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FINAL ASSESSMENT REPORT

PROPOSAL P294

**VARIATION TO
STANDARD 1.4.2 – MAXIMUM RESIDUE LIMITS**

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 extended the public comment period for an additional 4-weeks to allow further stakeholder consideration of the variation to Standard 1.4.2. FSANZ has now completed a Final Assessment of Proposal P294, which is within 12 months of the date of effect of the variation to the Code.

This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council. If the Ministerial Council does not request FSANZ to review the draft amendments to the Code, an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

In New Zealand, the New Zealand Minister of Health gazettes the food standard under the New Zealand Food Act. Following gazettal, the standard takes effect 28 days later.

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Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.gov.au or alternatively paper copies of reports can be requested from FSANZ's Information Officer at info@foodstandards.gov.au including other general enquiries and requests for information.

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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 P 294 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 conducted a further round of the public comment from the period 4 August to 1 September 2004 whilst highlighting proposed strategies to deal with the broader issues raised from submitters in the first round of public comment.

Statement of Reasons

FSANZ re-affirmed the amendments to Standard 1.4.2 gazetted 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 consider that the amendment to the Standard is necessary, to ensure that enforcement agencies can 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 Food Standards 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 (P 294) to seek an emergency amendment to the Code to correct this anomaly.

FSANZ in consultation with the States, Territories, New Zealand and 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 was considered under section 24(1) of the FSANZ Act as an urgent Proposal in order to protect public health and safety.

3. Background

3.1 Background

FSANZ arranged a teleconference on 22 April 2004 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 (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 levels of agricultural and veterinary chemicals in the food supply;
- 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
- import and Codex MRLs in the Code.

FSANZ is currently considering the issue of regulation of low-level agricultural and chemicals residues in food, and in particular:

- concerns from enforcement agencies about the current 'zero tolerance' approach to chemical residues not listed in Standard 1.4.2;
- 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 discussions with the relevant policy agencies continue in order to develop an overall policy in Australia on the regulation of low-levels of agricultural and veterinary chemicals in food in the food supply.

In light of the limited initial period of public comment for P 294, FSANZ sought additional public comment for four weeks to allow further stakeholder consideration of the current amendments to Standard 1.4.2 (Attachment 1). FSANZ has now completed a Final Assessment of Proposal P294 within 12 months of the date of effect of the variation to the Code.

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 Proposal 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

Queensland Health **supported** Proposal P294. It 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 was **not** necessary. If this is 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. Queensland Health also proposed that a review of Standard 1.4.1 – Contaminants and Natural Toxicants may 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

The 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.

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 Australian Government Department of Agriculture, Fisheries and Forestry (DAFF)

DAFF was concerned that the metabolites were not listed in bold type and believed 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 had been severely limited and did not resolve the wider regulatory issue of foods containing trace levels of contaminants when a risk assessment had 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 chemical contaminants, particularly, in imported foods.

5.5.1 Evaluation

FSANZ is currently considering the issue of regulation of low levels of agricultural and veterinary chemicals in the food supply and also the policy consideration on recognition of other MRLs (e.g. Codex) as detailed in Section 4.3.

5.6 Department of Human Services (DHS, Victoria)

The need for an urgent amendment is queried and it is DHS Victoria'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 was 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.

In addition, it facilitates enforcement by the jurisdictions. It is more straightforward for jurisdictions to take action in relation to breaches of the Code, where prohibited chemicals are present in food, rather than to prove that such chemicals have rendered a food unsafe or unsuitable under the Food Acts.

There was overall support for this position from other submitters.

5.7 NSW Health

NSW Health supported the intent of the proposed changes in Proposal P294, however, is concerned that this 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.

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

These groups **supported** 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

APVMA has been consulted on the drafting and has raised no concerns with the amended proposed drafting. In addition, the amended drafting excludes naturally occurring chemicals.

5.9 Capilano Honey Ltd

Capilano Honey **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.

5.10 MCOR Australia, Food Technology Association of Victoria and the AFGC

These groups believed the current drafting did not contain any exemptions for materials derived from packaging.

It was recommended that FSANZ consider including a further exemption to the definition of a chemical to cover migration of chemicals from food (e.g. in the possible case of one or more chemicals being chemically identical to an agricultural chemical or metabolite thereof).

Suggested drafting:

- (d) a substance in food that has migrated from the packaging material of that food.

5.10.1 Evaluation

While it might be possible that some packaging contaminants may bear some similarity in structure to residues of agricultural and veterinary chemicals, the reasons for their presence in food are vastly different and resemble the reasons relating to the presence of contaminants found in food.

On this basis, FSANZ considers that it is still necessary at this stage to have a mechanism of regulation of chemical contaminants from packaging (other than agricultural and veterinary chemicals) under Standards 1.4.1 – Contaminants and Natural Toxicants and Standard 1.4.3 – Articles and Materials in Contact with Food, as is currently the case for regulation of packaging contaminants. In the case of semicarbazide as mentioned in the submissions, they are currently permitted on the basis that the levels resulting from packaging migration are not a public health and safety concern.

5.11 New Zealand Food Safety Agency (NZFSA)

Internationally, metabolites are limited to those of toxicological significance. The suggested wording contained in Attachment 1 (*in both the Purpose text and subclause 2 (3) (b)*) would catch all metabolites down to (if it occurred) carbon dioxide and water, and any metabolites which may be common to the chemical in question and many other chemicals that were legally allowed in food. NZFSA proposed that the drafting was amended by adding the following underlined words, or other similar limiting words:

- Purpose text (second line) refers to any toxicologically significant metabolites, and subclause 2 (3) (b) refers to toxicologically significant metabolites.

5.11.1 Evaluation

A provision based upon toxicological significance previously existed in the Code. However, this was removed from Standard 1.4.2 during the review of the Code under Proposal P194, as it was a term that was deemed inherent in the Standard and was a term that was ambiguous, difficult to interpret and enforce.

In addition, FSANZ is not aware of any country that limits residues on the basis of a specific provision that refers to toxicological significance.

6. Regulatory Options

FSANZ was 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 following two regulatory options were 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 included:

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

FSANZ's preferred approach was Option 2 under the urgency provisions of the Code.

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 also undertook a further round of public comment in order to seek stakeholder views on the current Standard from 4 August to 1 September 2004, which are also summarised in Attachment 2.

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. Therefore, a notification was not made to the WTO.

9. Conclusion and Recommendation

FSANZ re-affirmed the amendments to Standard 1.4.2 gazetted 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, to ensure that enforcement agencies can take the action necessary to protect public health and safety.

ATTACHMENTS

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

**Draft 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 (5 to 12 May 2004)

Submitter	Comment
The Australia Consumers Association (ACA)	The ACA 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.
Nestlé Australia Ltd	Nestlé 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>Supports 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>Department of Human Services (DHS, Victoria)</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>Supports 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>

Summary of public submissions (4 August to 1 September 2004)

Submitter	Comment
<p>Australian Food and Grocery Council (AFGC)</p>	<p>The AFGC supports the changes to Standard 1.4.2.</p> <p>The AFGC recommends that FSANZ considers including a further exemption to the definition of chemical to cover migration of chemicals from food (e.g. in the possible case of one or more chemicals being chemically identical to an agricultural chemical or metabolite thereof).</p>

	<p>Suggested drafting:</p> <p>(d) a substance in food that has migrated from the packaging material of that food.</p>
AMCOR Australasia	<p>The current drafting does not contain any exemption for materials derived from packaging.</p> <p>A literal reading of the Standard does not appear to exempt the presence of semicarbazide in foods due to migration from packaging materials from the ban on metabolites. Further, the specific exemptions in the standard appear to imply that packaging migration is intended to be included in the ban.</p> <p>Amcors requests consideration to include wording that specifically transfers regulation of materials migrating from packaging materials to the general section on contaminants in foods, Standard 1.4.1.</p>
Heinz Australia/Heinz Wattie's New Zealand	<p>Support the AFGC submission</p>
Queensland Health	<p>Reiterates comments in that the Proposal does not address the issues raised in relation to Table 5 of the MRL Standard listing substances where residues do not or should not occur in foods or animal feeds; or where the residues are identical to or indistinguishable from natural food components; or are otherwise of no toxicological significance.</p> <p>Furthermore, there appears to be a need to review Standard 1.4.1 – Contaminants and Natural Toxicants since there appears to be similarities between it and Standard 1.4.2 – Maximum Residue Limits.</p>
NZFSA	<p>Internationally, metabolites are limited to those of toxicological significance. The suggested wording contained in Attachment 1 (<i>in both the Purpose text and subclause 2 (3) (b)</i>) would catch all metabolites down to (if it occurred) carbon dioxide and water, and any metabolites which may be common to the chemical in question and many other chemicals that are legally allowed in food. It does not think this is the intent of the variation.</p> <p>Its suggestion is that the proposed drafting is amended by adding the following underlined words, or other similar limiting words:</p> <p>Purpose text (second line) refers to <i>any <u>toxicologically significant</u> metabolites</i>, and subclause 2 (3) (b) refers to <i><u>toxicologically significant</u> metabolites</i>.</p>

FTA Victoria	<p>The Committee agreed with Option 2 – to amend Standard 1.4.2 in order to implement the original intent and to avoid any potential public health and safety implications.</p> <p>In the Draft Variation to the Code, the definition of the term ‘chemical’ includes the term ‘processing’ with examples of processing given. Would packing and packaging be included as ‘processing’ as semicarbazide is reported to be derived from packaging materials (particular plastics) i.e. seals in caps? Examples of foods could include honey and jams that are either warm or hot filled and cooled and not further processed. Hence the validity of the clause [1.2] (b) is questioned.</p>
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