Food and Agriculture Organization of the United Nations

Understanding international harmonization of pesticide maximum residue limits with Codex standards

A case study on rice

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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
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FOREWORD

The FAO/WHO Codex Alimentarius is the most important internationally recognized standard-setting body on food safety and quality. Its primary objectives are to protect the health of consumers and ensure fair practices in international food trade. Codex standards are based on solid and independent scientific advice provided by FAO and WHO and are discussed and agreed through an inclusive and transparent process that allows global trust in the safety of food.

Since its establishment in 1963, Codex has developed hundreds of internationally recognized standards, guidelines and codes and has defined thousands of permitted levels of additives, contaminants and chemical residues in food. Among them, pesticide Maximum Residue Limits (MRLs) define the maximum concentration of a pesticide residue to be legally permitted in food commodities and animal feeds, ensuring that food is safe for consumers and public health is protected.

Globalization and growing volumes of traded food have increased the chances that the food produced in one place affects the diets and health of people living elsewhere. Internationally recognized food standards developed by Codex, including pesticide MRLs, ensure that trade and food safety go together and that the food reaching the plate is safe and of expected quality. It is in this context, that the WTO Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures strongly encourages governments to harmonize their food safety regulations, using Codex standards as the benchmark. Through that, the SPS Agreement seeks to strike a balance between WTO Members` rights to regulate legitimate objectives, such as ensuring food safety of their populations, while avoiding that such regulations are used as unnecessary barriers to international trade.

The harmonization of national regulations with Codex pesticide MRLs has been discussed in different fora for several years. Within the Codex Alimentarius Commission (CAC) concerns were at first raised about the loss of pesticide MRLs due to the periodic review policy applied by the Codex Committee on Pesticide Residues (CCPR). Within the relevant WTO bodies, Codex pesticide MRLs and their relevance for trade have been repeatedly called into question. At the 11th WTO Ministerial Conference, held in Buenos Aires in December 2017, a joint statement on pesticide MRLs and trade was signed by ministers from a number of developed and developing countries, calling for greater harmonization across national and regional MRLs.

This publication focuses on pesticide MRLs in rice. It builds on a pre-study carried out by FAO in 2017 which showed that the level of harmonization of the pesticide MRLs of five major economies with Codex MRLs was very low for particular commodities, including rice.

Rice is a staple food for billions of people globally and plays a significant role in food security, in particular in many developing regions. Developing countries account for more than 96 percent of global rice production and a similar share of world rice consumption. At the same time, eight out of the ten major rice exporters are developing countries, accounting for almost three quarters of global rice exports.

The publication explores the harmonization of national standards with Codex pesticide MRLs from three different angles. It assesses the level of harmonization of pesticide MRLs among the main rice producing and trading countries, explores the possible effects on trade, and investigates the reasons behind differing levels of harmonization. We hope that it will offer valuable insights for decision-makers and other stakeholders involved in setting standards and designing food policy at national and international levels. Their role is important for both shaping the international MRL standard-setting process under Codex and enhancing harmonization with Codex MRLs at the national level.

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BACKGROUND AND STRUCTURE OF THE STUDY

For many years, trade issues related to differences in nationally imposed regulatory limits for pesticide residues have been highlighted by different countries. Within the Codex Alimentarius Commission (CAC), an internationally recognized standard-setting body, concerns were initially raised mainly by Latin American countries about the loss of pesticide maximum residue limits (MRLs), due to the periodic review policy applied by the Codex Committee on Pesticide Residues (CCPR). More recently, issues related to the compliance with Codex pesticide MRLs and its relevance for trade has been repeatedly raised in other relevant fora, including the World Trade Organization (WTO). At the 11th WTO Ministerial Conference, held in Buenos Aires on 8-13 December 2017, a joint statement was signed by a number of ministers from both developed and developing countries, supporting actions "to increase the capacity and efficiency of Codex in setting international standards on pesticide MRLs; to improve transparency and predictability in Members' setting of national MRLs; and to achieve greater harmonization across national and regional MRLs".

In 2017, The Food and Agriculture Organization of the United Nations (FAO) carried out a pre-study, on the basis of publicly available information, in a systematic effort to assess the level of harmonization among countries and Codex MRLs on food. It was established that countries tend to apply stricter pesticide MRLs than those recommended by Codex, especially in the categories 'Cereals' and 'Herbs & Spices' , and in particular for commodities such as rice, chilli pepper and spices.

The observed low level of harmonization with Codex MRLs triggered a series of questions and highlighted the need to understand better the different dimensions of this complex issue. To investigate the nature of the problem better, the current study was designed to analyse two main areas:

PART A

THE LEVEL OF HARMONIZATION WITH CODEX RICE PESTICIDE MAXIMUM RESIDUE LIMITS AND ITS IMPACT ON TRADE

Part A explores the harmonization of national pesticide MRLs with Codex MRLs for the main players in the global rice market and its possible impact on trade in rice. Rice was chosen as a case study because it is an important staple food in many developing countries and was one of the commodities for which low harmonization with Codex MRLs was identified in the pre-study. The harmonization of national pesticide MRLs with Codex pesticide MRLs was assessed using publicly available information and direct communications with the governments of the countries included in the analyses.

The impact of differing levels of harmonization with Codex MRLs on trade in rice was analysed for a sample of 17 countries/markets. The results of the analysis were peer-reviewed.

PART B

THE REASONS BEHIND DIFFERING LEVELS OF HARMONIZATION WITH CODEX MAXIMUM RESIDUE LIMITS

Part B investigates the differences in risk assessment procedures and risk management policies that may lead to divergent MRLs. Data for five countries/region were analysed in this part of the study based on availability and public accessibility to risk assessments and risk management documents.

ABBREVIATIONS AND ACRONYMS

ADI	Acceptable daily intake
AfCFTA	African Continental Free Trade Area
AFSA	African Food Safety Agency
AoF	All other Foods
APEC	Asia-Pacific Economic Cooperation
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	Acute reference dose
AVEs	Ad Valorem Equivalents
BMD(L)	Benchmark Dose (Level)
CAC	Codex Alimentarius Commission
CIFOCOss	FAO/WHO Chronic Individual Food Consumption database
CCPR	Codex Committee on Pesticide Residues
CSAF	Chemical-specific adjustment factor
EFSA	European Food Safety Authority
FAO	Food and Agriculture Organization of the United Nations
FAOSTAT	FAO Corporate Statistical Database
FQPA	Food Quality Protection Act
GAP(s)	Good Agricultural Practice(s)
GECDE	Global estimate of chronic dietary exposure
GEMS	Global Environmental Monitoring System
GDP	Gross Domestic Product
HBGVs	Health-based guidance values
HS	Harmonized Commodity Description and Coding System
IEDI	International Estimate of Daily Intake
IESTI	International Estimated Short-term Intake
IMR	Inverse Mill's Ratio
ITC	International Trade Centre
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	FAO/WHO Joint Meeting on Pesticide Residues
LDC	Least Developed Countries
LIFDC	Low-Income Food-Deficit Countries
LOQ	Limit of quantification
MRL(s)	Maximum Residue Limit(s)
NAFTA	The North American Free Trade Agreement
NOAEL	No-Observed-Adverse-Effect Level
NTMs	Non-Tariff-Measures
OECD	Organization for Economic Co-operation and Development
OLS	Ordinary Least Squares
PCPA	Pest Control Products Act
PMRA	Canada's Pest Management Regulatory Agency
POD	Point of departure
PRIMO	Pesticide residue intake model
SDGs	Sustainable Development Goals
SPS	Sanitary and Phytosanitary Measures
STCs	Specific Trade Concerns
STDF	Standards and Trade Development Facility
STMR	Supervised trial median residue
TBT	Technical Barriers to Trade
TRR	Total Radioactive Residue
TTC	Threshold of Toxicological Concern
USA	United States of America
US EPA	United States Environmental Protection Agency
WHO	World Health Organization
WTO	World Trade Organization

TERMINOLOGY

The definitions of some terms that are used for the purpose of this study are reported below.

Alignment with a Codex MRL: a national MRL is aligned with the Codex MRL when it has the same value as the Codex MRL.

Corresponding Codex MRL: an MRL for the same combination pesticide/commodity exists at Codex level, regardless of its value (does not imply alignment).

Corresponding national MRL: an MRL for the same combination pesticide/commodity exists at national level, regardless of its value (does not imply alignment).

Harmonization with Codex MRLs: it is used as a synonym of alignment with Codex MRLs.

MRL **higher** than Codex = less conservative/less strict than Codex.

MRL **lower** than Codex = more conservative/stricter than Codex.

EXECUTIVE SUMMARY

Through the joint FAO/WHO Codex Alimentarius Commission, governments establish science-based food standards. Codex standards aim at protecting consumer health and ensuring fair practices in international food trade. Among food standards, pesticide MRLs are the maximum concentration of a pesticide residue to be legally permitted in food commodities and animal feeds. Codex MRLs are based on solid, independent scientific advice jointly provided by FAO and WHO Scientific Advice Programme and are established following an inclusive and transparent consultative process that ensures that MRLs are set at the appropriate level to protect health and facilitate trade. Nonetheless, despite long-standing efforts towards international harmonization of allowable thresholds for pesticide residues in foods, differences in national implementation of MRLs continue to exist, raising questions with regard to their impact on trade. This publication assesses the international harmonization of national MRLs with Codex pesticide MRLs from different angles, using rice as a case study.

Part A of the publication examines the extent of harmonization of national MRLs with Codex rice pesticide MRLs in 19 major rice producing and trading economies and investigates its impact on trade. To define the level of harmonization, the analysis looks at the rate of adoption of Codex MRLs at national level, at the different MRL enforcement policies adopted by countries and at factors influencing harmonization levels, such as food classification. The analysis also considers the level of transparency in relation to pesticide MRL-related processes and policies. While it was found that many pesticide MRLs registered at national level do not have corresponding Codex MRLs, the analysis also revealed that the majority of Codex rice MRLs are not adopted at national level. The level of harmonization with Codex rice MRLs varies greatly across countries and regions. In general, most of the developing countries analysed are found to rely strongly on Codex MRLs, showing high levels of harmonization with Codex. For the rest of the sample, alignment with Codex tends to be quite low, usually below 25 percent. This is generally due to countries not adopting Codex MRLs and not deferring to them when national MRLs do not exist. Differences in commodity classification also represent an important obstacle towards achieving better harmonization. Overall, great transparency was observed in relation to public availability of national MRLs. Conversely, limited information was publicly available for policies related to MRL establishment and enforcement.

The effects of different levels of harmonization of pesticide MRLs on trade in rice are explored for a sub-sample of 17 economies, where data were available The economic analysis, conducted using a gravity model, found that MRLs can affect trade in two ways. MRLs stricter than Codex in the importing country are associated with relatively more rice imports, possibly reflecting high consumption rates combined with strong consumer food safety awareness in those countries. At the same time, if MRLs on the importer side are stricter than on the exporter side, this may lead to additional costs for exporters in order to comply with the importing country's applied standards and dampen their exports to the markets with stricter MRLs. These higher costs may impede exports by developing economies to the countries with stricter regulation.

Part B of the publication explores the reasons behind various levels of harmonization, investigating different aspects of risk assessment procedures and risk management policies that may lead to divergent MRLs. This part of the study focuses only on Australia, Canada, the European Union, Japan and the United States of America and is based on publicly available risk assessments and risk management documents. Considerable variation has emerged in how countries are aligned with the FAO/WHO Joint Meeting on Pesticide Residues (JMPR)/Codex process for the development and establishment of pesticide MRLs. In general, many of the observed differences in risk assessments do not seem to have a significant impact on the overall outcome of the pesticide safety evaluation. Some of the major differences in MRLs and residue definitions are due to the consideration of different data for the various countries/region and to inconsistency among the commodity descriptions in different countries. Automatic harmonization with Codex MRLs is not the norm because such practice is not embedded in national legislations. For MRLs not established at national level, the default practice is, in general, to set a default value, usually at the limit of quantification, or not to establish any tolerance level or MRL.

While Codex MRLs continue to be an important point of reference during national policy setting processes, the way in which they are considered varies among countries. Many developing countries continue to rely strongly on Codex MRLs when setting their national MRLs, or in the absence of national MRLs, while other countries seem to use Codex MRLs as a reference when carrying out their own risk assessments but do not necessarily harmonize with them.

The study shows that any changes towards further international alignment of pesticide MRLs for rice to facilitate trade will have to find a balance between the demand for strict food safety regulation on the importer side and the additional costs incurred on the exporter side.

Different steps could be taken by countries towards improving harmonization with Codex standards.
For example, Codex MRLs could be taken into consideration in the absence of national MRLs. For the optimal functioning of the Codex MRL standard-setting process, it would be important that countries proactively notify whenever they have reservations and are not in a position to adopt a newly established Codex MRL. Attention should also be given to developing country needs for a better and more active participation in the Codex standard-setting process. Findings of this analysis could be used to stimulate an international dialogue to improve harmonization.

PART A

LEVEL OF HARMONIZATION OF RICE PESTICIDE MAXIMUM RESIDUE LIMITS WITH CODEX AND IMPACT ON TRADE

PART A LEVEL OF HARMONIZATION OF RICE PESTICIDE MAXIMUM RESIDUE LIMITS WITH CODEX AND IMPACT ON TRADE

The value of agricultural and food exports grew almost threefold, in nominal terms, over the past decade, reaching USD 1.8 trillion in 2018[1], with exports of emerging economies and developing countries growing much faster than those of developed economies. The significant role of trade as an enabler for sustainable development is acknowledged in the Sustainable Development Goals (SDG targets 17.10, 17.11 and 17.12). Enabling agricultural and food producers in developing countries to access international markets is crucial for the economic growth of regions and nations (UN-DESA, 2018).

While the reduction in tariffs through bilateral and regional agreements and the result of the agreement establishing the WTO in 1995 contributed to the expansion of global trade, concerns have increasingly grown about the impact of Non-Tariff-Measures (NTMs) on agricultural and food exports. NTMs in agrifood markets are policy measures, other than ordinary customs tariffs, that can affect international trade by changing quantities traded or prices, or both (MAST, 2008). NTMs are used by governments with the aim to ensure food safety and to protect animal and plant health (Sanitary and Phytosanitary measures – SPS) or to regulate technical characteristics of the products, such as marketing standards (Technical Barriers to Trade – TBT). NTMs are particularly important for agricultural trade. Figure 1 shows that the Ad Valorem Equivalents (AVEs) of NTMs are much higher for agriculture than for other economic sectors, while for food products, in particular, AVEs of NTMs are on average almost three times higher than normal tariffs.

SPS measures are the most important NTMs concerning agricultural products, covering almost 20 percent of the world's total merchandise imports, with an average of six measures per product in each country, more than any other NTM category (UNCTAD and the World Bank, 2018).

1 Information retrieved from WTO data in March 2020.

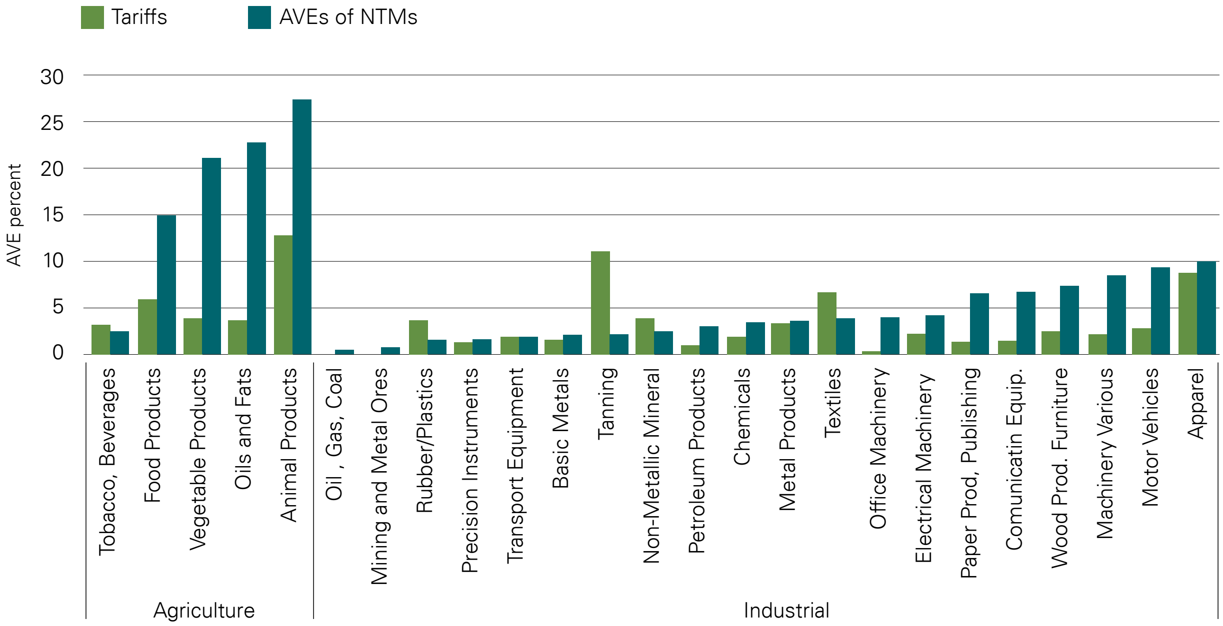
Trade and SPS measures are closely related. While governments apply food standards, for example, to ensure that food is safe and meets quality and labelling requirements, to access international markets and to be able to trade internationally, producers must be able to meet the food standards of their trading partners. As such, when countries apply different national requirements and specifications, trading food across borders may become difficult (FAO and WTO, 2017).

In this context, the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) sets out the framework for the application of international standards by governments to ensure the safety of internationally traded food products. The SPS Agreement states that no member should be prohibited from adopting or enforcing measures necessary for protecting human, animal or plant life or health. However, these measures should not be employed in a way that would "arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail […] or constitute a disguised restriction on international trade." The Agreement encourages governments to harmonize or base their national food safety measures on the international standards developed by the joint FAO/WHO Codex Alimentarius Commission (WTO, 1995)[2]. The SPS Agreement seeks to strike a balance between Members` rights to regulate legitimate objectives, such as food safety, while avoiding that such regulations be used as unnecessary barriers to international trade. It does so *inter alia* by strongly encouraging harmonization with Codex standards.

The Codex Alimentarius is a collection of international food standards, guidelines and codes of practice that have the dual objective of protecting consumer health

2 The SPS Agreement allows WTO Members to deviate from international standards where they wish to achieve a higher level of health protection than that reflected in international standards, so long as their measures are based on an appropriate assessment of risks and the level of health protection sought is consistent.

Figure 1: Tariffs and AVEs of NTMs, by economic sector



Source: UNCTAD and the World Bank, 2018

and facilitating trade through harmonized regulations (FAO and WHO, 2019).

Codex standards are based on sound science provided by independent international risk assessments carried out by the Joint FAO/WHO Scientific Advice Programme and cover the whole food safety spectrum, from microbiological to chemical issues, including, among many other provisions, pesticide MRLs in food[3].

Codex MRLs are established by the CCPR, through an open, participatory and transparent process that allows all member states to participate in the development of the standards. Once approved by the CCPR, MRLs are forwarded for adoption by the CAC. These two bodies carry out the risk management functions of the MRL-setting process. Their decisions are supported by the work of the FAO/WHO Joint Meeting on Pesticide Residues (JMPR), which is responsible for conducting the risk assessment and estimating MRLs. JMPR is an independent expert scientific panel, administered jointly by FAO and the WHO[4] (FAO and WHO, 2019).

This publication addresses the issue of harmonization of national pesticide MRLs with Codex pesticide MRLs from different angles, by taking rice as a case study. Part A identifies the level of harmonization in the main rice producing and trading countries and explores the possible effects on trade, while Part B investigates the reasons behind differing levels of harmonization.

The broader objective is to offer insights for decision-makers involved in setting standards and designing food policy at national and international level on the significance of harmonization of pesticide MRLs, but also on areas of improvements for the standard-setting international process and the ways that these standards are implemented at the national level.

3 Codex Pesticide Maximum Residue Limits (MRLs) are the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the CAC to be legally permitted in or on food commodities and animal feeds. MRLs are based on GAP data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable (definition from the Codex Procedural Manual, 27th ed., 2019).

4 JMPR evaluates the toxicology of pesticides and estimates health-based guidance values (HBGVs), including acceptable daily intake (ADI) and acute reference doses (ARfD). Based on this, and with data on registered use patterns, fate of residues, animal and plant metabolism, analytical methodology and residue data derived from supervised residue trials, JMPR proposes residue definitions and maximum residue limits for the pesticides in food and feed.

1 GLOBAL RICE MARKET

Rice is one of the most important food staples, playing an essential role in the food security of a large part of the global population. Rice is produced throughout the world, although most of the leading rice producers are located in Asia (Table 1). Although rice production has become increasingly important in other regions, namely in Africa, Asia remains the global rice hub, accounting for close to 90 percent of world production.

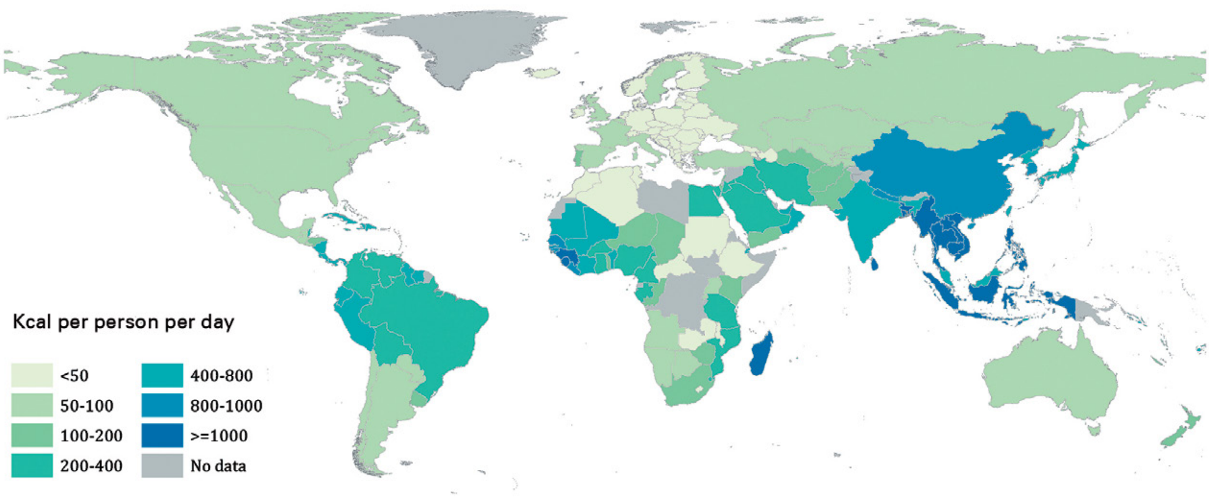
Rice is predominantly a food crop, with great significance in human diets, particularly in the Far East, western Africa, Latin America and Near East (Figure 2).

The global rice market is dominated by developing countries[5], where rice provides a livelihood for many poor farming households. Put together, developing countries account for more than 96 percent of global rice production and a similar share of world rice intake (Table 2).

Moving to international trade, although world trade in rice has grown significantly over time, rice remains a relatively thinly traded commodity, compared to other grains that are also used as feedstock for animal fodder and the food industry.[6] Rice volumes traded around the world represented 9.1 percent of global production in 2017-2019, compared with 23 percent for wheat and 14.2 percent for maize (FAO Markets and Trade Division, CCBS database). However, it is worth mentioning that rice plays a more significant role in the exports of developing countries than wheat or maize. According to calculations based on UN Comtrade data, rice exports of the developing countries reached USD 20.5 bn on average for the 2017-2019 period. The respective amounts for maize and wheat were USD 17.3 bn and USD 13.5 bn.

On the import side, the global rice market exhibits limited concentration, with the top 20 importers

Figure 2: Rice available for consumption (kcal/capita/day), average 2015-2017



Source: Based on FAOSTAT data

5 For this purpose, developing countries are classified according to the United Nations Statistics Division (UNSD) M49 classification.

6 A non-negligible share of rice trade is also conducted informally, through undocumented cross-border exchanges. These flows are not accounted for in the official trade data reported in this study.

Table 1: Top ten rice producers in the world (in metric tonnes – paddy)

COUNTRY	TOTAL AVERAGE (2016–2018)
WORLD	**767 904 795**
CHINA	211 966 333
INDIA	168 260 000
INDONESIA	81 180 120
BANGLADESH	53 672 728
VIET NAM	43 307 314
THAILAND	30 064 074
MYANMAR	25 571 946
PHILIPPINES	18 656 562
BRAZIL	11 612 049
PAKISTAN	10 750 577

Source: Own calculation based on FAOSTAT database

Table 2: World rice production and domestic use (milled equivalent), average 2017-2019

PRODUCTION Rice, milled equivalent	**TOTAL AVERAGE** (thousands of tonnes)	**GLOBAL SHARE** (%)
WORLD	502 060	**100.0**
Developed regions	16 473	**3.3**
Developing regions	485 587	**96.7**
Low-Income Food-Deficit Countries (LIFDC)	199 869	**39.8**
Least Developed Countries (LDC)	76 013	**15.1**
TOTAL DOMESTIC USE Includes use of rice as food, feed and other uses (namely seed, non-food industrial uses and post-harvest losses), milled equivalent	**TOTAL AVERAGE** (thousands of tonnes)	**GLOBAL SHARE** (%)
WORLD	499 754	**100.0**
Developed regions	17 948	**3.6**
Developing regions	481 807	**96.4**
Low-Income Food-Deficit Countries (LIFDC)	192 855	**38.6**
Least Developed Countries (LDC)	83 480	**16.7**

Source: FAO Markets and Trade Division, Country Cereal Balance Sheet (CCBS) database

accounting for 58.7 percent of the total value of imports in 2017-2019 (Table 3). China, Islamic Republic of Iran, Saudi Arabia and the European Union[7] (intra-European Union trade was excluded) were the top importers during that period in value terms.

In contrast to imports, on the export side there is strong concentration, with the top ten exporters accounting for 85 percent of total exports in 2017–2019. India, Thailand and Viet Nam were the top exporters during that period, accounting for more than 59 percent of the global value of rice exports (Table 4).

7 The analysis is based on data until 2019. All data referring to the European Union therefore includes the European Union and the United Kingdom of Great Britain and Northern Ireland.

Table 3: Top 20 rice importers in the world, average 2017-2019

	USD THOUSAND	SHARE (%)
WORLD	24 014 054	100.0
CHINA	1 560 409	6.5
EUROPEAN UNION	1 501 362	6.3
IRAN (ISLAMIC REPUBLIC OF)	1 490 884	6.2
SAUDI ARABIA	1 250 266	5.2
UNITED STATES OF AMERICA	926 850	3.9
BENIN	838 263	3.5
IRAQ	711 750	3.0
PHILIPPINES	675 016	2.8
UNITED ARAB EMIRATES	620 267	2.6
CÔTE D'IVOIRE	507 012	2.1
SOUTH AFRICA	498 415	2.1
JAPAN	446 925	1.9
INDONESIA	420 207	1.7
SENEGAL	415 707	1.7
BANGLADESH	415 394	1.7
MALAYSIA	401 454	1.7
MEXICO	377 120	1.6
CANADA	352 201	1.5
YEMEN	329 669	1.4
GHANA	305 429	1.3

Note: Intra-European Union trade is excluded

Source: Own calculations on the basis of data from UN Comtrade database

Table 4: Top ten rice exporters in the world, average 2017-2019

	USD THOUSAND	SHARE (%)
WORLD	24 292 576	100.0
INDIA	7 183 787	29.6
THAILAND	4 976 079	20.5
VIET NAM	2 233 323	9.2
UNITED STATES OF AMERICA	1 762 037	7.3
PAKISTAN	1 658 662	6.8
MYANMAR	847 689	3.5
CHINA	843 846	3.5
URUGUAY	416 769	1.7
UNITED ARAB EMIRATES	395 073	1.6
CAMBODIA	360 022	1.5

Source: Own calculations on the basis of data from UN Comtrade database

2 PESTICIDES USED ON RICE AND HARMONIZATION WITH CODEX MAXIMUM RESIDUE LIMITS

This chapter examines the extent of harmonization of national rice pesticide MRLs with Codex MRLs in 19 selected countries/region[8]. To define the level of harmonization, the analysis looks first at how many Codex MRLs have a corresponding MRL at national level; then examines the different MRL enforcement policies adopted by the covered countries/region and explores the factors influencing harmonization levels, such as food classification. The analysis also considers the level of transparency in relation to pesticide MRL processes and policies.

Key messages:

- The level of harmonization with Codex rice MRLs varies greatly across countries and regions. Many of the developing countries analysed strongly rely on Codex MRLs and the level of harmonization is very high or even total in some cases. For the rest of the countries analysed, alignment with Codex tends to be quite low, usually below 25 percent.
- Many Codex MRLs do not have corresponding MRLs at national level, and at the same time many MRLs registered at national level do not have corresponding Codex MRLs.
- Deferral to Codex MRLs when national MRLs do not exist is not a common practice – default limits are usually applied.
- Differences in commodity classification represent an important obstacle towards achieving better harmonization.
- While great transparency was observed in relation to public availability of national MRLs, limited information was available for policies related to MRL establishment and enforcement.

8 Australia, Bangladesh, Brazil, Cambodia, Canada, China, European Union, India, Indonesia, Islamic Republic of Iran, Japan, Myanmar, Pakistan, Philippines, Saudi Arabia, Thailand, United Arab Emirates, United States of America and Viet Nam.

2.1. DATA SOURCES AND METHODOLOGY

Codex pesticide MRLs

Codex MRLs for pesticide residues in specific food commodities are adopted annually by the CAC. Every year the CCPR, on the basis of scientific expert advice provided by JMPR, prepares a list of proposed MRLs and forwards it to the CAC for adoption. For the purpose of this study, values for Codex pesticide MRLs adopted between 1971 and 2018 were collected from the CCPR annual reports (FAO and WHO, 1971–2018a), while confirmation of their adoption was verified in the CAC annual reports (FAO and WHO, 1971–2018b).

National pesticide MRLs

National rice MRLs were taken from national resources that were publicly available online (online databases or official documents/regulations) as of the end of October 2019. When no resources could be found online, national authorities were contacted to seek their support in identifying the relevant documents. For all countries/region, national authorities were contacted to confirm the validity of the sources used in the study. A complete list of references to these sources is reported in Annex A-1. The Bryant Christie Global pesticide MRL database was also considered as a cross check (Bryant Christie Inc., 2019).

The MRL values have been taken as they appear in the national legislation (and/or national database when available). Residue definitions were not verified when comparing national MRLs with Codex MRLs. The issue of residue definitions is investigated in more detail in part B of the study (see Part B, chapter 1.1).

Compilation and data analysis

Codex pesticide MRLs for rice adopted between 1971 and 2018 were set as the reference values. National MRLs units were verified to be consistent with Codex MRLs units (i.e. mg/kg). Subsequently values from national MRLs were compared with Codex MRLs, and classified as (i) aligned with; (ii) higher than; or

(iii) lower than, the corresponding Codex MRL value. A database was created for the analysis of the data.

Food classification

Box 1. Major species of rice

There are only two major species of cultivated rice: *Oryza sativa* (OS), or Asian rice, and *Oryza glaberrima* (OG), or African rice. The rice varieties grown across the world are overwhelmingly OS, while cultivation of OG is confined to Africa. Even in that region, however, OG varieties are fast being replaced by OS, which produces much higher yields than OG, a characteristic that has prevailed over the special advantages afforded by OG, in the form of weed tolerance, pest resistance or fast growth (FAO, 2006).

Codex sets rice MRLs for *Oryza sativa* for three different processing levels: rice (with husk); rice husked (brown rice); and rice polished. Rice (with husk) is also regulated under "cereal grains"[9] when group MRLs are established. One Codex MRL is set for wild rice (*Zizania aquatica*).

To match national food commodity descriptions to the Codex food classification, reference was made to Codex-relevant documents: i) the draft revision of the Codex Classification of foods and animal feeds (FAO and WHO, 2006); ii) the Codex Draft and Proposed Draft Revision of the Classification of Food and Feed (Appendix VIII to XII) (FAO and WHO, 2017); and iii) the Codex Standard for Rice – CXS 198-1995 (FAO and WHO, 1995).

Rice classifications from the countries/region analysed were taken from their national legislations when available and confirmed with the countries/region to match them properly with Codex rice classification. Some countries (i.e. Australia, Canada) also set MRLs for generic groups of food (such as "All other foods"). When available, and in the absence of specific rice MRLs, they have been used as a match for any type of rice for which a Codex MRL existed. A detailed matching of rice classification across Codex and countries/region is reported in Annex A-2.

2.2. CODEX MAXIMUM RESIDUE LIMITS FOR RICE

There were 82 rice pesticide MRLs adopted by Codex between 1971 and 2018.[10, 11, 12, 13] These refer to five different Codex commodities: three of them denote different levels of processing of common rice (rice; rice husked and rice polished), a fourth one is a different rice variety (wild rice), and the last one is a commodity group (cereal grains) that includes all cereals, including rice and wild rice[14]. The majority of Codex rice MRLs are set for "rice (with husk)", as shown in Table 5, followed by rice husked and rice polished.[15]

2.3. NATIONAL MAXIMUM RESIDUE LIMITS FOR RICE

At national level the total number of MRLs established for rice varies widely from one country to another, as presented in Figure 3, where the highest number is observed in the European Union (486 rice MRLs), and the lowest number is found in Cambodia (11 rice MRLs).

In general, very few national rice MRLs have a corresponding Codex rice MRL, for the same combinations of pesticide/commodity, as presented in Figure 4.

In about half of the countries/region analysed, less than half of national rice MRLs have a corresponding Codex rice MRL (Australia, Brazil, Cambodia, China, European Union, India, Islamic Republic of Iran, Japan, Philippines, and United States of America). In a handful of other countries (Canada, Indonesia, Saudi Arabia, Thailand and Viet Nam) most national MRLs do have corresponding Codex MRLs, while in four countries (Bangladesh, Myanmar, Pakistan and United Arab Emirates) all national MRLs have a corresponding Codex MRLs. The high (or sometimes complete) correspondence

9 Cereal grains comprise rice (with husk) of *Oryza sativa* and *Oryza glaberrima*, and also wild rice.

10 For a more detailed description of each Codex rice commodity, please refer to Annex A-2.

11 Although Codex provides MRLs for both food commodities and feed, this study only focuses on food commodities. Feed and rice by-product pesticide MRLs were excluded from the analysis (these are: rice bran, rice hulls, and rice straw and fodder).

12 Codex MRLs adopted in 2019 were excluded from the analysis based on the consideration that it might take some time for countries to receive and eventually adopt new Codex MRLs in their regulations.

13 The Codex MRLs analysed in the study can be retrieved on the Codex Pesticides Database, at (please refer only to MRLs adopted between 1971 and 2018):

Rice: http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities-detail/en/?lang=en&c_id=158

Rice husked: http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities-detail/en/?lang=en&c_id=78

Rice polished: http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities-detail/en/?lang=en&c_id=75

Cereal grains: http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities-detail/en/?lang=en&c_id=164

Wild rice http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities-detail/en/?lang=en&c_id=653

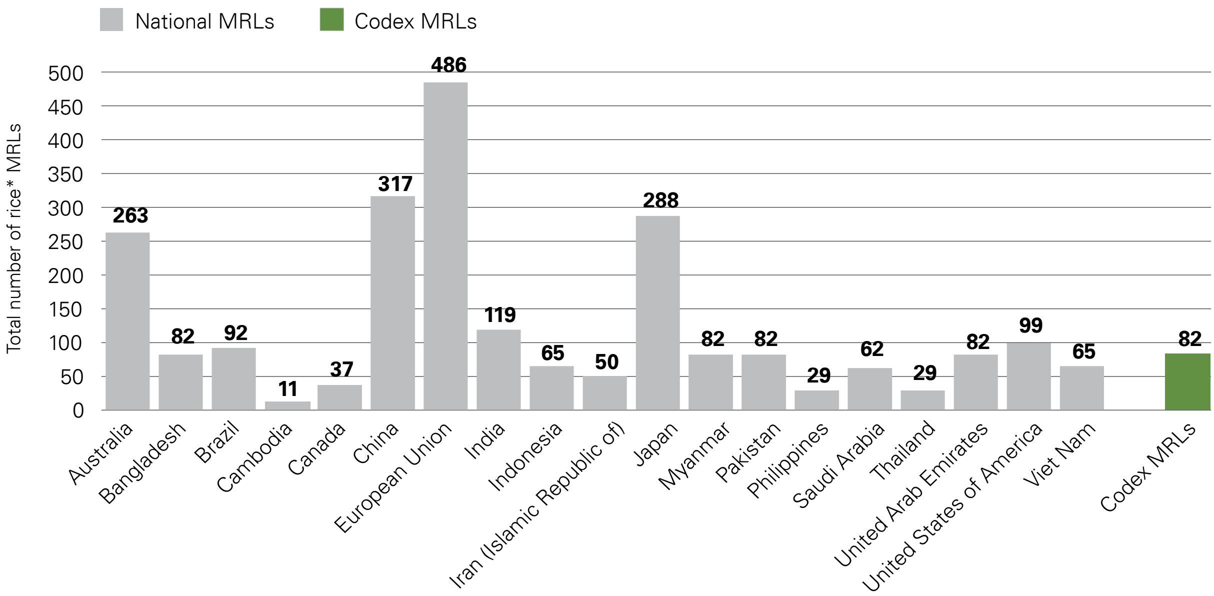
14 Codex MRLs can be set for single commodities or for a group of commodities (group MRL).

15 For the matching with HS codes and share of trade, please refer to Annex A-3.

Table 5: Codex MRLs for rice

CODEX NAME	CODEX CODE	TOTAL # OF MRLS
Rice *(defined as "rice with husks that remain attached to kernels even after threshing: kernels with husks")*	GC 0649	**25**
Rice husked	CM 0649	**18**
Rice polished	CM 1205	**13**
Wild rice	GC 0655	**1**
Cereal grains (= rice; wild rice)	GC 0080	**25**
		Total: 82

Figure 3: Total number of national MRLs established for rice in the 19 countries/region analysed



** Rice refers to any type of rice regulated at national level (rice with husk, rice husked, rice polished and cereal grains).*

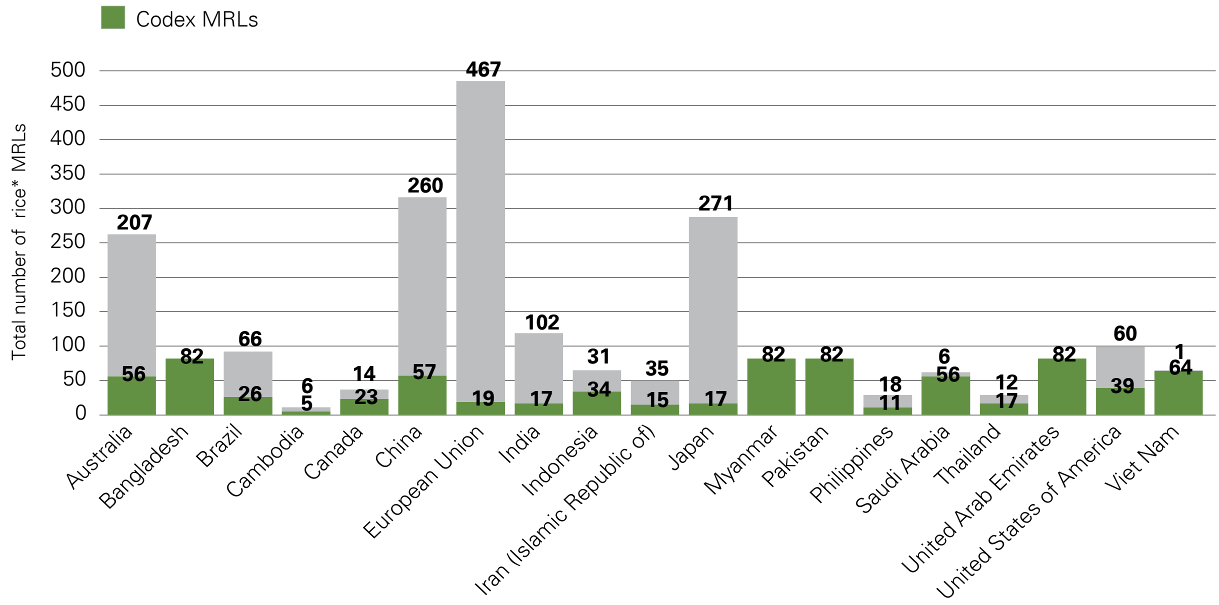
between national and Codex MRLs is usually explained by national policies of deferring to Codex MRLs: either automatically, for all MRLs established at national level, or only in the absence of national MRLs (national policies are further analysed in section 2.4.3).

To gain a better idea of the type of pesticides not regulated at Codex level (and to verify if this could be due to toxicity concerns), pesticides that did not have a Codex MRL for rice were screened to check if they had Codex MRLs for other commodities. It was found that on average around one third of these pesticides did have Codex MRLs for other commodities, for all countries/region analysed (see Figure 5).

Non-existence of MRLs for these pesticides at Codex level may hint at toxicity concerns, but this was not explored further. Limited capacities/resources of Codex to develop new MRLs is another reason that could play a role here. Even more so when pesticides have been assessed at Codex level but not for all commodities of interest, such as for rice in this case. The absence of MRLs for use in traded products is a significant concern that has been brought to the attention of the CAC recently. With food safety being increasingly recognized as a priority issue in many countries, the request for scientific advice has also increased. However, despite the significant efforts that are being made by FAO/WHO to streamline procedures and to manage the process of scientific review as efficiently as possible, the number of requests for evaluation by the JMPR of new compounds and new uses (as well as for periodic re-evaluations of existing MRLs) far exceeds the current capacity.

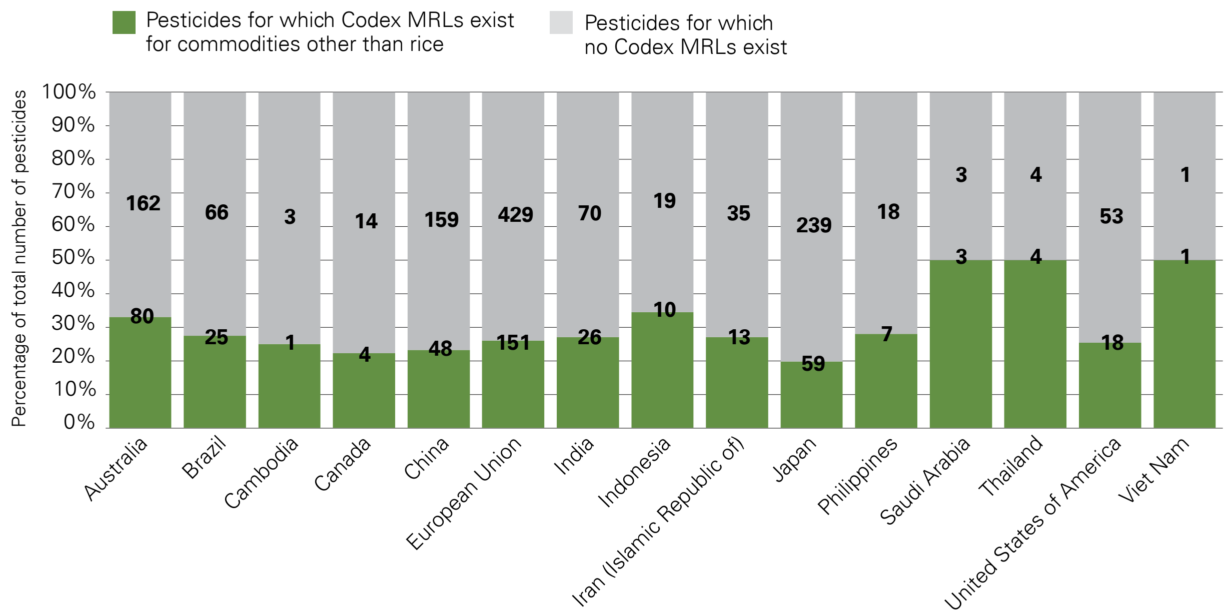
There could be many other reasons behind the low number of Codex rice MRLs compared with national

Figure 4: Share of national rice MRLs for which a corresponding Codex MRL exists, in the 19 countries/region analysed



** Rice refers to any type of rice regulated at national level (rice with husk, rice husked, rice polished and cereal grains).*

Figure 5: Share of pesticides, with national rice MRLs but not Codex MRLs, for which a Codex MRL exists for commodities other than rice



Note 1: Bangladesh, Myanmar, Pakistan and the United Arab Emirates were excluded from this analysis as all their national MRLs have corresponding Codex MRLs.

Note 2: Labels show the total number of MRLs.

rice MRLs, nevertheless further analysis of this was outside the scope of the current study.

2.4. CODEX MAXIMUM RESIDUE LIMITS (MRLs): EXISTENCE OF CORRESPONDING NATIONAL MRLs AND THEIR LEVEL OF HARMONIZATION

2.4.1. Codex MRLs and existence of corresponding MRLs at national level

The level of alignment with Codex MRLs varies greatly across the countries/region analysed, as shown in Figure 6. National MRLs that are aligned with Codex MRLs are marked in dark green. Higher and lower values than Codex are reported light green and red, respectively. Figure 6 also indicates the number of missing MRLs for each country as compared to total Codex MRLs (grey section of the bars). For most countries/region (11 out of 19), more than half of Codex rice MRLs do not have a corresponding MRL at national level.

There might be many reasons behind the low number of Codex MRLs for which corresponding MRLs exist at national level. For example, some economies may not have procedures for establishing import MRLs, or may have policies that do not allow for consideration of foreign Good Agricultural Practices (GAPs) when there is a domestic GAP in place. There might also be a tendency for countries to adopt Codex MRLs only for export purposes and not for import. As explored in Part B of the study, missing national MRLs could partly be explained by the differences in the time of MRL adoption at Codex and at national level. For some markets, there may not be resources or routine procedures in place to review national MRLs at the time Codex adopts new ones. This difference in time may also impact the level of alignment with Codex MRLs for markets that set MRLs prior to Codex MRL establishment. The time difference may entail changes in the scientific data packages evaluated by the different authorities (e.g. different GAPs reflecting different pests and diseases, different pesticide labels, availability of different studies, etc.) leading to different results, which could explain the low level of alignment. However, time difference may not be the only reason. Rice classification seems also to play an important role in terms of establishment of national MRLs and their alignment with Codex MRLs, as explained below.

2.4.2. Rice classification and processing level of rice

The classification of rice was very heterogeneous across the countries/region analysed and Codex. During the analysis difficulties emerged regarding how to match national MRLs to codex MRLs (see Annex A-2). Sometimes the same name referred to different stages of processing of rice in different countries/region (e.g. "rice" in Codex refers to rice with husk; in the European Union and in Japan it refers to rice husked; in Canada and Brazil it refers to both rice husked and unhusked). Differences in rice classifications can also be determined by national consumption patterns (i.e. the type of rice most commonly consumed in the country and the way rice is distributed and sampled), which may be shaped by consumer preferences or habits. For example, in Japan, rice is kept in husked form (brown) until the near end of the marketing chain. That is, rice is polished just before reaching the consumer as a way to ensure that the product remains fresh and of higher quality.

To study if these differences could affect the number of national MRLs and their level of harmonization with Codex MRLs, the 82 Codex rice MRLs were classified into three main categories, reflecting different processing levels of rice[16], and analysed by category:

- U - Rice unprocessed: which includes rice (with husk); wild rice; and cereal grains (51 Codex MRLs)
- H - Rice husked (18 Codex MRLs)
- P - Rice polished (13 Codex MRLs)

Figure 7 demonstrates that for some countries/region the number of national MRLs corresponding to Codex MRLs, and their compliance with Codex MRLs, is determined by these processing categories.

For the European Union and Japan, for example, the number of Codex rice MRLs for which corresponding national MRLs have been established is very low, covering 23 percent and 21 percent of all Codex rice MRLs, respectively (see Figure 6). However, this figure can be partially explained by the fact that the establishment of MRLs for unprocessed rice (U) and polished rice (P) is almost inexistent in these country and region. When looking only at husked rice (H), the number of Codex MRLs for

16 For more details on each Codex rice commodity, refer to Annex A-2.

Figure 6: 82 Codex rice MRLs: existence of corresponding MRLs at national level and level of alignment with Codex in the 19 countries/region analysed

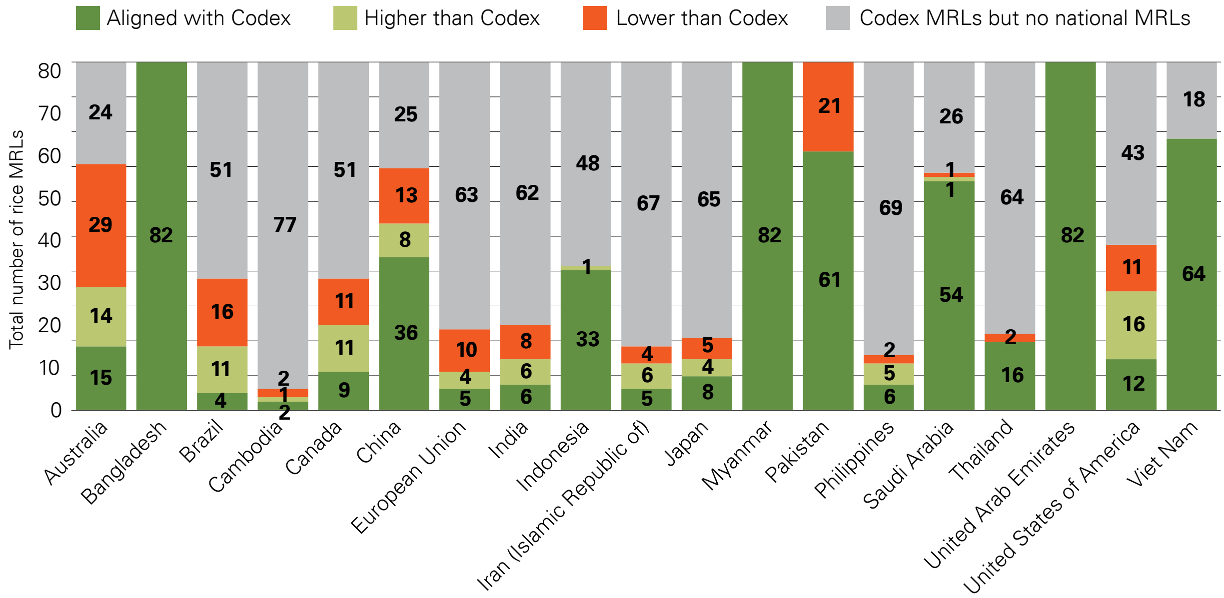
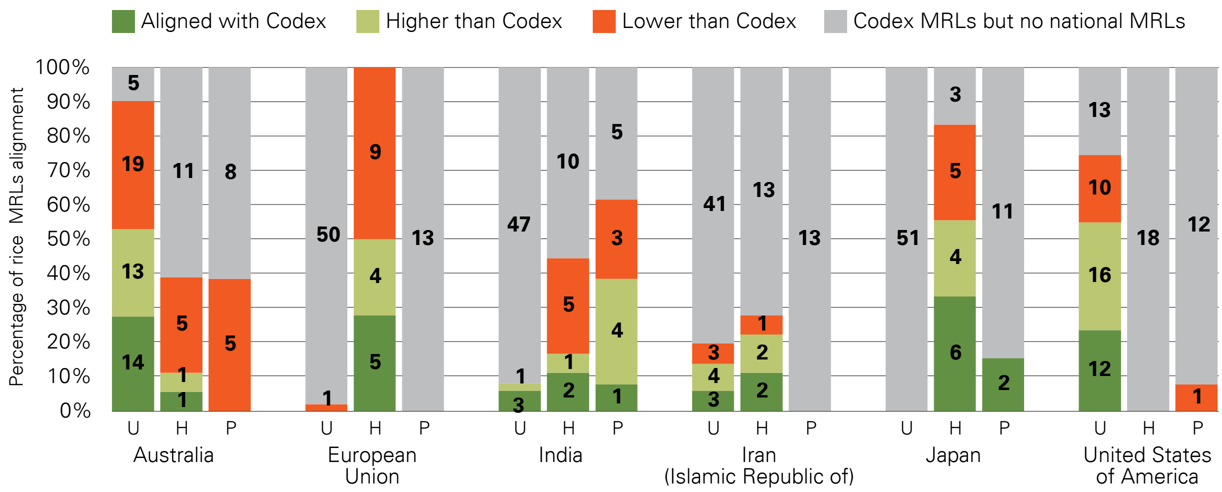


Figure 7: Level of alignment with Codex rice MRLs by processing level categories: Rice unprocessed (U), Rice husked (H), and Rice polished (P)[17]



U: Rice unprocessed: including rice (with husk), wild rice and cereal grains
H: Rice husked
P: Rice polished

Note: Labels show the actual number of MRLs.

which corresponding national MRLs exist rises to 100 percent and 83 percent, respectively. The same is true for Australia and the United States, but in this case, unprocessed rice (U) is the type of rice for which higher rates are reported of national MRLs corresponding to Codex MRLs.

As further described in Part B, to reduce the potential for confusion over multiple MRLs for different forms of a single pesticide/crop combination, consistency in commodity classification across countries and Codex should be improved where possible.

17 The countries that did not show marked changes were not reported in the graph.

Table 6: Existence of national MRLs and enforcement of Codex MRLs in the absence of national MRLs

COUNTRY/REGION	ESTABLISHMENT OF NATIONAL MRLS	ENFORCEMENT PROCEDURE FOLLOWED IN THE ABSENCE OF NATIONAL MRLS	PROCEDURE REPORTED IN NAT. LEGISLATION
THAILAND	Yes	**Defer to Codex**	Yes [18]
BRAZIL, CAMBODIA, INDONESIA	Yes	**Defer to Codex**	**No**
BANGLADESH, MYANMAR	No	**Defer to Codex**	**No**
SAUDI ARABIA	Yes	**Defer to Codex first -** then MRLs of the European Union or United States of America	**No**
UNITED ARAB EMIRATES	No	**Defer to Codex first -** then MRLs of the European Union, then default limit at: 0.01 ppm	Yes [19]
PAKISTAN	No	Defer to the lowest MRL among Codex, European Union and United States of America	**No**
EUROPEAN UNION, JAPAN, INDIA	Yes	Apply a default limit at: **0.01 ppm**	Yes [20]
IRAN (ISLAMIC REPUBLIC OF)	Yes	Apply a default limit at: **0.05 ppm**	**No**
CANADA	Yes	Apply a default limit at: **0.1 ppm**	Yes [21]
AUSTRALIA	Yes	Apply zero tolerance	Yes [22]
UNITED STATES OF AMERICA	Yes	The crop is considered adulterated and may be seized	Yes [23]
PHILIPPINES	Yes	Apply zero tolerance	**No**
CHINA, VIET NAM	Yes	*Not confirmed – it was assumed that in the absence of an official procedure, zero tolerance applies*	**No**

Source: Based on procedures outlined in national legislations of the countries/region analysed and/or confirmed by the national authorities

18 See Annex A-1: Thai Agricultural Standard TAS 9002-2016 point 3.4

19 See Annex A-1: UAE.S MRL 1: 2017 "Maximum Residue Limits (MRLs) for Pesticides in Agricultural and Food Products" – point 3

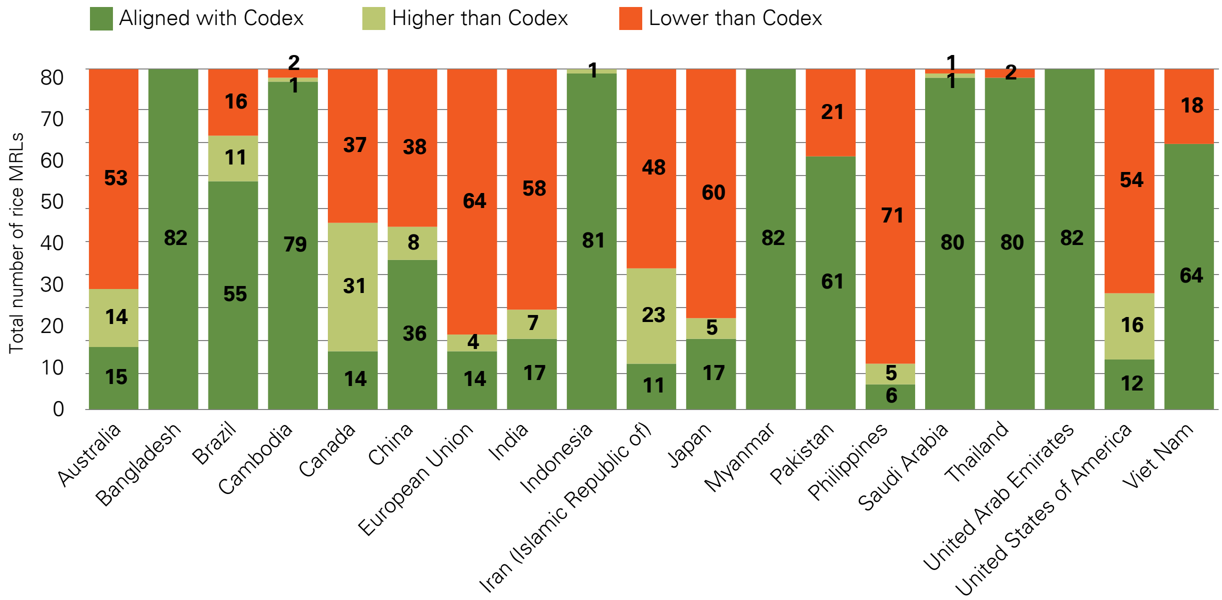
20 Europe - See: (European Union, 2005)
Japan - See (Japan, Ministry of Health, Labour and Welfare, 2006)
India - See Annex A-1: The Gazette of India: Gazette Notification on Food Safety and Standards (Contaminants, Toxins and Residues) - Part III-Sec.4 (note)

21 See: (Canada, 2019) under DIVISION 15 Adulteration of Food B.15.002

22 See: (FSANZ, 2016)

23 See: (United States Environmental Protection Agency (EPA), 2018). Pesticide Registration Manual, Chapter 11 - Tolerance Petitions, under "Tolerances and Exemptions from Tolerances": "If residues of a pesticide exceed the established tolerance, or no tolerance has been established, the crop is considered adulterated and may be seized by the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), or a state enforcement agency." Most pesticides analysed for enforcement purposes can be quantified at LOQ of 0.01 mg/kg, hence in practice, the USA enforcement outcomes are similar to those in countries/region that apply default values at 0.01 mg/kg.

Figure 8: Alignment with the 82 rice Codex MRLs in the 19 countries/region analysed [24]



2.4.3. Codex MRLs missing at national level

As mentioned earlier, the analysis revealed that there are many Codex MRLs that are missing at the national level (Figure 6, grey section of the bars). For most countries/region, more than half of Codex rice MRLs do not have a corresponding MRL at the national level. It was found that in the absence of national MRLs, different countries/region follow different enforcement procedures. Some countries automatically defer to Codex MRLs, others use default limits, mostly at the limit of quantification (LOQ), or apply zero tolerance. Table 6 reports the different enforcement procedures followed by each country.

The differences in the enforcement procedures followed in the absence of national MRLs can also have implications for the ability of some countries, in particular developing countries, to export. For example, as further discussed in Part B of the study, in Australia, Canada, the European Union, Japan and the United States of America when a national MRL is missing, an application can be made to have an MRL established. However, the process can be complex and lengthy (from a few months up to six years), depending on the country. This affects exporting partners negatively, especially in developing countries where they might have neither the financial nor the technical means to submit such an application.

2.4.4. Harmonization with Codex MRLs

Figure 8 reports the level of alignment with Codex MRLs after applying national policies for missing MRL values (e.g. deferral to Codex MRLs, LOQ, or zero tolerance). National MRLs that are aligned with Codex MRLs are marked in dark green. Higher and lower values than Codex are reported in light green and red, respectively. The level of alignment improves significantly for those countries that defer to Codex MRLs, while fewer changes are noted for the other countries/region. Overall, for more than half of the countries analysed, the level of alignment with Codex is higher than 50 percent, with eight countries showing complete or nearly complete alignment. The remaining seven countries/region present a much lower level of alignment, usually below 25 percent.

The countries presenting stronger alignment with Codex MRLs (dark green sections of the bars) are Bangladesh, Brazil, Cambodia, Indonesia, Myanmar, Pakistan, Saudi Arabia, Thailand, the United Arab Emirates and Viet Nam.

24 All national values have been taken from national databases, legislation or official documents. When national MRLs were missing, the national procedures reported in chapter 1.3.3. were applied (please refer to Table 6 for a more detailed overview of national MRL adoption procedures).

Because most of the countries do not automatically defer to Codex MRLs in the absence of national MRLs, differences in the MRL levels among trading partners could create obstacles to trade.

As further explored in chapter 3, stricter MRLs in importing than in exporting markets may entail higher costs for the exporters to comply with the importing market MRLs.

2.5. MOST USED PESTICIDES ON RICE IN MAJOR RICE PRODUCING COUNTRIES

Numerous pesticides are used in rice production. Codex has 82 rice MRLs for 67 different pesticides. For each country/region analysed, the total number of national MRLs ranged from 11 to 486. The analysis did not characterize the pesticides in terms of type, use and sales volumes. However, in an attempt to verify whether Codex MRLs cover the pesticides most used in developing countries, national authorities of ten developing countries were approached, through the FAO country offices, to obtain an indication of the pesticides most used on rice (in terms of volumes) in their countries. The information was self-reported by the countries with no uniform criteria for the collection of the data, so it is to be considered as indicative only. Nevertheless, it was noted that for the majority of these "most used" pesticides, very few Codex MRLs exist. Interestingly, the "most used" pesticides with no Codex MRLs, in most cases do not have national MRLs either. This might be because developing countries do not have enough capacity to assess MRLs at national level and strongly rely on Codex MRLs for the establishment of their national MRLs. This indicates that Codex MRLs remain important as many countries continue to make use of and rely on them. Codex MRLs are therefore crucial not only for trade, but also for ensuring food safety in the domestic markets of many developing countries.

2.6. TRANSPARENCY

The study implicitly ascertained the level of transparency offered by countries in relation to pesticide MRLs, particularly in making relevant information publicly available. This is particularly important as transparency helps trading partners to become aware of the requirements they need to meet when engaging in international trade.

Access to national MRLs

National MRLs of most countries/region analysed were publicly accessible online (see Annex A-1: *Sources of national pesticide MRLs for the 19 countries/region analysed*). Out of 19 countries/region, only three did not have publicly available information, because they do not establish national MRLs: Bangladesh, Myanmar and Pakistan. For most countries/region (11 out of 19) the information was available in English. National MRL databases were available only in the national language in Brazil, China, the Islamic Republic of Iran, Thailand and the United Arab Emirates. Some countries present their legislation in online documents, others in online databases with search functions, and some others in online databases without search functions. Most databases proved to be user-friendly and easy to navigate.

MRLs-related national regulations or policies

MRL-related national regulations or policies on procedures followed in the absence of national MRLs were more difficult to find and access. Out of 19 countries/region, nine did not have these procedures reported in their national legislations (See Table 6 and Part B of the study) and national authorities were contacted to obtain this information. In some cases, national authorities reacted promptly, providing all necessary information. In other cases, obtaining such information was a long and difficult process that took several weeks.

Documents on risk assessment methodologies, risk management considerations and MRL adoption procedures were not always easy to locate: this matter is addressed in detail in Part B of the study for five major markets (Australia, Canada, Japan, the European Union and the United States of America).

Countries' positions towards the development and adoption of new Codex MRLs

A low level of transparency was found on countries' positions towards the development and adoption of new Codex MRLs. By going through the annual CCPR and CAC reports, there appear to be limited notifications by countries on their reservations on new Codex MRLs, during the Codex standard development process. Among the countries/region analysed, the European Union seems to be the only Codex member openly raising reservations and communicating to Codex when not in a position to adopt a new Codex MRL, providing scientific reasons for the reservations and consequent non-alignment (see also Part B of the study).

2.7. CONCLUDING REMARKS

Alignment with Codex MRLs

The study unveiled different outcomes. On the one hand the analysis showed that many pesticide MRLs (around 2/3) registered at national level do not have corresponding Codex MRLs (see Figure 4). This would call for increased resources and capacities for Codex and the scientific advice programme for the development of new MRLs. On the other hand, the analysis also revealed that the majority of Codex rice MRLs do not have a corresponding MRL at national level (see Figure 6), with several markets covering less than 25 percent of Codex MRLs. This raises the concern that increasing numbers of countries are establishing their own national standards, not harmonized with Codex, thus undermining the relevance of Codex standards in international trade.

A similar trend was noted in the level of alignment with Codex MRLs, which varies greatly across the countries/region analysed. For developing countries, the alignment is very high or total in some cases. For the other countries, alignment tends to be quite low, usually lower than 25 percent.

It seems that low levels of alignment are usually due to the lack of national MRLs, non-deferral to Codex MRLs in the absence of national MRLs and differences in food classification. More specific insights on the reasons behind limited harmonization are given in Part B of the study.

Absence of national MRLs and reference to Codex MRLs

Deferral to Codex MRLs when national MRLs do not exist is not a common practice. For pesticide MRLs that are not registered under national legislations, different countries apply different approaches. With few exceptions, the developing countries analysed tend to defer to Codex MRLs, either entirely, or in combination with regional or national MRLs of major importing markets. This also explains the findings presented above, namely that most of the developing countries have better alignment with Codex MRLs. Developed countries showed different approaches. While some apply default limits, usually at the limit of quantification, others apply zero tolerance.

Rice classification and processing level of rice

It was also found that differences in rice classification (or level of processing of rice) have a significant impact on the level of harmonization with Codex MRLs (see Figure 7). Because inconsistency in food classification across countries and Codex is common to many commodities (see also Part B of the study) it is of the utmost importance that harmonization of food classification be given consideration at international level. In the specific case of rice for example, Codex MRLs could be established for all different processing levels of rice, rather than for a single one, so as to accommodate different classifications by different countries – see also Part B of the study.

Transparency

The study also gauged the degree of transparency of various countries regarding pesticide MRLs, especially regarding public availability of important information. Great transparency was observed in relation to the public availability of national MRLs, which for most countries were easily accessible online. MRL-related national regulations or policies on procedures followed in the absence of national MRLs were more difficult to find and access – only few countries report these procedures in their national legislations (See Table 6 and Part B) and obtaining them proved difficult in some cases.

3 WHAT DOES THIS MEAN FOR TRADE?

Sanitary and phytosanitary (SPS) measures have been used by governments for centuries in their efforts to ensure that food is safe for their populations and that public health is protected. However, when standards, including pesticide MRLs, are not harmonized among trading partners, this can represent major obstacles and impede the trade of food across borders. This chapter explores the possible effects of the limited harmonization of pesticide MRLs among countries, using rice as a case study.

Key messages:

- Many of the main rice importing countries have stricter MRLs on pesticides used in the production of rice than those established by Codex. Almost half of the main exporting countries also have MRLs stricter than Codex, while the rest of the countries are aligned with Codex.
- MRLs stricter than Codex in the importing country are associated with relatively more rice imports, possibly reflecting high import demand combined with strong consumer awareness of food safety in these countries.
- If MRLs on the importer side are stricter than on the exporter side, this may lead to additional costs for exporters in order to comply with the importing country's standards. These higher costs may impede the exports of developing countries to the countries with stricter regulations.

3.1 FOOD SAFETY STANDARDS AND TRADE

Ensuring that food is safe to be consumed has been among the important tasks that populations have entrusted on their governments. Throughout history, many countries have independently developed food laws and regulations, and often found different solutions to ensure that food was safe and met the quality expectations of consumers. However, the differences between national requirements and regulations can make it difficult to move food across country borders. At the same time, consumers have become increasingly concerned about food-related risks, including health hazards due to pesticide residues, other contaminants and unsafe food additives (FAO and WTO, 2017).

3.1.1 High consumer awareness of food safety in importing markets

Wealthier countries with more information about food safety risks tend to require more stringent food safety standards for both domestically produced and imported food products and are generally willing to pay more for higher levels of food safety (Buzby, 2001).

The growth of exports from developing countries in particular has been accompanied by increasing attention to food safety standards in many major importing markets (Maertens and Swinnen, 2009), with the rising consumer awareness often translated into more stringent public food safety standards. Even stricter private food safety standards imposed by large trading and retailing companies have emerged (Maertens and Swinnen, 2009; Unnevehr, 2015).

For example, 54 percent of 236 surveyed households in Georgia, the United States of America, in the early 2000s, perceived pesticide residues to be a serious or extremely serious food safety threat (Rimal *et al.*, 2001). Food safety concerns in high-income markets also apply to imported products. Between 31 and 43 percent of 387 respondents to a survey in Japan in 2002 perceived imported rice from the United States of America, Australia and China as being less safe than domestically produced rice, whereas only 7 to 16 percent perceived the rice imported from the three countries to be safer or equally safe compared to domestically produced rice (Peterson and Yoshida, 2004).

MRLs are often stricter in high-income countries than in emerging economies and developing countries (e.g. Xiong and Beghin, 2014 and Figure 8), while most food safety standards in export-oriented developing countries were initially imposed to meet the requirements in the major import markets. This process started in the 1970s and 1980s with public standards and continued with the emergence of private sector standards applied by supermarkets, fast food chains and large processors (Reardon *et al.*, 2019).

With rising incomes, increased education and changing lifestyles, consumer demand for food safety has gained momentum also in emerging economies and developing countries (Ortega and Tschirley, 2017; Unnevehr, 2015). Food safety was, for example, identified as the most important sustainability attribute for rice consumers in Nigeria (Okpiaifo *et al.*, 2020) and became a societal issue that received considerable attention in Viet Nam (Pham and Dinh, 2020). The intention of the African Union to establish an African Food Safety Agency (AFSA) is another relevant example. The Agency is expected to coordinate and provide leadership and support to meet the mounting need for enhanced food safety in the continent. That the food traded within the African continent is safe and satisfies the increasing consumer awareness is imperative considering Africa's push towards its integration agenda, notably through the African Continental Free Trade Area (AfCFTA). The establishment of the AfCFTA is expected to significantly promote intra-regional trade in agrifood products, which is projected to be 20-30 percent higher in 2040, compared to without the AfCFTA.[25]

Consumers often prefer domestic over imported food products when both options are available (Nuttavuthisit and Thøgersen, 2019). However, in developing countries this can sometimes co-exist with a preference for food products imported from developed countries, due to higher trust in the standards and certification schemes in these countries (Nuttavuthisit and Thøgersen, 2019).

For example, consumers of organic food in Thailand are found to prefer domestic production in general. At the same time, they also show high trust in imported products from developed countries, which are believed to adhere to higher standards and credible certification and control systems. Although similar products from developing countries are cheaper, credible institutions allow developed countries to compete successfully in the Thai market (Nuttavuthisit and Thøgersen, 2019). In another study, consumers in Beijing had a high demand for food safety assurance in beef products and were willing to pay more for Australian beef, which is believed to be safer than domestic (Chinese) beef or that from the United States of America (Ortega *et al.*, 2016).

3.1.2 Costs to comply with food safety standards in export markets

If food safety regulations in importing countries are stricter than in the exporting countries, it implies higher costs for the exporting country to meet the more stringent standards and certification requirements of the importing country. The costs for the stricter food safety management in the exporting country are incurred at all levels of the supply chain and comprise investment costs as well as expenses for improved monitoring and certification. The acquisition of new equipment for reducing risks and monitoring outcomes, the establishment of management and quality control systems, and capacity development cause extra costs (Unnevehr, 2015). Due to often weak rule enforcement and a typically large informal economy in agriculture and food supply sectors, in particular in developing countries, a number of challenges arise also from daily risk management (Pham and Dinh, 2020).

High investment costs can imply a heavier burden on small firms and farms than on larger enterprises, given their small capital and often limited access to credit and other financial resources. However, the evidence on whether higher food safety standards have led to the exclusion of smallholders from markets is mixed. Higher costs are incurred during the adaptation phase to stricter standards, but the overall impact of food safety compliance on livelihoods in developing countries tends to be positive due to declining transaction costs over time, better employment opportunities, higher wages and longer employment periods for low income workers in export supply chains (Unnevehr, 2015).

3.1.3 Effects of SPS measures and MRLs on trade

The high demand for food safety and related standards in importing markets and the additional costs incurred by exporting countries to comply with these standards,

25 https://www.uneca.org/stories/african-trade-agreement-catalyst-growth

have repeatedly featured in the empirical literature on the effects of food standards on trade.

Reflecting the strong demand for food safety, accompanied by a greater willingness to pay, food standards, including MRLs, tend to be stricter in high-income markets. A higher public and sometimes private regulatory stringency, including its enforcement in these markets, increases trust in domestically produced and imported food products and may increase effective demand by relieving consumer concerns about product quality and safety (Thilmany and Barrett, 1997). Regulatory distance between trading partners often reflects strong consumer preferences for stricter standards in one country and does not necessarily translate into a barrier to trade (Drogué and DeMaria, 2012). Without the use of food safety standards in international trade, trust in imported products would cease, which would likely imply reduced imports, in particular from countries with a real or perceived higher risk of pesticide contamination.

The Spanish horticultural sector, for example, suffered from several crises affecting consumer perception and demand in importing countries. In the "pepper crisis" in 2006, a residue of a non-authorized pesticide was discovered in one batch of Spanish sweet peppers exported to Germany. This led to a significant decline in the exports of sweet peppers from Spain between 2006 and 2007. The image loss spilled also over to other Spanish horticultural products as well as to horticultural exports from third countries, including the Netherlands (Serrano-Arcos, Sánchez-Fernández and Pérez-Mesa, 2019).

Food safety standards and MRLs can also hinder trade due to the higher costs implied for producers, processors and traders to comply with the standards. Producers may need to adapt production practices to meet the standards and also obtain certification. Inspection and testing procedures at customs points may prolong delivery time or result in rejection of particular shipments if standards are not met. The higher costs are also transmitted as higher product prices, which may lower demand on the importing side.

The interaction of these two effects, the demand-enhancing and the trade cost-raising, determines if MRLs facilitate or hinder trade overall (Xiong and Beghin, 2014).

Many analyses have been conducted on the effects of NTMs, SPS measures and MRLs on trade, often with mixed results. This is not only due to the opposite effects that these various measures can have, but the results also depend on many other factors, including the selection of countries, products and measures, the studies considered and the methodology applied in conducting the analyses (Santeramo and Lamonaca, 2019).

Also meta-analyses, which summarize the results of a multitude of similar studies, come to different conclusions. A meta-analysis of 27 papers in 2012, for example, found that many SPS regulations tend to impede agricultural and food trade flows from developing country exporters to high-income importing markets (Li and Beghin, 2012). A qualitative review of the literature conducted in 2017 concluded that studies predominantly report negative effects of MRL stringency on trade flows (Grant and Arita, 2017). However, the most recent and comprehensive meta-analysis, using statistical methods, and considering 62 papers on the topic, suggested that stricter MRLs tend to favour trade (Santeramo and Lamonaca, 2019). Some examples of the detailed effects found in empirical studies are presented below. These studies are also partly considered in the meta-analyses just described.

Several studies analysed the effects of specific MRLs on trade. Stricter MRLs applied by importing countries on the insecticide chlorpyrifos, for example, were found to reduce China's exports of vegetables (Chen, Yang and Findlay, 2008). Stricter MRL regulations also had a negative overall effect on exports of fresh fruits from Chile and an even larger effect if the standards were imposed by a developed country (Melo *et al.*, 2014). The European Union pesticide standards on tomatoes tend to inhibit exports from African countries, while standards on oranges, limes and lemons were shown to have a demand-enhancing effect and stimulated new trade relations (Kareem, Martínez-Zarzoso and Brümmer, 2018). Changes in European NTMs on green beans over the time period 1990–2011 appear to have led to adjustment effects of Kenyan suppliers with an initial reduction of trade followed by a catch-up with the previous situation (Henry de Frahan and Nimenya, 2013).

Mixed effects on trade were also found for SPS measures applied to animal products. For example, MRLs imposed by importing countries on the antibiotic Oxytetracycline appeared to reduce the exports of fish and aquatic products from China (Chen, Yang and Findlay, 2008), while MRLs on the antibiotic Chloramphenicol were found to negatively affect the intensity of imports of crustaceans by Canada, Japan, the United States of America and European Union-15 (Disdier and Marette, 2010). However, while some SPS measures were shown to significantly reduce trade in meat among the world's ten biggest importers and exporters, others had substantial positive impacts on trade (Schlueter, Wieck and Heckelei, 2009).

A broader study by the Organization for Economic Co-operation and Development (OECD) on the effect of NTMs on merchandise trade acknowledged that NTMs can affect trade through both a demand-enhancing and a trade cost-raising effect. In particular SPS measures including MRLs were found to be associated with expanding trade, even though trade costs rose (Cadot, Gourdon and van Tongeren, 2018).

Some studies explicitly refer to the level of harmonization of standards or specific harmonization events and their impact on trade. Harmonizing industry standards in general tends to increase trade flows by incentivizing investments and generating additional demand (Schmidt and Steingress, 2019). For instance, increasing the similarity of MRL regulations among countries appeared to increase the trade of apples and pears among these countries (Drogué and DeMaria, 2012). A study on the regulatory diversity of NTMs on eleven animal and plant products of the European Union and nine of its major trade partners showed that stricter pesticide MRLs in one country relative to its trade partners reduce exports to that country (Winchester *et al.*, 2012). Pesticide MRLs imposed by high-income OECD countries were found to be associated with more trade. However, the divergence in food safety regulations between importers and exporters reduced exports by imposing additional costs to comply with the importer's standards (Xiong and Beghin, 2014).

3.2 ANALYSIS OF THE EFFECT OF PESTICIDE MAXIMUM RESIDUE LIMITS ON TRADE IN RICE IN SELECTED COUNTRIES

So far, no study in the literature has specifically focused on the effects of MRLs on trade in rice. These effects are explored in this chapter.

To study the effects of MRLs on trade in rice, a gravity model is used, which is a widely applied methodological approach to estimate the effects of MRLs on trade. The gravity theory in international trade assumes that countries trade in proportion to their respective economic size and geographical and regulatory proximity (UNCTAD and WTO, 2012 and 2016). This means that countries more similar in economic size and income trade more with each other. Trade between two countries, however, is reduced if they are located farther away from each other and their standards, for example MRLs, are more heterogeneous. The relatively intuitive gravity model is generally found to explain a large part of the variation in bilateral trade flows and has proved to be consistent with theoretical models of trade (Feenstra, Markusen and Rose, 2001; UNCTAD and WTO, 2016).

The empirical specification of the gravity model applied here distinguishes between the likelihood that two countries trade or do not trade rice with each other, i.e. the extensive margin, and the magnitude of trade of rice between two countries if they already trade with each other, i.e. the intensive margin. The empirical approach is described in more detail in Annex A-4.

The trade analysis considers eight rice importing markets (Australia, Canada, China, the European Union, Indonesia, Japan, Saudi Arabia and the United States of America) and 12 exporting countries (Bangladesh, Brazil, China, Indonesia, India, Cambodia, Myanmar, Pakistan, Philippines, Thailand, the United States of America and Viet Nam).[26] Intra-European Union trade was excluded. The countries were selected based on their importance in the rice market (Table 3 and Table 4 refer) and considering data availability. Together, these countries account for around 90 percent of the global trade in rice.

The Harmonized Commodity Description and Coding System (HS) classifies rice under tariff item 1006. Within that, rice is classified according to its production and processing stages: rice in the husk (paddy or rough) (HS 100610); husked (brown) rice (HS 100620); and rice, semi-milled or wholly milled, whether or not polished or glazed (HS 100630). Moreover, broken rice is classified separately (HS 100640). The HS classification is compared with the classification used by Codex in Annex A-3.

26 The assessment of the harmonization of national MRLs with Codex in chapter 2 covered also the Islamic Republic of Iran and the United Arab Emirates. These two countries were not included in the analysis here due to missing tariff data (the Islamic Republic of Iran) and the unclear effects of a high share of re-exports in total trade (the United Arab Emirates).

In this analysis, bilateral trade flows of rice are distinguished according to the aforementioned classification. The trade flows were represented using both the value and quantity of trade with equivalent results, but the results presented below are based on the value of trade from 2012 to 2018.

The main focus of the analysis is to explore the effects of the different levels of harmonization of pesticide MRLs observed among trading partners on trade in rice. In order to identify better these effects, other determinants of international trade are also considered in the analysis. These include the production capacity of the exporting countries, the tariffs imposed by the importers, as well as several factors describing the relationship between trading partners. The variables and underlying data sources are described in Annex A-4.

3.3 STRINGENCY OF PESTICIDE MAXIMUM RESIDUE LIMITS COMPARED TO CODEX

Chapter 2 of the present report analysed national and Codex MRLs and the level of their harmonization. To accommodate the large number of MRLs for rice in the trade model, an index of MRL restrictiveness was created that summarizes the level of compliance with Codex in a single number per rice tariff line, year and country (the calculation of the index follows Li and Beghin (2014) and Xiong and Beghin (2014) and is described in Annex A-4).

The MRL index equals one if national MRLs are fully aligned with the Codex standards. It is greater than one if, averaging over all pesticide MRLs, national MRLs are stricter than Codex. If national MRLs are less stringent than those established by Codex, the index takes a value less than one.

It needs to be noted that the analysis focuses on the level of harmonization of national MRLs with Codex MRLs. As a result, the study only considers the MRLs for which a standard was adopted by Codex, i.e. it ignores those national MRLs for which no corresponding Codex MRLs exist.

Concerning the Codex MRLs, if a new MRL on a specific pesticide was adopted by Codex during the period under examination (2012–2018), this pesticide MRL was only considered starting from the year of its adoption. This means that trade flows in 2014, for example, were matched with the MRL index only for those Codex MRLs that had been adopted up to 2014.

With regard to national MRLs, where a Codex MRL existed, but no specific national MRL was adopted, this was replaced by the national default tolerance level (Table 6). For all the case studies except the European Union, only the most recent national MRLs could be retrieved, as MRLs from previous years were not available. As such, potential changes of national MRLs in the other countries could not be taken into account. For the European Union, the values of four MRLs changed during the 2012–2018 period. The MRL indices therefore do not vary much over time.

The MRL indices by rice tariff line and country/market for the year 2018 are shown in Figure 9 and Figure 10. Out of the 17 countries/markets covered by the analysis, ten have stricter pesticide MRLs than Codex. These are Australia, Canada, China, the European Union, India, Japan, Pakistan, Philippines, the United States of America and Viet Nam.[27] Half of the countries/markets with stricter MRLs than Codex are high-income economies (Australia, Canada, the European Union, Japan and the United States of America), while the other half are emerging economies or developing countries (China, India, Pakistan, Philippines and Viet Nam). With the exception of Saudi Arabia, all of the high-income countries considered in the analysis have considerably stricter MRLs than Codex.

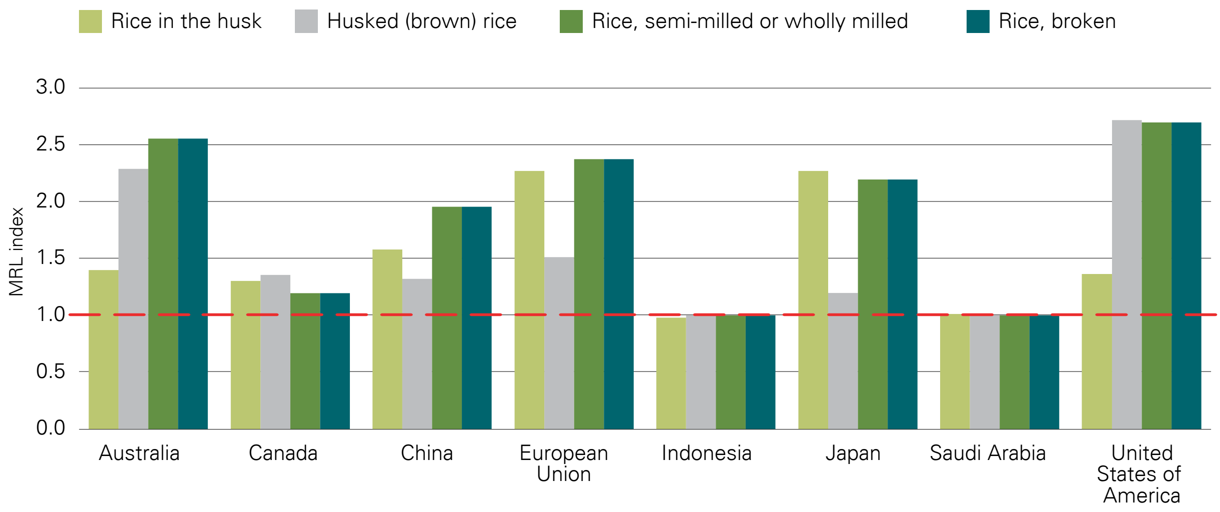
The MRLs of the remaining seven countries (Bangladesh, Brazil, Indonesia, Cambodia, Myanmar, Saudi Arabia and Thailand) are on average equivalent to Codex MRLs.

This implies that all importers considered in the analysis, with the exception of Indonesia and Saudi Arabia, have, on average across the pesticides, significantly stricter MRLs than Codex (75 percent, Figure 9). Seventy-five percent (six out of eight) of the markets considered on the importer side are high-income economies, five of them have stricter MRLs than Codex (i.e. 62.5 percent of the importing countries are high-income countries with stricter MRLs than Codex).

Half of the exporters considered in the analysis have their national MRLs aligned with Codex (Bangladesh, Brazil, Indonesia, Cambodia, Myanmar and Thailand).

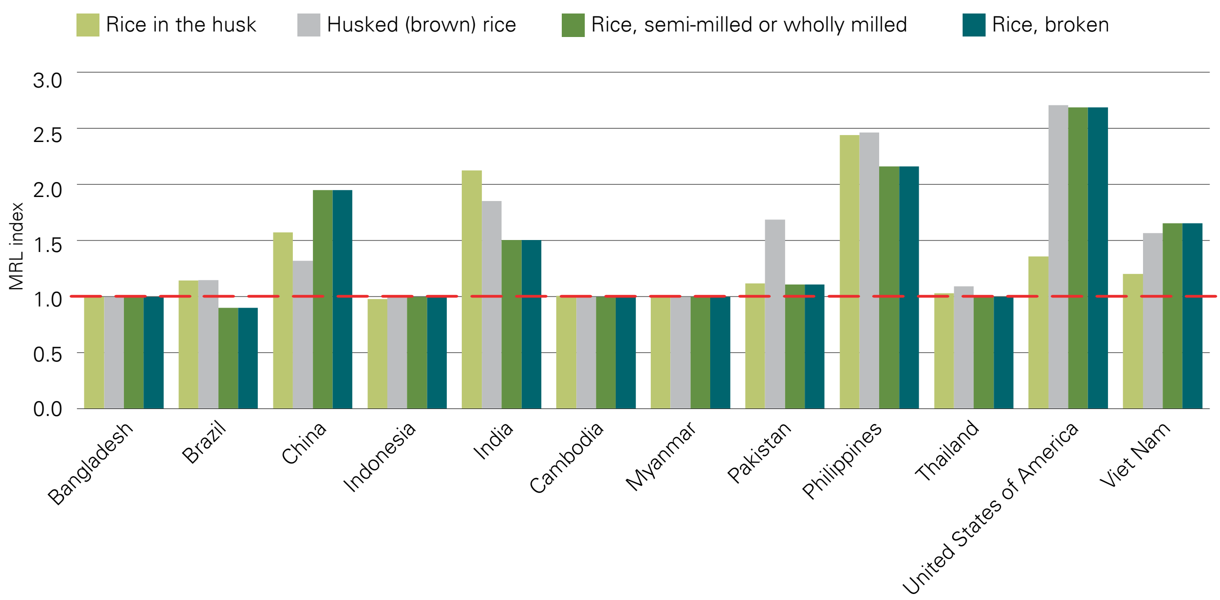
27 In some of the countries with stricter MRLs, for example the Philippines, the MRL stringency is strongly determined by those Codex MRLs for which a dedicated national MRL does not exist and the stringency of the default tolerance level which is applied in these cases.

Figure 9: MRL indices by tariff line and country, importing countries/markets, 2018



Note: The broken red line indicates alignment with Codex. The higher the MRL index, the stricter the national MRLs compared to Codex.

Figure 10: MRL indices by tariff line and country, exporting countries, 2018



Note: The broken red line indicates alignment with Codex. The higher the MRL index, the stricter the national MRLs compared to Codex.

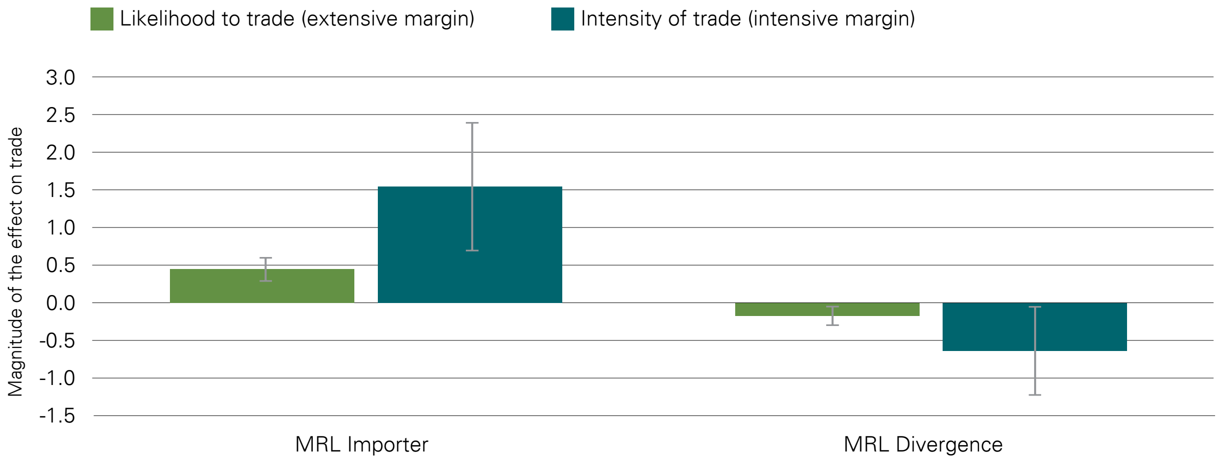
Exporting countries with stricter than Codex standards are China, India, Pakistan, Philippines, the United States of America and Viet Nam (Figure 10). Eleven of the twelve considered exporting countries are emerging economies or developing countries, of which five have stricter MRLs than Codex.

3.4 THE EFFECT OF PESTICIDE MAXIMUM RESIDUE LIMITS ON TRADE IN RICE

In order to reflect the dual effect that MRLs can have on trade, the analysis considers both the MRL stringency of the importing country (MRL importer) and the difference in MRL stringency between importer and exporter (MRL divergence).

As described above, the MRLs on the side of the importers may increase effective demand by relieving consumer concerns about product quality, while

Figure 11: The dual effect of pesticide MRLs on imports of rice



Note: The figure shows marginal effects that are evaluated at their means. The error bars show 95 percent confidence intervals. A confidence interval is an indicator of the certainty of an estimate by giving the range in which the true value would fall with a probability of 95 percent.

the regulatory divergence may affect trade due to the higher costs incurred by producers, processors and traders to comply with the stricter standards. If domestic food safety regulation with respect to MRLs on pesticides in rice of the exporting country is stricter or equal to that of the importing country, no additional trade barrier (i.e. costs related to trade) should apply. However, if the MRL regulation in the exporting country is laxer than in the importing country, this could imply higher obstacles to export to this country. Evidently, if both trading partners adopt internationally harmonized Codex standards, the MRLs should not cause any additional cost to trade. The results of the analysis for each of these opposite mechanisms are presented separately (Figure 11). As the results are based on an index, i.e. an aggregate measure of MRL stringency composed based on 82 rice pesticide MRLs adopted by Codex, the actual numbers are difficult to interpret. It is for this reason that the interpretation below and in the following sections focuses on the direction of the effects and their relation to each other.

The results reflect the dual effect that MRLs can have on trade. The effect of MRL stringency on the likelihood to trade on the importer side is positive, i.e. a higher MRL stringency is associated with a higher likelihood to import rice (MRL importer, extensive margin). There is also a significantly positive effect of importers' MRL stringency on the magnitude of the imports, i.e. stricter MRLs are associated with larger import volumes (MRL importer, intensive margin). However, this does not imply that the stricter MRLs lead to more imports of rice. Rather, it is more likely that countries with a high import demand tend to care more about the stringency of MRLs related to both their domestic production and imported products.[28,29]

The impacts of the regulatory divergence on trade are less pronounced than those of the importers' MRLs. However, as expected, they are clearly negative. Although the negative effect is relatively small, this means that the stricter the importing country's MRLs relative to those of the exporting country, the less likely they are to trade with each other (MRL divergence, extensive margin). If two countries already trade with each other, stricter MRLs on the importer side compared to those of the exporter are also negatively associated with the magnitude of trade (MRL divergence, intensive margin).

As indicated by the confidence intervals in Figure 11, the positive association between MRL stringency on the importer side and both the likelihood to trade and the magnitude of trade is more certain than the negative effect of the MRL divergence on trade. As the positive relationship between MRL stringency and trade on the importer side is also much stronger than the negative effect of the MRL divergence, the net effect on trade is positive, indicating that MRL stringency *per se* does not necessarily impede trade. Effects of other determinants on trade in rice are summarized in Box 2. Detailed results appear in Table 8 and Table 9, Annex A-5.

28 The potential endogeneity bias due to effects on policy design is largely accounted for by including fixed effects in the model setup (Xiong and Beghin, 2014).

29 The model identifies the relationship between MRL stringency and imports net of income effects. Although high-income countries tend to have stricter MRLs, income effects are covered by other model parameters and do not interact with the results on the effect of MRL stringency.

Box 2: Effects of other country-level and bilateral determinants on trade in rice

In addition to the effect of the MRLs, other determinants of trade were also considered in the analysis.

A greater volume of exportable production in the exporting countries is shown to increase the likelihood of trade and the volume of trade in rice (Table 8, Annex A-5). By contrast, and as expected, higher import tariffs in the importing countries are associated with both a lower likelihood to import and a lower magnitude of trade.

The farther two countries are located from each other, the less likely they are to trade and the lower is the traded volume. Moreover, in line with the gravity theory that countries trade with each other in proportion to their economic size, two countries with the same development status are more likely to trade with each other and the traded volume is likely to be much higher. Pointing to path dependency, a colonial relationship between two countries in the past is still associated with a higher volume of trade in rice today. The likelihood to trade at all, however, is no longer clearly associated with former colonial ties. Two countries, however, that traded rice in 1995 are still more likely to trade today with tendency for a larger traded volume.

The likelihood to trade and the scale of trade between two countries are also larger if the main rice varietal family (e.g. aromatic, indica, japonica) imported in one country matches the one the exporting country is specialized in.

3.5 CONCLUDING REMARKS

In this case study on rice, a gravity model analysis was conducted to assess the implications of different levels of harmonization of national with Codex pesticide MRLs on trade. The analysis covered eight importing markets and 12 exporting countries. Seventy-five percent of the main rice importing markets and 50 percent of the rice exporting countries considered in this study are found to have stricter on-average pesticide MRLs than those adopted by Codex. The MRLs of the other exporting case study countries are, on average, aligned with Codex MRLs.

Codex MRLs are based on solid scientific analysis and assessment and are established following an inclusive and transparent consultative process reassuring that MRLs are set at an appropriate level for public health to be protected.

However, in the majority of the main rice importing markets there appears to be a high tendency for applying stricter MRLs on pesticides than those established under Codex. The analysis shows that the effect of the strong demand for rice imports under strict food safety regulations outweighs the trade-impeding effect of the non-harmonization of national MRLs with Codex MRLs. A relaxation of the stricter standards of the importing countries could, therefore, lead to unpredictable effects on rice trade or the replacement of public by private standards.

Nonetheless, greater international harmonization of MRLs on pesticides in rice would ease access by exporting countries to the markets of the main rice importers. Although there is a growing consumer awareness about food safety in many developing countries, including a proliferation of public and private standards and traceability systems (Pham and Dinh, 2020), most of these countries would not be able to move immediately to the same standards and food safety outcomes found in high-income countries (Unnevehr, 2015).

Any changes towards further international alignment of pesticide MRLs on rice to facilitate trade will have to balance between the demand for stricter food safety regulations on the importer side and the additional costs incurred on the exporter side. Different steps could be taken by countries towards improving harmonization with Codex standards, considering also the technical issues elaborated in Part B of this study. For example, it would seem that consideration of Codex MRLs could be enhanced in the absence of national MRLs (as also foreseen by the SPS Agreement), as a first step towards better harmonization.

To increase developing countries' capacity to comply with the required food safety standards in both their export and domestic supply chains, commitment to, and consistent investment in, continuously improving food control systems and regulatory capacities are fundamental.

4 CONCLUSIONS AND WAY FORWARD

Lack of Codex MRLs

One of the findings of the study is that many pesticides (around 2/3) registered at national level do not have corresponding Codex MRLs (see Figure 4). The absence of MRLs for use in traded products is a significant concern that has been brought to the attention of the CAC in the past few years. With food safety increasingly being recognized as a priority issue in many countries, the request for scientific advice has also increased. However, despite the significant efforts that are being made by FAO/WHO to streamline procedures and to manage the process of scientific review as efficiently as possible, the number of requests for evaluation by the JMPR of new compounds and new uses (as well as for periodic re-evaluations of existing MRLs) far exceeds the current capacity.

At the same time, the absence of Codex MRLs for specific pesticides registered at national level, could be due to different factors, including, for example, concerns related to the toxicity of the chemicals, or the inability of countries to engage in the Codex work to advocate for pesticides of interest to them or to submit the data needed for the evaluation of MRLs. This first analysis provides grounds for further research on these matters.

Because of the importance of Codex MRLs, both for developing countries lacking capacity for risk assessment and for international trade, addressing the need for more Codex MRLs should be further considered.

Missing national MRLs

It was established that there are many Codex MRLs that do not have a corresponding MRL at national level. The analysis showed that many markets analysed have established only a very limited number of the MRLs set by Codex for rice (see Figure 4). Because most of these countries do not automatically defer to Codex MRLs in the absence of national MRLs, the result is that there could be a regulatory gap for trading partners wishing to export rice to these countries. There could be many reasons behind the high number of Codex MRLs that do not have a corresponding MRL at national level. For example, some economies may not have procedures for establishing import MRLs, or may have policies that do not allow for consideration of foreign GAPs when there is a domestic GAP in place. Sometimes, setting an MRL is part of the pesticide approval process, or is only possible after a pesticide has been approved for use in a country. There might also be a tendency for countries to establish MRLs only for export purposes and not for import. However, this was not further analysed in this case study.

Missing national MRLs could also be partly explained by differences in the time of MRL adoption at Codex and at national level, as indicated in Part B of the study. This difference in time may entail changes in the scientific data packages evaluated by the different authorities (e.g. different GAPs reflecting different pests and diseases, different pesticide labels, availability of different studies, etc.) leading to different results. While Australia, the European Union and Japan review Codex MRLs upon their establishment, Canada and the United States of America report to have no routine procedures in place to review national MRLs at the time Codex adopts new MRLs. The United States of America and Canada review MRLs as part of a national active substance review programme (see Part B for further details).

It seems that consideration of Codex MRLs could be enhanced in the absence of national MRLs, as also recommended by the SPS Agreement (see Annex C (1) "chaussette", and Article 8 of (WTO, 1995)): "the importing Member shall consider the use of a relevant international standard as the basis for access until a final determination is made".

Approaches taken by countries in the absence of national MRLs

In the absence of national MRLs, the procedures in place to deal with these missing MRLs differ among countries. In general, most developing countries analysed tend to defer to Codex MRLs, either entirely, or in combination with regional or national MRLs of major importing markets. Developed countries/region, on the other hand, either apply established default limits or set the limit at zero (see also Table 6). As further discussed later in the study, in all the five countries/region analysed in Part B, an application can be made to have an MRL established when a national MRL is absent. This is termed an import tolerance (in Canada, the European Union, Japan and the United States of America) or Schedule 20 amendment in Australia. The process can vary greatly in both complexity and duration (from a few months up to six years), depending on the country. Australia offers a streamlined process that takes place yearly and accepts JMPR and/or other national evaluations in whole or in part when they exist (FSANZ, 2018). In Canada and the United States of America, The North American Free Trade Agreement (NAFTA) guidance indicates that the presence of a JMPR evaluation could result in a less extensive procedure (NAFTA, 2005). Japan and the European Union appear to require a full new assessment even if other evaluations are available. Obviously, the re-evaluation of studies and data adds significantly to the time and cost for concluding the import tolerance. This negatively affects exporting partners, especially in developing countries where they might not have either the financial or the technical means for such application.

Codex MRLs are based on solid, independent scientific analysis and assessment and are established following an inclusive and transparent consultative process that reassures that MRLs are set at the appropriate level to protect health and facilitate trade. Deferral to Codex MRLs when national MRLs do not exist could be considered as a default practice (see also Part B).

Food classification

Food classification proved to be very heterogeneous among the countries/region analysed. During the analysis, difficulties emerged as of how to match national MRLs to Codex MRLs. This holds true also for the analysis of the reasons behind low harmonization (see Part B). In general, due to varying rice classifications across countries (see Annex A-2), matching the different Codex rice commodity types with the national ones proved challenging. Sometimes the same name would refer to different rice types in different countries. The study showed how differences in rice classifications can influence the extent of international harmonization for pesticide MRLs. While this issue emerged for rice, as the focus commodity of this study, similar issues also apply to other commodities such as cereal grains, nuts, pulses and many others. This triggers questions on how different definitions among commodities may also affect international trade and calls for enhanced international harmonization on this matter.

As further described in Part B, to reduce the potential for confusion over multiple MRLs for different forms of a single pesticide/crop combination, consistency could be improved where possible, i.e. set multiple MRLs for all pesticides to cover all likely fractions, or reduce the number of MRLs for some pesticide/crop combinations.

Transparency

Transparency is considered an important asset for either a country's capacity to comply with or be aware of regulatory changes/adoptions, to reduce its internal costs and so increase its trade.

While for national MRLs good public access has been ascertained for most countries/regions analysed (see Annex A-1), less transparency was evident for MRL-related national regulations or policies. Some difficulties have been faced when searching for procedures followed in the absence of national MRLs, as well as for documents on risk assessment methodologies and risk management procedures to establish national MRLs.

Having policies related to MRL establishment and enforcement available online would increase overall transparency and would be useful for trading partners. Transparency provisions in this regard are also included in the WTO SPS Agreement to ensure that measures taken to ensure food safety are made known to the interested public and to trading partners.

Finally, very little transparency was evident for country positions towards the development and adoption of new Codex MRLs. The European Union seems to be the only Codex member openly raising reservations and communicating to Codex when not in the position to adopt a new Codex MRL, providing scientific reasons for its reservations and non-alignment (see also Part B of the study).

For the optimal functioning of the Codex MRL standard-setting process, it would be important that countries actively notify Codex whenever they have any reservation and are not in the position to adopt a newly established Codex MRL, providing a science-based rationale.

Ongoing efforts undertaken by countries to improve harmonization with Codex MRLs

Despite the observed low level of harmonization, countries seem to be actively involved in the development and promotion of various regional and international initiatives to improve harmonization. For example, Canada, through its Pest Management Regulatory Agency (PMRA), and Australia as co-chair of the APEC Food Safety Cooperation Forum (APEC, 2016), have been very active in the acquisition of National and Codex MRLs through science-based research and workshops in their respective regions to achieve greater regulatory convergence of MRLs and greater alignment with international standards. More specifically, Australia is actively considering whether Codex MRLs adopted at each CAC meeting could be routinely included in their annual MRL harmonization proposal to amend the Food Standards Code (subject to certain tests which include an acceptable Australian dietary exposure assessment).

There is ongoing work also in the areas of residue definition for enforcement and risk assessment (by OECD, jointly with JMPR and JECFA) and chronic exposure assessments to improve harmonization also between JMPR and JECFA, by using individual food consumption data. These aspects are further explored in Part B.

Need for capacity development

Many developing countries continue to make use of and strongly rely on Codex MRLs. As Codex MRLs are critical to developing countries for the establishment of their national MRLs, greater attention should be given to the needs of those countries when developing new MRLs, as well as to means to facilitate their engagement and participation.

There seems to be limited understanding of the international processes around standard-setting and limited capacity to engage in the process by some countries. Throughout the analysis, it was noted how developing countries seem to lack access to relevant information (e.g. unable to identify problematic pesticides and provide data on relevant negative economic impact, etc.), as well as the capacities to engage in international fora and take advantage of the system. In this respect, it is worth noting that there has never been a WTO trade dispute triggered by pesticide residues. Beside the dispute settlement mechanism, which requires considerable legal expertise and financial resources, the WTO also provides a mechanism to express trade concerns during quarterly international committee meetings (i.e. the SPS Committee meetings). When looking at the total share of SPS Specific Trade Concerns (STCs) on pesticide residues, WTO statistics report that out of 408 SPS STCs raised between 1995 and 2017, 31 percent were related to food safety, of which 6 percent were on pesticide residues (WTO, 2016). The small share could be explained by many factors, including lack of capacity by the concerned countries to make use of the WTO forum for voicing and solving their trade concerns on pesticide residues. Nevertheless, the trend seems to have been changing in the past three years, when pesticide MRL discussions gained momentum at the WTO. Five new STCs on MRLs were raised in the SPS Committee during 2017 and two new STCs were raised both in 2018 and in 2019[30], which represents 17 percent of all new STCs raised between 2017 and 2019. Many of these STCs have been supported by a large number of countries.

Building on this new trend and demonstrated interest, consideration should be given to developing countries' needs for better and more active participation in the Codex standard-setting process and to the needs of those countries when developing new MRLs both at Codex and national level.

Role of international organizations

In this context it is important to recognize the role played by FAO in enhancing capacity of developing countries in food control and food safety management, as well as other relevant international organizations such as WHO and international partnerships such as the STDF. It is also important to note the role of the Codex Trust Fund[31] to support countries to build strong, solid and sustainable national capacity to engage in Codex.

30 2017: See STCs number 419, 422, 426, 427 and 428 in http://spsims.wto.org/en/SpecificTradeConcerns/Search
2018: See STCs number 447, 448 in http://spsims.wto.org/en/SpecificTradeConcerns/Search
2019: See STCs number 453, 457 in http://spsims.wto.org/en/SpecificTradeConcerns/Search
For WTO statistics see: http://spsims.wto.org/en/PredefinedReports/STCReport?Year=2020&YearFrom=2017&YearTo=2019&FilterType=0

31 See: http://www.fao.org/fao-who-codexalimentarius/about-codex/faowho-codex-trust-fund/en/

Dual effect of MRLs on trade

Seventy-five percent of the main rice importing markets and 50 percent of the rice exporting countries considered in this study have stricter pesticide MRLs than those adopted by Codex. The MRLs of the other exporting case study countries are on average aligned with Codex MRLs. The on average stricter standards of the importers appear to reflect high consumer awareness of food safety issues and are associated with a greater demand for rice imports. At the same time, higher market access costs incurred by exporting countries, if the importers' MRLs are more stringent than the MRLs of the exporting country, are shown to have trade-impeding effects. Further international alignment of pesticide MRLs on rice to facilitate trade will have to balance these two effects.

To increase developing countries' capacity to comply with food safety standards in both their export and domestic supply chains, commitment to and consistent investment in continuously improving food control systems and regulatory capacities are fundamental.

PART **B**

REASONS BEHIND DIFFERENT LEVELS OF PESTICIDE MRL HARMONIZATION

PART B REASONS BEHIND DIFFERENT LEVELS OF PESTICIDE MAXIMUM RESIDUE LIMIT HARMONIZATION

This part of the study aims at better understanding the reasons that underlie the different levels of harmonization with Codex pesticide MRLs. In collaboration with the Secretariat of the JMPR, two main areas that may lead to divergent MRLs were identified and evaluated:

1. Differences in risk assessment procedures for pesticides (see section 1.1)
2. Differences in risk management and policies for pesticide MRLs (see section 1.2)

In contrast to Part A of the study, this analysis focuses only on five countries/region (out of the 19 countries/region analysed in Part A of the study): Australia, Canada, the European Union, Japan and the United States of America, where regulations on risk assessment and risk management are advanced, publicly available and accessible online.

The study explores the different procedures and approaches applied in the risk assessment process and in risk management decisions that might lead to differing MRLs. Factors considered in this analysis include: variances in the residue definition approaches, differences in interpretation of toxicological studies, differences in exposure assessment methodologies, differences in extrapolation rules and other methodological issues.

The five countries/region analysed were first approached to gather their feedback. A list of key issues identified under the two main areas of investigation was shared for their (countries/region) comments and inputs, while they were asked to identify any other issue that might have not been considered. In addition to the information supplied by the countries/region analysed, publicly available legislation and guidance documents were used to provide additional insight.

Some of the data presented in Part A were also used to inform and support the analysis in this part of the study; for example, the list of pesticides for which Codex MRLs exist for rice was used to compare some of the different conclusions on health-based guidance values (HBGVs), residue definitions and MRLs established in different countries. The JMPR/Codex, Australia, the European Union and the United States of America were chosen as an example as comparators for various aspects of the report, due to the relatively easy access to relevant databases. The comparison was only intended to provide an indication of reasons for differences among countries and Codex. This information was then used as part of the analysis of residue definitions and risk assessment practices. The values were obtained from a number of publicly available databases, having various levels of detail, covering differing dates and because the ongoing evaluations are not included, should be considered as a worked example rather than providing a completely accurate description of the current situation.

Prior to finalization, the draft study was circulated to the authorities of the countries/region analysed and revised to incorporate comments submitted.

1 RISK ASSESSMENT METHODOLOGY

This chapter explores various aspects of the risk assessment methodology that could lead to different MRLs. The elements of the risk assessment that are analysed are:

1.1. Residue definitions

1.2. Interpretation of toxicity studies

1.3. Assessment of metabolism studies

1.4. Exposure assessments

1.5. Differences in GAP and selection of critical GAP

Key messages:

- There is considerable variation in how countries are aligned with the JMPR/Codex process for the development and establishment of pesticide MRLs.
- Many of the observed differences in risk assessments do not seem to have a significant impact on the overall outcome of the pesticide safety evaluations.
- Some of the major differences in MRLs and residue definitions are due to the presentation of different data to the various countries/region.
- Harmonization also depends on national authorities supplying updated consumption data to FAO/WHO, via the GEMS and CIFOCOss databases.
- Many of the guidance/procedural documents related to MRLs and human health risk assessments of pesticides were initially drafted 10 to 20 years ago, with subsequent, only occasional, updates and partial revisions. Consideration could be given to an update process that can be agreed internationally.

1.1. RESIDUE DEFINITIONS

The topic of residue definitions for pesticide is complex. Not only are there two types of residue definition, one for monitoring (MRL compliance/enforcement) and one for risk assessment, but the components of the residue can vary across crops and over time. In setting residue definitions for a pesticide, the aim is to have a simple definition that can be applied to most, if not all, commodities.

There can also be differences induced by:

- Different databases e.g. additional crops with different metabolite profiles.
- Different radiolabel positions in the chemical structure of the pesticide molecule.
- New studies with increased analytical sensitivity.
- Different conclusions/considerations of related metabolites (e.g. the inclusion, or not, of thiophanate-methyl in the residue definition for carbendazim).

Residue definition for <u>monitoring/compliance/enforcement</u>

There appears to be general agreement across different countries/authorities that the residue definition for monitoring compliance should be:

- as simple as possible;
- compatible with multi-residue analyses; and
- based on parent or a suitable marker compound.

For many pesticide/commodity combinations, the definition for compliance is unlikely to be a problem. However, it has been identified as an issue for the acceptance of Codex MRLs in some cases (e.g. saflufenacil, flunicamid).

One aspect that might prove a hindrance to accept Codex MRLs is that some pesticides consist of a number of isomers (e.g. synthetic pyrethroids). In some developing countries, racemic mixtures are on sale and the Codex MRLs relate to total pesticide, without any resolving of individual isomers. In other countries only resolved isomer versions are approved and the definition for compliance is based on individual isomers. This is an area where there is the scope for further harmonization, particularly when the health-based guidance values are the same for both resolved isomers and racemates.

Residue definitions for risk assessment

The residue for risk assessment is frequently more complex than that for monitoring as it needs to include metabolites/degradates, which will contribute significantly to the risk assessment. At present there is agreement that:

- Significant/major contributors should be included, although there is no precise definition for this.
- Compounds representing <10% of the Total Radioactive Residue (TRR) or at levels <0.01 mg/kg are normally considered to contribute negligibly to the dietary risk.

Comparing Codex, the European Union and the United States of America residue definitions for pesticides used on rice (Annex A-2) indicates that Codex and the European Union definitions had a good degree of overlap, but that the United States of America definitions tended to include more components even though the approaches to setting the definitions appear similar. Australia had a limited number of MRLs for the rice pesticides on the list considered, but the residue definitions were generally consistent with JMPR.

Where risk assessment residue definitions contain more, or different compounds than the JMPR evaluation, it is likely that the additional components would result in a higher intake estimate. However, this does not mean that the overall conclusion of the risk assessment using the more extensive residue definition will be unacceptable. Therefore, under the terms of the SPS agreement, a different residue definition, in isolation, is not a reason for not harmonizing with a Codex MRL. It is also possible that the additional components are only seen in a small number of crops and therefore would not impact on the risk assessment for other crops.

In the European Food Safety Authority (EFSA) guidance on residue definition for risk assessment ((EFSA, 2016) – not yet ratified), all metabolites detected in crop metabolism studies for pesticides in the quartile with the lowest ADIs/ARfDs need to be considered; and a minimum of 75 percent of the toxicological burden needs to be covered by the residue definition. The latter could lead to different definitions in cases where two or three metabolites cover 60 percent of the burden, but other metabolites are each at low levels. In this case the need to cover 75 percent of the toxicological burden could involve two or three extra compounds in the definition. This is a more complex approach than that of JMPR and other countries, and it might lead to further differences in risk assessment outcomes.

It should be noted that there is ongoing work by OECD, jointly with JMPR and JECFA, on the development of new guidance to standardize and improve harmonization on residue definition.

Level of consideration of Codex MRL

EFSA prepares detailed briefing documents for the European Union risk managers prior to the meetings of the CCPR (e.g. (EFSA, 2018)). These identify where there is agreement or disagreement with JMPR/Codex proposals. A number of points relating to residue definitions, which could lead to differences in approach included:

- Including compounds for which there are no analytical standards (e.g. captan).
- Where the Codex residue definition covered metabolites in addition to those listed in the European Union definition (e.g. fenpyroximate, carbendazim), the Codex definition would tend to be more precautionary in terms of risk assessment, as additional components are included.
- Where the European Union residue definition included additional components to those in the Codex definition, the European Union assessment could be more precautionary if the additional components were found in all commodities. However, this would not automatically result in an adverse risk assessment conclusion.

It is not clear whether such disagreements automatically lead to non-harmonization with the Codex MRL: brief summaries of the reservations of the European Union are presented in the reports of the CCPR (e.g. (FAO and WHO, 2017; FAO and WHO, 2018)). While the detailed reasoning behind the final decision is not in the public domain, the European Union has reported that deviations from the positions in the published document are typically limited.

This level of information provided by EFSA/European Union aids transparency, is interesting and useful but equivalent information did not appear to be available from other countries. To obtain information on the level of consideration of Codex MRL proposals from all countries/region, a workshop/discussion forum might be a useful way forward in identifying the main issues preventing harmonization of residue definitions.

1.2. INTERPRETATION OF TOXICITY STUDIES

The basic risk assessment methodologies used by JMPR and other regulatory agencies around the world contain many common elements in terms of data considered, interpretation of studies, determination of a NOAEL (or equivalent point of departure) and the application of safety factors to derive the HBGVs (ADI or ARfD).

In most instances the HBGVs derived by different countries or regions are either the same or differ by a factor of two or less. This is confirmed by the brief analysis of the pesticides used on rice (see Annex B-2). When comparing JMPR (WHO, 2019a) and the European Union values (European Union, 2019a) for pesticides used on rice it was found that:

- ADIs were derived by both the European Union and JMPR for 49 of the 68 pesticides.
- For 36/49 the ratio of the ADI values fell between 0.5 and 2.
- ARfDs were derived, or there was agreement that an ARfD was unnecessary, for 45 of the 68 pesticides.
- For 30 of the 45 ARfDs, the ratio of the values was between 0.5 and 2.
- For a number of pesticides there was divergence over whether an ARfD was unnecessary or not.
- Where there is a large ratio between the European Union and JMPR values these can often be linked with fundamental differences. For example, for mesotrione (ratio 50 for ADIs), JMPR discounted the rat data as inappropriate for human risk assessment, but in the European Union the rat data were used in HBGV derivation.
- For 23 of the pesticides where both ADI and ARfD were derived, the values for both ADI and ARfD were consistent within a factor of two.

A similar exercise was performed for JMPR and Australian (APVMA, 2019) HBGVs, and the conclusions are summarized below[32]. The findings are broadly in line with those described above in respect of the European Union:

- ADIs had been derived by both JMPR and APVMA for 60 of the 68 pesticides used on rice.
- For 37 of these the values were the same (taking account of rounding[33]) and for nine others the APVMA value was higher than that of JMPR.
- Of the 14 ADI values where JMPR was higher, two were higher by a factor of two or less.
- ARfDs had been derived, or determined to be unnecessary, by both JMPR and APVMA for 39 of the 68 pesticides. For several of the pesticides there was variability in whether or not an ARfD was necessary.
- For 26 of these the ARfD values (or conclusion on unnecessary[34]) were the same (taking account of rounding) and for six the APVMA value was higher.
- Of the seven ARfD values where JMPR was higher, two were higher by a factor of two or less
- For 26 of the 39 pesticides where ADIs and ARfDs were derived by both groups, the values for both ADI and ARfD were consistent within a factor of two or the APVMA value was higher than the JMPR equivalent.
- The major variation for ARfDs was carbaryl, where both APVMA and the European Union were 20-fold lower than JMPR.

For most pesticide risk assessments, a difference factor of two in HBGVs is not critical to the overall conclusion of acceptability, or not, and, if necessary, could be readily mitigated by minor changes to GAP such as pre-harvest intervals. For many of the rice pesticides considered, the JMPR intake estimates were <10% of the applicable HBGVs.

For the majority of pesticides there is nothing in the derivation of health-based guidance values that would trigger an automatic concern in respect of the health risks from consuming commodities containing the pesticides at the Codex MRL. For a number of those where there are significant divergences the reasons can be identified readily, e.g. use of human data or non-default safety factors.

Reasons for differences between HBGVs can be due to a variety of factors either singly or in combination:

- Different databases

32 The actual values are not presented in this report, but can be checked at: APVMA, 2019.

33 The HBGVs are considered ‘the same’ where the basis is the same study and dose but due to different conversions or rounding procedures the actual values differ.

34 A conclusion of ‘unnecessary’ is taken as being ‘higher’ than where an ARfD with a value was derived.

New studies on pesticides are often undertaken to meet new data requirements or to investigate or refine existing findings. As the review cycles of JMPR and regulatory agencies are not synchronized, there is the potential for different conclusions to be reached due to a different database available at the times of the reviews. Pesticide review programmes typically have a 10 to 20-year cycle.

For some older pesticides with multiple manufacturers, the company supporting the review through JMPR can differ from that supporting it through national or regional evaluations. Studies performed to supplement the original core database are likely to differ between the companies, resulting in differences in the databases.

JMPR considers that ethically performed human volunteer studies can provide relevant data for the human risk assessment of pesticides. This is not the position in the European Union due to the applicable legislation (European Union, 2009). The US position is currently that data from volunteer studies should not be used for determining points of departure (PODs) for human health risk assessments of pesticides. Australia has existing HBGVs for pesticides based on human volunteer data.

- Differing point of departure (POD):

  a. The United States Environmental Protection Agency (EPA) normally uses NOAELs in its assessments. However, it also uses benchmark dose (BMD) methodology as a tool in refining PODs (USEPA, 2002a). Evaluations have shown that in many instances a BMDL and a NOAEL for a specific study are not markedly different. Both JMPR and the European Union have made use of BMD on an occasional basis for pesticide risk assessments.

  b. For many end-points in toxicity studies, there is no clearly defined criterion for adversity. In determining adversity, and hence a NOAEL, experts will take account of many factors such as statistical significance, magnitude of the change, associated findings, normal background variation etc. It is therefore possible that a marginal change (e.g. 11 percent) in an end-point can be considered adverse by one group, but not adverse by another. If there is a five-fold spacing between doses this could result in a five-fold difference in an HBGV. In the future, this could be mitigated by the use of BMD, but this can be resource intensive to perform.

- Derivation of an ARfD:

  a. Deciding whether or not a pesticide requires an ARfD can have a major impact on the overall risk assessment. If an ARfD is considered unnecessary, then no acute exposure/intake assessment is triggered. If no acute assessment is performed as part of a JMPR assessment, yet other agencies consider one is required, this can be a reason for non-acceptance of a proposed Codex MRL. However, in such circumstances an acute risk assessment should be performed by the agency, using appropriate criteria, to ascertain if the risk assessment is unacceptable or not.

  b. As shown by the analysis of the rice pesticides (Annex B-2: Analysis of data on pesticides used on rice) there were a number of differences between the European Union and JMPR conclusions on when an ARfD was considered unnecessary. This was also true for Australia (see above), but Australia tended to derive fewer ARfDs than JMPR.

  c. Although guidance documents on deriving ARfDs have been produced by many agencies, and there is much in common, there is a high degree of uncertainty surrounding ARfD derivation. The main reason is that a well performed, single dose study, measuring critical end-points at the key time, is not available for the vast majority of pesticides. Even acute neurotoxicity studies can have study designs that often preclude the determination of NOAELs (e.g. use of three high doses) and contain no or few measurements of parameters other than those linked to neurotoxicity.

  d. Many end-points are only measured after four weeks of dosing, or longer. There is therefore considerable uncertainty and extrapolation in deciding if any changes seen after four weeks would have been produced by a single dose or dosing over a single day. The precautionary approach is to assume all findings could be related to a single dose.

  e. Companies have the option to present additional data to refine ARfD conclusions. Due to animal welfare considerations, this should only happen after other approaches (e.g. alternative GAPs) have been investigated and in the reviewer's experience refinement of an ARfD occurs very infrequently.

f. It might be useful to have an international discussion on criteria for determining when an ARfD is unnecessary, based on experience gained since original guidance documents were prepared.

- Choice of 'safety' factors:

a. The default approach of applying a 100-fold overall factor to a POD in driving an HBGV is used for the vast majority of pesticides.

b. For non-threshold cancer end-points, the US EPA and the Canadian PMRA apply linear low dose extrapolation (USEPA, 2000); (USEPA, 2002a); (Canada, 2014).

c. JMPR has adopted chemical specific assessment factors (CSAFs; (WHO, 2005)), where this approach has been supported by appropriate data, for a number of HBGVs, typically ARfDs. This has resulted in HBGVs higher than those that would have been derived with the default 100 factor. Such an approach is not possible in the European Union where the applicable legislation (Article 3.6.1 of Annex B-2: Analysis of data on pesticides used on rice of EC 1107/2009) requires a minimum factor of 100 to be applied to a NOAEL. Australia and the United States of America documentation indicates that CSAFs will be considered on a case-by-case basis.

d. JMPR and other agencies consider the application of additional factors where there is a small margin between a NOAEL and a serious effect, or there is a higher than normal level of uncertainty in the derivation of the HBGV. The decision whether to apply an extra factor is mainly down to expert judgement and can vary greatly between different organizations. However, the magnitude is typically three or five and might not be critical to the overall conclusion of the risk assessment. If factors of >10 are considered, the level of uncertainty is so great that a HBGV might not be set. In addition to the traditional safety factors, the US EPA applies an additional FQPA (Food Quality Protection Act) factor of ten to account for sensitivity of susceptible subgroups, especially children. The FQPA factor may be removed or modified based on available data showing that an alternative factor is appropriate (USEPA, 2002b). Similar to the US FQPA factor, Canada also applies the PCPA (Pest Control Products Act) factor, which is also a factor of ten by default, but can be removed or reduced depending on the available data and underlying concern. It is important to note, however, that unlike the other safety factors (e.g., interspecies factor), law in Canada and the United States of America, respectively mandates the requirement to apply the PCPA and FQPA factor.

- Rounding of values for HBGVs:

  The EFSA typically has two significant figures (after the zero(s)) in its HGBVs. Other agencies and organizations (US EPA, JMPR, APVMA) normally round to one significant figure, to acknowledge the overall level of uncertainty in the value. This rounding can result in numerically different values, but the margin is relatively small (<2) and will have no impact on the majority of risk assessments.

- There are a number of factors that potentially can result in numerically different HGBVs for the same pesticide. However, in the majority of cases, as supported by the rice analysis, the differences cover a relatively small range. Such differences will only have an impact on Codex MRL acceptability if predicted exposures/intakes represent a high proportion of the JMPR HGBV.

1.3. ASSESSMENT OF METABOLISM STUDIES

Rat metabolism studies are used to determine if the toxicity of metabolites found in the residue chemistry database (e.g., plant and livestock metabolism studies, confined rotational crop studies) could have been addressed in the toxicity studies using the pesticide active ingredient. There is general agreement that if a metabolite is present in the rat at 10 percent or more of the systemic dose its toxicity can be considered to be covered by the toxicity studies on the parent compound. Studies with *in vitro* metabolic systems permit multiple sampling times and can identify transient metabolites not identified in the *in vivo* studies. However, the *in vitro* systems are normally based on hepatic cells or slices and do not cover non-hepatic metabolism. There are no agreed approaches to the use of such *in vitro* studies in the assessment of metabolites found in agricultural commodities.

Where metabolites are found in crop metabolism studies, but not at significant levels in rat/*in vitro* metabolism studies, further work is necessary to determine whether the metabolites are toxicologically relevant. Depending on the amount of the metabolite in the crop, the requirements can be limited to *in silico* methods, threshold of toxicological concern (TTC), or involve repeat dose toxicity studies. Based on the information available, it is unclear to the author how consistent across different countries and regions the data requirements for crop metabolites are. Harmonization of approaches to determining the toxicological relevance of metabolites would help reach standardized residue definitions and potentially minimize animal testing.

Metabolism studies in crops should be performed at the critical GAP, or at higher application rates if residue levels are low. Studies should be performed on one or more crops from the five main groupings (root, leafy, fruit, pulses/oil seed, cereals). If data from three of these groups show good agreement, information on the other two is not required by JMPR, Australia, Canada or the European Union (1997 ref. annex VI B2-1). Methodology requirements such as use of multiple label positions, extraction methods and desired LOQs (0.01 mg/kg) appear to be common across all countries/region analysed.

Some old (pre-1990) residue definitions have been compromised by the use of a single radiolabel position (e.g. tri-allate; compounds containing two or more rings with labile bridging bonds). On cleavage of the molecule the unlabelled moiety cannot be traced, potentially resulting in a residue definition that omits some significant component(s). If new studies using multiple label sites are made available during some but not all subsequent reviews, this has the potential to result in differences in metabolite profiles and residue definitions.

It is more likely that major differences in the conclusions of crop metabolism studies will be due to differences in the studies and methodological aspects such as position of radiolabel and limits of detection/quantification, rather than differences in the assessment of the data. However, determination of the toxicological relevance of crop metabolites appears to be inconsistent across some countries/region analysed.

1.4. EXPOSURE ASSESSMENTS

Food consumption data used by FAO/WHO Expert Committees (JECFA, JMPR etc.) are based on data from countries around the entire world, and collected in the Global Environmental Monitoring System food database (GEMS) and/or in the "FAO/WHO Chronic Individual Food Consumption – summary statistics" (CIFOCOss) database. While GEMS food database contains average daily per capita consumption data, based on food cluster diets, the CIFOCOss provides individual food consumption data based on country surveys. National authorities carrying out risk assessment use their own national consumption data. In theory, the national consumption data will be included in the FAO/WHO databases and therefore be covered by the JMPR assessment. This depends on national authorities supplying updated consumption data to FAO/WHO.

For acute intake assessments (IESTI model), there is currently a scientific agreement regarding the use of the highest residue (HR) combined with large portion size data as the main intake component. A recent probabilistic study conducted by WHO confirmed that the IESTI is a conservative model for adults and children. The study did not show any appreciable risk for exceeding the ARfD based on the available data.

For chronic assessments (IEDI model) there is a difference between US EPA's and JMPR's use of the supervised trial median residue (STMR) and mean consumption data and that of some agencies (EFSA) which use STMR and a high percentile consumption value. This is linked to the way the data for the 17 GEMS/Food cluster diets are captured. An alternative global estimate of chronic dietary exposure (GECDE) model has been developed by JECFA (veterinary drugs) using individual food consumption data. Among other things, the advantage of using such data is that it would allow for more refined dietary exposure assessments, including for high-end consumers and for different population subgroups (e.g. children). A JECFA/JMPR Working Group performed an exercise comparing IEDIs and GECDEs. Dietary exposure estimates from the high consumer GECDE model were of the same order of magnitude as the highest IEDI cluster estimate for the majority of pesticide residues considered in this exercise. However, for some subpopulation groups, the estimated dietary exposure using the GECDE was higher than the highest IEDI cluster estimate. At the 2018 JMPR Meeting there was discussion on future work to enhance food consumption data and chronic dietary exposure assessment to be used by JMPR (see section 2.1 of (WHO, 2019b)).

When providing briefing on Codex, EFSA does not rely on the JMPR assessment but performs its own intake assessment using the approaches of the European Union and the lower of the HGBVs from the European Union or JMPR. This is positive in that any issues in terms of exposures are related to a risk assessment rather than being based purely on a perceived difference in approach or value for the ADI/ARfD. It is unclear if all countries/authorities adopt the same detailed approach. Australia and Japan indicate that risk assessments are performed using national consumption data and Australia will perform an assessment using both its own and JMPR HBGVs where the values differ.

1.5. DIFFERENCES IN GOOD AGRICULTURAL PRACTICE (GAP) AND SELECTION OF CRITICAL GAP

Data differences

JMPR will typically evaluate data from a wider range of geographical locations than those submitted to individual countries or authorities. This should mean that JMPR receives the most extreme GAPs, which should give rise to Codex MRLs being as high or higher than any others. However, looking at the analysis of the pesticides used on rice (Annex B-2) there are a number of cases (e.g. bentazone, chlorpyriphos-methyl, difenoconazole) where the MRLs of the European Union and the United States of America are significantly higher than the Codex MRL, suggesting that the data of the European Union and the United States of America were probably not submitted to JMPR or that there are differences in crop groupings used to establish a group MRL. A similar situation was identified for some Australian MRLs. This may indicate that there can be significant deficiencies in the data available to JMPR, due to incomplete submissions or the availability of new data since the conclusion of the JMPR review. Companies or countries submitting data should ensure JMPR receives all critical GAPs to support the worldwide applicability of Codex MRLs. It is expected that there will be differences in GAPs/MRLs across countries or regions for various reasons such as climate and pest pressure. However, as JMPR/Codex should be provided with data covering the most GAPs it is expected that the Codex MRL will cover all uses in major Codex member countries.

For approval of a pesticide in individual countries/region, residue studies are normally expected to be performed in that country or area by covering a number of sites and if necessary climatic conditions (e.g. northern and southern areas of the European Union). This variation in conditions could potentially have a greater impact on the MRL than variations in the criteria used to determine the critical GAP. However, recent work has suggested that zone-specific conditions do not have a significant impact on MRLs (Nguyen *et al.*, 2019).

Number of studies required

There are differences in the minimum number of studies required to be performed at the critical GAP to support the establishment of an MRL. The OECD has described the minimum number of trials that would be needed to support an MRL in all OECD member countries. This information is set out in Appendix XII of the FAO manual (FAO, 2016).

Some countries/authorities have a relatively simple approach (e.g. 16 trials for a major crop, eight trials for a minor crop with the possibility for fewer trials if there is limited variability in results). Others have a detailed consideration of the importance of a particular crop to the national diet. This may lead to significant differences between closely related countries. For example, Canada requires 16 trials for rapeseed, while the United States of America require only eight; for maize the numbers are five and 20 respectively (NAFTA, 2005). Therefore, if a Codex MRL is supported by the minimum number of trials for one country, it might not meet acceptance criteria in other countries. The JMPR expects a minimum of six to eight trials for major crops (with 15 or more recommended).

The European Union commented that because of differing legislative provisions, it has more flexibility in the number of trials required for harmonizing a Codex MRL than in the assessment of an import tolerance or application for approval.

There appear to be differences in how the concept of ‘limited variability of results’ is applied to accepting a reduced number of trials. In some instances, it is accepted when all values are below the LOQ, but not accepted when results are tightly grouped around a value above the LOQ.

There are some differences in how many growing seasons are required – JMPR will accept just one season under certain conditions but some other authorities require two.

There is potential for greater harmonization in the number of trials required to support an MRL.

Reading across from studies not complying with critical GAP

Studies used to support an MRL should be performed according to the critical GAP conditions described on the label (e.g. worst-case application rate, volume, formulation type, application stage, PHI etc.). There appears to be agreement that the majority of studies should be performed at or above the GAP but there is some flexibility for using studies that do not comply exactly with GAP, provided the variation in one of the critical parameters is <25%. If there is variation in more than one critical parameter, read across might not be possible.

This seems to be a consistent area.

Statistical assessment of data in critical studies

The application of the OECD calculator, supplemented by expert judgement was identified from the survey responses as a common approach in MRL derivation. However, differences between some national/regional MRLs and Codex MRLs have been reported to be related to the application of different statistical approaches to some elements of the dataset (e.g. sampling error). International agreement on the application of statistical methods used in the setting of MRLs should be sought.

2 RISK MANAGEMENT CONSIDERATIONS

This chapter reviews various risk management aspects that could lead to the establishment of different MRLs. The aspects considered are the following:

2.1. Establishment of MRLs for specific commodities / groups

2.2. MRL extrapolation rules

2.3. Application of processing factors

2.4. Application of default MRLs for non-registered pesticides

2.5. Risk management factors applied to the toxicology evaluation

2.6. Import tolerances

2.7. Commodity descriptions

Key messages:

- Automatic harmonization with Codex MRLs is not the norm because such practice is not embedded in national legislations. For non-registered MRLs, the accepted practice is to set a default value, usually at the limit of quantification, or to not establish any tolerance/MRL.
- In the absence of a national MRL, an application can be made to have an MRL established, which is termed an import tolerance. The process can vary greatly in both complexity (extent of acceptance of evaluations performed by JMPR) and duration (from several months up to six years), depending on the country.
- During the Codex step-process for the development and adoption of new Codex pesticide MRLs, only the European Union actively notifies whenever a Codex MRL is not going to be adopted in the European Union, and provides scientific reasons for that decision.
- Differences in the time of MRL adoption at Codex and at national level may entail changes in the scientific data packages evaluated by the different authorities. Only Australia, the European Union and Japan have routine procedures in place to review national MRLs at the time Codex adopts new MRLs.
- There is great inconsistency among the commodity descriptions across different countries/region.

2.1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS FOR SPECIFIC COMMODITIES/GROUPS

Rather than setting MRLs on a number of closely related commodities, so termed 'group MRLs' can be set covering a number of similar commodities. Because different pesticides can behave differently in even closely related commodities, there are few default rules for using data from one or two commodities to produce a group MRL.

The relevant commodities on which to perform trials are those that would be expected to give the highest residues (e.g. based on surface area to volume, water content, edible portion). Where data are available on a number of commodities within a group, it is expected that there should be a relatively small variation (ratio of <5; or appropriate statistical methods); and that the representative commodity for the group: (i) will be the one that gives the highest MRL, (ii) is a major contributor to the diet, and (iii) is morphologically representative of other members of the group.

JMPR uses the Codex classification of groupings. The NAFTA has its own system that has much in common with Codex, but there are some varieties present in the NAFTA groupings, which are not in Codex and vice versa. The European Union has general groupings with no independent listing of varieties, but appears to use the Codex system. Variations in crop groupings have been cited as reasons for reservations being raised on Codex MRLs. Australia uses the Codex classifications and groupings.

There would appear to be some potential to get further harmonization of commodities within groups.

2.2. MAXIMUM RESIDUE LIMIT EXTRAPOLATION RULES

The concept of extrapolation of MRLs within a crop grouping seems to be an accepted approach either by direct application of an MRL from a major crop to a related minor one, or by use of field trials data on a related commodity to supplement the database of another. However, there appear to be no definitive rules regarding the application of the extrapolation procedures and it is typically case-by-case, depending on the available information. Aspects that have been identified as precluding such an extrapolation include:

- different residue definitions;
- different databases, giving differences in the appropriate crop to extrapolate from;
- minimum number of trials required by national/regional authorities; and
- differences in the crops within a group that can be used as the basis for extrapolation.

2.3. APPLICATION OF PROCESSING FACTORS

The use of default processing factors appears to be limited in terms of number of examples and applicability to major components of the diet. Where processing factors are involved, they are generally calculated case-by-case based on data. Different processing technologies might apply to a commodity in different countries, resulting in different processing factors.

Australia calculates processing factors on a case-by-case basis using the available data to determine residues in the edible portion/derived product of a commodity.

The European Union does not set MRLs for processed commodities but uses processing factors in intake estimates. A number of default factors are incorporated into the PRIMO spreadsheet (EFSA, 2019) (many taken from an OECD 2008 citation) but these are mainly for relatively minor commodities/products.

In the absence of a harmonized list of processing factors within Europe, the European Union is developing a database of processing types and processing factors compatible with the EFSA food classification and description system FoodEx2[35]. In assessing Codex MRLs, the European Union considers available data on residue levels in peel or inedible skin, but appears to have different criteria to JMPR in determining the acceptability of such data.

35 See: https://www.bfr.bund.de/en/database_of_processing_techniques_and_processing_factors_compatible_with_the_efsa_food_classification_and_description_system_foodex_2_-202963.html

2.4. APPLICATION OF DEFAULT MAXIMUM RESIDUE LIMITS FOR NON-REGISTERED PESTICIDES

The default position in all responders except Australia and the United States of America is to establish default MRLs for non-registered products. Europe and Japan set the default MRL value at 0.01 mg/kg, which in most instances corresponds to the LOQ. Canada has a "general MRL" of 0.1 mg/kg (Section B.15.002 of (Canada, 2019)). The United States of America and Australia commented that they do not establish by default any tolerances/MRLs for non-registered products, so any residue detected for non-registered pesticides could be considered violative.

In order to remove these default values or establish MRLs, it appears that a specific request (domestic and/or import tolerance) needs to be made.

For new Codex MRLs, specific requests (import tolerances) may not be necessary in certain countries/region. In the European Union, new Codex MRLs are reviewed upon their establishment and the MRLs of the European Union are raised to the same level of Codex MRLs, if three conditions are fulfilled: (1) that the European Union sets MRLs for the commodity under consideration, (2) that the current MRL of the European Union is lower than the Codex MRL, and (3) that the Codex MRL is acceptable to the European Union with respect to areas such as consumer protection, supporting data, and extrapolations. Automatic review of newly adopted Codex MRLs takes place also in Japan. In Australia, Codex MRLs for pesticides are incorporated into the Australian Code based on need, through an open and transparent process. Any country, sponsoring company or other third party can apply for the incorporation of the individual Codex MRL into the Code whenever such a need is identified. This MRL harmonization process is free-of-charge to applicants and the needed Codex MRL will be incorporated into the Code unless an estimate of dietary exposure exceeds the HBGVs using Australian food consumption data. In addition, Australia is considering automatic adoption of new Codex MRLs (subject to a suitable exposure assessment) in the near future.

In cases where Codex MRLs exist, unless a proven scientific justification is provided, the application of LOQ MRLs rather than Codex MRLs seems to be contrary to the SPS text, as the JMPR considerations of toxicology and residues will have been performed according to internationally accepted procedures.

There is scope for developing criteria for wider acceptance of Codex MRLs for pesticides not registered in specific countries/regions (e.g. large margins can be demonstrated between predicted exposures and HBGVs).

2.5. RISK MANAGEMENT FACTORS APPLIED TO THE TOXICOLOGY EVALUATION

The US EPA applies an extra ten-fold factor to the default 100 when establishing HGBVs. This factor arises from the Food Quality Protection Act (FQPA). Canada has an equivalent approach. The factor is removed entirely or reduced depending on the information in the toxicology and exposure databases for assessing sensitive subgroups, particularly children (USEPA, 2002b). JMPR and other agencies will add additional factors if databases are lacking, not as a default. It is also possible that an element of the FQPA factor could remain due to uncertainties in the non-dietary exposure, which would not be relevant to MRL considerations.

Australia and Japan appear to have no further risk management requirements precluding acceptance of Codex MRLs, if the national risk assessment of the pesticide (or its residues) has a satisfactory outcome and the biosecurity/quarantine requirements are met.

In the European Union, any pesticide that is classified as Cat 1A or 1B for reproduction or carcinogenicity or mutagenicity, or is considered to have endocrine disrupting properties, cannot be approved unless exposure is 'negligible' (3.6 of Annex II of EC 1007/2009). The negligible exposure applies to both dietary and non-dietary exposures. It is possible that a negligible exposure could be demonstrated for dietary exposure but no approval would be given based on non-dietary exposures.

The European Union also has a number of environmental criteria which preclude approval of a pesticide, e.g. if it is a persistent organic pollutant, failing the environmental assessment for groundwater (0.1ug/L).

In commenting on a draft of this report, the European Union stated that these risk management criteria are for the approval of active substances in the European Union and are not applied to import tolerance assessments that would follow a standard risk assessment.

2.6. IMPORT TOLERANCES

If a Codex MRL for a pesticide/commodity combination has not been harmonized by an importing country, or there is no national MRL in the importing country, an application can be made to have an MRL established. This is termed an import tolerance (NAFTA (US + Canada), Japan and the European Union, or Schedule 20 amendment (Australia)). This process can vary greatly in both complexity and duration (from several months up to six years), depending on the country. There is also inconsistency among countries/region regarding the extent of acceptance of evaluations performed by other organizations (e.g. JMPR) or national authorities versus performing a *de novo* evaluation:

- The Australian guidance indicates a willingness to accept JMPR and/or other national evaluations in whole or in part (FSANZ, 2018).
- The NAFTA guidance indicates that the presence of a JMPR evaluation could result in a less extensive procedure (NAFTA, 2005).
- In the European Union and Japan, a full, new assessment appears to be required even if other evaluations are available. When considering setting MRLs under an import tolerance application, the European Union uses the GAP and supporting information from the notifier. The supporting information is assessed against the same acceptance criteria (e.g. number of trials, sampling protocols etc.) as would be used for a standard MRL evaluation of the European Union.

The re-evaluation of studies and data adds significantly to the cost and time of concluding on the import tolerance. If non-harmonization of Codex MRLs cannot be resolved, it would be a benefit to trade if agreement could be reached on a common approach to import tolerances. In particular, the level of acceptance of evaluations performed by other authorities using accepted risk assessment procedures.

2.7. COMMODITY DESCRIPTIONS

There is some inconsistency in the way commodities are described in respect of the MRLs. This is true both within individual schemes and between them. The differences highlighted during the comparisons performed on rice pesticides are reported below as an example of this variation across countries/region[36]:

CODEX

Within the Codex database (Codex, 2019), MRLs for rice were found with the following commodity descriptions:

- Rice
- Rice polished
- Rice husked
- Wild Rice
- Cereal grains

In some instances, the MRLs were the same for two or more of the descriptions, in other cases there were marked differences (e.g. dichlorvos). These values and descriptions would presumably have related to the data considered during the evaluations of the pesticide. However, there was great variability, with different pesticides having between one and four of the descriptions.

AUSTRALIA

Within Schedule 20 (Australia, 2018) there are four different commodity descriptions relating to rice:

- Rice
- Rice, husked
- Rice, polished
- Cereal grains

CANADA

- Rice
- Wild rice

THE EUROPEAN UNION

The data of the European Union were all presented as 'rice', covering primarily husked rice, but also a number of types and forms of rice (European Union, 2019b). [Within the PRIMO intake calculation software (EFSA, 2019) a default processing factor of 0.4 can be applied for milling or polishing of rice].

JAPAN[37]

- Rice (brown rice)
- Rice milled

The United States of America

Within the United States of America MRLs databases[38] ((Bryant Christie Inc., 2019); (e-CFR, 2019)) there was again great variation in the commodity descriptions:

- Rice (*Oryza sativa*)
- Rice post-harvest
- Wild rice (*Zizania aquatica*)
- Rice, wild, grain
- Rice, wild, grain, post-harvest
- Rice grain
- Rice, grain, post-harvest
- Rice polished
- Rice polished post-harvest
- Grain, cereal, group 15

As with Codex, there was great variability in how many rice related MRLs were set for any individual pesticide.

There was inconsistency between the commodity descriptions for individual pesticides across different countries/region. For example, for sulfuryl fluoride, there are: Codex MRLs for rice polished and rice husked; but the United States of America has MRLs for rice grain and rice polished, plus three specified processed fractions plus a generic one for commodities not otherwise listed.

In general, due to variation in rice classifications across countries, it was not easy to match the different Codex rice commodity types with the national ones. Much investigation work and interactions/clarifications between FAO and the countries/region analysed were necessary to understand how to match national rice MRLs properly to Codex rice MRLs.

Although the above is only based on rice, similar issues also apply to other commodities such as cereal grains, nuts, grapes (e.g. table, wine, dried, raisins), pulses (e.g. with pods, without pods, dried) etc.

36 See also Part A: Annex A-2 and Chapter 2.3.

37 In Japan, rice is not normally sold in a highly processed form hence the unexpectedly low number of descriptions for rice.

38 US MRLs were consulted both in the official US Electronic Code of Federal Regulations (https://www.ecfr.gov/cgi-bin/retrieveECFR?g-p=&SID=b4b3755e18a86aaeab34590c6eb9b576&mc=true&n=pt40.26.180&r=PART&ty=HTML), and in the Bryant Christie database (run by a commercial organization but linked from the USDA website: https://www.fas.usda.gov/maximum-residue-limits-mrl-database). When discrepancies existed between the two sources, preference was given to the US Electronic Code of Federal Regulations.

It is unclear why there is so much variation within schemes. Some are due to the availability of data on different fractions of rice but it is unclear why there are such variations in the available data. If MRLs are required (available) for multiple rice fractions for one pesticide, why does another pesticide only have one rice MRL? It seems very unlikely that the subsequent treatment of harvested rice will vary greatly depending on which pesticides have been applied.

Whether these differences in commodity descriptions can result in rejection of Codex MRLs was not investigated in this project. However, to reduce the potential for confusion over multiple MRLs for different forms of a single pesticide/crop combination, it would appear logical to look to improve consistency where possible, i.e. set multiple MRLs for all pesticides to cover all likely fractions, or reduce the number of MRLs for some pesticide/crop combinations.

3 CONCLUSIONS AND WAY FORWARD

The feedback obtained from the five markets analysed, together with the additional information sources used in the analysis, were not sufficient to provide a complete picture for the reasons behind lack of harmonization with Codex MRLs. Despite these limitations, some conclusions could be drawn and some of the findings are reported below.

Risk management considerations

The analysis showed that automatic harmonization with Codex MRLs is not the norm because such practice is not embedded in national legislations. For non-registered pesticides and non-registered uses in specific countries/region, the default practice is to set a default value, usually at the limit of quantification, or to not establish any tolerance/MRL, which results in zero tolerance. In these cases, specific applications (with varying levels of detail) are required to establish a specific MRL or support harmonization with Codex MRLs.

During the Codex step-process for the development and adoption of new Codex pesticide MRLs, only the European Union actively notifies whenever a Codex MRL is not going to be adopted in the European Union, and provides the (scientific) reasons for not adopting the Codex MRL. Such information was found very informative in terms of preparing this report, but was not identified for any of the other countries analysed.

Some authorities do not harmonize with Codex MRLs pending the conclusion of ongoing reviews, some of which can take several years to finalize. This is a one-sided position because existing 'national' MRLs are not suspended during the review.

Differences in the time of MRL adoption at Codex and at national level may entail changes in the scientific data packages evaluated by the different authorities (e.g. different GAPs reflecting different pests and diseases, different pesticide labels, availability of different studies, etc.). While Australia, the European Union and Japan review Codex MRLs upon their establishment, Canada and the United States of America report to have no routine procedures in place to review national MRLs at the time Codex adopts new MRLs. The United States of America and Canada review MRLs as part of a national active substance review programme.

In the absence of a national MRL in the importing country, an application can be made to have an MRL established, which is termed an import tolerance. The process can vary greatly in both complexity (extent of acceptance of evaluations performed by JMPR) and duration (from several months up to six years), depending on the country. The re-evaluation of studies and data adds significantly to the time and cost of concluding on the import tolerance.

There is great inconsistency between the commodity descriptions for individual pesticides across different countries/region. While this study only considered rice, the same is true also for other commodities. It was not investigated whether these differences in commodity descriptions can result in rejection of Codex MRLs.

Risk assessment methodology

A considerable variation was perceived in how countries/region are aligned with the JMPR/Codex process for the development and establishment of pesticide MRLs. Australia is closely aligned, and although not automatically harmonizing with Codex MRLs, indicates it is willing to accept at least a proportion of the conclusions of JMPR assessments as part of an application. Canada, the European Union, Japan and the United States of America, although having a number of aspects of their procedures that are closely aligned, perform an extensive independent evaluation of the study reports according to their own national criteria.

Many of the differences in risk assessments do not seem to have a significant impact on the overall outcomes. The review of pesticides used on rice, as well as the experience, showed that the health-based guidance values typically vary within a factor of +/-2. In addition, for a number of pesticides used on rice, the JMPR intake estimates were well below the applicable HBGVs, leaving a significant margin for differences in

HBGVs and consumption data to be accommodated within an acceptable risk assessment.

What is unclear is whether having a slightly different ADI/ARfD or consumption value within the risk assessment is sufficient to trigger a reservation regarding a Codex MRL – even if the risk assessment is/would be satisfactory based on national/regional criteria.

In only a very few cases there were large (ten fold or more) differences between JMPR ADIs/ARfDs and those of other countries/region analysed.

From the limited review of pesticide MRLs for rice, there are indications that some of the major differences in MRLs and residue definitions are due to the presentation of different data to the different countries/regions and authorities. Some of the differences in residue definitions are due to different forms of a pesticide being available (e.g. racemic versus resolved isomer preparations), which have no or minimal impact on the risk assessment. The reasons behind the differences in data availability are varied, including different data requirements, availability of data to different companies and differences in timings of reviews. Increased harmonization of review timetables could overcome some, but not all of these.

Furthermore, national authorities conduct exposure assessments using their own consumption data, while JMPR assessments are based on data from countries around the world, as submitted via the GEMS food system or CIFOCOss database. Harmonization thus also depends on national authorities supplying updated consumption data to FAO/WHO.

The use of the OECD MRL calculator tool, with the addition of expert judgement, is common to all countries/region analysed. However, inputs to the OECD calculator are not fully harmonized (e.g. crop groupings), which could lead to different MRLs.

National GAPs are used when setting national MRLs, as enforcement tools for compliance with nationally registered pesticide uses (label information), with limited if any consideration of other GAPs, other than those which are part of import tolerance applications. On the other hand, the objective of Codex MRLs is to support international trade of products and, as such, they are based on the highest residues of international GAPs.

Many of the guidance/procedural documents, related to MRLs and human health risk assessments of pesticides identified during this review were initially drafted 10 to 20 years ago, with occasional updates and partial revisions subsequently. Consideration could be given to an update process that can be agreed internationally. With differing legislative constraints there will not be complete agreement. However, there are a number of areas where there are relatively minor variations in approaches and an internationally acceptable approach might be determined, which could facilitate the acceptance of Codex MRLs.

It is also worth recognizing the ongoing work to address some of the issues that might lead to deferring MRLs. For example, this includes the work underway at OECD, jointly with JMPR and JECFA, on the development of a guidance document to standardize residue definition approaches, or the efforts to improve harmonization on chronic exposure assessments between JMPR and JECFA, by using individual food consumption data.

The following points were drawn from the general findings of the analysis on the reasons behind different levels of harmonization, as a way forward to facilitate further discussion on how to improve international harmonization:

1. When not subject to national legal requirements that govern the use of a default MRL value, in line with the WTO SPS Agreement, harmonization with Codex MRLs should be sought as a default position (because the JMPR assessments are performed to internationally accepted standards), while non-harmonization should be supported by scientific arguments[39]. Where legal requirements restrict harmonization with Codex MRLs, the reason for the legal decision should be reviewed.

2. For increased transparency, it would help if Codex member countries actively notify CCPR of reservations, or non-harmonization on Codex MRLs, providing background information for non-harmonization with newly developed Codex MRLs (along the lines of that provided by the European Union when they do not harmonize with a Codex MRL). This information could then be evaluated with a view to identifying and resolving common areas of concern.

3. Bodies such as OECD and/or JMPR and/or Codex could consider improving harmonization/consistency in the following areas:

39 WTO SPS Agreement, Art. 3: https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm

a. crop groupings;
b. extrapolation of data between crops/ commodities;
c. number of field trials required to support an MRL for a particular crop;
d. statistical methods applied to field trial data;
e. consideration of isomers (and other minor differences in chemical structure e.g. esters) in residue definitions;
f. the necessity for setting MRLs on different parts of a crop (e.g. straw, grain, husked grain, bran);
g. use of existing reviews in the evaluation of applications for import tolerances;
h. data requirements for crop metabolites not present in mammalian metabolism;
i. criteria for deciding if an ARfD is required or not; and
j. impact of risk management practices, especially those not directly related to dietary risk assessment.

4. As also indicated in some of the feedback received by interested parties, countries could notify CCPR/ JMPR Secretariat if they receive new data that casts significant doubt on the continuing validity of an existing Codex MRL. For example, results of a new crop metabolism study using additional radiolabel positions, or significantly adverse toxicity data.

5. If non-harmonization of Codex MRLs cannot be resolved, it would be a benefit to trade if agreement could be reached on a common approach to import tolerances. In particular, the level of acceptance of evaluations performed by other authorities using accepted risk assessment procedures.

6. Findings of these analyses could be used to stimulate an international discussion to identify reasons behind non-harmonization with Codex MRLs and steps to improve the situation.

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GLOSSARY

Taken from EHC 240 (WHO, 2009) and CODEX definitions where possible. It is acknowledged that other organizations might have slightly different definitions.

Acceptable Daily Intake (ADI) – The estimate of the amount of a chemical 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. It is derived on the basis of all the known facts at the time of the evaluation. The ADI is expressed in milligrams of the chemical per kilogram of body weight (a standard adult person weighs 60 kg). It is applied to food additives, residues of pesticides and residues of veterinary drugs in food.

Acute Reference Dose (ARfD) – 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 24h or less without appreciable health risk to the consumer. It is derived on the basis of all the known facts at the time of evaluation. The ARfD is expressed in milligrams of the chemical per kilogram of body weight.

Benchmark Dose (BMD) – A dose of a substance associated with a specified low incidence of risk, generally in the range of 1–10 percent, of a health effect; the dose associated with a specified measure or change of a biological effect. Normally considered along with the upper (BMDU) and lower (BMDL) confidence intervals from the analysis.

Chemical-specific adjustment factor (CSAF) – A modified default ten-fold uncertainty factor that incorporates appropriate data on species differences or human variability in either toxicokinetics (fate of the chemical in the body) or toxicodynamics (actions of the chemical on the body).

Codex – The Codex Alimentarius (Food Code) is a collection of standards, guidelines and practices adopted by the Codex Alimentarius Commission. The aim is to contribute to the safety, quality and fairness of international trade in food commodities.

GEMs food – The World Health Organization's Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme, which maintains databases on contaminant levels in foods and estimates of dietary exposure to food chemicals. Collects information and maintains databases on consumption levels of agricultural commodities.

Good Agricultural Practice (GAP) – For pesticide use, includes the nationally authorized safe uses of pesticides 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 manner 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.

Health Based Guidance Values (HBGV) – A numerical value derived by dividing a point of departure (a no- observed-adverse-effect level, benchmark dose or benchmark dose lower confidence limit) by a composite uncertainty factor to determine a level that can be ingested over a defined time period (e.g. lifetime or 24h) without appreciable health risk. Related terms: ADI, Provisional maximum tolerable daily intake, Provisional tolerable monthly intake, Provisional tolerable weekly intake and Tolerable daily intake.

Joint Meeting on Pesticide Residues (JMPR) – The abbreviated title for the Joint Meeting of the FAO Panel of Experts and the WHO Core Assessment Group on Pesticide Residues in Food and Environment, which has met since 1963. The meetings are normally convened annually. The FAO Panel of Experts is responsible for reviewing residue and analytical aspects of the pesticides considered, including data on their metabolism, fate in the environment and use patterns, and for estimating the maximum residue levels and supervised trials median residue levels that might occur as a result of the use of the pesticide according to (GAP). The WHO Core Assessment Group on Pesticide Residues is responsible for reviewing toxicological and related data on the pesticides and, when possible, for estimating ADIs and long-term dietary intakes of residues. As necessary, acute reference doses for pesticides are estimated along with appropriate estimates of short-term dietary intake. JMPR is a technical committee of specialists acting in their individual capacities. Each is a separately constituted committee. When the term "JMPR" or "the Meeting" is used without reference to a specific meeting, it is meant to imply the common policy or combined output of the separate meetings over the years. Makes recommendations for MRLs to the CCPR.

Maximum Residue Limit (MRL) – The maximum concentration of a pesticide residue (expressed as milligrams per kilogram) recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feed. MRLs are based on (GAP) data, and food derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable. Consideration of the various dietary residue intake estimates and determinations, at both the national and international level, in comparison with the ADI intake should indicate that foods complying with Codex MRLs are safe for human consumption.

No-Observed-Adverse-Effect Level (NOAEL) – Greatest concentration or amount of a substance, found by experiment or observation, that causes no adverse alteration of morphology, functional capacity, growth, development or lifespan of the target organism distinguishable from those observed in normal (control) organisms of the same species and strain under the same defined conditions of exposure.

Point of Departure (POD) – A value for the dose (obtained from relevant dose-response data) that serves as the starting point for estimating the equivalent (acceptable) dose in a target human population. Can be based on a NOAEL or a BMD analysis.

Residue Definition – A chemical or mixture of chemicals present in food commodities resulting from the use of a pesticide; can include its subsequent metabolites or degradation/reaction products that are considered to be of toxicological significance. Residue definitions for monitoring or enforcement might differ from those for use in risk assessment.

ANNEXES

1 ANNEX PART A
SOURCES OF NATIONAL PESTICIDE MAXIMUM RESIDUE LIMITS FOR THE 19 COUNTRIES/REGION ANALYSED

COUNTRY/ REGION	NATIONAL MRLS SOURCE	PUBLICLY AVAILABLE	AVAILABLE IN ENGLISH	LINK
AUSTRALIA	Australia New Zealand Food Standards Code-Scheduled 20-Maximum residue limits (Compilation 43 – Oct 2019)	Yes	Yes	https://www.legislation.gov.au/Series/F2015L00468
	Australia New Zealand Food Standards Code – Schedule 21 – Extraneous residue limits	Yes	Yes	https://www.legislation.gov.au/Details/F2017C00330
BANGLADESH	-	No	-	-
BRAZIL	Regularização de Produtos – Agrotóxicos (Monografias Autorizadas)	Yes	No	http://portal.anvisa.gov.br/registros-e-autorizacoes/agrotoxicos/produtos/monografia-de-agrotoxicos/autorizadas
CAMBODIA	Proclamation No. 002 MAFF, 03/01/2017 on the list of Maximum Residue Limit of Pesticides in Agricultural Product of Plant Origin	Yes	Yes	http://extwprlegs1.fao.org/docs/pdf/cam81986.pdf
CANADA	Health Canada: online database on Maximum Residue Limits for Pesticides	Yes	Yes	http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php
CHINA	GB 2763-2019	Yes	No	https://www.sdtdata.com/fx/fmoa/tsLibList
EUROPEAN UNION	Pesticides Database of the European Union	Yes	Yes	http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN
INDIA	Gazette Notification on Food Safety and Standards (Contaminants, Toxins and Residues) Amendment Regulation related to MRL of pesticide (December, 2018)	Yes	Yes	https://archive.fssai.gov.in/home/fss-legislation/notifications/gazette-notification.html
INDONESIA	Main document: Permentan (ministry regulation) no. 55 / PERMENTAN / KR.040 / 11/2016 concerning Food Safety Monitoring of Fresh Food Material Imports	Yes	Yes	http://ditjenpp.kemenkumham.go.id/arsip/bn/2016/bn1757-2016.pdf (55/PERMENTAN/KR.040/11/2016)
	If a commodity is not specified in the Permentan, then refer to: SNI 7313: 2008, Maximum Limits of Pesticide Residues in Agricultural Products	Yes	Yes	https://kupdf.net/download/sni-batas-maksimum-pestisida_58f8da3bdc0d60f361da97e3_pdf
IRAN (ISLAMIC REPUBLIC OF)	Pesticides - The maximum residue limit of pesticides-cereals	Yes	No	http://www.standard.ac.ir/en/research-centers Select Risk Analysis Office

COUNTRY/ REGION	NATIONAL MRLS SOURCE	PUBLICLY AVAILABLE	AVAILABLE IN ENGLISH	LINK
JAPAN	Positive List System for Agricultural Chemical Residues in Foods: Maximum Residue Limits (MRLs) List of Agricultural Chemicals in Foods	Yes	Yes	http://db.ffcr.or.jp/front/pesticide_detail?id=3900
MYANMAR	-	No	-	-
PAKISTAN	-	No	-	-
PHILIPPINES	Philippine National Standard PNS/BAFS 162: 2015: Pesticide residues in rice - Maximum Residue Limits (MRLs)	Yes	Yes	http://www.bafs.da.gov.ph/images/Approved_Philippine_Standards/PNS-BAFS162-2015PesticideResiduesinRiceMRLs.pdf
SAUDI ARABIA	Saudi Food & Drug Authority SFDA.FD 382/2018 Maximum Limits of Pesticide Residues in Agricultural and Food Products	Yes	Yes	http://apeda.gov.in/apedawebsite/HACCP/SFDA_FD_382_eng.pdf
THAILAND	For MRLs: Thai Agricultural Standard: TAS 9002-2016	Yes	No	http://www.acfs.go.th/standard/download/MAXIMUM-RESIDUE-LIMITS.pdf
	For Extraneous MRLs: Thai Agricultural Standard: TAS 9003-2004	Yes	No	http://www.acfs.go.th/standard/download/eng/EMRL.pdf
UNITED ARAB EMIRATES	UAE.S MRL 1: 2017 Maximum Residue Limits (MRLs) for Pesticides in agricultural and food products	Yes	No	http://www.aecegypt.com/Uploaded/Pdf/2907182.pdf
UNITED STATES OF AMERICA	Electronic Code of Federal Regulations: Part 180 - Tolerances and exemptions for pesticide chemical residues in food	Yes	Yes	https://www.ecfr.gov/cgi-bin/text-idx?SID=6cb75e3393c27ab4458f4b56494cf72c&mc=true&tpl=/ecfrbrowse/Title40/40cfr180_main_02.tpl
	CPG Sec. 575.100 Pesticide Residues in Food and Feed - Enforcement Criteria	Yes	Yes	https://www.fda.gov/media/75151/download
VIET NAM	Circular No. 50/2016/TT-BYT from Ministry of Health	Yes	Yes	http://content.bcimonitor.com/DataServices/Circular%20No.%2050-2016-TT-BYT%20effective%2001JULY2017%20(English%20translation).doc

Notes:

For the purpose of this study, all MRL sources were consulted during October 2019.

Australia and Thailand establish both MRLs and extraneous residue limits (ERLs): both were considered in the analysis.

2 ANNEX PART A RICE CLASSIFICATION

Matching rice classification of the 19 countries/region analysed to Codex

CODEX	**RICE** GC 0649	**WILD RICE** GC 0655
Codex Food Commodity Description	(*Oryza sativa* L.; several ssp. and cultivars) **"Rice with husks that remain attached to kernels even after threshing: kernels with husks** (Note: For rice, only about 10% of traded grains is with husk). Portion of the commodity to which the MRL applies (and which is analysed): Whole commodity in trade**"** *CCPR 2017 report - REP17/PR - Appendix XI*	Wild rice (*Zizania palustris* L.) Wild Rice, Eastern *(Zizania aquatica* L.)
AUSTRALIA	Rice Cereal grains All other foods All other foods except animal food commodities	Cereal grains All other foods All other foods except animal food commodities
BRAZIL	Rice / Arroz	Rice / Arroz
CAMBODIA	Rice Cereal grains	Rice Cereal grains
CANADA	Rice *Raw cereals* All food crops; All food crops (other than those listed in this item)	Wild rice *Raw cereals* All food crops; All food crops (other than those listed in this item)
CHINA	Rice / 稻谷	NA
EUROPEAN UNION	NA	Rice
INDIA	Food grains	NA

RICE, HUSKED CM 0649	**RICE, POLISHED** CM 1205	**CEREAL GRAINS** GC 0080 / GC 2088
"**Brown rice (or cargo rice) is paddy rice from which the husk only has been removed**. The process of husking and handling may result in some loss of bran" CXS 198-1995	"**Milled rice (white rice) is husked rice from which all or part of the bran and germ have been removed by milling**" CXS 198-1995	**Group 020 - Cereal grains - Class A (up to July 2017)** GC 0649 **Rice** (*Oryza sativa* L.; several ssp.& cultivars) GC 0655 **Wild rice** (*Zizania aquatica* L.) *Codex Classification of Foods and Animal Feeds-2006* **Subgroup 020C - Rice Cereals (since July 2017)** GC 0649 **Ric**e (*Oryza sativa* L.; several ssp.& cultivars) GC 3088 **Rice, African** (*Oryza glaberrima* Steud.) GC 0655 **Wild rice** (*Zizania palustris* L.) **Wild Rice, Eastern**, (*Zizania aquatica* L.) *CCPR 2017 report - REP17/PR - Appendix XI*
Rice, husked All other foods All other foods except animal food commodities	Rice, polished All other foods All other foods except animal food commodities	Cereal grains Rice All other foods All other foods except animal food commodities
Rice / Arroz	Rice / Arroz	Rice / Arroz
Rice, husked	Rice, polished Rice (milled or polished)	Cereal grains Rice
Rice *Raw cereals* All food crops; All food crops (other than those listed in this item)	Rice *Raw cereals* All food crops; All food crops (other than those listed in this item)	Rice Wild rice *Raw cereals* All food crops; All food crops (other than those listed in this item)
Rice, husked / 糙米	Rice, polished / 大米	Grains / 谷物 (Rice / 稻谷)
Rice	NA	NA
Milled food grains Rice	Milled food grains Rice	Food grains

CODEX	RICE GC 0649	WILD RICE GC 0655
INDONESIA	Rice / Beras Cereal grains / Cereal Cereal grains / Biji-bijian padi	NA
IRAN (ISLAMIC REPUBLIC OF)	Rice / برنج	Rice / برنج
JAPAN	NA	NA
PHILIPPINES	Rice	NA
SAUDI ARABIA	Rice Cereal grains	NA
THAILAND	Rice paddy / ข้าวเปลือก *(Rice paddy: means non-glutinous rice or glutinous rice with husk)* Cereal / ธัญพืช	Cereal / ธัญพืช
UNITED STATES OF AMERICA	Rice Rice, grain Grain, cereal, group 15 All food commodities (including feed commodities) not otherwise listed in this subsection	Rice wild Rice wild, grain Rice Rice, grain Grain, cereal, group 15 All food commodities (including feed commodities) not otherwise listed in this subsection
VIET NAM	Rice	NA

Note: Bangladesh, Myanmar, Pakistan and the United Arab Emirates are not reported as they do not establish national MRLs (hence do not have national lists of MRLs) but automatically defer to Codex.

RICE, HUSKED CM 0649	RICE, POLISHED CM 1205	CEREAL GRAINS GC 0080 / GC 2088
Rice husked / Beras pecah kulit	Rice polished / Beras, dipoles (disosoh)	Rice / Beras Cereal grains / Cereal Cereal grains / Biji-bijian padi
Rice / برنج	Rice / برنج	Rice / برنج
Rice (brown rice)	Milled rice	NA
Rice	Rice	Rice
Rice, husked	Rice, polished	Cereal grains Rice
Rice / ข้าวสาร *(Rice: means paddy in which husk has been removed or polished)* Cereal / ธัญพืช	Rice / ข้าวสาร *(Rice: means paddy in which husk has been removed or polished)* Cereal / ธัญพืช	Cereal / ธัญพืช Rice paddy / ข้าวเปลือก *(Rice paddy: means non-glutinous rice or glutinous rice with husk)*
Rice husked All food commodities (including feed commodities) not otherwise listed in this subsection	Rice polished All food commodities (including feed commodities) not otherwise listed in this subsection	Grain, cereal, group 15; Rice; Rice, grain All food commodities (including feed commodities) not otherwise listed in this subsection
Rice, husked	Rice, polished	Cereal grains

3 ANNEX PART A HS CODES AND CODEX RICE CLASSIFICATION

Matching of Codex rice classification with HS classification

<table>
<tr><th colspan="2">CODEX CLASSIFICATION</th><th colspan="2">HS CLASSIFICATION</th></tr>
<tr><td>GC 0649</td><td>Rice</td><td rowspan="2">100610</td><td rowspan="2">Rice in husk (paddy or rough)</td></tr>
<tr><td>GC 0080</td><td>Cereal grains</td></tr>
<tr><td>CM 0649</td><td>Rice husked</td><td>100620</td><td>Husked rice (brown)</td></tr>
<tr><td rowspan="2">CM 1205</td><td rowspan="2">Rice polished</td><td>100630</td><td>Semi-milled or wholly milled rice, whether or not polished or glazed (rice, parboiled; Basmati rice)</td></tr>
<tr><td>100640</td><td>Broken rice</td></tr>
</table>

4 ANNEX PART A
METHODOLOGY AND DATA OF THE TRADE MODEL

Analysis of the effects of non-harmonization of pesticide MRLs on trade in rice

In order to assess the impact of pesticide MRLs on trade, most empirical studies revert to the gravity model, which states that countries trade in proportion to their respective Gross Domestic Products (GDPs) and geographical proximity (UNCTAD and WTO, 2012; UNCTAD and WTO 2016).

In a general representation of the gravity model, Y_{ij}, the trade flow from the exporting country *i* to the importing country *j* is determined by a function *f* of exporter-specific factors S_i (e.g. exporter's GDP), importer-specific factors M_j (e.g. importer's GDP) and the ease of market access ϕ_{ij} to market *j* of exporter *i*:

$$Y_{ij} = f(S_i, M_j, \phi_{ij}).$$

Here, a generalized gravity equation is applied to disentangle the effects of different levels of harmonization of national MRLs with Codex MRLs on the trade in rice. The empirical specification of the model closely follows Disdier and Marette (2010), Xiong and Beghin (2012) and, especially, Xiong and Beghin (2014). A two-step Heckman estimation procedure is applied to correct for sample selection bias (Heckman, 1979). Sample selection bias can, for example, occur if some countries do not trade specific tariff lines for unknown reasons or countries simply do not report their trade.

In its first step, a probit estimation, the Heckman model explores the impacts of MRLs and other explanatory variables on the propensity to trade at all, i.e. the extensive margin. The second step determines the impact of the explanatory variables on the magnitude of trade, i.e. the intensive margin. In the second step, therefore, only actually observed (positive) trade flows are considered. This step is estimated via Ordinary Least Squares (OLS). To correct for potential sample selection bias, the second step includes an additional explanatory variable, the Inverse Mill's Ratio (IMR), which is derived from the first step estimation. In order to avoid identification problems, one variable from the first step is dropped in the second step (Greene, 2002; Mittelhammer, Judge and Miller, 2000).

Definitions and dimensions of dependent and explanatory variables are given in Table 7.

Data and variables used in the analysis

Trade data

Bilateral trade data for the time period 2012–2018 are retrieved from UN-COMTRADE. Trade flows of rice are distinguished based on four tariff lines at HS-6 digit level (see Annex A3): (1) Rice in the husk (paddy or rough) (HS 100610); (2) husked (brown) rice (HS 100620); (3) rice, semi-milled or wholly milled, whether or not polished or glazed (HS 100630); and (4) rice, broken (HS 100640). The eight importing markets considered in the analysis are: Australia, Canada, China, the European Union, Indonesia, Japan, Saudi Arabia and the United States of America. The twelve exporting countries considered are: Bangladesh, Brazil, China, Indonesia, India, Cambodia, Myanmar, Pakistan, Philippines, Thailand, the United States of America and Viet Nam.

Pesticide MRLs on rice

Information on rice pesticide MRLs is retrieved from the database created for the analysis in chapter 2 of this report. MRL restrictiveness for application in the trade model is measured based on a stringency index first defined by Li and Beghin (2014) and also applied by Xiong and Beghin (2014) and Kareem, Martínez-Zarzoso and Brümmer (2018):

$$MRLindex_{jpt} = \frac{1}{K}\left(\sum_{k=1}^{K} exp\left(\frac{MRL_{codex,kpt} - MRL_{jkpt}}{MRL_{codex,kpt}}\right)\right),$$

where $MRLindex_{jpt}$ is the MRL index of product tariff line *p* imposed by country *j* at time *t*. $MRL_{codex,kpt}$ is the MRL recommended by Codex for pesticide *k* and product *p* at time *t*. The index defined by rice tariff line, year and country is lower and upper bounded between zero and e≈2.718. The index equals one if

Table 7: Definition of dependent and explanatory variables

VARIABLE NAME	DEFINITION
Y_{ijpt}	Trade flow of rice tariff line ***p*** from country ***i*** to country ***j*** in year ***t***
$MRLimporter_{jpt}$	MRL index of importing country *j* applied to tariff line ***p*** in year ***t***
$MRLdivergence_{ijpt}$	Difference between the MRL index of importing country *j* and the MRL index of exporting country *i* in tariff line ***p*** and year ***t***
$Production_{ipt}$	Exportable production in tariff line ***p*** of country ***i*** in year ***t***
$Tariff_{ijp}$	Tariff rate applied by country ***j*** on imports in tariff line ***p*** from country ***i***
$Distance_{ij}$	Distance between exporting country *i* and importing country *j*
$DevelopmentStatus_{ij}$	Dummy variable indicating if country *i* and country *j* have the same development status
$Colony_{ij}$	Dummy variable indicating if country *i* and country *j* have ever been in a colonial relationship with each other
$Trade1995_{ijp,1995}$	Dummy variable indicating if there was a trade flow in rice tariff line ***p*** from country ***i*** to country *j* in year 1995
$RiceVariety_{ij}$	Dummy variable indicating if country *i* and country *j* engaged mainly in trade of the same rice variety
$WTOaccession_{ij}$	Dummy variable indicating if country *i* and country *j* both acceded the WTO after 1995
FE_{it}	Fixed effect for exporting country *i* and year ***t***
FE_{jt}	Fixed effect for importing country *j* and year ***t***
FE_{p}	Fixed effect for tariff line ***p***

national MRLs are completely aligned with Codex, is greater than one if, averaging over the pesticides, national MRLs are stricter than Codex and less than one if national regulation is less stringent than Codex. The analysis considers only MRLs for which a standard was adopted by Codex, ignoring national MRLs for which no Codex MRL existed. Missing national MRLs were replaced by the national default tolerance level (see Table 6).

In line with Xiong and Beghin (2014), the analysis considers both the MRL stringency of the importing country (MRL importer) and the difference in MRL stringency between importer and exporter (MRL divergence). If domestic food safety regulation with respect to MRLs on pesticides in rice of the exporting country is stricter or equal to the one in the importing country ($MRLindex_{importer,p} \leq MRLindex_{exporter,p}$), no additional trade barrier (i.e. costs related to trade) should apply. However, if the MRL regulation in the exporting country is laxer than in the importing country ($MRLindex_{importer,p} > MRLindex_{exporter,p}$), this could imply higher obstacles to export to this country. If both trading partners adopt internationally harmonized standards, the MRLs should not cause an additional cost to trade.

Other determinants of trade considered in the analysis

In addition to the MRLs, standard variables considered in gravity analyses and variables covering bilateral relationships and trade costs were used to explain the trade flows. Following Xiong and Beghin (2014), the exportable production, i.e. the sum of a country's exports to all destinations globally, was considered to proxy production capacity. The data were retrieved from UN-COMTRADE. Apart from NTMs such as MRLs, trade can also be hampered through tariffs. Tariff rates expressed as AVEs were used to cover other policy induced trade costs than MRLs. Tariff data were taken from the Macmap database of the International Trade Centre (ITC). For the estimation, only tariff data from 2012 were used to avoid possible endogeneity with the dependent variable through the computation of the AVEs (Xiong and Beghin, 2014).

As standard variables used in gravity equations, the distance between trading partners, as a proxy for trade costs (UNCTAD and WTO, 2012), and a bilateral dummy capturing colonial ties were used. These variables were derived from the CEPII gravity database (Head, Mayer and Ries, 2010). Different variants of a variable indicating common language did not exert any significant effects on trade flows and were not considered in the final model specification. Other variables reflecting a historical trade relationship between two countries are a bilateral dummy indicating whether two countries traded rice in 1995 based on FAOSTAT data and a bilateral dummy indicating whether a pair of countries entered the WTO only after its establishment in 1995. The WTO accession variable was used as exclusion variable in the Heckman model, i.e. it was only considered in the first step, but not in the second to avoid identification problems. To account for other factors except the MRLs that might affect trade flows due to a different economic status of exporting and importing country, a binary variable indicating whether trade partners have the same development status was added to the model. A binary variable indicating whether two countries engaged mainly in trade of the same rice variety was used to capture the importance of countries' specialization in specific varieties. The variable was created based on the varietal family that accounted for the largest share of overall volumes traded between two countries in 2012–2016.

Multilateral trade resistance terms in both the importing and exporting countries (Anderson and van Wincoop, 2003), were controlled for by including year-specific importer and year-specific exporter fixed effects (Feenstra, 2015; Xiong and Beghin, 2014). In addition, fixed effects are included for the four tariff lines considered. Income effects in the countries are entirely absorbed by the year-specific importer and exporter fixed effects (Xiong and Beghin, 2014). Also, specific policies referring to rice as a staple in many of the exporting countries, e.g. temporary bans on rice exports, are captured by the year-specific exporter fixed effects. Overall, the analysis covers seven years, four tariff lines, eight importers and 12 exporters.

5 ANNEX PART A
DETAILED RESULTS OF THE TRADE MODEL

Table 8: Estimated coefficients for rice imports[40]

	DEPENDENT VARIABLE:	
	PROBIT EXTENSIVE MARGIN (1)	OLS INTENSIVE MARGIN (2)
MRLimporter	1.149*** (0.202)	1.551*** (0.434)
MRLdivergence	-0.431*** (0.161)	-0.634** (0.299)
ln(Production)	0.065*** (0.011)	0.139*** (0.027)
ln(Tariff)	-0.255*** (0.091)	-0.930*** (0.143)
ln(Distance)	-0.796*** (0.113)	-0.805*** (0.142)
DevelopmentStatus	0.772*** (0.154)	4.807*** (0.401)
Colony	-0.130 (0.281)	1.352*** (0.381)
Trade1995	0.581*** (0.106)	1.453*** (0.268)
RiceVariety	0.318*** (0.086)	0.726*** (0.213)
WTOaccession[413]	-0.432** (0.172)	
IMR[42]		1.915*** (0.335)
Observations	2,604	1,366
R2		0.629
Adjusted R2		0.587
Log Likelihood	-965.557	
Akaike Inf. Crit.	2,211.114	
Residual Std. Error		2.405 (df = 1226)
F Statistic		14.982*** (df = 139; 1226)

*Note: Significance levels *p<0.1; **p<0.05; ***p<0.01*

40 For brevity, the table does not report the year-specific importer and exporter fixed effects and tariff line fixed effects. However, these were included in the regression.

41 The WTO accession variable did not significantly influence the intensive margin of trade in model test runs. It was therefore used as the exclusion variable in the second step estimation (the intensive margin).

42 IMR indicates the inverse Mill's ratio, which is only used in the second step, i.e. the estimation of the intensive margin. As it is highly significant, it points to selection bias and justifies the application of the Heckman model.

Table 9: Marginal effects and standard errors of MRLs on rice imports

	EXTENSIVE MARGIN		INTENSIVE MARGIN	
MRL Importer	0.448	***	1.551	***
	(0.079)		(0.434)	
MRL Divergence	-0.168	***	-0.634	**
	(0.063)		(0.299)	

*Note: Significance levels *p<0.1; **p<0.05; ***p<0.01.*

The marginal effects are evaluated at their means. Due to characteristics of the Heckman model, the marginal effects differ from the estimated coefficients in the first step (Table 8), but are equivalent with the coefficients in the second step of the estimation.

1 ANNEX PART B

POSSIBLE AREAS OF INVESTIGATION TO UNDERSTAND BETTER THE ISSUES THAT MIGHT LEAD TO DIFFERENT NATIONAL AND CODEX MAXIMUM RESIDUE LIMITS

Summarized consolidated feedback received from the five countries/region analysed. Additional conclusions of the report author are presented in italics.

Overview

Australia closely follows the JMPR approaches in most areas. Adoption of Codex MRLs currently requires an application, but the process appears to be relatively simple with facilitated acceptance of JMPR evaluations/Codex MRLs indicated in the guidance document (FSANZ, 2018). Australia is considering automatic adoption of new Codex MRLs in the near future, subject to a suitable exposure assessment. In Australia there are two separate lists of MRLs for agricultural and veterinary chemical residues in food commodities: the APVMA MRL standard based on domestic uses; and MRLs contained in Schedule 20 of the Australia New Zealand Food Standards Code (the Code), which contains domestic MRLs and imported MRLs – whichever is higher. The APVMA MRL standard is used for the enforcement of good agricultural practice (GAP) within Australia, usually near the farm gate. In contrast, the MRLs in the Code apply to food at the point of sale and for imported foods at entry into Australia.

The European Union feedback noted that there are several areas of variation between the European Union and JMPR/Codex. New guidance from EFSA on residue definitions for risk assessment (EFSA, 2016) – not yet ratified, proposes a different approach to that used by JMPR.

The Canadian and United States of America feedback and available supporting documents (USEPA, 2000) (NAFTA, 2005) identified some common approaches but a number of methodological differences continue to exist. However, critical differences are actively being explored through various international fora, including the OECD and JMPR (e.g. the work underway at the OECD/JMPR/JECFA level on residue definition).

Feedback from Japan indicates similarities with JMPR/Codex, but further analysis is hindered by the main guidance/requirement documents being available only in Japanese.

1. Differences in risk assessment procedures

JMPR and different countries'/region's authorities may utilize different procedures and methods in the risk assessment process. A better understanding of this would require an analysis that looks into the different procedures and approaches applied by JMPR and the different national authorities. This is an area where there may be different elements to be considered including possible differences in the following issues:

PROPOSED AREAS OF INVESTIGATION	AUSTRALIA	CANADA
Residue definition approaches	JMPR approach	OECD Residue Definition Guidance Document *Takes into account approaches, such as those used by JMPR* *Support development of standardised approaches at international level.*
Methodology on residue data extrapolation, pooling, and trial	JMPR approach	• Consideration of independence of trials based on following criteria: Location; Timing; Variety. When criteria are met, average residues from replicate trials are used for MRL calculation. (While in JMPR: variety is not typically considered as a criterion for independence. If remaining criteria are met, highest residue from replicate trials is used for MRL calculation) • Application of proportionality on a case-by-case basis (while JMPR: Only when there is insufficient data reflecting cGAP)
Interpretation of toxicological studies (e.g. different end-points used to derive ADI and/or ARfD)	JMPR approach	Broadly similar to JMPR in terms of study evaluation. Apply default factors (ten fold or three fold) for reproductive or severe effects for ADI/ARfD setting, unless reassuring data available (i.e. PCPA factor, which can defer from other schemes).
Approach on the assessment of metabolism studies	JMPR approach	Same data requirements *Broadly similar approach to JMPR*
Exposure assessment methodologies both for chronic and acute exposure scenarios	Same approach as JMPR, except utilizing the detailed national food consumption data that are available for Australian consumers.	**Acute and Chronic Dietary Risk Assessment** Consumption: US NHANES / WWEA data and: DEEM-FCID™, Version 4.02, 05-10-c
Differences in Good Agricultural Practices (GAPs) and related selection of the critical GAP on which the estimation of the MRL is based	Australian MRLs are based either on: (i) Australian GAP; or for import MRLs; (ii) An overseas national MRL which is based on their national GAP; or (iii) A Codex MRL. Where MRLs have not been established by (i), (ii) or (iii) above, an AoF MRL may be considered for all other crops for registered pesticides. Since these MRLs are not established on the basis of GAP, an alternative risk assessment approach is used. AoF MRL is not a default MRL; it is intended to allow for inadvertent presence of residues (e.g. by spray drift, crop rotation) and is established using risk assessment methodology.	Use patterns: Proposed Canadian use pattern or exporting country's registered use pattern. Crop field trials: Canada/US only and those from exporting country [for import MRL request].

EUROPEAN UNION	JAPAN	UNITED STATES OF AMERICA
Agreed, there are different approaches on deriving residue definitions. It might be appropriate to analyse the situation separately for residue definitions for dietary intake and for MRL compliance. *New EFSA guidance could lead to different definitions.*	Same approach as JMPR.	Currently - Simplest possible; In the past - Toxic residue E-fate given low consideration (JMPR: e-fate included in the evaluation) *However, the United States of America tends to have more complex definitions than JMPR/European Union*
This is a point that should be discussed in the section below on policy issues. We believe that the overall impact on numbers of non-aligned MRLs is small, compared to the points on residue definition approaches and interpretation of toxicological studies.	Same approach as JMPR.	Appears that current practices by the United States of America and JMPR may be converging with regard to extrapolation practices and data pooling. In the past there may have been differences related to use of the proportionality concept and global zoning and residue trial exchangeability. Also see below on policies related to crop groups.
Important point as well. The discussion should not only focus on parent compounds but also on metabolites. Slightly different ADI/ARfD or consumption value within the risk assessment would not trigger a reservation regarding a Codex MRL, as long as the risk assessment remains favourable.	Broadly similar to JMPR, some unique studies required.	In general, diverging opinions on toxicological points of departure may be related to how weight of evidence is approached, or different policies for addressing uncertainty. *Use of BMD, combined exposures and FQPA 10x factor differs from other schemes.*
Agreed. Different approach to decide on the relevance of metabolites observed in metabolism studies.	Broadly similar to JMPR, some unique studies required.	See above response on residue definition approaches. *Appears broadly similar to JMPR*
EFSA Primo model	Japan has conducted chronic and acute exposure assessment using average daily food consumption per person (g/day) and 97.5th percentile daily consumption (g/day), on the basis of the results obtained from "Food Intake and Frequency Questionnaire in Japan" in FY 2005 to 2007 (n = 40,394).	Acute: diet based, probabilistic (JMPR – commodity based, deterministic) Chronic: diet based, average consumption, tiered residues (only difference JMPR: median residues).
Provided all other points are not problematic, this would only apply to the European Union for substance/commodity combinations where the GAP of the European Union is more critical than the one assessed by JMPR. However, any analysis of non-alignment with Codex MRLs should focus on national/regional MRLs that are lower than Codex MRLs.	Japan has regarded the results of residue trials data with a maximum change of +/-25% in each parameter as confirming GAP, and adopted them for an establishment of MRL.	The United States of America bases its MRLs on the field trials/GAPs that are submitted by the applicant and selects the critical GAP to establish the MRL. Differences in MRLs related to GAP selection seem most likely to arise when different GAPs/trials are submitted to the United States of America and JMPR for review. This could be the case with new chemistries, where the United States of America may register the substance several years before it is evaluated by JMPR, and new data are generated in the interim and provided to JMPR but not the United States of America *The reverse can also apply if the first registration is outside the United States of America*

PROPOSED AREAS OF INVESTIGATION	AUSTRALIA	CANADA
MRLs calculators/tools	OECD MRL Calculator (for estimation of MRLs) OECD Feed Calculator (for estimation of livestock dietary burden, used to set animal commodity MRLs)	OECD MRL Calculator
Other?		

2. Different risk management considerations and policies on the setting of MRLs

PROPOSED AREAS OF INVESTIGATION	AUSTRALIA	CANADA
Policies related to the establishment of MRLs for specific commodities and/or crop groups	For domestic use, the MRL is based on approved national GAP. Adoption of MRLs based on an overseas national MRL (based on their national GAP), or the adoption of Codex MRLs, is *based on need*. Australia has an open and transparent process to incorporate these MRLs for pesticides into the Food Standards Code. Any country, sponsor company or other third party can apply for the incorporation of these MRLs whenever such a need is identified. This MRL harmonization process is free-of-charge to applicants and the needed MRL will be incorporated into the Code unless an estimate of dietary exposure exceeds the health based guidance value(s) (HBGVs) using Australian food consumption data.	It is important to note that some policies are rooted in legislation. For example, in Canada, while the PMRA specifies science-based MRLs under the Pest Control Products Act, in the absence of such an MRL, pesticide-commodities can be subject to Food and Drug Regulations GMRL of 0.1 ppm. Crop Groupings: International Crop Grouping Consultation Committee (ICGCC) [While JMPR: Codex Classification of Food and Feed]
MRLs extrapolation rules	Australia has crop group guidelines which indicate representative crops for extrapolation purposes https://apvma.gov.au/crop-groups	Extrapolation between commodities is covered under policies on crop groups.
Policies related to the application of processing factor/s,	JMPR approach	Reliance on default processing factors, where available, when chemical specific processing studies are not submitted. MRLs are specified for processed commodities only when chemical-specific data demonstrate a concentration in residues that exceeds the RAC MRL.
Application of default values for non-registered pesticides	The only exception to the JMPR approach is in relation to default values and specific MRLs for *All other foods except animal food commodities* (AoF) because these specific MRLs are not based on GAP. AoF MRLs are considered for registered pesticides, instead of default MRLs, using an alternative risk assessment approach.	0.1 mg/kg (ppm)

EUROPEAN UNION	JAPAN	UNITED STATES OF AMERICA
This point is more or less harmonized. The OECD calculator is at least in the European Union the standard tool that is used to derive MRL proposals.	Japan has set the MRLs with OECD calculator in principle. When the number of residue trials data is insufficient, Japan has calculated the MRL with allowance by Japanese method taking into account variations in results of residue trials data.	Both the United States of America and JMPR currently utilize the OECD calculator. (In the past, the United States of America historically relied on best judgment. The NAFTA calculator was used prior to development of the OECD calculator).
We would like to add the processing data: the need to submit standard hydrolysis studies is part of the European Union data requirements, but as far as we understand this is not mandatory for JMPR.		

EUROPEAN UNION	JAPAN	UNITED STATES OF AMERICA
Agreed. The European Union follows with great interest (and is actively engaged in) the review of the crop grouping in CCPR.	Japan has classified foods based on Codex Classification of Foods, considering the current food situation in Japan (daily intake, size of agricultural products). (*Japan is reviewing food classification now, not all of Japan's food classification is consistent with Codex Classification of Foods.)	Differences of crop groupings between the United States of America and Codex may result in different MRLs. Crop groups of the United States of America can be found at in the Code of Federal Regulations, 40 CFR 180.41.
Agreed.	Japan has set MRLs based on the extrapolation of Codex MRLs, considering whether part and form of samples, characteristics of growing and usage of pesticide are the same. (*Japan is reviewing food classification now, not all of Japan's food classification is consistent with Codex Classification of Foods).	Extrapolation between commodities is covered under policies on crop groups.
The European Union sets MRLs for raw agricultural commodities. In contrast to CCPR, the European Union does currently not set MRLs for processed products. See point below on products to which MRLs apply. *Processing included as part of the PRIMO intake assessment.*	Japan has adopted the Codex MRLs for processed food in principle. In the case where the values converted into the concentration in the raw material using the processing factor does not exceed the MRL of the raw material, Japan has not set the MRLs for processed food.	Default for some commodities. US EPA OCSPP Guideline 860.1520 describes requirements for processed food/feed. The guideline is available at: https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-860-residue-chemistry-test-guidelines
In the absence of information to set MRLs based on authorized uses, including Codex MRLs, the European Union applies the LOQ for a given substance/matrix combination or the legal default value of 0.01 mg/kg.	0.01 ppm	The United States of America do not apply a default MRL or defer to other MRLs in the absence of a national MRL. An applicant may submit a request to establish import tolerances for substances that are not registered in the United States of America.

PROPOSED AREAS OF INVESTIGATION	AUSTRALIA	CANADA
Other national policy decision related to trade or other relevant considerations. For example: • **More stringent policy for imports than for exports** • **Specific Level of Protection for pesticides**	For trading purposes and at the point of food sale, MRLs apply to both imported and domestically produced food. To facilitate trade, while protecting the consumer, Australia's approach is to have an established open and transparent process to incorporate Codex MRLs, or MRLs based on third country GAPs, for pesticides into the Australian Food Standards Code *based on need*. Further details are given above.	Looking to consider global GAP where possible.
Other?		Submission of same data package to Codex shortly after approval in Canada.

3. Timing of national and Codex MRL establishment

For markets that set MRLs prior to Codex MRL establishment, there may not be resources or routine procedures in place for those markets to review national MRLs at the time Codex adopts new MRLs

PROPOSED AREAS OF INVESTIGATION	AUSTRALIA	CANADA
Procedures to review national MRLs at the time Codex adopts new MRLs	*Has a regular consideration of Codex MRLs*	*No procedures in place*
	MRL harmonization process	PMRA establishes MRLs in some instances many years ahead of Codex based on scientific analysis – it is primarily established for domestic production – when Codex MRLs are ultimately established there is no policy nor resources to go back to see why there is a divergence from the Canadian results. Codex MRLs may be considered when the product comes up for re-evaluation or when establishing import tolerances. For example, the Canadian MRL of 5 ppm for fludioxonil on pomegranates was established in 2016 and was based on residue data of the United States of America and the use of the OECD MRL calculator. The Codex MRL of 2 ppm was established in 2011 based on the same residue data of the United States of America but using the NAFTA calculator. Based on the timing of when each jurisdiction reviewed the data and the policies in place at the time the data were reviewed, different MRLs were established. Engagement of JMPR in parallel review with national authorities may lead to the timelier setting of Codex MRLs and alignment between national and Codex values.

EUROPEAN UNION	JAPAN	UNITED STATES OF AMERICA
Once an European Union MRL is established, it applies to food on the European Union market regardless of the country of origin, i.e. equally to products produced in the European Union and imported from outside the European Union. European Union MRLs do not apply to products exported from the European Union to a non-European Union country, if it has been established by appropriate evidence that the country of destination requires or agrees with the particular treatment.	None	United States of America law does not distinguish between MRLs for domestic production and imported food. MRLs apply equally to domestic and imported products. United States of America policy allows for the setting of a higher MRL to facilitate trade, so long as the MRL meets the safety standard. The United States Environmental Protection Agency must be able to make a safety finding when setting MRLs, i.e., a finding that the pesticide can be used with a reasonable certainty of no harm, taking into account the special susceptibility of children by applying an additional tenfold safety factor, and also considering aggregate risk from exposure to pesticides from multiple sources (food, water, residential, and other non-occupational exposure), as well as cumulative exposure to pesticides that have a common mechanism of toxicity. This safety standard applies equally to domestic and imported food.
Currently, the European Union does not set MRLs for feed-only products (e.g. straw) or for processed products (e.g. ketchup). It is thus not possible to align to Codex MRLs in these areas.		

EUROPEAN UNION	JAPAN	UNITED STATES OF AMERICA
Has a regular consideration of Codex MRLs	*Has a regular consideration of Codex MRLs*	*No procedures in place*
Not applicable to the European Union. The European Union routinely implements new Codex MRLs every year, unless (1) the European Union MRL is the same or higher, (2) the European Union does not set MRLs for that commodity, or (3) the European Union introduced a reservation, for which many of the possible reasons are captured above. The European Union also takes old Codex MRLs (i.e. those established prior to the current European Union policy and MRL legislation) into account when reviewing MRLs for substances.	Only when Codex adopts an MRL that is higher than the Japanese MRL. The Food Safety Commission of Japan conducts risk assessments for each component, and Ministry of Health, Labour and Welfare of Japan sets and reviews MRLs based on their results. Therefore, Codex MRLs might not be adopted immediately. Codex MRLs are not adopted in cases where estimated chronic and acute exposure exceeds ADI or ARfD in exposure assessment using "Food Intake and Frequency Questionnaire in Japan". When the residue definition of Japan differs from that of Codex, Japan may establish MRLs that differ from Codex MRLs.	Participation by JMPR in a joint review when a new active substance is first brought to market would potentially help to address this issue. Further exploration of the benefits and challenges to JMPR participation in global joint reviews is underway for discussion at CCPR51. The United States of America review each registered pesticide at least every 15 years to ensure that it continues to meet the standard for registration. During this review the United States of America seek to harmonize its tolerances with Codex MRLs. An applicant may also submit a request for modification of an existing tolerance in the United States of America, including a request to harmonize with the Codex MRL.

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2 ANNEX PART B

ANALYSIS OF DATA ON PESTICIDES USED ON RICE

The information in this section provides some real-world examples of the differences between residue definitions, MRLs for rice and HBGVs across some of the countries/region analysed in this study. A similar evaluation was performed for Australian data but has not been presented here, in an effort to keep the table legible. Some of the conclusions from this evaluation of Australian data are summarized in the main text – the tabulated values can be made available on request.

The information was obtained from publicly available databases or reports in November–December 2018 and checked for any updates in August–September 2019.

Where there are MRLs for multiple descriptions of rice, or the term cereals is used, in the databases of the United States of America and CODEX, the table includes information on the description of the rice associated with the cited MRL. The European Union only uses the term ‘rice’. United States of America MRLs for ‘aspirated fractions’ are not used because they appear to have no equivalent in the Codex system (they are typically very high relative to MRLs for grain).

The information in this table is not intended to be a definitive description of the values, but to provide information for internal use in the production of this project report. IT SHOULD NOT BE USED FOR OTHER PURPOSES WITHOUT BEING INDEPENDENTLY CHECKED.

Notes:

The JMPR ADI value is the upper bound of the range.
X in the ARfD column indicates not considered due to the age of the evaluation.
CXL = Codex MRL
NA = No information available.
UN = Unnecessary – compound has no toxicity associated with a single dietary exposure
ADI and ARfD values were taken from the WHO database (https://apps.who.int/pesticide-residues-jmpr-database) and European Union database (https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN).
Intake as % ADI or % ARfD are taken from the most recent JMPR report item found to contain the appropriate information.
ADI and ARfD ratios are JMPR / European Union: values >1 indicate JMPR Health Based Guidance Values are higher than those of the European Union.
PTDIs are set for contaminants, not pesticides in current use.
The list consists of the all pesticides for which a Codex MRL for rice exists.

	CODEX CODE	COMMON NAME	ADI (mg/kg bw)		ADI Ratio	ARFD (mg/kg bw)		ARFD Ratio
			JMPR	European Union		JMPR	European Union	
1	20	**2,4-D**	0.01	0.02	0.5	UN	0.3	∞
2	177	**Abamectin**	0.001	0.0025	0.4	0.003	0.005	0.6
3	95	**Acephate**	0.03	NA	∞	0.1	NA	∞
4	280	**Acetochlor**	0.01	0.0036	2.8	1.0	1.5	0.7
5	1	**Aldrin and Dieldrin**	0.0001	0.0001	1.0	X	0.003	∞
6	229	**Azoxystrobin**	0.2	0.2	1.0	UN	UN	1.0
7	172	**Bentazone**	0.09	0.09	1.0	0.5	1.0	0.5
8	221	**Boscalid**	0.04	0.04	1.0	UN	UN	1.0
9	47	**Bromide ion**	1.0	NA (see MeBr)	-	X	No entry	1.0
10	8	**Carbaryl**	0.008	0.0075	1.1	0.2	0.01	20.0
11	72	**Carbendazim**	0.03	0.02	1.5	0.1	0.02	5.0
12	96	**Carbofuran**	0.001	0.00015	6.7	0.001	0.00015	6.7
13	230	**Chlorantraniliprole**	2.0	1.56	1.3	UN	UN	1.0
14	12	**Chlordane**	0.0005	0.0005	∞	X	NA	1.0
15	17	**Chlorpyrifos**	0.01	0.001	10.0	0.1	0.005	20.0
16	90	**Chlorpyrifos-Methyl**	0.01	0.01	1.0	0.1	0.1	1.0
17	238	**Clothianidin**	0.1	0.097	1.0	0.6	0.1	6.0
18	179	**Cycloxydim**	0.07	0.07	1.0	2.0	2.0	1.0
19	146	**Cyhalothrin (includes lambda-cyhalothrin)**	0.02	0.0025 (lambda-cyhalothrin)	8.0	0.02	0.005 (lambda-cyhalothrin)	4.0
20	118	**Cypermethrins (including alpha- and zeta-cypermethrin)**	0.02	0.05	0.4	0.04	0.2	0.2

INTAKE JMPR % ADI	INTAKE JMPR % ARFD	COMPONENTS IN RESIDUE DEFINITION			MRLS FOR RICE (mg/kg)			COMMENT
		JMPR	USA	European Union	Codex	European Union	USA	
20	NA	1	1	4	0.1 husked	0.1	0.5 Grain	USA includes conjugates determined as acid
5	60	1	-	3	0.002 husked	0.01*	NA	USA 0.4 on aspirated fractions
0	4	2	-	1	1 husked	0.01*	NA	Not approved in European Union
4	1	2	-	1	0.04 wild rice	0.01*	0.05	Not approved in European Union
<100	NA	2	2	2	0.02 cereal	NA	0.02 cereal	PTDI. Not approved in European Union
20	NA	1	2	1	5	5 husked	5	USA mentions E & Z isomers
0	<3	1	3	4	0.01* cereal	0.1 husked	0.05	
40	NA	2	-	3	0.1 cereal	0.15 husked	0.20 cereal	USA 3 on aspirated fractions
-	-	1	-	1	50 cereal	50 husked	50	Br ion not mentioned in USA lists. See also methyl bromide
560	-	1	1	1	1 polished	0.01 husked	15 grain	Not approved in European Union; but other cereal MRLs 0.5.
-	0	3	-	2	2 husked	0.01*	NA	JMPR ARfD for general population = 0.5. Not approved in European Union
30	4	2	4	2	0.1 husked	0.01*	0.2 grain	Not approved in European Union. US is import tolerance
1	NA	1	1	1	0.4 rice	0.4 husked	0.15	CXL 0.04 for rice polished
-	NA	2	-	2	0.02	NA	NA	PTDI. Not approved in European Union but cite JMPR PTDI. No cereal MRLs listed in European Union, other crops have MRLs
1	<4	1	-	1	0.5	0.5 husked	NA	
110	20	1	2	1	NA	3 husked	6 grain	USA 30 for polished
3	-	1	1	1	0.5	0.5 husked	0.01	
50	<1	3	-	4	0.09 rice	0.09 husked	NA	JMPR ARfD UN for general population
9	9	1	2	1	1	0.01 husked	1	Only lambda-cyhalothrin approved in European Union. USA lists isomers separately
30	20	1	-	1	2	2 husked	1.50 rice grain	

	CODEX CODE	COMMON NAME	ADI (mg/kg bw)		ADI Ratio	ARFD (mg/kg bw)		ARFD Ratio
			JMPR	European Union		JMPR	European Union	
21	21	**DDT**	0.01	0.01	1.0	UN	NA	1.0
22	135	**Deltamethrin**	0.01	0.01	1.0	0.05	0.01	5.0
23	274	**Dichlobenil**	0.01	0.01	1.0	0.5	0.45	1.1
24	25	**Dichlorvos**	0.004	0.0008	5.0	0.1	0.002	50.0
25	224	**Difenoconazole**	0.01	0.01	1.0	0.3	0.16	1.9
26	130	**Diflubenzuron**	0.02	0.1	0.2	UN	UN	1.0
27	255	**Dinotefuran**	0.2	NA	∞	1.0	NA	∞
28	184	**Etofenprox**	0.03	0.03	1.0	1.0	1.0	1.0
29	37	**Fenitrothion**	0.006	0.005	1.2	0.04	0.013	3.1
30	39	**Fenthion**	0.007	NA	∞	0.01	NA	∞
31	202	**Fipronil**	0.0002	0.0002	1.0	0.003	0.009	0.3
32	211	**Fludioxonil**	0.4	0.37	1.1	UN	UN	1.0
33	243	**Fluopyram**	0.01	0.012	0.8	0.5	0.5	1.0
34	205	**Flutolanil**	0.09	0.09	1.0	UN	UN	1.0
35	256	**Fluxapyroxad**	0.02	0.02	1.0	0.3	0.25	1.2
36	175	**Glufosinate-Ammonium**	0.01	0.021	0.5	0.01	0.021	0.5
37	114	**Guazatine**	0	0.0048	∞	X	0.04	∞
38	43	**Heptachlor**	0.0001	0.0001	1.0	X	NA	1.0
39	46	**Hydrogen Phosphide (phosphine; phosphane)**	UN	0.022	∞	UN	0.038	∞

INTAKE JMPR % ADI	INTAKE JMPR % ARFD	COMPONENTS IN RESIDUE DEFINITION			MRLS FOR RICE (mg/kg)			COMMENT
		JMPR	USA	European Union	Codex	European Union	USA	
NA	NA	4	3	4	0.1 cereal	0.05 husked	0.50 cereal	PTDI. Not approved in European Union but cite JMPR PTDI
50	-	1	3	1	2 cereal	1 husked	1 cereal	USA mentions 3 isomers separately
1	<1	1	-	1	0.01* cereal	0.01 husked	NA	JMPR ARfD UN for general population. Not approved in European Union. Residue as 2,6-dichlorobenzamide
30	70	1	-	1	7 rice	0.01* husked	NA	Not approved in European Union. 3 CXLs (0.15 to 7 mg/kg). USA 0.5 for bagged processed food
70	NA	2	1	1	8 rice	3 husked	7	
20	NA	1	3	1	0.01*	0.05 husked	0.02	Pome fruit MRLs at 5 mg/kg
2	2	3	3	NA	8 rice	8 husked	9	Not approved in European Union CXL 0.3 rice polished
3	<1	1	1	1	0.01*	0.5 husked	0.01	
780	190	1	-	1	6 cereal	0.05 husked	NA	Not approved in European Union
-	-	4	-	4	0.05 husked	0.01*	NA	Not approved in European Union
-	-	2	4	2	0.01	0.005 husked	0.04	Not approved in European Union.
90	NA	1	1	1	0.05 cereal	0.01 husked	0.02 cereal	Fruit MRLs 5–10 mg/kg
80	NA	1	-	1	4 rice	0.01 husked	NA	Other European Union cereal MRLs up to 1.8 mg/kg. No CXLs for cereals
1	NA	1	1	1	2 husked	2 husked	7 grain	4 CXLs for rice. US & JMPR res. def. is for all TFMBA components; European Union has flutolanil other than for fruits.
20	2	3	1	1	5 rice	5 husked	5 grain	4 CXLs for rice
10	5	3	3	4	0.9 rice	0.9 husked	1	Not approved in European Union-Cat 1B repro
NA	NA	1	-	1	0.05*	0.05 husked	NA	ADI could not be established by JMPR. Not approved in European Union
-	-	2	2	2	0.02 cereal	0.01 husked	0.03 cereal	PTDI. Not approved in European Union but cite JMPR PTDI
-	-	1		1	0.1 cereal	NA	0.1	JMPR - Based on absence of residues in food

	CODEX CODE	COMMON NAME	ADI (mg/kg bw)		ADI Ratio	ARFD (mg/kg bw)		ARFD Ratio
			JMPR	European Union		JMPR	European Union	
40	276	**Imazamox**	3.0	3.0	1.0	3.0	3.0	1.0
41	266	**Imazapic**	0.7	0.46	1.5	UN	UN	1.0
42	289	**Imazethapyr**	0.6	NA	∞	UN	NA	∞
43	206	**Imidacloprid**	0.06	0.06	1.0	0.4	0.08	5.0
44	111	**Iprodione**	0.06	0.02	3.0	X	0.06	∞
45	299	**Isoprothiolane**	0.1	NA	∞	UN	NA	∞
46	277	**Mesotrione**	0.5	0.01	50.0	UN	0.02	∞
47	138	**Metalaxyl**	0.08	0.08	1.0	UN	0.5	∞
48	100	**Methamidophos**	0.004	0.001	4.0	0.01	0.003	3.3
49	147	**Methoprene**	0.09	NA	∞	UN	NA	∞
		S-methoprene	0.05	NA	∞	UN	NA	∞
50	52	**Methyl Bromide (bromomethane)**	Bromide ion only	0.001	∞	X	0.003	∞
51	57	**Paraquat**	0.005	0.004	1.3	0.006	0.005	1.2
52	120	**Permethrin**	0.05	NA	∞	1.5	NA	∞
53	62	**Piperonyl Butoxide**	0.2	NA	∞	UN	NA	∞
54	86	**Pirimiphos-Methyl**	0.03	0.004	7.5	0.2	0.15	1.3
55	142	**Prochloraz**	0.01	0.01	1.0	0.1	0.025	4.0
56	63	**Pyrethrins**	0.04	0.04	1.0	0.2	0.2	1.0
57	287	**Quinclorac**	0.4	NA	∞	2.0	NA	∞

INTAKE JMPR % ADI	INTAKE JMPR % ARFD	COMPONENTS IN RESIDUE DEFINITION			MRLS FOR RICE (mg/kg)			COMMENT
		JMPR	USA	European Union	Codex	European Union	USA	
0	0	2	-	1	0.01*	0.05 husked	NA	
0	NA	1	-	1	0.05*	0.05 husked	NA	Not approved in European Union
0	NA	1	2	NA	0.1*	NA	0.3 grain	Not approved in European Union
5	-	2	-	1	0.05 cereal	1.5 husked	0.05 grain	
-	-	1	3	1	10 husked	10 husked	10 grain	Not approved in European Union
-	NA	NA	-	1	6 husked	6 husked	NA	Not approved in European Union. CXL 1.5 polished
0	NA	1	-	1	0.01* husked	0.01* husked	NA	
-	NA	1	2	1	0.05* cereal	0.01 husked	0.1 cereal	Includes metalaxyl M. Some European Union MRLs on fruit up to 2 mg/kg
-	-	1	-	1	0.6 husked	0.01* husked	NA	Not approved in European Union
40	NA	1	-	1	10 cereal	5 husked	NA	Not approved in European Union. Includes S-methoprene in European Union. CXL 40 for rice hulls
60	NA	NA	-	1	10 cereal from methoprene	5 husked from methoprene	NA	Not approved in European Union. Codex does not list separately - from methoprene
-	-	1	1	1	5 cereal	NA	50	Res def. as bromide ion (CXL, USA + European Union). European Union ref doses based on MeBr not Br ion. Not approved in European Union. CXL 0.01 as MeBr in cereal products
-	0	1	1	1	0.05	0.05 husked	0.05	Not approved in European Union
-	-	1	-	1	2	NA	NA	Not approved in European Union. USA 0.5 aspirated fraction
-	NA	1	1	NA	30 cereal	NA	20	Not considered a PPP in European Union. Used in biocides
-	30	1	-	1	7 cereal	0.5 husked	NA	European Union MRLs for cereals up to 5 mg/kg. Codex value is for cereal grains
-	-	2	-	2	2 cereal	1 husked	NA	European Union citrus MRLs at 10 mg/kg
1	-	1	3	1	0.3	3 husked	3	No CXL for rice - 0.3 is cereal grain
0	1	3	1	NA	10 rice	5 husked	5	Not approved in European Union

	CODEX CODE	COMMON NAME	ADI (mg/kg bw)		ADI Ratio	ARFD (mg/kg bw)		ARFD Ratio
			JMPR	European Union		JMPR	European Union	
58	251	**Saflufenacil**	0.05	NA	∞	UN	NA	∞
59	259	**Sedaxane**	0.1	0.11	0.9	0.3	0.3	1.0
60	233	**Spinetoram**	0.05	0.025	2.0	UN	0.1	∞
61	203	**Spinosad**	0.02	0.024	0.8	UN	UN	1.0
62	218	**Sulfuryl fluoride**	0.01	0.014	0.7	0.3	0.7	0.4
63	189	**Tebuconazole**	0.03	0.03	1.0	0.3	0.03	10
64	196	**Tebufenozide**	0.02	0.02	1.0	0.9	NA	∞
65	223	**Thiacloprid**	0.01	0.01	1.0	0.03	0.03	1.0
66	143	**Triazophos**	0.001	0.001	1.0	0.001	0.001	1.0
67	213	**Trifloxystrobin**	0.04	0.1	0.4	UN	0.5	∞
68	303	**Triflumezopyrim**	0.2	NA	∞	1.0	NA	∞

* = **LOQ**

INTAKE JMPR % ADI	INTAKE JMPR % ARFD	COMPONENTS IN RESIDUE DEFINITION			MRLS FOR RICE (mg/kg)			COMMENT
		JMPR	**USA**	**European Union**	**Codex**	**European Union**	**USA**	
20	NA	1	3	3	0.01 cereal	0.03 husked	0.03 cereal	Not approved in European Union
0	0	1	1	1	0.01* cereal	0.01*	0.01 cereal	
2	NA	3	-	1	0.02* husked	0.05* husked	NA	
40	NA	2	2	2	1 cereal	2 husked	1.5 cereal	
1	0	1	1	1	0.1 polished & husked	0.05 husked	0.04 grain 0.01 polished	Separate consideration for F in some schemes. USA does not mention fluoride but has 6 different MRLs related to rice
9	5	1	1	1	1.5 rice	1.5 husked	NA	USA 16 aspirated fractions
-	-	1	-	1	0.1 husked	3 husked	NA	
10	0	1	-	1	0.02	0.02 husked	NA	Some fruit MRLs at 1 in European Union
NA	100	1	-	NA	0.6 polished	0.02 husked	NA	Not approved in European Union but cite JMPR ref doses
4	7	2	2	2	5 rice	5 husked	3.5	
1	NA	NA	1	NA	0.2 rice	0.01 husked	0.4 grain	USA MRL is for import tolerance. 4 CXLs for rice

Understanding international harmonization of pesticide Maximum Residue Limits (MRLs) with Codex standards: a case study on rice.

The FAO/WHO Codex Alimentarius is the international point of reference on food safety and quality. Internationally recognized food standards developed by Codex, including pesticides Maximum Residues Limits (MRLs), aim to protect consumers' health and ensure fair practices in international food trade. Despite long-standing efforts towards international harmonization of allowable thresholds for pesticide residues in foods, differences in the national implementation of MRLs continue to cause trade concerns. This publication explores international harmonization with Codex pesticides MRLs from different angles, using a case study on rice. Part A assesses the level of harmonization of pesticide MRLs in main rice producing and trading countries and explores its effects on trade. Part B investigates the reasons behind varying levels of harmonization, looking at differences in national risk assessment procedures and risk management policies that may lead to divergent MRLs. Ultimately this publication aims to offer insights for decision-makers involved in standards setting and designing of food policies to facilitate better international harmonization.

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