



Food Standards Australia New Zealand Amendment Bill 2010

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Law and Bills Digest Section

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Food Standards Australia New Zealand Amendment Bill 2010

Date introduced: 13 May 2010

House: House of Representatives

Portfolio: Health and Ageing

Commencement: Schedule 1 on a date to be fixed by Proclamation but no later than six months after the date of Royal Assent; all remaining provisions on the day of Royal Assent.

Links: The [links](#) to the Bill, its Explanatory Memorandum and second reading speech can be found on the Bills page, which is at <http://www.aph.gov.au/bills/>. When Bills have been passed they can be found at ComLaw, which is at <http://www.comlaw.gov.au/>.

Purpose

The primary purpose of the Food Standards Australia New Zealand Amendment Bill 2010 (the Bill) is to ensure that the residue risk assessments made by the Australian Pesticides and Veterinary Medicines Authority (APVMA) are recognised by Food Standards Australia New Zealand (FSANZ) for the purposes of the Australia New Zealand Food Standards Code (the Food Standards Code).

Background

On 12 October 2005 the then Prime Minister, Mr Howard, announced the appointment of a taskforce to identify practical options for alleviating the compliance burden on business from Government regulation.¹ The final report of the taskforce contained 178 recommendations.² In particular, recommendation 4.58 proposed that the Council of

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1. J Howard (former Prime Minister) and P Costello (former Treasurer), *Taskforce on reducing the regulatory burden on business*, joint press release, Canberra, 12 October 2005, viewed 27 May 2010, <http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22media%2Fpressrel%2FVHKH6%22>
 2. *Rethinking regulation: report of the Taskforce on reducing the regulatory burdens on business*, Commonwealth of Australia, Canberra, January 2006, viewed 27 May 2010, http://www.regulationtaskforce.gov.au/_data/assets/pdf_file/0007/69721/regulationtaskforce.pdf

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Australian Governments (COAG) establish a high-level taskforce to oversee an independent public review of chemicals and plastics regulation.³

In delivering the final government response to that report, the former Treasurer, Mr Costello, stated that ‘COAG members are actively working to address overlaps and inconsistencies in a number of regulatory ‘hotspots’, including ... chemicals and plastics’.⁴

The Productivity Commission was tasked with undertaking a study of chemicals and plastics regulation to inform COAG, and in particular to:

Investigate and document the current system of regulation of chemicals and plastics in Australia, including the interrelationships between the Australian, State and Territory government agencies, and local government layers of regulation, and the effect of these relationships on economic, public health and safety, occupational health and safety, and environmental outcomes. In examining these relationships, issues such as duplication and inconsistency both within and across jurisdictions should be identified.⁵

The current state of regulation

FSANZ

Australia and New Zealand have a joint system for regulating food safety. This system is underpinned by an intergovernmental agreement—the Food Regulation Agreement—between the Commonwealth, state and territory governments (and a treaty with New Zealand).⁶ The Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council) is responsible for setting policy, and amending or rejecting food

3. Ibid.

4. P Costello (former Treasurer), ‘*Report of the Taskforce on Reducing Regulatory Burdens on Business—Final Government Response*’, press release, Canberra, 15 August 2006, viewed 27 May 2010, <http://www.treasurer.gov.au/DisplayDocs.aspx?pageID=&doc=pressreleases/2006/088.htm&min=phc>

5. Productivity Commission, ‘Chemicals and Plastics Regulation’, *Research Report*, Commonwealth of Australia, Melbourne, 7 August 2008, p. v, viewed 27 May 2010, <http://www.pc.gov.au/projects/study/chemicalsandplastics/docs/finalreport>

6. Council of Australian Governments, *Food Regulation Agreement*, 3 July 2008, viewed 27 May 2010, http://www.coag.gov.au/coag_meeting_outcomes/2008-07-03/docs/food_regulation_IGA.pdf; Model Food Provisions Annex A http://www.coag.gov.au/coag_meeting_outcomes/2008-07-03/docs/food_regulation_IGA_annex_a.pdf; Model Food Provisions Annex B http://www.coag.gov.au/coag_meeting_outcomes/2008-07-03/docs/food_regulation_IGA_annex_b.pdf

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standards.⁷ The standards are developed by FSANZ, a trans-Tasman standard-setting body.⁸

Within Australia, the states and territories administer and enforce the standards for all foods offered for sale. The Australian Quarantine and Inspection Service inspects and samples imported foods at the border to ensure they comply with the standards.⁹

Chemicals and plastics are subject to three areas of food regulation. These involve limits on the extent to which foods may contain:

- residues from agricultural and veterinary (agvet) chemicals
- food additives and processing aids
- contaminants, including residues from plastics used in packaging.¹⁰

APVMA

The use of agvet chemical products can pose potentially significant risks to human health and the environment. In addition, the use of agvet chemical products on exported primary produce can affect Australia's international trade. In recognition of their hazardous properties, direct environmental and human exposure paths, and direct trade impacts, agvet chemical use is regulated via a dedicated regime.¹¹

The National Registration Scheme for agvet chemicals regulates the introduction and use of all agvet chemicals and products.¹² This includes:

- the assessment and registration of agvet chemicals and products
- development of conditions of use and product quality monitoring, and

7. Australia and New Zealand Food Regulation Ministerial Council website, viewed 27 May 2010, <http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-anz.htm>

8. Food Standards Australia New Zealand website, viewed 27 May 2010, <http://www.foodstandards.gov.au/>

9. Productivity Commission, op. cit., p. 129.

10. Ibid.

11. Ibid., p. 199.

12. '*Agricultural chemicals*' are defined in clause 4 of the Agricultural and Veterinary Chemicals Code to include all pesticides including herbicides, fungicides, insecticides and plant growth regulators, but exclude fertilisers, which are defined as industrial chemicals for the purpose of assessment. '*Veterinary medicines*' are defined broadly in clause 5 of the Agricultural and Veterinary Chemicals Code to include all substances that can be used to prevent, cure or alleviate a disease or injury of an animal.

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- control-of-use of agvet products after retail sale.¹³

Under the National Registration Scheme, the APVMA is a statutory authority which undertakes the assessment and registration of agvet chemical products. Its functions include:

- assess the suitability for sale in Australia of chemical products, active constituents for proposed or existing chemical products, and labels for containers for chemical products
- provide information to governments about approved active constituents, registered products, and approved labels
- evaluate the effects of the use of chemicals in states and territories
- facilitate the introduction of uniform national standards on controlling the use of chemicals.¹⁴

When maximum residue limits are being determined, the APVMA considers the most extensive permitted use of the product taking into account such factors as:

- how rapidly the chemical may be processed by either plant and/or animal tissues
- how rapidly the chemical may be degraded by soil and other environmental processes
- how frequently and at what intervals the chemical is used, taking into account the potential for bio-accumulation
- how close to harvesting of plants, collection of milk and eggs and/or slaughtering of livestock the chemical is used (including withholding periods)
- the acceptable dietary exposure to low levels of chemicals in food, and
- the effects of processing (e.g. flour from wheat; wine and dried fruit from grapes; sugar from sugar cane).¹⁵

When the APVMA sets a maximum residue limit in food, it recommends that FSANZ incorporate this maximum residue limit into the Food Standards Code.¹⁶

13. Further information about the National Registration Scheme is available on the Department of Environment, Water, Heritage and the Arts website, viewed 28 May 2010, <http://www.environment.gov.au/settlements/chemicals/assessments/about.html>

14. Section 7 *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

15. Australian Pesticides and Veterinary Medicines Authority website, viewed 28 May 2010, <http://www.apvma.gov.au/residues/setting.php>

16. Section 13A *Agricultural and Veterinary Chemicals Code Act 1994*.

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The nature of the problem

Both the APVMA and FSANZ prescribe limits on agvet chemical residues in food—termed maximum residue limits—and do so in separate regulations:

- APVMA prescribes maximum residue limits that reflect ‘good agricultural practice’ so breaches of agvet control-of-use requirements can be detected
- FSANZ prescribes maximum residue limits so that crops and animals treated with chemicals can be verified as being safe for human consumption.¹⁷

The APVMA consults with a wide range of groups through a number of consultative and liaison committees. In addition to these consultative structures, the APVMA routinely conducts consultations with its stakeholders, seeks their input on issues, decisions and scientific assessment outcomes relating to registration activities and the review of existing chemicals, as well as on proposals to reform requirements or procedures. By comparison, FSANZ assessments are developed through public consultation, and provide an opportunity for importers to have input into the setting of residue standards.¹⁸

According to the Productivity Commission:

There is potential for two different maximum residue limits to be prescribed for the same chemical in the same food by the two agencies. In such cases, primary producers in most jurisdictions would have to comply with the most stringent maximum residue limit.¹⁹

There is some co-ordination between the two agencies. The usual procedure is that the APVMA first prescribes a maximum residue limit as part of its conditions of approval for an agvet product, and then submits an application to FSANZ to include the maximum residue limit in the Australia New Zealand Food Standards Code.²⁰

FSANZ has never rejected a maximum residue limit application from the APVMA. This can be attributed to the fact that the APVMA assesses the human-health impacts of a maximum residue limit before approving it, and does so using dietary models and reference health standards from FSANZ. For this reason, FSANZ does not usually undertake its own dietary exposure assessment when considering a maximum residue limit submitted by the APVMA.²¹

17. Productivity Commission, op. cit., p. 131.

18. Productivity Commission, op. cit., p. 132.

19. Ibid.

20. Section 13A *Agricultural and Veterinary Chemicals Code Act 1994*.

21. Productivity Commission, op. cit., p. 132.

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Inconsistencies do arise, however, because there is a time lag between when the APVMA prescribes a maximum residue limit and when FSANZ mirrors it in food standards. This has led to situations where farmers complying with agvet control-of-use requirements set by the APVMA cannot sell their produce because FSANZ has yet to duplicate a relevant maximum residue limit in food standards.²²

The time lag arises, in part, because of the administrative arrangements for approval of food standards:

- First, if FSANZ concludes that a proposed maximum residue limit would be an appropriate food standard, their decision has to be submitted to the FSANZ Board for approval.
- Secondly if the Board agrees, the decision then has to be submitted to the Australia and the Ministerial Council for its consideration
- Thirdly the Ministerial Council has 60 days to request a review of FSANZ's decision before it is incorporated into the Food Standards Code.

Productivity Commission

The Productivity Commission concluded that the existing governance arrangements are not consistent with best-practice. In its draft report, the Productivity Commission recommended that maximum residue levels, as set by the APVMA, be automatically incorporated into the Food Standards Code.²³

This Bill is a response to that recommendation.

Committee consideration

The Bill has been referred to the Senate Community Affairs Committee (the Committee) for inquiry and report by 15 June 2010.²⁴

The reasons stated for referral of the Bill are that it involves domestically grown produce, residue risk assessment and chemicals/pesticides on crops, public health and safety considerations, and State and Territory relations.

There were few submissions to the Committee and all supported the proposed amendments.

22. Ibid., p. 133.

23. Productivity Commission, 'Chemicals and Plastics Regulation', *Draft Research Report*, Commonwealth of Australia, Melbourne, March 2008, recommendation 5.9, p. 138.

24. Details of the inquiry are at:
http://www.aph.gov.au/Senate/committee/clac_ctte/fsanz_amend_10/index.htm

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Financial implications

According to the Explanatory Memorandum implementation of this reform was agreed by COAG without the provision of additional funding. Therefore the reform will have to be funded through existing resources. The amendments will result in a transfer of some functions from FSANZ to the APVMA. Funding associated with these functions will be transferred as appropriate.^{25\}

Main provisions

Amendments—Agricultural and Veterinary Chemicals (Administration) Act 1992

Item 1 of Schedule 1 to the Bill amends the *Agricultural and Veterinary Chemicals (Administration) Act 1992* which establishes the APVMA to insert **proposed subsection 7(1C)**. The proposed subsection will confer functions and powers on the APVMA under the *Foods Standards Australia New Zealand Act 1991* (FSANZ Act).²⁶

Amendments—Agricultural and Veterinary Chemicals Code Act 1994

Schedule 1 to the *Agricultural and Veterinary Chemicals Code Act 1994* (the Code Act) contains the Agricultural and Veterinary Chemicals Code (the Code). Existing section 10 of the Code provides that a person may apply to APVMA:

- for approval of an active constituent for a proposed or existing chemical product
- for registration of a chemical product, or
- for approval of a label for containers for a chemical product.

Similarly, existing section 27 provides that an *‘interested person’* in relation to any of the above, may apply to the APVMA for a variation of either the particulars of the approval or registration, or a variation of the conditions of the approval or registration.²⁷

The proposed amendments to section 13A set out three circumstances in which the APVMA must notify FSANZ:

25. Explanatory Memorandum, p. 1.

26. Note that the functions and powers referred to in **item 1** of the Bill are inserted into the FSANZ Act by **item 14** of the Bill.

27. Section 3 of the Code defines the term *‘interested person’* as the person who made the original application, a person with whom the original applicant has entered into a contract about the constituent or product, the legal personal representative of either the original applicant or the person with whom he has contract, or if the ‘person’ is a body corporate—the successor in law of the body corporate.

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- where an application under section 10 or section 27 is made to the APVMA, and it is likely that, if the application were granted, a Maximum Residue Limits Standard would have to be varied: **proposed subsection 13A(1)**²⁸
- where a reconsideration of an approval or registration would be likely to lead to a variation of a Maximum Residue Limits Standard: **proposed subsection 13A(1A)**, and
- where an application for a permit under section 110 is made to the APVMA, and it is likely that, if the permit were granted a Maximum Residue Limits Standard would have to be varied: **proposed subsection 13A(1B)**.

Items 3 and 4 of the Bill amend subsection 13A(2) to specify that the APVMA must notify FSANZ ‘as soon as practicable’ after an application or a variation is made.²⁹

Existing subsection 14(1) of the Code provides that the APVMA must grant an application under section 10 if it is satisfied about a range of matters which are listed in existing subsection 14(3) of the Code. Existing subsection 14(5) prescribes those matters that the APVMA must have regard to, in order to be so satisfied. **Item 5** of the Bill inserts **proposed paragraph 14(5)(ea)** so that the APVMA must also consider comments about dietary exposure assessment, or any dietary exposure assessment prepared, by FSANZ.³⁰

Amendments—Food Standards Australia New Zealand Act 1991

Part 1

Item 13 of the Bill repeals existing Subdivision H of Division 2 of Part 3 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). That subdivision currently sets out the rules for a variation of the Maximum Residue Limits Standard. **Items 8–12** and **items 15–18** are amendments which are a consequence of the repeal of Subdivision H.

In its place, **item 14** of the Bill inserts **proposed Division 2A** into the FSANZ Act. According to **proposed section 80** the Division applies if the APVMA notifies FSANZ of an application or variation in relation to a chemical product.³¹ As soon as practicable after it has received the notice, FSANZ must do the following:

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28. According to section 3 of the Code a ‘*maximum residue limits standard*’ is the maximum residue limits standard made under the FSANZ Act as in force from time to time.
 29. This requirement is mirrored in **proposed subsection 82(3)** of the FSANZ Act which is in **item 14** of the Bill.
 30. Note that **item 14** of the Bill will provide for the FSANZ to prepare, or comment on, dietary exposure assessments.
 31. That notification is made by the APVMA under section 13A of the Code.

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- give public notice of the receipt of the notice from the APVMA setting out the particulars of the application or variation, and any other matter that it thinks appropriate: **proposed section 81**, and
- prepare a dietary exposure assessment of the proposed variation—and give a copy to the APVMA and to the Ministerial Council: **proposed subsection 82(4)**.

Proposed subsection 82(1) empowers the APVMA to vary the Maximum Residue Limits Standard to include or change a permitted maximum residue limit to cover a chemical product. Although the variation is a legislative instrument, it is not subject to the disallowance procedures or to the requirement in the *Legislative Instruments Act 2003* for sunseting: **proposed subsection 82(2)**.

The APVMA must not make a variation to a maximum residue limits standard without first considering the dietary exposure assessment which has been prepared and given by FSANZ: **proposed subsection 82(5)**.³²

Once the APVMA has decided to vary a maximum residue limits standard it must give a copy of the variation to FSANZ and publish a copy of the variation in the Gazette: **proposed subsections 82(6) and (7)**. Under **proposed subsection 82(8)**, the variation of the maximum residue limit takes effect in the Food Code on the date that it is published in the Gazette.

Proposed section 83 confirms that Division 2A will not limit FSANZ's power to vary the Maximum Residue Limits Standard. For example, 'FSANZ will continue to process applications to set maximum residue limits that relate to imported food'.³³

Part 2

Section 146 of the FSANZ Act authorises charges to be paid to FSANZ for services and facilities that it provides to a body or person. Those charges are fixed by regulation. Existing subsection 146(6) provides that a charge may only be fixed if it relates to an application to develop or vary a standard and either:

- the development or variation of the standard would confer an exclusive, capturable commercial benefit on the applicant, or
- the applicant has elected to have the consideration of the application expedited.

Item 22 repeals and replaces subsection 146(6) to provide that a charge may be fixed in relation to an application to develop or vary a standard only if the development or variation of the standard would confer an exclusive, capturable commercial benefit on the

32. This amendment is consistent with the proposed amendment to the Code contained in **item 5** of the Bill.

33. Explanatory Memorandum, p. 6.

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applicant; or the applicant has elected to have the consideration of the application expedited.

Although the rewording is only subtly different from the existing wording, the amendment means that FSANZ may charge third parties for a greater range of services or activities—not just for certain applications to develop or vary a food standard, as is currently the case.

Items 25–38 amend section 152 which sets out those matters which FSANZ must include in its annual report. In particular, **item 36** inserts **proposed paragraphs 152(pa)–(pd)** so that numbers of proposals for development or variation of food regulatory matters are included.

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