



**Asia-Pacific
Economic Cooperation**

IMPORT MRL GUIDELINE FOR PESTICIDES

*A guideline on possible approaches to achieve alignment of
international MRLs*

**APEC Food Safety Cooperation Forum
Sub-Committee on Standards and Conformance**

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Glossary of terms

Acceptable daily intake (ADI)

The ADI is the estimate of a chemical in food or drinking-water that can be ingested over a life-time without appreciable health risks to the consumer. It is derived on the basis of all the known facts at the time of the evaluation. It is expressed in milligrams of the chemical per kilogram of body-weight.

Acute reference dose (ARfD)

The ARfD is an estimate of the maximum amount of a substance in food or drinking water, expressed as milligrams per kilogram of body-weight that can be ingested in a period of 24 hours or less without appreciable health risk to the consumer, on the basis of all the known facts at the time of the evaluation.

Authorized use

Authorized use refers to the safe use of a pesticide based upon a use pattern determined at the domestic level. It includes domestically approved, registered or recommended uses, which take into account public and occupational health and environmental safety considerations¹.

Codex Alimentarius Commission

The Codex Alimentarius Commission (CAC), established by FAO and WHO in 1963, develops harmonised international food standards, guidelines and codes of practice to protect the health of the consumers and ensure fair practices in food trade. The Commission also promotes coordination of all food standards work undertaken by international governmental and non-governmental organizations. Visit the [Codex Alimentarius website](#) for more information

Codex MRL

Codex MRLs are primarily intended to apply in international trade, are derived from estimations made by FAO/WHO expert committees such as the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The JMPR recommends maximum residue levels for consideration by Codex following a toxicological assessment of the pesticide and its residues; a review of residue data reflecting domestic authorised uses; and dietary intake risk assessments to indicate that foods complying with Codex MRLs are safe for human consumption.

Definition of the residue

For each pesticide used on food or feed commodities, regulatory authorities need to choose which residue(s) will be used for i) dietary risk assessment and ii) setting and enforcing tolerances/MRLs. The “definition of the residue” or the “residue definition” refers to those residues chosen for these two regulatory purposes².

¹ FAO Manual on the submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed. FAO 2015.

² [OECD \(2009\), OECD Environmental Health and Safety Publications Series on Testing and Assessment Number 63 and Series on Pesticides Number 31: Guidance Document on the Definition of Residue \(as revised in 2009\)](#)

Definition of residues (for compliance with MRLs)

The definition of a residue (for compliance with MRLs) is that combination of the pesticide and its metabolites, derivatives and related compounds to which the MRL applies³.

Definition of residues (for estimation of dietary intake)

The definition of a residue (for estimation of dietary intake) is that combination of the pesticide and its metabolites, impurities and degradation products of toxicological significance for risk assessment purposes and HR apply.

Domestic MRL

A domestic MRL refers to a standard established at the domestic economy level.

Dietary exposure assessment

A dietary exposure assessment is the process of estimating how much of a food chemical a population, or population sub group, may be exposed to from the diet and is usually compared to a relevant health-based guidance value. Internationally accepted 'dietary modelling' techniques are available to conduct such dietary exposure assessments. Dietary exposure to (or intake of) food chemicals is estimated by combining food consumption data with food chemical concentration data. Visit the [WHO GEMS/food website](#) for general information and/or templates for dietary exposure assessments.

Food Group/Crop Group

A collection of foods/crops subject to MRLs that have similar characteristics (for example Stone fruits) and similar potential for residue for which a common group MRL can be set. The Codex classification of food and animal feed commodities describe the various food groups moving in trade and lists commodities included in each group⁴. The commodities included within food groups may differ between Codex and APEC economy databases.

Good Agricultural Practice

Good agricultural practice in the use of pesticides (GAP) includes the domestically authorized safe uses of pesticides under actual conditions necessary for effective pest, disease or weed control. It encompasses a range of levels of pesticide applications up to the highest authorized use, applied in a manner which leaves a residue which is the smallest amount practicable.

Authorized safe uses are determined at the domestic level and include registered or recommended uses, which take into account public and occupational health and environmental safety considerations⁵. Actual conditions include any stage in the production, storage, transport, distribution of food commodities and animal feed.

Health Based Guidance Value (HBGV)

Health based guidance values, such as an acceptable daily intake (ADI) or acute reference dose (ARfD), are levels of human exposure considered to be without appreciable health risk.

³ JMPR Report 1995, 2.8.1.

⁴ Codex (Codex Alimentarius Commission) 2006. Joint FAO/WHO Food Standards Programme. Codex Classification of Foods and animal Feeds. Food and Agriculture Organization of the United Nations World Health Organization. Draft revision-1, 2006.

⁵ <http://www.fao.org/waicent/faostat/Pest-Residue/pest-e.htm>

Highest residue (HR)

The highest residue of a pesticide and its metabolites, impurities and degradation products included in the definition of the residue for dietary intake, expressed as mg/kg, found in a commodity from a supervised trial that results from using the chemical according to maximum Good Agricultural Practice (GAP). Where the residue definitions for dietary intake estimation and for MRL-compliance are the same, the MRL is usually based on this figure.

HR-P

The HR-P is the residue in a processed commodity calculated by multiplying the highest residue in the raw agricultural commodity and the corresponding processing factor, each based on the residue definition for dietary risk assessment.

International Dietary Exposure Assessments (IDEA)

An international Dietary Exposure Assessment (IDEA), in this document, refers to the quantitative evaluation undertaken at an international level by the JMPR of the chronic (IEDI) and, where relevant, acute (IESTI) exposures of a chemical when compared to relevant health based guidance values.

International estimated daily intake (IEDI)

The IEDI is a prediction of the long-term daily intake of a pesticide residue on the basis of the assumptions of average daily food consumption per person and median residues from supervised trials, allowing for residues in the edible portion of a commodity and including residue components defined by the JMPR for estimation of dietary intake. Changes in residue levels resulting from preparation, cooking, or commercial processing are included. When information is available, dietary intake of residues resulting from other sources should be included. The IEDI is expressed as a percentage of the ADI⁶.

International estimated short-term intake (IESTI)

The IESTI is a prediction of the short-term intake of a pesticide residue on the basis of the assumptions of high daily food consumption per person and highest residues from supervised trials, allowing for residues in the edible portion of a commodity and including residue components defined by the JMPR for estimation of dietary intake. The IESTI is expressed in milligrams of residue per kg body weight.

Note: IESTI has been used as an acronym for “international estimated short-term intake” and “international estimate of short-term intake”. Both are intended to have the same meaning.

Joint FAO/WHO meeting on pesticide residues (JMPR)

The "Joint Meeting on Pesticide Residues" (JMPR) is an expert *ad hoc* body administered jointly by Food and Agriculture Organisation and World Health Organisation. The JMPR has met annually since 1963 to conduct scientific evaluations of pesticide residues in food.

It provides advice on the acceptable levels of pesticide residues in internationally traded food. The JMPR consists of experts who attend as independent internationally-recognized specialists acting in a personal capacity and not as representatives of national governments. Visit the Food and Agriculture Organisation of the United Nations website for more information.

⁶ WHO (1997) Guidelines for predicting dietary intake of pesticide residues. 2nd Revised Edition, GEMS/Food Document WHO/FSF/FOS/97.7, Geneva

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Limit of determination (LOD)

The LOD is the lowest concentration of a pesticide residue or contaminant that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis. (Codex Alimentarius, Vol. 2A)

Explanatory note: LOD has also been used as an abbreviation for “limit of detection,” which may be confusing. JMPR has now adopted LOQ – see the following definition

Limit of quantification (LOQ)

The LOQ is the smallest concentration of the analyte that can be quantified. It is commonly defined as the minimum concentration of analyte in the test sample that can be determined with acceptable precision (repeatability) and accuracy under the stated conditions of the test. *Reference:* Joint FAO/IAEA Expert Consultation on ‘Practical Procedures to Validate Method Performance of Analysis of Pesticide and Veterinary Drug Residues, and Trace Organic Contaminants in Food’ (Hungary, 8-11 Nov, 1999). Annex 5, Glossary of Terms. www.iaea.org/trc/pest-qa_val3.htm.

Explanatory note: ‘Limit of quantification’ and ‘limit of quantitation’ are used synonymously and are abbreviated to LOQ. The FAO Panel estimates the LOQ of an analytical method for residues in specified substrates as being the lowest level where satisfactory recoveries were achieved. JMPR has used LOD (limit of determination) in the past with the same meaning as LOQ

Maximum residue limit (MRL)

A Maximum Residue Limit⁷ (MRL) is the maximum concentration of a pesticide residue legally permissible in or in food commodities and animal feeds. MRLs are based on good agricultural practice (GAP) data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable. .

National Dietary Exposure Assessments (NDEA)⁸

A National Dietary Exposure Assessment (NDEA), in this document, refers to the quantitative evaluation undertaken by an economy of the chronic (NEDI) and, where relevant, acute (NESTI) exposures of a chemical when compared to relevant health based guidance values.

National estimate of dietary intake (NEDI)

A national estimate of dietary intake (NEDI) for a chemical calculated across the population of an economy for all food commodities with a MRL for that chemical. The estimated dietary exposure derived from the NEDI is compared to the relevant ADI in order to determine whether long term exposure to the chemical is likely to be a risk to public health and safety. Residues used in the calculation are based on the risk assessment residue definition.

National estimate of short-term intake (NESTI)

A national estimate of short-term intake (NESTI) for a chemical calculated for high consumers, of an economy, of a food commodity that has a MRL and an ARfD. It determines short term exposure over one meal or one day. Estimated exposure is calculated for each food commodity separately and is not summed across all foods. The estimated dietary exposure is compared to the ARfD in order to

⁷ The term ‘Maximum Residue Limits’ for crops is the same as the term ‘Maximum Residue Levels’ in the European Union or ‘Tolerances’ in the United States

⁸ The term national, rather than domestic, is used with regards to dietary exposure assessments reflecting current international terminology.

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determine whether short term exposures are likely to be a risk to public health and safety. Residues used in the calculation are based on the risk assessment residue definition.

Pesticide

Pesticide means any chemical substance intended for preventing, destroying, attracting, repelling, or controlling any pest including unwanted species of plants or animals during the production, storage, transport, distribution and processing of food, agricultural commodities, or animal feeds or which may be administered to animals for the control of ectoparasites. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant, fruit thinning agent, or sprouting inhibitor and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport. In this Guideline the term excludes fertilizers, plant and animal nutrients, food additives, and animal drugs.

Pesticide Residue

Pesticide Residue means any specified substance in food, agricultural commodities, or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products, and impurities considered to be of toxicological significance.

Processing factor

The processing factor for a specific pesticide residue, commodity and food process, is calculated by dividing the residue level in the processed product by the residue level in the raw commodity before processing.

Supervised trial median residue (STMR)

The expected residue level (expressed as mg/kg) in the edible portion of a food commodity when a pesticide has been used according to maximum GAP conditions. The STMR is estimated as the median of the residue values (one from each trial) from supervised trials conducted according to maximum GAP conditions.

STMR-P

Supervised trials median residue in a processed commodity calculated by multiplying the STMR in the raw commodity by the corresponding processing factor, each based on the residue definition for dietary risk assessment.

SECTION 1

1.1 Introduction

Each economy in the APEC region has developed its own regulatory system aimed at protecting the environment, public and consumer health, resulting in significant diversity in regulatory policies and approaches towards pesticide Maximum Residue Limit (MRL) setting, compliance and recognition. Trade in food, across the APEC region, can be severely disrupted when non-compliance with importing economy standards occurs. Such non-compliance can be due to MRL disparities arising either from MRLs based on differing use patterns (GAP)⁹ or the absence of a MRL in an importing economy. Dealing with such breaches can be problematic, particularly where there may be no public health concerns over potential dietary exposure (food safety).

To assist in minimising such discrepancies and facilitate trade, while continuing to protect human health from potential pesticide risks, the APEC Food Safety Cooperation Forum has developed this guidance document on approaches to achieve alignment of MRLs for pesticides within APEC. The primary benefit of this guidance is the development of a convergent regulatory approach, based on agreed principles that would allow economies to balance their regulatory needs with the goal of facilitating trade. Other important benefits include providing communication contacts with relevant APEC economy practitioners and increased opportunities for cooperation, collaboration and work sharing.

Codex standard for MRLs

Codex standards are identified in the WTO's SPS Agreement as international standards upon which Members can harmonise their sanitary measures to the extent possible in order to facilitate the international trade of safe food. Currently, most APEC economies incorporate or recognise Codex MRLs to some extent within their MRL standards. Some economies automatically recognise Codex MRLs in their standards (by reference); although generally this recognition only applies if no domestic MRL exists. In other economies, Codex MRLs can be considered (where appropriate) where the promulgation of domestic MRLs is under consideration or they are recognised as informal reference standards for imported food. In many cases the methodology that underpins Codex standards is applied in the development of domestic MRLs in APEC economies.

MRL-setting

The MRL-setting systems in many APEC economies follow a 'positive list' approach, where the legislation specifies that when there is no domestic MRL (and in some economies, no Codex MRL) for a pesticide-food combination, residues must be either 'zero' (not detectable or not measurable), below a specified default limit (generally 0.01 mg/kg) or below the concentration of dietary intake concern¹⁰. In economies that do not use a positive list approach, Codex MRLs (and in some cases exporting economy MRLs) are often used as reference standards when deciding on the acceptance of imported food tested and found to contain residues not covered in their legislation.

This guidance document seeks to provide a framework within which science based standards can be developed and applied uniformly and transparently across APEC economies.

⁹ Differing GAP can result from differing pest/disease complexes, and differing public and occupational health and environmental considerations at the domestic level.

¹⁰ Below the relevant ADI or ARfD and unlikely to present a public health concern

Introduction

1.2 Purpose

This *Guideline* is intended to facilitate a greater degree of clarity and alignment around the application of assessment methodologies involved in considering import MRL requests, from the perspective of consumer protection, across the APEC region. The aim being to not only increase consumer confidence in the MRL setting process, but where practical and appropriate, also achieve greater regulatory convergence of MRLs, promoting greater alignment with international standards, while reducing the regulatory burden across APEC economies and facilitating trade.

1.2 Scope

In the context that APEC agreements are non-binding on APEC economies, this *Guideline* is meant to be used on a voluntary basis, as an aid for APEC economies when considering the alignment of domestic pesticide MRLs of plant protection products, with relevant international or regional standards (e.g., Codex, ASEAN MRLs) or an exporting economies MRLs. The overall objective is to provide a coherent framework within which APEC economies can identify the minimum dataset, to the extent necessary¹¹, upon which to assess a request for pesticide import MRLs where health based guidance values (ADI and ARfD), authorised use patterns and MRLs have been established, either internationally or in the exporting economy.

The *Guideline* is intended to also create opportunities to share relevant residue trial data and information across the APEC region. This *Guideline* provides an outline of the processes that could be followed when evaluating MRL alignment. This *Guideline* is not intended to cover pesticides that are banned or restricted in the importing economy.

1.3 How do I use this guideline?

The *Guideline* is intended to be a reference tool. Section 2 provides information on the import MRL assessment process and Section 3 details the type of information that may be required to enable dietary risk assessments to be undertaken.

Further details on the process and information that could be required to consider an import MRL request is provided in Section 3 and **Attachment 1** outlines the factors that may need to be addressed. **Attachment 2** provides detailed scenarios showing the type of information that could be submitted in under differing situations and potential outcomes based on the information provided.

¹¹ The minimum dataset required by an importing economy's authorising agency to fulfil its statutory requirements in undertaking a NDEA

Section 2 Import MRL process

2.1 What is a pesticide Import MRL request?

Essentially, a pesticide import MRL request is seeking approval from the importing economy to allow the importation of goods that may contain pesticide residues at a level that is not covered in their domestic standards. The nature of the requests will vary, with an importing economy asked to accept or adopt either a Codex or exporting economy MRL or amend their domestic standards to align with either internationally-established Codex MRLs, regional (e.g. ASEAN) MRLs or those of the trading partner for a pesticide/commodity combination.

If approved, the import MRL may apply to commodities imported from other economies, as provided by domestic regulation. These are sometimes referred to either as ‘import MRLs’ or import tolerances or any other form of MRL for food import control purposes¹². Such requests should contain specific information to enable the importing economy to undertake any required assessments.

Prior to submission, discussions should be held between the proponent¹³ of the request and the relevant importing economy authority to clarify the form, minimum information requirements and regulatory processes, to enable an import MRL to be established. The nature and type of information required may vary depending upon whether or not a Codex MRL exists for the particular commodity/pesticide for which an import MRL is requested. In the absence of a JMPR assessment and Codex MRL, agreement will be needed on the source and derivation of alternative values, i.e., their currency and methodological basis¹⁴, and other additional information that the importing economy agency may require.

This could include agreement on the submission language, clarification of what is required to verify authorised GAP, e.g., approved label or other authorisation, the quality of data upon which the requested MRL is based, and the source of health based guideline values, e.g., ADI or ARfD, in the absence of importing economy or JMPR established values.

The request should then contain information supporting the requested MRL. This should include information on the relevant authorised use pattern (i.e., GAP), the applicable MRL, and the relevant health based guidance value where necessary. Additional information on the pesticide and commodity may be required such as summary information derived from supporting supervised residue trials, e.g., STMR and HR values and if pertinent STMR-P and HR-P values following processing.

Finally, to ensure transparency, when an import MRL request is approved the importing economy’s relevant authority should seek to inform other economies of the decision via the notification pursuant to the WTO SPS Agreement.

¹² Such as provisional MRLs or temporary MRLs

¹³ An import MRL request could originate from a variety of sources, e.g., a commercial enterprise or an exporting economy. Such requests may be submitted through the competent authority of the exporting economy. However, this should not prevent a commercial enterprise from making a request and if required, it should be agreed upon by the relevant agencies of the importing and exporting economies.

¹⁴ That the alternative values to be applied, and their derivation, are consistent with currently accepted risk analysis principles

2.2 Overview of the import MRL proposal process

An overview of the import MRL process is outlined in **Table 1** and **Figures 1 and 2**. Proposals are from an exporting economy seeking recognition or adoption of either Codex MRLs or alignment with the exporting economy MRLs, where no bilateral trade accord exists. Where appropriate (and if required, with the agreement of the importing and exporting economy agencies), proposals may also be prepared by commercial entities including exporters, importers, producer groups or pesticide registrants/manufacturers.

The first step in the proposal process is the notification of an intention to submit a request to the relevant importing economy agency, prior to the formal submission. The notification should contain details of the scope of the proposal, i.e., single commodity/pesticide(s). Following consultation and agreement on data requirements, the timing for the submission and subsequent assessment timeframes can be agreed.

Table 1 Overall process for reviewing MRL adoption/recognition requests

Process
<p>Pre-Proposal</p> <ul style="list-style-type: none"> • Importing economy authority notified. <ul style="list-style-type: none"> ○ Notification to contain information on the scope of the planned proposal, i.e., new MRL(s) or amended MRL(s) for the pesticide and commodities involved. ○ The purpose is for the importing economy to provide information on its application pathway, data requirements and to confirm assessment timeframes
<p>Proposal submission</p> <ul style="list-style-type: none"> • Agreed content of review information provided (refer to Figures 1 and 2) depending upon whether <ul style="list-style-type: none"> ○ Codex MRL established but not recognised (Figure 1) or ○ No Codex MRL established or lower domestic MRL (Figure 2)
<p>Prior to the assessment, it is anticipated that each request would undergo preliminary screening to ensure that the requested pesticide MRL is appropriate and that <u>basic criteria</u> have been met¹⁵ to complete an assessment.</p>
<p>Conduct assessment</p> <ul style="list-style-type: none"> • Review information provided (refer to Figures 1 and 2) <ul style="list-style-type: none"> ○ Formal assessment of data <ul style="list-style-type: none"> ▪ Required dietary risk assessments, e.g., NEDI and or NESTI assessments • Prepare assessment summary and any related supporting documents
<p>Agency/Governmental considerations</p> <p>Completion of relevant internal governmental procedural steps with regards to the assessment outcome and or ratification.</p>
<p>Assessment Outcome</p> <ul style="list-style-type: none"> • Supportive or not supportive

¹⁵ Basic criteria includes: Data presented in the agreed language; the commodity is for human consumption; the commodity is described in the Codex Classification for Food and Animal Feeds; and all essential information, e.g., evidence of authorised use, internationally recognised health based guidance values, e.g., JMPR, to support the request has been provided.

Import MRL process

- Response to requesting economy
- If supportive prepare formal notification of decision
- Prepare notification pursuant to WTO SPS Agreement.

Scenario 1: Codex MRL established for the requested pesticide × commodity combination where no importing APEC economy MRL and no bilateral trade accords exists between economies

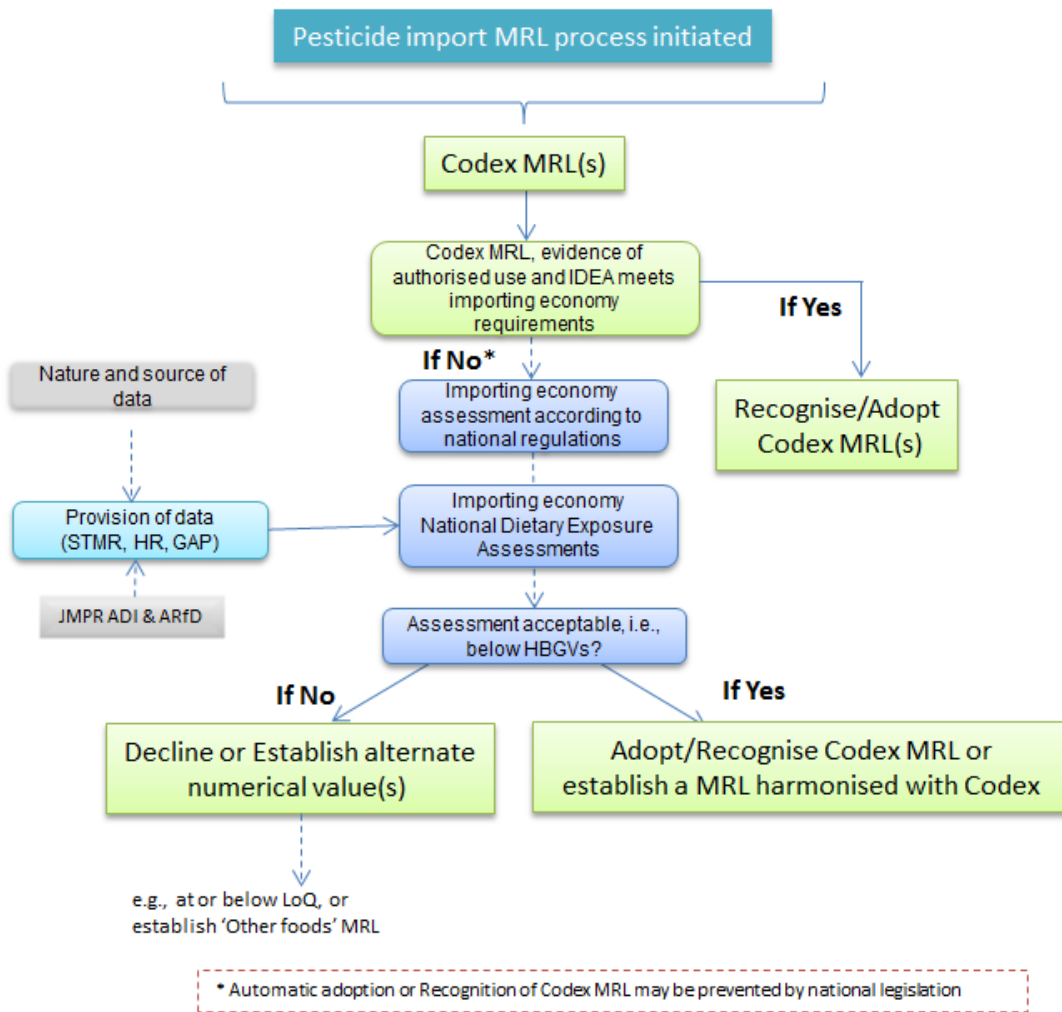


Figure 1 Outline of indicative import MRL assessment process

Figure 1 outlines three potential pathways for an import MRL request based on an existing Codex MRL and International Dietary Exposure Assessments in which estimates of exposure are considered unlikely to pose a public health concern. The first is where an importing economy can recognise or adopt the Codex MRL. The second and third where the importing economy undertakes a National Dietary Exposure Assessment in which it is either concluded that the estimates of exposure are acceptable, i.e., below health based guidance values and unlikely to pose a public health concern, or not acceptable. The former resulting in the recognition or adoption of the Codex MRL, while the latter could result in either the request being declined or a lower protective MRL being established by the importing economy.

Import MRL process

Scenario 2: Where NO Codex MRL has been established and no MRL exists in the importing¹⁶ economy or the domestic MRL is lower

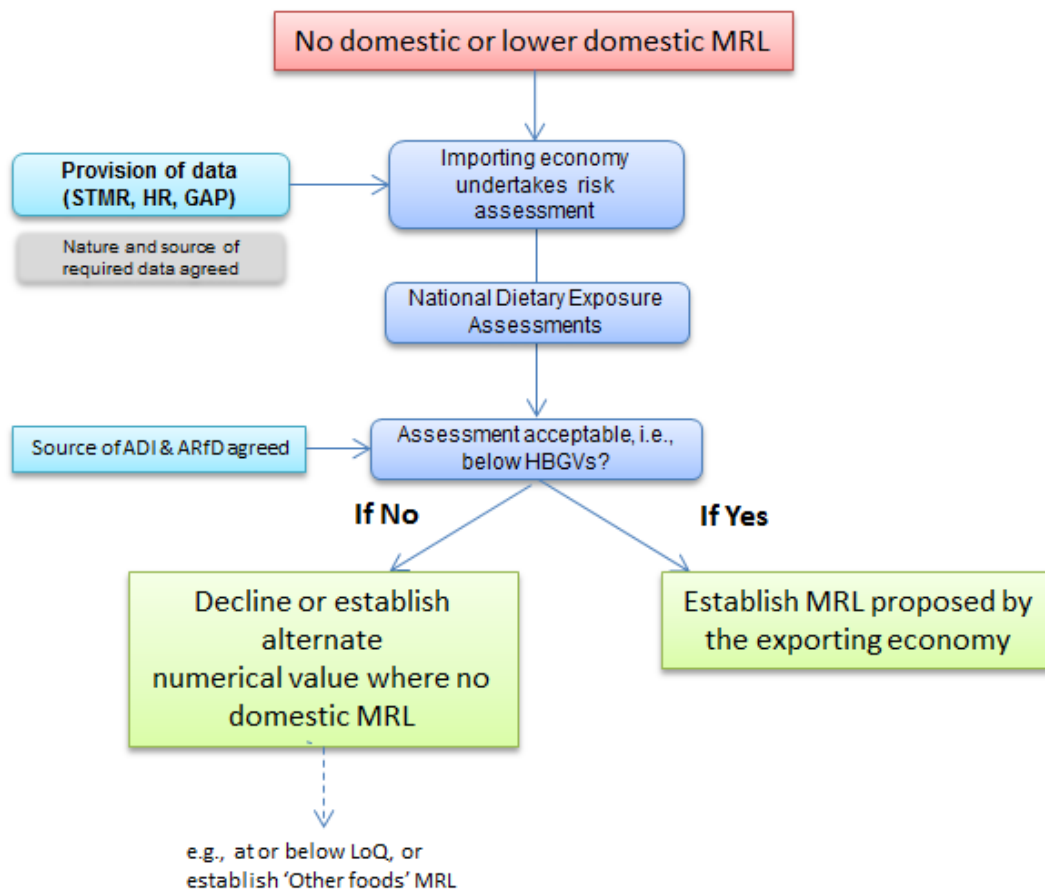


Figure 2 Outline of import MRL assessment process where there is no Codex MRL

Key issues for the importing economy in the assessment of import MRL requests are that residues do not pose a potential public health concern and are the result of approved use in the exporting economy.

Figure 2 outlines the potential pathways for an import MRL request where there is no existing Codex MRL and there is either a lower or no MRL in the importing economy. In this scenario it is anticipated that the relevant agency of the importing economy would undertake a dietary exposure assessment. This would require agreement on the nature, i.e. level of detail, and source of the data to be submitted. Following the completion of the National Dietary Exposure Assessments if the estimates of exposure are considered unlikely to pose a public health concern, i.e., below health based guidance values, the importing economy can recognise or adopt the MRL proposed by the exporting economy. However, should it be concluded that based on the estimates of exposure the importing economy cannot be satisfied that residues would not pose a public health concern the request could either be declined or a lower protective MRL established in the absence of a domestic MRL.

Other aspects

All requests should be reviewed to ensure that they are not sought by more than one requestor, noting that requests for the same pesticide/commodity combination may be submitted by more than one

¹⁶ However, the compound could be approved for use in other crops

Import MRL process

requestor. Import economies should inform trading partners of changes to their regulations through the WTO notification procedures and published in their domestic list of regulations.

Should more than one request be received for the same commodity, in the absence of a Codex MRL, and different MRLs are requested, the highest MRL should be considered first, pending outcomes from the National Dietary Exposure Assessments (NDEA), i.e., the NEDI and where required, the NESTI¹⁷. If requests for the same pesticide MRL are received for both a food/Crop group¹⁸ and an individual food that sits within the broader food group, the crop group MRL request should be considered first. If the NDEA for the crop group is found to be unacceptable, then the assessment of the individual commodity should be undertaken. If the assessment of the requested crop group MRL is acceptable the NDEA for the individual commodity will be unnecessary¹⁹.

Examples:

Import MRL requests may be received for the same pesticide for *Grapes*, for the *Small fruit, vine climbing* sub group and for the larger *Berries and other small fruit* commodity group. In this instance, the request for *Berries and other small fruit* commodity group would be considered in the first instance, pending outcomes from the NDEA.

Where requests are received for multiple individual commodities within a food group²⁰, the importing economy can consider the whole food group at the highest MRL requested, pending outcomes from the dietary risk assessment.

Example:

Individual requests received for the following commodities and MRLs: Blackberries 2 mg/kg; Cranberry 1.8 mg/kg; Currants, black, red 1.8 mg/kg; Grapes 2 mg/kg; Raspberries, red, black 1 mg/kg; Strawberry 2.5 mg/kg.

- The importing economy authority could consider the food group *Berries and other small fruits* at 2.5 mg/kg, pending outcomes from the dietary modelling.

When a request is considered for adoption or recognition of an Import MRL and all required information has been submitted, the requestor should be formally notified the request has been accepted for further consideration²¹. The NDEA then determines whether, in the context of the importing economy's diet, consuming residues of the pesticide on specific food products, is likely to be within relevant health-based guidance values²². Only MRL requests that result in estimated dietary exposures to the pesticide below the relevant guidance values can be accepted.

If the importing economy food consumption data is covered within the relevant GEMS-Food cluster diet, then a NDEA may not be required, as the JMPR IDEA, supporting the Codex MRL, has concluded that intake is unlikely to present a public health concern. However, such an approach may be inconsistent with the importing economy's legislative rules, e.g., the importing economy competent authority may be required to undertake its own assessment. Also, if the importing economies diet is not covered within the GEMS Food clusters, the importing economy can conduct its own NDEA.

¹⁷ Details are provided in Attachment 1, Element 6.

¹⁸ Crop groups are described in the Codex Classification of Foods and Animal Feeds.

¹⁹ See Section 3.3 'The Requested Commodity' for more details

²⁰ Groupings as elaborated either in the Codex Classification for Food and Animal Feeds or as applied by the importing economy. Whichever approach is followed it is anticipated would be at the discretion of the importing economy.

²¹ Requestors would only be informed about the requests they have submitted.

²² Details are provided in Attachment 1, Element 2.

Import MRL process

If the NDEAs for a given pesticide exceed the relevant health based guidance values the importing economy may inform the requestor/s of this outcome prior to finalisation to explore whether further refinement of the assessment is possible²³. Such refinement, for example, could occur through the consideration of an alternative GAP.

Following the completion of the assessment and any internal governmental procedural/regulatory steps, the importing economy would then notify the requestor of the final review outcome. Where an amendment to or establishment of a domestic MRL is proposed the importing economy's relevant authority should seek to inform other economies of the decision via WTO notifications.

²³ Details are provided in Attachment 1, Element 6.

Information requirements

Section 3 Information that may be required to support a request

This section describes the spectrum of information that may be required when seeking the establishment of import MRL. (See the application outline in **Attachment 2**)

Section 3, questions (a) to (n) give guidance on and match the categories of information that could be required to support a MRL adoption or recognition request.

Requestors should note that the full range information may not be required initially, but may be requested during the assessment. Inability to provide necessary information may result in a request being declined. However, rejection does not preclude a requestor from re-lodging the request for consideration in the future should additional information become available.

Note:

Information may be requested to clarify the request or for NDEA purposes, such as if the NDEAs need refinement.

The request and supporting information must be presented in the agreed language. Supporting information written in another language should be accompanied by a full translation if the information is highly relevant to the request.

3.1 Pre-Proposal notification

(a) Nature of the request

Summary information outlining pesticide(s) /commodity for which MRL(s) sought.

- is this request being made for a single commodity or crop group
- and the basis for MRLs sought, i.e., relevant Codex MRLs or exporting economy MRLs

(b) Is this pesticide currently approved for use in the importing economy? (y/n)

If no approval exists for the use of a pesticide in an importing economy but internationally recognised evaluations have been completed, e.g., JMPR, US EPA or EFSA, and health-based guidance values have been established and are recognised by the importing economy, import MRLs can still be adopted or recognised. Where these guidance values are not recognised, a significant data package and a more comprehensive assessment process may be required; this latter situation is outside the scope of this guideline document. The importing economy is encouraged to notify the receipt of such requests through (normal processes/the WTO SPS Enquiry Point) to promote the exchange of scientific and other relevant information.

3.2 Requested pesticide

(a) State the name of the pesticide to be considered (not the trade name)

This information should include the ISO common name and IUPAC equivalent of the pesticide.

Where relevant the residue definition(s) for both MRL compliance and dietary intake assessment and their origin could be included. For example, for spinetoram the residue definition for compliance is *Spinetoram* while for dietary intake *Spinetoram and N-demethyl and N-formyl metabolites of the major of the major spinetoram component*.

Information requirements

(b) State the relevant Acceptable Daily Intake (ADI) for this pesticide. Include source of this information

This information must be sourced either through the importing economy domestic regulator (in the first instance where a value has been established at the domestic level) or the Joint FAO/WHO meeting on Pesticide Residues (JMPR). Where no domestic or JMPR values has been established a value sourced from an agency or authority recognised/nominated by the importing economy should be provided. The key criteria will be the currency and methodology employed in establishing the health based guidance value²⁴.

Useful links:

JMPR: [Inventory of evaluations performed by the JMPR and JMPR Reports and evaluations](#)

(c) Where required state the relevant Acute Reference Dose (ARfD) for this pesticide (if available). Include source of this information²⁵

This information must be sourced either from the relevant importing economy regulator (in the first instance where a value has been established) or from the Joint FAO/WHO meeting on Pesticide Residues (JMPR). Where no domestic or JMPR values has been established a value sourced from an internationally recognised regulator can be nominated²⁶. The key criteria will be the currency and methodology employed in establishing the health based guidance values.

Useful links:

JMPR: [Inventory of evaluations performed by the JMPR and JMPR Reports and evaluations](#)

Examples

Example number ²⁷	a) Name of the pesticide to be considered	b) Relevant ADI for this pesticide. Include source of this information (mg/kg bw)	c) Relevant ARfD for this pesticide (if available). Include source of this information (mg/kg bw)
1	Azoxystrobin	0-0.2 (JMPR)	Unnecessary (JMPR)
2	Buprofezin	0-0.009 (JMPR)	0.5 (JMPR)
3	Captan	0-0.1 (JMPR)	0.3 (JMPR)
4	Cyflufenamid	0-0.04 (AUST)	0.1 (AUST)
5	Difenoconazole	0-0.01 (JMPR)	0.3 (JMPR)
6	Fludioxonil	0-0.4 (JMPR)	Unnecessary (JMPR)
7	Propiconazole	0-0.07 (JMPR)	0.3 (JMPR)
8	Spirotetramat	0-0.5 (JMPR)	1.0 (JMPR)

²⁴ That the values to be applied, and their derivation, are consistent with currently accepted risk analysis principles

²⁵ Where short-term dietary risk assessments are undertaken by the importing economy

²⁶ The acceptance of an alternative source of health based guidance values would be at the discretion of the importing economy

²⁷ Examples 1, 2 and 3 are consistent through sections 3.2 – 3.8.

Information requirements

3.3 Requested commodity

(d) State the name of the requested commodity or food group, as described by Codex or domestic nomenclature

All requested commodities should be described by using either the standard domestic nomenclature or the Codex Classification. Where commodity names differ, the equivalent Codex name should also be provided as a synonym. Where requests are made for individual commodities the binomial name should also be provided.

Useful links:

Requestors may refer to the relevant Codex document/s when preparing their request. It is advised that the most current up to date version of the Codex Classification be used.

- Codex Classification of Foods and Animal Feed²⁸
- Codex Pesticide Residues in Food and Feed Commodity Categories²⁹

(e) Include Codex Code for commodity or food group (if relevant)

Examples:

d) Name of the requested commodity or food group, as described by Codex³⁰	e) Codex Code for commodity or food group (if relevant)
Berries and other small fruit	FB 0018
Small fruit vine climbing	FB 2008
Grapes	FB 0269
Table-grapes	FB 1235
Wine-grapes	FB 1236
Assorted tropical fruit and sub-tropical fruits – inedible peel	FI 0030
Assorted tropical and sub-tropical fruits – inedible smooth peel - large	FI2022
Mango	FI 0345

²⁸ 1993 Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, Codex Alimentarius Volume 2, Pesticide Residues in Food, Second Edition.

²⁹ Codex Classification of Foods and Animal Feeds

http://www.codexalimentarius.org/download/standards/41/CXA_004_1993e.pdf ;

<ftp://ftp.fao.org/codex/meetings/ccpr/ccpr38/pr38CxCl.pdf> and ftp://ftp.fao.org/codex/reports/reports_2012/rep12_pre.pdf

³⁰ Draft Revision to the Codex Classification of Food and Animal Feed (fruit commodity groups) REP12/PR The Codex Classification is currently being revised .

Information requirements

3.4 Requested MRL and source

(f) State the requested MRL (mg/kg) and the origin/source of the requested MRL (e.g. Codex/economy/regulator)

The requested MRL should be coupled with evidence of authorised use upon which the MRL is based.

Examples:

Example No.	Example	Requested MRL (mg/kg)	
		Grapes	Mango
1	Azoxystrobin	2 (Codex)	0.7(Codex)
2	Buprofezin	1 (Codex)	0.1 (Codex)
3	Captan	25 (Codex)	5 (Philippines)
4	Cyflufenamid	0.1 (AUST APVMA)	-
5	Difenoconazole	3 (Codex)	0.07 (Codex)
6	Fludioxonil	2 (Codex)	2 (Codex)
7	Propiconazole	-	1 (ASEAN)
8	Spirotetramat	2 (Codex)	0.3 (Codex)

(g) State the name of the commodity or the food or crop group that the source MRL applies to, as described in the relevant international database

Does the source/ existing MRL data apply to an individual food or a group of foods:

- **Individual foods:** If the commodity is described in a different form to the commodity that has been requested, the submission should include the rationale for this extrapolation.
- **Food or crop group:** The commodities included in this food group (covered by the requested MRL) should be compared to the commodities included in the requested food. Ensure all of the commodities to be included with the request are captured.

When the request relates to a food or crop group:

Where a food group MRL is requested, the GAP should be comparable and applicable for the whole food group. Relevant and adequate summary residue trial data, to be agreed by each economy, should be provided for at least one representative commodity of the group³¹. This approach recognizes that adequate data from major representative crops of a group may be sufficient to estimate maximum residue levels for the whole group.

In the submission it should be stated what commodities, captured in the food or crop group, will be and/or currently are imported. Where food group names differ, the equivalent Codex name should also be provided as a synonym.

³¹ For example, application rate, method and number, frequency, pre-harvest interval, LoQ, matrix analysed

Information requirements

(h) Provide reference link/s to the published MRL in Codex (if available)

Examples: Mango

Pesticide	g) Origin/source of the requested MRL ^a	h) Name of the commodity or food group to which the MRL applies ^b	i) Reference link/s to published MRL in Codex (if available)
Azoxystrobin	Codex	Mango	http://www.codexalimentarius.net/pestres/data/pesticides/search.html
Buprofezin	Codex	Mango	http://www.codexalimentarius.net/pestres/data/pesticides/search.html
Difenoconazole	Codex	Mango	http://www.codexalimentarius.net/pestres/data/pesticides/search.html
Fludioxonil	Codex	Mango	http://www.codexalimentarius.net/pestres/data/pesticides/search.html
Spirotetramat	Codex	Mango	http://www.codexalimentarius.net/pestres/data/pesticides/search.html

Pesticide	g) Origin/source of the requested MRL ^a	h) Name of the commodity or food group to which the MRL applies ^b	i) Reference link/s to published MRL in Codex (if available)
Azoxystrobin	Codex	Grapes	http://www.codexalimentarius.net/pestres/data/pesticides/search.html
Buprofezin	Codex	Grapes	http://www.codexalimentarius.net/pestres/data/pesticides/search.html
Captan	Codex	Grapes	http://www.codexalimentarius.net/pestres/data/pesticides/search.html
Difenoconazole	Codex	Grapes	http://www.codexalimentarius.net/pestres/data/pesticides/search.html
Fludioxonil	Codex	Grapes	http://www.codexalimentarius.net/pestres/data/pesticides/search.html
Spirotetramat	Codex	Grapes	http://www.codexalimentarius.net/pestres/data/pesticides/search.html

(i) Provide reference link/s to the published MRL if it was established by a source other than Codex

Examples: Mango

Pesticide	g) Origin/source of the requested MRL ^a	h) Name of the commodity or food group to which the MRL applies ^b	j) Reference link/s to published MRL if established by source other than Codex.
Captan	Japan MHLW Philippine FDA	Mango	http://www.m5.ws001.squarestart.ne.jp/foundation/search.html http://fpa.da.gov.ph/
Propiconazole	ASEAN	Mango	http://www.asean.org/communities/asean-economic-community/category/other-documents-6

^a Codex or economy/regulator

^b As described in the relevant international database

Information requirements

Examples: Grapes

Pesticide	g) Origin/source of the requested MRL ^a	h) Name of the commodity or food group to which the MRL applies ^b	j) Reference link/s to published MRL if established by source other than Codex.
Cyflufenamid	Aust APVMA	Grapes	http://www.comlaw.gov.au/Details/F2015C00165

^a Codex or economy/regulator

^b As described in the relevant international database

(j) Indicate the commodity or commodities intended to be imported using the requested MRL, including any processed commodities associated with this request.

Where the request is for a raw agricultural commodity, but the intention is to import processed commodities using this MRL these commodities should also be listed in the application.

Examples:

- Request is for *Grapes*; this request is to support the importation of table grapes and wine
- Request is for *Mangoes*; this request is to support only the importation of dried mango
- Request is for *Stone fruits*; this request is to support the importation of all stone fruits
- Request is for *Berries and other small fruits*; this request is to support the importation of blueberries, raspberries and elderberries.

When the request relates to, or includes processed commodities:

Generally, separate MRLs for a processed commodity should only be considered if the resulting residues in the processed commodity is higher than the MRL of the corresponding raw commodity.

For the purpose of dietary intake risk assessment, the STMR and HR values of the raw commodity are multiplied by the processing factor to give the median and highest residue in the processed commodity. The STMR and HR values estimated in this way for the processed commodity are referred to as the STMR-P and HR-P of the processed product.

STMR-P and/or HR-Ps, where relevant, for commodities for human consumption should be provided by the requestor as part of the information submitted to enable a National Dietary Exposure Assessment to be undertaken.

Information requirements

3.5 Comparisons to current status

(k) State the current status for this MRL in Codex, the exporting economy and elsewhere

Note whether the pesticide is currently listed:

- Indicate if listed in Codex, but that the commodity is not captured.
- If listed, and the commodity is captured, state all of the applicable commodities and the current Codex MRLs.
- Indicate relevant MRLs in other jurisdictions in applicable commodities and the current MRL permissions.

Examples:

Example	m) Current status for this MRL in Codex	n) Current status for this MRL internationally
Captan-Mango	Commodity not listed	2 mg/kg (EU), 5 mg/kg (Hong Kong, Japan, Korea, Philippines, Thailand)
Cyflufenamid-Grapes	Pesticide not listed	0.1 mg/kg (AUST); 0.15mg/kg (EU, USA); 0.2 mg/kg (Chinese Taipei); 5 mg/kg (Japan)

Information requirements

3.6 Data to support the dietary exposure assessment

The Dietary exposure assessment process provides an estimate of exposure to a pesticide residue from the diet by combining food consumption data with residue data. The resultant estimated dietary exposure can then be compared to the relevant health-based guidance values to determine whether such residues may or may not present a public health concern. There can be two components in the dietary assessment process; chronic or long-term exposure against the ADI and acute or short-term exposure against the ARfD where required.

As a first tier in the assessment process the requested import MRL value could be used in a screening level assessment of exposure. Such an approach, while applying a more conservative approach, would not require the submission of data derived from residue trials upon which the requested import MRL was based³². However, should further refinement be required, information on the magnitude of pesticide residues would be needed upon which chronic or acute dietary exposure assessments could be based, i.e., the supervised trial median residue (STMR) value for the chronic and the highest residue (HR) value for the acute.

(l) State Highest Residue (HR) and Supervised Trial Median Residue (STMR)

The requestor should provide relevant information on the magnitude of residues derived from supervised residue trials, i.e., STMR or HR values, to support the NDEA, calculated according to the dietary exposure residue definition, if available through JMPR. If no JMPR published values are available the requestor should provide a copy of an Assessment Report, or a link to a publication, supporting the nominated values.

If data are available for the residues in the edible portion of the commodity, e.g., in mango flesh, the HR and STMR should be estimated directly from the residues in the edible portion found in supervised trials at the maximum registered use rate (as opposed to using pesticide residue values for the whole commodity). If these data are not available for the edible portion, the whole commodity residue values can be used in the estimation of dietary exposure³³.

When the request relates to, or includes processed commodities:

Separate MRLs for a processed commodity should only be requested if the resulting residue value is higher than the MRL of the corresponding raw commodity.

For the purpose of NEDI and NESTI assessments, the STMR and HR values of the raw commodity are multiplied by the processing factor to give the median and highest residue in the processed commodity. The STMR and HR values estimated in this way for the processed commodity are referred to as the STMR-P and HR-P of the processed product.

STMR-P and/or HR-Ps, where relevant, for commodities for human consumption should be provided by the requestor as part of the information submitted to enable a dietary exposure assessment to be undertaken.

³² Such an approach could only be followed where allowed under an importing economies legislation

³³ This approach potentially results in an over-estimate of the actual residues likely to be consumed

Information requirements

(m) Provide a link to the publication of the HR and STMR data

Examples:

Pesticide	o) Highest Residue (HR) and Supervised Trial Median Residue (STMR)	p) Link to the publication of the HR and STMR data
Azoxystrobin	In grapes (JMPR) 0.53 mg/kg (STMR)	2008 Report http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-rep/en/
	In wine (JMPR) 0.36 mg/kg (STMR-P)	
Buprofezin	In mango (JMPR) 0.05 mg/kg (STMR)	2009 Report http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-rep/en/
	In grapes (JMPR) 0.17 mg/kg (STMR) 0.74 mg/kg (HR) White wine (JMPR) 0.15 mg/kg (STMR-P) Red wine (JMPR) 0.1 mg/kg (STMR-P)	
Captan	In mango (JMPR) 0.01 mg/kg (STMR) 0.01 mg/kg (HR)	2008 Report http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-rep/en/
	In grapes (JMPR) 3.7 mg/kg (STMR); 22 mg/kg (HR)	
Cyflufenamid	In mango HR and STMR not available	Not available
	In grapes (Aust APVMA) 0.02 mg/kg (STMR); 0.07 mg/kg (HR)	http://apvma.gov.au/node/11376
Difenoconazole	In mango (JMPR) 0.03 mg/kg (STMR); 0.04 mg/kg (HR)	2013 Report http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-rep/en/
	In grapes (JMPR) 0.52 mg/kg (STMR); 1.5 mg/kg (HR) In wine (JMPR) 0.094 mg/kg (STMR-P)	
Fludioxonil	In mango (JMPR) 0.02 mg/kg (STMR)	2007 Report http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-rep/en/
	In grapes (JMPR) 0.28 mg/kg (STMR) In wine (JMPR) 0.01 mg/kg	
Propiconazole	In mango HR and STMR not available	2004 Report http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-rep/en/
Spirotetramat	In mango (JMPR) 0.16 mg/kg (STMR); 0.25 mg/kg (HR)	2012 Report http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-rep/en/
	In grapes (JMPR) 0.41 mg/kg (STMR); 1.3 mg/kg (HR) In wine (JMPR) 0.23 mg/kg (STMR-P)	
		2008 Report http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-rep/en/
		2011 http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-rep/en/

ATTACHMENT 1: Provision of data**Element 1 The requested pesticide³⁴**

Pesticide name (ISO)³⁵	
<i>IUPAC</i>	
<i>CAS No.</i>	
<i>Residue definitions</i>	Source
<i>For compliance with MRLs</i>	
<i>For estimation of dietary intake</i>	
Health based guidance values	
ADI	
ARfD	
Authorised GAP	
<i>Residue Summary</i>	
<i>Supervised Trial Median Residue (STMR)</i>	
<i>Highest Residue (HR)</i>	
<i>Link to the source of the HR, STMR data</i>	

Chemical identity of the pesticide

Provide the ISO common name, pesticide name and relevant residue definitions for the requested pesticide.

Pesticide GAP

Provide information on the approved or authorised use of the pesticide leading to the presence of residues in the imported product may for which the MRL is being requested.

Residue definition(s)

Verify that the residue definition(s) for each pesticide for which MRL adoption or recognition is requested is consistent with the established residue definition(s) in the importing economy. If the residue definitions are different, then the requestor needs to ensure that the information provided reflects the definition of the importing economy.

Example:

If a request is to harmonise with a Codex MRL, the JMPR residue definition(s) should be compared to the definition(s) in the importing economy.

If requests relate to pesticides that have not been previously evaluated in the importing economy, agreement may be needed on the appropriate residue definitions prior to any evaluation. If required the requesting economy may need to nominate residue definitions and identify the source of the definitions for compliance and estimating dietary exposure, e.g., the JMPR.

³⁴ Minimum required information highlighted in **bold**. Additional information that may be required indicated in *italics*

³⁵ ISO common name

Attachment 1

Health-based guidance values – ADI and ARfD³⁶

An ADI is used to assess long-term or chronic dietary exposure to pesticide residues. The ARfD is used to assess acute dietary exposure to pesticide residues. However, an ARfD is not always established because some pesticides are not acutely toxic.

In the first instance the relevant guidance values of the importing economy should be used for the dietary exposure assessments. Where no values have been established by the competent agency within the importing economy then values established through the JMPR should be used. Utilisation of reference values established by the JMPR is preferred in the aim of facilitating greater regulatory convergence between economies due to its standing internationally recognised independent scientific advisory body to FAO/WHO. If no guidance values have been established for a pesticide by the JMPR then alternative sources could be considered, e.g. the exporting economy, the US EPA or the EU (EFSA)³⁷. If no guidance values have been established, the pesticide cannot be considered under the import MRL process. This decision making process is described in Figure A1.

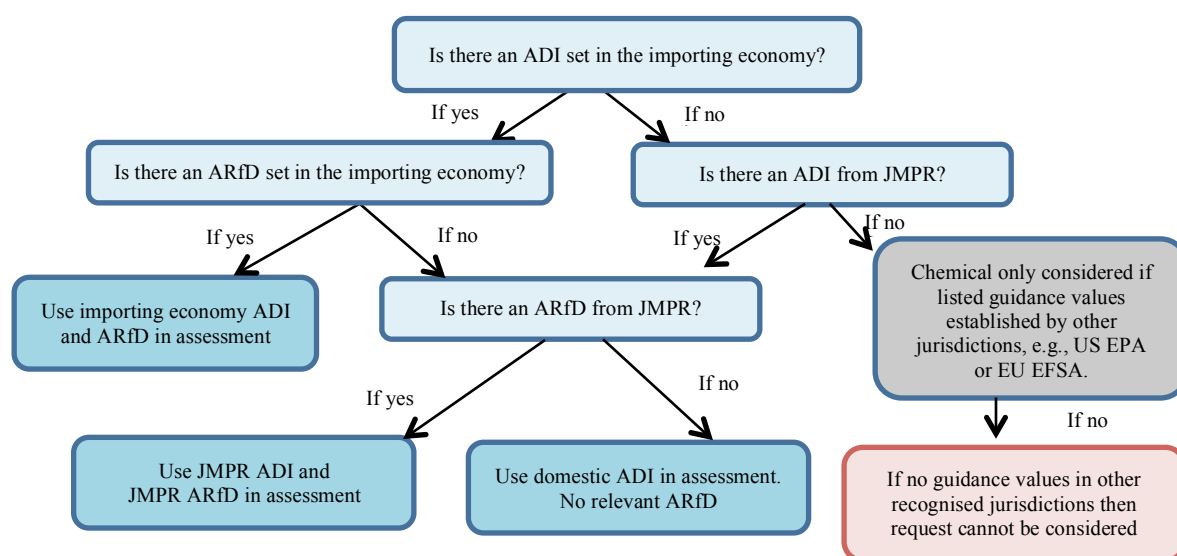


Figure A1 Process for considering health based guidance values

³⁶ Where required by importing economy regulator

³⁷ The values established through the JMPR are preferred as they have been developed by internationally recognised WHO/FAO expert panels. The recognition of any alternative source of health based guidance values would be at the discretion of the importing economy

Element 2 The requested commodity³⁸

Name of the requested commodity or food group (as described by Codex or the importing economy agency)	
<i>Codex Code for commodity or food group (if relevant)</i>	
<i>Commodity or commodities intended to be imported using this MRL, including any processed commodities associated with this request</i>	

An appropriate description of the food commodity should be provided to ensure that import MRLs apply to the traded commodity. The description should be consistent with the Codex Classification. If commodity or food group descriptions vary greatly from the Codex Classification the commodity descriptor utilised in the importing economy should be used with the appropriate Codex description provided as a synonym.

The description is important as commodities (and food groups) are often described differently across international databases so providing the description in the same terms as the Codex Classification minimises the chance of misinterpretation.

Requests may be received for individual commodities or food or crop groups:

Example:

In all economies mango is accepted as the individual commodity name. However, care would be needed where a food or crop group MRL might be sought.

In Codex mango, falls under *Assorted tropical and sub-tropical fruits – inedible peel – large*.

In Chinese Taipei mango falls under the Drupe crop group

In the US mango is currently not included in any crop group³⁹

Individual foods: MRLs are usually applied to raw and unprocessed commodities. Physical processing may be required for some commodities (e.g. milling, drying or steaming) and may result in separate MRLs. The Internationally accepted approach is that unless a separate MRL is included for a processed food, then the MRL for the raw food applies to the processed food. The requesting economy must state if there are any processed foods associated with the import MRL request.

Where requests are received for multiple individual commodities within a food group, the importing economy can consider the whole food group at the highest MRL requested, pending outcomes from the dietary risk assessment.

Example:

Individual requests received for the following commodities and MRLs: Blackberries 2 mg/kg; Cranberry 1.8 mg/kg; Currants, black, red 1.8 mg/kg; Grapes 2 mg/kg; Raspberries, red, black 1 mg/kg; Strawberry 2.5 mg/kg.

- The importing economy authority could consider the food group *Berries and other small fruits* at 2.5 mg/kg, pending outcomes from the dietary modelling.

Food or crop groups: It is important to note that food/crop group descriptors can vary from economy to economy and these groups can often contain different commodities. When a request is for a

³⁸ Minimum required information highlighted in **bold**. Additional information that may be required indicated in *italics*

³⁹ US EPA to establish a new crop group in which Mango included, entitled Tropical and Subtropical Fruit, Inedible Peel, Crop Group 24: Docket ID: EPA-HQ-OPP-2006-0766-0054. It is anticipated this will come into effect in January 2016.

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food/crop group, the commodities that are included in the food group should follow those as described in the Codex Classification.

Example:

In the Codex Classification, the food group – *Assorted tropical and sub-tropical fruits – inedible peel – small*, contains the following commodities:

Aisen; Bael fruit; Burmese grape; Ingá; Litchi; Longan; Madras-thorn; Manduro; Matisia; Mesquite; Mongongo; Pawpaw, Small-flower; Satinleaf; Sierra Leone-tamarind; Spanish lime; Tamarind; Velvet tamarind; Wampi; White star apple.

The requestor will need to verify these commodities are covered by the existing source MRL.

Element 3 The requested MRL⁴⁰

Requested MRL (in mg/kg)	Source
--------------------------	--------

Import MRL requests may be received for any MRL that has been established by Codex or in another economy. MRLs may be described differently from economy to economy. For example, the United States term for MRL is ‘tolerance’ and is stated in parts per million (ppm). The Codex system lists MRLs in mg/kg.

Element 4 The existing/source MRL data³⁷

Origin/source of the requested MRL (e.g. Codex/ economy/ regulator)	
<i>Link/s to published Codex MRL or alternative source (if available)</i>	

Origin/source of the MRL

The requested MRL should be from the economy in which the product was grown and where a domestic or regional MRL has been applied.

The name of the commodity or food group for which the existing/source MRL applies

The requestor must ensure the proposed MRL has been established for a commodity or food group by Codex or in another economy, and is appropriate to the requested commodity or food group.

Individual foods: Where a commodity is described in a different form between the request and the source MRL, for example, dried versus fresh, additional information would be required to demonstrate the requested MRL is covered by the source data (the existing MRL).

⁴⁰ Minimum required information highlighted in **bold**. Additional information that may be required indicated in *italics*

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Examples:

- Request is for peas and existing/source MRL is for dried peas. Additional information is required to show that the MRL also applies to fresh peas – otherwise the request could be considered as relating to the Codex commodity VD 0072 Peas (dry).
- Request is for Peppers, Chilli and existing/source MRL is for Sweet peppers/bell peppers. Additional information is required to show that the MRL also applies to chili peppers – otherwise the request could be considered as relating to the Codex commodity VO 0445 *Peppers, Sweet*.

Food groups: Separate requests are required for commodities that are included in the food group that has the existing MRL (source data), but is not listed in the food group that has been requested.

Example:

The U.S. food group: *Vegetable, tuberous and corn, subgroup 1C* lists the following commodities: Arracacha; arrowroot; artichoke, Chinese; artichoke, Jerusalem; canna, edible; cassava, bitter and sweet; chayote (root); chufa; dasheen; ginger; leren; potato; sweet potato; tanier; turmeric; yam bean; yam, true.

- Note if the request was for *Root and tuber vegetables* (Codex code VR 75), the following would not be captured - Arracacha, Chayote, Ginger, Leren, Tanier, Turmeric (separate requests would be required for these)

Current status of the MRL⁴¹

To ensure an import MRL request is suitable the requesting economy should provide additional supporting information indicating current MRL standards established in other jurisdictions. This can be particularly important when the requested MRL is higher than the MRL set by Codex or the importing economy.

Current status for this MRL in Codex	Include year of JMPR assessment and Codex promulgation
<i>Current status for this MRL in other jurisdictions</i>	<i>Provide information on any relevant MRLs existing in internationally</i>

⁴¹ Minimum required information highlighted in **bold**. Additional information that may be required indicated in *italics*

Element 5 Dietary exposure assessment process

A key consideration for all import MRL requests is the outcome of the dietary exposure assessments⁴². The assessments are conducted per pesticide, and consider all commodities with an existing or requested MRL for that given pesticide. The estimated dietary exposure must always be below the relevant guidance values for the request to be considered for approval. If the importing economy diet is covered in the relevant GEMS-Food cluster diet, then a NDEA may not be required, as the JMPR dietary risk assessment, supporting the Codex MRL, has concluded that intake is unlikely to present a public health concern. The assessment process is illustrated in **Figure A2**.

Types of Dietary exposure assessments

Two types of dietary exposure assessments may be performed for each request. The approaches taken in completing dietary exposure assessments may vary between economies with respect to food consumption data sets and population groupings to which these are applied.

1. *A National Estimate of Dietary Intake (NEDI)*

- i. This dietary exposure assessment is for a long-term chronic exposure estimate. This estimate is based on the sum of exposure from all current and requested MRLs for each commodity (raw and processed) for a given pesticide and toxicologically significant metabolites. This estimate of mean dietary exposure for the general population is compared against the ADI.
- ii. If domestic consumption data are unavailable, a IEDI assessment can be undertaken utilising the average daily per capita consumption levels indicated in the 17 GEMS/Food Consumption cluster diets⁴³, where the data for a cluster in which an economy sits could be used. See Attachment 2 for an example.

2. *A National Estimate of Short Term Intake (NESTI)*

- i. If required this assessment is performed for individual commodities (raw and processed) for a given pesticide and toxicologically significant metabolites where an ARfD has been established. When used it can be performed for the general population or for specific age groups within the population utilising domestic consumption data for high consumers⁴⁴.
- ii. If domestic large portion data are unavailable an IESTI assessment can be undertaken as a substitute. In this approach the consumption levels are estimated for children and general population on the basis of the values provided by WHO GEMS/Food for the highest large-portion diet with the associated body weight and economy⁴⁵. See Attachment 2 for an example.

Dietary exposure approach

If required by the importing economy and the pesticide has an ARfD, the NESTI should be conducted first, for each commodity (raw and processed) that has a proposed MRL. If the NESTI exceeds the ARfD for a commodity, the importing economy may consider using alternate datasets to refine the estimate of exposure. If the NESTI continues to exceed the ARfD, the commodity is excluded from

⁴² Dietary exposure assessments for agvet chemicals should be based on importing consumption data, where available.

⁴³ https://extranet.who.int/sree/Reports?op=vs&path=/WHO_HQ_Reports/G7/PROD/EXT/GEMS_cluster_diets_2012
http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/

⁴⁴ For example, children aged 2-6 years (Australia & USA), other children aged 3-9 years (EFSA)

⁴⁵ http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/

Attachment 1

the proposal and not included in the NEDI calculations. If the NESTI is less than the ARfD or there is no ARfD for the pesticide, the NEDI calculations are then undertaken⁴⁶.

⁴⁶ FAO/WHO (2009). *Principles and methods for the risk assessment of chemicals in food*. Geneva, World Health Organization, (Environmental Health Criteria, No. 240);

Attachment 1

If the NEDI and, where required, the NESTI are lower than the relevant guidance values for a given pesticide, the import MRL request(s) can then be accepted and steps taken for formal acknowledgement and agreement, e.g., applicant receives formal notification.

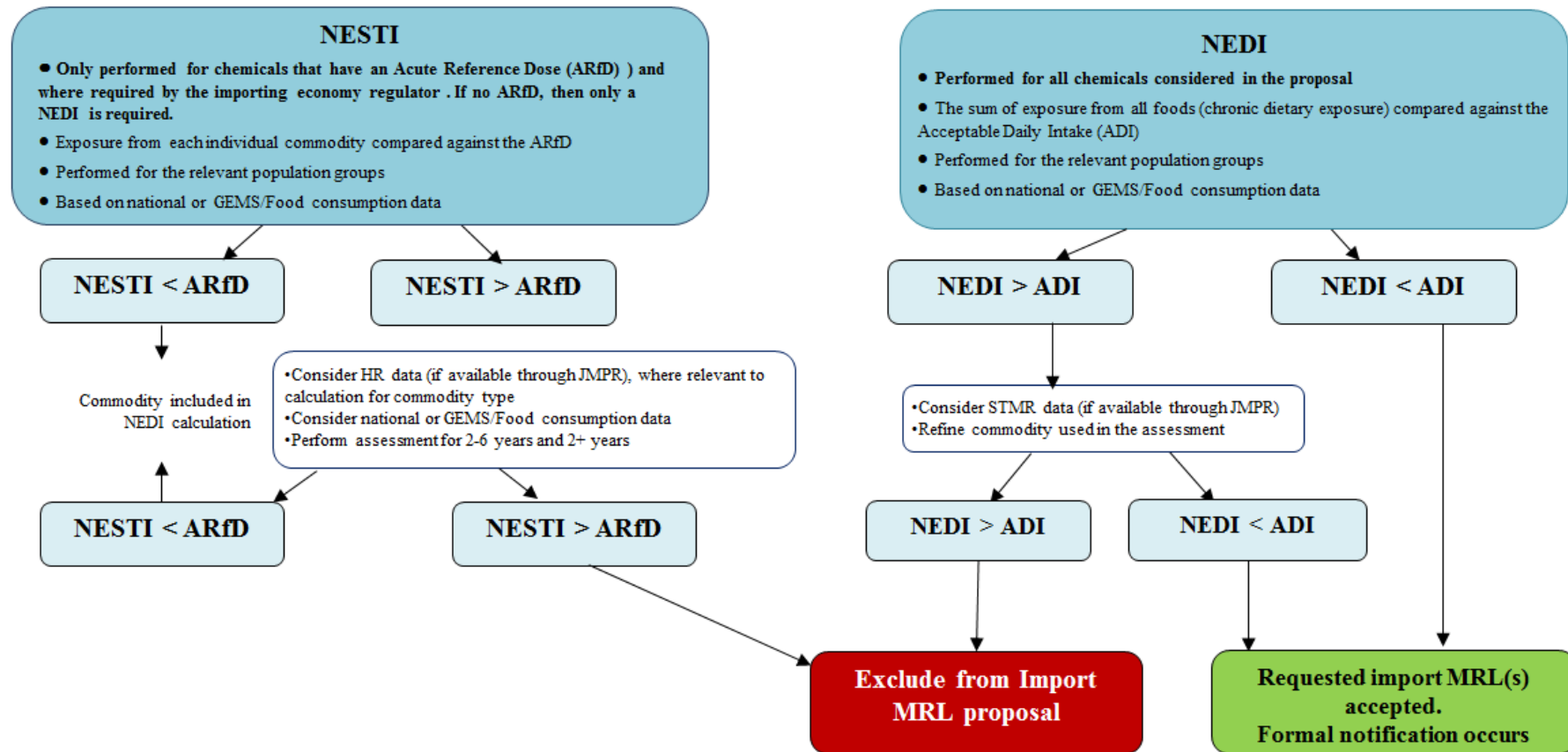


Figure A2 The dietary exposure assessment process

ATTACHMENT 2: Illustrative examples of the application process

Scenario 1 Existing Codex MRL can be adopted/recognised without a National Dietary Exposure Assessment

An APEC economy is seeking the establishment of an import MRL for the insecticide spinetoram in grapes. The MRL sought is 0.3 mg/kg.

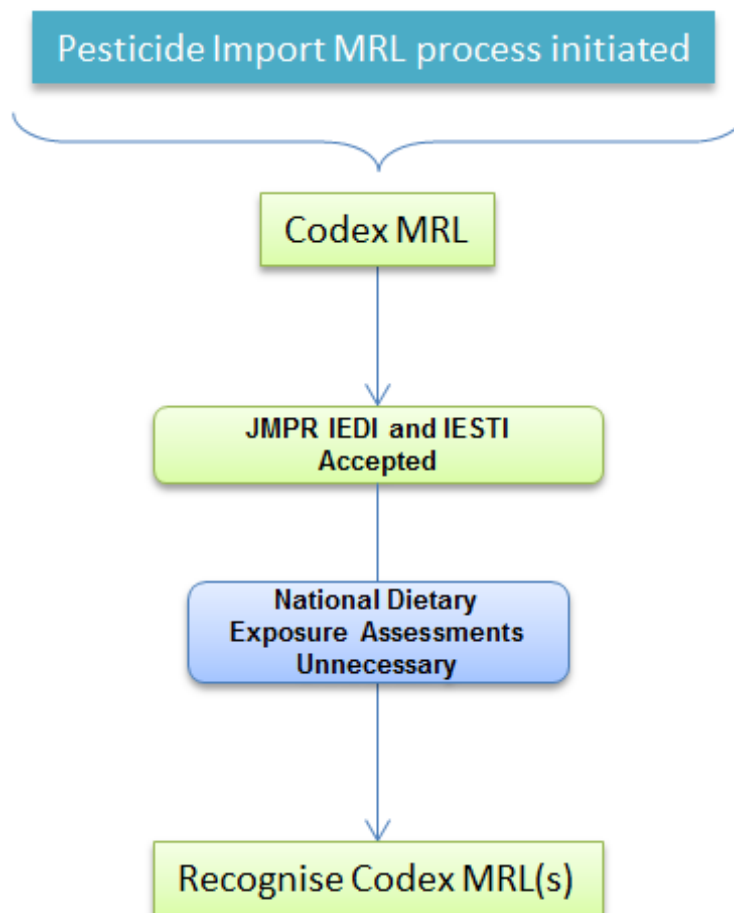


Figure A3 Illustrative import MRL application process for spinetoram in grapes where an importing economy can either accept or confirm a JMPR assessment of dietary exposure.

Background

The compound is approved for use against a number of insect pest species in grapes in the exporting economy. It is also approved for use in other crops and situations in the importing economy. The importing economy recognises or adopts the Codex MRL.

Information provided on the authorised use pattern, the proposed MRL and the relevant JMPR IEDI and IESTI assessments, see below.

Attachment 2

Data to be provided in support of an import MRL request⁴⁷

Pesticide name (ISO)	Spinetoram	
<i>IUPAC</i>	<p>(2R,3aR,5aR,5bS,9S,13S,14R,16aS,16bR)-2-(6-deoxy-3-O-ethyl-2,4-di-O-methyl-α-L-mannopyranosyloxy)-13-[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methylpyran-2-yloxy]-9-ethyl-2,3,3a,4,5,5a,5b,6,9,10,11,12,13,14,16a,16b-hexadecahydro-14-methyl-1H-as-indaceno[3,2-d]oxacyclododecine-7,15-dione*</p> <p>(2R,3aR,5aS,5bS,9S,13S,14R,16aS,16bS)-2-(6-deoxy-3-O-ethyl-2,4-di-O-methyl-α-L-mannopyranosyloxy)-13-[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methylpyran-2-yloxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-1H-as-indaceno[3,2-d]oxacyclododecine-7,15-dione**</p>	
<i>CAS No.</i>	187166-40-1* & 187166-15-0**	
<i>Residue definitions</i>		<i>Source</i>
<i>For compliance with MRLs</i>	Spinetoram	JMPR
<i>For estimation of dietary intake</i>	Spinetoram and N-demethyl and N-formyl metabolites of the major spinetoram component	JMPR
Health based guidance values		
ADI	0-0.05 mg/kg bw	JMPR
ARfD	Unnecessary	JMPR
Authorised GAP	5 g ai/hL with a 7 day Pre Harvest Interval.	
<i>Residue Summary</i>		
<i>Supervised Trial Median Residue (STMR)</i>	0.074 mg/kg	
<i>Highest Residue (HR)</i>	–	
<i>Link to the source of the HR, STMR data</i>	http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-rep/en/	
Note: In addition to HR and STMR values individual economies may require the submission of full residue studies as per domestic regulations		
Name of the requested commodity or group	Grapes	
Commodity to be imported, including any processed commodities	Grapes RAC	
<i>Codex Code</i>	FB 0269	
Requested MRLs	0.3 mg/kg	
Origin/source of the requested MRL (e.g. Codex/ economy/ regulator)	Codex (CAC 2013)	
<i>Reference link/s to published MRL in Codex or by alternative source other than Codex (if available)</i>	http://www.codexalimentarius.net/pestres/data/pesticides/search.html	
<i>Current status for this MRL in other jurisdictions</i>		

* Major component ** Minor component

⁴⁷ Minimum required information highlighted in **bold**. Additional information that may be required indicated in *italics*

Scenario 2: Codex MRL with dietary exposure assessment

An APEC economy is seeking the establishment of an import MRL for the insecticide buprofezin in mango and grapes. The MRLs sought is 0.1 mg/kg for mangoes and 1 mg/kg in grapes.

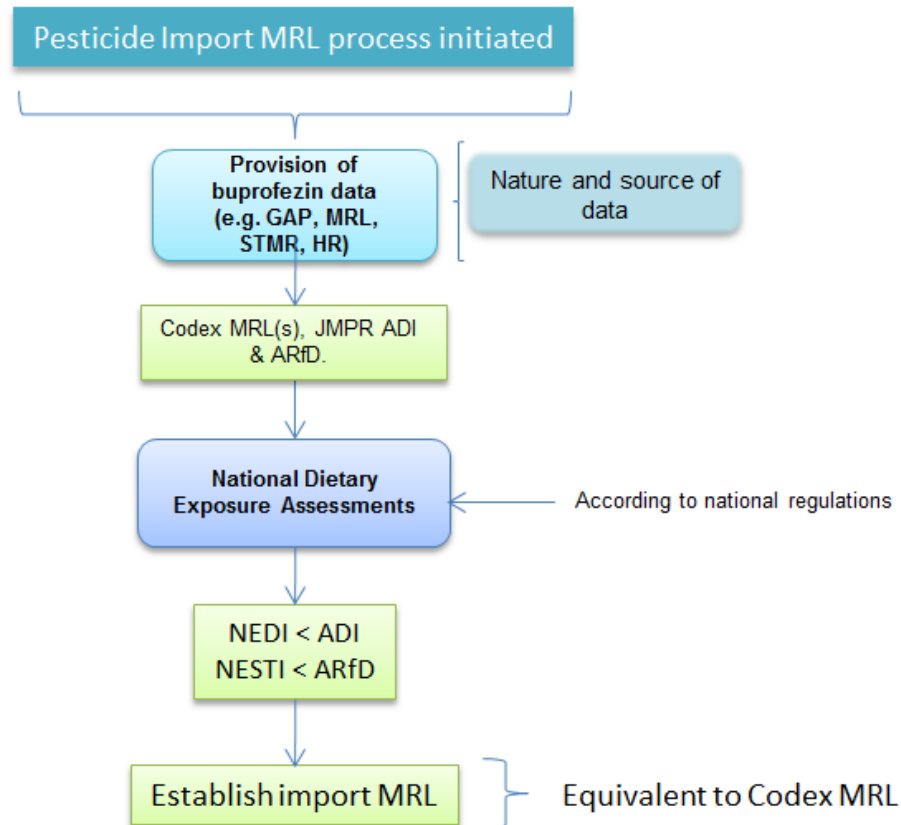


Figure A4 Illustrative import MRL application process for buprofezin in mango

Background

The compound is approved for use against a number of insect pest species in mango in the exporting economy. It is also approved for use in other crops and situations in the importing economy.

The importing economy requires a NDEA to be undertaken. Information to be provided on the authorised use pattern, the proposed MRL and supporting information needed to allow the dietary intake assessment to be undertaken, i.e., the JMPR health based guidance values and STMR and HR values reported by the JMPR.

Attachment 2

Data to be provided in support of an import MRL request⁴⁸

Pesticide name (ISO)	Buprofezin	
<i>IUPAC</i>	<i>2-tert-butylimino-3-isopropyl-5-phenyl-1,3,5-thiadiazinan-4-one</i>	
<i>CAS No.</i>	953030-84-7	
<i>Residue definitions</i>		<i>Source</i>
<i>For compliance with MRLs</i>	<i>Buprofezin</i>	<i>JMPR</i>
<i>For estimation of dietary intake</i>	<i>Buprofezin</i>	<i>JMPR</i>
Health based guidance values		
ADI	0-0.009 mg/kg bw	JMPR
ARfD	0.5 mg/kg bw	JMPR

Authorised GAP	10 g ai/hL with a 15 day Pre Harvest Interval
Name of the requested commodity or group	Mango
Commodity to be imported, including any processed commodities	Mango RAC
<i>Codex Code</i>	<i>FI 0345</i>
Requested MRLs	0.1 mg/kg
Origin/source of the requested MRL (e.g. Codex/ economy/ regulator)	Codex (CAC 2009)
<i>Residue Summary</i>	
<i>Supervised Trial Median Residue (STMR)</i>	<i>0.01 mg/kg</i>
<i>Highest Residue (HR)</i>	<i>0.01 mg/kg</i>
<i>Link to the source of the HR, STMR data</i>	http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-rep/en/
Note: In addition to HR and STMR values individual economies may require the submission of full residue studies as per domestic regulations	
<i>Reference link/s to published MRL in Codex or by alternative source other than Codex (if available)</i>	http://www.codexalimentarius.net/pestres/data/pesticides/search.html
<i>Current status for this MRL in other jurisdictions</i>	

Authorised GAP	10 g ai/hL with a 15 day Pre Harvest Interval
Name of the requested commodity or group	Grapes
Commodity to be imported, including any processed commodities	Grapes RAC
<i>Codex Code</i>	<i>FB 0269</i>
Requested MRLs	1 mg/kg

⁴⁸ Minimum required information highlighted in **bold**. Additional information that may be required indicated in *italics*

Attachment 2

Origin/source of the requested MRL (e.g. Codex/ economy/ regulator)	<i>Codex (CAC 2010)</i>
<i>Residue Summary</i>	
<i>Supervised Trial Median Residue (STMR)</i>	<i>0.17 mg/kg</i>
<i>Highest Residue (HR)</i>	<i>0.74 mg/kg</i>
<i>Link to the source of the HR, STMR data</i>	http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-rep/en/
Note: In addition to HR and STMR values individual economies may require the submission of full residue studies as per domestic regulations	
<i>Reference link/s to published MRL in Codex or by alternative source other than Codex (if available)</i>	http://www.codexalimentarius.net/pestres/data/pesticides/search.html
<i>Current status for this MRL in other jurisdictions</i>	

Attachment 2

Model Dietary Exposure Assessments

Based on the information outlined above the following estimates of dietary exposure can be calculated. The first step could be to assess acute exposure. Should the estimated exposure be determined acceptable the chronic dietary risk assessment could then be undertaken.

Short-term dietary exposure assessment

BUPROFEZIN

Mango

International estimate of short term intake (IESTI)

Acute RfD= 0.500 mg/kg bw (500 µg/kg bw)

Maximum %ARfD: 0% 0% 0% 0%
all- children women gen pop mixed

Codex Code	Commodity	Processing	STMR HR or diet or HR-P corn		Mixed population groups			Large portion, weight, g/person	Unit edible portion, g	Variability factor	Case % acute RfD rounded	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded		
			STMR- mg/kg P	mg/kg	Coun try	Population n group										
-	Mango	raw without peel		0.01	1.0	NL	toddler, 8-20 m	11	160.4	288.8	3	2b	0%	0%	0%	0%

The NESTIs for all relevant commodities were all less than 0.1% of the acute reference dose. It can be concluded that the acute dietary exposure is acceptable.

Grapes

International estimate of short term intake (IESTI) Acute RfD= 0.500 mg/kg bw (500 µg/kg bw)

Maximum %ARfD: 10% 10% 3% 5%

all- children women gen pop mixed

Codex Code	Commodity	Processing	STMR HR or diet or HR-P corn		Mixed population groups			Large portion, weight, g/person	Unit edible portion, g	Variability factor	Case % acute RfD rounded	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded	
			STMR- mg/kg P	mg/kg	Coun try	Population n group									
-	Grape	raw with skin		0.74	CN	Child, 1-6 yrs	232	366.7	636.6	3	2b	10%	10%	3%	5%
DF 0269	Grape	dried (currants, raisins, sultanas)		1.63	AU	Child, 2-6 yrs	918	83.5	1.0	NR	1	1%	1%	-	0%
JF 0269	Grape	juice (pasteurised)	0.17	0.03	NL	Child, 2-6 yrs	8	803.2	NR	NR	3	0%	0%	0%	0%
-	Grape	red wine	0.10		FR	Gen pop, > 3 yrs	95.8%	1006.5	NR	NR	3	0%	0%	0%	0%
-	Grape	white wine	0.15		FR	Gen pop, > 3 yrs	95.8%	1006.5	NR	NR	3	1%	0%	0%	1%

The NESTIs for all relevant commodities were all less than 10% of the acute reference dose. It can be concluded that the acute dietary exposure is acceptable.

Attachment 2

Long-term dietary exposure assessment

Where an exporting economy is seeking to export mangoes to an APEC economy represented in GEMS/Food Clusters G09 or G10 the following could be used as a substitute in the event local consumption data were unavailable⁴⁹.

Mango

BUPROFEZIN		International Estimated Daily Intake (IEDI)				
Commodity description	Expr as	STM ^R mg/kg	G09 diet	G09 intake	G10	G10
					diet	intake
Mango, raw (incl canned mango, incl mango juice)	RAC	0.01	10.05	0.10	1.07	0.01
Total intake (µg/person)=				0.10	0.01	
Bodyweight per region (kg bw) =				55	60	
ADI (µg/person)=				495	540	
%ADI=				0.02%	0.002%	
Rounded %ADI=				0%	0%	

Grapes

BUPROFEZIN		International Estimated Daily Intake (IEDI)				
Commodity description	Expr as	STM ^R mg/kg	G09 diet	G09 intake	G10	G10
					diet	intake
Grape, raw	RAC	0.17	5.21	0.89	9.38	1.59
Grape, dried (= currants, raisins and sultanas)	PP	0.37	0.10	0.04	1.38	0.51
Grape juice	RAC	0.03	0.10	0.00	2.24	0.07
Grape wine (incl vermouths)	RAC	0.15	1.84	0.28	25.07	3.76
Total intake (µg/person)=				1.2	5.9	
Bodyweight per region (kg bw) =				55	60	
ADI (µg/person)=				495	540	
%ADI=				0.2%	1.1%	
Rounded %ADI=				0%	1%	

Based on the cluster diets and the IEDI for buprofezin, the added dietary contribution of residues for the commodities under consideration is 1% of the acceptable daily intake or less.

Decision:

The estimates of short and long-term intake were calculated for mango and grapes. It can be concluded that the residues of buprofezin resulting from the uses under the authorised GAP are unlikely to present a public health concern. Therefore, on the basis of the data provided it could be recommended to establish an import MRL at the level nominated by the requestor economy, i.e., at the Codex level of 0.1 mg/kg for mango and 1 mg/kg for grapes.

⁴⁹ Group 9 Bangladesh, Cambodia, China, DPR Korea, Guinea Bissau, Indonesia, Loa, Myanmar, Nepal, Philippines, Sierra Leone, Thailand, Timor Leste, Viet Nam.

Group 10 Belarus, Bulgaria, Canada, Croatia, Cyprus, Estonia, Italy, Japan, Latvia, Malta, New Zealand, Republic of Korea, Russian Federation, USA

Scenario 3: No Codex MRL

An APEC economy is seeking the establishment of an import MRL for the fungicide captan in mango. The MRL sought is 5 mg/kg.

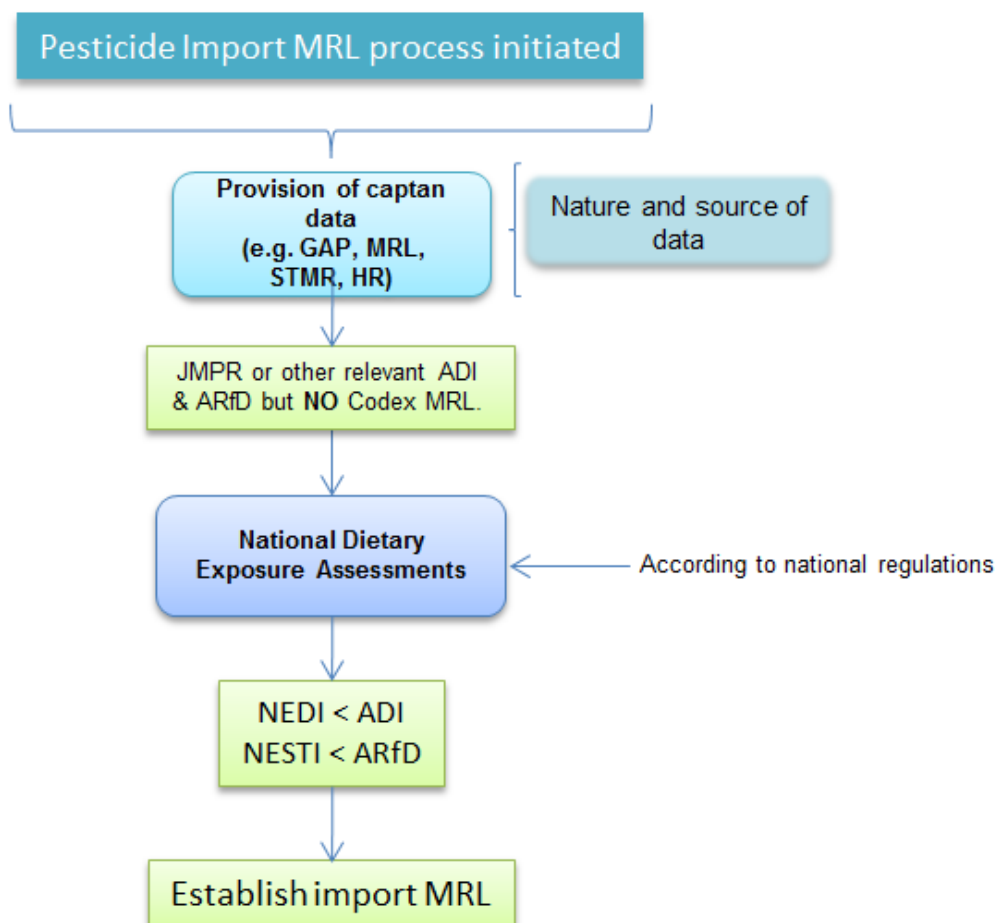


Figure A4 Illustrative import MRL application process where there is no Codex MRL and the proposed MRL is used to assess exposure in the absence of STMR and HR values

Background

The compound is approved for use against anthracnose in mango in the exporting economy. It is also approved for use in other crops and situations in the importing economy.

Information to be provided on the authorised use pattern, the proposed MRL and supporting information needed to allow the dietary intake assessment to be undertaken. For captan however, information on the STMR and HR is not available. The proposed MRL value can therefore be used as a default value for the dietary exposure calculations.

Attachment 2

Data to be provided in support of an import MRL request⁵⁰

Pesticide name (ISO)	Captan	
<i>IUPAC</i>	<i>N-(trichloromethylthio)cyclohex-4-ene-1,2-dicarboximide</i>	
<i>CAS No.</i>	133-06-2	
<i>Residue definitions</i>		<i>Source</i>
<i>For compliance with MRLs</i>	<i>Captan</i>	<i>JMPR</i>
<i>For estimation of dietary intake</i>	<i>Captan</i>	<i>JMPR</i>
Health based guidance values		
ADI	0-0.1 mg/kg bw	<i>JMPR</i>
ARfD	0.3 mg/kg bw	<i>JMPR</i>

Authorised GAP	0.13 kg ai/hL with a 14 day Pre Harvest Interval	
Name of the requested commodity or group	Mango	
Commodity to be imported, including any processed commodities	Mango RAC	
<i>Codex Code</i>	<i>FI 0345</i>	
Requested MRLs	<i>5 mg/kg</i>	
Origin/source of the requested MRL (e.g. Codex/ economy/ regulator)	<i>Exporting economy</i>	
<i>Residue Summary</i>		
<i>Supervised Trial Median Residue (STMR)</i>	<i>Not available</i>	
<i>Highest Residue (HR)</i>	<i>Not available</i>	
<i>Link to the source of the HR, STMR data</i>		
Note: In addition to HR and STMR values individual economies may require the submission of full residue studies as per domestic regulations		
<i>Reference link/s to published MRL in Codex or by alternative source other than Codex (if available)</i>		
<i>Current status for this MRL in other jurisdictions</i>	MRL of 5 mg/kg in Japan, Hong Kong, Korea, Philippines and Thailand	

⁵⁰ Minimum required information highlighted in **bold**. Additional information that may be required indicated in *italics*

Attachment 2

Model Dietary Exposure Assessments

Based on the information outlined above the following estimates of dietary exposure can be calculated using the **MRL value of 5 mg/kg as the default STMR**.

The first step could be to assess acute exposure. If the estimated acute exposure is determined to be acceptable the chronic dietary risk assessment could then be undertaken.

Short-term dietary exposure assessment

CAPTAN

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw) Maximum %ARfD: 20%
WOMEN women

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FI 0345	Mango (all commodities)	0	5	1.000	AU	gen pop, > 2 yrs	227.4	NR	2a	60.15	20%

The NESTI calculated for mango, using the MRL in the absence of any supervised trial data and assuming that residues are evenly distributed in the pulp and peel, estimated potential exposure for women of child bearing age at 20% of the acute reference dose. It can be concluded that the estimated acute dietary exposure is acceptable.

Long-term dietary exposure assessment

Where an exporting economy is seeking to export mangoes to an APEC economy represented in GEMS/Food Clusters G09 or G10 the following could be used as a substitute in the event local consumption data were unavailable⁵¹.

CAPTAN				Diets as			
Codex Code	Commodity description	Expr as	STMR mg/kg	g/person/day		Intake as µg/person/day	
				G09 diet	G09 intake	G10 diet	G10 intake
FI 0345	Mango, raw	RAC	5	9.73	48.65	1.07	5.35
	Total intake (µg/person)=				48.65		5.35
	Bodyweight per region (kg bw) =				55		60
	ADI (µg/person)=				5500		6000
	%ADI=				0.9%		0.1%
	Rounded %ADI=				0%		0%

Based on the cluster diets and the IEDI for captan the added dietary contribution of residues in mango is less than 1% of the ADI).

⁵¹ Group 9 Bangladesh, Cambodia, China, DPR Korea, Guinea Bissau, Indonesia, Loa, Myanmar, Nepal, Philippines, Sierra Leone, Thailand, Timor Leste, Viet Nam.
 Group 10 Belarus, Bulgaria, Canada, Croatia, Cyprus, Estonia, Italy, Japan, Latvia, Malta, New Zealand, Republic of Korea, Russian Federation, USA

Attachment 2

Decision:

The estimates of short and long-term intake were calculated for mango. It can be concluded that the residues of captan resulting from the use under the authorised GAP is unlikely to present a public health concern. Therefore, on the basis of the data provided it could be recommended to establish an import MRL at the level nominated by the requestor economy, i.e., at the nominated level of 5 mg/kg.

Scenario 4: Import MRL sought is higher

An APEC economy is seeking the establishment of an import MRL for the fungicide pyraclostrobin in mango. The MRL in the importing economy is 0.05 mg/kg while the import MRL sought is 0.1 mg/kg.

Where no domestic MRL or bilateral trade accords exists

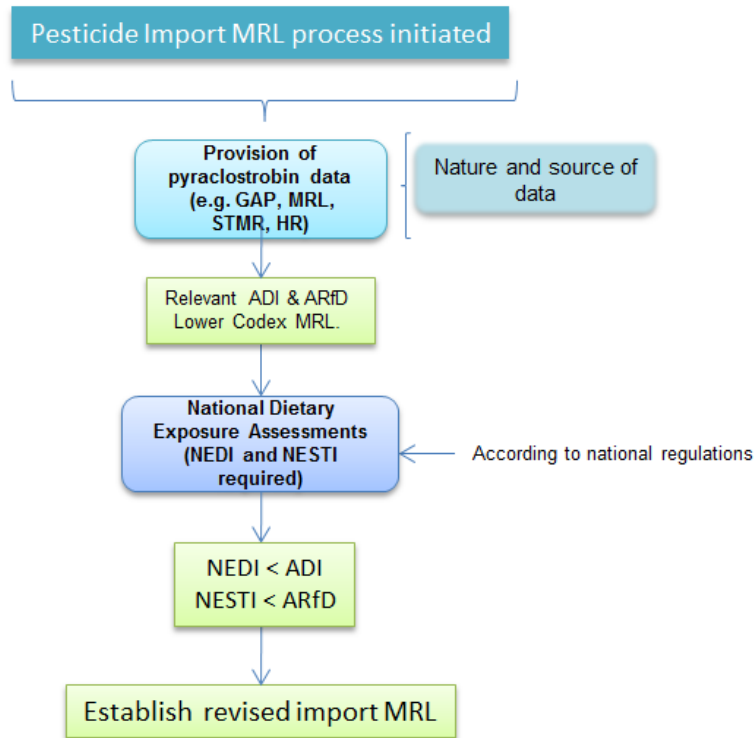


Figure A5 Illustrative import MRL application process for pyraclostrobin in mango, where the proposed MRL is higher than the current domestic MRL of the importing economy.

Background

The compound is approved for use against anthracnose (*Colletotrichum gloeosporioides*) and Stem end rots (*Botryosphaeria* spp.) in mango in the exporting economy. It is also approved for use in other crops and situations in the importing economy.

Information to be provided on the authorised use pattern, the proposed MRL and supporting information needed to allow the dietary intake assessment to be undertaken. For pyraclostrobin, the JMPR health based guidance values are proposed, i.e., an ADI of 0-0.3 mg/kg bw with an ARfD of 0.05 mg/kg bw.

Attachment 2

Data to be provided in support of an import MRL request⁵²

Pesticide name (ISO)	Pyralostrobin	
<i>IUPAC</i>	Methyl <i>N</i> -{2-[1-(4-chlorophenyl)-1 <i>H</i> -pyrazol-3-yl]oxymethyl]phenyl}(<i>N</i> -methoxy)carbamate	
<i>CAS No.</i>	175013-18-0	
<i>Residue definitions</i>		<i>Source</i>
<i>For compliance with MRLs</i>	<i>pyraclostrobin</i>	<i>JMPR</i>
<i>For estimation of dietary intake</i>	<i>pyraclostrobin</i>	<i>JMPR</i>
Health based guidance values		
ADI	0-0.03 mg/kg bw	<i>JMPR</i>
ARfD	0.05 mg/kg bw	<i>JMPR</i>

Authorised GAP	2 × 0.015 kg ai/hL with a 14 day harvest interval⁵³	
Name of the requested commodity or group	Mango	
Commodity to be imported, including any processed commodities	Mango RAC	
<i>Codex Code</i>	<i>FI 0345</i>	
Requested MRLs	0.1 mg/kg	
Origin/source of the requested MRL (e.g. Codex/ economy/ regulator)	Exporting economy	
<i>Residue Summary</i>		
<i>Supervised Trial Median Residue (STMR)</i>	<i>0.05 mg/kg⁵⁴</i>	
<i>Highest Residue (HR)</i>	<i>0.05 mg/kg</i>	
<i>Link to the source of the HR, STMR data</i>	http://apvma.gov.au/node/11046	
Note: In addition to HR and STMR values individual economies may require the submission of full residue studies as per domestic regulations		
<i>Reference link/s to published MRL in Codex or by alternative source other than Codex (if available)</i>	http://www.codexalimentarius.net/pestres/data/commodities/details.html?id=134 https://www.comlaw.gov.au/Series/F2012L02501	
<i>Current status for this MRL in other jurisdictions</i>	Codex MRL 0.05* mg/kg ⁵⁵ MRL of 0.1 mg/kg in Australia.	

⁵² Minimum required information highlighted in **bold**. Additional information that may be required indicated in *italics*

⁵³ Australian authorised GAP

⁵⁴ STMR value derived from residues found in the edible portion, i.e., mango flesh, whereas the MRL is established on a whole fruit basis

⁵⁵ Codex MRL based on a critical GAP of Brazil 0.1 kg ai/ha with a 7 day harvest interval.

Attachment 2

Model Dietary Exposure Assessments

Based on the information outlined above the following estimates of dietary exposure can be calculated using the STMR value of 0.05 mg/kg for mango flesh. No short-term exposure assessment is required. Consequently the chronic assessment will be needed.

Short-term dietary exposure assessment

Pyraclostrobin

Acute RfD= 0.05 mg/kg bw (50 µg/kg bw)

Maximum %ARfD:

2%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
General population											
FI 0345	Mango (all commodities)	0	0.05	1.000	FRA	gen pop, > 2 yrs	227.4	3	2a	0.91	1%
Children up to 6 years											
FI 0345	Mango (all commodities)	0	0.05	1.000	AUS	Child, 1-6 yrs	227.4	3	2b	0.91	2%

The NESTI calculated for mango, using the HR value from the supervised trial data, is estimated at 1% of the acute reference dose for the General population and 2% for children. It can be concluded that the estimated acute dietary exposure is acceptable.

Long-term dietary exposure assessment

Where an exporting economy is seeking to export mangoes to an APEC economy represented in GEMS/Food Clusters G09 or G10 the following could be used as a substitute in the event local consumption data were unavailable⁵⁶.

PYRACLOSTROBIN		Diets as g/person/day					
		Expr as	STMR mg/kg	G09 diet	G09 intake	G10 diet	G10 intake
Codex Code	Commodity description						
FI 0345	Mango, raw	RAC	0.03	9.73	0.49	1.07	0.05
-	-	-	-	-	-	-	-

Bodyweight per region (kg bw) =	55	60
ADI (µg/person)=	1650	1800
%ADI=	0.00002%	0.00003%
Rounded %ADI=	0%	0%

Based on the cluster diets and the IEDI for pyraclostrobin the added dietary contribution of residues in mangoes is less than 0.00003% of the ADI.

⁵⁶ Group 9 Bangladesh, Cambodia, China, DPR Korea, Guinea Bissau, Indonesia, Loa, Myanmar, Nepal, Philippines, Sierra Leone, Thailand, Timor Leste, Viet Nam.

Group 10 Belarus, Bulgaria, Canada, Croatia, Cyprus, Estonia, Italy, Japan, Latvia, Malta, New Zealand, Republic of Korea, Russian Federation, USA

Attachment 2

Decision:

The estimates of long-term intake were calculated for mango. It can be concluded that the residues of pyraclostrobin resulting from the use under the authorised GAP is unlikely to present a public health concern. Therefore, on the basis of the data provided it could be recommended to establish an import MRL at the level nominated by the requestor economy, i.e., at the nominated level of 0.1 mg/kg.

Scenario 5: With JMPR assessment, No Codex MRL

An APEC economy is seeking the establishment of an import MRL for the insecticide methidathion in mango. The MRL sought is 2 mg/kg.

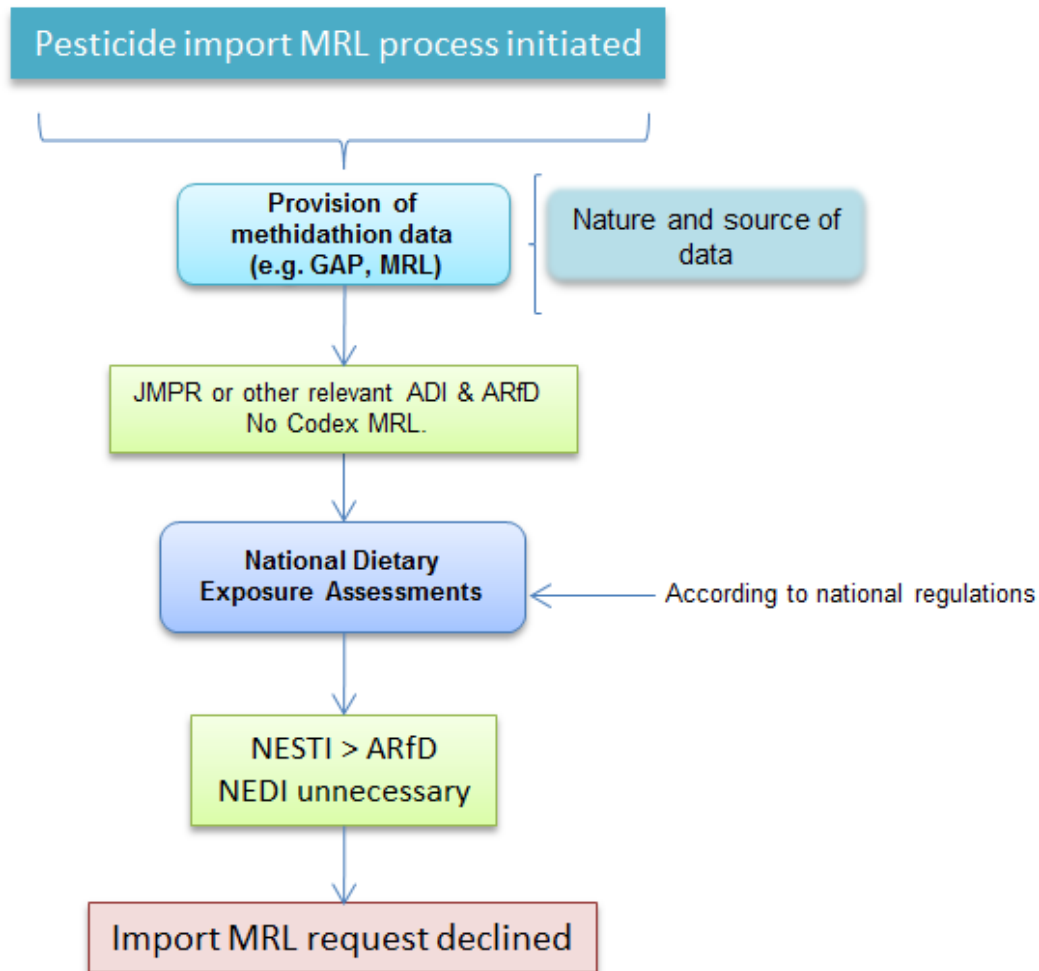


Figure A6 Illustrative import MRL application process for methidathion in mango, where the proposed MRL fails the dietary risk assessment.

Background

The compound is approved for use against a number of insect pest species in mango in the exporting economy. It is not approved for use in other crops and situations in the importing economy.

Information to be provided on the authorised use pattern, the proposed MRL and supporting information needed to allow the dietary intake assessment to be undertaken. For methidathion however, information on the STMR and HR is not available. The proposed MRL value can therefore be used as a default value for the dietary exposure calculations.

Attachment 2

Data to be provided in support of an import MRL request⁵⁷

Pesticide name (ISO)	Methidathion	
<i>IUPAC</i>	3-(dimethoxyphosphinothioylsulfanylmethyl)-5-methoxy-1,3,4-thiadiazol-2-one	
<i>CAS No.</i>	950-37-8	
<i>Residue definitions</i>		<i>Source</i>
<i>For compliance with MRLs</i>	<i>Methidathion</i>	<i>JMPR</i>
<i>For estimation of dietary intake</i>	<i>Methidathion</i>	<i>JMPR</i>
Health based guidance values		
ADI	0-0.001 mg/kg bw	<i>JMPR</i>
ARfD	0.01 mg/kg bw	<i>JMPR</i>

Authorised GAP	50 g ai/hL with a 21 day Pre Harvest Interval
Name of the requested commodity or group	Mango
Commodity to be imported, including any processed commodities	Mango RAC
<i>Codex Code</i>	<i>FI 0345</i>
Requested MRLs	2 mg/kg
Origin/source of the requested MRL (e.g. Codex/ economy/ regulator)	<i>Exporting economy</i>
<i>Residue Summary</i>	
<i>Supervised Trial Median Residue (STMR)</i>	<i>Not available</i>
<i>Highest Residue (HR)</i>	<i>Not available</i>
<i>Link to the source of the HR, STMR data</i>	
Note: In addition to HR and STMR values individual economies may require the submission of full residue studies as per domestic regulations	
<i>Reference link/s to published MRL in Codex or by alternative source other than Codex (if available)</i>	https://www.comlaw.gov.au/Series/F2012L02501
<i>Current status for this MRL in other jurisdictions</i>	MRL of 2 mg/kg in Australia.

⁵⁷ Minimum required information highlighted in **bold**. Additional information that may be required indicated in *italics*

Attachment 2

Model Dietary Exposure Assessments

Based on the information outlined above the following estimates of dietary exposure can be calculated using the MRL value of 2 mg/kg as HR and STMR values are unavailable.

The first step could be to assess acute exposure. If the estimated acute exposure is determined to be acceptable the chronic dietary risk assessment could then be undertaken.

Methidathion

		Acute RfD= 0.01 mg/kg bw (10 µg/kg bw)			IESTI Maximum %ARfD:			360%	240%	360%			
								all	gen pop	child			
Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FI 0345	Mango		2	1.000	AU	Child, 2-6 yrs	227.4	3	2b	36.3867	360.0%	240.0%	360.0%

Short-term dietary exposure assessment

The NESTI calculated for mango, using the MRL in the absence of any supervised trial data, estimated potential exposure for 240% of the acute reference dose for children and 360% of the ARfD for the general population. It can be concluded that the estimated acute dietary exposure is unacceptable.

Long-term dietary exposure assessment

No long-term dietary intake assessment required as the proposed import MRL failed the short-term assessment.

Decision:

The estimates of short-term intake were calculated for mango. It can be concluded that based on the available information the requested import MRL for methidathion would be unacceptable due to public health concerns. Therefore, the request to establish an import MRL at the level nominated by the requestor economy, i.e., 2 mg/kg, would be declined.

Scenario 6: No JMPR Assessment, No Codex MRL

An APEC economy is seeking the establishment of an import MRL for the fungicide fenpyrazamine in grapes. The MRL sought is 3 mg/kg.

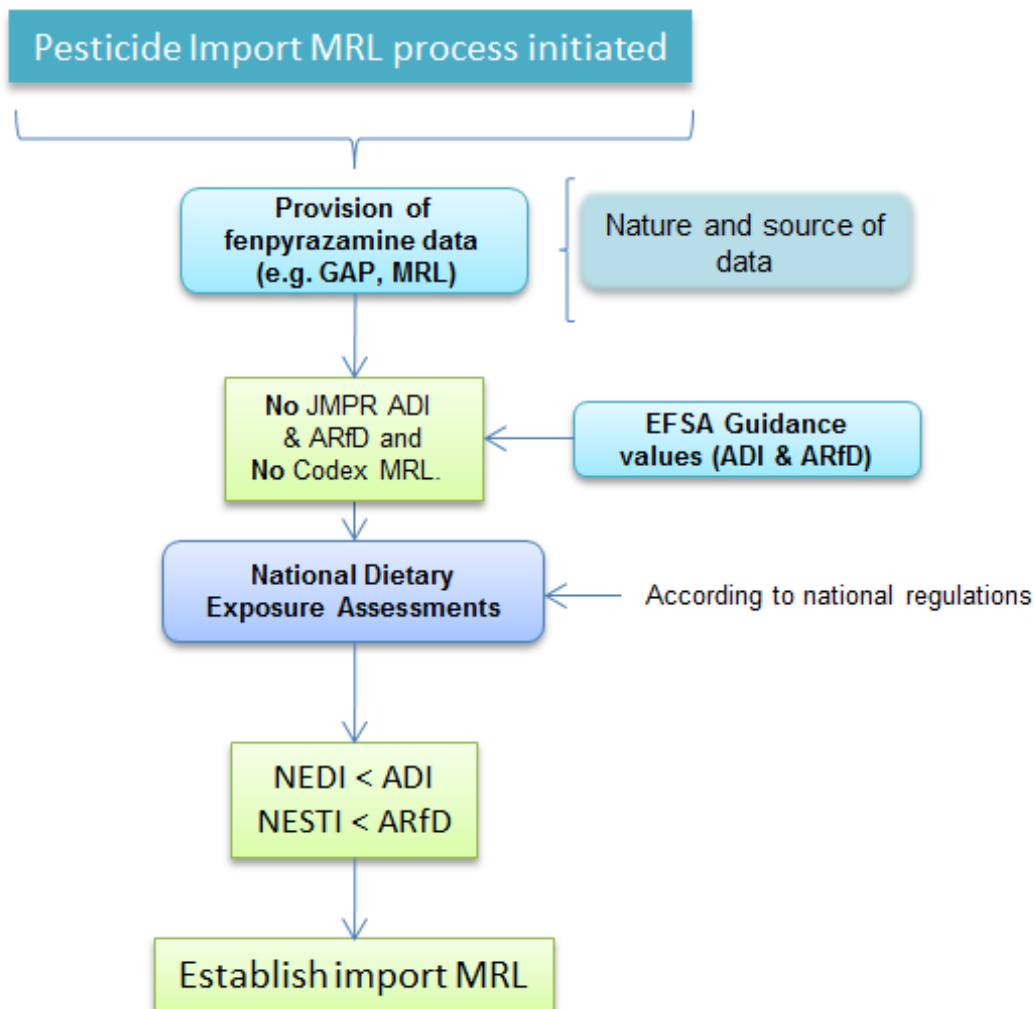


Figure A7 Illustrative import MRL application process for fenpyrazamine in grapes, where there are no JMPR health based guidance values or MRLs.

Background

The compound is approved for use against downy mildew in grapes in the exporting economy. It is also approved for use in other crops and situations in the importing economy.

Information to be provided on the authorised use pattern, the proposed MRL and supporting information needed to allow the dietary intake assessment to be undertaken. For fenpyrazamine, JMPR has not established health based guidance values as the compound had not been evaluated. It is proposed that the relevant guidance values established by EFSA be used, i.e., an ADI of 0-0.13 mg/kg bw with an ARfD of 0.3 mg/kg.

Attachment 2

Data to be provided in support of an import MRL request⁵⁸

Pesticide name (ISO)	Fenpyrazamine	
<i>IUPAC</i>	S-allyl 5-amino-2-isopropyl-4-(2-methylphenyl)-3-oxo-2,3-dihydropyrazole-1-carbothioate	
<i>CAS No.</i>	473798-59-3	
<i>Residue definitions</i>		<i>Source</i>
<i>For compliance with MRLs</i>	<i>Fenpyrazamine</i>	<i>EFSA</i>
<i>For estimation of dietary intake</i>	<i>Fenpyrazamine + S 2188-DC</i>	<i>EFSA</i>
Health based guidance values		
ADI	0-0.13 mg/kg bw	<i>EFSA</i>
ARfD	0.3 mg/kg bw	<i>EFSA</i>

Authorised GAP	600 g ai/ha with a 14 day Pre Harvest Interval	
Name of the requested commodity or group	Grapes	
Commodity to be imported, including any processed commodities	Grapes, to cover residues in red wine (max PF=1.38) and white wine (PF=0.78)	
<i>Codex Code</i>	<i>FB 0269</i>	
Requested MRLs	3 mg/kg	
Origin/source of the requested MRL (e.g. Codex/ economy/ regulator)	<i>Exporting economy</i>	
<i>Residue Summary</i>		
<i>Supervised Trial Median Residue (STMR)</i>	<i>0.33 mg/kg</i>	
<i>Highest Residue (HR)</i>	<i>1.59 mg/kg</i>	
<i>Link to the source of the HR, STMR data</i>	http://www.efsa.europa.eu/en/pesticides/pesticidesdocs.htm	
Note: In addition to HR and STMR values individual economies may require the submission of full residue studies as per domestic regulations	<i>Best estimate of average residues in wine is 0.57 mg/kg</i>	
<i>Reference link/s to published MRL in Codex or by alternative source other than Codex (if available)</i>	http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=homepage&language=EN	
<i>Current status for this MRL in other jurisdictions</i>	MRLs of 3 mg/kg in the EU and the USA	

⁵⁸ Minimum required information highlighted in **bold**. Additional information that may be required indicated in *italics*

Attachment 2

Model Dietary Exposure Assessments

Based on the information outlined above the following estimates of dietary exposure can be calculated. The first step could be to assess acute exposure. Should the estimated exposure be determined acceptable the chronic dietary risk assessment could then be undertaken.

FENPYRAZAMINE

Long-term dietary exposure assessment

Where an exporting economy is seeking to export grapes or grape by-products (e.g. wine) to an APEC economy represented in GEMS/Food Clusters G09 or G10 the following could be used as a substitute in the event local consumption data were unavailable⁵⁹.

FENPYRAZAMINE		International Estimated Daily Intake (IEDI)						
Codex Code	Commodity description	Expr as	STMR-P mg/kg	G09 diet	G09 intake	G10 diet	G10 intake	
JF 0269	Grape juice	PP	0.04	0.10	0.00	2.24	0.09	
-	Grape wine (incl vermouths)	PP	0.46	1.84	0.85	25.07	11.53	
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.55	0.10	0.06	1.38	0.76	
FB 0269	Grape, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.33	5.21	1.72	9.38	3.10	
Total intake (µg/person)=							2.6	15.5
Bodyweight per region (kg bw) =							55	60
ADI (µg/person)=							7150	7800
%ADI=							0%	2%
Rounded %ADI=							0%	0%

Based on the cluster diets and the IEDI for fenpyrazamine, the added dietary contribution of residues in grapes and processed grape commodities (including wine) is less than 0.2% of the ADI).

⁵⁹ Group 9 Bangladesh, Cambodia, China, DPR Korea, Guinea Bissau, Indonesia, Loa, Myanmar, Nepal, Philippines, Sierra Leone, Thailand, Timor Leste, Viet Nam.

Group 10 Belarus, Bulgaria, Canada, Croatia, Cyprus, Estonia, Italy, Japan, Latvia, Malta, New Zealand, Republic of Korea, Russian Federation, USA

Attachment 2

FENPYRAZAMINE

Short-term dietary exposure assessment

International estimate of short term intake (IESTI) Acute RfD= 0.300 mg/kg bw (300 µg/kg bw)
 Maximum %ARfD: 40% 40% 9% 20%
 all- children women gen pop
 mixed

Codex Commodity Processing Code	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet or diet-P corr fact	Mixed population groups Coun try	Population n group	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case % acute RfD rounded	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded			
-	Grape	raw with skin	0.33	1.59	1.000	CN	Child, 1-6 yrs	232	366.7	636.6	3	2b	40%	40%	9%	20%
DF 0269	Grape	dried (currants, raisins, sultanas)		3.26	1.000	AU	Child, 2-6 yrs	918	83.5	1.0	NR	1	5%	5%	-	1%
JF 0269	Grape	juice (pasteurised)	0.04		1.000	NL	Child, 2-6 yrs	8	803.2	NR	NR	3	1%	1%	0%	0%
-	Grape	red wine	0.46		1.000	FR	Gen pop, > 3 yrs	95.8%	1006.5	NR	NR	3	3%	1%	2%	3%
-	Grape	white wine	0.26		1.000	FR	Gen pop, > 3 yrs	95.8%	1006.5	NR	NR	3	2%	0%	1%	2%

The NESTIs for all relevant commodities were less than 40% of the acute reference dose (up to 3% in wine). It can be concluded that the acute dietary exposure is acceptable.

Decision:

The estimates of short and long-term intake were calculated for grapes. It can be concluded that the residues of fenpyrazamine resulting from the use under the authorised GAP is unlikely to present a public health concern. Therefore, on the basis of the data provided it could be recommended to establish an import MRL at the level nominated by the requestor economy, i.e., at the nominated level of 3 mg/kg.

Attachment 3

ATTACHMENT 3: Contact details, economy web links

Economy	Contacts	Links to economy specific requirements	Links to resource materials	Links/details of domestic authorities related to pesticide MRL regulation
AUSTRALIA	<p>Food Standards Australia New Zealand</p> <p>Boeing House 55 Blackall Street BARTON ACT 2600</p> <p>PO Box 5423 Kingston ACT 2604 Australia</p> <p>Email: MRL.Contact@foodstandards.gov.au Telephone: +61 2 6271 2222 Facsimile: +61 2 6271 2278</p>	<p>Information for stakeholders: http://www.foodstandards.gov.au/code/changes/limits/Pages/default.aspx</p> <p>Information on the MRL Proposal process, where FSANZ considers requests to harmonise with MRLs for import purposes: http://www.foodstandards.gov.au/code/changes/limits/Pages/MRL-proposals.aspx</p> <p>Information on MRL Applications: http://www.foodstandards.gov.au/code/changes/limits/Pages/MRL-applications.aspx</p>	<p>Guideline for submitting requests for MRL proposals: http://www.foodstandards.gov.au/publications/Pages/Guide-for-Submitting-Requests-for-MRL-Proposals.aspx</p> <p>Information on Applications: http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx</p>	<p>The Australian Pesticides and Veterinary Medicines Authority is the Australian government authority responsible for the assessment and registration of pesticides and veterinary medicines.</p> <p>General contact details: Telephone: +61 2 6210 4701 E-mail: +61 2 6210 4701 Email: enquiries@apvma.gov.au</p> <p>The Department of Agriculture and Water Resources sets biosecurity requirements for importing goods to Australia. Codex Australia coordinates Australia's position on Codex Standards.</p> <p>Telephone toll-free: 1800 900 090 General enquiries: http://www.agriculture.gov.au/general-inquiries?query=nrs</p>
BRUNEI DARUSSALAM				
CANADA	<p>Pest Management Information Service Pest Management Regulatory Agency Health Canada 2720 Riverside Drive Ottawa, Ontario Address Locator: 6606D2 K1A 0K9</p> <p>E-mail: pmra.infoserv@hc-sc.gc.ca</p>	<p>Information for Registrants and Applicants: http://www.hc-sc.gc.ca/cps-spc/pest/registraire/index-eng.php</p> <p>Requirements for the establishment of import MRLs for a new active ingredients: http://www.hc-sc.gc.ca/cps-spc/pest/registraire/arborescence-decision-tree-eng.php?pageID=6_a</p>	<p>Policies and Guidelines: http://www.hc-sc.gc.ca/cps-spc/pubs/pest_pol_guide/index-eng.php</p>	<p>Health Canada's Pest Management Regulatory Agency is the government body responsible for regulating pesticides in Canada, which includes responsibility for specifying MRLs.</p> <p>Acts and Regulations: http://www.hc-sc.gc.ca/cps-spc/legislation/acts-lois/index-eng.php</p>

Attachment 3

Economy	Contacts	Links to economy specific requirements	Links to resource materials	Links/details of domestic authorities related to pesticide MRL regulation
	Telephone: 613-736-3799 Toll-free: 1-800-267-6315 Facsimile: 613-736-3798 Teletypewriter: 1-800-465-7735 (Service Canada)	Requirements for the establishment of import MRLs for a previously assessed active ingredient: http://www.hc-sc.gc.ca/cps-spc/pest/registrant-titulaire/arborescence-decision-tree-eng.php?pageID=6_b		
CHILE	<p>Lorena Rodríguez Jefa del Departamento de Alimentos y Nutrición Ministerio de Salud lorena.rodriguez@minsal.cl</p> <p>Paulina Chávez, Profesional Asesor del Departamento de Alimentos y Nutrición Ministerio de Salud pchavez@minsal.cl</p>	http://dipol.minsal.cl/departamentos-2/nutricion-y-alimentos/reglamento-sanitario-de-los-alimentos/		www.minsal.cl
CHINA		www.chinapesticide.gov.cn	www.chinapesticide.gov.cn	www.chinapesticide.gov.cn
HONG KONG, CHINA	Hong Kong, China	Centre for Food Safety	http://www.legislation.gov.hk/eng/home.htm (see Chapter 132CM, Pesticide Residues in Food Regulation)	http://www.cfs.gov.hk/english/whatsnew/whatsnew_fstr/whatsnew_fstr_21_Pesticide.html
INDONESIA				
JAPAN	N/A	http://www.mhlw.go.jp/english/topics/foodsafety/residue/index.html	http://www.mhlw.go.jp/english/policy/health-medical/food/index.html	N/A
REPUBLIC OF KOREA	Dr. Yoon, Hae Jung Director, Food Standard Divison, MFDS	http://www.foodnara.go.kr/residue/article/view.do?articleKey=942&searchTitleFlag=1&boardKey=0&menuKey=4&subMenuKey=5&currentPageNo=1	referred same link	http://www.foodnara.go.kr/residue/main.do

Attachment 3

Economy	Contacts	Links to economy specific requirements	Links to resource materials	Links/details of domestic authorities related to pesticide MRL regulation
	<p>Dr. Kim, Jin Sook Deputy Director, Food Standard Division, MFDS</p> <p>Dr. Kwon, Chan Hyeok Scientific Officer, Food Standard Division, MFDS</p> <p>Dr. Kim, Hyochin Scientific Officer, Food Standard Division, MFDS</p>			
MEXICO	<p>José Alberto Rosales Castillo (jarosales@cofepris.gob.mx)</p> <p>Luis Ignacio Sánchez Córdoba (lisanchez@cofepris.gob.mx)</p> <p>Pamela Suárez Brito (psuarez@cofepris.gob.mx)</p>	<p>http://www.cofepris.gob.mx/MJ/Documents/Decretos/130214decretoplaguicidas.pdf</p>	<p>http://www.cofepris.gob.mx/AZ/Paginas/Plaguicidas%20y%20Fertilizantes/PlaguicidasYFertilizantes.aspx</p> <p>http://www.senasica.gob.mx/?id=4099</p>	<p>http://senasica.gob.mx/</p> <p>http://www.cofepris.gob.mx/Paginas/Inicio.aspx</p>
MALAYSIA	<ol style="list-style-type: none"> 1. Badruzzaman bin Abdul Rahim Food Safety and Quality Division Ministry of Health Malaysia E-mail : badruzzaman@moh.gov.my 2. Mohd Nazrul Fahmi bin Abdul Rahim Pesticides Control 	<p>http://www.doa.gov.my/maklumat-racun-perosak</p>	<p>http://www.doa.gov.my/maklumat-racun-perosak</p> <p>http://fsq.moh.gov.my/v5/ms/food-regulations-1985/</p>	<p>Food Safety and Quality Division Ministry of Health Malaysia http://fsq.moh.gov.my/v5/ms/</p>

Attachment 3

Economy	Contacts	Links to economy specific requirements	Links to resource materials	Links/details of domestic authorities related to pesticide MRL regulation
	<p>Division Department of Agriculture E-mail : nazrulfahmi@doa.gov.my</p> <p>3. Nurul Emilia binti Abd Karim Food Safety and Quality Division Ministry of Health Malaysia E-mail : nurulemia@moh.gov.my</p>			
NEW ZEALAND	<p>Warren Hughes Principal Adviser ACVM Regulation & Assurance, Systems Audit, Assurance & Monitoring Directorate Regulation and Assurance Branch Ministry for Primary Industries Warren.hughes@mpi.govt.nz</p>	<p>http://www.foodsafety.govt.nz/elibrary/industry/register-list-mrl-agricultural-compounds.htm</p>	<p>http://www.foodsafety.govt.nz/elibrary/industry/register-list-mrl-agricultural-compounds.htm</p>	<p>http://www.foodsafety.govt.nz</p>
PAPUA NEW GUINEA	<p>Mr. Joel Kolam Joel_Kolam@health.gov.pg Ms. Diane Kave dianelkave@gmail.com</p>	<p>For wine products: Schedule 2A, item 14.2.2 to 14.2.4 (Food Sanitation Regulation 2007)</p>	<p>Nil online information database.</p>	<p>Food Sanitation Council, Ministry of Health</p>

Attachment 3

Economy	Contacts	Links to economy specific requirements	Links to resource materials	Links/details of domestic authorities related to pesticide MRL regulation
PERU (a)	Ms. Leonor PICON lpicon@digesa.minsa.gob.pe	http://www.digesa.minsa.gob.pe/expedientes/tupas.aspx http://www.digesa.minsa.gob.pe/Expedientes/Leyes-Reglamentos.aspx	http://www.digesa.minsa.gob.pe/Expedientes/Leyes-Reglamentos.aspx	Dirección general de salud Ambiental e Inocuidad Alimentaria (DIGESA) http://www.digesa.minsa.gob.pe
PERU (b)	Eng. Jorge Barrenechea Cabrera National Head of the National Agrarian Health Service. jbarrenechea@senasa.gob.pe			National Agrarian Health Service – Servicio Nacional de Sanidad Agraria (SENASA) www.senasa.gob.pe is a technical public body specialized in agricultural health under the Ministry of Agriculture and Irrigation with attributions in matters of agricultural health, safety of agricultural foods of primary production and processing including animal feed, organic production, and entry control to the country of modified live organisms in plants, animals and products of animal origin for purposes of reproduction or propagation.
PERU (c)	Eng. Josue Carrasco Valiente –General Director of Agricultural Inputs and Agrifood Safety. jcarrasco@senasa.gob.pe			Directorate of Agricultural Inputs and Agrifood Safety establishes mechanisms for monitoring, recording and control of agricultural and forestry; conducts the registration of producers; verifies quality of chemical pesticides for agricultural use, biological products for agricultural pest control; pharmaceutical, veterinary biological products and animal feed; registration of residues; development of residue plans and performs the corresponding monitoring in coordination with other functional units of SENASA.
PERU (d)	Eng. Pedro Molina Salcedo – Director Agrifood Safety Subdirectorato pmolina@senasa.gob.pe	Technical assistance in understanding the risk assessment to set MRLs for pesticides / food, determinants of tolerance in food imports.		Agrifood Safety Subdirectorato protects the health of consumers and the competitiveness of the agricultural sector.
PERU (e)	Eng. Gerard Blair Arce – Director Agricultural Inputs Subdirectorato gblair@senasa.gob.pe			Subdirectorato of Agricultural Inputs establishes and conducts the registration and control of chemical pesticides for agricultural use and biological products.

Attachment 3

Economy	Contacts	Links to economy specific requirements	Links to resource materials	Links/details of domestic authorities related to pesticide MRL regulation
PERU (f)	Q.F. Orlando Lucas Director of the Unit of Input Control Center and Toxic Residues olucas@senasa.gob.pe	<p>- Requires Proficiency tests on the determination of pesticide residues in mangos, quinoa, cacao, table grapes, etc., together with APEC economy members.</p> <p>- Participation in proficiency tests:</p> <p>a) European Union Reference Laboratory for Pesticide Residue in Fruits and Vegetables. European Proficiency Test- EUPT-FV16</p> <p>b) EC JRC - Institute for Reference Materials and Measurement. IMEP-37 Pesticides in Grapes</p>		Unit of the Input Control Center and Toxic Residues maintains the capacity of official control for agricultural inputs and the detection of toxic residues in food products and provide services in a competitive condition. ISO/IEC 17025:2005 accreditation by ANSI-ASQ National Accreditation Board, with Certificate Number AT-1824 Issued 11/03/2015 and valid to 11/26/2017.
PHILIPPINES			•	•
RUSSIA	Ministry for agricultural development; the government of the Russian Federation	<p>There are four types of danger:</p> <ul style="list-style-type: none"> • the pesticides of the first class are not recommended for the application in agriculture; retail sales are forbidden; • the pesticides of the second class of danger, the retail sales is restricted; • the pesticides of the third and the forth classes are applied in accordance with special enactments; it is allowed to use the agrochemical substances for personal use in housing, gardens, against insects. • According to the State catalogue pesticides and agrochemical substances, permitted to being applied on the territory of Russia, the 	<ul style="list-style-type: none"> • The Federal law dated from 19th July, 1997 #109-FL The safe application of pesticides and agrochemical substances; • SanPin 1.2.2584-10 Sanitary requirements to the process of treatment, storage, transportation, realization, application and utilization of pesticides and agrochemical substances; • The State Catalogue of 	<ul style="list-style-type: none"> • Due to article 8.3 of the Russian Code on the administrative offenses concerning the storage, transportation, application of pesticides and other substances, there is a special fine; • The application of pesticides in each case is realized after the preliminary research of agricultural grounds; • There is a special state procedure of pesticides registration that is implemented by Ministry for agricultural development, the list of documents is introduced in the Order dated the 10th 2007; • Among the agrochemical substances, the obligatory registration spreads for chemical meliorates (ground limestone, phosphate fertilizer and others); the substances of natural and organic extraction, such as wood ash, natural chalk, drainage sand and others are not submitted to the registration. • There is no permission to apply the pesticides within the

Attachment 3

Economy	Contacts	Links to economy specific requirements	Links to resource materials	Links/details of domestic authorities related to pesticide MRL regulation
		<p>examples of such substances are:</p> <ul style="list-style-type: none"> - Bacillus thuringiensis, var.kurstaki, - Bacillus thuringiensis, var. Thuringiensis, -Metarhizium anisopliae P-72, -Steinernema carpocasae (Weiser) and others. 	<p>pesticides and agrochemical substances, permitted to being applied on the territory of Russia (official annual edition).</p>	<p>water zones;</p> <ul style="list-style-type: none"> • The production, storage and transportation of agrochemical substances are fulfilled in the special zones.
SINGAPORE	<p>Dr. Paul Chiew, Group Director Laboratories Group Agri-Food & Veterinary Authority of Singapore Email: Paul_CHIEW@ava.gov.sg</p> <p>Dr. Wu Yuan Sheng Deputy Director Pesticide Residues Section VPHL Chemistry Department Laboratories Group Agri-Food & Veterinary Authority of Singapore Email: WU_Yuan_Sheng@ava.gov.sg</p>	<p>http://www.ava.gov.sg/docs/default-source/default-document-library/food-regulations-2-feb-2016.pdf (Note: the MRLs are subject to revision from time to time)</p> <p>For setting pesticide MRLs or Import Tolerance Levels, Singapore generally follows the requirements as described in the following two documents: 1). Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues; and 2). JMRR Manual on the Submission and Evaluation of Pesticide Residues Data.</p>	<p>Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues: http://www.fao.org/docrep/010/a1472e/a1472e00.HTM</p> <p>JMRR Manual on the Submission and Evaluation of Pesticide Residues Data: http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/</p>	<p>Agri-Food & Veterinary Authority of Singapore Tel: +65-6805 2992 (General Enquiries) Fax: +65-6334 1831 Public website: www.ava.gov.sg</p>
CHINESE TAIPEI	<p>Dr. Yi-Ting, Emily Kao Taiwan Food and Drug Administration Emily.kao@fda.gov.tw</p>	<p>http://www.fda.gov.tw/TC/download.aspx?pn=2&cid=99</p>	<p>http://consumer.fda.gov.tw/Law/Detail.aspx?nodeID=518&lang=1&lawid=127</p>	<p>http://consumer.fda.gov.tw/Law/Detail.aspx?nodeID=518&lang=1&lawid=127</p>
THAILAND	<p>National Bureau of Agricultural Commodity and Food Standards e-mail: codex@acfs.go.th</p>		<p>http://www.doa.go.th/ard/ (Available only Thai version)</p>	<p>http://iodinethailand.fda.moph.go.th/fda/new/web_cms/subcol.php?SubCol_ID=77&Col_ID=14</p>

Attachment 3

Economy	Contacts	Links to economy specific requirements	Links to resource materials	Links/details of domestic authorities related to pesticide MRL regulation
<p>UNITED STATES OF AMERICA</p> <p>Environmental Protection Agency (EPA)</p> <p>Office of Pesticide Programs</p>	<p>It is best to Contact the Specific Branch Assigned to a Specific Chemical for Information</p> <p>To Find a Branch for a Specific Chemical refer to: Registration Division Chemical List with Branch Assignments https://www.epa.gov/sites/production/files/2014-10/documents/publicchemicalbranchpmreport102414_dr_3.pdf</p> <p>To find the contact for the Specific Branch refer to: Contacts in the Office of Pesticide Programs, Registration Division https://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-registration-division</p>	<p>NAFTA Guidance Document on Data Requirements for Tolerances on Imported Commodities in the United States and Canada https://www.epa.gov/sites/production/files/2015-10/documents/nafta-guidance.pdf</p> <p>Toxicity test guidelines: http://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-870-health-effects-test-guidelines</p> <p>Residue Chemistry test guidelines: http://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-860-residue-chemistry-test-guidelines</p>	<p>Import Tolerances https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions#import</p> <p>Pesticide Registration Manual: Chapter 11 - Tolerance Petitions https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions</p> <p>PRIA Fee Category Table - Registration Division - Import and Other Tolerances https://www.epa.gov/pria-fees/pria-fee-category-table-registration-division-import-and-other-tolerances</p>	<p>Specific MRLs (Tolerances) can be found in the Code of Federal Regulations Title 40 Part 180 Subpart C - Specific Tolerances</p> <p>Search for e-cfr</p> <p>180.101 through 180.2020 http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=bd81dcf10062525f6728fc406170f3fc&h=L&mc=true&n=pt40.24.180&r=PART&ty=HTML</p>
<p>VIETNAM</p>	<p>Mr. Le Hoang phongtckn@gmail.com / lehoang@vfa.gov.vn</p> <p>Vu Van Hong hongvu@tcvn.gov.vn</p>		<p>1. MRL for pesticides in foods http://vfa.gov.vn/van-ban/thong-tu-so-242013tt-byt-ban-hanh-quy-dinh-muc-gioi-toi-da-du-luong-thuoc-thu-y-trong-thuc-pham-cua-bo-y-te.html</p> <p>2. MRL for veterinary drugs in foods</p>	<p>Name: Vietnam Food Administration, Ministry of Health of Vietnam Add: 138A, Giang Vo Str, Ba Dinh Dist, Ha Noi, Vietnam Link: http://vfa.gov.vn/</p>

Attachment 3

Economy	Contacts	Links to economy specific requirements	Links to resource materials	Links/details of domestic authorities related to pesticide MRL regulation
			http://vfa.gov.vn/van-ban/quyet-dinh-462007qd-byt-cua-bo-y-te-ve-viec-ban-hanh-quy-dinh-gioi-han-toi-da-o-nhiem-sinh-hoc-va-hoa-hoc-trong-thuc-pham.html	