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## Agricultural and Veterinary Chemicals Legislation Amendment Bill 2002

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I N F O R M A T I O N   A N D   R E S E A R C H   S E R V I C E S

Bills Digest  
No. 107 2002–03

Agricultural and Veterinary Chemicals Legislation  
Amendment Bill 2002

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7 February 2003

# Contents

Purpose . . . . .	1
Background . . . . .	1
Main Provisions . . . . .	5
Schedule 1 . . . . .	5
Schedule 2 . . . . .	9
Schedule 3 . . . . .	9
Appendices . . . . .	10
Appendix 1: Assessment of Chemicals (At a Glance) . . . . .	10
Appendix 2: Legislation Reviews and the Public Interest Test. . . . .	11
Bibliography. . . . .	12
Endnotes. . . . .	13

# Agricultural and Veterinary Chemicals Legislation Amendment Bill 2002

**Date Introduced:** 12 December 2002

**House:** House of Representatives

**Portfolio:** Agriculture, Fisheries and Forestry

**Commencement:** The amending provisions commence on a day to be fixed by Proclamation.

## Purpose

To amend the *Agricultural and Veterinary Chemicals Code Act 1994* to:

- improve the effectiveness of the existing chemicals registration arrangements, and
- implement parts of an inter-governmental response to a legislation review,

and to amend the *Agricultural and Veterinary Chemicals (Administration) Act 1994* and the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* to make consequential and other miscellaneous amendments.

## Background

The bill amends legislation dealing with agricultural and veterinary (agvet) chemicals. Agvet chemicals are chemicals that are designed to destroy or repel pests or plants or to prevent, diagnose or treat animal diseases. They may be compared with industrial chemicals, therapeutic goods and food additives (see the table in **Appendix 1**).

Agvet chemicals are subject to two layers of regulation. The assessment, registration and review of agvet chemicals is conducted pursuant to the National Registration Scheme by the National Registration Authority for Agricultural and Veterinary Chemicals (NRA). Essentially, this relates to all dealings with agvet chemicals up until the point of retail sale. Secondly, the States and Territories each have 'control of use' legislation which relates to dealings with agvet chemicals (and other chemicals) beyond the point of retail sale.

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Agvet chemicals are regulated through a number of statutes, including:

- *Agricultural and Veterinary Chemicals Code Act 1994* (the Act),
- *Agricultural and Veterinary Chemicals (Administration) Act 1992*, and
- *Agricultural and Veterinary Chemical Products (Collection of Levies) Act 1994*.

### National Registration Scheme and the NRA

The National Registration Scheme was introduced in 1991 to replace separate registration arrangements in the States and Territories. At the time, '[c]ompanies had to make separate applications to each State or Territory where they wished to market a particular product'.<sup>1</sup>

A person may apply to the NRA for approval of active constituents, for registration of chemical products and/or for approval of labels for chemicals. Typically an applicant will do 'extensive product development, testing and field trials that both justify registration ... and meet the rigorous standards imposed by the NRA's assessment standards'.<sup>2</sup>

For its part, the NRA assesses the application against criteria in the Agricultural and Veterinary Chemicals Code (the Code) which is contained in the Schedule to the Act.

The key criteria for approval of *active constituents* are that they will not be:<sup>3</sup>

- an undue safety hazard for handling of the constituent or containers
- likely to have an effect that is harmful to human beings
- likely to have an effect that is harmful to animals, plants or the environment, or
- unduly prejudicial to international trade or commerce.

The key criterion for registration of *products* is that use, consistent with 'recommendations for use', would be 'effective according to criteria determined by the NRA for the product'.<sup>4</sup> In common parlance, this is referred to the 'efficacy review' of agvet chemicals.

The key criteria for approval of *labels* is that they will contain adequate instructions on:<sup>5</sup>

- the circumstances, manner, times and frequency of use for the product
- the withholding and re-entry periods after the use of the product
- the disposal of the product and any containers
- safe handling and first aid, and
- any other matters prescribed by the regulations.

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In the process, the NRA may receive expert advice from relevant agencies including the Department of Health and Aged Care, Environment Australia, the National Occupation Health and Safety Commission and other Commonwealth, State and Territory agencies.

Following assessment, the Code provides for public consultation.

## Review

The bill is, in part, the end product of a long series of reviews of chemicals legislation. The need to review agvet chemicals regulation emerged out of a more discrete interest in industrial chemicals, competition and cost and administrative burdens on small business.

### Competition Review (1999)

In 1997 the Victorian Government commissioned a national review of agvet legislation pursuant to the *Competition Principles Agreement* of the National Competition Policy (NCP). The review covered Commonwealth registration legislation and State and Territory 'control of use' legislation in Victoria, Queensland, Western Australia and Tasmania, the other jurisdictions conducting separate reviews of their control of use legislation.<sup>6</sup>

The nature of legislation reviews under the NCP is discussed in **Appendix 2**.

The review report was released in March 1999 by the Standing Committee on Agriculture and Resource Management (SCARM). At the same time, a working group was established of signatories to the agvet National Registration Scheme. The Signatories Working Group (SWG) was to prepare an inter-governmental response to the report's recommendations. An intergovernmental response was endorsed by the Agriculture and Resource Management Council of Australia and New Zealand (ARMCANZ) in August 2000.

### Time for Business (1996)

The review was commissioned following a decision of ARMCANZ. It was originally scheduled for 1998-99 but was brought forward by the Prime Minister to 1997-98 as part of *More Time for Business*, the Commonwealth Government's policy statement in response to the *Time for Business* report by the Small Business Deregulation Taskforce.

The *Time for Business* report identified small-business concern about 'the assessment procedures for chemicals, the dissemination of information about the chemicals, costs of assessment and registration, labelling and lack of consistency and coordination between chemical assessment schemes'.<sup>7</sup> It recommended that the Productivity Commission 'inquire into and report on the most efficient and effective way to regulate industrial, agricultural and veterinary chemicals'.<sup>8</sup> The recommendation was not followed by the Government as there had been considerable work undertaken in the area and various studies were planned or underway. But, in its policy statement, *More Time for Business*, the Government did agree to bring forward the national review proposed by Victoria.<sup>9</sup>

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### Work, Health and Safety (1995)

The recommendation was prompted by a 1995 Industry Commission report, *Work, Health and Safety*, which recommended a single body for the assessment, registration and labelling of industrial chemicals. It recommended that the Commonwealth 'consider creating a single agency to provide scientific advice on hazardous materials', including industrial and agvet chemicals.<sup>10</sup> Among other issues under consideration was what one submission stated as the 'more important issue of Commonwealth–State harmonisation'.<sup>11</sup>

The *Work, Health and Safety* report also recommended a risk management approach to assessment in which the regulatory agency 'could be made more effective by prioritising assessments to those chemicals which are likely to pose the greatest risks to workers, the public and the environment'.<sup>12</sup> In addition, it recommended some outsourcing of chemical assessment: '[c]hemical producers and importers could be allowed to nominate chemicals for assessment, or to prepare their own assessments for auditing by NICNAS. This would create an incentive for companies to develop safer chemicals',<sup>13</sup> with civil sanctions where manufacturer product information or assessments are inadequate. It would also address a scarcity of expertise in chemical assessments in Australia.<sup>14</sup> These recommendations were, in turn, prompted by a review of industrial chemicals regulation earlier in 1995.<sup>15</sup>

### Intergovernmental Response

In summary, some of the themes raised by the reviews have been:

- regulatory costs and a risk management approach to low risk chemicals
- the choice to retain licencing arrangements for manufacturers
- the choice to limit 'efficacy review' to 'claimed efficacy'
- the choice of a monopoly and/or an outsourcing of assessment decisions
- the confidentiality of commercial information and restraint of trade, and
- Commonwealth-State cooperation on regulation of manufacture, sale and use

The Competition Review recommended that the NRA registration monopoly be retained,<sup>16</sup> but that the NRA 'both accept alternative suppliers of assessment services and actively alert likely providers of this fact'.<sup>17</sup> It recommended that the Code 'provide for the identification of low risk chemicals, hence enabling potentially faster registration'<sup>18</sup> and 'provide guiding principles for the inclusion or exclusion of chemicals by regulation'.<sup>19</sup>

In relation to efficacy review, it recommended that it extend 'only to ensuring that the chemical product meets the claimed level of efficacy on the label'.<sup>20</sup> In relation to data protection and restraint of trade, it recommended that the compensation provisions 'adopt the procedures and principles for determining third party access pricing under the various

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Codes in operation under Part IIIA of the [*Trade Practices Act 1974*].<sup>21</sup> It recommended that 'the levy be changed to a simple flat rate levy ... with no exemptions or caps'.<sup>22</sup>

Following the report, various bills were introduced into State and Territory parliaments to implement recommendations going to control of use.<sup>23</sup> A Commonwealth Government response to the Competition Review was agreed by ARMCANZ on 18 August 2000.<sup>24</sup> The response essentially supported all recommendations, except those relating to licences for chemical manufacturers and the efficacy review.<sup>25</sup> As at 13 December 2002, a federal taskforce was 'in the process of implementing most of these recommendations and [was] giving consideration to its response to the issue of off-label chemical use'.<sup>26</sup>

## Main Provisions

Most of the key provisions are contained in the schedules. However, **proposed section 4** serves a significant function in relation to the preservation of existing regulations.

### Schedule 1

**Schedule 1** amends the *Agricultural and Veterinary Chemicals Code Act 1994*.

### Definitional Matters

Various amendments are made to the definitions in the Code:

- **approved person:** this amendment 'ensures that there is a contact point in Australia responsible for making applications and providing notice, consent, information, report, sample or other thing under the Code'<sup>27</sup> regardless of changes in ownership or foreign ownership of business that produce agvet chemicals, and
- **Instructions for use:** this amendment 'ensures that instructions for use includes instructions for *any* dealing with the [active] constituent or [chemical] product'<sup>28</sup>

### Preliminary Assessments

The Bill amends the mechanisms for approvals.

Applications may be made for approval of an active constituent, registration of a chemical product or approval of a label for a chemical product container.<sup>29</sup> **New clause 11A** provides for preliminary assessments, allowing invalid applications to be amended, provided they 'can reasonably be rectified' (**new subclause 11A(3)**) and allowing partial withholding of application fees for those 'unrectifiable' applications (**new subclause (4)**).

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### Recommendations, Instructions and Directions

The code does not deal *directly* with use of chemicals. But, it does deal with it *indirectly* because, for example, approved labels must contain 'recommendations', 'instructions' or 'directions' as to use (each of these terms is used 'more or less interchangeably' throughout the code<sup>30</sup>) and the NRA must consider the value of any 'recommendations', etc. that it 'proposes to approve' in relation to the labels and the constituents or chemicals involved.<sup>31</sup>

**Items 28 and 29** substitute these 'interchangeable' terms with 'instructions'. This is part of a push throughout the bill with these terms to provide 'clarity as to whether a matter is advisory or mandatory ... for regulators, manufacturers and users'.<sup>32</sup> They also substitute the expression 'proposes to approve' with 'has approved or approves' to capture any instructions that may be approved or may have been approved in the past. Approvals for labels or active constituents and decisions to register chemical products can then take account of any past instructions or future instructions or 'any new instructions being given under this application as well as any relevant instructions approved in the past'.<sup>33</sup>

### Foreign Standards

**Item 33** inserts **new clause 14A** which allows the NRA to approve active constituents based on their registration overseas where relevant information is not readily available in Australia. The NRA may refer to the *European Pharmacopoeia*, *British Pharmacopoeia* and the *United States Pharmacopoeia* or any other publication that it thinks appropriate.

Significantly, the NRA may approve an active constituent 'whether or not an application has been made for approval'. So, it may approve active constituents unilaterally.

### Variations and Reconsideration

**Item 39** ensures that, if particulars relating to registrations or approvals are varied, the date of the actual registrations or approvals is brought forward to the date of the variation.

**Item 72** inserts **new clause 34A** which allows the NRA to reconsider approval of labels at any time on the basis of their compliance with requirements listed in the regulations. In this way, regulations can add or amend requirements relating to labels and the NRA may review approval of existing labels against those added or amended requirements.

**Item 78** inserts **new subclause 40(2)** which provides that, in the reconsideration process, the NRA may suspend or cancel the approval of the label if the interested person does not submit a variation of the label in accordance with the added or amended requirements.

This may be significant. Withdrawing approval for a label may limit sale of chemical products. Indirectly, this could be made to serve a regulatory purpose in relation to approved constituents or registered products. The Explanatory Memorandum explains that '[i]t is not intended that the NRA will undertake a series of label reconsiderations as a substitute for a full review of the product registration'. The intention is that the

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requirements for labels may be amended to take into account parallel changes in standards by other organisations which are often the original source of the label requirements.<sup>34</sup>

### Deemed Permits

If an approval or registration is suspended or cancelled, the NRA must publish a notice in the *Gazette*. If the suspension or cancellation was prompted by concerns regarding safety, harm to humans, harm to animals, plants or the environment; or the adequacy of directions on a label, the notice must contain instructions about use or dealings with the constituent or product. But, a person who uses or deals with the constituent or product *in accordance with the instructions* is deemed to have been issued with a permit to do so.

**Item 97** amends these provisions to apply a time limit of 2 years to the 'deemed permit'.

**Items 84** and **92** apply this 'deemed permits' model to other, more general, circumstances.

**Item 84** amends the existing provisions regarding notice of suspension or cancellation. **New clause 45A** provides for notices that allow possession, use, etc. of products where an approval or registration has been suspended cancelled. The permission may run for 2 years and any possession, use, etc. must follow any instructions in the notice. A failure to comply with a notice is an offence where there is possession with intent to supply.

The purpose is to avoid unnecessary adverse consequences in terms of long term storage, recall or disposal of constituents or products by wholesalers or retailers. In some cases, despite suspension or cancellation, existing stocks may still be used without compromising health or safety standards, subject to time limit and instructions in the notice.

**Item 92** provides a similar savings arrangement regarding notice of expired registrations. **New subclauses 54(2)-(6)** operate in much the same way as **new clause 45A**.

### Listable Chemical Products

**Item 106** inserts **new Part 2A** which deals with 'listable chemical products' and 'listed registration'. Basically, **new clauses 56A-56ZU** provide for the registration of products, or classes of products, *on application* against pre-established standards in regulations.

**In effect, there is a move towards regulation of chemicals by way of standards rather than by registration of individual active constituents, chemical products or labels.**

The regulations may contain lists of products that can be granted 'listed registration'. The Minister may list products where s/he is satisfied that the use of the product in accordance with instructions in an established standard would be safe, etc. (**new clause 56C**). There may be public consultation over decisions to list products (**new subclause 56C(3)**).

The NRA must establish standards for each 'listable chemical product' (**new clause 56D**). The standards may relate to products or classes of products which may be identified in various ways (eg. composition, properties, quantities, manufacture, pharmacopoeias, etc).

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In preparing a standard, the NRA must satisfy itself of the matters that currently apply to the approval or registration of active constituents, products and labels (**new clause 56E**).

Any instruments that establishes or varies these standards must be published in the *Gazette* (**new subclauses 56D(8) and 56F(4)**). They are 'disallowable instruments' that must be tabled in each House of Parliament (**new clause 56H**).

An application for registration of a listed product may be approved if the NRA is satisfied that it complies with the established standards, etc. (**new clause 56K**). The product is then given a unique number and is granted 'listed registration' (**new clause 56M**). Registration may be granted on conditions, such as a requirement that the product be supplied in a particular container or that registration be limited to less than a year (**new clause 56O**).

As with other approval or registration of constituents, products and labels, the NRA may:

- vary particulars or conditions of listed registration (**new clauses 56S-56U**)
- reconsider listed registration (**new clauses 56V-56Z**), or
- suspend or cancel listed registration (**new clauses 56ZA-56ZN**).

Registration expires at the end of the financial year (**new clause 56ZK**), subject to any conditions on registration (**new clause 56O**) or suspension (**new clause 56ZI**). Applications for renewal must be received one month before the registration ends, subject to extensions accepted by the NRA or prescribed in regulations (**new clause 56ZL**).

### Reserved Chemicals

**Item 106** inserts **new Part 2B** which deals with 'reserved chemical products'. Effectively **new clause 56ZU** provides for registration of products, or classes of product, *without application* subject to conditions for use in regulations. In these cases, the NRA must be satisfied that the use of the product in accordance with the conditions would be safe, etc.

### 2 Year Savings Period

As noted above, various amendments allow for continued use of chemical products, etc. for a 2 year period beyond suspension, cancellation or expiry of approval or registration. **Item 119** permits the supply of registered chemical products under expired labels, subject to NRA approval and within a 2 year period or other period approved by the NRA.

### Miscellaneous

It is an offence to knowingly provide false or misleading information to the NRA.<sup>35</sup> Currently, this offence is punishable by a maximum fine of 30 penalty units or \$330. However, this is considered to be 'too low a penalty for the gravity of the offence'.<sup>36</sup>

**Item 154** rewrites and restructures this provision.

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The maximum penalty will be increased *tenfold* (300 penalty units or \$3 300) for cases relating to ordinary registration, listed registration or manufacturing licences and twofold (60 penalty units or \$660) for cases relating to other NRA functions or powers.

The NRA may issue 'evidential certificates' in relation to various matters in respect of 'any legal or administrative proceeding under or for the purposes of [the agvet code]'.<sup>37</sup>

**Item 155** excludes any proceedings for an offence that may involve imprisonment.

## Schedule 2

**Schedule 2** amends the *Agricultural and Veterinary Chemicals (Administration) Act 1994*.

Most of the amendments take account of amendments to the Code from **Schedule 1**.

**Items 5 to 8** deal with the timing of the NRA Corporate Plan and Annual Operating Plan.

**Item 10** amends an offence provision in a similar way to **item 154** of **Schedule 1**.

**Item 11** serves a similar function to **item 155** of **Schedule 1**.

## Schedule 3

**Schedule 3** amends the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*. Significantly, while the schedule deals with separate levies for registration and listed registration, it does not seem to change the levy structure to a 'flat rate' as recommended by the Competition Review in 1999.

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## Appendices

### Appendix 1: Assessment of Chemicals (At a Glance)<sup>38</sup>

	<i>Industrial Chemicals</i>	<i>Agricultural &amp; Veterinary Chemicals</i>	<i>Medicine &amp; Medicinal Products</i>	<i>Food Additives</i>
AGENCY	National Industrial Chemicals Notification & Assessment Scheme (NICNAS) within NOHSC	National Registration Authority (NRA) for Agricultural and Veterinary Chemicals	Therapeutic Goods Administration (TGA)	Australia New Zealand Food Authority (ANZFA)
MINISTRY	Employment, Workplace Relations & Small Business	Agriculture, Fisheries and Forestry	Health & Aged Care	Health & Aged Care
SCOPE	Assessment only, not registration based	Assessment & Product Registration	Assessment & Product Registration	Assessment & Product Registration
RELEVANT LEGISLATION	Industrial Chemicals (Notification & Assessment) Act 1989	Agricultural & Veterinary Chemicals (Code) Act 1994 Agricultural & Veterinary Chemicals Administration Act 1994	Therapeutic Goods Act 1989	Australia New Zealand Food Authority Act 1994. Food Standards Code
ABOUT THE CHEMICALS	Industrial chemicals are varied and cover, for example, dyes, solvents, adhesives, plastics, laboratory chemicals, paints, as well as chemicals used in cleaning products and cosmetics & toiletries.	Agricultural products include chemicals which generally destroy /repel pests or plants. Veterinary products are used to prevent, diagnose, or treat diseases in animals.	Therapeutic goods include prescription and non-prescription (OTC) medicines. OTCs include complementary medicines (herbals, vitamins, minerals and homeopathic preparations), and some sterilants and disinfectants.	Chemicals are added to food for a number of reasons, for instance as a processing agent, preservative or as a flavouring or colouring. These are known as food additives.

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## Appendix 2: Legislation Reviews and the Public Interest Test

'Legislation reviews' are covered in the Competition Principles Agreement of the NCP. Their guiding principle is that legislation 'should not restrict competition unless it can be demonstrated that (a) the benefits ... to the community as a whole outweigh the costs and (b) the objectives of the legislation can only be achieved by restricting competition'.<sup>39</sup> This 'public interest test' requires a review to clarify the objectives of the legislation, identify the nature and effect of any restrictions on competition, analyse costs and benefits and consider alternative regulatory arrangements 'including non legislative approaches'.<sup>40</sup>

The timetable of reviews and agenda for reform are controlled by each party to the NCP. Where a review has a 'national dimension or effect on competition', a party must consider whether a national review is appropriate and must consult with other interested parties. A party may even request the National Competition Council to conduct national reviews.<sup>41</sup>

The review of agvet legislation was the first national legislation review under the NCP.<sup>42</sup> There have been 12 national reviews, including reviews into legislation regulating the architectural profession, consumer credit and drugs, poisons and controlled substances.<sup>43</sup>

In part, the push for a national review of agvet chemicals may be explained by concerns regarding Commonwealth-State and State-State coordination, especially for control of use:

As a national review, many of the recommendations relate to restrictions on competition arising from inconsistencies [in] the operation of equivalent legislation in each State, in addition to the restrictions arising from particular legislation.<sup>44</sup>

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- 2 National Registration Authority, [NRA Facts](#), NRA No. 1, February 1999.
- 3 Agvet Code, paragraph 14(3)(e).
- 4 Agvet Code, paragraph 14(3)(f).
- 5 Agvet Code, paragraph 14(3)(g).
- 6 The review was conducted by Price Waterhouse Coopers and Francis Abourizk Lightowlers Lawyers between October 1997 and July 1998. It was overseen by representatives of the Commonwealth, Victorian and Western Australian Governments: Price Waterhouse Coopers and Francis Abourizk Lightowlers, National Competition Policy Review of Agricultural and Veterinary Chemicals Legislation, [Issues Paper](#), 29 August 1998; National Legislation Review: Agricultural and Veterinary Chemicals, [Final Report](#), 13 January 1999.
- 7 Charles Bell, [Time for Business](#), Report of the Small Business Deregulation Task Force, 1 November 1996 (the Bell Report), p. 83.
- 8 Charles Bell, [Time for Business](#), Report of the Small Business Deregulation Task Force, 1 November 1996 (the Bell Report), p. 7.
- 9 Department of Industry, Tourism and Resources, [More Time for Business](#), 24 March 1997, Part 2, pp. 50–51
- 10 Industry Commission, [Work, Health and Safety](#), Inquiry Report, 11 September 1995, Recommendation 46.
- 11 Industry Commission, [Work, Health and Safety](#), Inquiry Report, 11 September 1995, p. 255.
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- 20 Competition Review, *Final Report*, Recommendation 6.
- 21 Competition Review, *Final Report*, Recommendation 11.
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- 23 For example, the Agricultural and Veterinary Chemicals (Control of Use) (Amendment) Bill 2000 (Vic); Agricultural and Veterinary Chemicals Legislation Amendment Act 2002 (Qld); Agricultural and Veterinary Chemicals (Control of Use) Amendment Act (No. 2) 2002 (Tas).
- 24 Agriculture and Resource Management Council of Australia and New Zealand, [\*Endorsement of the Intergovernmental Response to the National Competition Policy Review of Agricultural and Veterinary Chemicals Legislation\*](#), 18 March 2000.
- 25 National Competition Council, [\*Legislation Review Compendium\*](#), 4<sup>th</sup> Ed, February 2002, Chapter 2, p. 8.
- 26 Treasury, [\*Commonwealth National Competition Policy Annual Report 2000-2001\*](#), 13 December 2002, p. 80.
- 27 Explanatory Memorandum, p. 7.
- 28 Explanatory Memorandum, p. 8 (emphasis added).
- 29 *Agricultural and Veterinary Chemicals Code Act 1994*, clause 10.
- 30 Explanatory Memorandum, p. 12.
- 31 For example, paragraphs 14(3)(e) and (f) and subclauses 14(4) and (5).
- 32 Explanatory Memorandum, p. 12
- 33 Ibid.
- 34 Explanatory Memorandum, p. 24.
- 35 Clause 145.
- 36 Explanatory Memorandum, p. 24.
- 37 Clause 155.
- 38 See '[Assessment and regulation of chemicals in Australia](http://www.nicnas.gov.au)' on the NICNAS Website at <http://www.nicnas.gov.au>.
- 39 Clause 5(1) of the *Competition Principles Agreement*, 11 April 1995 in National Competition Council, [\*Compendium of National Competition Policy Agreements\*](#), 2<sup>nd</sup> Ed., June 1998, p. 19.
- 40 Ibid, clause 5(9).
- 41 Ibid, clause 5(8).
- 42 National Legislation Review: Agricultural and Veterinary Chemicals, [\*Final Report\*](#), 13 January 1999, p. vi.
- 43 National Competition Council, [\*Annual Report 2001-02\*](#), p. 21.
- 44 National Legislation Review: Agricultural and Veterinary Chemicals, [\*Final Report\*](#), 13 January 1999, p. vi.

**Warning:**

*This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.*

*This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.*