

26 October 2016
[26–16]

Approval report – Proposal P1027

Managing Low-level Ag & Vet Chemicals without MRLs

Food Standards Australia New Zealand (FSANZ) has assessed a proposal prepared by FSANZ to manage low-level agricultural and veterinary (agvet) chemicals without Maximum Residue Limits (MRLs) in Schedule 20 of the Australia New Zealand Food Standards Code (the Code). That is, the food commodity is not listed for an agvet chemical currently in the Code.

On 22 April 2016, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 13 submissions.

FSANZ approved the draft variation on 19 October 2016. The Australia and New Zealand Ministerial Forum on Food Regulation (Forum) was notified of FSANZ's decision on 25 October 2016.

This Report is provided pursuant to paragraph 63(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

Table of contents

EXECUTIVE SUMMARY	3
1 INTRODUCTION	4
1.1 THE PROPOSAL	4
1.2 THE CURRENT STANDARD	5
1.2.1 <i>International consideration</i>	5
1.3 REASONS FOR PREPARING THE PROPOSAL.....	6
1.4 ARRANGEMENTS WITH NEW ZEALAND	7
1.5 PROCEDURE FOR ASSESSMENT	7
1.6 DECISION	7
2 SUMMARY OF THE FINDINGS	7
2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS	7
2.2 RISK ASSESSMENT	8
2.3 RISK MANAGEMENT	9
2.4 RISK COMMUNICATION.....	9
2.4.1 <i>Consultation</i>	9
2.4.2 <i>World Trade Organization (WTO)</i>	10
2.5 FSANZ ACT ASSESSMENT REQUIREMENTS	10
2.5.1 <i>Section 59</i>	10
2.5.2 <i>Subsection 18(1)</i>	11
ATTACHMENT A – APPROVED DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS</i> <i>CODE</i>	13
ATTACHMENT B – EXPLANATORY STATEMENT	16

Supporting documents

The [following supporting documents](#)¹ which informed the assessment of this Proposal are available on the FSANZ website.

- SD1 The risk assessment approach used in Proposal P1027 to establish *All other foods except animal food commodities* MRLs (at Approval)
- SD2 Summary of issues raised in the submissions and FSANZ response.

¹ <http://www.foodstandards.gov.au/code/proposals/Pages/P1027.aspx>

Executive summary

Proposal P1027 was prepared to develop an approach to assess agricultural and veterinary (agvet) chemicals currently listed in Schedule 20 in the *Australian New Zealand Food Standards Code* (the Code) for suitability to establish *All other foods except animal food commodities* maximum residue limits (MRLs). These MRLs are intended to address the presence of low level inadvertent agvet chemical residues in food commodities, and apply only to Australia.

Current food regulatory requirements specify there must be no detectable residue of an agvet chemical in a food commodity (zero tolerance) if there is no established MRL in Schedule 20 for the particular agvet chemical/ food combination. However, even with good agricultural practice, due to spray drift or crop rotation, agvet chemical residues can inadvertently occur in foods that have no associated MRLs. The absence of MRLs for these foods means they cannot legally be sold even if there are no public health and safety concerns. The 'zero tolerance' approach has caused concerns for primary food producers and enforcement agencies.

Through P1027, FSANZ has developed an approach to assess agvet chemicals listed in Schedule 20 to avoid application of 'zero tolerance' to the presence of low level inadvertent agvet chemical residues in food commodities. The approach was developed in consultation with the Australian Pesticides and Veterinary Medicines Authority (APVMA) which establishes MRLs for agvet chemicals registered for use in Australia.

The approach was piloted with 19 agvet chemicals currently listed in Schedule 20 and the risk assessment process developed was applied to each chemical on a case-by-case basis. The process ensured *All other foods except animal food commodities* MRLs were low enough to capture inadvertent residues but not too high to encourage 'off-label' use of the chemicals. The exclusion of animal food commodities came about because the absence of existing MRLs for key animal food commodities for some agvet chemicals may have caused major variations in the MRLs between plant and animal food commodities if they were to be included in the *All other foods except animal food commodities* MRLs.

The results of the dietary exposure assessment undertaken as part of the risk assessment process for the 19 chemicals indicate that the *All other foods except animal food commodities* MRLs are safe and would not pose public health and safety concerns. The values proposed for each agvet chemical have been included in the draft amendment to Schedule 20.

Currently, there are six agvet chemicals that have *All other foods* MRLs in the Code. These were set by the APVMA based on data from rotational crop trials and have not been included in P1027. They will be maintained as such in both the Code and the APVMA MRL Standard.

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 commodities from the joint food standards setting system.

The majority of stakeholders support this approach and see it as a practical and balanced way to address the presence of legitimate low level inadvertent agvet chemical residues in food commodities.

1 Introduction

1.1 The Proposal

P1027 addressed the long-standing issue of the application of 'zero tolerance' to the presence of low level inadvertent agricultural and veterinary (agvet) chemical residues in food commodities by developing an approach that proposes *All other foods except animal food commodities* MRL for chemicals in Schedule 20 in the *Australia New Zealand Food Standards Code* (the Code) where low level inadvertent agvet chemical residues may be present in food commodities that do not have an established MRL. The proposed *All other foods except animal food commodities* MRLs have been assessed using a robust scientific process, and do not present any public health and safety concerns.

FSANZ developed the approach in consultation with the Australia Pesticides and Veterinary Medicines Authority (APVMA), and used it to propose *All other foods except animal food commodities* MRL for 19 agvet chemicals currently listed in the Code. A full risk assessment and dietary exposure assessment was completed for each agvet chemical as shown in Supporting Document 1 (SD1).

Veterinary medicines were excluded from the approach because their use is species-specific and concerns about potential antimicrobial resistance. In addition, the APVMA sets MRLs in animal food commodities to control the use of veterinary drugs and therefore 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, were also excluded.

Among the factors considered in establishing the MRL values for agvet chemicals in this new category were the numerical values of existing MRLs. The absence of MRLs for key animal food commodities for some agvet chemicals influenced the values of the *All other foods except animal food commodities* MRLs established. Generally, animal food commodity MRLs are lower than plant commodity MRLs. To ensure the *All other foods except animal food commodities* MRL values were not too low to capture inadvertent presence of the residues in a plant commodity, and not higher than those for animal food commodities with existing MRLs, animal food commodities were excluded and the descriptor for the new MRL category changed to its current form. The exclusion safeguarded the established values from promoting 'off-label' use of agvet chemicals. This modification also ensured that whether the agvet chemicals had MRLs for key animal food commodities or not when the *All other foods except animal food commodities* MRLs were established, the value would adequately account for the contribution to the estimated total dietary exposure of plant commodities with MRLs in the Code.

The *All other foods except animal food commodities* MRL for a specific agvet chemical is therefore established such that it is high enough to allow for the presence of inadvertent residues of that agvet chemical in plant food commodities, but low enough to discourage off-label use in food production. Excluding animal food commodities from the descriptor did not change the robustness of the scientific risk assessment approach used.

The *All other foods except animal food commodities* MRL category for a specific agvet chemical therefore includes any plant food commodity for which an MRL is not listed in the Code. It is used as a 'catch-all' for food commodities 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.

1.2 The current Standard

Schedule 20 lists MRLs for agvet chemicals that are permitted in food commodities sold on the Australian market. Under the current national food regulatory system (subject to some exceptions for foods sourced from New Zealand), there must be no detectable residue of an agvet chemical in a food commodity if it has no MRL listed in the Code (zero tolerance). The MRLs are mandatory requirements that apply to all food commodities on the market whether produced domestically or imported. They ensure that residues of agvet chemicals in food commodities are kept as low as possible and are consistent with the registered and approved use of the 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 P1027 to establish *All other foods except animal food commodities* MRLs. They will be retained as such in the APVMA MRL Standard and Schedule 20, since they reflect requirements for good agricultural practice (GAP) based on the approved instructions for use of the agvet chemicals. The *All other foods except animal food commodities* MRLs for low level inadvertent residues will therefore be included only in the Code and not in the APVMA MRL Standard, so that the latter continues to be the primary reference for GAP for food producers.

1.2.1 International consideration

FSANZ considered approaches used by other international food regulatory agencies in addressing the issue of low level inadvertent agvet chemical residues in food commodities. Some international regulators use *Default MRLs* for residues of agvet chemicals without MRLs, including the presence of inadvertent agvet chemical residues in food commodities. Codex does not specify a *Default MRL* for agvet chemicals without MRLs and has not established MRLs for 'low level' agvet chemical residues as described above. No international food regulator has yet established *All other foods except animal food commodities* MRL for inadvertent residues of agvet chemicals that may be found in or on food commodities.

Currently, there are two sets of default values used by countries that have adopted the *Default MRL* approach. Canada, New Zealand, the European Union and Japan fall into this category. Canada and New Zealand use a *Default MRL* value of 0.1 mg/kg (set in the 1970s) and the European Union and Japan use 0.01 mg/kg (set in 2005 and 2006 respectively).

The [United States Environmental Protection Agency approach](#)² establishes MRLs (called *Tolerances*) for pesticide residues for various food and feed commodities. 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 agvet chemical residue level must comply with Federal Regulations.

Default MRLs are not based on dietary exposure assessments for the agvet chemicals, which is in contrast to the case-by-case risk assessment approach used by FSANZ to establish *All other foods except animal food commodities* MRLs.

² <http://npic.orst.edu/health/residue.html>

1.3 Reasons for preparing the Proposal

P1027 was prepared to address issues presented by the application of the 'zero tolerance' approach to food commodities with low level inadvertent agvet chemical residues for which MRLs have not been established in Schedule 20. The proposal developed an approach that established *All other foods except animal food commodities* MRLs for the presence of low level inadvertent residues of approved agvet chemicals in food commodities when assessed as safe.

Although the 'zero tolerance' approach ensures that any food commodity presented for sale on the Australian market is safe for consumers and complies with the Code, it also provides an assurance that registered agvet chemicals have been used as prescribed by the label directions and approvals granted by the APVMA. However, the regulatory system creates difficulties for the presence of legitimate low level inadvertent residues of approved agvet chemicals in food commodities for a number of reasons. Some of these are:

- Low level residues may be due to inadvertent exposure from spray drift, crop rotation or use of packaging equipment during the food production process. However, since the chemicals have no MRLs listed for the food commodities in which they are found, they are non-compliant with the Code, and therefore not legal for sale. This is the case even if the detected levels are considered to be of very low risk to public health.
- Increasing numbers of residue non-compliance in domestic and imported food commodities is being identified due to progressively sensitive analytical methods that reliably detect agvet residue amounts in parts per billion. The requirement that there should be no detectable agvet chemical residue present in food for which no MRL is established (zero tolerance) is therefore becoming difficult to meet. The consequence is that the resource cost to food producers and state/territory food regulators is escalating.
- Agricultural pests, diseases and environmental factors vary in different countries around the world and results in agvet chemicals being used differently for food production. This means that agvet chemical residues in imported foods may legitimately differ from those in domestically produced foods. However, detections of very low levels of non-complying residues of agvet chemicals in imported foods (that may not present a health risk) have caused disruptions in international food trade and generated considerable media and consumer interest.
- Jurisdictions may have to divert resources from other more significant food safety tasks to address inadvertent breaches of the Code which may not pose health and safety risks to consumers.

These are longstanding issues that have not been adequately addressed to date.

The P1027 approach provides a way forward in addressing non-compliance with the Code by food commodities containing legitimate levels of low level inadvertent agvet chemical residues, using a process that assesses them as safe and permits their sale. The approach does not impact other risk assessment measures available under Commonwealth, state or territory laws where food is non-compliant, including being removed from the food supply. The 'zero tolerance' approach would still apply to agvet chemicals not listed in the Code and to agvet chemical residues in commodities that do not have *All other foods except animal food commodities* MRL listed in the Code.

1.4 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 Arrangement](#) (TTMRA³). 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 the two countries.

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 was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect following gazettal. The approved draft variation on which submissions were sought is at Attachment A.

The related 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.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ sought public comment on the risk assessment approach developed to establish *All other foods except animal food commodities* MRLs for the 19 chemicals used in the pilot study.

Comments were also sought on any public health and safety considerations which may have been overlooked in association with the established *All other foods except animal food commodities* MRLs.

FSANZ received 13 submissions from domestic food industry groups, government food regulatory departments and an overseas government agency (the USA) through the WTO notification process.

The majority of the submissions supported the approach developed and used, and noted the impact of the approach on improving domestic food trade and importation of food into Australia. Supporters viewed the approach as a practical and balanced way to manage low level inadvertent chemical residues in food commodities by providing relief from the application of 'zero tolerance' and national consistency for regulators and the food industry.

³ <https://www.coag.gov.au/the-trans-tasman-mutual-recognition-arrangement>

A few domestic food industry groups did not support the approach, viewed it as unnecessarily complicated and not timely in dealing with the immediate needs of food producers. They would have preferred the use of *Default MRL* which has been used for years by some other regulators instead of case-by-case risk assessment for each agvet chemical approach proposed by P1027.

The US submission sought confirmation that the P1027 approach would not impact the FSANZ annual MRL harmonisation process and was not related to the New Zealand proposal for new Codex work titled, *Risk Management Approach to Address Detection in Food of Chemicals of Very Low Public Health Concern*. FSANZ provided the required confirmation in a response through the WTO process.

A summary of the issues raised in the submissions received and FSANZ's response to them is provided as Supporting Document 2 (SD2).

2.2 Risk assessment

The approach was a two-stage process. The first stage identified and screened a manageable sub-set of chemicals in the Code that were used to set *All other food except animal food commodities* MRLs on a case-by-case basis. An initial list of 132 agvet chemicals compiled from data provided by stakeholders such as state and territory enforcement agencies, the APVMA and from the imported food inspection data (Australian Government Department of Agriculture and Water Resources (DAWR)) was reduced to 19, for a case-by-case consideration in the second stage.

The second stage used a robust risk assessment including dietary exposure for the Australian population and a number of principles were set specifically for this MRL category and was developed in consultation with the APVMA, to guide the setting of *All other foods except animal food commodities* MRL for each chemical. The methodology ensured that a consistent approach was used, and that chemicals of concern were excluded from consideration. The approach also considered the magnitude of existing MRL permissions for the chemicals and set the MRL values high enough to allow for the inadvertent presence of the agvet chemical in other foods but low enough to discourage 'off-label' use of the agvet chemicals.

At the completion of the Stage 2 assessment process, *All other foods except animal food commodities* MRLs were established for these chemicals: 2-phenylphenol, ametoctradin, azoxystrobin, bifenthrin, captan, cyfluthrin, deltamethrin, fenhexamid, fludioxonil, glyphosate, iprodione, methomyl, thiodicarb, penthiopyrad, pyrimethanil, spinosad, thiabendazole, triadimefon and triadimenol. Details of the risk assessment process are provided in SD1.

FSANZ has reviewed the approach and assessed its long-term use to establish *All other foods except animal food commodities* MRLs for other agvet chemicals listed in the Code. It has also taken into consideration possible ongoing amendments to Schedule 20 of the Code as proposed by the APVMA based on chemical registration applications, any reviews it undertakes and FSANZ's annual MRL harmonisation process. It is intended that the establishment of *All other foods except animal food commodities* MRLs as proposed in P1027 would, if P1027 were to be approved, be an additional step that would be integrated into the [routine FSANZ/APVMA MRL-setting process](http://www.foodstandards.gov.au/code/changes/limits/Pages/default.aspx) (*shared responsibilities*⁴) into the future. The document that details the risk assessment approach developed is at SD1.

⁴ <http://www.foodstandards.gov.au/code/changes/limits/Pages/default.aspx>

2.3 Risk management

The implementation, monitoring and enforcement of the MRL requirements in the Code are undertaken within Australia by state and territory food regulatory agencies and at the national borders by DAWR. Currently, if an agvet chemical residue without an MRL in the Code is detected in a food commodity, a 'zero tolerance' approach is applied which means the regulator 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 P1027, the 'zero tolerance' approach would not apply to low level inadvertent agvet chemical residues in food commodities where it has been assessed as safe to establish *All other foods except animal food commodities* MRLs, which would allow the sale of foods containing legitimate levels of inadvertent agvet chemical residues. The 'zero tolerance' approach would still apply to agvet chemicals not already listed in the Code or those deemed unsuitable to have *All other foods except animal food commodities* MRLs. In addition, other risk management measures currently available under Commonwealth, state or territory laws are maintained and food commodities that do not comply with the Code can be removed from the food supply.

The approach provides a nationally consistent process to address the presence of low level inadvertent residues of permitted agvet chemicals in food commodities. It saves the jurisdictions from individually undertaking 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. With imported food commodities, the *All other foods except animal food commodities* MRL provides a clear and transparent monitoring level for food producers and regulators.

2.4 Risk communication

2.4.1 Consultation

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

FSANZ undertook a second (and statutory) round of public consultation on a draft variation in April 2016 for a 6-week period. FSANZ developed and applied a basic communication strategy to this Application. The call for submissions was notified via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News.

In addition, other formal and informal discussions were had with stakeholders, some through the FSANZ MRL Contact point, face-to-face meetings and at presentations on the approach at relevant jurisdictional meetings.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Proposal. Every submission on a proposal was considered by the FSANZ Board and all comments are valued and contribute to the rigour of our assessment.

The FSANZ Board's decision has been notified to the Australia and New Zealand Ministerial Forum on Food Regulation. If the decision is not subject to a request for a review by Ministers, stakeholders will be notified of the gazettal of the variation to the Code by email and on the FSANZ website.

2.4.2 World Trade Organization (WTO)

Australia as a member of the World Trade Organization (WTO) 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.

There are no current relevant international standards similar to the proposed *All other foods except animal food commodities* MRLs. Amending the Code to incorporate the *All other foods except animal food commodities* MRLs category is unlikely to have a significant adverse effect on international trade. It removes the application of 'zero tolerance' to food commodities containing inadvertent residues of agvet chemicals approved for use and assessed as safe to be sold, thereby liberalises trade.

FSANZ made a notification to the WTO for this Proposal in accordance with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures. The US Government provided comments which were addressed in a response to the relevant US agency through the WTO process.

2.5 FSANZ Act assessment requirements

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 that is varied as a result of this Proposal outweigh the costs to the community, Government or industry.

A cost-benefit analysis was not required for the Proposal because the proposed variation to the Code is minor in nature. The Office of Best Practice Regulation had previously stated (ID 12065) that no further analysis in the form of a Regulation Impact Statement is required for the *All other foods except animal food commodities* MRL amendments.

The *All other foods except animal food commodities* MRL variation to the Code removes application of 'zero tolerance' to the presence of inadvertent agvet chemical residues without MRLs in food commodities. It benefits state and territory food regulators, primary producers and importers. It also liberalises trade, both domestic and overseas, and has the potential to increase the choice of food available on the Australian market to consumers.

2.5.1.2 Other measures

There are no other measures available to FSANZ that would be more cost-effective than a food regulatory measure developed or varied as a result of the Proposal.

FSANZ considered the comment by some stakeholders that FSANZ should consider the use *Default MRLs*, but remains of the view that the proposed approach is a better option that overcomes the limitations of a *Default MRL* while minimising direct and indirect costs to food producers, regulators and the food industry. The stakeholders that support the approach (majority of submitters) consider it a practical and balanced way to manage low level inadvertent agvet chemical residues in food commodities.

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 commodities from the system that sets joint food standards. Australia and New Zealand therefore independently and separately develop MRLs for agvet chemical residues in food commodities.

New Zealand uses a *Default MRL* of 0.1 mg/kg for agricultural chemical/commodity combinations not specifically listed in the New Zealand MRL Standard. 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.

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.

2.5.2.1 Protection of public health and safety

The risk assessment process used to establish *All other foods except animal food commodities* MRLs for the agvet chemicals in the draft variation and to be used to set this MRL category for other agvet chemicals into the future, ensures that the levels established do not pose a 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

This objective is not relevant to matters under consideration under P1027.

2.5.2.3 The prevention of misleading or deceptive conduct

This objective is not relevant to matters under consideration under P1027.

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**

The measures in the draft variation are based on robust risk assessment undertaken using the best available scientific data.

- **the promotion of consistency between domestic and international food standards**

Establishing *All other foods except animal food commodities* MRLs provides a clear and transparent compliance target for monitoring inadvertent low level agvet chemical residues in food commodities whether produced domestically or imported. It also removes unwarranted regulation through application of the current 'zero tolerance' approach to residue detections.

- **the desirability of an efficient and internationally competitive food industry**

The draft amendment provides *All other foods except animal food commodities* MRLs for low level inadvertent chemical residues in food commodities assessed as safe. It prevents application of the zero tolerance approach to such foods and makes them available for sale.

- **the promotion of fair trading in food**

The amendment facilitates trade in domestic and imported foods that are considered safe for human consumption but which would have been in violation of the Code and deemed unsaleable. This is supported by information in section 2.5.1.1 of this report.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The draft amendment was developed in accordance with the Policy Guideline on the *Regulation of Residues of Agricultural and Veterinary Chemicals in Food*. Particular consideration was given to the *Specific Policy Principles* that apply to alternative approaches that FSANZ might consider to address issues regarding the 'zero tolerance' approach to the enforcement of the Code.

Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement

Attachment A – Approved 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 a 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; and
- (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 <i>Permitted residue—commodities of plant origin:</i> <i>Ametoctradin</i> <i>Permitted residue—commodities of animal origin:</i> <i>Sum of ametoctradin and 6-(7-amino-5-ethyl [1,2,4] triazolo [1,5-a] pyrimidin-6-yl) hexanoic acid</i>		Agvet chemical: Deltamethrin <i>Permitted residue: Deltamethrin</i>	
All other foods except animal food commodities	0.2	All other foods except animal food commodities	0.05
Agvet chemical: Azoxystrobin <i>Permitted residue: Azoxystrobin</i>		Agvet chemical: Fenhexamid <i>Permitted residue: Fenhexamid</i>	
All other foods except animal food commodities	0.1	All other foods except animal food commodities	0.1
Agvet chemical: Bifenthrin <i>Permitted residue: Bifenthrin</i>		Agvet chemical: Fludioxonil <i>Permitted residue—commodities of animal origin:</i> <i>Sum of fludioxonil and oxidisable metabolites, expressed as fludioxonil</i> <i>Permitted residue—commodities of plant origin:</i> <i>Fludioxonil</i>	
All other foods except animal food commodities	0.03	All other foods except animal food commodities	0.02
Agvet chemical: Captan <i>Permitted residue: Captan</i>		Agvet chemical: Glyphosate <i>Permitted residue: Sum of glyphosate, N-acetyl-glyphosate and aminomethylphosphonic acid (AMPA) metabolite, expressed as glyphosate</i>	
All other foods except animal food commodities	0.1	All other foods except animal food commodities	0.2
Agvet chemical: Cyfluthrin <i>Permitted residue: Cyfluthrin, sum of isomers</i>		Agvet chemical: Iprodione <i>Permitted residue: Iprodione</i>	
All other foods except animal food commodities	0.05	All other foods except animal food commodities	0.1

Agvet chemical: Methomyl	
<i>Permitted residue: Methomyl</i>	
All other foods except animal food commodities	0.05
Agvet chemical: Penthioopyrad	
<i>Permitted residue—commodities of plant origin: Penthioopyrad</i>	
<i>Permitted residue—commodities of animal origin: Sum of penthiopyrad and 1-methyl-3-(trifluoromethyl)-1H-pyrazol-4-ylcarboxamide, expressed as penthiopyrad</i>	
All other foods except animal food commodities	0.05
Agvet chemical: 2-Phenylphenol	
<i>Permitted residue: Sum of 2-phenylphenol and 2-phenylphenate, expressed as 2-phenylphenol</i>	
All other foods except animal food commodities	0.1
Agvet chemical: Pyrimethanil	
<i>Permitted residue: Pyrimethanil</i>	
All other foods except animal food commodities	0.1
Agvet chemical: Spinosad	
<i>Permitted residue: Sum of spinosyn A and spinosyn D</i>	
All other foods except animal food commodities	0.01

Agvet chemical: Thiabendazole	
<i>Permitted residue—commodities of plant origin: Thiabendazole</i>	
<i>Permitted residue—commodities of animal origin: Sum of thiabendazole and 5-hydroxythiabendazole, expressed as thiabendazole</i>	
All other foods except animal food commodities	0.03
Agvet chemical: Thiodicarb	
<i>Permitted residue: Sum of thiodicarb and methomyl, expressed as thiodicarb</i>	
All other foods except animal food commodities	0.1
Agvet chemical: Triadimefon	
<i>Permitted residue: Sum of triadimefon and triadimenol, expressed as triadimefon</i>	
see also <i>Triadimenol</i>	
All other foods except animal food commodities	0.05
Agvet chemical: Triadimenol	
<i>Permitted residue: Triadimenol</i>	
see also <i>Triadimefon</i>	
All other foods except animal food commodities	0.05

Attachment B – 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.

The Authority 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 approved a draft variation of a Standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft variation of a standard.

Section 94 of the FSANZ Act specifies that a variation of a standard in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved amendments to Schedule 20, which relate to allowing *All other foods except animal food commodities* MRLs for the legitimate presence of low level inadvertent residues of certain agvet chemicals, assessed as safe, in the food.

The amended provisions in Schedule 20 are section S20—2 and the table to section S20—3.

Section S20—2, which is an interpretation provision, was amended to include an explanation of what ‘animal food commodities’ mean.

The table to section S20—3 was amended to include a new food category ‘All other foods except animal food commodities’ and associated MRLs for 19 chemicals. The table lists the MRLs for residues of agvet chemicals which may occur in or on food commodities following their legitimate use in food production. If there is no MRL for a particular agvet chemical and food combination in the Code, a ‘zero tolerance’ approach is applied and means there must be no detectable residue of the chemical in the food. Prior to the commencement of the draft variation, any food commodity to which the zero tolerance approach was applied would have been in breach of the Code and may not have been sold.

The approved draft variation permits the sale of certain food commodities with detectable low level inadvertent agvet chemical residues. It is a technical amendment to address the unintended contamination of the food commodities through spray drift, crop rotation or use of packaging equipment.

The approach used a scientific risk assessment process including dietary exposure to ensure the values established for this MRL category do not present any public health and safety concerns.

3. Documents incorporated by reference

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

4. Consultation

The Authority's consideration of P1027 included two rounds of public consultation.

The first public consultation was undertaken on 16 December 2014 following assessment of the proposal. This was a non-statutory public consultation. The second public consultation was undertaken in accordance with the procedure set out in Division 2 of Part 3 of the FSANZ Act, in which submissions were called for on 22 April 2016 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed amendments to Schedule 20 are likely to have a minor impact on business and individuals (OBPR ID 12065).

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] amends Schedule 20. Sub item [1.1] amends section S20—2 by inserting an explanation of what 'animal food commodities' means.

Item [1.2] amends section S20—3 by inserting a new food category 'All other foods except animal food commodities' and associated MRLs for the following 19 chemicals:

- Ametoctradin
- Azoxystrobin
- Bifenthrin
- Captan
- Cyfluthrin
- Deltamethrin
- Fenhexamid
- Fludioxonil
- Glyphosate
- Iprodione
- Methomyl
- Penthiopyrad
- 2-Phenylphenol
- Pyrimethanil
- Spinosad
- Thiabendazole
- Thiodicarb
- Triadimefon
- Triadimenol.