

**3-04**  
**5 May 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:  
**5pm (Australian Eastern Standard Time) on 12 May 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.

### **INVITATION FOR PUBLIC SUBMISSIONS**

FSANZ has prepared an Assessment Report of Proposal P294, which includes 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 has been 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 has specified a submission period of five working days. After submissions have been received, FSANZ will consider the proposal further, and will have regard to any submissions received.

FSANZ invites public comment on this Assessment Report based on regulation impact principles and the draft variation to the Code under the emergency provisions of the Code.

Written submissions are invited from interested individuals and organisations to assist FSANZ in considering this Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. 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](http://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](http://www.foodstandards.govt.nz)**

Submissions should be received by FSANZ **5pm (Australian Eastern Standard Time) on 12 May 2004.**

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](mailto: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](mailto:info@foodstandards.gov.au).

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## Executive Summary and Statement of Reasons

Standard 1.4.2 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 residues of that chemical in any food. The Standard has been interpreted this way by the National Health and Medical Research Council / NFA / ANZFA / FSANZ, the jurisdictions and industry since 1987.

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. nitrofurans<sup>1</sup>) 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, are not prohibited in food. This position has been confirmed by legal advice.

The objective of this Proposal is 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 would be exposed to undesirable chemical residues in the food supply and enforcement agencies could not take corrective action to reduce this exposure in terms of Standard 1.4.2.

### Statement of Reasons

FSANZ recommends the approval of the drafting and the raising of a Proposal for the following reasons:

- The draft 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 is 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 enforcement agencies consider that the amendment to the Standard is necessary, under urgency provisions, to ensure that enforcement agencies can take the action necessary to protect public health and safety.

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

## 1. Introduction and Regulatory Problem

Standard 1.4.2- Maximum Residues 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 residues of that chemical in any food. The Standard has been interpreted this way by the National Health and Medical Research Council/NFA/ANZFA/FSANZ, the jurisdictions and industry since 1987.

However, upon investigating the interpretation of Standard 1.4.2 in relation to residues of nitrofurans in honey, FSANZ has 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, recent legal advice is that the Code does not prohibit the presence of nitrofurans in food. The crux of this advice is 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 presently drafted, this is not the case.

This would now appear to be a longstanding problem, which is 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. FSANZ is now raising this Proposal to seek an emergency amendment to the Code to correct this anomaly.

FSANZ in consultation with the States, Territories, New Zealand and AQIS has discussed this problem and the opinion of jurisdictions generally is that they can 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 are supportive of an amendment to the Code under urgency provisions to address the anomaly.

## 2. Objective

The objective of this Proposal is 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 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 (1) 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 is that chemicals not specifically listed, such as nitrofurans, are not prohibited in food. Legal advice has confirmed this position.

## 4. Relevant Issues

The Australian Pesticide and Veterinary Medicines Authority (APVMA) currently assess 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).

Relevantly, this proposal involves an amendment to Standard 1.4.2 to correct the current anomaly by restoring the common understanding of the effect of Clause 2 (2) in Standard 1.4.2 which currently states:

‘In 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 is not made this may place 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 AG/VET chemicals in Australia.

## 5. 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 of this Clause to avoid any potential public health and safety implications.

## 6. 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.

## **7. Consultation**

FSANZ is seeking public comment in order to assist in assessing this Proposal. Such comments could cover:

- 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.

Under section 24 (1) of the FSANZ Act, FSANZ has declared this proposal as 'urgent' and will now conduct five working days of consultation with stakeholders.

### **7.1 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.

## **8. Conclusion and Recommendation**

FSANZ recommends the approval of the draft variations to Standard 1.4.2 for the following reasons:

- The draft 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 is 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.
- 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 enforcement agencies consider that the amendment to the Standard is necessary, under urgency provisions, 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*

**Draft Variation to the *Australia New Zealand Food Standards Code***

**To commence: on gazettal**

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

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

**chemical** means an agricultural or veterinary chemical and/or their metabolites,  
whether or not listed in bold type in the shaded boxes in Schedules 1 or 2.

**Drafting note:**

This definition has been extended to include chemicals **and/or their metabolites**. Particular comment is sought on this aspect of the draft variation.

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

2(3) If a chemical is not listed in this Standard there must be no detectable residue of that chemical in food (whether or not the food is listed in Schedules 1, 2 or 4).