

22 April 2016 [10–16]

Call for submissions – Proposal P1027

Managing Low-level Ag & Vet Chemicals without MRLs

FSANZ has assessed a Proposal to manage low-level agricultural and veterinary chemicals without MRLs (i.e. the food is not listed in Schedule 20, but the chemical is), and has prepared a draft food regulatory measure. Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at information for submitters.

All submissions on Applications and Proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at <u>information for submitters</u>.

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on <u>documents for public comment</u>. You can also email your submission directly to <u>submissions@foodstandards.gov.au</u>.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 3 June 2016

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to <u>standards.management@foodstandards.gov.au</u>. Hard copy submissions may be sent to one of the following addresses:

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Supporting document

The following document which informed the assessment of this Proposal is available on the FSANZ website at http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1026lupinas5830.aspx:

SD1 The risk assessment approach to establishing *All other foods except animal food commodities* MRLs

Executive summary

This Proposal has been prepared to establish an approach to assess agricultural and veterinary (agvet) chemicals currently listed in Schedule 20 of the *Australian New Zealand Food Standards Code* (the Code) for suitability of *All other foods except animal food commodities* maximum residue limits (MRLs). These MRLs would account for low levels of inadvertent agvet chemical residues in food commodities, and only applies to Australia.

At present, MRLs are established for specific commodities and there must be no detectable residue of an agvet chemical in a food commodity where there is no MRL for that chemical/ food combination. Agvet chemical residues can inadvertently occur in foods without an associated MRL e.g. due to spray drift. If these foods do not have an MRL, they cannot legally be sold, even if there are no public health and safety concerns. This 'zero tolerance' approach has created issues for enforcement agencies and primary producers.

FSANZ has developed an approach to assess some of the agvet chemicals currently listed in Schedule 20 of the Code and proposed *an All other foods except animal food commodities* MRL to address 'zero tolerance' to the presence of low level inadvertent agvet chemical residues in food commodities. The approach has been piloted with 19 agvet chemicals, and includes a full risk assessment and dietary exposure assessment for each chemical. It was developed in consultation with the Australian Pesticides and Veterinary Medicines Authority (APVMA), which establishes MRLs for agvet chemicals registered for agricultural and veterinary use in Australia.

In the approach, the absence of existing MRLs for key animal food commodities caused major variations in the MRLs between plant and animal food commodities. To resolve this issue, animal food commodities have been excluded from this proposal and the descriptor modified to *All other foods except animal food commodities* MRLs, from the initially proposed descriptor *All other foods* MRLs.

The results of the dietary exposure assessment for the 19 chemicals indicate that the proposed *All other foods except animal food commodities* MRLs are safe and there are no public health and safety concerns.

Currently, there are six agvet chemicals that have *All other foods* MRLs in the Code but have not been included in this pilot assessment approach. It is anticipated these agvet chemicals would be assessed and their description changed to *All other foods except animal food commodities* through the proposed P1027 approach that would become an integral component of the APVMA MRL setting process¹ and the annual FSANZ MRL harmonisation process².

The Proposal has no impact on the Agreement between the Governments of Australia and New Zealand concerning a Joint Food Standards System (the Treaty) which excludes MRLs for agvet chemicals in food from the joint food standards setting system.

¹ Information on the APVMA MRL setting process is available at <u>http://test.apvma.gov.au/residues/setting.php</u> ² Information on the FSANZ MRL harmonisation process is available at

http://www.foodstandards.gov.au/code/changes/limits/Pages/MRL-proposals.aspx

1 Introduction

1.1 The Proposal

Proposal P1027 aims to address the issue of Australia's 'zero tolerance' approach to the presence of low level inadvertent agricultural and veterinary (agvet) chemical residues in food commodities. The Proposal sets out an approach that will allow for an *All other foods except animal food commodities* MRL to be set in the *Australia New Zealand Food Standards Code* for certain agvet chemicals where there are no public health and safety concerns.

FSANZ has piloted the approach (developed in consultation with the Australia Pesticides and Veterinary Medicines Authority (APVMA)) with 19 agvet chemicals. A full risk assessment and dietary exposure assessment was completed for each agvet chemical before an *All other foods except animal food commodities* MRL has been proposed.

No veterinary medicines were included in the pilot risk assessment approach because their use is species-specific and because of concerns about potential antimicrobial resistance. The establishment of MRLs for low level residues of veterinary drugs are not required because inadvertent residues should not occur for veterinary drugs. Veterinary drug residues should only occur where there are specific approved uses. Niche agvet chemical products and highly toxic agvet chemicals, such as rodenticides and vertebrate poisons, have also been excluded.

In piloting the approach, it was observed that the absence of MRLs for key animal food commodities for some agvet chemicals affected the proposed *All other foods except animal food commodities* MRLs. The approach considered the numerical value of existing MRLs and as animal food commodity MRLs are often lower than plant commodity MRLs, the outcome would have been an *All other foods except animal food commodities* MRL that was too low to allow for inadvertent presence of agvet pesticide residues in a plant commodity. However, if *All other foods except animal food commodities* MRLs, the permission for animal food commodities captured in an *All other foods except animal food commodities* MRL could be higher than those for animal food commodities MRL could be higher than those for animal food commodities were excluded and the descriptor modified to *All other foods except animal food commodities* MRLs from the initially proposed descriptor of *All other foods*.

The revised descriptor ensures that irrespective of whether the agvet chemical had MRLs established for key animal food commodities at the time of establishing the *All other foods except animal food commodities* MRLs, the proposed value would adequately account for the contribution of plant commodities with MRLs in the Code to the estimated dietary exposure.

The *All other foods except animal food commodities* category includes any plant food for which an MRL is not listed in the Code for a specific agvet chemical. This MRL category is used as a 'catch-all' for foods other than the primary commodity, raw agricultural commodity or derived foods that have MRLs currently listed in the Code. It also extends beyond the narrow Codex commodity definitions.

The established value for a specific agvet chemical in this MRL category is high enough to allow for the presence of inadvertent residues of that agvet chemical in plant commodities, but low enough to discourage off-label use of the agvet chemical. Changing the category description did not change the technical risk assessment approach used.

Supporting document 1 (SD1) contains details on how the *All other foods except animal food commodities* MRLs have been calculated.

1.2 The current Standard

Standard 1.4.2 and Schedule 20 set out the MRLs for agvet chemicals that are permitted in food commodities for sale in Australia. Under the current national food regulatory system (subject to some exceptions for food sourced from New Zealand, see Sections 1.4.1 and 2.5.1.3 below), there must be no detectable residue ('zero tolerance') of an agvet chemical in a food commodity for which an MRL has not been listed in the Code.

The MRLs in the Code constitute a mandatory requirement that apply to all food products of a particular class whether produced domestically or imported. The MRL ensures that residues of agvet chemicals in food commodities are kept as low as possible, and are consistent with the registered use of approved agvet chemicals to control pests and diseases in food production.

Schedule 20 currently has six agvet chemicals (Boscalid, Chlorantraniliprole, Cyantraniliprole, Cypermethrin, Fluensulfone and Fluxapyroxad) with *All other foods* MRLs set by the APVMA based on data from rotational crop trials. These agvet chemicals are not included in this approach developed to propose the *All other foods* except animal food commodities MRLs. However, they will have the *All other foods* MRLs reviewed and changed to *All other foods* except animal food commodities MRLs through the process that integrates the P1027 proposed approach into the regular FSANZ and APVMA MRL-setting process.

1.3 Reasons for preparing the Proposal

The purpose of this Proposal is to address issues posed by a 'zero tolerance' approach to food commodities for which an MRL has not been established in Schedule 20 of the Code. It proposes an approach to establish *All other foods except animal food commodities* MRLs to accommodate the presence of low level inadvertent residues of approved agvet chemicals in food commodities, thus removing the application of the 'zero tolerance' approach.

The 'zero tolerance' approach ensures that any food commodity presented for sale complies with the Code, and that compliance with the Code means the food when sold, is safe for consumers. It also provides an assurance that agvet chemicals have not been used illegally, or in a way that is contrary to label directions and approvals granted by the APVMA³. The current regulatory system for agvet chemicals poses a number of issues for the presence of low level inadvertent residues of approved agvet chemicals in food commodities. These include:

• During the production process, domestically-produced food, livestock or crops may have inadvertently been exposed to agvet chemicals that do not have an MRL listed in the Code for that specific chemical-food combination. These low level residues may be due to spray drift, crop rotation or use of packaging equipment. As the chemicals have no MRLs listed for the food commodities in which they are found, the foods are non-compliant with the Code, and are not regarded as legal for sale. This is the case even if the detected levels are considered to be of very low risk to public health.

³ Section 1.1 of the consultation paper provides the background and relevant details and is available on the FSANZ website <u>http://www.foodstandards.gov.au/code/proposals/Documents/P1027-ConsultPaper.pdf</u>

- Agvet chemicals are used differently in different countries around the world as pests, diseases and environmental factors vary and therefore the chemical use patterns may also vary. This means that agvet chemical residues in imported foods may legitimately differ from those in domestically produced foods. However, detections of non-complying residues of agvet chemicals in imported foods have previously led to disruptions in international food trade and considerable media and consumer interest, even though the very low levels of non-compliant agvet chemical residues may not present a health risk.
- Non-compliant agvet chemical residues in domestically produced and imported food are being identified more frequently because of improved sensitivity of analytical detection systems that can reliably detect amounts in parts per billion. As such, the requirement to ensure there is no detectable agvet chemical residue present in food for which no MRL is established is becoming increasingly strict. Consequently the obligation on food producers is becoming increasingly difficult to meet.
- Jurisdictions may divert resources from other more significant food safety tasks to address inadvertent technical breaches of the Code which may pose a very low health risk to consumers.

These are longstanding issues which the Food Regulation Standing Committee (FRSC), FSANZ, the APVMA and stakeholders have sought to address. The proposed approach addresses the potential for technical violations of the Code and permits the sale of food commodities containing legitimate levels of inadvertent agvet chemical residues assessed as safe.

The approach does not impact on other risk assessment measures available under Commonwealth, state or territory laws where food is non-compliant, including removal from the market. The 'zero tolerance' approach would still apply to agvet chemicals not listed in the Code and to agvet chemicals in commodities that are not listed in the Code where there are no All other foods except animal food commodities MRL.

The Proposal does not preclude an organisation or person from making an Application to FSANZ at any time for consideration of *All other foods except animal food commodities* MRLs for specific agvet chemicals.

1.4 International consideration

FSANZ and the APVMA have considered existing approaches used by other international regulatory agencies to address the issue of low level inadvertent agvet chemical residues in food commodities. To date, no international food regulator has established *All other foods except animal food commodities* MRL for inadvertent residues of agvet chemicals that may be found in or on food commodities.

Some international regulators use default MRLs for agvet chemicals for which MRLs have not been established, including the presence of inadvertent agvet chemical residues. Codex does not specify a default MRL for agvet chemicals without MRLs and has not established 'low level' MRLs for the purpose described.

Currently, there are two default values used by countries that have adopted the use of default MRLs (Table 1). Notably, these default MRL values are not based on dietary exposure assessments for each agvet chemical and do not take into account the agvet chemical's toxicity. This is in contrast to the case-by-case risk assessment approach proposed by FSANZ for establishing *All other foods except animal food commodities* MRLs.

Table 1: Summary of MRL default limits used by some developed countries

Country	Default MRL value (mg/kg)	When established and how used
Canada	0.1	Value set in the 1970s and applies where no specific MRL has been established for an agvet chemical.
European Union	0.01	Value set in 2005 and applies where no specific MRL has been established.
Japan	0.01	Value set after 2006 with introduction of the positive list system specifically for imported food.
New Zealand	0.1	Value set in the 1970s and applies where no specific MRL has been established for an agvet chemical.

The United States Environmental Protection Agency (USEPA) establishes MRLs (also called *Tolerances*) for pesticide residues that apply to various food and feed commodities⁴. There is no default 'Tolerance' (MRL), but exemptions do exist for so called 'Minimum Risk' products (e.g. garlic, garlic oil, sesame, sesame oil, clove, clove oil etc.). Therefore, in the USA unless the agvet chemical has an exemption, the residue level must comply with Federal Regulations.

In addition to inconsistencies in *default MRL* values between countries, other issues with using default limits were highlighted by Australian regulators are detailed in the 1st Call for submission report published in December 2014⁵. These include:

- Default limits may not adequately ensure that dietary exposure to an agvet chemical does not exceed relevant health based guidance values (HBGVs⁶) as they do not account for chemicals with HBGVs lower than the default limit.
- Existing default limits are usually equivalent to the Level of Determination (LOD) in most analytical assays, as it is the lowest concentration of agvet chemical residue that can be determined. However, the current increased capability to detect agvet chemical residue levels lower than an existing default value (e.g. 0.1 mg/kg or 0.01 mg/kg) with new analytical instruments means such default limits may become outdated.

For these reasons, FRSC did not adopt the *default MRL* option following previous public consultations on the draft policy guidelines to address the issues posed by a 'zero tolerance' approach to low level inadvertent agvet chemical residues in food commodities. FSANZ has therefore not pursued this option as it would be contrary to the requirements of the Forum Policy Guideline⁷ which in section 2a of the *High Order Policy Principles* indicates *the need for standards to be based on risk analysis using the best available scientific evidence.*

 ⁴ Information on the EPA approach to MRLs is available at <u>http://www2.epa.gov/pesticide-tolerances</u>
 ⁵ The 1st CFS report is available at <u>http://www.foodstandards.gov.au/code/proposals/Documents/P1027-</u>

ConsultPaper.docx

⁶ HBGVs for MRLs are the scientifically calculated amounts of the food chemical that can be ingested over a lifetime or in a short period without significant risk to health. Consumer exposure is only of concern if the estimated dietary exposure to a pesticide exceeds one of these set values.

⁷ The Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food is available at

http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Documents/Regulation%20of%20low%20level%20residues %20from%20Ag%20_%20Vet%20chemicals%20Oct%202006.pdf

1.4.1 Arrangements with New Zealand

Australia has a specific arrangement with New Zealand with regard to the transfer of food commodities across the Tasman through the Trans-Tasman Mutual Recognition Agreement (TTMRA⁸). The TTMRA is a non-treaty agreement between the Australian Government, Australian State and Territory Governments and the Government of New Zealand. Under the TTMRA with a few exceptions, a food commodity that is legally sold in New Zealand may be sold in Australia, and vice versa. This is regardless of differences in standards or other sale-related regulatory requirements between Australia and New Zealand.

Due to this arrangement, the proposed *All other foods except animal food commodities* MRL does not apply to food commodities imported into Australia from New Zealand. However, there is a temporary exemption mechanism in the TTMRA that gives participating jurisdictions the right to ban unilaterally, for 12 months, the sale of goods in their jurisdictions for health, safety or environmental reasons.

1.5 Procedure for assessment

The Proposal is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Summary of issues raised in submissions

FSANZ received sixteen submissions on the consultation paper released for comment in late 2014. The submissions were from domestic and overseas food industry groups and government departments. No comments were received from public health or consumer groups. All submitters agreed there was a need to address the existing 'zero tolerance' approach to low level inadvertent agvet chemical residues in food commodities because it places an unnecessary burden on the food industry and regulators, and restricts trade.

Submissions that supported the proposed approach (75%) agreed with underpinning the approach with a science-based process that includes a case-by-case dietary exposure assessment for each agvet chemical. There was also support for establishing All other foods except animal food commodities MRLs over the status quo, use of general default MRL or case-by-case risk assessment by individual jurisdictions.

Some stakeholders (25%) did not support the setting of *All other foods except animal food commodities* MRLs for agvet chemicals already listed in the Code. They would prefer the establishment of a general *Default MRL* for agvet chemicals without MRLs in the Code as used by New Zealand.

A number of food industry groups expressed concerns about the consistency of the proposed approach with that of international trading partners and the impact on trade. There were also comments relating to the absence of details on the risk assessment approach for the Proposal.

Submissions are available on the FSANZ website at http://www.foodstandards.gov.au/code/proposals/Pages/P1027.aspx.

A summary of the main issues raised in the submissions is provided in Table 2.

⁸ Details of the TTMRA are available at <u>https://www.coag.gov.au/the_trans-</u> tasman_mutual_recognition_arrangement

Table 2: Summary of issues

Issue	Raised by	FSANZ response
There is a need to amend the Code to address the current 'zero tolerance' approach to the inadvertent presence in food commodities of low level agvet chemicals without MRLs in the Code.	All 16 submissions	Noted. FSANZ has therefore proposed an approach that addresses the regulatory issue of technical violation of the Code by establishing an <i>All other foods except animal food commodities</i> MRL for some agvet chemicals.
Support the FSANZ proposed approach	 Agriculture and Agri-Food Canada Australian Mushroom Growers Association CropLife Australia Flavour and Fragrance Association of Australia and New Zealand WA Department of Health Grain Trade Australia NSW Food Authority Qld Health, Qld Department of Agriculture, Fisheries and Forestry and Safe Food Production Queensland Stock Feed Manufacturers' Council of Australia Victorian Department of Health and Human Services (DHHS) and Department of Economic Development, Jobs, Transport and Resources (DEDJTR) Victorian Farmers Federation (VFF) 	Noted.

Issue	Raised by	FSANZ response
Important that the proposed approach is underpinned by risk assessment principles including dietary exposure assessments for the specific agvet chemical.	 Agriculture and Agri-Food Canada CropLife Australia Flavour and Fragrance Association of Australia and New Zealand Grain Trade Australia DHHS and DEDJTR VFF WA Department of Health Qld Health and Qld Department of Agriculture, Fisheries and Forestry. 	Agrees. The proposed approach implemented by the proposed amendment to the Code is based on, and reflects, the outcome of risk assessments using the best scientific evidence available including dietary exposure assessments for each specific agvet chemical. See details in Attachment 2 - SD1
FSANZ to consider a default MRL approach. Disagree with the listed disadvantages of use of default MRL limits. For example, the Trans- Tasman Mutual Recognition Arrangement (TTMRA) allows food that meets New Zealand's default MRL requirement into Australia.	 Australian Food and Grocery Council (AFGC) Dairy Australia Food & Beverages Importers' Association Nutreco Nederland B.V. 	 Noted. FSANZ has had regard to the concerns raised by stakeholders but after consideration remains of the view that the proposed approach is a better option. The Consultation Paper (1st CFS) published in late 2014 listed the disadvantages of the default MRL model. FSANZ considers that these limitations remain valid. FSANZ also considers that the proposed approach overcomes the latter while complying with the Ministerial Policy Guideline provided to inform FSANZ's assessment of alternative models. The TTMRA is a specific arrangement with New Zealand by the COAG for cross-Tasman purposes.

Issue	Raised by	FSANZ response
The proposed approach does not address the increasing sensitivity of current chemical analytical methods.	 Agriculture and Agri-Food Canada: Market Access Secretariat, Asia and Oceania Division AFGC Australian Mushroom Growers Association Grain Trade Australia 	The proposed approach recognises that with increasingly sensitive analytical methodology, there is potential for increased detection of low levels of agvet chemicals, leading to residue non-compliance. For that reason, the current analytical level of detection for each agvet chemical is taken into consideration when setting the <i>All other</i> <i>foods except animal food commodities</i> MRL. The values would be set such that deliberate off-label use of an agvet chemical would be apparent compared to the inadvertent presence of the agvet chemical.
The proposed approach does not address consistency with international trading partners nor facilitate trade.	 AFGC CropLife Australia Dairy Australia Grain Trade Australia Qld Health 	Removal of the current 'zero tolerance' approach to agvet chemical residues present in food commodities due to inadvertent exposure represents a reduction of trade barriers. The approach proposed in P1027 is not for MRL harmonisation. Harmonisation with international MRLs to facilitate trade is addressed through FSANZ's annual MRL harmonisation proposal process, noting that agvet chemicals are used differently in different countries around the world due to differences in pests, diseases and environmental factors and therefore the chemical use patterns may differ.
FSANZ to consider consistency with other international MRLs e.g. Codex, USA and the European Union.	 AFGC Dairy Australia Grain Trade Australia VFF 	 For food import purposes, FSANZ currently has an annual MRL harmonisation program and considers all requests to harmonise with a Codex or trading partner MRL, recognising and supporting the Codex principles for setting MRLs. Information on FSANZ's MRL harmonisation process is available at http://www.foodstandards.gov.au/code/changes/limits/Pages/MRL-proposals.aspx The P1027 proposed approach is consistent with the effective regulation of the registration, permission and use of agvet chemicals in Australia through the APVMA. It does not duplicate the current MRL harmonisation program by FSANZ.

Issue	Raised by	FSANZ response
 The proposed approach: Does not cover trade policy issues relating to Principle number 2 of the High Order Policy Principles. Is not consistent with guidelines 4 and 5 of the Specific Policy Principles of the policy guideline and provides no certainty or benefits to the Australian food industry. Is not consistent with Australia's obligations under the World Trade Organisation (WTO) Sanitary and Phytosanitary Agreement 	• AFGC	 FSANZ remains satisfied that the proposed approach is consistent with the Ministerial Guideline. The proposed approach: removes 'zero tolerance' MRLs for both imported and domestic products where there is no health risk, thereby facilitating trade. sets an MRLs for both domestic and imported foods where appropriate, and adopts a consistent methodology in order to do so. is consistent with Australia's obligation under the SPS Agreement. Although the approach is not identical to those of some international trading partners, it is consistent with Australia's obligations under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures as the measures contained in the draft variation are based on a robust scientific risk assessment. It also promotes the use of a consistent methodology for setting MRLs for both domestic and imported foods where appropriate. The purpose of this approach is to address the presence of low levels of inadvertent agvet chemical residues in food commodities following legitimate use of the agvet chemicals on other crops, and which would constitute a technical violation of the Code.
The scope of P1027 should be extended to include some veterinary chemicals/ food combinations and derived products.	 AFGC Australian Mushroom Growers Association Food and Beverages Importers Association Nutreco Nederland B.V DEDJTR DHHS WA Department of Agriculture and Food WA Department of Health 	 Noted. The aim of the proposal to: develop an approach to address the presence in food of inadvertent low level agvet chemicals already permitted in Schedule 20 of the Code; and use that approach in a pilot assessment to establish <i>All other foods except animal food commodities</i> MRLs for <i>specific</i> agvet chemical/food combinations in the chemical categories of herbicides, fungicides and insecticides. Veterinary medicines were not included in the pilot assessment process because their use is species-specific and because of concerns about potential antimicrobial resistance.

Issue	Raised by	FSANZ response
		Amendment of the Code to include <i>All other foods except animal food commodities</i> MRLs for veterinary chemicals can be considered in the future through Proposals or Applications.
The proposed approach is resource intensive, not pragmatic and may be unworkable.	 Australian Food and Grocery Council Food and Beverages Importers Association NSW Food Authority Nutreco Nederland B.V 	 FSANZ acknowledges that to establish new protocols and develop the approach to propose <i>All other foods except animal food commodities</i> MRLs requires considerable effort and input on its part. However, this project has been prioritised due to the long-standing need to address issues associated with the 'zero tolerance' approach to low level inadvertent agvet chemical residues in food commodities in Standard 1.4.2. Once established and approved, it is anticipated that the process would become part of FSANZ's routine MRL procedures.
Comprehensive assessment of alternative approaches was not undertaken		Disagrees. FSANZ has had regard to the assessment of alternative approaches considered by the Food Regulation Standing Committee working group on the issue. Based on this earlier assessment and further stakeholder consultations in 2014, FSANZ concluded that the reasons for the rejection of the alternatives presented at the time are still valid. FSANZ has developed the current suggested alternative approach that would expedite action, and provide a transparent workable option for the food industry and enforcement agencies.

Issue	Raised by	FSANZ response
Insufficient detail is provided on the application and management of the proposed approach	 Australian Food and Grocery Council CropLife Australia Qld Department of Agriculture, Fisheries and Forestry Qld Health and Safe Food Queensland. 	Noted. Further detail is provided in this call for submissions. FSANZ has developed and refined the protocols and approach (see SD1) following release of the Consultation Paper (1 st CFS) and after further consultation with a range of stakeholders particularly the APVMA.
The APVMA MRL Standard should continue to be the primary reference for good agricultural practice.	 DHHS DEDJTR WA Department of Health 	Agrees. The proposed approach would not replace the APVMA MRL Standard as the primary reference for use of agvet chemicals in Australia. However, it is consistent with the APVMA's risk assessment framework for approving and registering agvet chemical products, and with the risk assessment process for setting MRLs. The approach also allows FSANZ and the APVMA to review the MRLs as required based on new scientific information and data made available through state/territory and border regulatory activities.

2.2 Risk assessment

The presence of low levels of inadvertent agvet chemical residues in food commodities does not necessarily represent a food safety risk. However, to confirm the absence of a risk to consumers, an assessment of the Australian population's estimated short term and/or chronic dietary exposure to the agvet chemical residue was undertaken.

A manageable sub-set of agvet chemicals currently listed in Schedule 20 was selected and used for the pilot risk assessment approach developed by FSANZ in consultation with the APVMA. The selection of the agvet chemical and risk assessment process included screening criteria, established principles, and a case-by-case dietary exposure assessment (DEA). The approach is detailed in SD1.

The risk assessment process consisted of two stages:

- Stage 1(screening phase) a sub-set of agvet chemicals for consideration was compiled from imported food inspection data from the Department of Agriculture and Water Resources, data from the APVMA and state-based enforcement agencies. This process produced a list of 132 agvet chemicals (from approximately 500 agvet chemicals in Schedule 20 in the Code). The short list of agvet chemicals was then screened (see SD1) to generate a list of 19 agvet chemicals for case-by-case consideration in the second stage of the risk assessment process. The screening criteria included factors such as existing MRL permissions, available health-based guidance values (HBGVs⁹), chemical analytical limits and food consumption data. Figure 1 provides an overview of the screening and dietary exposure assessment process.
- Stage 2 (exposure assessment phase) an estimate of the dietary exposure resulting from all food permissions including the proposed *All other foods except animal food commodities* MRLs was calculated for each of the agvet chemicals that passed the Stage 1 screening criteria. This stage used the dietary exposure assessment approach developed in consultation with the APVMA which includes key principles to establish *All other foods except animal food commodities* MRL values on a case-by-case basis for each agvet chemical in the selected list of agvet chemicals. The details are provided in SD1.

The principles established, provide a consistent, appropriate and scientifically robust risk assessment approach that used internationally agreed methodologies and undertook DEAs for each agvet chemical in addition to supporting good agricultural practice.

The assessment considered current estimates of dietary exposure from existing MRL permissions and a conservative 'worst case' assessment of the potential additional contribution to dietary exposure from *All other foods except animal food commodities* MRLs. Both chronic, and where appropriate, acute dietary exposures were considered. HBGVs used in the DEAs were those listed on the web pages of the Australian Government's Office of Chemical Safety (OCS) or the Food and Agricultural Organization/World Health Organization's (FAO/WHO) Joint Meeting of Pesticide Residues (JMPR). Overall, an agreed principle was that the *All other foods except animal food commodities* MRL should be low enough to ensure the *All other foods except animal food commodities* contribution to total chronic dietary exposure would not exceed approximately 20% at the time the MRL was proposed. This is to enable future commodity-specific MRLs for a chemical and not result in dietary exposure estimates that exceeded relevant HBGVs.

⁹ HBGVs include the Acceptable Daily Intake (ADI) or the Acute Reference Dose (ARfD). See Glossary in the supporting document (SD1) for definition of ADI and ARfD.

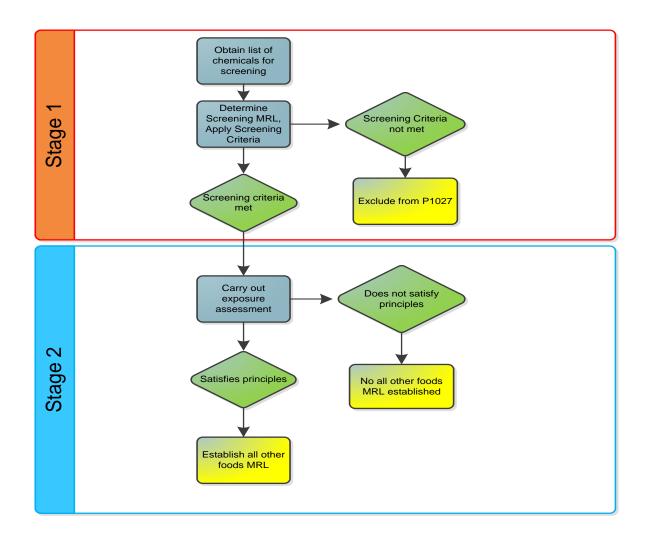


Figure 1: Overview of the process for establishing All other foods except animal food commodities MRLs

At the end of this process, the estimated dietary exposures estimates for the agvet chemical residues did not exceed their respective HBGVs, therefore FSANZ assessed the proposed *All other foods except animal food commodities* MRLs as acceptable and unlikely to pose health and safety risks to Australian consumers. *All other foods except animal food commodities* MRLs were therefore proposed for: 2-phenylphenol, ametoctradin, azoxystrobin, bifenthrin, captan, cyfluthrin, deltamethrin, fenhexamid, fludioxonil, glyphosate, iprodione, methomyl, thiodicarb, penthiopyrad, pyrimethanil, spinosad, thiabendazole, triadimefon and triadimenol.

The principles and processes used to propose *All other foods except animal food commodities* MRL for the listed chemicals protect the health and safety of the Australian population, while also being practical and adequately manage the risk of off-label use. They also provide a consistent approach for reviewing agvet chemicals listed in Schedule 20 to establish *All other foods except animal food commodities* MRLs on a case-by-case basis where appropriate when considering future amendments to Schedule 20.

2.3 Risk management

State and territory governments implement, monitor and enforce the MRL requirements in the Code, and the Australian Government Department of Agriculture and Water Resources (Department of Agriculture) monitors compliance of imported products with the Code at the border. Presently, if a non-compliant agvet chemical residue is detected in a food commodity, the relevant authority must consider whether to remove the food from the market or institute criminal action against the food producer for the sale (or intended sale) of the food.

Under this Proposal, the 'zero tolerance' approach would not apply to all low level inadvertent agvet chemical residues in food commodities. The *All other foods except animal food commodities* MRLs would permit the sale of foods with legitimate levels of inadvertent agvet chemical residues assessed as safe.

It removes the regulatory burden on jurisdictions to undertake case-by-case risk assessments when non-compliance to the Code is due to low level inadvertent agvet chemical residues in food commodities, and provides a uniform enforcement approach. In relation to imported food commodities, the *All other foods except animal food commodities* MRL in the Code provides a clear and transparent monitoring level for food producers and the Department of Agriculture.

The 'zero tolerance' approach would still apply to agvet chemicals not already listed in the Code or those deemed not appropriate to have an *All other foods except animal food commodities* MRLs. In addition, other risk management measures currently available under Commonwealth, state or territory laws are maintained where food commodities that do not comply with the Code can be removed from the food supply.

Figure 2 provides the additional step that would be added to current processes by the APVMA and FSANZ to establish MRLs to include *All other foods except animal food commodities* in the risk management process. The additional step is noted under 'FSANZ Process' in the green box. The term 'Forum' in Figure 2 refers to the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum).

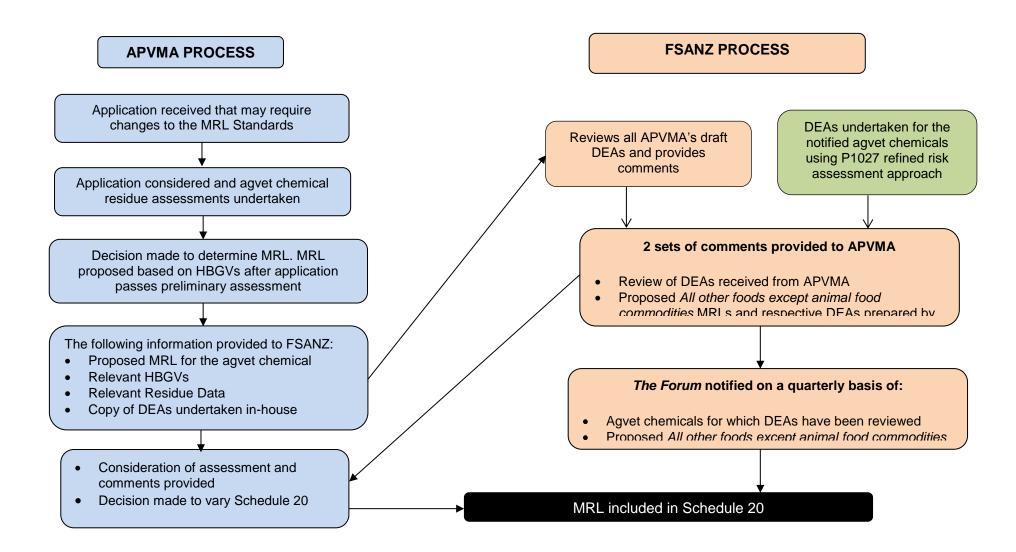


Figure 2: Proposed summary process for integrating the establishment of 'All other foods except animal food commodities' MRLs into the regular MRL process

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process.

FSANZ initially consulted on this Proposal as outlined in section 2.1. FSANZ has also worked closely with the APVMA to develop the risk assessment methodology used to establish the *All other foods except animal food commodities* MRLs.

In December 2014, FSANZ called for submissions on a consultation paper. All calls for submissions are notified in the FSANZ Notification Circular with a media release, through social media and Food Standards News, as well as through email alerts.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Proposal. Every submission on a proposal is considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment. Individuals and organisations that make submissions on this Proposal will be notified at each stage of the assessment.

If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Forum. If the Board's decision is not subject to a request for a review, stakeholders, including the public, will be notified of the gazettal of the variation to the Code on the website and through email notifications.

2.4.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia is obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards. Amending the Code to incorporate *All other foods except animal food commodities* MRLs is unlikely to have a significant adverse effect on international trade as it liberalises trade by enabling food commodities containing inadvertent residues of agvet chemicals approved for use and assessed as safe to be sold. It also provides agvet chemical users, importers and regulators with a clear and transparent compliance target for monitoring inadvertent agvet chemical residues in food commodities. The *All other foods except animal food commodities* MRLs will be based on robust scientific risk assessments.

However, a notification to the WTO under Australia's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement has been made to enable other WTO members to comment on the proposed variations.

2.5 FSANZ Act assessment requirements

When assessing this Proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

2.5.1 Section 59

2.5.1.1 Cost benefit analysis

The direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Proposal outweigh the costs to the community, Government or industry.

A cost-benefit analysis is not required for the Proposal because the proposed variation to the Code is minor in nature. The Office of Best Practice Regulation has previously stated (ID 12065) that no further analysis in the form of a Regulation Impact Statement is required for MRL amendments.

The proposed MRL variation to the Code benefits state and territory regulatory agencies, primary producers and importers in that it removes the 'zero tolerance' approach to the presence of inadvertent agvet chemical residues in food commodities without MRLs, by establishing *All other foods except animal food commodities* MRLs for those assessed as safe. It also liberalises trade (domestic and overseas) and may increase the choice of food available to consumers.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more costeffective than a food regulatory measure developed or varied as a result of the Proposal. FSANZ has considered the issues raised by submitters and remains of the view that the proposed approach is a better option and overcomes the limitations of default MRLs while minimising direct and indirect costs to food producers and industry.

2.5.1.3 Any relevant New Zealand standards

The Agreement between the Governments of Australia and New Zealand concerning a Joint Food Standards System (the Treaty) excludes MRLs for agvet chemical residues in food from the system that sets joint food standards. Therefore, Australia and New Zealand, independently and separately develop MRLs for agvet chemical residues in food commodities. However, under the TTMRA, Australia and New Zealand accept food commodities that are legal for sale in each country regardless of the sale-related regulatory requirements in the individual country.

All domestically produced food sold in New Zealand must comply with the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2012 and any amendments (the New Zealand MRL Standards). If food is imported into New Zealand, such food must comply either with the New Zealand MRL Standards or with Codex MRLs (except for food imported from Australia).

Under the New Zealand MRL Standards, agricultural chemical residues in food must comply with the specific MRLs listed in the Standards. The New Zealand MRL Standards also include a provision for residues of up to 0.1 mg/kg for agricultural chemical/commodity combinations not specifically listed.

Further information about the New Zealand MRL Standards is available on the New Zealand Ministry for Primary Industries website¹⁰.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

¹⁰ <u>http://www.foodsafety.govt.nz/industry/sectors/plant-products/pesticide-mrl/</u>

2.5.2.1 Protection of public health and safety

Based on the outcome of the risk assessment described above and in SD1, FSANZ is satisfied that the proposed *All other foods except animal food commodities* MRL provided for each agvet chemical in the draft variation does not pose any health or safety risk to Australian consumers.

2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

The objective is not relevant to matters under consideration in the Proposal.

2.5.2.3 The prevention of misleading or deceptive conduct

The objective is not relevant to matters under consideration in the Proposal.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

• the need for standards to be based on risk analysis using the best available scientific evidence

FSANZ is satisfied that the measures contained in the draft variation are based on a risk assessment undertaken using the best scientific evidence available.

• the promotion of consistency between domestic and international food standards

The proposed *All other foods except animal food commodities* MRL variations provide a consistent and scientific approach to addressing legitimate levels of inadvertent agvet chemical residues (assessed as safe) in food commodities, whether domestically produced or imported. Harmonisation of domestic standards (Standard 1.4.2 and related Schedules) with international standards (Codex and others) is addressed through FSANZ's annual MRL harmonisation process.

• the desirability of an efficient and internationally competitive food industry

The proposed variation ensures clarity around legitimate inadvertent chemical residues in food commodities, and is a transparent, effective and efficient approach.

The variation addresses the regulatory challenge posed by the 'zero tolerance' approach to inadvertent chemical residues in food commodities that result from legitimate use of the chemicals on other crops. It also facilitates trade through the remove of unwarranted regulation ('zero tolerance') by proposing the *All other foods except animal food commodities* MRLs.

• the promotion of fair trading in food

The amendment enables the sale of food commodities that have been in technical violation of the Code and deemed unsaleable. This is supported by information in section 2.5.1.1.

• any written policy guidelines formulated by the Forum on Food Regulation

The draft variation was developed in accordance with the Policy Guideline on the *Regulation* of *Residues of Agricultural and Veterinary Chemicals in Food*. In particular, the *Specific Policy Principles* that apply to alternative approaches that FSANZ might consider for addressing issues surrounding the 'zero tolerance' approach to the enforcement of the Code.

FSANZ is satisfied that the proposed approach is consistent with the Ministerial Guideline in that it:

- removes 'zero tolerance' MRLs for both imported and domestic products where the agvet chemicals residue levels are assessed as safe and would not pose health risk to Australian consumers
- sets MRLs for both domestic and imported foods where appropriate, and adopts a consistent methodology in doing so
- is consistent with Australia's obligation under the WTO/ SPS Agreement.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

Attachments

- A. Draft variation to the Australia New Zealand Food Standards Code
- B. Draft Explanatory Statement

Attachment A – Draft variation to the Australia New Zealand Food Standards Code



Food Standards (Proposal P1027 – Managing Low-level Ag & Vet Chemicals without MRLs) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the Food Standards (Proposal P1027 – Managing Low-level Ag & Vet Chemicals without MRLs) Variation.

2 Variation to a standard in the Australia New Zealand Food Standards Code

The Schedule varies as Standard in the Australia New Zealand Food Standards Code.

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Schedule 20 is varied by

- [1.1] omitting paragraph S20—2(b) and substituting
 - (b) the symbol 'T' indicates that the maximum residue limit is a temporary maximum residue limit
 - (c) **animal food commodities** means an animal food commodity listed in Schedule 22, including secondary commodity of animal origin listed in that Schedule

[1.2] inserting in the table to section S20—3 for each of the following agvet chemicals, the foods and associated MRLs in alphabetical order

Agvet chemical: Ametoctradin	Agvet chemical: Deltamethrin
Permitted residue—commodities of plant origin:	Permitted residue: Deltamethrin
Ametoctradin Permitted residue—commodities of animal origin:	All other foods except animal food 0.05 commodities
Sum of ametoctradin and 6-(7-amino-5-ethyl [1,2,4] triazolo [1,5-a] pyrimidin-6-yl) hexanoic acid	Annat chamical. Fankayanid
All other foods except animal food 0.2	Agvet chemical: Fenhexamid
commodities	Permitted residue: Fenhexamid
Anvet chemical: Azovyetrohin	All other foods except animal food 0.1 commodities
Agvet chemical: Azoxystrobin	
Permitted residue: Azoxystrobin	Agvet chemical: Fludioxonil
All other foods except animal food 0.1 commodities	Permitted residue—commodities of animal origin. Sum of fludioxonil and oxidisable metabolites,
Agvet chemical: Bifenthrin	expressed as fludioxonil
Permitted residue: Bifenthrin	Permitted residue—commodities of plant origin: Fludioxonil
All other foods except animal food 0.03 commodities	All other foods except animal food 0.02 commodities
Agvet chemical: Captan	Agvet chemical: Glyphosate
Permitted residue: Captan	Permitted residue: Sum of glyphosate and
All other foods except animal food 0.1 commodities	Aminomethylphosphonic acid (AMPA) metabolite, expressed as glyphosate
	All other foods except animal food 0.2
Agvet chemical: Cyfluthrin	commodities
Permitted residue: Cyfluthrin, sum of isomers	Agvet chemical: Iprodione
All other foods except animal food 0.05 commodities	Permitted residue: Iprodione
	All other foods except animal food 0.1 commodities

Agvet chemical: Methomyl		Agvet ch
Permitted residue: Methomyl		Permitted
All other foods except animal food	0.05	triadimeno
commodities		see also 7
Aquat abamical: Ponthianurad		All other for commodition
Agvet chemical: Penthiopyrad		commoun
Permitted residue—commodities of plant ori Penthiopyrad	gin:	Agvet ch
Permitted residue—commodities of animal of	origin:	Permitted
Sum of penthiopyrad and 1-methyl-3- (trifluoromethyl)-1H-pyrazol-4-ylcarboxamide	۵	see also 7
expressed as penthiopyrad	σ,	All other f
All other foods except animal food commodities	0.05	commodit
Agvet chemical: 2-Phenylphenol		
Permitted residue: Sum of 2-phenylphenol a phenylphenate, expressed as 2-phenylphen		
All other foods except animal food commodities	0.1	
All other foods except animal food commodities	0.1	
Agvet chemical: Spinosad		
Permitted residue: Sum of spinosyn A and s D	spinosyn	
All other foods except animal food commodities	0.01	
Agvet chemical: Thiabendazole		
Permitted residue—commodities of plant or Thiabendazole	igin:	
Permitted residue—commodities of animal of Sum of thiabendazole and 5-hydroxylthiaben expressed as thiabendazole		
All other foods except animal food commodities	0.03	
Agvet chemical: Thiodicarb		
Permitted residue: Sum of thiodicarb and methodicarb and methodicarb	nethomyl,	
All other foods except animal food	0.1	

All other foods except animal food	0.1
commodities	

mical: Triadimefon

esidue: Sum of triadimefon and expressed as triadimefon

see also	Triadimenol
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All other foods except animal food	0.05
commodities	

mical: Triadimenol

esidue: Triadimenol

riadimefon

All other foods except animal food	0.05
commodities	

Attachment B – Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a Proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a Proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P1027 to manage the presence in food commodities of low level inadvertent agvet chemical residues without MRLs in the Code. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has prepared a draft Standard.

2. Purpose

The Authority has prepared the amendment to establish for agvet chemicals already listed in the Code, *All other foods except animal food commodities* MRLs for the presence of low level inadvertent residues of agvet chemical residues in food commodities.

Section 3 in Schedule 20 lists the limits for agvet chemical residues permitted in food commodities. Under current regulatory requirements, if a particular agvet chemical/food combination has no MRL listed in the Code, the food must not have detectable residues of that agvet chemical. This general prohibition, referred to as 'zero tolerance', means that food commodities containing low level inadvertent residues of an agvet chemical without MRLs in the Code cannot be sold on the Australian market.

The *All other foods except animal food commodities* MRLs proposed for the specific agvet chemicals are based on the risk assessment approach developed for the Proposal. The dietary exposure assessments indicate that the proposed *All other foods except animal food commodities* MRLs would not pose public health and safety risks to consumers.

The *All other foods except animal food commodities* MRLs in the Code would remove application of the 'zero tolerance' approach to the presence of low level inadvertent agvet chemical residues in food commodities, and prevent such food from being in breach of the Code. It would also ensure that the food commodities can be legally traded as they are assessed as safe.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1027 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated report. An initial round of public consultation was undertaken to assist consideration of the proposed approach following preparation of the Proposal.

A Regulation Impact Statement was not required because the proposed variations to Schedule 20 are likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item 1.1 inserts into section S20—3 of Schedule 20 a definition for *animal food commodities* The term is defined to mean an animal food commodity listed in Schedule 22, including secondary commodity of animal origin listed in Schedule 22.

Item 1.2 amends the table to section S20-3 by inserting *All other foods except animal food commodities* and associated MRLs for the listed agvet chemicals.