

**Comments on the Productivity Commission Performance**  
**Benchmarking of Australian and New Zealand Business**  
**Regulation: Food Safety Draft Research Report - Chapter 13**  
**Maximum residue limits**

Food Standards Australia New Zealand (FSANZ) is an independent statutory agency established by the *Food Standards Australia New Zealand Act 1991*. Working within an integrated food regulatory system involving the governments of Australia and the New Zealand Government, we set food standards for the two countries. FSANZ is part of the Australian Government's Health and Ageing portfolio.

FSANZ would like to submit Attachment 1 as a consolidated summary of the MRL setting process in Australia and the respective roles of the Australian Pesticides and Veterinary Medicines Authority (APVMA) and FSANZ.

**General comments on Chapter 13 are as follows:**

Processes and, where relevant, the timeframes for developing maximum residue limits (MRLs) in the *Australia New Zealand Food Standards Code* (the Code) are stipulated in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). There is no mention of the FSANZ Act in Chapter 13 other than in the diagrams. FSANZ's principal role is a developer of food standards.

FSANZ is not responsible for specifying MRLs that apply in Australia. The MRLs that apply in Australia are the responsibility of the APVMA (notifier of MRLs resulting from registered or approved product use). However, FSANZ and the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) do have the power to amend any standards notified to it by FSANZ, including for MRLs.

Chapter 13 provides comprehensive detail on processes that may be used to assess MRLs for inclusion in the Code but could emphasise the process that is predominantly used.

The following points are considered relevant:

- The 9 month statutory time limit does not apply to any of the Applications or Proposals relating to MRLs considered in the Productivity Commission study. The 9 month consideration period stipulated in the *Food Standards Australia New Zealand Regulations 1994* only applies in certain circumstances. For Proposals, Subdivision H of the FSANZ Act and regulation 10, i.e. the 9 month consideration period, only applies where the APVMA notifies FSANZ under section 13A of the AgVet Code of an Application to register a chemical product and an MRL variation is required<sup>1</sup>. To date, FSANZ has not received such a notification.
- Otherwise, MRL Proposals are generally raised and considered under Subdivision B of the FSANZ Act. The general procedure applies and there is no prescribed period for FSANZ to complete its consideration of these Proposals.
- MRLs are primarily assessed for inclusion in the Code by FSANZ in Proposals as this provides the most flexibility to consider both APVMA MRLs and other MRLs needed to facilitate trade. Typically, FSANZ has included other MRLs, in addition to APVMA MRLs, in the regular MRL Proposals that FSANZ prepares to consider APVMA MRLs (Refer to Attachment 1). This minimises costs for business while still ensuring adequate public consultation and the protection of public health and safety.
- Advancement of MRLs is afforded a high priority in the agency and FSANZ aims to complete its consideration of MRLs once all the required information is received and as soon as the current processes allow.
- FSANZ prepares approximately three to four Proposals a year for MRLs to minimise the time taken for MRLs to be considered through the FSANZ Act processes. The scope, number and timing of Proposals is dependent on when MRLs are notified to FSANZ by the APVMA and comments from public consultation. These notifications and comments are not within the control of FSANZ

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<sup>1</sup> Section 80 of the FSANZ Act provides that Subdivision H applies if (a) the APVMA notifies the Authority under section 13A of the Agvet Code of an application to register a chemical product; and (b) it is likely that the chemical product would, if used, be present in foods at a level that is not already permitted under the Maximum Residue Limits Standard.

and so timing will always be uncertain, although FSANZ undertakes detailed planning for the Proposals once it receives the notifications from the APVMA.

- In terms of Applications received after 1 October 2007, a statutory timeframe of 9 months applies. These Applications are placed on the FSANZ Workplan and start after the allocated date unless an Applicant chooses to pay fees to have the application expedited.

The report refers to 'time delays' and previous Productivity Commission reports about duplication (p 311). FSANZ understands that legislative change to the FSANZ Act would be required to implement the arrangements referred to on p311 in the report. This is not within FSANZ's ambit and it should be identified that FSANZ is not charged with advancing the Council of Australian Government (COAG) reforms. The COAG MRL reform agenda is being progressed by the Department of Health and Ageing (DoHA) and other agencies involved in policy on MRLs. DoHA has regularly consulted FSANZ on the COAG reforms for MRLs and obtained technical input, as required, to assist it in this work.

### **Specific Comments**

#### **P 299**

##### *Key Points*

*Dot point 1*-makes reference to the Treaty between Australia and New Zealand excluding MRLs. However, it should be noted that under the Trans Tasman Mutual Recognition Arrangement (TTMRA), food produced or imported into Australia that complies with Standard 1.4.2 of the Code can be legally sold in New Zealand. Food produced or imported into New Zealand that complies with the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2008 and amendments can also be legally sold in Australia.

*Dot Point 3*-comments on the time taken to assess MRLs. The following indicates the timeframes for assessment for completed MRL Proposals under the assessment procedures in place from 1 October 2007:

- M1001 3 months from the clock start
- M1002 4.5 months from clock start
- M1003 6.5 months from the clock start

Indicative timeframes for the similar MRL Applications under the previous assessment procedures were:

A610	5.5 months from the clock start
A607	5.5 months from the clock start
A599	5 months from the clock start
A591	4 months from the clock start

As FSANZ bundles consideration of MRLs for efficiency reasons, FSANZ is not able to formally start work on an MRL Proposal until the last monthly notification from the APVMA has been received.

There should be clarification within this dot point to indicate that the delay between approval and gazettal is due to statutory requirements for the Ministerial Council to consider the decision, before gazettal can proceed. This is not a requirement in New Zealand.

#### P 300

##### *Para 1-*

MRLs are regulatory measures, but it is questioned whether it is appropriate to describe them as protecting 'the health of consumers'. MRLs are primarily verification measures used in monitoring the legitimate use of agricultural or veterinary chemical products. MRLs are based on good agricultural or veterinary practice and are not direct safety limits, but monitoring limits set to ensure that chemical products are used in accordance with approved conditions of use.

*Para 2 dot point 3-* Though not for compliance purposes, foods that are ready to eat are also tested for residue levels under the Australian Total Diet Study (ATDS) not just raw foods.

#### P 302

Para 1-The point needs to be made that FSANZ is not responsible for specifying MRLs that apply in Australia, but has responsibility for considering MRLs for inclusion in the Code for agricultural and veterinary drug residues in food already set by the APVMA for Australia or requested by another party.

### P 303

The statement that 'Before FSANZ can set any MRLs.... must be registered with the APVMA..' is not correct. FSANZ can and has included MRLs other than APVMA MRLs in the Code through recent Applications and Proposals. This has provided a transparent and cost-effective mechanism for considering MRLs needed to facilitate trade.

### P 305

*Dot point-* Predominately FSANZ prepares a Proposal in response to notifications from the APVMA recommending MRL variations. These MRLs may be associated with new chemicals, extensions of use, permits or chemical reviews. FSANZ may also consider other countries' MRLs/Codex MRLs in Proposals on a case-by-case basis (See Attachment 1).

Figure 13.2 should also indicate that a preferred timeframe of 9 months exists but that this is not an actual statutory timeframe of 9 months for a Proposal prepared under Subdivision B of the FSANZ Act. Also, an administrative assessment is not required in the Proposal process under the FSANZ Act; however FSANZ conducts an assessment for Proposals that is equivalent to the administrative assessment required for applications.

### P 306

It should be noted that a 'stop clock' would not apply to a Proposal, only an Application.

### P 311

FSANZ has never rejected an MRL notified to it by the APVMA

FSANZ continues to monitor and improve administrative processes to set MRLs and incorporate them in the Code. The amendments to the FSANZ Act in 2007 enable FSANZ to consider MRLs for inclusion in the Code in accordance with an amended and streamlined (Proposal) procedure, in line with the changed procedures for Applications.

#### P 316

The first statement that all MRL assessments completed by FSANZ from 1 July 2007 until 30 June 2009 were the result of notifications from the APVMA is incorrect because some FSANZ assessments included MRLs requested by industry for various foods including prawns, tea, cherries, honey and grapes during this time.

#### P 317

The data on which fig 13.7 is based is not clear. The times appear to be taken from the time of APVMA notifications to FSANZ and should not be measured against the statutory time limit which does not apply. Also, it is not clear why there are 14 Proposals shown for this time period since FSANZ considered 5 Applications and 2 Proposals in this time period (as shown in table 13.7). The sources listed below fig 13.7 indicate that some NZFSA assessments may have been included.

## **Attachment 1**

### **Role of the APVMA in establishing maximum residue limits (MRLs)**

Agricultural chemical products and veterinary chemical products are used to control pests and diseases of plants and animals and assist producers in providing wholesome foods from healthy plants and animals. The Australian Pesticides and Veterinary Medicines Authority (APVMA) administers the National Registration Scheme for Agricultural and Veterinary Chemicals in Australia. The Scheme registers and regulates the manufacture and supply of all agricultural chemical products and veterinary chemical products used in Australia, up to the point of wholesale sale<sup>2</sup>.

The safety and performance of all chemicals that are used in food producing crops and animals must be assessed by the APVMA prior to registration to ensure that the health and safety of consumers is protected. As part of that assessment process, using data submitted with the registration application, the APVMA determines the likely level of chemical residues remaining at the time of harvesting or slaughter. Drawing on this information and considering relevant health standards the APVMA recommends MRLs. No product is registered unless these levels are safe for people consuming treated foods.

### **Role of FSANZ in establishing MRLs in food legislation**

The APVMA regularly makes notifications to Food Standards Australia New Zealand (FSANZ) for specific maximum residue limits (MRLs) to be included in the *Australia New Zealand Food Standards Code* (the Code) so that the MRLs in the Code reflect the approved use of agricultural and veterinary chemical products in Australia.

FSANZ's primary role in developing food regulatory measures for agricultural and veterinary chemicals is to ensure that the potential

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<sup>2</sup> <http://www.apvma.gov.au/registration/registering.shtml>.

[http://www.apvma.gov.au/about\\_us/pdf/overview\\_agvet\\_national\\_system.pdf](http://www.apvma.gov.au/about_us/pdf/overview_agvet_national_system.pdf)

[http://www.apvma.gov.au/residues/residue\\_questions\\_and\\_answers.shtml](http://www.apvma.gov.au/residues/residue_questions_and_answers.shtml)

residues in food are within reference health standards. FSANZ conducts and reviews dietary exposure assessments in accordance with internationally accepted practices and procedures.

In assessing the public health and safety implications of chemical residues, FSANZ considers the dietary exposure to chemical residues from potentially treated foods in the diet by comparing the dietary exposure with the relevant reference health standard. FSANZ will not approve variations to limits in the Code where dietary exposure to the residues of a chemical could risk public health and safety.

The estimated dietary exposure to a chemical is compared to the relevant reference health standard/s for that chemical in food (i.e. the acceptable daily intake (ADI) and/or the acute reference dose (ARfD)). FSANZ considers that dietary exposure to the residues of a chemical is acceptable where the best estimate of this exposure does not exceed the relevant standard/s.

#### **Standard 1.4.2 – Maximum Residue Limits**

This Australia-Only Standard includes MRLs in the Schedules to the Standard for permitted chemicals along with the specific commodities or food products that may contain them. Currently, under Commonwealth, State and Territory food legislation (subject to exceptions for food from New Zealand) there must be no detectable residue in a food commodity for which an MRL has not been listed in Standard 1.4.2.

It should be noted that MRLs are not direct safety limits but are monitoring limits set to ensure that approved chemical products are used in accordance with approved conditions of use. However, as noted above, consideration is always given to the relevant reference health standard when an MRL is established. MRLs are included in food legislation to allow the legal sale of safe and legitimately treated food.

#### **Relationship between Australia and New Zealand in establishing MRLs**

All food imported into Australia must comply with the requirements in Standard 1.4.2, except for food from New Zealand. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food. The Trans Tasman Mutual Recognition



Arrangement (TTMRA) between Australia and New Zealand commenced on 1 May 1998. The following provisions apply under the TTMRA:

1. Food produced or imported into Australia that complies with Standard 1.4.2 can be legally sold in New Zealand.
2. Food produced or imported into New Zealand that complies with the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards can be legally sold in Australia.

### **Establishing MRLs other than those notified by the APVMA**

FSANZ seeks comment on all amendments to MRLs in the Code, and identifies relevant Codex MRLs as part of the consultation documentation. FSANZ also considers submissions for legitimate MRLs that may be different from an MRL notified by the APVMA. In addition to the regular consideration of APVMA MRLs, applications may be made direct to FSANZ for any MRL and this would be considered in accordance with the FSANZ Act. Guidelines and formats for making an application are available on the website of FSANZ<sup>3</sup>. Key issues for FSANZ will be the safety of the residues, the legitimacy in food and the justification for presence in food.

Therefore, interested parties may advocate specific MRL amendments through the following mechanisms:

- the regular public consultation processes on proposed changes to the Code;
- in certain circumstances by requesting an MRL where residues in an imported food are consistent with a Codex MRL or other MRL established by a competent regulatory authority; or
- by making an application to amend the Code.

Potential applicants and advocates of MRL amendments are encouraged to contact FSANZ.

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<sup>3</sup> <http://www.foodstandards.gov.au/standardsdevelopment/informationforapplicants/index.cfm>