

16 December 2014
[26–14]

Consultation Paper – Proposal P1027

Managing Low-level Ag & Vet Chemicals without Maximum Residue Limits

FSANZ has prepared a proposal to manage the presence of low-level residues of agricultural and veterinary chemicals without specific maximum residue limits (MRLs). Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions on a consultation paper to assist consideration of the proposed approach.

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 [information for submitters](#).

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 [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

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) 10 February 2015

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 standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
CANBERRA BC ACT 2610
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel +64 4 978 5630

Table of Contents

EXECUTIVE SUMMARY.....	2
1 INTRODUCTION	3
1.1 BACKGROUND.....	3
1.1.1 Ministerial Policy Guidelines	3
1.2 THE CURRENT STANDARD.....	5
1.2.1 Existing processes for varying Standard 1.4.2.....	5
1.3 REASONS FOR PREPARING THE PROPOSAL.....	6
1.4 PROCEDURE FOR ASSESSMENT	7
2. PROPOSED APPROACH	7
2.1 SCOPE	7
2.2 RISK ASSESSMENT	8
2.3 RISK MANAGEMENT	8
2.3.1 Cost benefit analysis.....	9
2.4 RISK COMMUNICATION.....	9
2.4.1 Consultation.....	9
2.4.2 World Trade Organization (WTO).....	9

Executive summary

Standard 1.4.2 in the *Australia New Zealand Food Standards Code* (the Code) sets limits for residues of agricultural and veterinary (agvet) chemicals permitted in food. Maximum residue limits (MRLs) are listed in the schedules to the Standard for permitted chemicals, along with the specific commodities or food products that may contain them. Under current Australian state, territory and Commonwealth Government food legislation, there must be no detectable residue (zero tolerance) in a food commodity for which an MRL has not been set in Standard 1.4.2.

Under certain circumstances, for example, due to spray drift or in some rotational crop situations, 'inadvertent' or 'adventitious' residues may be found in food commodities following legitimate use of an agvet chemical. Foods containing low levels of residues with no MRL are illegal for sale; even if the residue poses a very low or no risk to public health. The zero tolerance approach places a significant burden on industry and jurisdictions.

The Ministerial Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food¹ (Policy Guideline) provides specific principles for FSANZ to consider when suggesting alternative approaches that might address issues with the current 'zero tolerance' approach for regulating agricultural and veterinary chemical residues in food.

This Proposal has been prepared to consider an approach that sets MRLs for '*all other foods*' to address the inadvertent presence of low level chemical residues in food commodities that were not treated with a specific agvet chemical product.

Under this Proposal, specific MRLs in Standard 1.4.2 would be set at an appropriate level for *all other foods* to account for inadvertent low levels of residues for a nominated set of agvet chemicals. The levels set will be underpinned by a risk assessment which includes a dietary exposure assessment for the whole population. This means the foods in the *all other foods* category for certain agvet chemicals could legally be sold on the Australian market, when they contain residues up to the low level MRL. The approach, which would apply to domestic and imported foods, also means state/territory regulatory authorities would not have to put resources into the individual assessment of non-compliant food.

The zero tolerance approach would still apply to chemicals not already listed in Schedule 1 of Standard 1.4.2 as well as veterinary medicines, niche products and/or highly toxic chemicals with low health-based guidance values. Other risk management measures available under Commonwealth, state or territory laws, including removing a food from the food supply, will remain open to enforcement agencies if needed.

¹ The Policy Guideline was notified to FSANZ by the then Australia and New Zealand Food Regulation Ministerial Council on 31 October 2006
<http://www.foodstandards.gov.au/media/Pages/mediareleases/mediareleases2006/jointcommuniquefoodm3392>
and is available at <http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-consult-previous#residues>

1 Introduction

1.1 Background

Under the current MRL provisions in the Code (Schedule 1 of Standard 1.4.2), there must be no detectable residues of any chemical in a food commodity for which an MRL has not been established. This establishes a “zero tolerance” for any residue not accommodated by an existing MRL/food listing in the standard.

The purpose of the zero tolerance approach is to ensure 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 Australian Pesticides and Veterinary Medicines Authority (APVMA).

However, under certain circumstances, ‘inadvertent’ or ‘adventitious’ residues may be found in food commodities following legitimate use of an agvet chemical. In such situations, the presence of an inadvertent residue leads to a non-compliance of the Code. State and territory authorities through trace-back investigations often find that products have been used legally but the presence of the residue was unavoidable. In these situations, the residue itself may not pose a risk to public health and the food could be safely consumed. The regulatory challenge is to provide a way in which the food could be supplied for sale providing there are no food safety issues, while also addressing the current issue of a potential technical violation of the Code.

1.1.1 Ministerial Policy Guidelines

The Food Regulation Standing Committee (FRSC) has previously established a working group to address this issue and consulted on draft Ministerial Policy Guidelines about an alternative approach to address issues surrounding the regulation of low level residues of agvet chemicals in food.

Following consultation, the Policy Guideline² was approved and notified to FSANZ. The Policy Guideline provides specific principles for FSANZ to consider in suggesting alternative approaches to address the current ‘zero tolerance’ approach. The specific principles state that any changes to the existing regulatory approach for the regulation of residues of agvet chemicals in food should;

1. recognise the need to respond to any unexpected presence of residues in an efficient and timely manner,
2. not reduce the capacity of governments to prohibit the presence of any residue of a particular chemical in food where it would present an unacceptable public health risk,
3. be consistent with the effective regulation of the registration, permission and use of agricultural and veterinary chemicals,
4. promote a consistent approach to MRLs for both domestic and imported foods where appropriate, and
5. be consistent with Australia’s obligations under the World Trade Organisation (WTO) Sanitary and Phytosanitary Agreement (SPS Agreement).

²[http://www.health.gov.au/internet/main/publishing.nsf/Content/4DCF744789D1AF64CA257BF0001C9622/\\$File/Policy-Guideline-on-the-Regulation-of-Residues-of-Agricultural&Veterinary-Chemicals-Food.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/4DCF744789D1AF64CA257BF0001C9622/$File/Policy-Guideline-on-the-Regulation-of-Residues-of-Agricultural&Veterinary-Chemicals-Food.pdf)

Stakeholder responses³ to the Policy Guideline generally recognised the need for review of the current zero tolerance approach seeing it as unacceptable and unsustainable (for the reasons provided in Section 1.3).

1.1.1.1 Default Limits: regulatory benefits and disadvantages

The FRSC Policy Guidelines originally consulted on the proposal to establish a 'default MRL' to accommodate low level residues for all chemicals. Some international regulators such as Canada, the European Union (EU), and New Zealand have a default limit system. Japan also uses a default limit (uniform limit), established after 2006 when the positive list system was introduced specifically for imported food. Codex does not specify a default MRL for agvet chemicals without MRLs. Other than possibly introducing a default limit, no other solution was proposed by FRSC at the time.

Discussions with international regulators that have had default limits in place for many years, uncovered various issues that required further consideration. One of the key benefits that a default limit provides is a clear measurable target that is uniformly applied across all chemicals. It also provides a transparent standard that is easy to understand and apply. With modern analytical techniques, the limit should also be easy to achieve. Most default limits are in place in countries where a large proportion of food is imported.

However, some disadvantages of default limits highlighted by regulators include:

- Inconsistency between default limits in different countries i.e. Canada and New Zealand's default limits are quite high, being 0.1 mg/kg compared to the default limit of 0.01 mg/kg in the EU and Japan. These defaults were imposed before short-term dietary risk assessments were routinely conducted for setting MRLs for chemicals with an acute reference dose (ARfD).
- High default limits of 0.1 mg/kg do not adequately account for potential dietary exposures of chemicals with an ARfD where the residue can be detected at low levels. Similarly, they do not account for chemicals where the ADI and the ARfD are lower than 0.1 mg/kg.
- With new analytical instrumentation and the capability to detect down to levels lower than 0.01 mg/kg, a default limit would be outdated quickly.
- Some exclusions or exceptions would need to apply to account for chemicals that are highly toxic and able to be detected at very low levels. For example fipronil can be detected at 0.0005 mg/kg and lower, and has an ADI of 0.0002 mg/kg body weight and an ARfD of 0.02 mg/kg body weight.

For some of the reasons above, the default limit option proposed in 2006 was not adopted in Australia and these issues remain valid..

1.1.1.2 Case-by-case risk assessment by relevant authorities

FSANZ also considered an approach which would permit regulatory agencies to respond to unexpected low level agvet chemical residues in foods.

³[http://www.health.gov.au/internet/main/publishing.nsf/Content/A294B740C7928C3CCA257BF0001CFFF4/\\$File/eq-res-agvet-chem-summary.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/A294B740C7928C3CCA257BF0001CFFF4/$File/eq-res-agvet-chem-summary.pdf)

Under this approach, regulatory agencies would carry out a case-by-case risk assessment, and if the residue posed a low risk to public health and safety the food could be sold if approved by an authorised officer of a relevant authority. In this way, some low level residues would be deemed compliant with the Code.

This approach was considered an efficient response and met the *High Order Policy Principles* and objectives set by the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council for developing or reviewing food regulatory measures around the protection of public health and safety. However, disadvantages to this approach were identified including:

- decreased harmonisation in approaches of enforcement agencies (including state/territory food jurisdictions and Department of Agriculture at the border) to assess compliance with standards, confounding the situation for food or commodities that are moved across state borders (or are imported)
- lack of clear information for food producers that supply to retailers under Quality Assurance programs on acceptable residue levels
- lack of a clear limit for users of the Code when inadvertent residues are found
- lack of a transparent regulatory change for importers bringing food commodities into Australia
- an increase in regulatory burden for jurisdictions (food and primary industry departments) if risk assessments have to be conducted every time a non-compliant residue is found

For the reasons above, FSANZ has taken the approach outlined in this Proposal that aims to maintain public health and protect the safety of consumers and also facilitate trade.

1.2 The current Standard

Standard 1.4.2 regulates the residues of agvet chemicals that are permitted in food. MRLs are listed in the Schedules to the Standard for permitted chemicals along with the specific commodities or food products that may contain them.

Standard 1.4.2 applies to food in Australia only and applies to both domestically-produced and imported foods. New Zealand has its own standards for chemical residues in food set in a MRL Standard issued under 11C and 11L of the *Food Act 1981*. Food imported into Australia from New Zealand that complies with New Zealand regulations is exempt from complying with Standard 1.4.2 under the Trans-Tasman Mutual Recognition Arrangement.

1.2.1 Existing processes for varying Standard 1.4.2

There are two routes for establishing or changing MRLs. The first is through an APVMA-led process as a result of an application to the APVMA for domestic use of an agvet chemical. The second mechanism is through a FSANZ-led process to raise a proposal to change MRLs.

Since March 2011, the APVMA has been able to amend Schedule 1 of Standard 1.4.2 under the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

This delegation of power formed part of the package of amendments to the FSANZ Act that were made to give effect to the Council of Australian Governments' reform to streamline the domestic food MRL standards development process.

FSANZ may also vary Standard 1.4.2. In general, FSANZ prepares one proposal per year to consider variations including consideration of MRL variations proposed by the APVMA through their chemical review process, as well as MRL import harmonisation requests from other interested parties. An Application may also be made to FSANZ to vary Standard 1.4.2.

1.3 Reasons for preparing the Proposal

Currently, under Australian state, territory and Commonwealth Government food legislation (subject to some exceptions for food from New Zealand), there must be no detectable residue (zero tolerance) in a food commodity for which an MRL has not been established in Standard 1.4.2.

The Public Consultation Paper on the Draft Ministerial Policy Guidelines (April 2006) articulated a number of issues with the current regulatory system:

- when low level residues of agvet chemicals with no MRL are found in food, the food commodity becomes illegal for sale even if it poses a very low risk to public health
- the current zero tolerance approach fails to recognise the increasing sensitivity of analytical techniques
- very low but detectable residues may occur in commodities following legitimate use of a chemical, for which no MRL has previously been established
- trade issues associated with domestic and imported food.

State and territory food laws specify that food is unsuitable for sale if it contains a chemical residue that is foreign to the nature of the food, but excludes residues of agvet chemicals at levels that do not contravene the Code. The zero tolerance approach means that all residues for which there is no MRL will cause a relevant food to be deemed unsuitable for sale. Selling unsuitable food is an offence under state and territory food law.

During the production process, domestically-produced food, livestock or crops may have inadvertently been exposed to chemicals that do not have an MRL listed in Standard 1.4.2 for that specific chemical-food combination. The level of residue present from inadvertent exposure is generally so low that there is rarely a public health and safety concern. The consequence is that the food is non-compliant, and the supplier may be subject to criminal prosecution, although the food may be safe. These circumstances are currently managed through the prosecutorial discretion.

Agvet chemicals are used differently in different countries around the world as pests, diseases and environmental factors differ and therefore product use patterns may differ. This means that 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 very low levels of non-compliant chemical residues may not present a health risk to the Australian population.

Non-compliant residues in food are being identified more frequently because of the improved sensitivity of analytical detection systems that can reliably quantify down to parts per billion.

As such, the requirement to ensure there is no detectable residue present in food for which no MRL is established, places an obligation on food producers that is becoming increasingly difficult, if not impossible, to meet. Growers are unlikely to be paid for rejected or condemned produce. An additional opportunity cost is that industry quality assurance resources can be diverted from more important food safety tasks by the need to address technical breaches to food standards that pose a very low risk to public health, and do not represent any misuse of agvet chemicals.

1.4 Procedure for assessment

The Proposal is being assessed under the General Procedure.

2 Proposed approach

Consideration of the Policy Guideline and different approaches to address the current zero tolerance (e.g. application of a default limit or case by case assessment) has helped shape the current proposed approach to managing low level agvet chemical residues. The proposed approach is that MRLs be set for *all other foods* for specific chemicals to account for the presence of low level residues in commodities that could be inadvertently exposed to the chemical product.

This approach requires no substantial change to the Code, is currently used by the APVMA for a limited number of chemicals⁴, is consistent with the APVMA's risk assessment framework for approving and registering agvet chemical products and is consistent with the risk assessment approach for setting MRLs. The approach gives chemical users, importers and food regulators a clear and transparent target. Furthermore, it allows the MRLs to be reviewed as required based on new information made available through state/territory and border regulatory activities.

Additional advantages of this approach include:

- use of a risk-based approach, rather than the same default limit being applied across all chemicals. In effect this means that a conscious decision is made to set a limit underpinned by a risk assessment.
- meeting the higher order policy principles set down by Ministers
- setting limits that would make deliberate off-label use apparent for state regulators controlling use of chemicals.

2.1 Scope

It is proposed to establish a low level MRL for *all other foods* for specific chemical/food combinations in the chemical categories of herbicides, fungicides and insecticides. This entry is intended to cover all foods that do not have a specific entry for the chemical in the standard.

Certain chemicals will not be amenable to this approach, for example most veterinary medicines as the uses are species specific and also due to concerns related to antimicrobial resistance.

⁴ Existing MRLs for *all other foods* in the Code and Agricultural and Veterinary Code (Agvet Code) include boscalid; chlorantraniliprole; cyantraniliprole and fluxapyroxad. These MRLs were set by the APVMA based on data from rotational crop trials.

Niche products and highly toxic products, such as rodenticides and vertebrate poisons, will also not be considered under this approach as well as chemicals with low health-based guidance values⁵.

Request for information:

Regulatory agencies and industry (including food producers, importers, processors, manufacturers and food retailers) are invited to present specific examples of cases where unexpected agvet chemical residues were identified in foods and reasons why this has occurred if known. This information will enable a priority list of agvet chemicals requiring risk assessment and MRLs to be established.

2.2 Risk assessment

The presence of non-permitted agvet chemicals in food at low levels does not necessarily represent a food safety risk. To confirm a low risk, an assessment of the estimated short term and/or chronic dietary exposure to the chemical residue is usually required to confirm if estimated exposures are likely to exceed the relevant health-based guidance value for the agvet chemical⁶.

For some agvet chemicals the APVMA has established specific MRLs to account for trace levels of those residues being present in other commodities even when the intended crop is treated according to the registered product label. Two examples currently in Schedule 1 of Standard 1.4.2 are:

- the fungicide boscalid has an *all other foods* MRL of 0.5 mg/kg in the Code, while MRLs for crops that are directly treated range from 1 to 10 mg/kg.
- similarly, for the insecticide chlorantraniliprole, the *all other foods* MRL is 0.01 mg/kg, while MRLs for crops that are directly treated range from 0.3 to 20 mg/kg.

For each agvet chemical/crop combination an appropriate MRL for *all other foods* can be established to account for low level residues which may unexpectedly occur.

A joint protocol with agreed inclusion/ exclusion criteria to enable MRLs for *all other foods* to be established will need to be developed by FSANZ and the APVMA to support the implementation of the proposed approach.

2.3 Risk management

State and territory governments are responsible for implementing, monitoring and enforcing the requirements in Standard 1.4.2. The Australian Government Department of Agriculture monitors compliance of imported products with the Code. At present, if a non-compliant residue is detected, the relevant authority must consider whether to institute criminal action for sale (or intended sale) of the non-compliant food.

Under this Proposal, some low level residues may no longer be non-compliant. Accordingly, food containing these residues at low levels could be sold. In relation to imported food, the Proposal provides a clear and transparent level for the Australian Government Department of Agriculture to monitor.

⁵ Health based guidance values are numerical values reflecting the level of a chemical that can be ingested over a defined time period (eg. lifetime or 24 hours) without appreciable health risk.

⁶ An explanation of how dietary exposure assessments are carried out can be found at <http://www.foodstandards.gov.au/science/exposure/Pages/dietaryexposureandn4438.aspx>

However, it still maintains other risk management measures available under Commonwealth, state or territory laws where food is non-compliant, including removing a food from the food supply.

The zero tolerance approach would still apply to chemicals not already listed in Schedule 1 of Standard 1.4.2 or those deemed not appropriate to have an *all other foods* category.

The current processes for varying Standard 1.4.2 will not be affected by this Proposal.

2.3.1 Cost benefit analysis

This is a preliminary consultation paper and a decision has yet to be made in terms of the regulatory approach. It is envisaged that expanding the *all other foods* MRL category for existing agvet chemicals in the scope of the Proposal, will liberalise current requirements and benefit Australian Government, state and territory agencies, growers and producers and the domestic and imported food industry. FSANZ will consult with the Office of Best Practice Regulation to ascertain whether a Regulation Impact Statement is required. If an amendment to Standard 1.4.2 is prepared, then FSANZ will consult with all stakeholders again in 2015.

Request for information:

Please provide information on any costs or benefits envisaged if the MRL category for *any other foods* is expanded in Schedule 1 of Standard 1.4.2 for agvet chemicals in the scope of this Proposal to allow for low level residues.

2.4 Risk communication

2.4.1 Consultation

FSANZ continues to work closely with the APVMA, the Australian Government Department of Agriculture and state/territory governments to develop the Proposal. Informal updates on progress with the Proposal have also been held with key industry members and peak bodies.

Every submission to this consultation paper will be reviewed by FSANZ staff that will examine the issues identified and respond to those issues. While not all comments may be taken on board during the process, they are valued and all contribute to the rigour of the assessment.

FSANZ notifies the community about proposals and applications in a number of different ways, including via the Notification Circular, media release, social media, email notifications and in publications e.g. Food Standards News.

2.4.2 World Trade Organization (WTO)

As a member of the World Trade Organization (WTO), Australia is obliged to notify WTO member nations 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.

Amending the Code to manage low-level agvet chemicals without MRLs may have an effect on international trade as detections of non-complying residues have previously led to disruptions in international food trade. Therefore, if variations to Standard 1.4.2 are prepared as a result of this Proposal, a notification to the WTO under Australia's obligations under the WTO Sanitary and Phytosanitary Measures Agreement will be made to enable other WTO member countries to comment on any proposed amendments.