et al., "Product Standards and Margins of Trade: Firm-Level Evidence," September 2015, 36–39. This study did not draw firm conclusions with respect to differences in export pricing behavior by firm size.

[1245] Cadot and Gourdon, "NTMs, Preferential Trade Agreements, and Prices: New Evidence," February 2015, 1, 14–16.

[1246] Detrimental reputational effects can persist beyond the original violation. Import refusals at the border have been found to decrease exports to the United States. Grundke and Moser, "Hidden Protectionism? Evidence from Non-Tariff Barriers to Trade in the United States," March 2019. In a dataset of U.S. import refusals from 1998 to 2008, the odds of import refusal due to an SPS measure in the current year increase by more than 300 percent if there was a refusal in the previous year. Studies have also found there were cross-product spillovers in default levels, growers may change production practices, including reductions in pesticide use. However, growers around the world rely on pesticides to increase crop yield, improve crop quality, and protect against crop failure. In order to assess evidence from the literature concerning the economic effects of lower (or modified) pesticide use, this section considers examples of studies that have analyzed the effects of pesticide use on agricultural productivity. Given that there are many studies on pesticide use and its effects, this review is not intended to be comprehensive, but instead provides a broad cross-section of the types of literature and viewpoints.

Several studies have found significant economic benefits from using pesticides, particularly from their ability to increase crop yields. For example, Oerke estimated that, without crop protection practices, pests (including weeds, diseases, and animal pests) had the potential to cause significant losses in all regions of the world in 2001–03, ranging from just under 60 percent to almost 90 percent of crops planted, depending on the region. However, because of the mechanical, biological, and chemical crop protection practices employed, actual crop losses due to pests were between 20 and 60 percent of crops planted, depending on the region.[1247] The study attributed the considerably lower crop losses in Northwest Europe and North America to the greater availability of pesticides in those regions.[1248]

Other studies have shown that pesticide use can help improve agricultural productivity by improving crop quality. Babcock, Lichtenberg, and Zilberman, in a study on apples grown in North Carolina, found that fungicides reduced both yield losses and quality damage, while insecticides were effective at reducing quality damage.[1249] Kawasaki and Lichtenberg found that the improved quality of Japanese wheat due to fungicide use contributed to an 18 percent increase in overall revenue, as fungicides helped to control various diseases affecting wheat production.[1250]

Despite evidence that chemical pesticides play a substantial role in improving agricultural productivity and crop quality, there are also a variety of studies that highlight adverse economic, environmental, and health effects of pesticide use and overuse, which may counteract pesticide-related gains. In a report from the U.S. Department of Agriculture's Economic Research Service on pesticide use in U.S. agriculture, Fernandez-Cornejo et al. described how pesticide use can have diminishing returns for farmers, with lower marginal effectiveness as more pesticides are used. The study demonstrated that at a certain threshold, the cost of additional pesticide use for a farmer will outweigh any additional benefit from crop damage reduction.[1251]

Aside from diminishing marginal effectiveness on crop yield and quality, pesticides may cause potential harm to the environment, farm worker health, and pest resistance, which may in turn have long-term adverse effects on agricultural productivity. To this end, Sexton, Lei, and Zilberman asserted that it was

enforcement—i.e., a country's exports of a particular product experienced more import refusals if closely related products were also subject to refusals. Jouanjean, Maur, and Shepherd, "Reputation Matters: Spillover Effects in the Enforcement of US SPS Measures," December 2011.

1247 Oerke, "Crop Losses to Pests," February 2006, 40. Across all regions analyzed, the average percent reduction of crop losses due to crop protection (i.e., the difference between the potential and actual loss divided by the potential loss for each region) was 50 percent.

1248 Oerke, "Crop Losses to Pests," February 2006, 39.

1249 Babcock, Lichtenberg, and Zilberman, "Impact of Damage Control and Quality of Output: Estimating Pest Control Effectiveness," February 1992, 170–71.

1250 Kawasaki and Lichtenberg, "Quality versus Quantity Effects of Pesticides," July 2015, 20–21.

1251 Fernandez-Cornejo et al., "Pesticide Use in U.S. Agriculture: 21 Selected Crops, 1960–2008," May 2014, 59–61.

important to compare the economic benefits of pesticide application to the total cost borne by society—including environmental, health, worker safety, and economic costs—rather than solely the input cost to the farmer.[1252] The authors found that in addition to environmental and worker safety costs, pesticide use also can reduce the effectiveness of crop protection measures through the destruction of beneficial species and increased pest resistance to pesticides.[1253] This study also demonstrated that crop damage from pests is inherently uncertain from season to season, and this uncertainty encourages farmers to apply pesticides beyond optimal levels.[1254] In a study focused on Chinese wheat, rice, and maize farmers, Zhang et al. found that while pesticide use led to significant agricultural productivity increases, farmers also substantially overused these pesticides, raising their input costs beyond optimal levels and potentially endangering the environment and human health in the process.[1255]

In a cost-benefit analysis of pesticide use that noted these diverse findings, Popp, Pető, and Nagy summarized multiple studies on the economic benefits of greater crop yields from pesticide use. They found that according to the literature surveyed, every dollar spent on pesticides increased the value of gross agricultural output by $3 to $6.50.[1256] Addressing the long-term sustainability of pesticide use, the authors stated that the correct use of pesticides could deliver environmental benefits if it enabled sustainable farm management by improving the efficiency with which farmers use natural resources such as soil, water, and land. Nonetheless, the study also highlighted the emergence of more efficient or alternative crop protection methods which had the potential to reduce pesticide use. Such industry trends included modern pest-management tools to increase application efficiency by reducing “spray drift”; increased use of GM crops that did not require the same level of pesticide application; and the introduction of biopesticides and integrated pest-management programs as alternatives to chemical pesticide use. Nonetheless, the authors concluded that chemical pesticides would continue to play a role in pest management because of their economic benefits and ready availability compared to newer alternatives.[1257]

Lechenet et al. reached a similar conclusion, noting that pesticide use could be substantially reduced without any financial cost and without any loss to their productivity and/or profitability for 77 percent of French farms. They found that these farms were in situations favorable to pesticide reduction, with average reduction potential of 37 percent for herbicides, 47 percent for fungicides, and 60 percent for insecticides. They noted, however, that adoption of the low-pesticide management strategies required to reduce pesticide use would potentially be challenging for farmers facing more complex farm

[1252] Sexton, Lei, and Zilberman, “The Economics of Pesticides and Pest Control,” September 17, 2007, 279–80.
[1253] Sexton, Lei, and Zilberman, “The Economics of Pesticides and Pest Control,” September 17, 2007, 286–97.
[1254] Sexton, Lei, and Zilberman, “The Economics of Pesticides and Pest Control,” September 17, 2007, 280–86.
[1255] Zhang et al., “Productivity Effect and Overuse of Pesticide in Crop Production in China,” 2015, 1909.
[1256] Popp, Pető, and Nagy, “Pesticide Productivity and Food Security. A Review,” October 17, 2012, 247, 249, citing Zilberman et al., “The Economics of Pesticide Use and Regulation, ”August 1991; Headley, “Estimating the Productivity of Agricultural Pesticides,” 1968; Pimentel, “Pesticides and Pest Controls,” 2009; Gianessi and Reigner, *The Value of Fungicides in US Crop Production*, September 2005; Gianessi and Reigner, “The Value of Herbicides in US Crop Production,” 2007; Gianessi, *The Value of Insecticides in US Crop Production*, March 2009; and Popp, “Cost-Benefit Analysis of Crop Protection Measures,” March 2011. An important difference between the methodologies used in these studies is the type of estimates for the indirect costs of pesticide use that are included in calculation. Some of these studies provide estimates specific to the United States, while others provide global estimates.
[1257] Popp, Pető, and Nagy, “Pesticide Productivity and Food Security. A Review,” October 17, 2012, 249–53.

management decisions, technical hurdles related to new technologies, and uncertainty and risk aversion associated with these changes.[1258] Citing this study along with others demonstrating the positive effects of pesticide use,[1259] Keulemans, Bylemans, and De Coninck concluded that without any plant protection products (which include pesticides), farming would see considerably lower crop yields and higher yield instability. However, they also concluded that long-term efforts to encourage pesticide reduction without sacrificing crop yields were worth pursuing in order to reduce adverse environmental effects.[1260]

Conclusion

Economic studies of MRLs are part of a larger body of literature focused on the effects of NTMs on trade, and therefore share common methodologies and approaches with that broader literature. A majority of studies have concluded that more stringent MRLs or those that differ between exporter and importer pairs (i.e., are more heterogeneous) have trade-reducing effects. Such studies have frequently theorized that compliance with stringent or heterogeneous MRLs imposes both fixed and recurring compliance costs on exporters, who may choose to reduce or forego their exports to destinations with restrictive MRLs as a result. Some studies have concluded that lower importer MRLs have trade-increasing effects, for which they offer the possible explanation that MRLs serve to increase demand for imports by communicating information to consumers about product quality or the provision of a public good. Many studies have found that the magnitude and direction of effects can vary across countries, with lower-income exporters more likely to reduce exports to destinations with lower MRLs due to their relative inability to afford the additional costs necessary to meet more restrictive import requirements.

A review of economic literature focused on non-MRL factors reveals potential implications of MRLs for production, prices, and income. Several studies have analyzed the economic effects of agricultural NTMs generally or other types of agricultural NTMs specifically, and have found that these measures are associated with higher importer prices and mixed effects on exporters' production and income, depending on whether they can bear the costs necessary to adhere to these NTMs. Other studies suggest that exporters seeking to comply with low MRL policies in destination countries may experience decreases in output if they are forced to reduce pesticide applications. This would occur because, as these studies have found, appropriate pesticide use reduces crop yield loss and increases perceived crop quality. However, other studies identified adverse effects of pesticide use and overuse in terms of long-term crop yields through increased pest resistance to pesticides, destruction of pest predators, and environmental degradation. Several studies have found that long-term reduction of pesticide use is possible without sacrificing productivity or income.

[1258] Lechenet et al., "Reducing Pesticide Use While Preserving Crop Productivity and Profitability on Arable Farms," March 2017, 4–5.
[1259] In addition to the Lechenet et al. article, this study cited Oerke, "Crop Losses to Pests," February 2006; Kawasaki and Lichtenberg, "Quality versus Quantity Effects of Pesticides," July 2015; and others demonstrating the positive effects of pesticide use on crop yields.
[1260] Keulemans, Bylemans, and De Coninck, *Farming without Plant Protection Products: Can We Grow without Using Herbicides, Fungicides and Insecticides?* March 2019, 11–14.

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Appendix A
Request Letter

THE UNITED STATES TRADE REPRESENTATIVE
EXECUTIVE OFFICE OF THE PRESIDENT
WASHINGTON

August 30, 2019

The Honorable David S. Johanson
Chairman
U.S. International Trade Commission
500 E Street, SW
Washington, DC 20436

Dear Chairman Johanson:

I am writing today regarding the Office of the United States Trade Representative's ongoing efforts to address barriers to U.S. agricultural trade exports, specifically sanitary and phytosanitary (SPS) barriers. The Administration seeks to gain a greater understanding of existing and emerging challenges to the current international and country-specific frameworks for pesticide maximum residue levels (MRLs), particularly in major markets, and a better understanding of whether current frameworks provide adequate support for agricultural trade. Farmers worldwide are confronted with numerous challenges affecting their use of plant protection products, including missing and low MRLs, and are increasingly concerned about the lack of adherence to well-established scientific principles in MRL decision-making processes.

Therefore, under authority delegated by the President to the United States Trade Representative and pursuant to section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)), I request that the U.S. International Trade Commission conduct an investigation and prepare a report on the global economic impact of national MRL policies on plant protection products. The report should include, to the extent practicable, information and analysis regarding the economic impact of pesticide MRLs on farmers in countries representing a range of income classifications (e.g., low income, lower middle income, upper middle income, etc.) as well as the United States. To the extent information is available, the report should cover the years 2016-2019, or the latest 3 years for which data are available, but may, where appropriate examine longer-term trends. This report should include the following:

(1) An overview of the role of plant protection products and their MRLs in relation to global production, international trade, and food safety for consumers. Describe the current and expected challenges to global agricultural production, including the impact of evolving pest and diseases pressures in differing regions and climates.

(2) A broad description of the approaches taken in setting national and international MRLs for crops. Describe the risk-based approach to setting MRLs in the context of agricultural trade, including the guidelines and principles of the Codex Alimentarius. Describe the procedures in the Codex Alimentarius for setting pesticide MRLs, including the role of the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) in conducting risk assessments. Compare this risk-based approach to a hazard-based approach. Describe U.S. efforts to advance the use of lower-risk pesticides globally.

(3) A description of how MRLs for plant protection products are developed and administered in major markets for U.S. agricultural exports. Describe the specific regulations, processes, practices, and timelines in these major markets for establishing, modifying, and administering MRLs. Describe specific MRL enforcement practices and processes, including practices and procedures for addressing non-compliant imported plant products. Provide examples of how Codex MRLs are adopted into national legislation or regulation. Identify trade-facilitative practices and processes.

(4) A description of challenges and concerns faced by exporting countries in meeting importing country pesticide MRLs, such as when MRLs are missing or low. Explain the reasons for missing and low MRLs.

(5) Through case studies, describe the costs and effects of MRL compliance and non-compliance for producers in countries representing a range of income classifications, such as uncertainty in planting decisions, segregation of products, crop protection costs, yield implications, storage issues, product losses, and consequences of MRL violations. Include information on costs of adopting new plant protection products or those related to establishing, modifying, or testing for new or existing MRLs in export markets. To the extent possible, include effects on producers in countries with tropical climates where products are subject to high levels of pest and disease pressure.

(6) A review of the economic literature that assesses both qualitatively and quantitatively how missing and low MRLs affect countries representing the range of income classifications, particularly low income countries, with regard to production, exports, farmer income, and prices.

(7) Through case studies, describe the costs and effects of MRL compliance and non-compliance for U.S. producers, such as uncertainty in planting decisions, segregation of products, crop protection costs, yield implications, storage issues, product losses, and consequences of MRL violations. Include information on costs of adopting new plant protection products or those related to establishing, modifying, or testing for new or existing MRLs in export markets. To the extent possible, include effects on U.S. producers of specialty crops.

(8) To the extent possible, quantitatively and qualitatively assess how missing and low MRLs affect production, exports, farmer income, and prices, both on the national level and, to the extent possible, for small and medium size farms.

I request that the Commission prepare this report, "*Global economic impact of missing and low pesticide MRLs*", in two volumes and deliver it according to the dates set forth below:

- Volume 1 by April 30, 2020 covering bullets (1) - (6) above, and
- Volume 2 by October 31, 2020 covering bullets (7) – (8).

It is my intent to make the Commission's report available to the public in its entirety. Therefore, the report should not include any business confidential information.

I appreciate the cooperation and attention of the Commission on this matter.

Sincerely yours,

Robert E Lighthizer

Robert E. Lighthizer

Appendix B
Federal Register Notices

concerning subject imports from Canada before a bi-national Panel established pursuant to Article 1904 of the North American Free Trade Agreement. The Panel affirmed in part and remanded in part the Commission's determinations. *In the Matter of Softwood Lumber from Canada: Interim Decision and Order of the Panel,* Secretariat File No. USA–CDA–2018–1903–03 (September 4, 2019). Specifically, the Panel remanded for the Commission to reconsider certain aspects of its analysis and findings concerning the conditions of competition and the volume of subject imports and their price effects.

Participation in the proceeding.—Only those persons who were interested parties that participated in the investigations (*i.e.,* persons listed on the Commission Secretary's service list) and also parties to the appeal may participate in the remand proceedings. Such persons need not make any additional notice of appearances or applications with the Commission to participate in the remand proceedings, unless they are adding new individuals to the list of persons entitled to receive business proprietary information (''BPI'') under administrative protective order. BPI referred to during the remand proceedings will be governed, as appropriate, by the administrative protective order issued in the investigations. The Secretary will maintain a service list containing the names and addresses of all persons or their representatives who are parties to the remand proceedings, and the Secretary will maintain a separate list of those authorized to receive BPI under the administrative protective order during the remand proceedings.

Written Submissions.—The Commission is not reopening the record and will not accept the submission of new factual information for the record. The Commission will permit the parties to file comments concerning how the Commission could best comply with the Panel's remand instructions.

The comments must be based solely on the information in the Commission's record. The Commission will reject submissions containing additional factual information or arguments pertaining to issues other than those on which the Panel has remanded this matter. The deadline for filing comments is October 15, 2019. Comments shall be limited to no more than thirty (30) double-spaced and single-sided pages of textual material, inclusive of attachments and exhibits.

Parties are advised to consult with the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subpart A (19 CFR part 207) for provisions of general applicability concerning written submissions to the Commission. All written submissions must conform to the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on E-Filing,* available on the Commission's website at *http://edis.usitc.gov,* elaborates upon the Commission's rules with respect to electronic filing.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, will not be accepted unless good cause is shown for accepting such submissions or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

By order of the Commission.
Issued: September 23, 2019.

Lisa Barton,
Secretary to the Commission.

[FR Doc. 2019–20976 Filed 9–26–19; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–573]

Global Economic Impact of Missing and Low Pesticide Maximum Residue Levels Institution of Investigation and Scheduling of Hearing

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation and scheduling of public hearing.

SUMMARY: Following receipt of a request from the U.S. Trade Representative (USTR) on August 30, 2019, under the Tariff Act of 1930, the U.S. International Trade Commission has instituted Investigation No. 332–573, *Global Economic Impact of Missing and Low Pesticide Maximum Residue Levels,* for the purpose of providing a report that examines the global economic impact of maximum residue level (MRL) policies.

DATES:

October 17, 2019: Deadline for filing requests to appear at the public hearing
October 21, 2019: Deadline for filing prehearing briefs and statements
October 29, 2019: Public hearing
November 5, 2019: Deadline for filing posthearing briefs
December 13, 2019: Deadline for filing all other written submissions for volume 1
April 30, 2020: Transmittal of volume 1 of Commission report to the USTR
June 5, 2020: Deadline for filing all other written submissions for volume 2
October 31, 2020: Transmittal of volume 2 of Commission report to the USTR (Delivered Monday, November 2, 2020)

ADDRESSES: All Commission offices, including the Commission's hearing rooms, are located in the United States International Trade Commission Building, 500 E Street SW, Washington, DC. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW, Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov/edis3-internal/app.*

FOR FURTHER INFORMATION CONTACT: Project Leader Sabina Neumann (volumes 1 and 2) (202–205–3000 or *sabina.neumann@usitc.gov*) or Deputy Project Leader (volume 1) Steven LeGrand (202–205–3094 or *steven.legrand@usitc.gov*) or Deputy Project Leader (volume 2) Justin Choe (202–205–3229 or *justin.choe@usitc.gov*) for information specific to this investigation. For information on the legal aspects of this investigation, contact William Gearhart of the Commission's Office of the General Counsel (202–205–3091 or *william.gearhart@usitc.gov*). The media should contact Margaret O'Laughlin, Office of External Relations (202–205–1819 or *margaret.olaughlin@usitc.gov*). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its website (*https://www.usitc.gov*). Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2002.

Background: As requested by the USTR, under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)), the Commission will conduct an investigation and prepare a report on the global economic impact of national maximum residue level (MRL) policies on plant protection products, with a focus on the impacts that low and missing standards have on agricultural trade. The USTR requested that the report include, to the extent practicable, information and analysis regarding the economic impact of pesticide MRLs on farmers in countries representing a range of income classifications (*e.g.,* low income, lower middle income, upper middle income, etc.) as well as the United States. The letter further requested that, to the extent information is available, the report cover the years 2016–2019, or the latest three years that data are available, but may, where appropriate, examine longer-term trends.

More specifically, the USTR asked that the report include the following:

(1) An overview of the role of plant protection products and their MRLs in relation to global production, international trade, and food safety for consumers. Describe the current and expected challenges to global agricultural production, including the impact of evolving pest and diseases pressures in differing regions and climates.

(2) A broad description of the approaches taken in setting national and international MRLs for crops. Describe the risk-based approach to setting MRLs in the context of agricultural trade, including the guidelines and principles of the Codex Alimentarius. Describe the procedures in the Codex Alimentarius for setting pesticide MRLs, including the role of the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) in conducting risk assessments. Compare this risk-based approach to a hazard-based approach. Describe U.S. efforts to advance the use of lower-risk pesticides globally.

(3) A description of how MRLs for plant protection products are developed and administered in major markets for U.S. agricultural exports. Describe the specific regulations, processes, practices, and timelines in these major markets for establishing, modifying, and administering MRLs. Describe specific MRL enforcement practices and processes, including practices and procedures for addressing non-compliant imported plant products. Provide examples of how Codex MRLs are adopted into national legislation or regulation. Identify trade-facilitative practices and processes.

(4) A description of challenges and concerns faced by exporting countries in meeting importing country pesticide MRLs, such as when MRLs are missing or low. Explain the reasons for missing and low MRLs.

(5) Through case studies, describe the costs and effects of MRL compliance and non-compliance for producers in countries representing a range of income classifications, such as uncertainty in planting decisions, segregation of products, crop protection costs, yield implications, storage issues, product losses, and consequences of MRL violations. Include information on costs of adopting new plant protection products or those related to establishing, modifying, or testing for new or existing MRLs in export markets. To the extent possible, include effects on producers in countries with tropical climates where products are subject to high levels of pest and disease pressure.

(6) A review of the economic literature that assesses both qualitatively and quantitatively how missing and low MRLs affect countries representing a range of income classifications, particularly low income countries, with regard to production, exports, farmer income, and prices.

(7) Through case studies, describe the costs and effects or MRL compliance and non-compliance for U.S. producers, such as uncertainty in planting decisions, segregation of products, crop protection costs, yield implications, storage issues, product losses, and consequences of MRL violations. Include information on costs of adopting new plant protection products or those related to establishing, modifying, or testing for new or existing MRLs in export markets. To the extent possible, include effects on U.S. producers of specialty crops.

(8) To the extent possible, quantitatively and qualitatively assess how missing and low MRLs affect production, exports, farmer income, and prices, both on the national level and, to the extent possible, for small and medium size farms.

The USTR asked that the Commission prepare its report in two volumes, with volume 1 covering bullets (1)–(6) above transmitted by April 30, 2020, and volume 2 covering bullets (7)–(8) transmitted by October 31, 2020 (delivered on Monday, November 2, 2020).

Public Hearing: The Commission will hold a public hearing in connection with this investigation at the U.S. International Trade Commission Building, 500 E Street SW, Washington, DC, beginning at 9:30 a.m. on October 29, 2019. Persons wishing to appear at the public hearing should file a request to appear with the Secretary, no later than 5:15 p.m., October 17, 2019, in accordance with the requirements in the ''Submissions'' section below. All pre-hearing briefs and statements should be filed no later than 5:15 p.m., October 21, 2019; and all post-hearing briefs and statements responding to matters raised at the hearing should be filed no later than 5:15 p.m., November 5, 2019. In the event that, as of the close of business on October 17, 2019, no witnesses are scheduled to appear at the hearing, the hearing will be canceled. Any person interested in attending the hearing as an observer or nonparticipant should contact the Office of the Secretary at 202–205–2000 after October 17, 2019, for information concerning whether the hearing will be held.

Written Submissions: In lieu of or in addition to participating in the hearing, the Commission invites interested parties to submit written statements concerning this investigation. All written submissions should be addressed to the Secretary, and should be received no later than 5:15 p.m., December 13, 2019 for matters to be covered by volume 1 of the Commission's report, and June 3, 2020 for matters to be covered by volume 2 of the Commission's report. All written submissions must conform with the provisions of section 201.8 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.8). Section 201.8 of the Rules (as further explained in the Commission's *Handbook on Filing Procedures*) requires that interested parties file documents electronically on or before the filing deadline and submit eight (8) true paper copies by 12:00 p.m. Eastern Time on the next business day. In the event that confidential treatment of a document is requested, interested parties must file, at the same time as the eight paper copies, at least four (4) additional true paper copies in which the confidential information must be deleted (see the following paragraph for further information regarding confidential business information or ''CBI''). Persons with questions regarding electronic filing should contact the Office of the Secretary, Docket Services Division (202–205–1802).

Confidential Business Information (CBI): Any submissions that contain CBI must also conform to the requirements of section 201.6 of the *Commission's Rules of Practice and Procedure* (19 CFR 201.6). Section 201.6 of the Rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the ''confidential'' or ''non-confidential'' version, and that the CBI is clearly identified using brackets. The Commission will make all written submissions, except for those (or portions thereof) containing CBI, available for inspection by interested parties.

In his request letter, the USTR stated that his office intends to make the Commission's report available to the public in its entirety, and asked that the Commission not include any CBI in the report that it delivers to the USTR.

The Commission will not include any of the CBI submitted in the course of this investigation in the report it sends to the USTR. However, all information, including CBI, submitted in this investigation may be disclosed to and used (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission, including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel for cybersecurity purposes. The Commission will not otherwise disclose any CBI in a manner that would reveal the operations of the firm supplying the information.

Summaries of Written Submissions: The Commission intends to publish any summaries of written submissions filed by interested persons. Persons wishing to have a summary of their submission included in the report should include a summary with their written submission, titled "Public Summary," and should mark the summary as having been provided for that purpose. The summary may not exceed 500 words, should be in MSWord format or a format that can be easily converted to MSWord, and should not include any CBI. The summary will be published as provided if it meets these requirements and is germane to the subject matter of the investigation. The Commission will identify the name of the organization furnishing the summary and will include a link to the Commission's Electronic Document Information System (EDIS) where the full written submission can be found.

By order of the Commission.

Issued: September 23, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–20959 Filed 9–26–19; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as Amended

On September 19, 2019, the United States of America ("United States"), through attorneys for the Department of Justice, and the Commonwealth of Pennsylvania, Department of Environmental Protection ("PADEP"), lodged a proposed Consent Decree with the United States District Court for the Middle District of Pennsylvania in the lawsuit entitled *United States et al.* v. *Foster Wheeler Energy Corporation,* Civil Action No. 3:19–cv–01620–UN4.

In their Complaint, also filed on September 19, 2019, pursuant to Sections 106, 107(a), and 113(g) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended ("CERCLA"), 42 U.S.C. 9606, 9607(a), and 9613(g), and pursuant to Sections 507 and 1103 of the Hazardous Sites Cleanup Act, Act of October 18, 1988, Public Law 756, 35 P.S. §§ 6020.507 and 6020.1103 ("HSCA"), the United States and PADEP ("Plaintiffs") allege that Defendant Foster Wheeler Energy Corporation ("FWEC") is liable for cleanup costs incurred and to be incurred by the United States and PADEP in connection with the cleanup of the Foster Wheeler Energy Corporation/Church Road TCE Superfund Alternative Site ("Site") in Mountain Top, Luzerne County, Pennsylvania. The Site includes a former industrial site used to manufacture and fabricate large pressure vessels that was formerly owned and operated by FWEC (the "Former FWEC Facility"). The Site also includes any areas at which hazardous substances released at or from this facility have come to be located, including an area of groundwater contamination located south and southwest of the Former FWEC Facility and encompassing approximately 295 acres of mixed land use (mainly residential), which extends from east to west along Church Road and Watering Run, and eight surrounding industrial properties located immediately south and west of the Former FWEC Facility.

The proposed Consent Decree resolves all allegations asserted in the Plaintiffs' Complaint and provides for FWEC to pay to the United States Environmental Protection Agency ("EPA") $950,000.00 in past response costs incurred with respect to the Site, and to pay to PADEP $56,051.21 in past state response costs incurred with respect to the Site. These payments are due within thirty (30) days after the Consent Decree becomes effective as a judgment, if it is entered by the Court. The proposed Consent Decree also requires FWEC to pay the United States' and PADEP's future response costs and to perform the Interim Remedy selected in EPA's Interim Record of Decision for the Site. In exchange, FWEC receives from both Plaintiffs covenants not to sue for the interim remedial work performed and payment of past and future federal and state response costs, subject to certain reservations and limitations.

The publication of this notice opens a federal period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States et al.* v. *Foster Wheeler Energy Corporation,* D.J. Ref. No. 90–11–3–12044. All comments must be submitted no later than 30 days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $39.50 (0.25 cents per page reproduction cost) payable to the United States Treasury for a copy of the full Consent Decree with appendices. For a paper copy without the appendices, the cost is $12.00.

Jeffrey Sands,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2019–20966 Filed 9–26–19; 8:45 am]

BILLING CODE 4410–15–P

21456 **Federal Register** / Vol. 85, No. 75 / Friday, April 17, 2020 / Notices

draft Criteria for Developing Refuge Water Management Plans 2020 (2020 Refuge Criteria) for public review and comment. Reclamation is publishing this notice in order to allow the public an opportunity to review the draft 2020 Refuge Criteria.

DATES: Submit written comments on the preliminary determinations on or before May 18, 2020.

ADDRESSES: Send written comments to Mr. David T. White, Bureau of Reclamation, 2800 Cottage Way, CGB–410, Sacramento, CA 95825; or via email at *dwhite@usbr.gov.*

FOR FURTHER INFORMATION CONTACT: To be placed on a mailing list for any subsequent information, please contact Mr. White at *dwhite@usbr.gov* or at 916–978–5208 (TDD 978–5608).

SUPPLEMENTARY INFORMATION: Section 3405(e) of the Central Valley Project Improvement Act (Title 34 Pub. L. 102–575) requires the Secretary of the Interior to, among other things, ''develop criteria for evaluating the adequacy of all water conservation plans'' developed by certain contractors. According to Section 3405(e)(1), these criteria must promote ''the highest level of water use efficiency reasonably achievable by project contractors using best available cost-effective technology and best management practices.'' In accordance with this legislative mandate, the Bureau of Reclamation developed and published the Refuge Criteria, which is updated every 3 years.

We invite the public to comment on our preliminary (*i.e.,* draft) 2020 Refuge Criteria.

A copy of the draft 2020 Refuge Criteria will be available for review at Reclamation's office in Sacramento, California, located at 2800 Cottage Way, CGB–410, Sacramento, CA 95825. If you wish to review a copy of the draft 2020 Refuge Criteria or receive an electronic copy via email, please contact Mr. White or visit *https://www.usbr.gov/mp/watershare.*

Sheryl Looper,

Acting Regional Resources Manager, Bureau of Reclamation, California-Great Basin—Interior Region 10.

[FR Doc. 2020–08155 Filed 4–16–20; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–573]

Global Economic Impact of Missing and Low Pesticide Maximum Residue Levels; Notice of Change in Completion Date, Clarification of Deadline for Filing Written Submissions

AGENCY: United States International Trade Commission.

ACTION: Change in date for transmittal of volume 1 of the Commission's report; clarification of a filing date relating to volume 2 of the report; and waiver of the requirement to file paper copies.

SUMMARY: The Commission has changed the date for transmittal of volume 1 of its report to the U.S Trade Representative (USTR) in this investigation from April 30, 2020 to June 30, 2020 due to COVID–19; is clarifying that the due date for written submission for volume 2 of its report is June 5, 2020; and has waived the requirement to file paper copies of those submissions.

DATES:

June 5, 2020: Deadline for filing all other written submissions for volume 2

June 30, 2020: Transmittal of volume 1 of Commission report to the USTR

October 31, 2020: Transmittal of volume 2 of Commission report to the USTR
(Delivered Monday, November 2, 2020)

ADDRESSES: All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW, Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov/edis3-internal/app.*

FOR FURTHER INFORMATION CONTACT: Project Leader Sabina Neumann (volumes 1 and 2) (202–205–3000 or *sabina.neumann@usitc.gov*) or Deputy Project Leader (volume 1) Steven LeGrand (202–205–3094 or *steven.legrand@usitc.gov*) or Deputy Project Leader (volume 2) Justin Choe (202–205–3229 or *justin.choe@usitc.gov*) for information specific to this investigation. For information on the legal aspects of this investigation, contact William Gearhart of the Commission's Office of the General Counsel (202–205–3091 or *william.gearhart@usitc.gov*). The media should contact Margaret O'Laughlin, Office of External Relations (202–205–1819 or *margaret.olaughlin@usitc.gov*). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its website (*https://www.usitc.gov*). Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2002.

SUPPLEMENTARY INFORMATION: The Commission published notice of institution of the above referenced investigation in the **Federal Register** on September 27, 2019 (84 FR 51178, September 27, 2019). In that notice the Commission stated that it would transmit volume 1 of its report to the USTR by April 30, 2020. However, due to COVID–19 and in accordance with a request on behalf of Ambassador Robert Lighthizer, the U.S. Trade Representative, the Commission will transmit volume 1 of its report to the USTR by June 30, 2020. This notice also corrects an ambiguity in the September 27, 2019 notice by clarifying that written submissions relating to volume 2 of the report should be filed with the Commission by June 5, 2020 (the original notice in one place gave June 3, 2020, as the due date). All other dates pertaining to this investigation remain the same as in the notice published in the **Federal Register** on September 27, 2019.

Written Submissions: In lieu of or in addition to participating in the hearing, the Commission invites interested parties to submit written statements concerning this investigation. All written submissions should be addressed to the Secretary, and should be received no later than 5:15 p.m., June 5, 2020 for matters to be covered by volume 2 of the Commission's report. All written submissions must conform with the provisions of section 201.8 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.8). Section 201.8 of the Rules (as further explained in the Commission's *Handbook on Filing Procedures*) requires that interested parties file documents electronically on or before the filing deadline (see the following paragraph for further information regarding confidential business information or ''CBI''). Persons with questions regarding electronic filing should email the Office of the Secretary, Docket Services Division at *EDIS3Help@usitc.gov.* The Commission has waived the requirement in section 201.8(d)(1) of its rules (19 CFR 201.8(d)(1)) that persons filing written submissions must also file paper copies of their written submissions by noon of the next day; no paper copies should be filed.

Confidential Business Information (CBI): Any submissions that contain CBI must also conform to the requirements of section 201.6 of the *Commission's Rules of Practice and Procedure* (19 CFR 201.6). Section 201.6 of the Rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the ''confidential'' or ''non-confidential'' version, and that the CBI is clearly identified using brackets. The Commission will make all written submissions, except for those (or portions thereof) containing CBI, available for inspection by interested parties.

In his request letter, the USTR stated that his office intends to make the Commission's report available to the public in its entirety and asked that the Commission not include any CBI in the report that it delivers to the USTR.

The Commission will not include any of the CBI submitted in the course of this investigation in the report it sends to the USTR. However, all information, including CBI, submitted in this investigation may be disclosed to and used (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission, including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel for cybersecurity purposes. The Commission will not otherwise disclose any CBI in a manner that would reveal the operations of the firm supplying the information.

Summaries of Written Submissions: The Commission intends to publish any summaries of written submissions filed by interested persons. Persons wishing to have a summary of their submission included in the report should include a summary with their written submission, titled ''Public Summary,'' and should mark the summary as having been provided for that purpose. The summary may not exceed 500 words, should be in MSWord format or a format that can be easily converted to MSWord, and should not include any CBI. The summary will be published as provided if it meets these requirements and is germane to the subject matter of the investigation. The Commission will identify the name of the organization furnishing the summary and will include a link to the Commission's Electronic Document Information System (EDIS) where the full written submission can be found.

By order of the Commission.

Issued: April 13, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–08102 Filed 4–16–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–620 and 731–TA–1445 (Final)]

Wooden Cabinets and Vanities From China

Determinations

On the basis of the record[1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is materially injured by reason of imports of wooden cabinets and vanities from China, provided for in subheadings 9403.40.90, 9403.60.80, and 9403.90.70 of the Harmonized Tariff Schedule of the United States, that have been found by the U.S. Department of Commerce (''Commerce'') to be sold in the United States at less than fair value (''LTFV''), and to be subsidized by the government of China.

Background

The Commission instituted these investigations effective March 6, 2019, following receipt of petitions filed with the Commission and Commerce by the American Kitchen Cabinet Alliance. The final phase of these investigations was scheduled by the Commission following notification of preliminary determinations by Commerce that imports of wooden cabinets and vanities from China were subsidized within the meaning of section 703(b) of the Act (19 U.S.C. 1671b(b)) and sold at LTFV within the meaning of 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on October 24, 2019 (84 FR 57050). The hearing was held in Washington, DC, on February 20, 2020, and all persons who requested the opportunity were permitted to appear in person or by counsel.

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

The Commission made these determinations pursuant to sections 705(b) and 735(b) of the Act (19 U.S.C. 1671d(b) and 19 U.S.C. 1673d(b)). It completed and filed its determinations in these investigations on April 13, 2020. The views of the Commission are contained in USITC Publication 5042 (April 2020), entitled *Wooden Cabinets and Vanities from China: Investigation Nos. 701–TA–620 and 731–TA–1445 (Final).*

By order of the Commission.

Issued: April 13, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–08091 Filed 4–16–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1124]

Certain Powered Cover Plates; Commission Determination Not to Review a Remand Initial Determination; Schedule for Filing Written Submissions on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review a remand initial determination (''RID'') issued by the presiding administrative law judge (''ALJ'') in the above-captioned investigation granting a motion for summary determination regarding whether certain redesigns infringe the asserted patents. The Commission requests briefing from the parties, interested government agencies, and interested persons on the issues of remedy, the public interest, and bonding.

FOR FURTHER INFORMATION CONTACT: Michael Liberman, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3115. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW, Washington, DC 20436, telephone (202) 205–2000. General

Appendix C
Calendar of Hearing Witnesses

Office of the Secretary

UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, DC 20436

MEMORANDUM OF RECORD

RE: Investigation No. 332-573

Concerning: Global Economic Impact of Missing and Low Pesticide Maximum Residue Levels

A public hearing in this investigation was held on:

October 29, 2019

A copy of the calendar of this hearing is attached. For further information, consult the transcript of the hearing, the exhibits, and the minutes of the Commission.

FILED BY:
Tyrell T. Burch
Management Analyst

CALENDAR OF PUBLIC HEARING

Those listed below are scheduled to appear as witnesses at the United States International Trade Commission's hearing:

Subject:	Global Economic Impact of Missing and Low Pesticide Maximum Residue Levels
Inv. No.:	332-573
Date and Time:	October 29, 2019 - 9:30 a.m.

A session was held in connection with this investigation in the Main Hearing Room (Room 101), 500 E Street, SW., Washington, DC.

EMBASSY APPEARANCES:

Embassy of the Republic of Paraguay
Washington, DC

The Honorable Minister Luis González Fernández, Deputy Chief of Mission

Taipei Economic and Cultural Representative Office
Washington, DC

James Tsai, Economic Officer

PANEL 1:

ORGANIZATION AND WITNESS:

U.S. Hop Industry Plant Protection Committee
Yakima, WA

Alinne Oliveira, Trade Policy Specialist, Bryant Christie Inc.

Northwest Horticultural Council
Yakima, WA

Dr. David Epstein, Vice President, Scientific Affairs

The Cranberry Institute
Carver, MA

Terry L. Humfeld, Executive Director

PANEL 2:

ORGANIZATION AND WITNESS:

U.S. Sweet Potato Council
Dillsburg, PA

Kay Swartz Rentzel, Executive Director

USA Dry Pea & Lentil Council
Moscow, ID

Dale Thorenson, Gordley Associates

CropLife America
Washington, DC

Christopher Novak, President and Chief Executive Officer

- END -

Appendix D
Summary of Views of Interested Parties

Views of Interested Parties

Interested parties had the opportunity to file written submissions to the Commission in the course of this investigation and to provide summaries of the positions expressed in the submissions for inclusion in this report. This appendix contains these written summaries, provided that they meet certain requirements set out in the notice of investigation. The Commission has not edited these summaries. This appendix also contains the names of other interested parties who filed written submissions during investigation but did not provide written summaries. A copy of each written submission is available in the Commission's Electronic Docket Information System (EDIS), https://www.edis.usitc.gov. The Commission also held a public hearing in connection with this investigation on October 29, 2019. The full text of the transcript of the Commission's hearing is also available on EDIS.

Written Submissions

Almond Board of California

No written summary. Please see EDIS for full submission.

American Farm Bureau Federation

No written summary. Please see EDIS for full submission.

American Peanut Council

No written summary. Please see EDIS for full submission.

American Soybean Association

No written summary. Please see EDIS for full submission.

Australian Government Department of Agriculture

Australia appreciates the opportunity to provide a written submission to the United States International Trade Commission (US ITC) Investigation into the Global Economic Impact of Missing and Low Pesticide Maximum Residue Limits (MRLs). The effect of missing or low MRLs impacts stakeholders at multiple points along the Global Value Chain, including both exporting and importing economies. Australia has long been a leader in recognising the need for science and risk based decision making processes that facilitate trade while still providing the appropriate level of protection for consumers.

Effective, efficient and sustainable agricultural production is critical to ensure an increasing global population has access to sufficient food sources. In order to meet this challenge, one of the key requirements is to provide farmers with the full suite of agricultural production technologies. It is also important to recognise that each economy experiences different biosecurity challenges, and that the need for pesticide use that comes with these challenges is different.

Australia has a robust regulatory system that allows for both the setting of MRLs for domestic use, and the establishment of MRLs for imported produce where there are differences. The system is jointly regulated by the Australia Pesticides and Veterinary Medicines Authority and Food Standards Australia New Zealand. Supporting these functions is comprehensive residue monitoring programs undertaken by the government and private businesses to ensure that Australian agricultural produce meets the relevant MRLs.

We support this through a range of multi-lateral fora, including through Asia-Pacific Economic Cooperation (APEC). Developing the APEC Import MRL Guideline for Pesticides has supported strong collaboration between economies and raised the profile of the benefits of harmonised systems. Further advocacy of this work will benefit the global community and provide an avenue to effectively and efficiently address the challenge of missing MRLs.

We are encouraged by the US initiative to gather global information on the economic impact of missing and low MRLs, and will continue to support work that addresses these problems. Measures by industry to manage this issue, including restricted trade programs and cessation on the use of some pesticides is not sustainable and adds an additional layer of cost and complexity to farmers and industry.

Australia continues to advocate internationally the benefits of our systems and the need for economies to support the setting and adoption of Codex MRLs. We encourage the international community to look at the Australian system as best practice and how it can be used as a positive example when considering policy decisions on MRLs in their own economies. Addressing the impact of missing and low pesticide MRLs, by having a system to allow import MRLs be established, has positively facilitated trade, decreased the rejection of food at the border and increased consumers choice of food available. In support of the US ITC for undertaking this work, Australia is happy to provide this written submission, detailing our systems and providing that knowledge to other economies and industry.

Bayer

No written summary. Please see EDIS for full submission.

California Cherry Board

No written summary. Please see EDIS for full submission.

California Citrus Quality Council

No written summary. Please see EDIS for full submission.

California Fresh Fruit Association

No written summary. Please see EDIS for full submission.

California Rice Commission

The California Rice Commission a statutory organization representing 2,500 rice growers and marketers producing the crop on an average of 500,000 acres. California is the second largest producing state growing mostly temperate japonica rice.

Our comments provide responses to the eight items listed in the public notice.
1) Half the crop is consumed domestically with shipments to countries utilizing our rice such as Taiwan, Korea, Turkey with Japan the largest market. We manage regulatory programs for California rice and, as an USA Rice member, coordinate on several programs including trade. Rice is a global commodity and the temperate japonica varieties are common in sushi, risotto and paella. An emerging armyworm problem expanding on a global basis is taxing availability of the most effective product for control.

2) For evaluating MRLs from foreign countries, we utilize Title 40 Code of Federal Regulations for pesticide tolerances established by the U.S. Environmental Protection Agency Office of Pesticide Programs (U.S. EPA OPP). The tolerances are United States MRLs established at the conclusion of the review process for pesticide registration. Pesticides sold and used in the United States are registered by the U.S. EPA OPP. Every state has a registration process for licensing the pesticide. California has a program that reviews and registers pesticides sold and used before they are eligible for licensing. As a result, California rice has fewer registered pesticides than other rice producing states. We provide the numbers and reference to the U.S. EPA OPP website for information on pesticide tolerances and background on Codex.

3) We receive WTO notices on adoption of Codex MRLs and our review includes comparison to the U.S. EPA OPP tolerances. We provide information on the number of chemicals we analyze in shipments to Japan.

4) Our comments outline two areas of concern on missing and low MRLs. The first relates to a missing MRL in one country we export rice. The second issue is the proposal to lower an MRL on a significant rice herbicide. These examples of missing and low MRLs could result in trade irritants.

5) The comment we provide briefly outlines the timeline for pesticide registration. The process could allow for harmonization by utilizing the U.S. EPA OPP review materials in establishing MRLs for commodities from the United States.

6) We provide an example of the impact a country could experience in banning three pesticides.

7) California rice has no impacts. We provide a scenario if the MRL on an herbicide is lowered to the proposed level.

8) Rice is family farmed, yet our small to medium acreage could be considered large in other countries. We provide examples of potential trade irritants from missing and low MRLs. The cost of holding a shipment at a foreign port is significant.

Our final message suggests collaboration at a governmental level through an agency to agency streamlined and effective approach. We realize our recommendation is a simple method to a complex issue. However, we have experience where the commitment to collaboration has proven effective and positive.

California Table Grape Commission

No written summary. Please see EDIS for full submission.

California Walnut Commission

No written summary. Please see EDIS for full submission.

Cranberry Institute

No written summary. Please see EDIS for full submission.

CropLife America and CropLife International

No written summary. Please see EDIS for full submission.

European Commission

The European Union (EU) is an accessible and open market that is committed to free trade. it is the second biggest importer worldwide of agricultural (food &feed) products with €116 billion worth of imports. The US is one of the great beneficiaries of a highly attractive and open EU-market for imported food & feed: EU agri-food imports from the USA were the fastest growing imports in 2018 and, with an impressive 12% increase, the EU became the third top destination for US agri-food exports after Canada and Mexico.

Pesticide residues resulting from the use of plant protection products (PPPs) on crops or food products that are used for food or feed production may pose a risk for public health. Each exporting country therefore needs to be in a position to meet the EU's food safety standards. The EU legislative regime on PPPs is transparent, predictable, and based on international standards and the best available science. Before an active substance can be approved in the EU it must undergo a thorough approval procedure carried out jointly by a Member State of the EU and the European Food Safety Authority (EFSA), the EU's independent risk assessment body for food and feed safety which assures that risk assessments are free from undue influence. The Authority is founded on the core values of independence, scientific excellence, transparency, and openness and uses internationally agreed risk assessment methodologies. A key part of this approval process is an assessment of risks to consumers. Plant protection products containing such approved substances must then be authorized by the EU Member States in a second step.

Additionally, the EU sets' pesticide maximum residue levels (MRLs) for each crop based on EFSA's risk assessment that apply indiscriminately to domestic and imported products placed on the EU market. The EU aligns its MRLs with Codex MRLs in the vast majority of cases: the EU has taken on board 1833 MRI: out of 2567 CXLs adopted by Codex between 2012 and 2,019 and is aligned with more than 70% of the CXLs established in this period.

The EU legislation provides for a review of the existing MRLs of all approved and certain nonapproved PPPs. The EU allows non-EU countries to request import tolerances even for active substances which are not authorised in the EU. Import tolerances permit EU-MRLs to be set based on Good Agricultural Practices (GAPs) authorised in non-EU countries at a level sufficiently high to meet the needs of international trade. Potential applicants, including foreign governments and exporters, have access to the risk assessment authorities at EU and Member State level, and the data they submit are always taken into account before decisions on MRLs and import tolerances are taken.

Compliance with Food Safety standards for EU produced and imported products is verified on the basis of samples taken in a proportionate and non-discriminatory manner. There are currently no US-products subject to reinforced checks due to pesticide MRLs exceeding statutory limits.

Government of Canada

No written summary. Please see EDIS for full submission.

IR-4 Project Headquarters

No written summary. Please see EDIS for full submission.

National Potato Council

No written summary. Please see EDIS for full submission.

Northwest Horticultural Council

No written summary. Please see EDIS for full submission.

North American Blueberry Council

No written summary. Please see EDIS for full submission.

Pesticide Policy Coalition

No written summary. Please see EDIS for full submission.

Taipei Economic and Cultural Representation Office in the United States

No written summary. Please see EDIS for full submission.

U.S. Grains Council, National Corn Growers Association, MAIZALL

No written summary. Please see EDIS for full submission.

U.S. Wheat Associates

No written summary. Please see EDIS for full submission.

U.S.A Rice Federation

No written summary. Please see EDIS for full submission.

U.S. Environmental Protection Agency

No written summary. Please see EDIS for full submission.

U.S. Hop Industry Plant Protection Committee

No written summary. Please see EDIS for full submission.

U.S. Sweet Potato Council

No written summary. Please see EDIS for full submission.

Wine Institute and the California Association of Winegrape Growers

No written summary. Please see EDIS for full submission.