

6-04
4 August 2004

ASSESSMENT REPORT

PROPOSAL P294

VARIATION TO STANDARD 1.4.2 – MAXIMUM RESIDUE LIMITS

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:

1 September 2004

(See 'Invitation for Public Submissions' for details)

FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

FSANZ prepared an Assessment Report for Proposal P294, which included the identification and discussion of the key issues and prepared a draft variation to the *Australia New Zealand Food Standards Code* (the Code). Proposal P294 was declared as an 'urgent' proposal under Division 5, section 24 of the *Food Standards Australia New Zealand Act 1991*.

Where a proposal has been declared 'urgent', FSANZ must seek submissions from interested parties on the proposal. The maximum time for making submissions where a proposal is urgent is ten working days. For Proposal P294, FSANZ specified a submission period of five working days. After the submissions were received, FSANZ then considered the Proposal further, and had regard to the submissions received which is detailed in this Report. The variation to Standard 1.4.2 was gazetted and took effect on **14 May 2004**.

However, in light of the limited period of public comment, FSANZ is seeking to extend the public comment period for an additional 6-weeks to allow further stakeholder consideration of the variation to Standard 1.4.2. FSANZ will then complete a Final Assessment of Proposal P294 within 12 months of the date of effect of the variation to the Code.

Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions should be received by FSANZ **by 1 September 2004.**

Submissions received after this date may not be considered, unless the Project Coordinator has given prior agreement for an extension.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

CONTENTS

EXECUTIVE SUMMARY AND STATEMENT OF REASONS	5
STATEMENT OF REASONS.....	5
1. INTRODUCTION AND REGULATORY PROBLEM.....	7
2. OBJECTIVE	7
3. BACKGROUND	8
3.1 BACKGROUND.....	8
4. RELEVANT ISSUES	9
4.1 THE ORIGINAL INTENT OF STANDARD 1.4.2	9
4.2 KEY ISSUES ARISING FROM THE DRAFTING.....	9
4.3 FSANZ’S PROPOSED ACTION IN THE FUTURE.....	10
5. EVALUATION OF ISSUES RAISED IN PUBLIC SUBMISSIONS.....	11
5.1 AFGC.....	11
5.2 QUEENSLAND HEALTH.....	11
5.3 INTERNATIONAL HONEY EXPORTERS ORGANISATION	12
5.4 DEPARTMENT OF AGRICULTURE, FISHERIES AND FORESTRY (AUSTRALIA).....	12
5.5 UNILEVER AUSTRALASIA, FOOD LIAISON LTD, FOOD AND BEVERAGE IMPORTERS ASSOCIATION (FBIA) AND NESTLÉ AUSTRALIA LTD	12
5.6 VICTORIA HEALTH.....	13
5.7 NSW HEALTH	13
5.8 DAIRY AUSTRALIA AND THE VICTORIAN DEPARTMENT OF PRIMARY INDUSTRIES, DAIRY FOOD SAFETY VICTORIA AND PRIME SAFE.....	13
5.9 CAPILANO HONEY LTD	13
6. REGULATORY OPTIONS.....	14
7. IMPACT ANALYSIS	14
8. CONSULTATION	14
8.1 WORLD TRADE ORGANIZATION (WTO)	15
9. CONCLUSION AND RECOMMENDATION	16
ATTACHMENT 1 - DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE.....	17
ATTACHMENT 2 - SUMMARY OF PUBLIC SUBMISSIONS.....	18

Executive Summary and Statement of Reasons

Standard 1.4.2 – Maximum residue Limits of the *Australia New Zealand Food Standards Code* (the Code) includes maximum limits on the levels of agricultural and veterinary chemical residues in food. The intent and spirit of the Standard is that where a chemical is not specifically listed in the Standard then there must be no detectable residues of that chemical in any food. This interpretation has been shared by FSANZ (and its statutory predecessors), the State and Territory food enforcement agencies, and the food industry (including the Australian Food and Grocery Council).

However, FSANZ recently was made aware of an alternative interpretation of the intent of Standard 1.4.2 in relation to chemicals not specifically listed (e.g. nitrofurans¹) in Standard 1.4.2. While investigating this interpretation, FSANZ became aware of a technical anomaly in Standard 1.4.2. The effect of this is that chemicals not specifically listed, such as nitrofurans, were not prohibited in food. This position was confirmed by legal advice.

The objective of this Proposal was to seek an urgent amendment to Standard 1.4.2 to correct the above anomaly, in order to protect public health and safety. This would have the effect of prohibiting residues of agricultural and veterinary chemicals in foods unless these residues were permitted by Standard 1.4.2.

If the corrective amendment were not made then Australian and New Zealand consumers may have been exposed to undesirable chemical residues in the food supply and enforcement agencies could not have taken corrective action to reduce this exposure in terms of Standard 1.4.2.

FSANZ previously sought input from stakeholders on P294 for a limited period of 5 business days (5 to 12 May 2004) before the FSANZ Board approved the variation under section 26 of the FSANZ Act. However, due to the number of issues raised in this period, FSANZ is inviting further consideration of the existing variation to Standard 1.4.2 whilst highlighting the proposed strategy to deal with the broader issues raised from submitters.

Statement of Reasons

FSANZ approved the amendments to Standard 1.4.2 and the preparing of a Proposal on 14 May 2004 for the following reasons:

- The variation to Standard 1.4.2 re-institutes the model regulatory approach adopted throughout the Code. Individual standards in the Code are constructed using a formula that prohibits substances in food unless those substances are expressly permitted. Standard 1.3.1 on food additives and Standard 1.3.3 on processing aids provide specific examples of the regulatory formula applied in the Code. This regulatory approach establishes the mechanism by which FSANZ effectively monitors the safety of substances in the food supply, thus enabling FSANZ to meet its statutory objective of protecting public health and safety.

¹ Nitrofurans are synthetic broad-based antimicrobial agents used in some countries in human and veterinary medicine.

- The amendment was required to correct an anomaly in Standard 1.4.2 to ensure that enforcement agencies can take action against the presence of undesirable chemical residues in food in terms of Standard 1.4.2.
- Although the general provisions in food legislation could potentially be used by enforcement agencies to take action against suppliers of foods containing these residues, given the potential public health implications, FSANZ and the majority of enforcement agencies considered that the amendment to the Standard was necessary, under urgency provisions, to ensure that enforcement agencies could take the action necessary to protect public health and safety.

1. Introduction and Regulatory Problem

Standard 1.4.2 – Maximum Residue Limits of the Code includes limits on the levels of agricultural and veterinary chemical residues in food. The intent and spirit of the Standard is that where a chemical is not specifically listed in the Standard then there must be no detectable residues of that chemical in any food. This interpretation has been shared by FSANZ (and its statutory predecessors), the State and Territory food enforcement agencies, and the food industry (including the Australian Food and Grocery Council).

However, upon investigating the interpretation of Standard 1.4.2 in relation to residues of nitrofurans in honey, FSANZ discovered an anomaly in regard to interpretation of the original intent of the Standard. While FSANZ originally understood that residues of nitrofurans in all foods were prohibited, legal advice was that the Code does not prohibit the presence of nitrofurans in food. The crux of this advice was as follows:

Subclause 2(1) provides an MRL permission for the presence of residues of listed chemicals in food, and its meaning is relatively straightforward. Subclause 2(2) effectively prohibits the presence of any detectable residue ‘for a chemical’ where no MRL is listed in the Standard. However, the wording of subclause 2(2), when construed properly with the definition of ‘chemical’ makes it clear that the prohibition applies only to those chemicals ‘listed in bold type in the shaded boxes in Schedules 1 or 2’. Nitrofurans are not listed in bold type in Schedule 1. Therefore, the prohibition in subclause 2(2) does not extend to nitrofurans in honey, or indeed any food. If nitrofurans were listed according to the definition of ‘chemical’ (that is, listed in bold type in the shaded boxes in Schedules 1 or 2’) and there was no MRL specified for honey in Schedule 1, then the prohibition would apply, and honey with any detectable residue of nitrofurans would breach the Code. However, as previously drafted, this was not the case.

This would now appear to be a longstanding problem, which was contrary to the common understanding of the purpose of the Standard, and not confined solely to nitrofurans, but could effectively apply to any chemical in food except those chemicals currently listed in the Standard. Consequently, FSANZ raised this Proposal (P294) to seek an emergency amendment to the Code to correct this anomaly.

FSANZ in consultation with the States, Territories, New Zealand and the Australian Quarantine and Inspection Service (AQIS) had discussed this problem and the opinion of jurisdictions generally was that they could potentially rely upon provisions under their own legislation to address the presence of nitrofurans residues in food. However, as these provisions have not been used to address chemical residues in food before, the majority of jurisdictions were supportive of an amendment to the Code under urgency provisions to address the anomaly.

2. Objective

The objective of this Proposal was to seek an urgent amendment to Standard 1.4.2 for the following reasons:

- to correct the above anomaly in order to protect public health and safety by specifically stating that chemical residues are not permitted in food unless they comply with the specific limits in Standard 1.4.2; and
- that where a chemical is not listed in the Standard then there should be no detectable residues of that chemical in any food. This would have the effect of eliminating exposure to chemicals that are not specifically permitted.

In developing or varying a food regulatory measure, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

This matter is being considered under section 24 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) as an urgent Proposal in order to protect public health and safety.

3. Background

3.1 Background

FSANZ recently (22 April 2004) arranged a teleconference with the State, Territory and New Zealand enforcement agencies to discuss State and Territory enforcement strategies for low-level residues of nitrofurans in honey. At this teleconference FSANZ was made aware of an alternative interpretation of Standard 1.4.2.

While investigating this interpretation, FSANZ became aware of a technical anomaly in the Standard. The effect of this was that chemicals not specifically listed, such as nitrofurans, were not prohibited in food. Legal advice has confirmed this position.

4. Relevant Issues

4.1 The original intent of Standard 1.4.2

The Australian Pesticide and Veterinary Medicines Authority (APVMA) currently assesses appropriate toxicology, residue, animal transfer, processing and metabolism studies, in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997*, to support the use of chemicals on commodities currently listed in Standard 1.4.2.

In addition, the Office of Chemical Safety of the Therapeutic Goods Administration (OCS) of the Australian Department of Health and Ageing undertakes an appropriate toxicological assessment of the chemicals and establishes, where appropriate, an acceptable daily intake (ADI) or an acute reference dose (ARfD).

This Proposal involved an amendment to Standard 1.4.2 to correct an anomaly by restoring the common understanding of the effect of clause 2 (2) in Standard 1.4.2 which currently states:

If an MRL for a chemical is not listed in this standard there must be no detectable residue of that chemical in that food.

If an amendment to Standard 1.4.2 to restore the intended effect was not made, this may have placed Australian and New Zealand consumers at risk of having an undesirable chemical in the food supply which has not been thoroughly assessed for its safety (including a rigorous toxicological assessment) under the current registration requirements for agricultural and veterinary chemicals in Australia.

4.2 Key issues arising from the drafting

In summary, the need for the urgent amendment to the Code was to prohibit residues of chemicals, including their metabolites² that were not listed in the Schedules to Standard 1.4.2 (i.e. unapproved chemicals). To draft this, FSANZ proposed to:

- amend the definition of chemical so that it was not limited to only those chemicals listed in the Schedules;
- extend the definition of chemical to include the metabolites of chemicals; and
- to include an additional provision prohibiting the presence of residues of chemicals that are not listed in the Schedules.

In consulting on this drafting, FSANZ became aware that extending the definition of chemical to include metabolites may have been problematic. As this definition applies to chemicals listed in the Schedules, the extension of the definition created a potential conflict with the 'residue definition' that currently applies to the chemicals listed in the Schedules.

² FSANZ included the reference to metabolites in order to encapsulate the parent chemical and any subsequent breakdown products (metabolites)

The intention was that for the chemicals listed in the Schedules only those chemical residues included in the residue definition should be analysed, and that all metabolites of these chemicals need not be analysed. Extending the definition of chemical to all metabolites of a chemical would have undermined this intention.

In addition, extending the definition of chemical to include all metabolites would have meant that the prohibition on residues would apply to all metabolites of approved chemicals (i.e. those listed in Schedule 1). This was not the intention. The intention was only to prohibit residues of unapproved chemicals and their metabolites.

In light of these issues, FSANZ amended the drafting to ensure the prohibition on metabolites only applies to unapproved chemicals; and that the prohibition does not apply to the presence of substances, including ingredients, food additives and processing aids that are otherwise permitted in the Code; and also substances naturally present in food, such as water or salt, or the presence in a food of substances that are formed naturally during processing of a food.

4.3 FSANZ's proposed action in the future

Under the urgency provisions of the Code, the key basis for exercising these powers was to fix an immediate problem with the operation of the Standard. However, a number of submissions requested that FSANZ consider the following:

- a review of other parts of Standard 1.4.2 (e.g. definitions of an agricultural and veterinary chemical);
- the broader issue of regulation of trace level chemical contaminants in the food supply;
- consideration of aligning the MRL standard with the general regulatory approach elsewhere in the Code (that is, set a prohibition and then provide permissions as an exception to the prohibition); and
- interpretation issues around the similarities between Standard 1.4.1 – Contaminants and Natural Toxicants and Standard 1.4.2.
- Consideration by FSANZ of import and Codex MRLs in the Code.

FSANZ is now proposing to look at the issue of low-level chemical residues in food, and in particular:

- concerns from enforcement agencies about the current 'zero tolerance' approach to chemical residues;
- an enforcement strategy/policy that is integrated with the Standards to ensure a consistent, defensible, open and transparent approach to the regulation of low level chemical residues in food; and
- the policy issues associated with the adoption of Codex MRLs and MRLs specifically for imported foods, particularly since FSANZ is currently discussing these issues with other regulatory agencies in order to establish a policy resolution.

The proposed strategy is that these liaison talks with the relevant agencies continue whilst FSANZ develops an options paper for consideration by the FSANZ Board on the regulation of low-level chemical contamination in the food supply (this paper will also consider the principles behind FSANZ acceptance of Codex and/or imported MRLs). An interdepartmental working group is already discussing the issues of inclusion of Import Maximum Residue Limits and Codex MRLS into the Code.

However, in light of the limited period of public comment for P294, FSANZ is seeking an additional public comment period for 6-weeks to allow further stakeholder consideration of the current amendments to Standard 1.4.2 (**Attachment 1**). FSANZ will then complete a Final Assessment of Proposal P294 within 12 months of the date of effect of the variation to the Code. The other broader policy issues will require a cross agency approach and may involve raising separate proposals following further consideration by FSANZ. Therefore, further comment is specifically sought to ascertain any stakeholder issues with the current amendments in **Attachment 1**.

5. Evaluation of issues raised in public submissions

The majority of submissions supported Proposal P294 and FSANZ's actions under the urgency provisions of the FSANZ Act. Some submissions raised additional issues and these are addressed below.

5.1 AFGC

The AFGC **supported** the overall principle of P294. However, the AFGC recommended that the drafting be modified to ensure that prohibition did not apply to normal ingredients in foods or permitted additives or processing aids, natural constituents of foods or chemicals naturally formed during the processing of foods.

5.1.1 Evaluation

FSANZ has amended the drafting in order to exclude the presence of substances, including ingredients, food additives and processing aids that are otherwise permitted in the Code; and also substances naturally present in food, such as water or salt, or the presence in a food of substances that are formed naturally during processing of a food as these substances are usually of no public health and safety significance.

5.2 Queensland Health

Supported P294. Proposed that a review be undertaken to seek views on whether a zero tolerance approach to agricultural and veterinary chemicals and/or their metabolites is appropriate for chemicals where the APVMA has indicated an MRL is **not** necessary. If this was not considered more fully, this may lead to a situation where the presence of a chemical is illegal, even though it has been assessed as not requiring an MRL. Also proposed that a review of Standard 1.4.1 – Contaminants and Natural Toxicants might be necessary, as there appeared to be similarities with Standard 1.4.2

5.2.1 *Evaluation*

FSANZ agrees with this and is proposing to consider these issues more comprehensively as detailed in Section 4.3 above.

5.3 **International Honey Exporters Organisation**

Questioned whether the definition of chemical encompassed antibiotic, pesticide or chemicals and/or their metabolites. It also raised the issue of the regulation of foods containing trace levels of contaminants.

5.3.1 *Evaluation*

The definition of a chemical would encompass antibiotic, pesticide or chemicals. However, FSANZ considers that the common interpretation in Standard 1.4.2 would adequately cover all types and forms of approved chemicals including their metabolites under the residue definition. FSANZ may consider this definition further at Final Assessment.

However, FSANZ currently cannot address the issue of trace level contaminants in the foods supply until there is further discussion and consultation with key stakeholders to decide an approach.

5.4 **Department of Agriculture, Fisheries and Forestry (Australia)**

Concerned that the metabolites are not listed in bold type and believe that the metabolites should be limited to those included in the residue definition and proposed the following text to be considered by FSANZ:

‘chemical means an agricultural or veterinary chemical and/or their metabolites, as defined by its residue definition, whether or not listed in bold type in the shaded boxes in Schedule 1 or 2.’

5.4.1 *Evaluation*

This issue has been addressed in the current drafting. The intention is only to prohibit residues of unapproved chemicals and their metabolites.

5.5 **Unilever Australasia, Food Liaison Ltd, Food and Beverage Importers Association (FBIA) and Nestlé Australia Ltd**

Unilever Australasia indicated that the review and consultation period were severely limited and did not resolve the wider regulatory issue of foods containing trace levels of contaminants when a risk assessment has demonstrated little or no public health and safety concerns. Food Liaison Ltd, the FBIA and Nestlé Australia similarly raised issues in relation to foods containing trace levels of contaminants, particularly, in imported foods.

5.5.1 *Evaluation*

Whilst acknowledging that the consultation was limited, FSANZ will further consider the issue of trace levels of contaminants in the food supply as detailed in Section 4.3.

5.6 Victoria Health

The need for an urgent amendment is **queried** and it was Victoria Health's position that the usual process for developing a Proposal should be followed, rather than use of the urgent provisions. In addition, there are adequate provisions under the unsafe and unsuitable provisions of the Food Acts or similar provisions in other State legislation.

5.6.1 Evaluation

FSANZ still considers that an amendment to Standard 1.4.2 is necessary to restore the intended effect of allowing regulation of undesirable chemicals in the food supply which have not been thoroughly assessed for safety (including a rigorous toxicological assessment) under the current registration requirements for agricultural and veterinary chemicals in Australia.

There is overall support for this position from other submitters.

5.7 NSW Health

Supported the intent of the proposed changes in P294, however, were concerned that this might encapsulate metabolites of chemicals in all cases where no MRL or health concern was evident. This might also include normal and harmless metabolites, derivatives and degradation products indistinguishable from chemicals inherently present in foods.

5.7.1 Evaluation

The issues raised by NSW Health have been addressed in the revised drafting.

5.8 Dairy Australia and the Victorian Department of Primary Industries, Dairy Food Safety Victoria and Prime Safe

Support was provided for the urgent amendment of Standard 1.4.2 to realise the intent and spirit of the Standard such that where a chemical was not listed, no residues might be found in that food. However, agricultural and veterinary chemicals themselves were not defined. It was suggested that the APVMA definition (*Agvet Chemical Code Act 1994*) was used or referenced. Consideration should also be given to excluding naturally occurring chemicals from the 'no residues allowed' principle for ag/vet chemicals not listed.

5.8.1 Evaluation

The APVMA was consulted on the drafting and raised no concerns with the amended proposed drafting. In addition, the amended drafting excluded naturally occurring chemicals. However, FSANZ will consider this issue in more detail at Final Assessment.

5.9 Capilano Honey Ltd

Supported the current action in relation to the Proposal but indicated that the long-term goal should be to consider test methods and background levels of chemicals in complex matrices such as honey.

5.9.1 Evaluation

FSANZ agrees with this and will further consider this issue as detailed in Section 4.3 above.

6. Regulatory Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and governments in Australia and New Zealand. The benefits and costs associated with the proposed amendment to the Code will be analysed using regulatory impact principles.

The following two regulatory options are available for this Proposal:

Option 1. Maintain the *status quo* and not amend Standard 1.4.2.

Option 2. Amend Standard 1.4.2 in order to implement the original intent and to avoid any potential public health and safety implications.

7. Impact Analysis

The parties potentially affected by the above options include:

- consumers, including domestic and overseas customers;
- growers and producers of domestic and export food commodities;
- importers of agricultural produce and foods; and
- Commonwealth, State and Territory agencies involved in monitoring and regulating the use of agricultural and veterinary chemicals in food and the potential resulting residues.

The impact of the proposed change to the regulation will be determined prior to FSANZ conducting a Final Assessment of the proposal. FSANZ's preferred approach is Option 2.

8. Consultation

FSANZ conducted an assessment of this Proposal under the urgent provisions of the Code [section 24 (1)] and public comments were called for from the period 5 May to 12 May 2004.

In addition, FSANZ targeted key stakeholders and invited comment on the Proposal. A total of 17 submissions were received and are summarised in **Attachment 2**.

FSANZ sought public comment in order to assist in assessing this Proposal on the following:

- any information relevant to the Proposal;
- parties that might be affected by having this Proposal approved or rejected;
- potential costs and benefits to consumers, industry and government.

FSANZ is now undertaking a further round of public comment in order to seek stakeholder views on the current Standard. Following that, FSANZ will conduct a Final Assessment of Proposal P294 and consider more fully the options of regulation, costs and benefits and the issue of WTO notification.

8.1 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated 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 correct an anomaly in the MRL Standard 1.4.2 is unlikely to have a significant effect on international trade and would protect public health and safety via restoration of the original intent of Standard 1.4.2 in relation to chemicals not 'listed' in the Standard.

This issue will be fully considered prior to Final Assessment of the Proposal, and if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

9. Conclusion and Recommendation

FSANZ approved the amendments to Standard 1.4.2 and the raising of a Proposal on 14 May 2004 for the following reasons:

- The variation to Standard 1.4.2 re-institutes the model regulatory approach adopted throughout the Code. Individual standards in the Code are constructed using a formula that prohibits substances in food unless those substances are expressly permitted. Standard 1.3.1 on food additives and Standard 1.3.3 on processing aids provide specific examples of the regulatory formula applied in the Code. This regulatory approach establishes the mechanism by which FSANZ effectively monitors the safety of substances in the food supply, thus enabling FSANZ to meet its statutory objective of protecting public health and safety.
- The amendment was required to correct an anomaly in Standard 1.4.2 to ensure that enforcement agencies can take action against the presence of undesirable chemical residues in food in terms of Standard 1.4.2.
- Although the general provisions in food legislation could potentially be used by enforcement agencies to take action against suppliers of foods containing these residues, given the potential public health implications, FSANZ and the majority of enforcement agencies considered that the amendment to the Standard was necessary, under urgency provisions, to ensure that enforcement agencies could take the action necessary to protect public health and safety.

ATTACHMENTS

1. Variation to the *Australia New Zealand Food Standards Code*
2. Summary of Public Submissions

Variation to the *Australia New Zealand Food Standards Code* approved by the FSANZ Board and gazetted on 14 May 2004.

To commence: on gazettal

[1] **Standard 1.4.2 of the *Australia New Zealand Food Standards Code* is varied by -**

[1.1] *inserting after the third sentence in the Purpose text –*

Also, if an agricultural or veterinary chemical is not listed in Schedule 1, there must be no detectable residue of that chemical and no detectable residue of any metabolites of that chemical in food (whether or not that the particular food is listed in Schedules 1, 2 or 4). However, this Standard does not limit the presence of substances, including ingredients, food additives and processing aids that are otherwise permitted in the Code. Nor does it limit the presence of a substance naturally present in food, such as water or salt, or the presence in a food of substances that are formed naturally during processing of the food.

[1.2] *omitting the definition of chemical in clause 1, substituting –*

chemical means an agricultural or veterinary chemical, whether or not listed in bold type in the shaded boxes in Schedules 1 or 2, but excludes –

- (a) a substance naturally present in food, for example, water or salt, before the food is processed; and
- (b) a substance in the food when naturally formed during processing, for example, heat treating, of the food; and
- (c) ingredients, food additives and processing aids that are permitted in this Code to be present in food.

[1.3] *inserting after subclause 2(2) –*

2(3) If a chemical is not listed in this Standard there must be no detectable residue of –

- (a) that chemical in food (whether or not the food is listed in Schedules 1, 2 or 4); and
- (b) metabolites of that chemical in food (whether or not the food is listed in Schedules 1, 2 or 4).

Summary of public submissions

Submitter	Comment
The Australia Consumers Association (ACA)	The Australian Consumers' Association supports the FSANZ recommendation to approve the draft variations to Standard 1.4.2. ACA agrees that the original intent of the Clause 2 was not to exclude residues of agricultural and veterinary chemicals not listed in Schedule 1 from prohibition in foods, and supports the amendment of the standard to reflect the true intentions of this clause. While this issue has been raised specifically in relation to nitrofurans, ACA supports the change of wording that would apply to any other chemical not listed in Schedule 1 or 2.
Australian Food and Grocery Council (AFGC)	The AFGC supports the overall principle of P294. However, the AFGC recommended that the drafting be modified to ensure that a prohibition did not apply to normal ingredients in foods or permitted additives or processing aids, natural constituents of foods or chemicals naturally formed during the processing of foods.
Edward Planken, President, International Honey Exporters Organisation	Supports in principle Proposal P294. Questioned whether the definition of chemical encompassed antibiotic, pesticide or chemical and/or their metabolites. FSANZ should state this clearly in Standard 1.4.2. Secondly in relation to subclause 2(3) states ... " <i>there must be no detectable residue of that chemical in food</i> ". Mr Planken asks what is not detectable? To resolve the problem he has suggested the following words to be considered in the drafting: "where a "chemical" is not listed in the Standard, there must be no detectable residue of that chemical in the food above 0.5 ppb unless it is toxicologically proven that the detected substance has a potential impact on public health and safety.
Nestle Australia Ltd	Nestle supports the comments provided by the AFGC and the FBIA. The proposal does not allow for those residues that are safe and not used in Australia to be regulated.
Bill Murray- representing AWB Ltd, CBH Ltd, Flour Millers' Council of Australia and Grain-Corp Ltd	These organisations consider the Proposal essential and support that the current wording of Standard 1.4.2 be altered to ensure that its original purpose and intention is clear.
Unilever Australasia	The review and consultation period have been severely limited and does not resolve the wider regulatory issue of foods containing trace levels of contaminants when a risk assessment has demonstrated little or no public health and safety concerns. Urge FSANZ to look at the wider issue of trace residues, particularly with respect to MRLs for imported foods.

Food Liaison Ltd	This Proposal can be used as an opportunity to revisit the policy of MRLs that are established for chemicals overseas as the present system of setting MRLs based on usage in Australia only can be viewed as a trade barrier. It is also an opportunity to harmonise with New Zealand in respect of the default level of 0.1 mg/kg for chemicals that are not listed in the New Zealand regulations.
Capilano Honey Limited	<p>Capilano supports the current action being taken by FSANZ on issues such as nitrofurans residues in honey, and with the spirit in which the Standard has been interpreted and actioned by FSANZ thus far. We applaud action taken by FSANZ, whereby the response is to work with industry and AQIS to remove contamination via import and quality control, while undertaking an appropriate response to contamination issues at consumer level solely based on public health and safety.</p> <p>Suggested three options in relation to the regulation of low-level contaminants in the food supply.</p>
Food and Beverage Importers Association	Support the Proposal. This Proposal should be used as an opportunity to review the policy underpinning Standard 1.4.2 to develop a more suitable mechanism for dealing with trace residues and import tolerances.
Dairy Australia	<p>Support is provided for the urgent amendment of standard 1.4.2 to realise the intent and spirit of the standard such that where a chemical is not listed, no residues may be found in that food.</p> <p>Ag/Vet chemical themselves are not defined. It is suggested that the APVMA definition (agvet Chemical Code Act 1994) is used or referenced.</p> <p>Consideration should be given to excluding naturally occurring chemicals from the ‘no residues allowed’ principle for ag/vet chemicals not listed.</p>
Australian Pesticide and Veterinary Medicines Authority (APVMA)	The APVMA supported the intent of the drafting.
Queensland Health.	<p>Supportive of the Proposal to implement the original intent of Clause 2 (2) of Standard 1.4.2.</p> <p>Propose that a review be undertaken to seek views on whether a zero tolerance approach to AG/VET chemicals and/or their metabolites is appropriate for chemicals where the APVMA has indicated an MRL is not necessary. If this is not considered more fully, this may lead to a situation where a chemical is present has been assessed as not requiring an MRL, yet its presence would then be illegal.</p> <p>Also propose that a review of Standard 1.4.1-Contaminants and Natural Toxicants may be necessary as there appear to be similarities with Standard 1.4.2</p>

<p>Ian Reichstein, Manager-Plant programs, National residue Survey DAFF</p>	<p>Supports the declaration of urgency under Proposal P294.</p> <p>Commented that although the residue definition is defined they consider that it is not explicitly linked to the definition of a chemical.</p> <p>Concerned that the metabolites are not listed in bold type and believe that the metabolites should be limited to those included in the residue definition.</p> <p>Proposed an alternative text for consideration by FSANZ:</p> <p>“chemical means an agricultural or veterinary chemical and/or their metabolites, as defined by its residue definition, whether or not listed in bold type in the shaded boxes in Schedule 1 or 2.</p>
<p>Department of Human Services, South Australia</p>	<p>Supports the draft variation to Standard 1.4.2.</p>
<p>Victorian Department of Primary Industries, Dairy Food Safety Victoria and Prime Safe</p>	<p>Support the Proposal. While there may be some argument that this issue is not an immediate threat to public health and safety, there is a clear expectation by the community that chemical residues that have not been assessed for safety would not be allowed in food for reasons of public health and safety.</p> <p>In order to ensure that there is no confusion or continuing legal anomaly concerning residues from chemicals not listed in Standard 1.4.2, we suggest that there is a clearer definition of agricultural and veterinary chemicals than that contained in the proposal.</p>
<p>Victoria Health</p>	<p>The need for an urgent amendment is queried and it is Victoria Health’s position that the usual process for developing a Proposal should be followed, rather than use of the urgent provisions. In addition, there are adequate provisions under the unsafe and unsuitable provisions of the Food Acts or similar provisions in other State legislation.</p>
<p>NSW Food Authority</p>	<p>Support the intent of the proposed changes in P294, however, are concerned that the drafting may encapsulate metabolites of chemicals in all cases where no MRL or health concern is evident. This may also include normal and harmless metabolites, derivatives and degradation products indistinguishable from chemicals inherently present in foods.</p>