FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Guide to submitting requests for maximum residue limit (MRL) harmonisation proposals

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Table of Contents

Glossary

Acceptable daily intake

For agricultural and veterinary (agvet) chemicals, the acceptable daily intake (ADI) is the amount of chemical that may be consumed every day for an entire lifetime without causing an appreciable risk to health. The units are expressed in milligrams per kilogram of body-weight (mg/kg bw). Where an 'm' is placed in front of the ADI (i.e. mADI), this refers to a microbiological ADI.

Acute reference dose

The acute reference dose (ARfD) is an estimate of the maximum amount of an agvet chemical in food or drinking water, expressed as milligrams per kilogram of body-weight (mg/kg bw), that can be ingested in one meal or one day, without appreciable health risk to the consumer. Where an 'm' is placed in front of the ARfD (i.e. mARfD), this refers to a microbiological ARfD.

Administrative Assessment Report

A report prepared by Food Standards Australia New Zealand (FSANZ) in accordance with the FSANZ Act, following receipt and acceptance of an application or an agreement to undertake a proposal. For the MRL Harmonisation Proposal, this report provides stakeholders with an estimate of the start date of the assessment and the proposed time lines for public comment, Board approval and gazettal.

Agvet chemical

Agvet chemical means an agricultural or veterinary chemical product as defined in Standard 1.1.2—2 subsection 3 of the Australia New Zealand Food Standards Code[1] (the Code) and is within the meaning stated in the Agricultural and Veterinary (Agvet) Chemicals Code Act 1994 (the Agvet Code).

Agvet Code

The Agricultural and Veterinary (Agvet) Chemicals Code Act 1994 is legislation administered by the Australian Pesticides and Veterinary Medicines Authority (APVMA). The Agvet Code details the provisions that allow the APVMA: to evaluate, approve or register and review active constituents of agvet chemical products (and their associated labels); to issue permits and to licence the manufacture of chemical products. It also provides guidelines on how to regulate the supply of agvet chemical products and ensures compliance and enforcement.

Approval Report

A report prepared by Food Standards Australia New Zealand (FSANZ) in accordance with the FSANZ Act, following the approval of a draft amendment to the Code. This report includes information about the assessment of an application or a proposal, and the reasons for approval.

1 https://www.foodstandards.gov.au/code/Pages/default.aspx (accessed 20 April 2023)

Australia New Zealand Food Standards Code (the Code)

The Australia New Zealand Food Standards Code (the Code) is a collection of food standards which set out the legal requirements for all food (raw, processed or handled) sold or prepared for sale in Australia and New Zealand. In accordance with Australian State and Territory and New Zealand food legislation, it is an offence to supply food that does not comply with the Code.

The Code can be changed through a proposal or an application. Anyone can make an application to FSANZ to vary the Code. Proposals are prepared by FSANZ whereas an application results from an external submission to FSANZ, under section 22 of the FSANZ Act, requesting a variation to the Code. Further information about the application process can be found in the FSANZ Application Handbook[2].

Standard 1.4.2 — Agvet chemicals[3] establishes the requirements for maximum residue limits of agvet chemicals in foods for sale. In Australia, a food for sale must not have, as an ingredient or a component, a detectable amount of an agvet chemical or a metabolite or a degradation product of the agvet chemical; unless expressly permitted by the Code.

Schedule 20 — Maximum residue limits[4] lists the maximum residue limits for agvet chemicals for food sold in Australia. Food commodities, subgroups and groups and classes of foods are as described in Schedule 22 — Foods and classes of food[5].

Australian Pesticides and Veterinary Medicines Authority

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an Australian government statutory authority established in 1993 to centralise the approval and registration of all agvet chemical products into the Australian marketplace. Visit www.apvma.gov.au for more information.

Codex Alimentarius Commission

The Codex Alimentarius Commission (Codex), established by the Food and Agriculture Organization (FAO) and World Health Organization (WHO) in 1963, develops harmonised international food standards, guidelines and codes of practice to protect the health of consumers and ensure fair practices in food trade. Codex also promotes coordination of all food standards work undertaken by international governmental and non-governmental organisations. Codex has a number of relevant committees for establishing MRLs, specifically the Codex Committee on Pesticide Residues (CCPR) and Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF). Visit https://www.fao.org/fao-who-codexalimentarius/en/ for more information.

Dietary exposure assessment

Dietary exposure assessment (DEA) is the process of estimating how much of an agvet chemical the population or a population subgroup, may be exposed to from the diet. The result from the DEA is usually compared to a relevant health-based guidance value (HBGV). FSANZ uses internationally accepted techniques to conduct DEAs. These assessments consider the potential dietary exposure of the Australian and New Zealand populations to chemicals such as agvet chemical residues, chemical contaminants, nutrients, food additives, food ingredients and other substances.

2 https://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx (accessed 20 April 2023)

3 https://www.legislation.gov.au/Series/F2015L00415 (accessed 20 April 2023)

4 https://www.legislation.gov.au/Series/F2015L00468 (accessed 20 April 2023)

5 https://www.legislation.gov.au/Series/F2015L00433 (accessed 20 April 2023)

Dietary exposure to agvet chemicals is estimated by combining food consumption data with agvet chemical concentration data. Section 4 of this Guide has more information on the DEA process for agvet chemical residues.

Extraneous Residue Limit

An extraneous residue level (ERL) is the maximum residue level of a chemical permitted to be present in a food and which arises from environmental sources other than the use of a chemical directly or indirectly on the food. The FSANZ MRL proposal process will not consider harmonisation of ERLs that may exist in other countries.

Food and Agriculture Organization of the United Nations

The Food and Agriculture Organization (FAO) is an intergovernmental organization with 194 member nations, two associate members and one member organization, the European Union. The FAO employs experts to identify and work collaboratively to meet demands posed by major global trends in food, agricultural development and natural resources. The FAO jointly administers the Joint Meeting on Pesticide Residues (JMPR) and Joint Expert Committee Meeting on Food Additives (JECFA) with the WHO. Visit www.fao.org for more information.

Good Agricultural Practice

Good agricultural practice (GAP) encompasses the activities to support sustainable and safe food production, from primary production, storage, transport, and distribution of food commodities and animal feed. A component of GAP is pest and disease management, which may involve the use of agvet chemicals such as pesticides and antibiotics. To ensure sustainability and safety, agvet chemicals should be authorised to ensure safe use under actual conditions necessary for effective pest, disease or weed control. Authorised safe use should take into account public, occupational health and environmental safety considerations and will include a range of levels of agvet chemical applications, up to the highest authorised use applied in a manner which leaves the smallest possible amount of residue achievable.

Harmonisation request template

This template is used by FSANZ to collect information from interested stakeholders making an MRL harmonisation request. It assists FSANZ to determine whether a harmonisation request should be included in the MRL proposal. The template is provided as Attachment 1 to this Guide.

Health-based guidance values

Health-based guidance values (HBGVs) are used to express a maximum level of exposure to a substance posing a minimum level of risk to health. With agvet chemicals, two common HBGVs used to assess exposure from food include acceptable daily intake (ADI) and acute reference dose (ARfD).

In Australia, the APVMA is responsible for establishing and publishing ADIs and ARfDs for agvet chemicals used in food producing crops or animals. Details of the Australian agvet chemical HBGVs can be found at: http://apvma.gov.au/node/26581 (accessed 17 April 2023).

Highest residue

The highest residue (HR) is the highest amount of residue (mg/kg) detected in a food commodity from a supervised field trial, where the chemical has been used according to the label directions and good agricultural practice. HRs may also have a processing factor, which is indicated as HR-P.

Import MRL

MRLs considered for inclusion or added to the Code as part of a FSANZ MRL harmonisation proposal may sometimes be referred to as an 'import MRL' for the purpose of this Guide. Import MRLs are not differentiated from domestic MRLs in the Code.

Joint FAO/WHO Meeting on Pesticide Residues

The Joint Meeting on Pesticide Residues (JMPR) is an expert *ad hoc* body administered jointly by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). They provide advice on the acceptable levels of agvet chemical residues in internationally traded food.

The JMPR has met annually since 1963. The expert group review pesticide residues, including the analytical aspects and toxicological data. They also determine maximum residue levels and HBGVs for humans.

Joint FAO/WHO Expert Committee on Food Additives

The Joint Committee Meeting on Food Additives (JECFA) is an international scientific expert committee administered jointly by the FAO and the WHO. JECFA works to evaluate the safety of food additives, contaminants, naturally occurring toxicants and residues of veterinary drugs in food. JECFA may establish HBGVs for humans during their review of veterinary drugs.

Maximum residue limit

A maximum residue limit (MRL) means the maximum amount of an agvet chemical legally permitted in a food for sale in Australia and is that identified in Schedule 20 for that agvet chemical in that food. MRLs are expressed in milligrams per kilogram (mg/kg) of food.

MRLs established by the APVMA reflect Australian registrations and patterns of use of agvet chemicals, when used in accordance with label instructions. Import MRLs are generally MRLs established in trading partner countries or adopted by Codex and added to Schedule 20 by FSANZ, typically through the MRL harmonisation proposal process.

The term 'Maximum Residue Limits' as used in this guide has the same meaning as the terms 'Maximum Residue Levels' in the European Union or 'Tolerances' in relation to crops as used in the United States of America.

National estimated daily intake

The national estimated daily intake (NEDI) is the estimate of exposure to a chemical residue through the diet, calculated across the population for all food commodities with an MRL for that chemical. The estimated dietary exposure derived from the DEA is compared to the relevant ADI in order to determine whether long term exposure to the chemical residue is likely to be a risk to public health and safety.

National estimate of short-term intake

The national estimate of short-term intake (NESTI) is the estimate of exposure through the diet, to a chemical residue that has an MRL and an ARfD and calculated for high consumers of a food commodity. It determines short term exposure over one meal or one day. The estimated dietary exposure is calculated for each food commodity separately and is not summed across all foods. The value is compared to the ARfD to determine whether short term exposures are likely to be a risk to public health and safety.

Pesticide

A pesticide is any substance, or mixture of substances, other than a feed additive:

The term excludes fertilisers or other plant nutrients and agents, such as veterinary medicines and feed additives administered to animals for purposes such as stimulating their growth or modifying their reproductive behaviour, and substances added during processing of food.

Pesticides are used for preventing, destroying or controlling any pest, including unwanted species of plants or animals during the production, processing, storage, transport or marketing of food, agricultural commodities or animal feedstuffs. They may be administered to animals for the control of insects, arachnids or other pests in or on their bodies and are intended for use as a plant growth regulator, defoliant, desiccant or plant thinning agent, or agent preventing the premature fall of fruit and substances applied to crops, either before or shortly after harvest, to protect the commodity from deterioration during storage and transport.

Raw agricultural commodity

A raw agricultural commodity (RAC) is any plant or part of a plant, animal or animal product that is to be bought or sold in the raw (unprocessed) form. For the purpose of establishing or enforcing maximum residue limits, the term means the commodity in, or nearly in, its natural state, intended for processing into food for sale to the consumer or intended for sale to the consumer as a food without further processing. It includes, but is not limited to:

- fresh fruits, whether or not they have been washed, waxed or otherwise treated in their unpeeled or natural form
- vegetables in their raw or natural state, whether or not they have been stripped of their outer leaves, washed, waxed or otherwise treated in their unpeeled form
- cereal grains
- nuts
- eggs
- raw whole milk
- meats
- other similar agricultural products.

Residue

In this guide, the term ‘residue’ has the same meaning as that given to the term ‘permitted residue’ in Standard 1.4.2 of the Code. The permitted residue of an agvet chemical means a chemical that is identified in Schedule 20 or Schedule 21 as being a permitted residue in relation to the agvet chemical.

Schedule 20 — Maximum residue limits

Schedule 20 is a standard in the Code that lists the permitted MRLs in food for sale in Australia.

Schedule 22 — Foods and classes of food

Schedule 22 is a standard in the Code that describes foods and classes of foods applicable to the MRLs in Schedule 20. It also provides the portion of a commodity to which the MRL applies.

The classification of each food commodity is divided into Class, Group and subgroup based on shared characteristics, shown in the table below.

Class	Group	Subgroup	Commodity
Fruit	Citrus fruit	Oranges, sweet, sour	Orange, sweet; Orange, sour
Nuts, seeds and saps	Oilseeds and oilfruits	Sunflower seeds	Safflower seed; Sunflower seed.
Derived edible commodities of plant origin	Vegetable oils, edible		Cotton seed oil, edible

Supervised trial median residue

Supervised trial median residue (STMR) is the median concentration of a chemical detected from a number of analyses of residues in the food, following application of the chemical according to the label instructions and good agricultural practice.

World Health Organization

The World Health Organization (WHO) is an intergovernmental organization that coordinates international health within the United Nation's system. The WHO jointly administers the Joint Expert Committee on Food Additives (JECFA) and Joint Meeting on Pesticide Residues (JMPR) with the FAO. Visit https://www.fao.org/home/en/ for more information.

World Trade Organization Notification

As members of the World Trade Organization (WTO), Australia is obliged to notify WTO member nations where proposed mandatory food regulatory measures are inconsistent with any existing or imminent international standards and the proposed food regulatory measure may have a significant effect on trade. As part of the MRL harmonisation proposal, a notification to the WTO under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement is made to enable other WTO members to comment on the proposed amendments. The WTO regards 60 days as the minimum period for comments to be received from member nations.

Preface

Purpose of this Guide

This Guide provides information for stakeholders to help in preparing a request to FSANZ to consider harmonising maximum residue limits (MRLs) in Schedule 20 of the Australia New Zealand Food Standards Code (the Code), with limits established by Codex or the country from which the food commodity was produced for importation into Australia. It provides an overview of the information FSANZ requires to assess such requests.

Anyone relying on this guide should note that FSANZ is bound by the requirements of the FSANZ Act when developing or varying food regulatory measures (see the Disclaimer at pages ii). The inclusion of a harmonisation request in an MRL proposal does not automatically mean that the request for a variation will ultimately be approved by the Australia New Zealand Food Minister's Meeting.

This Guide is intended to be used for general information only and may be updated when required. The current Guide is the 4th edition, published in 2023. The Guide is divided into five sections:

- Section 1 MRLs in Australia
- Section 2 MRL harmonisation proposals
- Section 3 Completing the harmonisation template
- Section 4 Supplementary information
- Section 5 Useful websites referenced in this Guide.

If your enquiry is not covered by information provided in this Guide or on the MRL section of the FSANZ website[6], please contact the MRL team at MRL.Contact@foodstandards.gov.au.

6 https://www.foodstandards.gov.au/Pages/default.aspx (accessed 17 April 2023)

1 MRLs in Australia

1.1 What is an MRL?

A maximum residue limit (MRL) is the highest amount of an agvet chemical residue permitted to be present in or on a food commodity following legitimate use and is based on good agricultural practice or good veterinary practice.

MRLs established for raw agricultural commodities also apply to the processed form of the raw agricultural commodities, unless specific MRLs have been established for the processed food.

The purpose of setting an MRL is to:

- permit the sale of foods containing legitimate agvet chemical residues
- minimise residues in foods consistent with the effective control of pests and diseases
- ensure residue levels do not pose health concerns for consumers.

MRLs for food for sale in Australia are listed in Schedule 20 – Maximum residue limits of the Australia New Zealand Food Standards Code.

Schedule 20 is an Australian only standard. The listed MRLs do not apply to New Zealand.

1.2 How are MRLs established in Australia?

1.2.1 Role of the Australian Pesticide and Veterinary Medicine Authority

Agvet chemical use in Australia is regulated by the Australian Pesticide and Veterinary Medicine Author (APVMA). The APVMA undertakes safety assessments of agvet chemicals, encompassing environmental, occupational and consumer impacts. As part of this process, they will set patterns of use, labelling, registration and supply conditions and will establish MRLs for treated food commodities where residues may be expected. These MRLs are published in the Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019.

Following the assessment and consultation process for MRL variations proposed by the APVMA for agvet chemicals in Australia, the APVMA will amend Schedule 20 in the Code, to ensure alignment between both standards. Notifications of the APVMA amendments of

Schedule 20 can be found on the APVMA Gazette[7] publications website. FSANZ also publishes an alert to these amendments through its Notification Circulars[8].

The APVMA only establishes MRLs for food production in Australia. In this regard, the MRLs listed in Schedule 20 apply only to Australia. New Zealand independently develops its own MRLs for agvet chemical residues for food sold in New Zealand.

1.2.2 Role of Food Standards Australia New Zealand

FSANZ recognises that pests, diseases and environmental factors vary around the world. As such, MRLs established by our trading partners differ depending on their environmental-specific good agricultural practices. This means that residues in imported foods may legitimately differ from those in domestically produced foods. To permit the sale of imported foods in Australia that contain residues of an agvet chemical, an express permission in the Code must be established.

To establish an MRL in the Code, stakeholders can request an amendment to Schedule 20. Changes to the Code are usually achieved by submitting an application to FSANZ, however the primary method open to stakeholders for MRL considerations is the MRL harmonisation proposal. The MRL harmonisation proposal is generally undertaken annually.

Stakeholders should be aware that the FSANZ Act requires FSANZ to have regard to policy guidance from the Australia and New Zealand Food Minister's Meeting, when developing food standards or making variations to the standards. The current *Policy Guideline on the Regulation of Residues of Agvet Chemicals in Food* [9] is available on the Food Regulation website.

MRL harmonisation proposals

The MRL harmonisation proposal enables FSANZ to consider requests from stakeholders to harmonise MRLs in Schedule 20 with MRLs established by either Codex or another regulatory authority. This process allows FSANZ to undertake a risk assessment of the MRLs established in or applicable to the country from where a food to be imported was produced, to protect Australian consumers. For further details on the MRL harmonisation process, see Section 2 of this Guide.

MRL applications

The FSANZ MRL application process provides an alternative route for requests that do not meet the requirements for an MRL harmonisation proposal or are not able to be accommodated by the timeframes for the proposal process.

7 https://apvma.gov.au/news-and-publications/publications/gazette (accessed 17 April 2023)

8 https://www.foodstandards.gov.au/code/changes/circulars/Pages/default.aspx (accessed 17 April 2023)

9 https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Regulation-of-Residues-of-Agricultural-and-Veterinary-Chemicals-in-Food (accessed 17 April 2023)

The FSANZ Application Handbook[10] sets out the information requirements and process for applications. Further information is also available at MRL applications[11].

Examples of when an application may be required:

- A request to harmonise a chemical that does not have HBGVs from the APVMA, JMPR or JECFA and has not been listed in Schedule 20 of the Code
- A request for a chemical and/or a food commodity combination that is time critical and does not fit in the timeline of a harmonisation proposal

Other MRL proposals

In addition to the annual MRL harmonisation proposals, FSANZ can prepare other MRL proposals when required. For example:

- Proposal P1027[12] – addressed low level inadvertent agvet chemical residues in foods without MRLs for agvet chemicals already listed in Schedule 20 of the Code.
- Proposal M1019[13] – updated Schedule 22 – Foods and classes of foods, to align the FSANZ food classification system more closely with Codex and the APVMA crop groups.

10 https://www.foodstandards.gov.au/code/changes/Pages/applicationshandbook.aspx (accessed 17 April 2023)

11 https://www.foodstandards.gov.au/code/changes/Pages/applicationshandbook.aspx (accessed 17 April 2023)

12 https://www.foodstandards.gov.au/code/proposals/Pages/P1027.aspx (accessed 17 April 2023)

13 https://www.foodstandards.gov.au/code/proposals/Pages/M1019---Review-of-Schedule-22-%E2%80%93-Foods-and-classes-of-foods-(2021).aspx (accessed 17 April 2023)

2 MRL harmonisation proposals

2.1 The FSANZ MRL harmonisation proposal process

An overview of the MRL harmonisation proposal process is outlined in Table 1 and a summary of the process for assessing requests is provided in Figure 1. There is a pre-proposal stage consisting of a Call for Requests and Administrative Assessment. The timeframe of this pre-proposal stage is generally 3-4 months. Once FSANZ determines that resources are available, the proposal will begin. The typical timeframe for the MRLs to come into effect (i.e. on gazettal of the variations to Schedule 20) is 12 months.

Table 1: Overview of the MRL harmonisation proposal process

Process	Approximate timeframes
Call for requests	Up to 12 weeks
• Public notification to open the call for MRL harmonisation requests • Harmonisation requests received	
Administrative assessment	1 month
• Preparation of Proposal • Administrative Assessment Report	
Risk assessment	6 months

• Review and assess harmonisation requests (refer to Figure 1)
• Prepare assessment summary and any related supporting documents
• Publish a public call for submissions on the prepared draft food regulatory measure
  ○ 4-6 weeks consultation period - domestic stakeholders
  ○ 60 days minimum consultation period – World Trade Organization (WTO) Members.	

Decision whether to approve the draft food regulatory measure	3 months
• Receive, review and evaluate submissions • Prepare Approval Report • FSANZ Board consideration	
Ministerial consideration (if approved by the FSANZ Board)	60 days
• Notification to and consideration by the Australia New Zealand Food Minister's Meeting (FMM)	

MRL harmonisation proposals are identified by an 'M' followed by a number and are usually prepared as a general procedure. The general procedure and key procedural steps are the same for both applications and proposals, and are described in Chapter 2, Section 2.2.5 of the FSANZ Application Handbook[14].

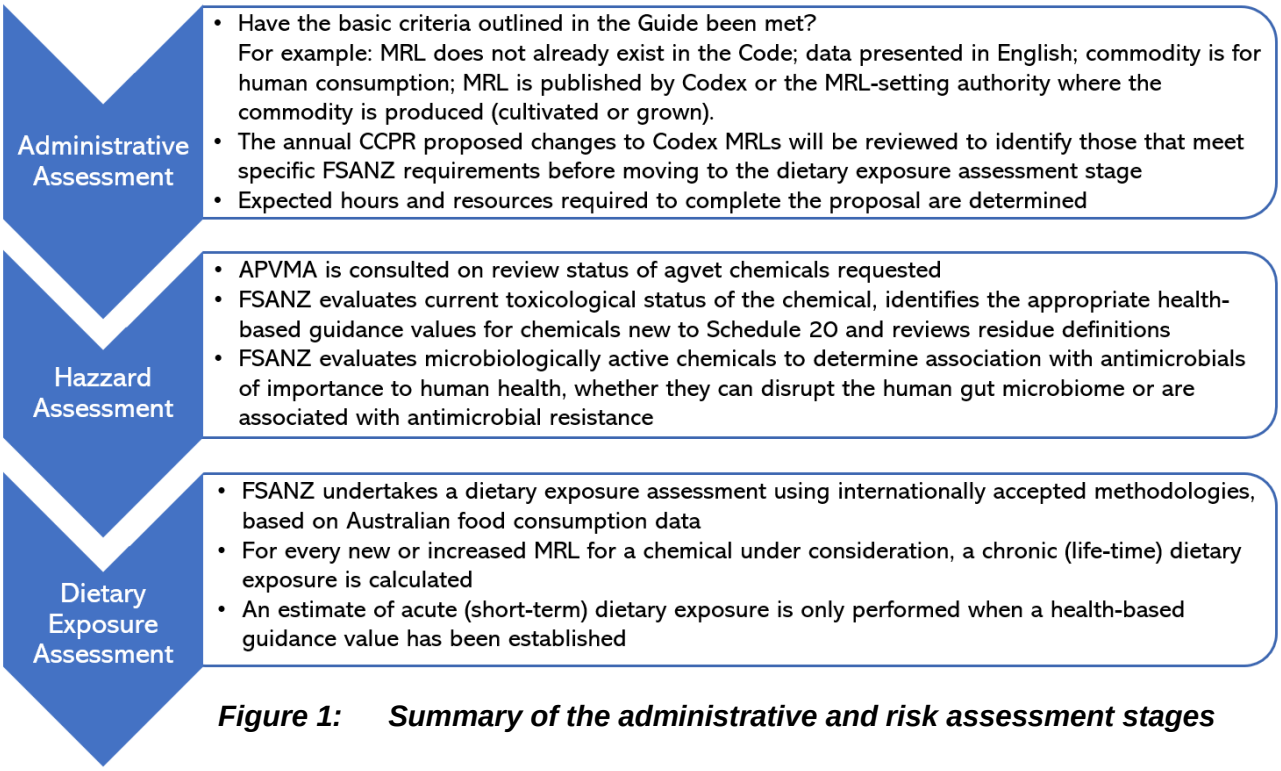


Figure 1: Summary of the administrative and risk assessment stages

2.1.1 Call for requests

A call for requests period provides stakeholders the opportunity to submit requests for the MRL harmonisation proposals. Information about the current status of MRL harmonisation proposals can be found at Maximum residue limits – variations[15]. Stakeholders may also subscribe to the FSANZ Notification Circulars[16] to receive the alert when the call for requests opens.

An MRL harmonisation request typically seeks to add a new MRL or increase an existing MRL in Schedule 20 to align with MRLs established either by Codex or an international trading partner, including ASEAN / EU, MRLs, from where food considered for import into Australia is produced. These MRLs are sometimes referred to as 'import MRLs'.

14 https://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx (accessed 17 April 2023)

15 https://www.foodstandards.gov.au/code/changes/limits/Pages/default.aspx (accessed 17 April 2023)

16 https://www.foodstandards.gov.au/code/changes/circulars/Pages/default.aspx (accessed 17 April 2023)

An MRL request **must** contain specific information to enable FSANZ to assess the request and make an informed, risk-based decision. FSANZ provides the MRL harmonisation request template (Attachment 1) to assist stakeholders in submitting their request. The template is an Microsoft Excel spreadsheet, containing an administrative information worksheet and a technical information worksheet (Figure 2).

The completed template, with a cover letter must be emailed to MRL.Contact@foodstandards.gov.au by the closing date for the call for requests.

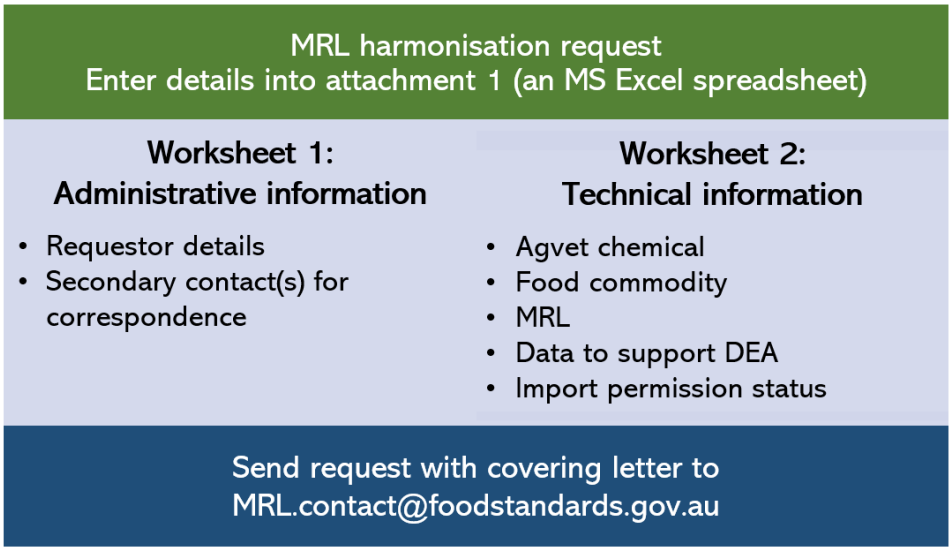


Figure 2: Outline of preparing and submitting an MRL harmonisation request

2.1.2 Administrative assessment

The administrative assessment process enables each harmonisation request to undergo preliminary screening to ensure the requested chemical and food commodity combination is appropriate for inclusion in the MRL harmonisation proposal and that the minimum required criteria for submitting the request have been met.

The administrative assessment also allows FSANZ to determine the scope of the MRL harmonisation proposal and estimate the timeframes for completion of the project. An Administrative Assessment report including these timeframes is prepared and published on the FSANZ website . Notification of the proposal preparation is published in the Notification Circular[17] and added to the FSANZ Work Plan[18].

FSANZ starts the assessment process when resources become available.

17 https://www.foodstandards.gov.au/code/changes/circulars/Pages/default.aspx (accessed 17 April 2023)

18 https://www.foodstandards.gov.au/code/changes/workplan/Pages/default.aspx (accessed 17 April 2023)

Minimum criteria to meet MRL harmonisation consideration include, but are not limited to:

- MRL does not already exist in the Code
- the food is for human consumption
- the food commodity, subgroup, group or class is clearly identified
- the requested MRL is either published by Codex, the EU, ASEAN or by the regulatory authority of country in which the food commodity was grown or produced
- data are presented in English (certified translations are accepted)
- all essential information to support the request is provided

2.1.3 Risk assessment

The primary focus for FSANZ in the risk assessment of an MRL request is consumer safety, based on the potential presence of agvet chemical residues in food. The risk assessment also considers whether any potential residues are the result of legitimate use, based on approved uses in the production of the relevant food in the country in which the MRL is established, whether the food is being imported, or intended for importation into Australia and also whether the food commodity is permitted for importation into Australia (i.e. meets biosecurity requirements).

During the risk assessment, FSANZ will consult with the APVMA on the requested chemical and food commodity combinations. Should the APVMA inform FSANZ that a chemical is flagged for review or the dietary exposure estimates based on current MRL permissions and requested MRLs are likely to exceed the relevant HBGV, FSANZ may not progress a harmonisation request. Harmonisation requests for veterinary chemicals, including antimicrobials, are considered on a case-by-case basis in consultation with the APVMA. This is often because some chemicals approved by Codex are not permitted for veterinary use in Australia due to antimicrobial resistance (AMR) considerations and exposure to residues through food may be of concern.

FSANZ has introduced a ***new process*** for consideration of antimicrobial resistance for new chemicals not listed in Schedule 20. For further information, see Section 3.2.

A dietary exposure assessment (DEA) is conducted to determine whether, in the context of the Australian diet, consumption of the chemical residues that may occur in the foods is likely to be within relevant HBGVs. Requests are only included in the proposal if the estimated dietary exposures for Australian consumers to the agvet chemical being considered are below the relevant HBGVs.

All requests are reviewed to ensure that they are not captured more than once, noting that requests for the same chemical and food commodity combination may be submitted by different stakeholders. During the risk assessment process, FSANZ may contact requestors for additional information to support the request. If the appropriate information is not provided, FSANZ may not be able to include the request in the proposal.

Following the risk assessment, FSANZ prepares a draft amendment as an attachment to the assessment summary and publishes all relevant documents for a call for submissions. This is notified to stakeholders through email, media release and social media. Public comment on the assessment summary and the proposed draft amendment is open for 4-6 weeks consultation period for domestic stakeholders and typically 60 days minimum consultation period for WTO members.

2.1.4 Decision

The next part of this decision process, including final approval through the FSANZ Board and the Food Minister's Meeting, are summarised in Table 1 and detailed in the FSANZ Application Handbook[19].

2.2 Keeping requestors informed

FSANZ sends an acknowledgement email to all stakeholders that have submitted an MRL harmonisation request, during the Call for Requests stage.

If you have not received an acknowledgement email within 7 working days of your submission, please contact the MRL Team (MRL.Contact@foodstandards.gov.au) to confirm your submission has been received.

During the administrative assessment process, FSANZ conducts preliminary evaluation of each request and, if required, may contact requestors for further information. All requests progressed through the risk assessment stage will undergo a dietary exposure assessment. Additional information or clarification may be sought throughout this stage, as required.

Requestors are formally notified if their requests will be included or excluded from the proposal prior to the publication of the Call for Submissions assessment report. Requestors are only informed about their own requests. Information on all other requests considered in the proposal are made available for public comment during the Call for Submissions period. At any stage of the proposal process, requestors may track progress of the proposal via the FSANZ Work Plan[20].

19 https://www.foodstandards.gov.au/code/changes/Pages/applicationshandbook.aspx (accessed 17 April 2023)

20 https://www.foodstandards.gov.au/code/changes/workplan/Pages/default.aspx (accessed 17 April 2023)

3 Completing the harmonisation template

This section provides instruction for completing the harmonisation request template (**Attachment 1**) and comprises separate administrative and technical information, as outlined in Table 2.

Please contact the MRL Team (MRL.Contact@foodstandards.gov.au) should you have any issue with accessing the harmonisation request template.

Table 2 Summary of how Section 3 relates to Attachment 1

Instructions for completing the harmonisation request template - Administrative and technical information requirements	Attachment 1 Harmonisation Request Template
3.1 Administrative information	**Worksheet 1** – Administrative information
3.2 Technical information	**Worksheet 2** – Technical information
3.2.1 Agvet chemical	Columns a, b and c
3.2.2 Food commodity	Columns d, e and f
3.2.3 MRL	Columns g, h, I, j, k and l
3.2.4 Data to support the dietary exposure assessment	Columns m, n, o, p, q, r, s, t, u and v
3.2.5 Import data	Columns w, x and y

If the required information is not provided or an appropriate reason not given for its omission, your request may be excluded from consideration in the MRL proposal.

Exclusion does not preclude a requestor from re-lodging the request to FSANZ with the required information, for consideration in future MRL harmonisation proposals or as an MRL application to amend Schedule 20.

The harmonisation request template and supporting information must be presented in English. Supporting information written in another language must be accompanied by a fully certified English translation.

3.1 Administrative information requirements

The following requirements can be found in the **Administrative information worksheet** of **Attachment 1**.

Requestor's name

Position title

Organisation name

Address

Telephone number

Please include international dialling codes and an extension number if relevant.

Primary contact email address

Secondary contact(s) email address

Please include anyone who should receive email correspondence about requests

Is this request being made on behalf of a single firm or organisation? (Y/N)

- **If Yes: state the nature of the business.**

  For example: food commodity producer; food processor; food trading company; chemical manufacturer; regulatory affair agent (representing a chemical manufacturer, food producer, food processor or trading company).

- **If No: provide details on other individuals, companies, industries or organisations associated with the request.**

3.2 Technical information requirements

The following information must be completed in the **Technical information** worksheet of **Attachment 1**.

The alphanumeric symbol (for example a), b) and c)) used for each subtitle, reflects the column in the harmonisation template worksheet where the information requirement applies.

3.2.1 Agvet chemical

a) Name

The agvet chemical name for which an MRL has been established ***must*** be provided.

It would be preferable if the name used matches the chemical name in Schedule 20, the Codex Pesticide Index or the Codex Index of Veterinary Drugs[21].

If the requested chemical is not listed in Schedule 20, the chemical name (in English) with residue definition if available, ***must*** be sourced from the regulatory authority of the country[22] where the MRL has been established and from where the requested food commodity is produced[23]. The trade name of the chemical is not required.

FSANZ will only accept MRL harmonisation requests for a ***new chemical*** that meets the definition of an agvet chemical as defined in Standard 1.1.2—2 subsection 3 of the Code.

FSANZ will only accept harmonisation requests for a ***new chemical*** that meets the health-based guidance values (HBGVs) requirements outlined in Section 3.2.4. These requirements are limited to HBGVs established by the APVMA, JMPR or JECFA.

b) CAS number

To assist FSANZ correctly identify the chemical to which an MRL request applies, a CAS number ***must*** be provided ***if the chemical is not listed in Schedule 20*** or the chemical name has similarity to one listed in Schedule 20 but ***you are unsure if they are the same chemical***. Please see Section 5.3 for a list of websites that can be used to find CAS numbers.

21 Please see Section 5 for the full link to the websites and databases referred to in this Section.

22 FSANZ recognises MRLs may be established by the European Union or ASEAN, while the food may be produced by specific countries within each of those jurisdictions.

23 When FSANZ is requesting information about the source of where food is produced, the meaning of *produced* is that a crop is cultivated or animal is grown.

c) Chemical Function

The function of the agvet chemical ***must*** be provided by the requestor. Examples of functions are provided in the Table 3. For an agvet chemical with more than one function, list all functions.

Table 3 A list of the most common agvet chemical functions

Agvet chemical functions	
Acaricide	Growth promotant
Antibiotic	Herbicide
Antifungal	Insecticide
Antiparasitic (anthelmintic; antiprotozoal)	Insect growth regulator
Antiviral	Nematicide
Bactericide	Plant growth regulator
Fumigant	Rodenticide
Fungicide	Virucide

Purpose of the Agvet chemical information requirements

Agvet chemicals can be known internationally by different names. It is therefore crucial that you provide the name as it appears in Codex or Schedule 20, to reduce any misinterpretation. If however you are unsure if the chemical is the same as that listed in Codex or Schedule 20, or if the chemical is not listed in either, a CAS number will allow FSANZ to correctly identify the agvet chemical.

Known examples where chemical names differ between Schedule 20 and our trading partners include: (a) phosphine, which is known in several international jurisdictions as hydrogen-phosphide and (b) maldison is currently used in Schedule 20 for the agvet chemical malathion but is known in several jurisdictions as mercaptothion and carbophos.

3.2.2 Food commodity

FSANZ does not accept requests to align MRLs for **animal feeds**

d) Codex commodity code

Codex commodity codes should be provided for each commodity requested, where available. This assists FSANZ in correctly identifying whether it is a single commodity, subgroup, group or class of food, or a processed form of the commodity, to which the MRL is to apply in the request. Please see Section 5.4 for information on links to the Codex commodity classification databases.

If the food commodity, subgroup or group is not described by Codex, state *Not available*.

e) Commodity name

All requested food commodity names should be consistent with Schedule 22 or Codex, or as listed in Schedule 20. If the requested food is not listed in Schedule 20, 22 or Codex, use the same commodity name as described by the regulatory agency that established the MRL. Please see Section 5.4 for links to food classification databases.

While some commodities described by Codex may be for a specific species of plant or animal, FSANZ may capture the same commodity in a broader commodity group. For example *Peppers, sweet* and *Peppers, chili* may be captured by the subgroup *Peppers*.

The MRL may apply to a processed form of a commodity not the raw agricultural commodity. If this is the case, this information must be provided in the commodity name field. For example *Dates, dried* or *Olive oil, edible*.

If the food commodity is not described by Codex or listed in the Code (schedules 20 or 22), please contact the MRL Team before submitting a request.

f) Source of raw agricultural commodity

For non-Codex MRL harmonisation requests, the name of the country where the plant foods / animal commodities are produced, and being sourced for importation, ***must*** be specified.

The MRL being requested must have been established in the country where the food is being produced (cultivated or grown).

Section 3.2.2 examples:

Example Number	Codex Commodity Code	Commodity Name	Country source of the raw agricultural (non-Codex requests)
1	VP 2863	Garden pea*	Canada
2	VP 2063**	Edible podded pea subgroup	USA
3	VD 0072	Peas (dry)	EU
4	FT 0295	Date	Turkey
5	DF 0295***	Dates, dried	USA
6	MM 0812	Cattle meat	USA
8	HH 3253	Stevia	Brazil

* There are two *garden pea* commodity codes: VP 0528 Garden pea (immature pods) and VP 2863 Garden pea (succulent seeds). As it is the Codex commodity code VP2863 that was provided, the entry FSANZ would propose for inclusion in the Code would be *Garden Pea (succulent seeds*) rather than *Garden pea*.

** Edible podded pea subgroup is a US food crop group, with no direct equivalent in Schedule 22. By providing the Codex commodity code VP 2063, FSANZ can identify the commodity subgroup as *Succulent peas without pods*.

*** For many processed products, the MRL can be the same as the raw agricultural commodity. By providing the Codex commodity code, FSANZ can verify that there is a distinct processed-based and MRL that has been established.

3.2.3 MRL information

g) Requested MRL value (mg/kg)

State the value of the requested MRL in mg/kg (which is equivalent to ppm).

h) Source of MRL

Identify whether the MRL is from Codex, a recognised region (e.g. EU or ASEAN) or another MRL-setting authority in the country where the food commodity is grown or produced and that applies nationally.

i) Link to published MRL

Provide a link to the officially published MRL from the source identified under Source of MRL.

j) Commodity to which the MRL applies at the source

For a non-Codex request only, provide the commodity description listed with the MRL for the source identified under Source of MRL. The commodity may be a class, group, sub-group or individual commodity.

k) Existing MRL for commodity(s) listed in Schedule 20

For this section, a commodity may be the class, group, subgroup or food commodity as described in Schedule 22 of the Code or the Codex Commodity classes.

- Where a commodity is listed in Schedule 20 at a lower MRL – report the commodity and MRL as listed in Schedule 20.
- If the food commodity is not listed –

  a) **Is the commodity MRL captured by an *All other foods except animal food commodities* (AoF) MRL?**

  If an AoF MRL exists for the agvet chemical, a request should only be made if the MRL being requested is greater than the AoF MRL.

  If the requested MRL is greater than the existing AoF MRL and the specific commodity is not listed separately for that chemical, report 'AoF' and state the AoF MRL.

  b) **Is the commodity captured by an existing class, group or subgroup MRL?**

  If a class of foods, food group or subgroup MRL exists for the agvet chemical, a harmonisation request should only be made if the individual commodity MRL being requested is greater than this MRL. Please refer to Schedule 22 to confirm if the commodity being requested is captured by a commodity subgroup or group. Schedule 22 also provides for commodities not expressly listed in the Schedule.

  If the requested MRL is greater than the existing subgroup or group MRL, report the entry (commodity name and the MRL) as listed in Schedule 20.

  c) **if there is no AoF, class / group or subgroup entry,** then report '*Commodity not listed' or 'Commodity not captured'*.

- Chemical not listed – If the agvet chemical is not listed in Schedule 20, report '*Chemical not listed'.*

l) Current status for this MRL in Codex (non-Codex requests only)

- Chemical not listed – If the agvet chemical is not listed in Codex, report '*Chemical not listed'.*
- Food commodity not listed – if the commodity is not listed or captured by a subgroup or group listing, report '*Commodity not listed'.*
- Food commodity listed – specify the commodity name, the MRL and the year the entry was listed in Codex. For example: Potato, 9 (2019).

Section 3.2.3 examples:

Example Number	Requested MRL (mg/kg)	Source of MRL	Link to published MRL	Commodity to which MRL applies at source (non-Codex requests only)	Existing MRL for commodity in Schedule 20	Current status for this MRL in Codex (non-Codex requests only)
1	0.15	Canada	pest-control.canada.ca/pesticide-registry/en/mrl-search.html	Dry navy beans	Pulses *0.01	Chemical not listed
2	4	Codex	www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticide-detail/en/?p_id=226	Commodity not listed	Stone fruits [except apricot; peach] 2	
3	0.2	USA	www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180/subpart-C/section-180.434	Banana	AoF 0.1	Banana 0.1 (2008)
4	0.04	USA	www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180/subpart-C/section-180.555	Vegetable, tuberous and corn, subgroup 1C	Commodity not listed	Potato *0.02 (2006)
5	2	EU	ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/products/details/168	Chives	Green onion 0.04	Green onions 0.01 (2019)
6	0.15	Canada	pest-control.canada.ca/pesticide-registry/en/mrl-search.html	Dry navy beans	Pulses *0.01	Commodity not listed

3.2.4 Data to support the dietary exposure assessment

The following information**, *if provided***, may assist FSANZ in their consideration of each harmonisation request. However, should FSANZ require the information outlined in this section to refine the dietary exposure assessment and this information is not provided, the request may be excluded from the MRL harmonisation proposal. The requestor may need to resubmit their request in full for the following harmonisation proposal. This decision will be provided in the formal response to requestors just prior to the Call for Submissions stage (Section 2.2).

Further information on the purpose of these requirements can be found in Section 4.3 of this Guide.

m) Have microbiological health-based guidance values (HBGV) been considered for this agvet chemical?

For new chemicals not yet listed in Schedule 20, where the agvet chemical function has antimicrobial activity, requestors should identify whether a microbiological HBGV, such as an mADI or mARfD, has been considered for the nominated agvet chemical. Similar to the toxicological HBGV, these must be from either the APVMA, JMPR or JECFA. This information can be found in the competent authorities assessment reports or identified from published HBGV (see Figures 3 and 4).

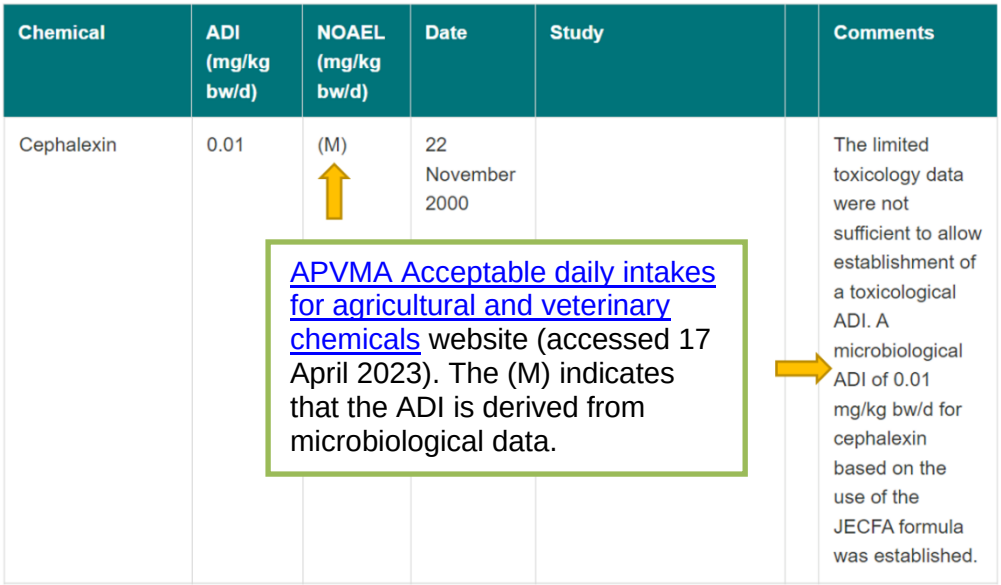
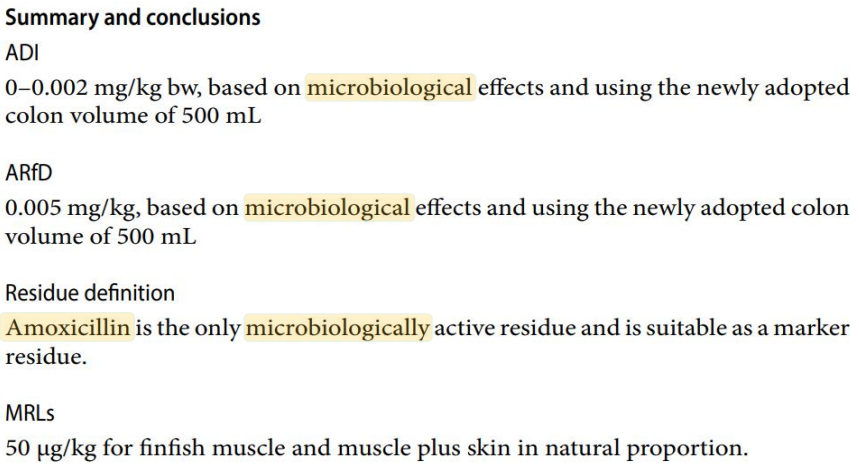


Figure 3 ***Microbiological HBGV from the APVMA.*** This screenshot of the Acceptable daily intakes for agricultural and veterinary chemicals website shows how the microbiological HBGV are indicated by the APVMA.



Summary and conclusions

ADI

0–0.002 mg/kg bw, based on microbiological effects and using the newly adopted colon volume of 500 mL

ARfD

0.005 mg/kg, based on microbiological effects and using the newly adopted colon volume of 500 mL

Residue definition

Amoxicillin is the only microbiologically active residue and is suitable as a marker residue.

MRLs

50 µg/kg for finfish muscle and muscle plus skin in natural proportion.

Figure 4 ***Microbiological HBGV from JECFA***. This except is from the *Evaluation of certain veterinary drug residues in food: eighty-fifth report of the Joint FAO/WHO Expert* (WHO Technical Report Series 1008). It shows the summary of the re-assessment of the antibiotic amoxycillin, where microbiological HBGV have been established.

n) Have the health-based guidance values been established based on microbiological or toxicological data?

This information will assist FSANZ in choosing which HBGVs to use in the dietary exposure assessments. While a microbiological HBGV may have been considered, the predominant hazard may relate to the toxicological effects and thus the toxicological HBGVs will take precedence.

o) Published acceptable daily intake

Note the value of the ADI in mg/kg body weight.

p) Source of ADI

In the first instance, the acceptable daily intake (ADI) established by the APVMA should be provided otherwise the ADI established by JMPR/JECFA will be accepted. Please see Section 5.5 for links to find these HBGV.

If an ADI has not been established by the APVMA or JMPR/JECFA and the requested chemical is listed in Schedule 20, please state *Chemical listed in S20*.

q) Published ARfD for agvet chemical

Note the value of the ARfD in mg/kg body weight.

r) Source of ARfD

In the first instance, the acute reference dose (ARfD) established by the APVMA should be provided otherwise the ARfD established by JMPR/JECFA will be accepted. Please see Section 5.5 for links to find these HBGV.

If an ARfD has not been established by the APVMA or JMPR/JECFA and the requested chemical is listed in Schedule 20, please state *Chemical listed in S20*.

If the ARfD only applies to a subgroup of the population, please include this information in the details.

If an ARfD has been considered by APVMA or JMPR/JECFA, and determined to be unnecessary, please state *ARfD unnecessary.*

Currently, FSANZ will only accept MRL harmonisation requests for a ***new agvet chemical*** where HBGV have been established by the APVMA, JMPR or JECFA. If there are no HBGV established by APVMA, JMPR or JECFA, the alternative application pathway may need to be considered. Please contact the MRL Team for advice on how to submit an application.

Section 3.2.4 examples covering ADI and ARfD data

Example number		Published ADI (mg/kg bw)	Source of ADI	Published ARfD (mg/kg bw)	Source of ARfD
1	Abamectin	0.001	APVMA (2018)	0.002	APVMA (2018)
2	Ethoprophos	0.0004	JMPR (1999)	0.05	JMPR (1999)
3	Metalaxyl	0.03	APVMA (1981)	Unnecessary	APVMA (2017)

s) Published highest residue (HR) data

HR data must be published by a competent authority in the source country of the requested MRL or in a JMPR/JECFA report. For processed commodities, highest residue processed (HR-P) may be available. For example, there may be a processing factor for commodities such as olives when processed into oil.

t) Link to HR data

The requestor may provide HR or STMR data, if available, to support the dietary exposure assessment.

To ensure that the HR or STMR data provided can be used in the dietary exposure assessment, the HR and STMR data must relate to the requested MRL and be for the crop or animal being considered or be an appropriate representative commodity. For crop-based commodities, appropriate representative commodities exist and can be identified in Annex 1 Raw Agricultural Commodities and Feedstuffs Derived from Crops in the OECD Test Guideline 509: Crop Field Trial (Links are provided in Section 5.5).

When the request relates to a food subgroup or group, and the chemical has an ARfD, HR and STMR data for each of the specific commodities may assist in the consideration of the MRL alignment request.

u) Published supervised trial median residue (STMR) data

STMR must be published by a competent authority in the source country of the requested MRL or in a JMPR/JECFA report.

v) Link to STMR data

See subsection t) above for information

Section 3.2.4 examples covering HR and STMR data

Example number		Published highest residue (HR) data (mg/kg)	Published supervised trial median residue (STMR) (mg/kg)	Link to STMR data
1	Abamectin / Raspberry	0.11	0.018	JMPR Report 2018
2	Ethoprophos / Tuberous and corm vegetables	0.03	0.01	JMPR Report 2004
3	Metalaxyl / Potato	0.02	0.01	JMPR Report 2004

Purpose of the Data to support DEA information requirements

A new process being adopted from June 2023 is a requirement for requestors to identify if the agvet chemical under consideration has antimicrobial properties. This change is part of the global One Health initiative to minimise the development of antimicrobial resistance. Should a chemical have, for example, fungicide or antibiotic activity, it would be of benefit if requestors could provide information on whether microbiological HBGV have been considered and published (Section 3.2.4). For further information on this new requirement and related questions, please see Section 4.3 of this Guide.

3.2.5 Import permission status

The links for the websites discussed in this section can be found in Section 5.6.

w) Commodity intended for importation (include any processed commodities)

Specify the commodity or commodities to be imported, either as the specific commodity, subgroup or group, as listed in Schedule 22.

Where the harmonisation request is for a raw food commodity MRL but the intention is to import a processed commodity into Australia, then identify the processed food commodity(ies) in the template.

Examples:

- Requested food commodity: *Grapes.* Is the product to be imported table grapes, wine grapes, dried grapes or wine? Is the product 'Grapes', intending to capture both table and wine grapes? If dried grapes, does this cover sultanas, currants and raisins?
- Requested food commodity: *Olives.* Is the product to be imported table olives, olives for oil production or olive oil (refined or edible)?
- Requested food commodity: *Stone fruits*. Does the product to be imported include all stone fruits, a specific commodity such as apricots or a subgroup of stone fruits such as peaches (subgroup), which include peach, nectarine and apricot? Is the product fresh and/or dried and/or juice?

x) Is the commodity currently permitted to be imported into Australia from source country identified in *Food commodity* and *MRL* sections? (y/n)

It is the responsibility of the requestor to confirm that the commodity to which an MRL is being requested is currently permitted for importation from the source country into Australia, in the form consistent with the request. The primary source for this information is the Biosecurity Import Conditions (BICON[24]) system from the Department of Agriculture, Fisheries and Forestry (DAFF).

If no (to the above), identify whether the Department of Agriculture, Fisheries and Forestry (DAFF) is currently undertaking a biosecurity import risk analysis and report the status of this process?

If the commodity is not currently permitted for importation, it is the responsibility of the requestor to identify whether DAFF is currently undertaking a biosecurity risk analysis for the commodity from the source country. The primary source for this information is the Biosecurity

24 BICON: https://bicon.agriculture.gov.au/BiconWeb4.0 (last accessed 18/5/2023)

Import Risk Analysis (BIRA[25]) website, where links to both animal and plant products currently under review or have completed review, can be found. Requests to harmonise an MRL for a commodity not permitted for importation from the source country will not be accepted, until the BIRA status has reached the Publish final report stage (see Figure 4). If FSANZ does not accept the request because the status of the BIRA precedes the final report stage, a request can be resubmitted once this stage has been reached.

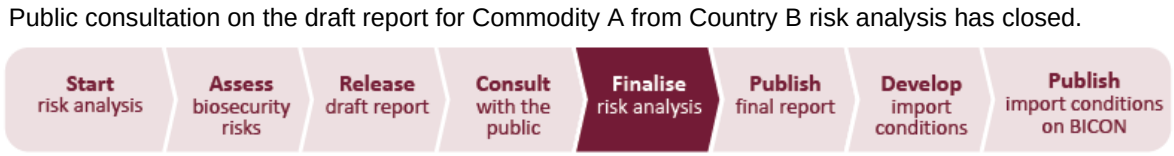


Figure 4 Outline of the eight major steps in the BIRA process. The status of the risk analysis is identified by the bolded section, which in the example shown is the *Finalise risk analysis* stage. This image is provided at the top of every BIRA proposal page.

Section 3.2.5 examples

Example number	Commodity intended for importation	Is the commodity currently permitted to be imported into Australia from source country, identified in *Food Commodity* and *MRL* sections? (y/n)
1	Fresh peas, dried peas	Yes
2	Fresh grapes (table and wine); wine	No – BIRA status at Develop Import Conditions
3	Frozen potato, dehydrated potato	No – BIRA status at Consult with the public
4	Nectarine, fresh	Yes

y) Volume of imports from source country where MRL established

The requestor may provide information, with evidence, of the current or expected volume of imports (or if known, market share of the imported product (that the MRL applies to) compared to that domestically produced). This information should be in kilograms/tons/tonnes of individual food commodities imported into Australia over the past 3-5 years **from the country where the MRL was established**. The volume should not include the total amount of the commodity imported from all countries into Australia. The volume of imported food may be used to inform the dietary exposure assessment when the results are above or near the health-base guidance values.

25 BIRA: https://www.agriculture.gov.au/biosecurity-trade/policy/risk-analysis (last accessed 18/5/2023)

When the request relates to a food group, state the food commodities captured in this food group that will be imported. Provide import data to support your request, as above. Please pay attention to the food group listed in Section 4, Table 4*,* as import data are particularly useful to support the commodities listed in this table.

4 Supplementary information

This section provides further details about the major informational requirements outlined in Section 3, to support stakeholders/requestors to understand how FSANZ considers this information and the MRL proposal process.

4.1 Food commodity

This information provides context to the Technical information requirements outlined in Section 3.2.2 Food commodity.

4.1.1 Commodity being considered

With the update to Schedule 22 in 2022, FSANZ has aligned our food classification system more closely to Codex. Schedules 20 and 22 only list food commodities for human consumption and excludes animal feed commodities. The Codex Classification of Foods and Animal Feeds[26] lists food commodities and a Codex commodity code for each commodity. Food commodities will be considered if they are listed within the following broad classes of foods:

- Class A – Primary food commodities of plant origin
- Class B – Primary food commodities of animal origin
- Class D – Processed foods of plant origin
- Class E – Processed foods of animal origin.

FSANZ does ***not*** accept requests to align MRLs to *Class C – Primary animal feed commodities*

FSANZ is aware that not all countries adopt the Codex classification system. In this situation, FSANZ requests that the equivalent (or closest) Codex food classification code be provided. All requests should include an appropriate description of the food commodity that is consistent with Schedule 22, Codex or as listed Schedule 20 of the Code. The food commodity descriptions listed in Schedules 20 and 22 are primarily based on Codex descriptors, but may vary slightly.

The description is important as food commodities, groups and subgroups are often described differently across international databases and how an individual commodity, subgroup or group is described may differ to Australia. Providing the description that you would like to be drafted in the Schedule 20 minimises the chance of misinterpretation, is important for the integrity of the Schedule and should ensure that the product you intend to import is captured.

- *Individual foods*: Where the requested food commodity is described in a different form to the food commodity that the source MRL applies to (for example, ‘dried’ versus ‘fresh’ forms), further information may be required to demonstrate the requested food commodity is captured by the source MRL.

26 www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXA%2B4-1989%252FCXA_004e.pdf (accessed 17 April 2023)

Example:

Request seeks to align an MRL for *Peas*. The source MRL is for *Peas, dried.*

Neither Schedule 22 nor Codex list *Peas* as a distinct food group, subgroup or commodity. The options in Schedule 22 include:

- Group: Legume vegetables or Pulses
- Subgroup: Peas with pods, Succulent Peas without pods or Dry peas
- Commodity: Garden pea or pea (dry)

In this example, FSANZ will require additional information from the requestor as to which group, subgroup or commodity the MRL applies.

- *Food groups:* Separate requests may be required for commodity differences between food classification systems, when comparing Schedule 22 or Codex to other international authorities.

Example:

In the US, the *Tuberous and corm vegetables* subgroup 1C captures:
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.

Under Schedule 22, *ginger* and *turmeric* are not classified as tuberous and corm vegetables. These commodities are classified as:

- Class: Herbs and Spices
- Group: Spices
- Subgroup: Spices, root or rhizome

To ensure that all of the commodities captured by the US subgroup would also be captured by MRLs in the Code, separate requests would be required for the ginger and turmeric commodities, when requesting an alignment to the US 1C - Tuberous and corm vegetables subgroup.

4.1.2 Processed food

MRLs are usually applied to raw agricultural commodities (RACs) and unprocessed food commodities. However, physical processing may be required for some food commodities (e.g. milling, drying or steaming) and may have separate entries in Schedule 20. The Code[27] states that unless Schedule 20 specifies a separate MRL for a processed food, the MRL applies to the food whether raw or processed.

Generally, separate MRLs for a processed commodity should only be considered if the resulting residues in the processed food commodity will be higher than the MRL of the corresponding raw food commodity. Where there may be processed foods associated with a request, and MRLs for processed foods have been established by Codex or trading partner, FSANZ may consider a processed food MRL, rather than the RAC MRL, for inclusion in a harmonisation proposal. The requestor should provide links to the published processed food MRL as well as publicly available residue data for processed products. This is useful in assisting FSANZ refine a DEA if required.

4.1.3 Food groups and subgroups

Where requests are received for the majority of commodities within a food group or subgroup (as described in Schedule 22), FSANZ may consider a single MRL for the food group or subgroup at the highest MRL requested. The option chosen will be dependent on the results from the DEA, especially if specific commodities at the requested MRL increase the likelihood that the results are greater than the HBGV.

Example:

Requests are received for food commodities and MRLs (mg/kg): Blackberries 2; Cranberry 2.3; Currants, black, red 1.8; Grapes 1.2; Raspberries, red, black 1.8; Strawberry 2.5.

FSANZ may consider establishing either of the options shown below in Schedule 20:

(a)	*Berries and other small fruits*	2.5
(b)	*Berries and other small fruits [except grapes]*	2.5
	Grapes	1.2
(c)	*Cane berries*	2
	Currants, black, red	1.8
	Grapes	1.2
	Low growing berries	2.5

27 Standard 1.4.2—3 (3)

Food group descriptors and food commodity names vary across international databases. Before FSANZ will consider a request for a food group MRL, the requestor should verify that the food commodities in the requested food group are covered by the existing source of the MRL. They should also verify that the class of foods as described in Schedule 22 captures all the requested food commodities.

When multiple requests are received for the same food commodity but different MRLs, the highest MRL will initially be considered in the DEA (see Section 4.3 for more details). If the same MRL is requested for a single commodity by one requestor and a food group by another requestor, the food group will be considered in the first instance.

Example:

Individual requests are received to insert a new MRL of 0.2 mg/kg for *Apricots* and *Stone fruits*. The request for *Stone fruits* will be considered in the first instance and pending outcomes of the DEA, may be adopted.

4.2 MRL

This section provides context to the Technical information requirements outlined in Section 3.2.3 MRL.

Australia uses the term maximum residue limits (MRL) with units of milligram per kilogram (mg/kg). FSANZ recognises that countries like the US, use the term tolerance with units as parts per million (ppm), which is equivalent to mg/kg.

4.2.1 Source of MRL

FSANZ considers requests to harmonise MRLs in the Code with those established by either Codex, EU, ASEAN or the MRL-setting authority in the country where the food commodity is grown or produced. Some exceptions may apply. For example, FSANZ may consider a request to align an EU MRL for cacao beans, where the beans are cultivated in an African country but processed into cocoa butter in a European country, and the cocoa butter is the commodity that moves in trade.

Harmonising with Codex MRLs

FSANZ acknowledges that Codex MRLs are established to facilitate international trade. Where a Codex MRL has been requested for harmonisation, then this MRL applies to the food commodity regardless of the country in which the food has been produced.

If a Codex MRL exists at the same level as an MRL established by a regulatory authority in a country where the food commodity is produced, FSANZ will align with the Codex MRL.

> **Example:**
>
> A request is received to align a *grapes, table* MRL from Japan. A Codex MRL exists at the same level as Japan. FSANZ will harmonise with Codex.
>
> However, should Codex later propose to reduce or delete their *grapes, table* MRL, prior to any amendment to the MRL in Schedule 20, FSANZ will determine the status of the MRL in Japan. If the Japanese MRL is still current, the MRL will be retained. If the MRL has been reduced, FSANZ will reduce the MRL.
>
> If the MRL has been increased, FSANZ will assess the safety of the increase for the Australian population before considering increasing the MRL in Schedule 20.

In 2020, FSANZ began a program to routinely consider in our MRL harmonisation proposals the MRL changes recently proposed by the Codex Committee on Pesticide Residues (CCPR) and adopted by the Codex Alimentarius Commission (CAC), which usually meets annually.

There are specific criteria FSANZ requires in order to consider including these Codex MRLs in the harmonisation proposal. These include, but are not limited to:

- higher than the existing Schedule 20 MRL
- higher than an existing *All other foods except animal food commodities* MRL
- higher than another harmonisation request to align with a trading partner MRL
- above or at the same limit as a temporary ('T') status MRL for the same commodity/group
- supported by the APVMA, and
- supported by acceptable DEA results.

Where Codex has adopted the deletion or reduction of a Codex MRL and there is a domestically approved use pattern for that commodity and an established MRL listed in Schedule 20, FSANZ will not proceed with the deletion unless it was supported and agreed to by the APVMA. Similarly, if a food commodity MRL deleted by Codex was added to Schedule 20 as a result of a prior harmonisation proposal request from a third party, and that MRL is still applicable, no action will be taken to remove the MRL from the Code.

Harmonising with MRLs established by a commodity source country

Where an MRL has been requested for harmonisation, it is assumed that the source country of the MRL is the only country to which the MRL applies[28]. FSANZ considers harmonising with MRLs established by the regulatory authority in the country in which the food commodity was produced (cultivated or grown).

28 FSANZ recognises MRLs may be established by the European Union or ASEAN, while the food may be produced by specific countries within each of those jurisdictions.

Examples:

- Barley grown in Germany is subject to MRLs established by EU legislation. FSANZ will consider harmonisation with EU or Codex MRLs for barley.
- Cacao beans cultivated in Malaysia could be subject to MRLs established by Malaysian legislation, Codex or the ASEAN. To which authority FSANZ will consider aligning in the first instance will be dependent on the MRLs established by any of these authorities and which MRL is highest.
- Raspberries cultivated in the USA are subject to MRLs established by US legislation, and could be established at the national, state or multi-state (US regional) level. FSANZ will only consider harmonisation with national US MRLs for raspberries, not US regional or state MRLs.

4.2.2 Current status of the MRL

MRLs in Schedule 20

Requestors are required to identify and report current MRL permissions in Schedule 20. It is important to note that an MRL in Schedule 20 may exist for the subgroup that captures the commodity being requested. If the subgroup MRL is higher, a request is not required. Similarly, if an *All other foods except animal food commodities* MRL exists and is higher than or equal to the MRL being requested, a request is not required.

FSANZ accepts that due to the regular changes to this schedule by the APVMA and the delay between approval and publication of the updated schedule, FSANZ could receive requests that may no longer be required.

MRLs established by Codex

Requestors are required to identify and report current MRL permissions from Codex, when the request is for an alignment to a specific international authority. The purpose of this is because under section 18 of the FSANZ Act, FSANZ must protect public health and safety, while promoting consistency between domestic and international standards. In order to meet these FSANZ objectives, the requested MRL is compared with the Codex MRL. When the requested MRL is higher than the Codex MRL, FSANZ will undertake an evaluation to determine if it is appropriate before proceeding with the request.

4.3 The dietary exposure assessment process

This information provides context to the Technical information requirements outlined in Section 3.2.4 Data to support the DEA.

A key consideration for all MRL harmonisation requests is the outcome of the dietary exposure assessment (DEA), which is based on the most recent Australian food consumption data[29]. DEAs are required for an MRL request which involves a new chemical or commodity MRL or an increased MRL[30]. When a DEA is conducted for a chemical, the assessment considers all individual commodities with existing permissions and any new MRLs for that chemical. The estimated dietary exposure must not exceed the relevant HBGV for the chemical if the request is to be included and progressed in the harmonisation proposal.

4.3.1 Health-based guidance values (HBGV)

For the MRL harmonisation proposal, HBGVs for all agvet chemicals must be sourced through the APVMA, JMPR or JECFA. FSANZ may consider a chemical without a HBGV established by the APVMA or JMPR if the chemical is currently listed in Schedule 20 of the Code. Where precedence in Schedule 20 has been established, FSANZ may use another HBGV from a credible authority.

Agvet chemicals that are not currently listed in Schedule 20 and do not have HBGVs from the APVMA, JMPR or JECFA will be excluded from consideration in the harmonisation proposal. In this situation, a request to amend Schedule 20 should be made through the FSANZ application process. An outline of the decision process is described in Figure 4.

29 FSANZ exposure assessments for agvet chemicals will be based on Australian consumption patterns from the 2011-12 National Nutrition and Physical Activity Survey (NNPAS) data, a 1 day 24-hour recall survey of 12,153 respondents aged 2 years and above. FSANZ also uses food consumption data for the 2011-12 NNPAS from 64% of respondents (n=7735) completing a second 24-hour recall on a non-consecutive day.

30 DEAs are not required for APVMA or Codex proposed deletions or reductions in MRLs or changes to the MRL status from temporary (T) to permanent.

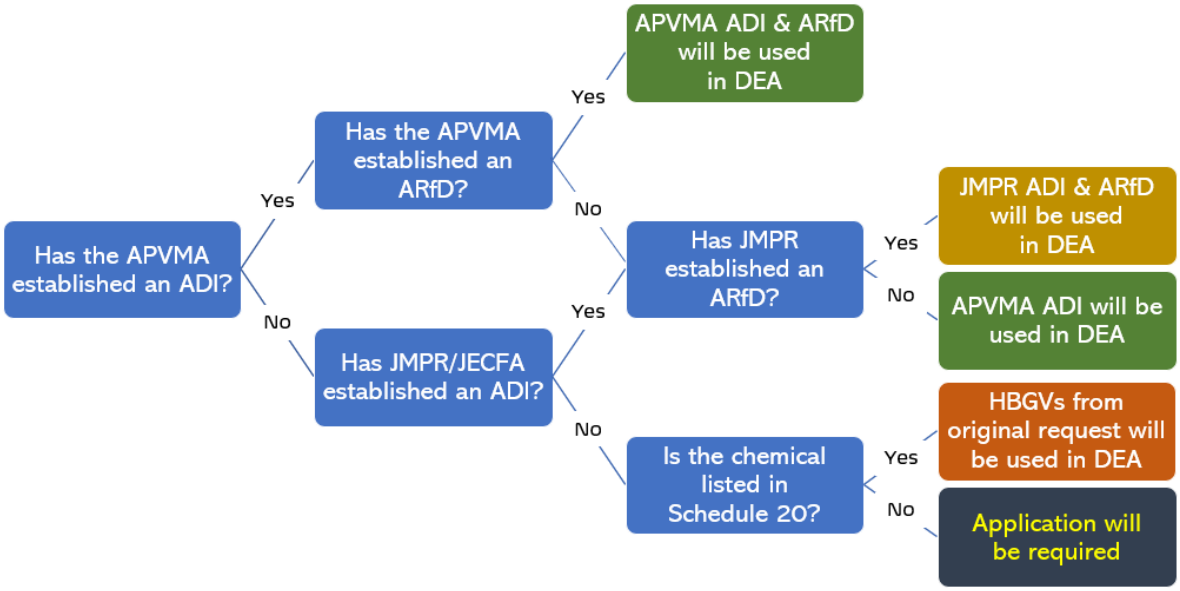


Figure 4: **An outline of the decision process for HBGVs**

When choosing which HBGV to use in the DEA, FSANZ will use paired HBGVs for DEAs from the same source. In other words, where there is only an ADI provided by the APVMA and they have not indicated that an ARfD is unnecessary but an ARfD is provided by JMPR, FSANZ will source both the ADI and ARfD through JMPR. FSANZ may also consider using the JMPR HBGVs if current APVMA HBGVs are in the process of being reviewed.

4.3.2 Toxicological and microbiological health-based guidance values

When a regulatory authority such as the APVMA establishes an MRL, the prominent hazards posed by each agvet chemical will be identified. If a toxicological hazard poses the highest risk, the HBGV will be based on the toxicological data. If a microbiological hazard is identified, the HBGV will be microbiologically based.

With the recent global focus on antimicrobial resistance and the Australian response to the One Health[31] initiative, FSANZ has developed a microbiological risk analysis framework to assess and characterise the risk of antimicrobial resistance in the food supply chain. A component of this framework will be the impact of agvet chemicals. The framework is consistent with the JECFA decision-tree approach for the *Safety Evaluation of Residues of Veterinary Drugs*[32].

31 ***One Health*** is an integrated, unifying approach to balance and optimize the health of people, animals and the environment. One Health involves the public health, veterinary, public health and environmental sectors. The One Health approach is particularly relevant for food and water safety, nutrition, the control of zoonoses (diseases that can spread between animals and humans, such as flu, rabies and Rift Valley fever), pollution management, and combatting antimicrobial resistance (the emergence of microbes that are resistant to antibiotic therapy). WHO 2023.

32 https://cdn.who.int/media/docs/default-source/food-safety/jecfa/jecfa-decision-tree-safety-evaluation-residues-veterinary-drugs.pdf?sfvrsn=501b6edf_6&download=true (accessed 17 April 2023)

Requestors should be aware that requests for new agvet chemicals not yet listed in Schedule 20, with antimicrobial activity, will be excluded from the MRL harmonisation proposal, if the antimicrobial is known to be of importance to human health. For a summary of antimicrobials that fit into this category, please review the World Health Organisations publication *Critically important antimicrobials for human health*[33]. While antimicrobials known to be of importance to human health may not be suitable for the MRL harmonisation proposal, requestors may consider submitting an application to FSANZ to vary the Code. Please contact the MRL Team at FSANZ to find out what is required for an MRL application.

4.3.3 The DEA approach

DEAs are based on 'worst-case' scenario data and are therefore conservative. Where the chemical has an ARfD, the NESTI is calculated first for each food commodity that has a proposed MRL. As outlined in Figure 5, if the NESTI exceeds the ARfD for a commodity, FSANZ may consider appropriate methods, such as using alternative datasets or concentration data, to refine the estimate of exposure (see Section 4.3.4 for more specific details). If the NESTI still exceeds the ARfD, the commodity will be excluded from the proposal.

If the NESTI is within the ARfD or where an ARfD has been considered unnecessary for the chemical, the NEDI calculations are then undertaken. Where the NEDI and, where relevant, the NESTI are lower than the HBGVs for a given chemical, the requested MRLs are included in the proposal.

33 https://www.who.int/publications/i/item/9789241515528 (accessed 17 April 2023)

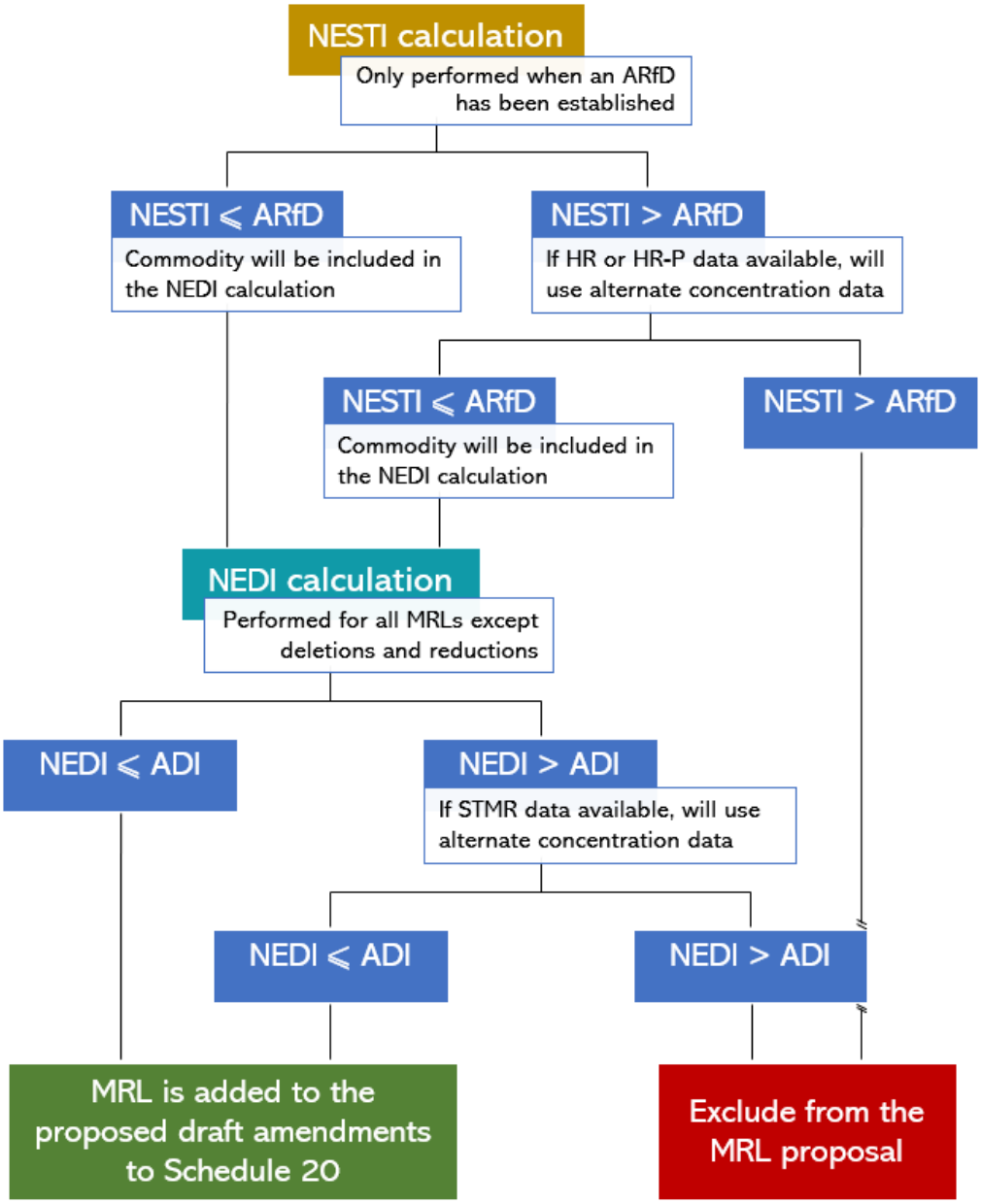


Figure 5: **An outline of the dietary exposure assessment decision tree**

4.3.4 Refining the DEA when exposure estimates exceed the HBGVs

Internationally established MRLs may be excluded from the proposal because different HBGVs may have been used in the assessment or Australian patterns of consumption for the food commodity differ to those in the source country the MRL was established. Refined assessments using published trial data may result in a lower estimate of dietary exposure.

Highest Residue (HR) and Supervised Trials Median Residue (STMR) data

HR data is the highest residue from a supervised trial that results from using the chemical according to label instructions and good agricultural practice. For processed foods, a processing factor may also be available. The HR applied to a processed product is referred to as HR-P. These data may be used in the NESTI to help refine the DEA for some commodity types.

STMR data is the median concentration of a chemical from a number of analyses in the food after applying the chemical according to label directions. These data may be used for some commodity types in the NEDI to assist in refining the DEA. It is also possible that a processing factor may be established, referred to as an STMR-P.

For agvet chemicals, FSANZ considers HR and STMR data published by the competent authority who established the MRL. Alternatively, where a Codex MRL is established, FSANZ may use the related data from the JMPR reports and evaluations.

In refining the DEA, FSANZ pays particular attention to individual commodities in a food group that have the greatest impact on the acute exposure assessment. Examples of commodities considered are provided in Table 3. Providing HR, HR-P, STMR and STMR-P data to support the commodities requested may assist with refining the DEA.

For veterinary chemicals, FSANZ will consider concentration data from JECFA to refine the DEA if available.

Other approaches to refine the DEA

If the NEDI exceeds the HBGV despite refinement of the DEA, it may be possible to further refine the DEA for the commodity considered in the assessment. For example, if a group or subgroup MRL has been requested for a chemical and the NEDI continues to exceed the HBGV, the DEA may be refined based on a selection of some of the individual food commodities within the group/subgroup. FSANZ will contact relevant requestors to prioritise which commodities they would like considered. If several requestors are involved, and a response to FSANZ is not forthcoming and/or a decision cannot be made, all MRL requests may be excluded from the MRL harmonisation proposal. Similarly, if the priority commodity(s) continue to exceed the HBGV, other commodities in the group/subgroup may still be considered and progressed.

Examples:

- If a request for *Grapes* is being considered for a chemical, and the NEDI exceeds the HBGV, it may be possible to refine this group to *Grape [except wine grapes].*
- If a request for Stone Fruits exceeds the HBGV, then it may be possible to adjust this to *Stone fruits [except peaches]* or consider only one of the commodities within this commodity subgroup (e.g. nectarines).

Another approach is to look at the volume of imports (market share) of the imported product compared to domestically produced, for refining the DEA. This requirement is part of Section 3.2.5 Import permission status.

As a principle, the more information that is provided to support a request, the more it will assist FSANZ in assessing and progressing a request through the risk assessment process.

Table 4 Examples of commodities described in Schedule 22 that impact the NESTI[34]

CROP COMMODITIES	
FRUIT	**Highest consumed commodities**
Citrus fruits	oranges, sweet; oranges, sour; oranges, for juice
Pome fruits	apples; apples, for juice
Berries and other small fruit	blueberries
Stone fruit	nectarine; peach
Assorted tropical and subtropical fruit – inedible peel	pineapple; papaya (pawpaw)
VEGETABLES	**Highest consumed commodities**
Bulb Vegetables	leek; onion, bulb
Brassica vegetables (except Brassica leafy vegetables)	broccoli; cabbages, head
Fruiting vegetables, cucurbits	melons, except watermelon; watermelon
Fruiting vegetables, other than cucurbits	eggplant (aubergine; Thai eggplant; pea eggplant); tomato; tomato, for juice; tomato, for canning.
Leafy vegetables	chard (silver beet); Chinese cabbage (Pak-choi); cos lettuce; lettuce; spinach
NUTS, SEEDS AND SAPS	**Highest consumed commodities**
Tree nuts	cashew nut; peanut
SECONDARY COMMODITIES OF PLANT ORIGIN	
Dried fruits	apricots, dried; dates, dried or dried and candied; prunes; raisins, dried

34 Data sourced from the 2011-12 National Nutrition and Physical Activity Survey (NNPAS)

4.4 Import permission status

This information provides context to the Technical information requirements outlined in Section 3.2.5 Import permission status.

The import permission status should be provided to support every food commodity requested. When a food group is requested, import requirements should be provided to support all the commodities in the food group being imported using this MRL. The requestor should also state any processed commodities associated with the request that may be imported and contain residues.

4.4.1 Import requirements

Commodities ***must*** meet the requirements set out in the Biosecurity Act 2015 and be permitted for import into Australia, in the form being requested, from the country source identified. The importance of confirming permission for importation from the source country demonstrates to FSANZ that the use of the chemical is legal and that it is being applied according to good agricultural practice.

The import permission status of the commodity can be confirmed by the requestor through the Australian Department of Agriculture, Fisheries and Forestry (DAFF) Biosecurity Import Conditions (BICON)[35] system. DAFF provides eLearning modules for BICON on the *Support using BICON*[36] webpage.

While Codex MRLs are established to facilitate international trade and products can be sourced from any country that support Codex MRLs, it is still a necessity for the requestor to confirm that the requested commodity is (a) permitted for importation into Australia in the form being requested and (b) that the form being requested matches the commodity description in Codex.

Should the commodity not be listed as permitted for import on BICON, then the requestor can use the Biosecurity Import Risk Analyses (BIRA)[37] webpages from DAFF, to identify if a current BIRA that matches the requested commodity is ongoing.

FSANZ is unlikely to accept an MRL harmonisation request when the final report has been published for the BIRA and import conditions are being developed.

Requests received to establish an MRL for a commodity that is not currently permitted or the BIRA has not reached the final decision stages will be excluded from the harmonisation proposal. If FSANZ does not accept a request on this basis, a request can be resubmitted once permission is granted or the appropriate BIRA stage has been reached.

35 https://www.agriculture.gov.au/biosecurity-trade/import/online-services/bicon (accessed 17 April 2023)

36 https://www.agriculture.gov.au/biosecurity-trade/import/online-services/bicon/help (accessed 17 April 2023)

37 https://www.agriculture.gov.au/biosecurity-trade/policy/risk-analysis (accessed 17 April 2023)

5 Websites referenced in the Guide

The following references and their web links may be useful for stakeholders and other interested parties in preparing MRL harmonisation requests. The weblinks in this section were accessed and confirmed as at 20 June 2023.

5.1 FSANZ MRL webpages, guide and handbook

- Variations to MRL limits in Schedule 20
  https://www.foodstandards.gov.au/code/changes/limits/Pages/default.aspx
- Maximum Residue Limits of chemicals in food
  https://www.foodstandards.gov.au/consumer/chemicals/maxresidue/pages/default.aspx
- MRL Proposals
  https://www.foodstandards.gov.au/code/changes/limits/Pages/MRL-proposals.aspx
- MRL Applications:
  https://www.foodstandards.gov.au/code/changes/limits/Pages/MRL-applications.aspx
- Guide to Submitting Requests for MRL Proposals:
  https://www.foodstandards.gov.au/publications/Pages/Guide-for-Submitting-Requests-for-MRL-Proposals.aspx
- MRL harmonisation request template:
  https://www.foodstandards.gov.au/publications/Pages/Guide-for-Submitting-Requests-for-MRL-Proposals.aspx
- FSANZ Application Handbook:
  https://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx

5.2 Australian and global MRL standards

- Agricultural and Veterinary Chemicals Code (Agvet Code) Act
  https://www.legislation.gov.au/Series/C2004A04723
- Agricultural and Veterinary Chemicals Code – MRL Standard
  https://www.legislation.gov.au/Series/F2019L01105
- Australia New Zealand Food Standards Code – Schedule 20 – Maximum residue limits (Australia only)
  https://www.legislation.gov.au/Series/F2015L00468
- Codex Pesticide Index
  https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticides/en/
- Codex Index of Veterinary Drugs
  https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/vetdrugs/veterinary-drugs/en/
- US Tolerances and exemptions for pesticide chemical residues in food
  https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180#se40.26.180_1101

- EU pesticides database
  https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/mrls
- Health Canada Pesticide Product Information Database
  https://pest-control.canada.ca/pesticide-registry/en/mrl-search.html
- NZ Food Notice: Maximum Residue Levels for Agricultural Compounds
  https://www.mpi.govt.nz/agriculture/agricultural-compounds-vet-medicines/maximum-residue-levels-agricultural-compounds/#:~:text=Residue%20levels%20in%20food%20must,MRL%20of%200.1%20mg%2Fkg
- NZ MPI pesticide maximum residue limit database (for food exports from New Zealand)
  https://www.mpi.govt.nz/resources-and-forms/registers-and-lists/maximum-residue-levels-database/

5.3 CAS numbers

- JMPR Inventory of evaluations
  https://apps.who.int/pesticide-residues-jmpr-database/Home/Range/All
- American Chemical Society
  https://support.cas.org/products/scifinder
- National Institutes of Health PubChem database
  https://pubchem.ncbi.nlm.nih.gov/

5.4 Food commodities and classification systems

- Australia New Zealand Food Standards Code – Schedule 22 – Food and classes of foods
  https://www.legislation.gov.au/Series/F2015L00433
- Codex Commodity Categories and Codes (for animal and processed products only)
  https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities/en/
- Codex Commodity Categories and Codes (for plant food commodities only)

  FSANZ has provided links to appendices that summarises the updated commodity classifications of plant food commodities on the following webpage:

  https://www.foodstandards.gov.au/consumer/chemicals/maxresidue/Pages/default.aspx
- US EPA crop group tables
  https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180/subpart-B/section-180.41

5.5 Data to support dietary exposure residues

- APVMA health-based guidance values
  https://apvma.gov.au/node/26581
- JMPR Inventory of evaluations of pesticides - listing health-based guidance values
  https://apps.who.int/pesticide-residues-jmpr-database/Home/Range/All

- JMPR Reports and Evaluations
  https://www.fao.org/pest-and-pesticide-management/guidelines-standards/faowho-joint-meeting-on-pesticide-residues-jmpr/reports/en/
- JECFA Residues of some veterinary drugs in foods and animals - listing acceptable daily intakes
  https://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-vetdrugs/en/
- JECFA Reports and Evaluations
  https://apps.who.int/food-additives-contaminants-jecfa-database/
- OECD Test Guideline for Crop Field Trials – Representative crops for HR or STMR data (see Annex 1)
  https://www.oecd.org/env/test-no-509-crop-field-trial-9789264076457-en.htm

5.6 Import permission requirements

- Biosecurity Act 2015
  https://www.legislation.gov.au/Series/C2015A00061
- Department of Agriculture, Fisheries and Forestry - Biosecurity Import Conditions (BICON) system
  https://www.agriculture.gov.au/biosecurity-trade/import/online-services/bicon
- Department of Agriculture, Fisheries and Forestry – Support using BICON
  https://www.agriculture.gov.au/biosecurity-trade/import/online-services/bicon/help
- Department of Agriculture, Fisheries and Forestry - Biosecurity Import Risk Analysis (BIRA)
  https://www.agriculture.gov.au/biosecurity-trade/policy/risk-analysis

Attachment 1

Harmonisation Request Template

The harmonisation request template[38] is a separate Microsoft Excel file to the Guide. It comprises two worksheets for completing - Administrative information and Technical information.

The completed template and a cover letter must be submitted as your MRL harmonisation request and sent to: MRL.Contact@foodstandards.gov.au during the period specified in the relevant Notification Circular[39] for the Call for Requests. Please contact us if you have not received an acknowledgement within 7 days of submitting your request.

38 https://www.foodstandards.gov.au/publications/Pages/Guide-for-Submitting-Requests-for-MRL-Proposals.aspx (accessed 17 April 2023)

39 https://www.foodstandards.gov.au/code/changes/circulars/Pages/default.aspx (accessed 20 June 2023)