



**Australian Government**  
**Australian Pesticides and  
Veterinary Medicines Authority**



## **APVMA risk assessment manual**

Residues and trade

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## 1 RESIDUES AND TRADE RISK ASSESSMENT

Residues that remain in food commodities after treatment of a crop or animal species with an agvet chemical have the potential to adversely affect the health of the consumers of treated food and unduly prejudice Australia's international trade in the treated commodity. A residues and trade assessment is undertaken to determine that the Australian Pesticides and Veterinary Medicines Authority (APVMA) can be satisfied that the proposed use of an agvet chemical meets the statutory safety criteria, related to consumer safety, and trade criteria.

For uses of agvet chemicals in non-food situations such as ornamental plants or companion animals, a residues and trade assessment is not required.

### 1.1 Residues assessment

The APVMA must be satisfied that consumer safety is not be adversely affected by residues of agvet chemicals and that these residue safety risks are determined by considering:

- the occurrence of residues in food produce and animal feed following treatment in accordance with proposed label or permit instructions, which is the basis for the setting of Maximum Residue Limits (MRLs);
- appropriate withholding periods for the proposed use pattern; and
- a dietary exposure assessment considering the expected residue exposure, Health Based Guidance Values for the active constituent and Australian consumption figures for the relevant food commodities.

The residues assessment will consider if new or amended MRLs are required should the application be supported by the APVMA.

The maximum residue limit (MRL) is defined as the maximum concentration of a residue resulting from the APVMA approved use of an agricultural or veterinary chemical which is legally permitted or recognised as acceptable to be present in or on a food, agricultural commodity or animal feed.

MRL amendments may be required in the two Australian MRL standards:

- The Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) 2012 contains MRLs for food and animal feed commodities for APVMA approved use patterns, as well as a list of situations where MRLs are not necessary
- Schedule 20 of the Food Standards Code is jointly administered by the APVMA and Food Standards Australia and New Zealand (FSANZ) and contains MRLs for Australian uses as well as MRLs set for use patterns approved in countries other than Australia where treated commodities may be imported. MRL establishment for import purposes is the responsibility of FSANZ.

### REFERENCES

[Pesticides and veterinary residues](#)

[Agricultural and Veterinary Chemicals Code Instrument No. 4 \(MRL Standard\) 2012](#)

[Australia New Zealand Food Standards Code—Schedule 20—Maximum residue limits](#)

## 1.2 Trade assessment

The APVMA must be satisfied that the proposed use of agvet chemicals does not unduly prejudice trade or commerce between Australia and places outside Australia.

Countries set MRLs in food and other commodities (such as livestock feed) to control and minimise exposure of people and animals to residues of agvet chemicals. If a country does not have an MRL set for a chemical, its laws may not allow any quantifiable residue in a commodity.

This situation can arise when the importing country's regulations do not yet recognise a new chemical, or when Australia needs to use a particular chemical (because of its unique pests or weeds) which is not used in the same manner elsewhere.

This means that Australian MRLs for agvet chemicals in food and other commodities may differ from those of our trading partners. This can result in potential risk, or prejudice, to trade.

The APVMA undertakes formal trade risk assessments in relation to agvet major chemical use on commodities where overseas trade is of significance to the Australian economy, such as for cereal grains and meat. Where there is little or no export trade in produce treated with agvet chemicals then no trade assessment is required. The APVMA uses an evidence-based approach to assess the risks that residues may pose to our overseas trade at the time of assessment.

A typical APVMA trade assessment involves comparing the level of residues that may occur in treated produce with the known residue standards in major export markets for that commodity, and with the international standards for residues set by the Codex Alimentarius Commission (Codex). Codex is a body established by the (World Health Organisation) WHO and the (Food and Agriculture Organisation) FAO for the protection of health of consumers, and to ensure fair practices in international food trade. Many countries apply Codex MRLs to food that they import.

Once a comparison with established national and international standards has been made, the potential for the proposed Australian MRL to pose a significant trade risk is communicated to stakeholders and their comments and suggestions for minimising the risk are requested. After consideration of this information, the APVMA determines whether the risk can be managed with appropriate conditions and systems of use. When this is possible the product can be registered for use as this will not unduly prejudice Australia's overseas trade.

The statutory tests for trade risk does not require the use to result in zero, or nil risk. Rather, the APVMA seeks to determine a level of risk that is manageable and acceptable to all the stakeholders involved, in order to allow producers, their crops and animals to benefit from the use of the agvet chemical, and to allow the Australian and international community to benefit from trade in safe produce.

REFERENCES

[Overseas trade \(part 5B\) agricultural](#)

[Overseas trade \(part 5B\) veterinary](#)

[Codex alimentarius international food standards](#)

## 2 REGULATORY FRAMEWORK

The Agricultural and Veterinary Chemicals Code (Agvet Code), scheduled in the *Agricultural and Veterinary Chemicals Code Act 1994* (the Act), provides the basis for using risk analysis to regulate agricultural and veterinary chemicals (agvet chemicals) in Australia.

The objective of the Code is for the evaluation, approval, and control of the supply, of active constituents for proposed or existing agricultural chemical products or veterinary chemical products; and the evaluation, registration, and control of the manufacture and supply, of agricultural chemical products and veterinary chemical products. The decision on whether to approve an active constituent or an agvet product is made by the APVMA.

The Act mandates that the APVMA implement the Code in a manner that reflects 'established best-practice principles for the assessment and management of risk, based on science'. To do this, the APVMA's regulatory scientists must balance regulatory effort and regulatory burden with the potential risk that agvet chemical use will present to the health and safety of human beings, animals and the environment.

The APVMA must be satisfied under s14 of the *Agricultural and Veterinary Chemicals Code Act 1994* that:

- the proposed use of the product meets the safety criteria with respect to s5A(1)(a) and (b);
- the requirements of s5A(3)(a)(i), (v), (vi) & (vii); s5A(3)(b)(i), (ii), (iii) & (vi); and 5D(1)(a)–(e) are met;
- assessment according to trade criteria as required under S5C(2), (3) and 5D(1)(–)–(e) is carried out;
- any required amendments to the MRL standard under s5A(3)(b)(iii) are made.

## 3 INTRODUCTION TO THE RESIDUES ASSESSMENT

### 3.1 Background to the application

Information that has been provided by the applicant is reviewed to identify the following:

- what the application is for
- whether any components of the proposed use has been previously approved in Australia
- has previous assessments been undertaken by the APVMA that is relevant to the application
- relevant details of the active(s), for example mode of action and if it is systemic.

### 3.2 Label and maximum treatment regime

The Good Agricultural Practice (GAP) or Good Veterinary Practice (GVP) specified in the proposed label is reviewed including the proposed crop or animal species to be treated, the application or dose rate, the number or applications and minimum re-treatment interval, critical comments relating to application timing or method, withholding period(s) and trade advice information including Export Slaughter Intervals (ESI).

The critical GAP or GVP, which is the use pattern that will result in the highest potential for residues (such as highest proposed rate, most frequent applications and shortest withholding period (WHP), will be determined. This critical GAP or GVP will be the basis of the residues and trade assessment.

### 3.3 Established and proposed MRLs

The current Australian MRL standard will be reviewed to identify any current MRLs that are relevant to the proposed use of the active(s). This will include MRLs for animal commodities (mammalian and poultry) if the proposed use is for a crop that may be fed to or grazed by animals (such as cereals). The current relevant residues definition(s) will also be identified.

The amendments to the MRL standard that have been proposed by the applicant, along with the proposed withholding period statements that outline the minimum interval that needs to elapse between treatment and harvest, grazing (or cutting for stock food), or slaughter for human consumption (for vet medicines) will be outlined in the applicant's submission documents.

#### REFERENCES

[Agricultural and Veterinary Chemicals Code Instrument No. 4 \(MRL Standard\) 2012](#)

[Limits on use and disclosure of information](#)



## 4 RESIDUES EVALUATION

### 4.1 Metabolism

The APVMA undertakes an assessment of metabolism data relevant to the proposed crop or animal. Metabolism data is generally not provided for all applications but is provided for applications for new active constituents and some major extensions of uses where metabolites and breakdown products require confirmation.

Metabolism data is used to characterise the nature and behaviour of the active constituent and its break down products and metabolites in treated crops, rotational crops and animals that may be directly treated or exposed to the active via treated feed. Metabolism studies utilise a radiolabelled active constituent to demonstrate the metabolic pathway for the active in treated plants or animals, identify the major components and determine at what percentage of the total radioactive residue (TRR) can be attributed to each component in each relevant crop or animal matrix and metabolite. The results are used to inform recommendations relating the residue definition for the active constituent which could include the parent compound and or its metabolite(s).

A residue definition is established based on the results of the metabolism studies, with regard also to the toxicological assessment of the active and its metabolites, the analytical methodology and the results of the residue trials. The residue definition for an active may be the same for all purposes or it may be different for commodities of plant and animal origin. The residue definition may also be different for the purposes of enforcement (for which the MRL applies) and dietary exposure assessment.

For veterinary medicines, in addition to informing the decision on an appropriate residues definition (or marker residue), a marker residue to total residue (MR:TR) ratio can be determined for each matrix for use in the dietary exposure assessment. Metabolism studies are also used to identify the target tissue for residue monitoring purposes.

#### REFERENCES—AGRICULTURAL CHEMICAL PRODUCTS

[Metabolism and kinetics \(part 4\) agricultural](#)

[Definition of residues for the purpose of setting a maximum residue limit \(residues\)](#)

[OECD guidelines 501, 502 and 503 and OECD Guidance document on the Definition of Residue](#)

[JMPR guidance](#)

#### REFERENCES—VETERINARY CHEMICAL PRODUCTS

[Metabolism and kinetics \(part 4\) veterinary](#)

[Comparative metabolism studies, selection of marker residues and ratios of marker residues to total residues](#)

[VICH guideline 46](#)

## 4.2 Analytical methods and storage stability

Analytical methods that have been used for the determination of the active constituent and or metabolites relevant to the residue definition in the residue studies are assessed. Each method is examined, based on its validation data and performance characteristics for its overall suitability for the intended purpose, the compounds determined by the method and the matrices that may be analysed. This assessment will consider:

- details of the extraction procedure and equipment used for each matrix
- the sensitivity of the method including the Limit of Detection (LOD) and the Limit of Quantification (LOQ)
- validation data which measures the recovery of active constituent from fortified samples to provide confidence of the accuracy of the method.

The stability of residues in stored (frozen) samples will be considered for commodities, storage conditions and storage durations relevant to each residue trial. For example, if a residue study for wheat involves the storage of grain, forage and fodder samples at  $-20^{\circ}\text{C}$  for 18 months, then acceptable storage stability should be demonstrated for each matrix in a cereal for storage for at least 18 months at  $-20^{\circ}\text{C}$ .

### REFERENCES—AGRICULTURAL CHEMICAL PRODUCTS

[Residue analytical methods \(residues\)](#)

[Generation of storage stability data for agricultural chemical products](#)

[OECD guideline 506 and Guidance Document on Pesticide Residue Analytical Methods](#)

[JMPR guidance](#)

### REFERENCES—VETERINARY CHEMICAL PRODUCTS

[Analytical methodology](#)

[VICH guideline 49](#)

## 4.3 Residues

An assessment of each submitted residue study is undertaken. The treatment regimens utilised in the residue trials are compared with the proposed GAP or GVP and the results from the relevant treatments are considered for MRL setting purposes. Residue data submitted for registration applications should be conducted in accordance with the OECD principles of GLP. The types of residues studies are different for agricultural and veterinary chemical products, as are some of the considerations that occur. Agricultural and veterinary product residue studies will be discussed separately below.

## Agricultural chemical products

### *Assessment of residue studies*

The residues assessment is divided into separate considerations for each crop or crop group, if multiple crops or crop groups are included on the proposed label. Crops within the same crop group will usually be considered together if the GAP is the same. Trial results are presented in a tabular format that will include the types of crops that were trialled. The field phase of the trial (how treatments were applied, the growth stage at application, the number and interval of applications and application rate) are detailed along with the location of the trials and the post harvest interval that samples were collected.

An analysis will be made if a sufficient number of relevant 'fit for purpose' trials are available to support an MRL for a crop or crop group. This will consider if the maximum proposed treatment regime was addressed and if the study was conducted in accordance with OECD and APVMA guidelines. The proposed harvest and grazing (if applicable) withholding period will be considered and if that cannot be supported due to a lack of relevant data or any identified dietary exposure concerns then an alternative withholding period or use pattern will be investigated if the dataset allows.

The results relevant to the proposed use pattern is considered and appropriate MRLs and withholding periods based on the available data are determined. The OECD MRL calculator is often used to estimate the MRL. There may also be analysis as to why the MRL recommendation may vary against the calculator estimation. If residue trials demonstrate that residues should not occur above the validated method LOQ in the commodity, then an MRL set at the LOQ prefixed with an asterisks (eg \*0.01 mg/kg) will be recommended.

The determination of relevant MRLs will occur for each relevant food or feed commodity for each crop or crop group. For example, a use in cereals will involve the consideration of residues in, and MRLs for, grain at harvest, straw (stubble or fodder) at harvest and forage at the proposed or alternate grazing withholding period. Residues in straw and forage are usually considered on a dry weight basis determined based on the sample moisture contents from the study report or using a standard moisture content from the OECD feed calculator if sample moisture contents were not determined in the study.

For broad acre crops including cereals, pulses and canola, forage data must be provided so that a grazing withholding period can be determined. A 'DO NOT graze restraint' is not considered to be practicable in broad acre crops as livestock may graze those crops, particularly in a failed crop situation. A failed crop is considered to be any crop that, because of adverse conditions, could be grazed by livestock during its vegetative growth stage rather than grown to maturity.

## REFERENCES

[Residues \(part 5A\) agricultural](#)

[Residue trials to obtain permanent maximum residue limits for crops \(residues\)](#)

[Withholding periods \(residues\)](#)

[Failed crops \(residues\)](#)

[OECD guideline 509, OECD Second Edition Guidance Document on Crop Field Trials and OECD Guidance Document on Overview of Residue Chemistry Studies](#)

[JMPR guidance](#)

[OECD MRL calculator](#)

### ***Processing studies***

Assessment is undertaken of any processing data for commodities that may be processed. Processing studies will generally be required when significant (greater than 0.1 mg/kg) residues are present in the raw commodities that are commonly processed such as cereals grains, oil seeds, citrus, grapes, apples, potatoes, fruit for dried fruit production and sugarcane.

Processing studies are used to determine processing factors, by comparing residues in the raw agricultural commodity (RAC) with that in the processed commodity. MRLs can be established for processed commodities that are traded (such as dried fruit and oil) if residues are expected to concentrate in the processed commodity. If actual residue results are not provided for processed commodities from local residue studies, MRLs for processing commodities are usually based on the HR-P which is calculated from the highest residue observed in the field trials for the RAC and the processing factor for the processed commodity. Processing factors can also be used to refine dietary exposure calculations (eg edible portion (pulp) data for citrus and tropical fruit) and trade assessments (eg for wine).

For commodities in which processing by-products may be fed to livestock (such as grape pomace, citrus pulp and tomato pomace), processing studies are used to consider appropriate MRLs for that animal feed commodity (Table 4 MRL Standard) as well as to assess the potential for residue transfer to animals.

### **REFERENCES**

[Processing studies \(residues\)](#)

[OECD guidelines 507 and 508 and OECD Guidance Document on Magnitude of Pesticide Residues in Processed Commodities](#)

[JMPR guidance](#)

### ***Animal transfer studies and animal commodity MRLs***

Assessment is undertaken of relevant animal transfer studies, which are generally undertaken in lactating cattle and laying hens. The result of those studies and the maximum expected feeding burden for mammalian livestock (such as beef cattle) and poultry are used to determine the required animal commodity MRLs.

The OECD feed calculator lists the percentage of animal's diets that animal feeds can contribute. This calculator together with the level of residue observed in each animal feed commodity that may be treated with that active is used to calculate the maximum feeding burden.

An animal transfer study is used to demonstrate the level of residues observed from known levels of dietary exposure for 28 days. The results of the animal transfer study is compared with the estimated calculated maximum feeding burden to determine the level of residues expected in, and appropriate MRLs for, animal tissues (muscle, fat, liver and kidney) as well as milk and eggs.

Animal transfer studies that include a depuration phase (days on clean feed after treatment) can be used to consider an Export Slaughter Interval for pesticide products (see section 6.4.1).

In certain scenarios such as negligible expected animal exposure, animal transfer data for mammals (lactating cow) and poultry (laying hen) may not be required. If metabolism studies have been conducted at dosing levels much higher than the anticipated dietary burden of animals, argument may be presented to demonstrate that detectable residues in tissues, milk or eggs should not occur. A validated analytical method for animal commodities would however be required to allow for LOQ MRLs to be considered.

## REFERENCES

[Animal transfer studies \(residues\)](#)

[OECD guideline 506 and OECD Guidance Document on Residues in Livestock](#)

[JMPR guidance](#)

### *Fat solubility and potential for bioaccumulation*

The potential for bioaccumulation in fat is assessed based on the octanol-water partition coefficient ( $\log_{10}K_{ow}$ ) value and the comparison of residues between meat and fat and between cream and milk. This consideration will inform the decision to establish meat MRLs on the fat portion of the commodity.

### *Crop rotation*

Rotational crop data is assessed. The assessment will generally be conducted for the first use of a pesticide product in a rotational crop situation (ie not permanent a planting such as tree crops or grapes), or when the maximum seasonal rate in a rotational situation has increased. The aim of the assessment is to consider if residues of a pesticide applied to one crop may occur in the following crop grown in the same paddock and examine the potential for dietary and trade risks. There may be a recommendation that a plant back interval is stated on the label to manage risks in following rotational crops to manage risk. There may also be a recommendation to establish an 'all other foods' and 'primary feed commodity' MRL to account for residues in following crops including animal feeds.

## REFERENCES

[OECD guidelines 502 and 504 and OECD Guidance Document on Residues in Rotational Crops](#)

[JMPR guidance](#)

### ***Spray drift***

The potential impact of spray drift on the international trade of animal commodities will be considered. Spray drift scenarios are used to determine the potential for the pesticide to drift based on application method, maximum application rate and spray quality specified on the proposed label.

Animal transfer information is used to determine the level of acceptable drift onto downwind pastures/livestock areas to prevent residues occurring in animal tissues above international MRLs for livestock that may be grazing in paddocks adjacent to treated areas. Mandatory down-wind buffer zones for livestock areas for the protection of international trade (livestock areas) may be the outcome of this assessment.

### **REFERENCES**

#### [Spray drift](#)

### **Veterinary chemical products**

The residues assessment is divided into separate considerations for each livestock species, if multiple species are included on the proposed label. Studies for milk, eggs or honey will be considered separately to any studies for tissues in which the animals are sacrificed for the collection samples for muscle, fat, liver, kidney and injection sites (for injectable products). The results of the residue depletion studies are presented in a tabular format that will include details on the treatment(s), the number of animals included in each group and the relevant post treatment intervals.

An analysis will be made if the provided studies are 'fit for purpose' considering if the maximum proposed treatment regimen was addressed, and if the study was conducted in accordance with VICH and APVMA guidelines for study design including the number of animals per time point and sample collection.

A statistical analysis, using for example the EMA meat and milk statistical software, is generally performed on the results of each residue depletion study to investigate the decline in residues overtime for each relevant commodity. MRLs for veterinary products are usually derived to represent the upper 95th confidence limit on the 95th percentile of the residues concentrations at the chosen point on the residue depletion curve.

For the first use of an active in a species, or in situations where an increase to an MRL is proposed, the appropriate MRL for the proposed withholding period will be determined based on the results of the residue depletion study. A dietary exposure assessment (Section 5) will then be conducted based on the residues expected at the proposed withdrawal time and if the dietary exposure is acceptable then that withholding period and MRL will be supported. If the dietary exposure assessment indicates a potential issue with the residues expected at the proposed withholding period then the data will be re-assessed based on the results and MRL recommendation for the next time point included in the residue depletion study. This process will continue until satisfactory dietary exposure is demonstrated. If the dietary exposure assessment indicates a potential issue with the residues expected at the last time point included in the study, then the proposed use may not be supported.

For the use of an active in a species for which relevant MRLs are currently established, an assessment will consider if the results demonstrate that residues should comply with the established MRLs at the proposed withholding period, or an alternative withholding period will be recommended to allow compliance with the established MRLs if the dataset allows.

When considering the domestic meat withholding period for a product, injection site residues may not comply with the Australian muscle MRL provided the acute dietary exposure level (ie consumption of injection site tissues) does not exceed the acute reference dose for the veterinary chemical.

#### REFERENCES

[Residues \(Part 5A\) veterinary](#)

[Food safety studies for veterinary drugs used in food-producing animals](#)

[VICH guideline 48](#)

[Environmental Health Criteria 240](#)

## 5 DIETARY RISK ASSESSMENT

Chronic and acute dietary exposure assessments are based on the expected residue, the Health Based Guidance Values for the active constituent and Australian consumption figures for the relevant food commodities.

The Health Based Guidance Values in Australia are established by the APVMA. Lists of established Acceptable Daily Intake (ADI) and Acute Reference Dose (ARfD) values can be found on the APVMA website.

The dietary exposure calculations are based on international methodologies (IEDI and IESTI) and consider Australian consumption data provided by FSANZ. Consumption figures are derived from the 2011–12 National Nutritional and Physical Activity Survey (2011–12 NNPAS). At the end of the assessment where MRL amendments are recommended for food commodities, a Dietary Exposure Estimate document is prepared by the APVMA and is confirmed by FSANZ. If the dietary exposure assessment does not identify a consumer safety issues, then the proposed use and MRL can be supported from a safety perspective. If a dietary risk is identified then a revised GAP or GVP will be investigated based on the available dataset. If a satisfactory dietary exposure assessment cannot be achieved then the use will not be supported from a safety perspective.

### 5.1 Chronic dietary exposure assessment

The chronic dietary exposure to the active is estimated by the National Estimated Daily Intake (NEDI) calculation encompassing all registered/temporary uses of the active and the mean daily dietary consumption data derived primarily from the 2011–12 National Nutritional and Physical Activity Survey. The NEDI calculation is made in accordance with WHO Guidelines (IEDI) and is a conservative estimate of chronic dietary exposure to chemical residues in food.

Assessment is made as to whether the chronic dietary exposure is acceptable, where a NEDI calculation less than 100 per cent of the ADI indicates that chronic dietary exposure is acceptable.

#### JECFA model diet for veterinary drug residues

For veterinary drugs, an additional method of chronic exposure assessment is undertaken. A model diet intended to cover high consumers of animal products is used by JECFA to determine that proposed MRLs for veterinary medicine residues would not result in the ADI being exceeded. The APVMA also uses the Estimated Dietary Intake (EDI) approach for chronic dietary exposure, which considers the median of residue distribution, when considering new MRLs for veterinary chemical products.

### 5.2 Acute dietary exposure assessment

The acute dietary exposure is estimated by the National Estimated Short Term Intake (NESTI) calculation. The NESTI calculations are made in accordance with the deterministic method used by the JMPR (IESTI) with 97.5th percentile food consumption data derived primarily from the 2011–12 National Nutritional and Physical Activity Survey. NESTI calculations are conservative estimates of short-term exposure (24 hour period) to chemical residues in food.



A NESTI calculation is required when an ARfD has been established in Australia (or by JMPR, if it has not been considered in Australia) and the acute (short-term) exposure calculation should include the relevant commodities associated with the proposed MRLs. A separate calculation is conducted for children (two to six years) and the general population (two plus years). If an ARfD is only set for women of childbearing age then only one calculation for that cohort is conducted.

Assessment is made as to whether the acute dietary exposure is acceptable where a NESTI calculation is less than 100 per cent of the ARfD the acute dietary exposure is deemed acceptable for each commodity associated with the application.

## REFERENCES

[ADI list](#)

[ARfD list](#)

[Dietary exposure and intake assessments](#)

[Environmental Health Criteria 240](#)

## 6 RESIDUE RELATED ASPECTS OF TRADE

The export of treated produce containing finite (measurable) residues of an active constituent may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

A detailed trade assessment is undertaken for uses on crops, animal feed or livestock that produce major export commodities.

When the establishment of a new MRL above the limit of quantitation (LOQ) for a major export commodity is proposed, the APVMA undertakes a public consultation on trade risk. This includes:

- new active constituents—Public Release Summary (PRS) consultation
- existing active constituents—Trade Advice Notice (TAN) consultation for new uses where finite MRLs are recommended

Where quantifiable residues are not expected in a major export commodity and a LOQ MRL is recommended the risk to trade is considered to be low and a TAN consultation may not be required.

### 6.1 Commodities exported

Major export commodities are defined in the APVMA Trade Guidelines and include animal commodities and certain plant commodities as listed in the data guidance 5B (cereal grains, specified pulses, canola, cotton seed, citrus fruit, grapes (including wine), stone fruit, pome fruit, sugar and oaten hay).

For agricultural chemicals used in situations in which a residue may be found in animal feeds, consideration is given to the potential for residues to occur in animal commodities and the subsequent potential impact on trade of animal commodities.

### 6.2 Destination and value of exports

For each major export commodity, the major export destinations and value of exports is determined from reputable public sources where possible such as the Australian Bureau of Agricultural and Resource Economics and Sciences (ABARES).

The significant export markets for Australian beef, sheep, pig meat and offal are listed in the APVMA Trade Guidelines.

### 6.3 Comparison of Australian MRLs with Codex and overseas MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits for pesticides and veterinary medicines. Codex MRLs are primarily intended to facilitate international trade, and accommodate differences in GAP or GVP employed by various countries. The APVMA considers whether the

active constituent has been considered by the Codex and if relevant codex MRL have been established for the relevant commodities.

The APVMA also considers contemporary lists of tolerances or MRLs that are established by the major export destinations for the relevant commodities.

Further, the APVMA considers the residue definitions established by Codex and the major export destinations as these may be different to that established in Australia. If differences in residue definition exist, the APVMA assesses the potential for the proposed Australian use to comply with the overseas MRL based on the relevant residue definition.

The APVMA considers the proposed Australian MRLs, the relevant Codex and the relevant MRLs for the major export destinations, and residue definitions established by Codex and major export destinations to identify potential trade risks. This information will also be presented in the PRS or TAN consultation documents to communicate the relevant international MRLs with industry stakeholders.

## 6.4 Management of potential risk to trade

### Export intervals

An important tool in the management of trade risk is the export interval. Export intervals may take several forms but they all advise producers of the minimum period of time that must elapse after treatment or exposure before the commodity can be harvested for export.

Quality assurance systems of major industry groups rely on APVMA to generate and provide export intervals and other relevant trade advice. This information is communicated to producers on labels of products registered by APVMA.

The most common type of export interval relevant to residues in animal commodities, is an Export Slaughter Interval (ESI). The export slaughter interval is the minimum time that should elapse:

- between the last treatment of an animal with a veterinary chemical product and the slaughter of that animal for export, or
- after the removal of grazing livestock to untreated pasture or feed (clean feed) and slaughter for export, where the livestock have been grazing a crop or pasture after treatment with an agricultural chemical product in accordance with the label instructions (including grazing withholding period).

The 'ESI endpoint' for each tissue is usually the lowest relevant MRL of a significant export market, or is a reasonable LOQ in situations where no relevant MRL has been established by a significant export market. The endpoint for ESI considerations may not be the lowest validated LOQ for and active constituent if the APVMA has previously used a higher LOQ as an ESI endpoint for that active. In some cases the APVMA may not default to an LOQ if the risk to trade is effectively mitigated by considering an alternative endpoint.

The APVMA Trade Guidelines provide a list of significant markets for trade considerations for cattle, pigs and sheep. The MRLs standards of the countries identified in this list will be considered by the APVMA when recommending ESIs.

## Responses to public consultation

If public consultation on the potential risk to trade is required, the relevant industry groups are given the opportunity to comment on the perceived level of risk and whether any industry-initiated strategies are required to manage the risk. If comments are received from industry stakeholder to indicate a valid potential risk to international trade, the APVMA will work with the applicant and the industry stakeholder(s) to determine if the identified risk can be addressed.

## REFERENCES

[Pesticides and veterinary residues](#)

[Overseas trade \(part 5B\) veterinary](#)

[Veterinary drug residues in food commodities and overseas trade](#)

[Dept. of Agriculture and Water Resources—publications](#)



## Appendix

## ABBREVIATIONS

Abbreviation	Full phrase
ABARES	Australian Bureau of Agricultural and Resource Economics and Sciences
ADI	Acceptable daily intake
ADWG	Australian Drinking Water Guidelines
AERP	Adverse Experience Reporting Program
ALARA	As low as reasonably achievable
APVMA	Australian Pesticides and Veterinary Medicines Authority
DAWR	Department of Agriculture and Water Resources
DEA	Dietary Exposure Assessment
DEE	Department of the Environment and Energy
EDI	Estimated Dietary Intake
ESI	Export Slaughter Intervals
FAISD	First aid instructions and safety directions
FAO	Food and Agriculture Organisation
FSANZ	Food Standards Australia New Zealand
GAP	Good Agricultural Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GVP	Good Veterinary Practice
HBGV	Health Based Guidance Value
HR-P	Highest residue in a processed commodity
IEDI	International Estimated Daily Intake
IESTI	International Estimated Short-Term Intake
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOD	Limit of Detection
LOQ	Limit of Quantification

Abbreviation	Full phrase
MLS	Manufacturers Licensing Scheme
MRL	Maximum Residue Limit
NEDI	National Estimated Daily Intake
NESTI	National Estimated Short Term Intake
NOAEL	No-observed-adverse-effect level
NRS	National Residue Survey
OECD	Organisation for Economic Co-operation and Development
OGTR	Office of the Gene Technology Regulator
PBI	Plant Back Interval
PHI	Post-Harvest Interval
RCP	Restricted Chemical Product. An RCP may be declared if special knowledge, skills, training and equipment are needed to be able to obtain, handle or use the product. This is based on the risks posed by the product to human health, animals, plants or the environment.
REI	Re-entry interval
TAN	Trade Advice Notice
TRR	Total radioactive residue
VICH	International Cooperation on Harmonization of Technical Requirements of Veterinary Medicinal Products
WHO	World Health Organization
WHP	Withholding period