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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

**AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT BILL
2002**

EXPLANATORY MEMORANDUM

(Circulated by authority of the Parliamentary Secretary to the Minister for Agriculture, Fisheries and Forestry, Senator the Hon Judith Troeth)

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Abbreviations

The following abbreviations are used in this explanatory memorandum.

Agvet Code	-	The Agricultural and Veterinary Chemicals Code scheduled to the <i>Agricultural and Veterinary Chemicals Code Act 1994</i>
Agvet Admin Act	-	<i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i>
Agvet Levy Act	-	<i>Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994</i>
Agvet Code Regulations	-	Agricultural and Veterinary Chemicals Code Regulations 1995.
AFFA	-	Department of Agriculture, Fisheries and Forestry - Australia
Crimes Act	-	<i>Crimes Act 1914 (Commonwealth)</i>
NRA	-	National Registration Authority for Agricultural and Veterinary Chemicals

AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT BILL 2002

OUTLINE

The Agricultural and Veterinary Chemicals Legislation Amendment Bill 2002 has as its basic aim the streamlining of the operation of the Agvet Code, its functions and the modernisation of review provisions. It also introduces a model for low regulatory approvals for certain chemicals which arise from the inter-governmental response to the review of agricultural and veterinary legislation initiated under the National Competition Policy.

This Bill will amend the *Agricultural and Veterinary Chemicals Code Act 1994*, the *Agricultural and Veterinary Chemicals (Administration) Act 1992* and the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* to:

- 1) introduce a regime for the management of agricultural and veterinary chemicals categorised as low regulatory activity;
- 2) permit greater flexibility to the NRA in dealing with the interested person or approved person;
- 3) provide a requirement that the label contain instructions for the use of the product;
- 4) provide for greater consistency in the use of certain language relating to the instructions for use used in labels;
- 5) enable the NRA to deem certain active constituents as approved thereby deferring a full consideration of the active constituent until a product containing the active constituent is to be assessed;
- 6) provide better administrative practice in terms of how a distinguishing number for an active constituent, registered product and / or approved label will be used;

- 7) enable the NRA to reject applications that are extremely deficient in the information they provide without formally considering them;
- 8) provide for the termination of old labels upon approval of a new label, except in certain circumstances;
- 9) provide for a mechanism to allow reconsideration of label approvals;
- 10) enable the NRA to retain a component of the already payable application fee to cover the cost of carrying out the preliminary assessment of the application;
- 11) increase the NRAs capacity to vary or change any particulars and conditions of the approval of an active constituent, the registration of a chemical product, or the approval of a label for containers for a chemical product, including but not limited to any condition of such approval or registration;
- 12) allow the NRA as part of a reconsideration process, to seek public comment in relation to any safety and efficacy matter;
- 13) enable the NRA to vary, on application, any aspect of an earlier approval or registration;
- 14) provide a mechanism to issue a deemed permit for the use of a product for a time after registration ends, is suspended or cancelled;
- 15) extend the capacity of the NRA to seek additional information for the purposes of approval of an active constituent, registration of a chemical product, approval of a label, permit or reconsideration of any of these matters;
- 16) extend the capacity of section 159(3) of the Agvet Code to treat an application as having been withdrawn to permits;
- 17) correct a technical error by providing for label approvals to be treated separately from product registration;
- 18) extend the requirement that *relevant information* about an agricultural or veterinary chemical be provided to the NRA post lodgement of application but prior to consideration of the application;
- 19) remove the provision which allows a State co-ordinator to request the additional information from a permit applicant;
- 20) increase certain penalty provisions and to bring the definition of penalty unit into line with the provisions of the *Crimes Act 1914*;
- 21) synchronise the production of the NRAs Corporate Plan and its Annual Operation Plan and to provide that a Corporate Plan does not have to be prepared every year;
- 22) permit the NRA to issue evidentiary certificates for any purpose of the Agvet Code relating to eligible law before a court or tribunal;
- 23) standardise definitions of residues and protected commodities;
- 24) provide that the NRA can release confidential commercial information of a previously approved active constituent and a previously registered chemical and a previously listed registered product, or previously reserved product in addition to the existing provisions contained in section 162 Agvet Code;
- 25) remove any doubt that compensation is not payable in respect of information previously provided to the NRA by the chemical industry, irrespective of whether or not the NRA makes a request for such information; and

26) correct minor errors which are mainly typographical errors.

FINANCIAL IMPACT STATEMENT

The amendments in this Bill are not expected to have any financial impact on the Commonwealth budget.

The NRA operates on a cost recovery basis, funded principally by a combination of a levy on wholesale sale of chemical products and a fee for service rendered. The combined result of the amendments proposed in this Bill is an anticipated decrease in costs for the NRA in the processing and handling of applications for approvals, registrations and permits.

In terms of the impact upon industry, the Bill streamlines existing procedures and introduces several efficiencies to industry's advantage. While the introduction of the low regulatory scheme (Parts 2A and 2B) introduces fees for the purposes of an evaluation or review of an application for inclusion of a chemical as a listed or reserved product, these fees duplicate those already required for a full registration and because of the nature of the low regulatory scheme will be a lesser charge than for an application for a full registration.

An essential part of the evaluation of an application is a preliminary assessment of an application including its supporting material (new section 11A). The assessment tests if the package meets the essential requirements of the Agvet Code, thereby ensuring efficiencies within the formal process of evaluation of an application.

In those cases where an application is found to be deficient and rejected, it is appropriate for the NRA to recover that part of the already payable application fee, to cover its administrative costs in line with its cost recovery framework.

The NRA will now be able to retain a component of the already payable fee for an application to cover the costs of the preliminary assessment of the application in the case where the application is subsequently determined to be deficient.

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Notes on clauses

Clause 1: Short Title

1. The short title of the Act is the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2002*.

Clause 2: Commencement

2. This section provides for the Act to come into effect on a single day to be fixed by Proclamation subject to subsection 3 as provided. Sections 1 to 3 come into effect on the day the Act receives Royal Assent.

Clause 3: Schedules

3. This section states that each Act specified in a Schedule to this Act is amended or repealed as set out in the relevant clause in the Schedule. Any other clause in a Schedule to this Act likewise has effect according to its terms. The Schedules are:

Schedule 1 - Amendment of the Agricultural And Veterinary Chemicals Code Act 1994

Schedule 2 - Amendment of the Agricultural And Veterinary Chemicals (Administration) Act 1992

Schedule 3 - Amendment of the Agricultural And Veterinary Chemical Products (Collection of Levy) Act 1994

Clause 4: Saving of Regulations

4. This section provides that where a regulation was in force immediately before the commencement of the single day fixed by Proclamation (subject to subsection 2(3)), the regulations have effect as if they had been made under the substituted provision .

Schedule 1: Amendment of the Agricultural And Veterinary Chemicals Code Act 1994

Agvet Code Part 1 - Preliminary

Clause 1 - after section 8

1. This clause inserts a new **section 9** after section 8. The new section will ensure that particular provisions of the Schedule, i.e. the Table of Contents and the list of terms defined by Section 3 of the Schedule that appear immediately after the Table of Contents, do not form part of the Act.

Clauses 2 to 19 inclusive - The Schedule interpretation Section 3 Definitions

2-19 Several new definitions are inserted into **section 3** of the Agvet Code and certain definitions no longer relevant to the legislation are repealed and substituted

" The definition of **approved person** is repealed and substituted. The new definition provides the NRA with greater flexibility in dealing with an *interested person* (usually the original applicant) in relation to an approved active constituent for a chemical product, a registered chemical product, a registered listed chemical product or an approved label for containers for a chemical product. The greater flexibility provided to the NRA allows for communication with additional parties authorised by the original applicant, or by process of law, to act on the behalf of the interested person.

Specifically, 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 Agvet Code; and that organisations and individuals who are off shore and responsible for making applications and providing notice, consent, information, report, sample or other thing, authorise a person who is resident in Australia, or an Australian incorporated body, to provide the notice, consent, information, report, sample or other thing on their behalf.

In addition, the identity of a corporate body incorporated in Australia, or a person residing in Australia, must be notified to the NRA to ensure that all notices from the NRA are properly given by the NRA in relation to an approved active constituent for a chemical product, a registered chemical product, a registered listed chemical product or an approved label for containers for a chemical product. **(clause 2)**

" A definition of **continued use** is inserted to ensure that any dealing with the active constituent or chemical product will be included in the meaning of continued use. **(clause 3)**

" The definition of **deal with** is amended to provide that *deal with* includes supply or otherwise dispose of an active constituent or chemical product. **(clause 4)**

" The scope of the definition of **eligible law** is extended to the entire Agvet Code (rather than the definition of permit as laid out in section 109). **(clause 5)**

" A definition for *established standard* is inserted and means a standard established for the product under the proposed new Division 3 of Part 2A of the Agvet code. **(clause 6)**

" A definition for *instructions for use* in relation to an active constituent for a proposed or existing chemical product or a chemical product will be inserted. The definition ensures that instructions for use includes instructions for any dealing with the constituent or product. **(clause 7)**

" The definition of *interested person* is repealed and substituted to include provision in relation to registered listed chemical products (as added by new Part 2A of these amendments). **(clause 8)**

" A definition of *listable chemical product* is inserted. This definition provides that a listable chemical product is a chemical product, or is a chemical product in a class of chemical products, included in the Listing Schedule. **(clause 9)**

" A definition of *listed registration* is inserted and means registration of a listable chemical product in force under proposed new Part 2A of the Agvet Code. **(clause 10)**

" A definition of *Listing Schedule* is inserted to mean the Schedule in the regulations under section 56B of the Agvet Code. **(clause 11)**

" The definition of *penalty unit* is repealed and substituted to have the same meaning as in section 4AA of the Crimes Act. **(clause 12)**

" A definition of *protected commodity* is inserted. For the purposes of greater clarity of intent and consistency within the scheme, the definition of protected commodity has been removed from the Agvet Admin Act (by repeal and substitution of section 7A) and inserted in section 3 of the Agvet Code. Additionally, the definition has been expanded to explicitly include any plant or animal; and any soil, water or other environmental component as an agricultural commodity which is a protected commodity. **(clause 13)**

" A definition of *registered listed chemical product* is inserted to mean a listable chemical product which has already been granted listed registration. **(clause 14)**

" The definition of *relevant particulars* is repealed and substituted to specifically detail those particulars that are required to be included in the Record of Approved Active Constituents and the Register of Chemical Products. Furthermore, in relation to the approval of a label for containers for a chemical product, the definition is extended to define the relevant particulars to be included on any relevant NRA file. **(clause 15)**

" A definition of *reserved* is inserted to mean reserved in relation to a chemical product or one of the class of chemical products by being specified in the Reserved Schedule. **(clause 16)**

" A definition of *reserved chemical product* is inserted to mean a chemical product that is or will be included in a class of chemical products that is particularised in the Reserved Schedule. **(clause 17)**

" A definition of *Reserved Schedule* is inserted. This definition means the Schedule in the regulations under section 56ZW. **(clause 18)**

" The definition of *residues* is repealed and substituted. The new definition ensures that the expression *residue*, in relation to an active constituent for a proposed or existing chemical product, or in relation to a chemical product, means any remains persisting in or on a protected commodity or only such of those remains specified in a notice published by the NRA in the *Gazette*. **(clause 19)**

Clause 20 - The Schedule (at the end of section 6)

20 This clause provides certainty that the NRA may vary or revoke a determination made, approval or exemption given, or other thing done by the NRA under the provisions of subsection (1), including in the case where there is no other provision of the Agvet Code which expressly authorises the

varying or revocation of the determination, the giving of an approval or exemption or the doing of any other thing by the NRA.

Agvet Code Part 2 - Approvals and Registration

Division 1 of Part 2 - Preliminary

Clause 21 - The Schedule (subsection 9(2))

21 This clause repeals the subsection and substitutes it with a revised explanation of the intent of Division 2 which provides that the Division now deals with the giving of approvals and the granting of registrations.

Clause 22 -The Schedule (heading to Division 2)

22 This amendment repeals the heading of Division 2 and substitutes a new heading. The new heading for Division 2 refers to granting or refusing approvals and registrations.

Division 2 of Part 2 - Applications for approval or registration

Clause 23 - The Schedule (after paragraph 11(1)(b))

23 This clause adds a new subsection **(ba)**, after paragraph 11(1)(b) which provides that applications for approval of an active constituent for a proposed or existing chemical product or for registration of a chemical product must contain proposed instructions for use of, or any other dealing with, the constituent or product.

Clause 24 - The Schedule (at the end of subsection 11(1))

24 This new subsection provides that the form must be lodged with the NRA. This removes any ambiguity as to where the appropriate applications should be lodged.

Clause 25 - The Schedule (subsections 11(2) and (3))

25.1 In some circumstances, the interested person who makes an application to the NRA is a person, or an overseas corporation, not resident in Australia. The legislation requires that there is a person within Australia who is legally responsible for the making of an application (*refer Definitions section 3*). Additionally, situations may arise where the interested person is deceased, or a body corporate has been taken over by another company and no longer exists.

25.2 Reference to an *approved person* (*refer Definitions section 3*) enables the NRA to accept the authority of a person resident in Australia or of an Australian body corporate, other than the applicant, in circumstances when the person or body corporate is lawfully acting on the applicants behalf.

25.3 Consequently, the amendments to subsection **11(2)** and **(3)** mean that the NRA can accept an application, alter an application, accept additional or varying information, and accept the request for a withdrawal of an application upon appropriate authority from an approved person.

Clause 26 - The Schedule (section 12)

26.1 This clause repeals old section **12** and substitutes it with proposed section **11A** and a new section **12**.

26.2 As part of its approval and registration process, the NRA has an administrative practice of undertaking preliminary assessment of applications to determine whether they meet the requirements of subsection **11(1)**. These amendments formalise this practice and define the processes by which the NRA must conduct a preliminary assessment.

26.3 Subsection **11A(1)** requires the NRA to conduct a preliminary assessment of an application for compliance with subsection 11(1) within one month after the application is lodged.

26.4 Subsection **11A(2)** requires the NRA to give written notice, as soon as practicable, to an approved person stating that the application has passed the preliminary assessment and will be given a full evaluation in due course.

26.5 Subsection **11A(3)** sets out the mechanism for treating applications in which the defects can reasonably be rectified, including written advice to an approved person stating that the application does not comply with subsection 11(1) and giving particulars of the defects and defining the period by when the defects must be rectified. In a case where the defects are not rectified to the satisfaction of the NRA, subsection 11A(3)(b) allows the NRA to defer consideration of the application or treat the application as having been withdrawn. Where the defects are not rectified to the satisfaction of the NRA, within the specified time frame, and the NRA elects to defer consideration or treat the application as withdrawn, the NRA must give immediate notice in writing to the approved person.

26.6 Subsection **11A(4)** extends the NRAs ability to deal with applications containing defects which cannot be reasonably rectified and enables the NRA to reject the application without formally accepting or considering the application in full. The NRA will also be able to retain a component of the application fee to cover the cost of the preliminary assessment of the application.

26.7 Subsection **11A(5)** establishes the procedures, which the NRA must comply with, if it decides to reject an application. The NRA must as soon as practicable, give a notice in writing to the approved person, advising them that the application has been rejected on the ground that it was not properly made out, identifying the defects in the application, providing particulars of why the application cannot be remedied and advising that a component of the application fee is being retained to cover the cost of the preliminary assessment of the application.

26.8 Subsection **11A(6)** requires the NRAs written notice deferring consideration of an application (refer subparagraph 11A(3)(b)(i)), treating it as withdrawn (refer subparagraph 11A(3)(b)(ii)), or rejecting it (refer paragraph 11A(5)) must properly advise the applicant of his or her rights of review of the NRAs decision.

26.9 Subsection **11A(7)** provides that any application which is rejected by the NRA on the grounds that it was not properly made will be taken not to have been validly made for the purposes of the Agvet Code and Part 7B of the Agvet Admin Act.

26.10 Section **12** provides that the NRA must publish a notice in the *Gazette*, and in any other manner it thinks appropriate, before it decides whether to approve an active constituent not previously contained in a chemical product registered in this or another jurisdiction under the Agvet Code or a corresponding previous law.

26.11 Section **12** is repealed and substituted. New section **12** structurally separates the acts associated with the making of a decision by the NRA to approve a new active constituent from those other actions which constitute the act of approval, that is, the act of including the required details in the Record of Approved Active Constituents (refer subsection 19(2)).

Clause 27 - The Schedule (Section 13)

27.1 Section **13** is repealed and substituted to provide that the NRA must publish a notice in the *Gazette*, and in any other manner it thinks appropriate, before it decides whether to register a chemical product containing an active constituent not previously contained in a chemical product registered in this or another jurisdiction under the Agvet Code or a corresponding previous law.

27.2 Section **13** now structurally separates the acts associated with the making of a decision by the NRA to register a chemical product containing a new active constituent from those other actions

which constitute the act of registration, that is the act of including the required details in the Register of Chemical Products (refer subsection 20(2)).

Clauses 28 and 29 - The Schedule (paragraphs 14(3)(e) and (f)) and subsections 14(4) and (5)

28.1 The term instruction is an inclusively (but not exhaustively) defined word that includes direction, caution, warning, or recommendation (*refer Definitions section 3*). Throughout the Agvet Code the words recommendations, directions and instructions are used at times more or less interchangeably in relation to the use of a product eg in paragraph **14(3)(f)** and **(g)** before amendment.

28.2 Within the Agvet Code, the use of the term recommendations, with its inherent meaning that the intent may only be advisory, and the use of the term direction, with its inherent meaning that the intent may be mandatory, has led to some confusion amongst regulators, manufacturers and users. By way of example, the Agvet Code commonly uses the term recommendations for use as matters that the NRA must be satisfied of (and therefore mandatory matters), when considering whether to grant, vary, or reconsider approvals and registrations. Additionally, despite the limits of recommendations; directions, warnings and cautions are also matters that are relevant to the context within which the regulatory decisions are made (either as mandatory or advisory matters).

28.3 To better provide certainty within the regulatory framework, a movement to the consistent use of the term instructions, when supported by greater precision in terms of defining and drafting label statements, improves clarity as to whether a matter is advisory or mandatory (for the purposes of compliance under the Agvet Code or relevant State law) for regulators, manufacturers and users.

28.4 Additionally, this clause omits the words proposes to approve and substitutes has approved or approves to ensure that, in the context of satisfying itself on any application made under section 10, the use of the active constituent or chemical product in accordance with the instructions for use, capture any new instructions being given under this application as well as any relevant instructions approved in the past.

28.5 In line with these intents, clauses 28 and 29 omit the term recommendations for its use that the NRA proposes to approve and substitute it with instructions for its use that the NRA has approved or approves where it appears in paragraphs **14(3)(e)**, **(f)**, and **subsections 14(4)**, and **14(5)**.

Clause 30 - The Schedule (at the end of paragraph 14(5)(f))

30 In the context of satisfying itself on any application for the purposes of subsection **14(1)** whether the use of the chemical product would be in accordance with approved residue limits and the intent to continue greater consistency of the use of the words 'directions, caution, warning or recommendation (*refer Definitions section 3*), this clause adds the words or approves to the end of the paragraph to ensure that approvals for the purposes of the application under consideration capture any new approval of residue limits being given under this application as well as any relevant approvals made in the past.

Clause 31 - The Schedule (subsection 14(6))

31 In the context of satisfying itself whether the use of a chemical product in accordance with the instructions for use would be effective and to continue the intent of greater consistency in the use of the words directions, caution, warning or recommendation (*refer Definitions section 3*), and to capture any new instructions being given under this application as well as any relevant instructions approved in the past, this clause omits the term recommendations for its use that the NRA proposes to approve and substitutes it with instructions for its use that the NRA has approved or approves.

Clause 32 - The Schedule (subsection 14(7))

32.1 This clause ensures that the provisions of section **14** dealing with the granting or refusing of an application are subject to the provisions of both sections 14A and 15.

32.2 Section **14A** is a new section which provides for deemed approval of certain active constituents for which all relevant information is not available as required by paragraph **11(1)(b)**.

Clause 33 - The Schedule (after section 14)

33.1 Section **14A** allows the NRA to approve active constituents for a proposed or existing chemical product, in certain circumstances, without all of the information that the NRA would otherwise require being readily available. Generally these circumstances relate to active constituents that are commonly used in industrial, non-agricultural or non-veterinary uses and whose characteristics are, consequently, well known.

33.2 Active constituents may be approved if the NRA considers that the information it requires under paragraph **11(1)(b)** is not readily available, or the constituent is, or is part of a product with a standard in certain Pharmacopoeia or other publications considered appropriate by the NRA, providing the NRA is satisfied of all the health, safety, trade and efficacy matters mentioned in paragraph **14(3)(e)**, having regard to matters mentioned in **14(4)**, where information about the matters mentioned in subsection **14(4)** is readily available.

33.3 Despite the approval of the active constituent being granted under section **14A**, without all of the information that the NRA would otherwise require for the granting or refusal of an application for an active constituent under section **14**, registration of a chemical product containing the approved active constituent can only be granted upon meeting the full requirements of section **14**.

Clause 34 - The Schedule (subsection 17(3))

34 Subsection **17(3)** is repealed and substituted with provisions that require the Record of Approved Active Constituents for Chemical Products be kept in 3 parts. One part consists of confidential commercial information relating to constituents approved under section **14**. Other information relating to constituents also approved under section **14** is kept in another part, while information relating to constituents approved under new section **14A** is kept separately.

Clause 35 - The Schedule (section 19)

35 Section **19** now structurally separates the acts associated with the making of a decision by the NRA to approve an active constituent for a proposed or an existing chemical product from those other actions which constitute the act of approval, that is the act of including the required details (relevant particulars, any other particulars prescribed by regulations and any conditions of the approval) in the Record of Approved Active Constituents.

Clauses 36 - The Schedule (section 20)

36 Section **20** now structurally separates the acts associated with the making of a decision by the NRA to register a chemical product from those other actions which constitute the act of registration, that is the act of including the required details (relevant particulars, any other particulars prescribed by regulations and any conditions of the approval) in the Register of Chemical Products.

Clause 37 - The Schedule (section 21)

37.1 Section **21** now structurally separates the acts associated with the making of a decision by the NRA to approve a label for containers for a chemical product from those other actions which constitute the act of approval, that is the act of including the required details (relevant particulars, any other particulars prescribed by regulations and any conditions of the approval) in the relevant NRA file

37.2 New subsection **21(2)** extends the requirements of the NRA, when approving a label for a container for a chemical product, to also include the determination of the size and type of the label, and the instructions for the use of the product. The NRA must place all relevant particulars (*refer*

Definitions section 3) and record any conditions of the approval in the relevant NRA file. The introduction of these additional clauses is made at the request of the States and Territories who have requested that the NRA specifically approve the actual product label rather than the text contained therein for the purposes of strengthening their control-of-use compliance activities.

Clause 38 - The Schedule (section 22)

38 In line with the intent that the making of a decision to approve an active constituent for a proposed or an existing chemical product, of registration of a chemical product or of approval of labels for containers for chemical product, is structurally separate from those other actions which constitute the act of approval, (that is the act of including the required details in the Record of Approved Active Constituents or the Register of Approved Chemical Products, or the recording of the required details in the relevant NRA file), this clause omits the words the relevant distinguishing number and.

Clause 39 - The Schedule (at the end of section 22)

39.1 Section 22 already provides for the recognition of the date of approval or registration.

39.2 This clause extends the provisions to ensure that if any of the relevant particulars (*refer Definitions section 3*) of an approval of an active constituent, or registration of a chemical product, or an approval of a label for containers, or any of the conditions of such approval or registration, are varied, then the date of the approval or of the registration or of the approval of the label or conditions as varied, is the date on which particulars of the variations are entered in the Record of Approved Active Constituents or in the Register of Chemical Products or are recorded in the relevant NRA file as the case may be.

Clause 40 - The Schedule (paragraphs 24(1)(a) and 25(1)(a))

40 In line with the intent set out in the definitions in section 3, this clause omits the applicant and substitutes it with *an approved person*(*refer Definitions section 3*) to enable the NRA to accept the authority of a person resident in Australia or of an Australian body corporate, other than the applicant, in circumstances when the person or body corporate is lawfully acting on the applicants behalf.

Clause 41 - The Schedule (paragraph 26(1)(b))

41 Section 26 deals with the circumstances where a particular is incorrectly recorded or registered. In line with the intent that both relevant particulars and conditions be included in the Record of Approved Active Constituents, in the Register of Chemical Products or in the relevant NRA file as part of the act of approval or registration (*refer sections 19, 20 and 21 respectively*), paragraph 26(1)(b) is amended to omit the words a particular and substitute them with a relevant particular or condition.

Clause 42 - The Schedule (paragraph 26(1)(b))

42.1 Paragraph 26(1)(b) provides for the circumstances when a person considers a particular to be incorrectly entered into the Record of Approved Active Constituents, incorrectly entered in the Register of Chemical Products, or incorrectly recorded in the relevant NRA file.

42.2 This clause omits in the Register of Chemical Products or and substitutes it with or in the Register of Chemical Products or recorded to make paragraph 26(1)(b) consistent with paragraph 21(2)(e), which requires the recording of any conditions of approval in the relevant NRA file when approving a label for a container for a chemical product.

Clause 43 - The Schedule (subsection 26(1))

43.1 Paragraph 26(1)(b) provides for the circumstances when a person considers a particular to be incorrectly entered into the Record of Approved Active Constituents, incorrectly entered in the Register of Chemical Products, or incorrectly recorded in the relevant NRA file.

43.2 This clause omits the incorrect particular and informing the NRA of the correct particular or and substitutes it with the incorrect particular or condition and informing the NRA of the correct particular or condition to make paragraph **26(1)(b)** consistent with paragraph **21(2)(e)**, which requires the recording of any conditions of approval in the relevant NRA file when approving a label for a container for a chemical product.

Clause 44 - The Schedule (subsection 26(2))

44.1 Subsection **26(2)** deals with the circumstances when the NRA must change an entry or record when satisfied the entry or record is not correct.

44.2 This clause repeals subsection **26(2)** and substitutes it to make subsection **26(2)** consistent with the language of paragraph **21(2)(e)**, which requires the recording of any conditions of label approval in the relevant NRA file.

Division 3 of Part 2 - Application for variation of relevant particulars, or of conditions, of approval or registration

Division 3 of Part 2 of the Agvet Code allows the NRA to vary, on application the relevant particulars or conditions of an approval or registration. The relevant particulars (*refer Definitions section 3*) are set out in the Record of Approved Active Constituents, or in the Register of Chemical Products or in the relevant NRA file. This Division is the most commonly used part of the Agvet Code and represents the majority of applications received by the NRA each year.

Clause 45 - The Schedule (heading to Division 3 of Part 2)

45 This clause repeals the heading of Division 3 and substitutes it with a new heading Application for variation of relevant particulars, or of conditions, of approval or registration.

Clause 46 - The Schedule (after paragraph 28(1)(b))

46.1 Section **27** enables an interested person to apply to the NRA for, amongst other things, a variation of the relevant particulars or conditions of the approval of a label for a container. Section **28** sets out how an application for variation is to be made.

46.2 Paragraph **(ba)** provides that an application to vary the relevant particulars or conditions of the approved label must be accompanied by a proposed new label.

Clause 47 - The Schedule (at the end of subsection 28(1))

47 Paragraph **28(1)(e)** adds certainty to the administrative process by providing that an application to vary the relevant particulars, or the conditions, of an approval of an active constituent or a label for containers for a chemical product, or registration of a chemical product, must be lodged with the NRA.

Clause 48 - The Schedule (subsections 28(2) and (3))

48.1 Subsection **28(2)** deals with the NRAs capacity to alter an application for variation upon written consent. Section **28(3)** deals with the capacity of a person to withdraw an application for variation upon written notice of the withdrawal to the NRA.

48.2 In line with the intent set out in the definitions in section **3**, this clause omits the applicant and substitutes it with an approved person (*refer Definitions section 3*) to enable the NRA to accept the authority of a person resident in Australia or of an Australian body corporate, other than the applicant, in circumstances when the person or body corporate is lawfully acting on the applicants behalf.

Clause 49 -The Schedule (paragraph 29(1)(a))

49.1 Section 29 deals with the requirements of the NRA in ensuring it is satisfied before it decides to vary the relevant particulars or conditions of approval of an active constituent, registration of a chemical product, or the approval of a label. The amendments to section 29 will:

enable the NRA to accept the authority of a person resident in Australia or of an Australian body corporate, other than the applicant, in circumstances when the person or body corporate is lawfully acting on the applicants behalf (*refer Definitions section 3*); and

in line with the intent that the making of a decision to approve an active constituent for a proposed or an existing chemical product, of registration of a chemical product or of approval of labels for containers for chemical product, structurally separate from those other actions which constitute the act of approval, that is the act of including the required details in the Record of Approved Active Constituents or the Register of Approved Chemical Products, or the recording of the required details in the relevant NRA file (*refer sections 19, 20 and 21*); and

in the context of satisfying itself on any application for variation for the purposes of subsection 29(1) whether the use of the chemical product would be affective according to the relevant criteria within section 29, provide greater consistency in the language used throughout the Agvet Code in terms of the use of the terms recommendation and instructions (*refer section 14*); and

standardise use of the term use of, or any other dealing with as used throughout the Agvet Code (*refer Definitions section 3*).

48.1.1 This clause repeals paragraph 29(1)(a) and substitutes the requirement that subsection 28(1) has been complied with. In the context of the above, this amendment removes reference to the applicant.

Clause 50 - The Schedule (paragraph 29(1)(e))

48.1.2 This paragraph omits the term use of and replaces it with continued use of to ensure that the NRA remains satisfied that the continued use of the active constituent or chemical product is safe and effective within the terms of paragraphs 29(1)(e) and (f), should the requested variation be granted by the NRA. Furthermore, in line with the intent for greater consistency in the language used throughout the Agvet Code, the term recommendations is omitted and replaced with instructions (*refer Section 14*).

Clause 51 - The Schedule (paragraph 29(1)(e))

48.1. 3 In line with the intent for greater consistency in the language used throughout the Agvet Code, the term recommendations is omitted and replaced with instructions (*refer Section 14*).

Clause 52 - The Schedule (paragraph 29(1)(f))

48.1.3 In line with the intent for greater consistency in the language used throughout the Agvet Code, the term recommendations is omitted and replaced with instructions (*refer Section 14*).

Clause 53 -The Schedule (paragraph 29(1)(h))

48.1.4 This clause extends the paragraph to include a provision to require the NRA, on granting an application, to vary the relevant particulars or the conditions of an approved label, by placing a new label containing the relevant particulars as varied, or recording any variation in the conditions, in the relevant NRA file and recording the date of such entry in the file.

Clause 54 - The Schedule (paragraph 29(1)(i))

48.1.5 This clause omits the term interested person and substitutes it with an approved person to enable the NRA to deal with a person who is resident in Australia or with an Australian body

corporate, other than the applicant, in circumstances when the person or body corporate is lawfully acting on the applicants behalf (*refer Definitions section 3*).

Clause 55 - The Schedule (paragraph 29(4)(a))

49 Paragraph **29(4)(a)** requires the NRA, should it refuse an application, to provide a written notice of the refusal and brief particulars of the reasons. The omission of the term the applicant and its substitution with an approved person ensures that there is a contact point in Australia with whom the NRA is to deal (*refer Definitions section 3*).

Division 4 Part 2 - Reconsideration of approval or registration

Reconsideration under Division 4 of Part 2 enables the NRA to ensure that all approvals and registrations satisfy current regulatory standards as set out in section **14** of the Agvet Code.

In order for the NRA to continue to be satisfied that active constituents or chemical products meet current safety, efficacy and other relevant standards, it may be necessary to review and consequently amend, add, delete or vary the particulars or conditions of the approval of the active constituent, the registration of a chemical product or the approval of a label, including cancellation or severe restriction.

As a consequence of the amendments below, the NRA is able to amend, add or delete, in addition to vary the relevant particulars (*refer Definitions section 3*), or a condition of an approval or product registration. Furthermore, the amendments provide the NRAs with the capacity to specifically reconsider the approval of a label for containers for a chemical product to allow for a more efficient and targeted reconsideration process.

Clause 56 - The Schedule (subsection 31(2))

56 This clause repeals subsection **31(2)** of the Act, which becomes redundant as the basis of the NRAs reconsideration as set out in paragraph **34(1)(d)** and referenced in new paragraph **32(1)(aa)** (*refer Clause 57*).

Clause 57 - The Schedule (subsection 32(1))

57 This clause extends the requirements of subsection **32(1)**, dealing with the circumstances when the NRA is to provide notices seeking public comment on any proposed reconsideration, if it thinks it is desirable to do so, to specifically include the circumstances when it is reconsidering the approval of a label for a container of a chemical product.

Clause 58 - The Schedule (paragraph 32(1)(a))

58 This clause extends the requirements of paragraph **32(1)(a)**, concerning the NRAs obligation to invite public comment on a reconsideration, to the circumstances when the NRA proposes to reconsider an approval of a label for a container of a chemical product.

Clause 59 - The Schedule (after paragraph 32(1)(a))

59 Further to the extension of the scope of paragraph **32(1)(a)**, inter alia, to include a reconsideration of an approval of a label for a container of a chemical product, this clause requires the NRA, in a notice seeking public comment on any proposed reconsideration, to set out the matters to be dealt with in the reconsideration and setting out the requirement, or requirements, prescribed by the regulations for continued approval or registration that form the basis of the reconsideration.

Clause 60 - The Schedule (paragraph 32(1)(b))

60.1 The NRA must consider only certain matters when making decisions regarding the reconsideration of approvals or registration (*refer section 34 above*).

60.2 Paragraph **32(1)(b)** provides that the capacity of a person, when making a submission in response to a notice seeking public comment on a proposed reconsideration, may address whether the approval or registration complies with any of the prescribed requirements for continued approval or registration rather than just whether or not the approval or registration should be continued (as previously provided). The prescribed requirements include nearly all of the standard criteria for a reconsideration as set out in subsection **34(1)** of the Agvet Code.

Clause 61 - The Schedule (subsection 32(2))

61.1 In line with the intent that the NRA be empowered to deal with persons other than an interested person in certain circumstances, subsection **32(2)** extends the requirement of the NRA to give written notice of the NRAs proposed reconsideration to the interested person, or an approved person (*refer Definitions section 3*), in relation to the active constituent or product.

61.2 Additionally, this clause makes the necessary changes consequential to the clarification of the capacity of the NRA to reconsider, separately and specifically, the approval of a label of a chemical product (*see note at Division 4 above*).

Clause 62 - The Schedule (subparagraphs 32(2)(b)(i) and (ii))

62 In line with the intent that the NRA is empowered to deal with persons other than an interested person in certain circumstances, subparagraphs **32(2)(b)(i)** and **(ii)** are amended to allow the NRA to accept information from either the interested or approved person (*refer Definitions section 3*).

Clause 63 - The Schedule (subsection 32(4))

63.1 In line with the intent that the NRA is empowered to deal with persons other than an interested person in certain circumstances, subsection **32(4)** is repealed and substituted to provide that, should the NRA receive a request from either the interested person or an approved person to cancel an approval or registration, and the NRA complies with the request, the requirement of subsection **32(3)** that those persons must provide the information that the NRA has requested (under subsection **32(2)**) need no longer be complied with.

63.2 Additionally, this clause makes the necessary changes consequential to the clarification of the capacity of the NRA to reconsider, separately and specifically, the approval of a label of a chemical product (*see note at Division 4 above*).

Clause 64 - The Schedule (subsection 33(1))

64 In line with the intent that the NRA is empowered to deal with persons other than an interested person in certain circumstances, this amendment to subsection **33(1)** extends the NRAs capacity to allow it to give a written notice to an approved person, thereby, requiring the interested person to conduct laboratory experiments or trials as the NRA considers necessary (*refer paragraph 33(1)(a)*) and to give the results to the NRA (*refer subsection 33(1)(b)*).

Clause 65 - The Schedule (subsection 33(3))

65 In line with the intent that the NRA is empowered to deal with either the approved person (*refer Definitions section 3*) or the interested person (*refer Definitions section 3*) in certain circumstances, subsection **33(3)** is amended to allow the NRA to accept a request under section **42** (before the end of the period stated in the notice) to cancel the approval of the active constituent or the registration of the product from either the approved person or the interested person in situations where the NRA has issued a written notice in accordance with subsection **33(1)**.

Clause 66 - The Schedule (paragraph 34(1)(a))

66 To provide greater consistency in the language used throughout the Agvet Code in terms of the use of recommendation and instructions (*refer clause 27*), this clause omits recommendations and

substitutes instructions in paragraph **34(1)(a)**, in those circumstances when the NRA is required to satisfy itself in any reconsideration for the purposes of subsection **34(1)**, whether the continued use of, or any other dealing with, the constituent or product in accordance with the instructions for its use would meet the criteria set out in paragraphs **34(1)(a) and (d)**.

Clause 67 - The Schedule (paragraph 34(1)(b))

67 To provide greater consistency in the language used throughout the Agvet Code in terms of the use of recommendation and instructions (*refer clause 27*), this clause omits recommendations and substitutes instructions in paragraph **34(1)(b)** in those circumstances when the NRA is required to satisfy itself in any reconsideration for the purposes of subsection **34(1)**, whether the use of the chemical product would meet efficacy criteria as determined by the NRA as set out in paragraphs **34(1)(b) and (d)**.

Clause 68 - The Schedule (paragraph 34(1)(c))

68 This paragraph ensures that if the reconsideration relates to an approval of a label, the label must also comply with any requirements prescribed by the regulations in relation to the label as well as contain adequate instructions relating to such matters as referred to in paragraph **14(3)(g)**.

Clause 69 - The Schedule (paragraph 34(1)(e))

69 In line with the intent that the NRA be empowered to deal with persons other than an interested person in certain circumstances, paragraph **34(1)(e)** is amended to allow the NRA to give written notice to either the interested person or approved person (*refer Definitions section 3*) stating that it affirms the approval or registration on the same conditions to which the approval or registration is currently subject and giving brief reasons for its decision.

Clause 70 - The Schedule (subsection 34(4))

70 In line with the intent that the NRA be empowered to deal with persons other than an interested person in certain circumstances, subsection **34(4)** is amended to allow the NRA to give written notice to either the interested person or approved person (*refer Definitions section 3*) when it is not satisfied as required in subsection **34(1)**.

Clause 71 - The Schedule (subsection 34(5))

71.1 The definition of *relevant particulars* is repealed and substituted to broaden those details that are required to be included in the Record of Approved Active Constituents, the Register of Chemical Products or recorded in the relevant NRA file.

71.2 In particular, it includes, in relation to the approval of a label for containers for a chemical product, the size and type of, and particulars contained on the label. The approved label must be recorded in the relevant NRA file (*refer Definitions, Section 3 and Clause 37*).

71.3 To ensure that the NRA is satisfied that its assessment criteria for health and safety, trade and efficacy are met, and continue to be met (as required by the Agvet Code), the NRA is provided with the capacity to establish or vary these relevant particulars in the Record of Approved Active Constituents, the Register of Chemical Products or recorded in the relevant NRA file. Consequently, the NRA is provided specifically with a capacity to:

determine the relevant particulars (section **21(2)**) which includes the determination of the size and type of the label, giving a distinguishing number to the label, and determining the particulars that are to be contained on the label (which include the instructions for the use of the product);

vary relevant particulars on application (paragraphs **29(1)(h)** [at clause 51] and **56W(1)(e)** [at clause 56ZW];

vary relevant particulars upon reconsideration (section **34(5)** [at clause 70] and paragraph **56ZB(5)** [at clause 56ZB]; and

vary relevant particulars upon reconsideration without notice (section **34A** - refer Clause 71).

71.4 In this context, subsection **34(5)** is repealed and substituted to allow the NRA to vary the relevant particulars upon reconsideration where the NRA is satisfied that the relevant particulars or the conditions can be varied in such a way that the requirements for the continued approval or registration (prescribed by regulations) will be complied with.

71.5 If the variation relates to the relevant particulars or conditions of approval of an active constituent or chemical product, the NRA must enter in the relevant Record of Approved Active Constituents, the Register of Chemical Products, particulars of the variation and the date on which the entry is made (refer new subparagraph **34(5)(a)(i)**).

71.6 In situations where the variation relates to the relevant particulars of the approval of a label, the new label must be placed on the relevant NRA file. This new label must contain the relevant particulars as varied. The NRA must record the date on which the new label was placed on the relevant file (refer new subparagraph **34(5)(a)(ii)**). If the variation relates to the conditions of the approval of a label, the NRA must also record on the relevant NRA file, particulars of the variation and date on which the record is made (refer new subparagraph **34(5)(a)(iii)**).

71.7 Paragraph **34(5)(b)** requires the NRA to state in the notice issued under subsection 34(5), the it is not satisfied that the relevant particulars or conditions meet the prescribed requirements for continued approval or registration although it is satisfied that they can be so carried and it has varied them accordingly, as set out in the notice.

71.8 Subsection **34(5A)** provides that the NRA may only vary the relevant particulars of the approval of a label if the interested person gives the NRA a new label containing the particulars as proposed to be varied.

71.9 Subsection **34(5B)** requires the NRA, if a variation would affect the instructions for use of an active constituent, or a chemical product, or any instructions on a label, to consult with each State co-ordinators before the variation is made, and to take into account any recommendations made by the co-ordinators.

Clause 72 - The Schedule (at the end of Division 4 of Part 2)

72.1 Subsection **34A(1)** permits the NRA to reconsider the approval of a label for containers for a chemical product and to decide if the particulars (included within the relevant particulars) on the label are adequate without notice to the interested or approved person in certain limited circumstances prescribed by the regulations for the purposes of this section. These circumstances are limited to matters that are also prescribed by paragraph **14(3)(d)** or subparagraph **14(3)(g)(x)** of the Agvet Code (subsection **34A(2)**).

72.2 It is not intended by the section **34A** that the NRA will undertake a series of label reconsiderations as a substitute for a full review of the product registration.

72.3 The practical effect of this constraint is to limit these circumstances to variation of text within a label which typically has been provided by an authoritative source to the NRA, such as the National Drugs and Poisons Scheduling Committee (of the Department of Health and Ageing) for Poison Scheduling headings, and the Therapeutic Goods Administration of the Department of Health and Ageing for First Aid and Safety Directions - both of which may be varied as a consequence of changes to standards and other codification.

72.4 In the context of maintaining current standards and consistency with other codification, should the NRA consider that the particulars on the labels are not adequate, the NRA must vary the

particulars (subsection **34A(3)**), give written notice setting out the particulars of the variation to an interested person or an approved person and require the interested person to give to the NRA, a new label containing the particulars as varied (*refer subsection 34A(4)*).

72.5 Subsection **34A(5)** provides that the provisions of sections **30** to **34** will not apply to reconsiderations under section **34A**.

Division 5 of Part 2 - Suspension or cancellation of approval or registration

Clause 73 - The Schedule (paragraph 37(1)(a))

73 In line with the intent that the NRA be empowered to deal with either the approved person or the interested person (*refer Definitions section 3*) in certain circumstances, paragraph **37(1)(a)** is repealed and substituted, to additionally require the NRA, when it considers suspending an approval or registration under subsection **37(1)**, to be satisfied that either an interested person or the approved person is aware of certain information relevant to the reconsideration, but has failed to provide that information to the NRA.

Clause 74 - The Schedule (paragraph 37(1)(b))

74.1 Subsection **33(1)** extends the NRAs capacity to allow it to give a written notice to the approved person requiring the interested person to conduct laboratory experiments or trials as the NRA considers relevant to its reconsideration (*refer subsection 33(1)(a)*) and to give the results to the NRA (*refer subsection 33(1)(b)*).

74.2 Paragraph **37(1)(b)** clarifies that it is the interested person (*refer Definitions, section 3*), of whom the NRA must be satisfied has not conducted, or caused to be conducted, the required trials and experiments, or has not given the results of the trials and experiments to the NRA.

Clauses 75 and 76 - The Schedule (subsection 38(1))

75.1 Should an interested person fail to comply with the requirements contained in a notice under section **159** (to provide information additional to that in an initial application upon the NRAs request) or with section **161** (to provide new information after approval or registration upon the NRAs request), without reasonable excuse, the NRA may suspend an approval or registration. Subsection **38(1)** provides that either the interested person or an approved person is responsible for complying with these notices.

75.2 In addition, Clause 76, subsection **38(1)**, extends those matters, with which the interested person or approved person must comply, to include new section **160A**, which establishes a requirement for the notification of new information to the NRA in respect of a pending application (*refer clause 158*).

Clause 77 - The Schedule (section 40)

77.1 As an adjunct to the amendments laid out in Division 4 (to be able to amend, add or delete, in addition to vary, the relevant particulars or a condition of an approval or product registration), this clause specifically deals with the circumstances when the NRA is not satisfied that the relevant particulars can be varied in such a way that the prescribed requirements for continued approval or registration can be complied with, then it may suspend or cancel that approval or registration.

77.2 Formerly, section **40** provided for the suspension or cancellation of an approval or registration following a reconsideration, where the NRA was not satisfied that the conditions relating to an approval or registration could be varied in such a way that the prescribed requirements for continued approval or registration would be complied with. Section **40** is amended to include relevant particulars, in addition to conditions as matters that the NRA must consider in this context.

Clause 78 - The Schedule (at the end of section 40)

78 Further to the circumstances as set out in clause 77 and Division 4 above, subsection **40(2)** provides that if the NRA becomes satisfied that the relevant particulars of the approval of the label can be varied in such a way that the prescribed requirements for continued approval will be complied with and the interested person fails to give the NRA a label varied in accordance with the request of the NRA, the NRA may suspend or cancel the approval.

Clause 79 - The Schedule (subsection 41(1))

79 To provide greater consistency in the language used throughout the Agvet Code in terms of the use of recommendation and instructions (*refer clause 28*), this clause omits recommendations and substitutes instructions in subsection **41(1)** dealing with the circumstances when the NRA may suspend or cancel the approval or registration for non-compliance with the criteria for approval of an active constituent for a proposed or existing chemical product or the registration of a chemical product as set out in subsection **41(1)** having regard to the matters referred to in subsections **14(4)** and **(5)** as the case requires.

Clause 80 - The Schedule (subsection 41(2))

80 To provide greater consistency in the language used throughout the Agvet Code in terms of the use of recommendation and instructions (*refer clause 28*), this clause omits recommendations and substitutes instructions in subsection **41(2)** dealing with the circumstances when the NRA may suspend or cancel the registration of a chemical product for non-compliance with efficacy criteria as set out in subsection **41(2)** having regard to the matters set out in subsection **14(6)**.

Clause 81 - The Schedule (subsection 41(3))

81 To provide greater consistency in the language used throughout the Agvet Code (in this case relating to the contents of a label) (*refer clause 28*), this clause omits a direction and substitutes any of the instructions in subsection **41(3)** dealing with the circumstances when the NRA may suspend or cancel the approval of a label where it appears to the NRA that the instructions referred to in paragraph **14(3)(g)** may no longer be adequate.

Clause 82 - The Schedule (at the end of section 41)

82 Similar to clause 78, but further to the circumstances as set out in clause 72 above inserting new section **34A** relating to the reconsideration of a label by the NRA without notice, subsection **41(4)** provides that if the NRA considers that the particulars on a label are not adequate and the interested person fails to give the NRA a label containing the particulars as proposed to be varied in accordance with a request by the NRA, then the NRA may suspend or cancel the approval of the label.

Clause 83 - The Schedule (paragraph 42(1)(a))

83 In line with the intent that the NRA be empowered to deal with either the approved person or the interested person (*refer Definitions, section 3*) in certain circumstances, paragraph **42(1)(a)** is amended to require the NRA to cancel an approval or registration upon a written notice, which states the reasons for the request, from either an approved person or the interested person.

Clause 84 - The Schedule (subsections 45(2), (3), (4) and (5))

84.1 When the NRA suspends or cancels the approval of an active constituent or the registration of a chemical product this effectively means that the manufacturer ceases production and supply of the active constituent or chemical product on that day. However, significant quantities of the active constituent or chemical product may still be held by wholesalers, retailers and end users (including farmers). Consequently, a suspension or cancellation may give rise to concerns about the need for appropriate disposal of these chemicals.

84.2 In many cases, despite the cancellation or suspension of an approval of an active constituent or registration of a chemical product, the active constituent and/or the chemical product could be used in a manner that would not contravene the requirements of subsection **14(3)**.

84.3 By way of example, an approval or registration may cease (by suspension, cancellation or ending) as a result of purely commercial factors, e.g.:

where there has been a failure by the owner of the active constituent or chemical product (the interested person) to pay a fee to the NRA [dealt with under section **54**] ; or

where the owner requests it when voluntarily deciding to discontinue an existing product line in favour of new or improved formulation [dealt with under section **42**];

or for more substantive reasons of an incapacity to be able to continue to meet the requirements of the Agvet Codes, eg:

where the NRA has decided to cancel an active constituent or chemical product for failure to meet more stringent current standards of safety and efficacy (as set out in subsection **14(3)** or subsection **34(1)**) [dealt with under sections **36, 40** or **41**].

84.4 Generally, in these kinds of circumstances, it is reasonable in risk management terms, to provide for the appropriate use of these chemicals as a mechanism to exhaust existing stocks and avoid the potential for subsequent adverse effects arising from long-term storage or other mechanism of disposal. It may also be safer, and more practical, to provide for the continued use of existing stocks - perhaps under more stringent conditions - than it would be to attempt to recall drums of product, often from remote locations, to have them destroyed or to effect a label change.

84.5 In the past, in some circumstances (*refer section 55 - Publication of notice of suspension or cancellation of approval or registration*), to provide for this remedy, the NRA issued a notice that had the effect that supply of a chemical was not an offence under the Agvet Code. Additionally, in more limited circumstances, the notice also contained instructions for using or otherwise dealing with (which included supply and disposal of) the active constituent or chemical product. A person who then used or otherwise dealt with an active constituent or chemical product in accordance with those instructions was taken to have been issued with a permit to use or otherwise deal with the active constituent or chemical product in accordance with those instructions.

84.6 This use of a *deemed permit* thereby allowed these unregistered products to be dealt with (including disposed of) for a time that the NRA determined after their approval or registration ceased, and also allowed its legal use during that period in accordance with State control-of-use legislation, in a safe manner.

84.7 It is the intention of **Divisions 6** and **Division 7** to more generally apply the model as provided for in section **55** to the circumstances of section **45A** (Notice of suspension or cancellation) and section **54** (Publication of notice of end of registration of chemical product).

84.8 The model, as provided in section **55** incorporates provisions to specifically provide for the possession and custody of the chemicals subject to a deemed permit so as to make it explicit that the possession and custody of the chemical is not an offence under the Agvet Code provided that the possession, custody of, use or other dealing with, is in accordance with the instructions contained in the permit. The inclusion of the new terms insures that the deemed permit is able to provide for all circumstances relating to the unregistered chemical, in a lawful manner, as intended by the model.

84.9 Finally, the model is amended to accommodate the introduction of Listed Registered Chemical Products and Reserved Chemical Products (*refer Parts 2A & 2B respectively*) and the new definition of deal with (*refer Definitions, section 3*).

84.10 To implement the model in the context of old section 45, subsections **45(2)**, **(3)**, **(4)** and **(5)** are repealed and substituted with section **45A** (entitled Notice of Suspension or Cancellation). This approach separates the mechanism of suspension or cancellation of an approval or registration from the subsequent provision of notice to relevant parties, including information relating to instructions, warnings, appeal rights and the issuance, of deemed permits. This structural approach is echoed in sections **54** and **55**.

84.11 Subsection **45A(1)** duplicates old subsection **45(2)** but with the amendment that, in line with the intent that the NRA be empowered to deal with either the approved person or the interested person (*refer Definitions section 3*) in certain circumstances, subsection **45A(1)** changes the previous requirement for the NRA to give written notice of the suspension or cancellation of an approval or registration, to a requirement to provide such notices to either the interested person or an approved person, subject to subsection **45A(3)**. In doing so, these amendments strengthen the NRAs capacity (as previously provided under section **55**) to provide a written notice (including instructions) to an interested person, or an approved person, in the specific context of these persons as the primary manufacturer and supplier of the chemical product.

84.12 Subsection **45A(2)** duplicates old subsection **45(3)** but, in line with the intent as set out above:

subparagraph **(b)(ii)** is amended to enable the NRA to additionally provide instructions for the possession and custody of, using or otherwise dealing with the constituent or chemical product within a notice issued under subsection (2)

subparagraph **(b)(iii)** is amended to expand the obligation of the NRA to provide warnings in the context of the possession or custody with the intention of supply, or supplying, the constituent or product that is not in accordance with the instructions in a notice issued under subsection **45A(1)**. Such warnings must include a statement of the consequences if a person fails to comply with the instructions, and a statement advising the period after which an offence against the Agvet Code arises.

84.13 Subsections **45A(3)** and **(4)** duplicate old subsections **45(4)** and **(5)** by providing that a notice is not required to be given to the person who requested the cancellation (under section **42**) and noting that there are additional matters, properly advising of the appeal rights, for inclusion in the statement advising of review (under section **168**).

84.14 In line with the basic model as set out in section **55**, subsections **45A(5)** through to **45A(8)** provide that a person (the interested or an approved person) who is issued with a notice under section **45A(1)** is placed in the same position as every other person to whom a public notice under section **55** applies, i.e. the interested or approved person is taken to have been issued with a permit allowing possession, custody of, use or other dealing with the unapproved active constituent or unregistered chemical product - in accordance with the instructions in the relevant notice.

84.15 Specifically, subsection **45A(5)** provides that if a person is issued with a notice of the suspension or cancellation of an active constituent or chemical product under subsection **45A(1)** then that person is taken to have been issued with a permit to possess, have custody of, use or otherwise deal with the active constituent or chemical product in accordance with the instructions in the notice until 2 years after the day of the suspension or cancellation; or the NRA revokes the suspension or cancellation; or the NRA by notice published in the *Gazette* declares that the provisions of the subsection cease to apply in respect of the active constituent or chemical product, whichever comes first.

84.16 By the new subsection **45A(6)**, if the NRA gives a notice under subsection **45A(1)** of the suspension or cancellation of an active constituent or chemical product to a person who has possession or custody with the intention of supply, then that person may only possess, have custody of, or otherwise deal with the active constituent or chemical product in accordance with the instruction in the notice. A breach of this proposed subsection will attract a penalty of 300 penalty units.

84.17 Subsection **45A(7)** provides that in paragraph **45A(6)(a)**, strict liability applies to the physical element of the circumstances, that the notice is a notice, given to the person under section **45A**.

84.18 Subsection **45A(8)** provides that subsection **45A(6)** does not apply to the possession, custody, or dealing with an active constituent, a registered chemical product or a reserved chemical product when the possession, custody or dealing took place, because the active constituent was approved or the chemical product was registered, or reserved (*refer Part 2B*) because of its having become approved, registered, or having become reserved after the previous approval or registration had been cancelled.

Clause 85 - The Schedule (subsection 46(2))

85 In line with the intent that the NRA be empowered to deal with either the approved person or the interested person (*refer Definitions section 3*) in certain circumstances, the amendment to subsection **46(2)** means that the NRA must give a written notice advising of the revocation of the suspension or cancellation of an approval or registration to the interested person or the approved person and to any other person whom the NRA believes such a notice should be given.

Division 6 of Part 2 - Duration and renewal of approval or registration

Clause 86 - The Schedule (after subsection 47(4))

86.1 Subsection **47(4)** provides that the approval of a label for containers for the product ends when the registration of the product ends.

86.2 In line with the intent to provide for the lawful dealing with a chemical product once the approval or registration has ended, the inclusion of subsection **47(4A)** provides that should a permit be issued to possess, have custody of, use or otherwise deal with the product under subsections **54(2)**, the approval of a label for containers for the product continues in force until the permit ceases to have effect.

Clause 87 - The Schedule (at the end of subsection 49(1))

87 Section **49** provides for how application for renewal of registration is to be made. Paragraph **49(1)(e)** provides that the form must be lodged with the NRA. This removes any ambiguity as to where the appropriate application should be lodged.

Clause 88 - The Schedule (subsections 49(2), (4) and (6))

88.1 In line with the intent that the NRA be empowered to deal with the approved person (rather than the applicant (the interested person)) (*refer Definitions section 3*) in certain circumstances, the amendments to subsection **49(2)**, **49(4)** and **49(6)** mean that the NRA:

may with the written consent of the approved person alter the application (subsection **49(2)**);

must grant the application and give written notice of the renewal and the period of the renewal to the approved person (subsection **49(4)**); and

must give written notice of a subsequent decision to grant or refuse an application to the approved person, in the circumstances when an application was timely and the NRA failed to grant the application before the registration ended (subsection **49(6)**).

Division 7 of Part 2 - Publication of notices by NRA

Clause 89 - The Schedule (subsection 53(1))

89 This clause inserts the words of the relevant before particulars thereby clarifying that the reference is to any relevant particulars having the meaning given by the Definitions in Section 3.

Clause 90 - The Schedule (subsection 53(1))

90 This amendment, by inserting the words of the before conditions, clarifies that it intends those conditions stipulated under section **23**.

Clause 91 - The Schedule (paragraph 53(2)(a))

91 This clause inserts the words relevant before particulars thereby clarifying that it is any of those relevant particulars referenced in subsection **53(1)**, having the meaning given by the Definitions in Section 3.

Clause 92 - The Schedule (after paragraph 54(b))

92.1 As discussed under clause 80A (section **45A**), it is reasonable in risk management terms, to provide for the appropriate use of chemicals, where they can be used safely to exhaust existing stocks and avoid the potential of subsequent effects arising from long term storage. In the circumstances, where the registration of a chemical product ends (section **54**), it is intended that provisions similar to those in section **55** (Publication of notice of suspension or cancellation of approval or registration) be provided to enable the public to legally possess, have custody of, use or otherwise deal with existing stocks for a period specified in the notice.

92.2 Specifically, this clause provides that, when the NRA publishes a notice under section **54** in the *Gazette* of the end of registration of any chemical product, the notice must contain additional matters, including:

instructions for possessing, having custody of, using or otherwise dealing with the product (paragraph **54(1)(ba)**); and

a warning of the consequence if a person fails to comply with the instruction (paragraph **54(1)(bb)**). Such warnings must include a statement of the consequences if a person fails to comply with the instructions, and a statement advising the period after which an offence against the Agvet Code arises; and

any other warning or explanations in relation to the product that the NRA thinks desirable (paragraph **54(1)(bc)**).

Clause 93 - The Schedule (at the end of section 54)

93.1 Following on from **Clause 90**, this clause inserts subsections **(2)** to **(6)** at the end of section **54**.

93.2 Subsection **(2)** provides that if, after publication of a notice stating that registration of a chemical product has ended, a person possesses, has custody of, uses or otherwise deals with the product in accordance with the instructions in the notice, then that person is taken to have been issued with a permit to so possess, have custody of, use or otherwise deal with the product in accordance with those instructions for 2 years (after the day on which registration ends); or the NRA publishes a notice in the *Gazette* declaring that this provision ceases to apply to the product.

93.3 Subject to subsection **(5)**, subsection **(3)** provides that, if the NRA has published a notice under subsection **(1)** stating that the registration of a chemical product has ended, and a person possesses or has custody of the product with the intention of supply, then that person may only possess, have custody of, or otherwise deal with that product if the possession, custody or dealing is in accordance with the instructions contained in the notice. The penalty for an individual convicted of an offence against this subsection is a maximum of 300 penalty units.

93.4 Subsection **54(4)** provides that in paragraph 54(3)(a), strict liability applies to the physical element of the circumstances, that the notice is a notice given to the person under section 54.

93.5 New subsection **54(5)** provides that subsection **54(3)** does not apply to the possession, custody, or dealing with a chemical product when the possession, custody or dealing took place, because the chemical product was registered, or reserved (*refer Part 2B*) because of its having been registered, or having become reserved after the previous registration had ended.

93.7 Subsection **54(6)** provides that, if the NRA publishes a notice under subsection **(1)** stating that the registration of a chemical product has ended, then the NRA must, as soon as practicable, cause a copy of the notice to be given to the interested person or an approved person, as well as to any other person who, in the opinion of the NRA, should be given notice, for example to major industry and user groups.

Clause 94 - The Schedule (paragraph 55(2)(c))

94.1 As noted in clause 84, section **55** provides a mechanism for legal possession, having custody of, use or other dealing with unregistered chemicals by the general public after suspension or cancellation of an approval or registration. It is the model that has been adopted (as amended below) in the Agvet Code in the circumstances, where a registration of a product ends (*refer section 54*) and where the NRA issues a notice to the interested person (or the approved person), when an approval or registration is suspended or cancelled (*refer section 45A*).

94.2 Section **55** is amended to accommodate the introduction of Listed Registered Chemical Products and Reserved Chemical Products (*refer Parts 2A and 2B respectively*) and the new definition of deal with (*refer Definitions, section 3*).

94.3 Specifically, in line with the intent for greater consistency in the language used throughout the Agvet Code, this clause omits the term directions and substitutes instructions (*refer Definitions section 3 and clauses 27 and 28*).

Clause 95 The Schedule (paragraph 55(2)(e))

95 In line with the intent as set out in Clauses 84 and 94 above, paragraph **(e)** is amended to enable the NRA to additionally provide instructions for the possession and custody of the active constituent or chemical product within a notice issued under subsection **(1)**.

Clause 96 - The Schedule (at the end of paragraph 55(2)(f))

96 In line with the intent as set out in Clauses 84 and 94 above, paragraph **(f)** is amended to expand the obligation of the NRA to provide warnings in the context of the possession or custody with the intention of supply, or supplying, a constituent or chemical product that is not in accordance with the instructions in a notice issued under subsection **55(1)**. Such warnings must include a statement of the consequences if a person fails to comply with the instructions, and a statement advising the period after which an offence against the Agvet Code arises.

Clause 97 - The Schedule (subsection 55(3))

97.1 As set out in the discussion in Clauses 84 and 94 above, it is the intent to provide a mechanism which facilitates safe use of an unregistered chemical, in certain circumstances so as to avoid the potential for adverse effects from long term storage or other mechanism of disposal.

97.2 Subsection **55(3)** is amended to provide that if, after publication under subsection **(1)** of a notice of the suspension or cancellation of an approval or registration, a person possesses, has custody of, uses or otherwise deals with the constituent or product with the intention of supply, or a product containing a label, in accordance with the instructions in the notice, then that person is taken to have been issued with a permit to so possess, have custody of, use or otherwise deal with the active constituent or product, or a product containing a label, in accordance with those instructions for 2 years (after the day of the suspension or cancellation); or the NRA revokes the suspension or

cancellation; or the NRA publishes a notice in the *Gazette* declaring that this provision ceases to apply to the constituent or product.

Clause 98 - The Schedule (subsection 55(4))

98 In line with the intent as set out in Clauses 84 and 94 above, subsection **55(4)**, is amended to extend its scope so that the person must not possess, have custody of, or otherwise deal with the active constituent or chemical product, or label, except in accordance with the instruction in the notice.

Clause 99 - The Schedule (subsection 55(5))

99 In line with the intent as set out in Clauses 84 and 94 above, subsection **55(5)**, is amended to provide that the exemption provided within this subsection accommodates the expansion of the scope of subsection (4) to possession, custody or dealing with the active constituent or chemical product, or label, except in accordance with the instruction in the notice by omitting the words a dealing and substituting them with a possession, custody, or dealing.

Clause 100 - The Schedule (subsection 55(5))

100 In line with the intent as set out in Clauses 84 and 94 above, subsection **55(5)**, is amended to provide that the exemption provided within this subsection accommodates the expansion of the scope of subsection (4) to possession, custody or dealing with the active constituent or chemical product, or label, except in accordance with the instruction in the notice by omitting the words when the dealing and substituting them with when the possession, custody, or dealing.

Clause 101 - The Schedule (subsection 55(6))

101 In line with the intent as set out in Clauses 84 and 94 above, subsection **55(6)**, is amended to extend the defence to a prosecution against subsection **55(4)** to the circumstances when the person possesses, has custody of, or otherwise deals with the active constituent or chemical product and could not reasonably be expected to have known of the existence of the notice by inserting after the words when the person, the words possessed, had custody of or .

Clause 102 - The Schedule (subsection 55(6))

102 In line with the intent as set out in Clauses 84 and 94 above, subsection **55(6)**, is amended to extend the defence to a prosecution against subsection **55(4)** to the circumstances when the person possesses, has custody of, or otherwise deals with the active constituent or chemical product and could not reasonably be expected to have known of the existence of the notice by omitting the words the dealing, and substituting them with the words the possession, custody or dealing.

Clause 103 - The Schedule (paragraph 55(7)(a))

103 Paragraph **55(7)(a)** is amended to make a correction that, where the NRA issues a notice of the suspension or cancellation of the registration of a chemical product under this section, it must give a copy of that notice to the interested person in relation to that product rather than the interested person in relation to the approved label for the product.

Clause 104 - The Schedule (at the end of paragraph 55(7)(a))

104 In line with the intent that the NRA be empowered to deal with either the approved person or the interested person (*refer Definitions section 3*) in certain circumstances, the amendment to paragraph **55(7)(a)** means that the NRA must, as soon as practicable, give a copy of the notice to each person who is an interested person or an approved person to which the notice relates advising of the suspension or cancellation of the registration of a chemical product.

Clause 105 - The Schedule (at the end of paragraph 55(8)(a))

105 In line with the intent that the NRA be empowered to deal with either the approved person or the interested person (*refer Definitions section 3*) in certain circumstances, the amendment to paragraph **55(8)(a)** means that the NRA must, as soon as practicable, give a copy of the notice advising of the suspension or cancellation of a label for containers for a chemical product to the interested person or the approved person.

Clause 106 - The Schedule (after Part 2)

106 This clause inserts two new parts in the Agvet Code **Parts 2A and 2B**.

Part 2A establishes a new, more simplified, means of authorising (to be known as listed registration (*refer definitions section 3*)) of certain agricultural or veterinary chemical products resulting in their entry to the market.

Part 2B (*refer new section 56ZW*) establishes a mechanism to provide for the possession, custody, use or otherwise dealing with an agricultural and veterinary chemical products, without either a registration or a listed registration in certain circumstances.

The process of obtaining registration for all chemical products has been broadly the same a one size fits all approach. In essence, in order to grant an application for registration of a chemical product, the NRA had to be, (and has to continue to be) satisfied of all the matters referred to in section 14(3) of the Agvet Code. The Agvet Code does not prescribe exactly how the NRA is to go about its business in terms of the registration of chemical products. This is determined administratively and, consequently, provides a significant level of flexibility to the registration of chemical products.

Notwithstanding this flexibility, there are some products for which, having regard to the known risks associated with their use, even the least effort regulatory approach available under the registration process was disproportionately burdensome. Many argue that chemical products such as swimming pool chemicals, home aquarium products, and vitamin and mineral supplements fall into this category on the basis that the time, cost and regulatory burden in obtaining registration is not commensurate with the known risks associated with these chemical products, when compared to other mainstream agricultural and veterinary chemical products.

It is worth noting that a similar tiered system of approval for the regulation of human therapeutic goods has been effectively used for many years.

Part 2A establishes a system of listed registration for some chemical products provided they are consistent with a prescribed standard. In doing so, the part encompasses the intentions, as laid out previously, to standardise, and consistently use, terminology such as instructions (*refer Definitions Section 3 and clauses 27 and 28*) and deal with (*refer Definitions Section 3*) and building the additional flexibility for the NRA in its dealings with interested persons and approved persons (*refer Definitions Section 3*).

Part 2A - Listable chemical products

This Part is divided into nine Divisions.

Division 1 - Preliminary

Clause 56A - Explanation of Part

This clause explains, in general terms, the purpose of this Part and of the nine Divisions of the Part. Several of the Divisions or clauses mirror the equivalent provision relating to the existing registration of chemical products.

Clause 56B - Exclusion of restricted chemical products

This clause provides that this Part does not apply to chemical products that are restricted chemical products. Restricted chemical products are more hazardous chemicals that can only be supplied to and used by persons who have specialised knowledge, or skills. It is not consistent with the aims of this Part that any product that is a restricted chemical product could ever be granted listed registration and thus such products are expressly outside the listed registration provisions.

Division 2 - Schedule of listable chemical products

Clause 56C - Regulations may contain schedule of chemical products

Subclause (1) provides that the regulations may contain a schedule listing chemical products, or classes of products, that are eligible to be granted listed registration under this Part.

Subclause (2) provides that, before a regulation can be made listing a chemical product (or a class of chemical products) (*relevant matters*), then the listing must have been recommended to the Minister by the NRA supported by the following:

written particulars of the relevant products;

a draft of the standard for the relevant products that the NRA proposes to submit for approval of the Minister, if the product is granted listed registration;

a written explanation as to why the NRA is satisfied that the use of the relevant products in accordance with the instructions that the NRA proposes to approve would meet all the standard assessment criteria or matters in paragraphs 56D(1)(a) to (e), having regard to the relevant matters in 56D(2) where information about those matters is readily available; and

a written statement identifying the consultations held by, as well as setting out the advice given to, the NRA in relation to the proposed listing of the relevant products.

Subclause (3) broadly mirrors section 13 of the Agvet Code in that it provides that the public may be given an opportunity to comment on the NRAs proposal to recommend the listing of a relevant product. The Minister may, before a regulation is made listing a relevant product, require the NRA to widely publish a notice stating that it has recommended the listing of the relevant product, setting out particulars of the relevant product, giving reasons for the recommendation, and inviting written submissions as to whether the recommendation should be confirmed or withdrawn and stating the grounds on which the submission is based (which must be matters mentioned in paragraphs 56D(1)(a) to (e)).

Subclause (4) requires the NRA to take into account any submissions received. The NRA must then inform the Minister whether it confirms or withdraws its recommendation.

Division 3 - Establishing standards for listable chemical products

Clause 56D - NRA to prepare standards

This clause provides for the establishment of standards for listable chemical products.

Subsection (1) provides that section 56C applies to each listable chemical product, whether or not the product already has a standard set out in one of the recognised pharmacopoeia monographs.

Subsection (2) requires the NRA to prepare a written standard for each listable chemical product and submit that standard to the Minister for the Ministers approval of the standard. A standard may relate to a specified chemical product or products, or to each product in a specified class of chemical products.

Subsection (3) provides that the standard must require that the product be labelled in a manner specified in the standard and that the product be kept in containers that comply with requirements in the standard.

Without limiting the generality of subsection (3), subsection (4) provides that, in a standard, the NRA may direct that the particulars required by the standard on chemical products, their containers and the product label, be as set out in a manner specified in the standard.

Without limiting the generality of the preceding provisions of this section, subsection (5) provides that a standard may be specified by reference to any one or more of the following:

- the composition and form of the constituents of the product;
- the physical and chemical properties of the chemical product;
- the quantity of the chemical product in the specified container;
- procedures to be carried out in the manufacture of the chemical product;
- a monograph in the British Pharmacopoeia or the British Pharmacopoeia (Veterinary);
- a monograph in another publication approved by the NRA;
- a monograph referred to in the last two points as modified in a manner specified in the standard;
- a standard published by Standards Australia International Limited;
- such other matters as the NRA thinks fit.

The NRA may also require that a matter relating to the standard be determined in accordance with a particular test.

Subsection (6) provides that if the Minister decides not to approve a standard, the Minister must inform the NRA of the reasons for the decision. The NRA must then prepare in writing a revised standard for the product as may be required until the Minister endorses his or her approval on the instrument containing the standard concerned.

Subsection (7) provides that if the Minister decides to approve a standard for a listed chemical product, the Minister must endorse his or her approval on an instrument containing the standard for the standard to become effected and that the standard becomes the standard established for the product from the time of the endorsement.

Subsection (8) requires the NRA to publish the standard established for a listable chemical product in the *Gazette*.

Clause 56E - Matters to be taken into account in preparing a standard

This clause broadly mirrors section 14 of the Agvet Code in that it sets out the basic criteria on which the NRA must prepare a standard.

Subclause 56D(1) provides that the NRA must not submit a standard for a chemical product to the Minister for approval unless the NRA is satisfied that use of the product is in accordance with the standard and:

- would ensure that the product would not be an undue hazard to people in terms of occupational health and safety or because of its residues;

- would ensure that the product would not be likely to be harmful to humans because of its toxicology;

would ensure that the product would not be likely to be harmful to animals, plants, or things, or to the environment;

would not unduly prejudice Australia's trade;

would be effective according to criteria determined by the NRA for the product;

would contain, or would require a label for containers for the product to contain, adequate instructions (relating to, amongst other things, how and when the product should be used, any withholding or re-entry period, first aid instructions, the disposal of the product, and any other matters prescribed by the regulations) (*refer paragraph 56D(1)(f)*).

Subsection 56D(2) mirrors subsection **14(5)** (as amended) of the Agvet Code. In satisfying itself of the standard assessment criteria (that the product would not be an occupational health and safety or residues hazard; would not be harmful to humans; and would not be harmful to target animals/plants, or to the environment), then the NRA must have regard to a specified range of matters including, amongst other things, the product's toxicity, poison classification, formulation, the acceptable daily intake of each active constituent, residues, stability, container specifications, and any other matters prescribed by the regulations.

Subsection 56D(3) mirrors section **14(6)** (as amended) in that the NRA when satisfying itself whether the use of a product in accordance with the standard would be effective, that the NRA must have regard to whether the NRA must have regard to whether any trials or laboratory experiments have been carried out to determine the efficacy of the product and if so, the results of those trials or experiments, and any other matters prescribed by the regulations.

Clause 56F - Variation or revocation of standards

This clause provides that the NRA may at any time prepare a written variation of any standard established for a listable chemical product and submit the variation to the Minister for approval. If the Minister approves the variation, then the varied standard becomes the established standard. The NRA may also, with the approval of the Minister, revoke the standard established for a listable chemical product. The NRA must publish a copy of an instrument of variation or revocation of the standard in the Gazette.

Clause 56G - Date of effect of standards

This clause provides that a standard takes effect on the day it is published in the Gazette, or on a later day, if that date is specified in the instrument containing the standard. Similarly, a variation or revocation of a standard takes effect on the day the variation or revocation is published in the Gazette, or on a later day if that date is specified in the instrument containing the variation or revocation.

Clause 56H - Standards to be disallowable

The instruments containing standards established for listable chemical products, or which vary or revoke a standard, are disallowable instruments for the purposes of the *Acts Interpretation Act 1901*.

Division 4 Application for registration of listable chemical products

Clause 56I - Application

This clause mirrors section **10** (as amended) of the Agvet Code. It provides that a person may apply to the NRA for a chemical to be granted listed registration for a chemical product, provided it is a listable chemical product and for which there is an established standard.

Clause 56J - How application is to be made

This clause mirrors section **11** of the Agvet Code. It explains how an application is to be made, specifying that it must have all the information that the NRA requires, be signed by an approved person, be accompanied by the required fee and be lodged with the NRA. It also provides that the NRA may with the consent of the approved person vary, alter or withdraw the application, at any time before the application has been determined.

Clause 56K - Grant or refusal of application

Subsections **56K(1)** and **(2)** provide that the NRA must grant an application made under section 56H, if it is satisfied that the application has been lodged properly; the requirements for the provision of samples and further information has been complied with (sections **157** and **159** respectively), that if necessary appropriate consultation have been undertaken with the Gene Technology Regulator; that the chemical product complies with the relevant established standard and with any other requirements prescribed by the regulations and that the prescribed fee, or any other amount that is payable by the applicant or any other person, for the product have been paid. In order to be so satisfied, the NRA may have regard to the results of its own inquiries or it may rely on a written declaration produced to it by an approved person.

Subsection **(3)** provides that if the NRA is not satisfied as above, then it must refuse the application.

Clause 56L - Multiple listed registrations

This clause mirrors section **16** of the Agvet Code. The clause makes it clear that the listed registration of a chemical product on the application of a person does not preclude the listed registration of the same product on the application of some other person.

Clause 56M - How listed registration of chemical product is effected

This clause mirrors section **20** of the Agvet Code. The clause provides that if the NRA grants an application for a listable chemical product, either unconditionally or subject to conditions (refer section 56Q) then the NRA must give a distinguishing number to the product and grant listed registration of that product

Listed registration takes place by the NRA entering in the Register of Chemical Products the relevant particulars (which are a notation signifying that the product is a listable chemical product, its distinguishing number, any particulars that are prescribed by the regulations) and any conditions of the listed registration.

Clause 56N - Date of listed registration

This clause partially mirrors section **22** (as amended) of the Agvet Code.

Subsection **(1)** provides that the date of listed registration of a chemical product is the date on which the relevant particulars entry is made in the Register of Chemical Products.

Subsection **(2)** provides that if any of the relevant particulars or conditions of the listed registration of a chemical product are varied on application of a person, the date of listed registration of the product as varied is the date the entry of the variation is made in the Register.

Clause 56O - Conditions of listed registration

This clause mirrors section **23** of the Agvet Code.

Subsection **(1)** gives the NRA wide powers to set conditions on the listed registration of a chemical product.

Without limiting the generality of subsection (1), subsection (2), provides that a particular matter that may be regulated by conditions is the kind of container that the product must only be supplied in or the type of container that the product must not be supplied in.

Subsection (3) further provides that a condition that may be imposed on a chemical product granted listed registration, is a condition that the listed registration remains in force only for a stated period that is not more than one year. Subsection (4) provides that the period of time may be extended for further periods of a year in certain circumstances.

Clause 56P - Notice of listed registration

This clause mirrors section 24 (as amended) of the Agvet Code.

Subsection (1) requires the NRA to give written advice of the granting of a listed registration to an approved person (*refer Definitions section 3*). The NRA may cause a material safety data sheet about the product to be made publicly available (paragraph (1)(a)). The notice given under paragraph (1)(a) must contain the information prescribed in the regulations (subsection (2)).

Subsection (3) requires a notice issued under subsection (1) to properly advise the applicant of his or her rights of review of the NRAs decision granting listed registration in respect of a chemical product subject to conditions (*refer section 168*).

Clause 56Q - Notice of refusal of application

This clause mirrors section 25 (as amended) of the Agvet Code.

The clause requires the NRA to give written advice of its decision to refuse an application for listed registration of a chemical product to an approved person and include brief particulars of the reasons for the refusal.

The NRA is also required to properly advise of any rights of review of the NRAs refusal to grant an application (*refer section 168*).

Clause 56R - Notice of incorrectly registered particulars

This clause mirrors section 26 (as amended) of the Agvet Code.

Subsection (1) requires (under penalty of a maximum of 60 penalty units for an individual) that where a person who is the interested person in relation to a registered listed chemical product believes that any matter entered in the Register of Chemical Products is not correct in a material respect, then that person must provide a written notice signed by an approved person to be given to the NRA.

Subsection (2) obliges the NRA to change any matter in the Register if it is satisfied following a notice signed by an approved person under subsection (1), that the information is not correct.

Division 5 - Application for variation of relevant particulars, or of conditions, of listed registration

This Division allows the interested person (*refer Definitions section 3*) in respect of a registered listed chemical product to apply to the NRA to vary that listed registration.

The Division closely mirrors Division 3 of Part 2 of the Agvet Code (sections 27 to 29), which provides for variation of the relevant particulars and conditions of a registered chemical product.

Clause 56S - Who may apply

This clause provides that the interested person in relation to a registered listed chemical product may apply to the NRA to vary the relevant particulars, or the conditions, of the listed registration.

Clause 56T - How application is to be made

This clause explains how an application for variation is to be made, specifying that it must be in writing in or to the effect of the approved form, have all the information that the NRA requires, be signed by an approved person, be accompanied by the required fee and be lodged with the NRA.

It also provides that the NRA may alter the application with the written consent of the approved person (subsection (2)).

At any time after an application has been made and before it has been determined, an approved person may withdraw the application by giving the NRA written notice of the withdrawal signed by the approved person (subsection (3)).

Clause 56U - Grant or refusal of application

This clause sets out the standard criteria against which the NRA must evaluate an application for variation of a listed registration. These criteria substantially duplicate the matters of which the NRA must be satisfied in preparing a standard under section 56D.

Subsection (1) provides that the NRA must grant an application for variation made under section 56V, if it is satisfied that:

the application has been properly made (paragraph (a));

any requirement for samples or additional information, reports or samples has been met (paragraph (b));

if necessary, appropriate consultation have been undertaken with the Gene Technology Regulator (paragraph (c));

any other requirement prescribed by the regulations in relation to the variation of the relevant particulars, or of conditions, of a listed registration have been complied with (paragraph (d));

if the variation applied for was made, the continued use of, or any other dealing with, the product in accordance with instructions in the established standard would;

ensure that the product would not be an undue hazard to people in terms of occupational health and safety or because of its residues;

ensure that the product would not be likely to be harmful to humans because of its toxicology;

ensure that the product would not be likely to be harmful to animals, plants, or things, or to the environment;

not unduly prejudice Australia's trade; and

be effective according to criteria determined by the NRA for the product (paragraph (e))

that any fee that is payable to the NRA in respect of the product has been paid (paragraph (f)).

If the NRA is satisfied, it must grant an application for variation, and must vary those particulars or conditions by entering in the Register of Chemical Products the particulars of the variation and the date on which the entry was made (paragraph (g)). The NRA must give written advice to an approved person that the variation has been made and provide details of the variation (paragraph (h)).

Subsection (2) provides that in satisfying itself for the purposes of subparagraph (1)(e)(i), (ii) and (iii) (relating to undue hazard to the safety of people during its handling or use; harmful effect to human beings; and unintended harmful effects to the environment respectively), the NRA must have regard to the matters referred to in subsection 56D(2).

Subsection (3) provides that in satisfying itself for the purposes of subparagraph (1)(e)(v) (relating to efficacy), the NRA must have regard to the matters referred to in subsection 56D(3).

Subsection (4) requires that if the NRA cannot be satisfied as required by subsection (1), it must refuse the application.

Subsection (5) provides that if the NRA refuses an application it must give written notice of the refusal to the approved person and include in the notice brief particulars of the reasons for the refusal.

Subsection (6) also requires the NRA to properly advise the approved person of his or her rights of review of the NRA's decision to refuse the application for variation (refer section 168).

Division 6 - Reconsideration of listed registration

This Division allows that NRA to reconsider its decision to grant an application for listed registration of a chemical product and to affirm, vary as appropriate, or set aside its earlier decision to ensure that all listed registration satisfy current regulatory standards set out in new section 56D.

This Division closely mirrors Division 4 of Part 2 of the Agvet Code (sections 30 to 34), which provides for reconsideration by the NRA of its earlier decision to grant an application for registration of a chemical product.

Clause 56V - NRA may invite the public to propose registered listed chemical products for reconsideration

This clause seeks to engage the public in the reconsideration process by which the NRA ensures it remains satisfied that chemicals with listed registration continue to meet contemporary standards.

Subsection (1) of this clause allows the NRA, by notice in the *Gazette* or other means, to invite the public to propose chemical products whose listed registration might be reconsidered by the NRA.

Subsection (2) provides that in publishing a notice the NRA must state the criteria to be taken into account in reconsidering the listed registration.

Subsection (3) provides that a person must support a proposal by submitting reasons based on the criteria stated in the notice.

Clause 56W - NRA may reconsider listed registration

This clause empowers the NRA to reconsider the listed registration of a chemical product at any time in accordance with this Division.

Clause 56X - NRA may give notice of proposed reconsideration

Subsection (1) gives the NRA the option of inviting the public to give the NRA written submissions on their views as to whether the listed registration of a chemical product, that the NRA intends to reconsider, meets the health, safety and other criteria prescribed by the regulations for continued listed registration.

If the NRA decides to seek public comment on the reconsideration of a listed registration of a chemical product, it must publish a notice inviting public views setting out the relevant particulars of the listed registration of the product; the matters to be dealt with in the reconsideration; the requirement(s) prescribed by the regulations for the continued registration of the product (refer new paragraph 56ZB(1)(b)); and the closing date for submissions which must be a minimum period of 28 days.

Subsection (2) deals with the requirements for the NRA to give written notice to the interested or approved person when reconsidering the listed registration of a chemical product. The written notice

must set out the particulars of the listed registration of the product (subsection **(2)(a)**); set out the matters to be dealt with; obliges the interested or approved person either to give the NRA any particular information that it asks for, or provide any relevant information to the reconsideration of which the person is aware, within the period requested (which must be a minimum period of 28 days) (refer subsection **(2)(b)**); and inviting the person to give the NRA a written submission about the matters referred to in paragraph **(2)(a)**).

Subsection **(3)** establishes that a person, subject to a penalty of 120 penalty units, must comply with a requirement under paragraph **(2)(b)**.

Subsection **(4)** provides that it is a strict liability offence for an individual not to comply with the NRAs request for information. This offence carries a penalty of 120 penalty units for an individual.

Subsection **(5)** establishes that subsection (3) does not apply if the interested or approved person chooses to seek voluntary cancellation rather than supply the requested information at any time before the end of the period stated in the notice.

Subsection **(6)** provides that any submissions made to the NRA in accordance with an invitation contained in a notice, must be taken into account in its reconsideration.

Clause 56Y - NRA may require trials or laboratory experiments to be conducted

Subsection **(1)** enables the NRA, by written notice given to the interested or approved person to require the interested person to conduct, or cause to be conducted, trials or laboratory experiments, within a reasonable stated period, in relation to the product for the purposes of the NRAs reconsideration. Results of the trials or laboratory experiments must be given to the NRA.

By subsections **(2)** and **(3)**, it is a strict liability offence, punishable by an individual fine of 120 penalty units, for a person not to comply with the NRAs request to conduct trials or laboratory experiments.

Subsection **(4)** provides an exemption to the offence established by subsection **(2)**, if the interested or approved person chooses to seek voluntary cancellation of the listed registration of the chemical product (under section **56ZL**) rather than conduct the requested trials or laboratory experiments and the NRA complies.

Clause 56Z - Reconsideration by NRA of continued listed registration

This clause sets out the standard criteria against which the NRA must reconsider the listed registration of a chemical product and specifies the process for notifying certain parties and varying the Register of Chemical Products.

Subclause **(1)** provides that the NRA must affirm a listed registration of a chemical product if it is satisfied that, provided any conditions of the listed registration are complied with, the continued use of, or other dealing with, the product in accordance with the instructions contained in the established standard would meet all of the standard assessment, i.e. the criteria that there would be no undue occupational health or safety hazard and residue hazard (subparagraph **(1)(c)(i)**), unlikely to have a harmful effect to humans (subparagraph **(1)(c)(ii)**), unlikely to harm target animals/plants or the environment (subparagraph **(1)(c)(iii)**), no undue prejudice to trade (subparagraph **(1)(c)(iv)**); and that it would be effective (subparagraph **(1)(c)(v)**). In addition, before affirming the listed registration of the product, the NRA must also satisfy itself that any requirement it has for further information or report samples has been complied with (subsection **(1)(a)**); any consultation, if necessary, with the Gene Technology Regulator has been undertaken (subsection **(1)(b)**); and any other prescribed requirements for the continued listed registration would be complied with (subsection **(1)(d)**).

Further, if the NRA affirms a listed registration of a chemical product then the NRA must, as soon as practicable, give written notice to the interested or approved person (*refer Definitions section 3*) of

that listed registration stating that it has so affirmed the listed registration on the existing conditions. The NRA must also give brief particulars of the reasons for its decision (subsection **(1)(e)**).

If the NRA sought public comments on the proposed reconsideration under subsection **56Z(1)** it must also publish a notice stating that it has affirmed the listed registration on the existing conditions (paragraph **(1)(f)**).

Subsection **(2)** provides that, in making a decision that it is satisfied for the purposes of subparagraphs **(1)(a)(i), (ii)** or **(iii)** the NRA must have regard to the specified range of matters earlier referred to in subsection **56D(2)**.

By subsections **(3), (4)** and **(5)**, if the NRA is not satisfied that the continued use of, or other dealing with, the listed registration product would continue to meet the standard assessment criteria, but is satisfied that the relevant particulars or the conditions of the listed registration can be varied in such a way that would meet those criteria, then the NRA must so vary the listed registration by an appropriate entry in the Register of Chemical Products. The NRA must also give notice to the interested person or an approved person of the listed registration, stating that although it is not satisfied, it is satisfied that the listed registration can be appropriately varied, and that the NRA has so varied the relevant particulars or the conditions of the listed registration.

Under subsections **(6)** and **(7)**, the notice given under subsection **(4)** must detail the variations and give brief particulars of the reasons for the NRAs decisions. The notice must also properly advise the applicant of his or her rights of review of the NRAs decision to vary the relevant particulars or the conditions of the listed registration (refer section **168**).

By subsections **(5)** and **(8)**, if the NRA is not satisfied that the conditions of the listed registration can be appropriately varied, then section 56ZG provides that the NRA can suspend or cancel the listed registration. Subsection **(4)** requires the NRA to give to the interested person or an approved person notice that it is not satisfied.

Division 7 - Suspension or cancellation of listed registration

This Division gives the NRA six specific grounds on which it may suspend or cancel the listed registration of a chemical product. The Division closely mirrors Division 5 of Part 2 of the Agvet Code (sections **35** to **46** inclusive), which provides for the suspension or cancellation of the registration of a chemical product.

Clause 56ZA - Notice of proposed suspension or cancellation to be given to co-ordinators

This clause prevents the NRA from suspending or cancelling a listed registration unless notice of the proposed suspension or cancellation has been given to all co-ordinators (*refer Definitions section 3*) and 10 working days, or any other period that the NRA thinks adequate in a particular case, has elapsed since the notice was given.

Clause 56ZB - Suspension or cancellation of listed registration for breach of condition

The NRA may suspend or cancel the listed registration of a chemical product if there is a breach of a condition of that listed registration.

Clause 56ZC - Suspension of listed registration for failing to give information, or results or trials or experiments, to NRA

Subsection **(1)** allows the NRA to suspend the listed registration, at the end of the period stated in the relevant notice:

where a person has failed to give the NRA information requested for a reconsideration under subsection 56Z(2), and the NRA is satisfied that the interested person or an approved person is aware of the information; or

where the NRA is satisfied that the interested person has not conducted the trials or experiments or has not given the results of these to the NRA as required by subsection 56ZA(1).

Subject to subsection (4), subsections (2) and (3) provide that the NRA must revoke the suspension when it is satisfied that all the information relevant to the reconsideration has been given to it; or it has received the results of the trials or experiments.

Subclause (4) provides that the NRA may cancel the listed registration if the information or results are not given to it within a reasonable period after the suspension takes place.

Clause 56ZD - Suspension of listed registration for failing to give information, report or sample to the NRA

Subsection (1) provides that the NRA may suspend the listed registration of a chemical product if the interested person for that listed registration or an approved person, fail to comply with a requirement made in a notice under:

section 159 (the NRA or other authority may require to additional information, report or sample to the NRA other than in an application); or

section 160A (to provide any new or additional information to the NRA while an application is pending); or

section 161 (to provide further new information to the NRA after registration).

Subject to subsection (3), subsection (2) provides that the NRA must revoke a suspension (imposed under subsection (1)) when it is satisfied that the relevant information, report or sample has been given to it.

Subsection (3) provides that the NRA may cancel the listed registration if the information, result or sample is not given to it within a reasonable period after the suspension takes place.

Clause 56ZE - Suspension or cancellation of listed registration following reconsideration

This clause allows the NRA to suspend or cancel the listed registration of a chemical product if, on reconsideration, it is not satisfied that the particulars or the conditions of the listed registration can be varied in such a way that the prescribed requirements for continued listed registration (that is, the continued use of the product would meet all the standard assessment criteria in subsection 56ZB(1), including having regard to the specified range of matters referred to in subsection 56D(2)), are being met.

Clause 56ZF - Suspension or cancellation of listed registration for non-compliance with criteria

Subsection 56ZH(1) allows the NRA to suspend or cancel the listed registration of a chemical product if, having regard to the matters referred to in subsection 56D(2), it appears to the NRA that the continued use of, or any other dealing with, the product, in accordance with instructions contained in the established standard, may not meet all the standard assessment criteria in paragraph 56W(1)(e) i.e. the criteria that there would be no undue occupational health or safety hazard and residue hazard (paragraph (1)(a)), unlikely to have a harmful effect to humans (paragraph (1)(b)), unlikely to harm target animals/plants or the environment (paragraph (1)(c)), or no undue prejudice to trade (paragraph (1)(d)).

Subsection 56ZH(2) allows the NRA to suspend or cancel the listed registration of a chemical product if, having regard to the matters referred to in subsection 56D(3), it appears to the NRA that the continued use of the product, in accordance with instructions contained in the established standard, may not be effective according to the criteria determined by the NRA for the product.

Clause 56ZG Cancellation of listed registration on request

This clause requires the NRA to cancel the listed registration of a chemical product if the interested person in relation to a listed registration, or an approved person, voluntarily requests the NRA, in writing, to so cancel it.

However to ensure that the NRA is fully aware of any possible safety or efficacy problem with chemical products, the voluntary cancellation advice must state the reasons for the request and the NRA must be satisfied that there is no valid reason why it should not agree to the cancellation request. For example, if the reasons for the request for cancellation were solely commercial, then the NRA would have no valid reason for not agreeing to the cancellation. If on the other hand, the real reason for the request for cancellation goes to the safety or efficacy of the product then the NRA may not agree to the cancellation unless it receives all of the relevant information and data that has prompted the cancellation request and has taken appropriate regulatory action such as deciding that it will reconsider all similar products under Division 6.

By subsection (2), the NRA must give written notice of its decision on the cancellation request to the person who made it.

Clause 56ZH Effect of suspension of listed registration

Subsection (1) provides that the suspension of a listed registration must be for a stated period.

Subsection (2) provides that the effect of suspension of a listed registration is that the listed registration is taken to be not in force during any period in which it is suspended, except for the purposes of section 75 of the Agvet Code, which makes it an offence for a supplier to have possession or custody of the product.

Subsection (3) provides that a listed registration may be cancelled even though it is suspended.

Clause 56ZI - How listed registration is suspended or cancelled

This clause closely mirrors section 45 and explains how the listed registration of a chemical product is suspended or cancelled. The model discussed in section 45A of using instructions issued under a notice as a deemed permit to allow stocks of unregistered product to be lawfully sold and used for a period that the NRA determines after registration ceases is also used here.

Subsection (1) provides that suspension or cancellation of a listed registration is made by entering in the Register of Chemical Products that the listed registration has been suspended or cancelled; the period of suspension; and, the date of the entry.

Subsection (2) provides that, subject to subsection (4), if the NRA suspends or cancels a listed registration, it must give written notice of the suspension or cancellation to the interested person or an approved person as well as to any other person to whom, in the NRAs opinion, such a notice should be given. Thus, if it is appropriate, major user groups could also be given notice of the suspension or cancellation.

Subsection (3) provides that a notice given under subsection (2) must tell the person (to whom the notice is given) of the suspension or cancellation; and contain:

brief reasons for the suspension or cancellation (subparagraph (3)(b)(i));

instructions for possessing, having custody of, using or otherwise dealing with the product (subparagraph (3)(b)(ii));

a warning of the consequences if a person fails to comply with the above instructions; including a statement as to when it will be an offence against the Agvet Code to have possession or custody of the product with the intent of supply, or supplying the product (subparagraph (3)(b)(iii)); and

any other warnings or explanations in relation to the product that the NRA thinks desirable(subparagraph **(3)(b)(iv)**).

Subsection **(4)** exempts the NRA from the requirement under subsection **(2)** to give a notice of the cancellation to any person who requests a voluntary cancellation under section **56ZL**.

Subsection **(5)** provides that the notice must also properly advise the applicant of his or her rights of review of the NRAs decision to suspend or cancel a listed registration (refer section **168**).

Subsection **(6)** provides that if, after notice of the suspension or cancellation of the listed registration of a chemical product is given to a person, then the interested person is taken to have been issued with a permit to possess, have custody of, use or otherwise deal with the product in accordance with the instructions in the notice for 2 years after the day of the suspension or cancellation; or the NRA revokes the suspension or cancellation; or the NRA publishes a notice in the Gazette declaring that this provision ceases to apply to the product.

Subsection **(7)** provides that, subject to subsection **(9)**, if the NRA gives a notice of the suspension or cancellation of a listed registration of a chemical product to a person, and the person has possession or custody of the product with the intention of supply, then that person may only possess, have custody of, or otherwise deal with that product if the possession, custody, or other dealing with is in accordance with the instructions contained in the notice. The penalty for an individual convicted of an offence against this subsection is 300 penalty units.

Subsection **(8)** provides that in paragraph **(7)(a)**, strict liability (as defined in the *Criminal Code*) applies to the physical element of circumstance that the notice is given to the person under this section.

Subsection **(9)** provides that the offence provision of subsection **(7)** does not apply to any possession, custody, or other dealing with the chemical product by a person if, when the possession, custody, or other dealing with took place, the product was a registered product, a registered listed chemical product, or a reserved chemical product because of its having been registered or granted listed registration, or having become reserved after its previous registration had been cancelled.

Clause 56ZJ - How suspension or cancellation of listed registration is revoked

Subsection **(1)** provides that a suspension or cancellation of a listed registration is revoked by making an appropriate entry in the Register of Chemical Products to that effect and including the date of the entry.

Subsection **(2)** provides that the NRA is required, as soon as practicable, to give written notice of the revocation of the suspension or cancellation to the interested person or an approved person (*refer Definitions section 3*) as well as to any other person to whom, in the NRAs opinion, such a notice should be given. Thus, if it is appropriate, major user groups could also be given notice of the revocation of suspension or cancellation.

Subsection **(3)** provides that if the cancellation of a listed chemical product is revoked, the cancellation is taken never to have occurred.

Division 8 - Duration and renewal of listed registration

This Division provides that the listed registration of a chemical product expires annually and explains how it may be renewed. The Division closely mirrors Division 6 of Part 2 of the Agvet Code (sections **47** to **51**) that provides for the duration and renewal of approvals of active constituents and labels and registrations of chemical products.

Clause 56ZK - Period of listed registration

Subsection (1) provides that, subject to this Division, the listed registration of a chemical product ends on 30 June each year, except where there is a condition imposed by subsection 56Q(3) on the product that states that it ends at an earlier date; or the product has been suspended under subsection 56ZJ(2).

Clause 56ZL - Application for renewal of listed registration of chemical product

Subsection (1) provides that the interested person (*refer Definitions section 3*) may apply for the renewal, each year, of the listed registration.

The application for renewal must be made by 31 May each year unless the NRA allows a later date (subsection (2)). A late application may be accepted by the NRA, upon payment of the late fee, in the circumstances prescribed by the regulations provided the late application is made on or before a date determined by the NRA (subsection (3)).

Clause 56ZM - How application for renewal of listed registration is to be made

This clause describes how to make an application for renewal of a listed registration.

Subsection (1) provides that the application must be in writing, generally be in the approved format, and be lodged with the NRA. It must also contain the information that the NRA requires, be signed by an approved person, be accompanied by the prescribed fee and be lodged with the NRA.

Subsection (2) allows the NRA to alter the application, provided it has the written consent of the approved person.

Subsection (3) allows the applicant to withdraw the application at any time after it has been made but before it has been determined, by giving appropriate, written advice to the NRA, signed by the approved person.

Subsection (4) provides that the NRA must grant the renewal application by 30 June each year, if it was properly made in time. If the renewal application is an accepted late application, however, the NRA must grant the application within one month of it being properly made. The NRA must give written notice to an approved person that the renewal has been effected and state the period of the renewal.

Subsection (5) allows the NRA to refuse to renew the listed registration of a chemical product, if any amount of money, fee, tax or penalty, payable to the NRA in respect of that particular product has not been paid by the applicant or any other person.

Subsection (6) provides that if an application for renewal of listed registration is properly made in accordance with subsection 56ZN(2), and the NRA does not renew that listed registration before 30 June in any year, then the listed registration remains in force until either the NRA grants the late application or the NRA give notice to the applicant of its decision to refuse the application for non-payment of any fee or other money as mentioned in subsection (5).

Subsection (7) provides that, if the NRA accepts a late application for a listed registration under subsection 56ZN(3), and it decides to renew that listed registration, then the listed registration does not end on 30 June that year but continues in force until that late application is granted.

Clause 56ZN - Renewal of listed registration of chemical product

This clause provides that the renewal of the listed registration of a chemical product is granted by entering in the Register of Chemical Products a statement that the listed registration has been renewed and the date on which the renewed listed registration ends. The renewal takes effect at the beginning of the next day after the previous listed registration ended.

Division 9 Publication of notices and certain other instruments by NRA

This Division requires the NRA to publish notices of listed registrations, variations of listed registrations, the ending of listed registrations, the suspension or cancellation of listed registrations, the revocation of the suspension or cancellation of listed registrations and the variation of the established standard for a listable chemical product. The Division mostly mirrors Division 7 of Part 2 of the Agvet Code (sections **52** to **56**), which provides for the publication of similar notices for registered chemical products.

Clause 56ZO - Publication of notice of listed registration of chemical product

Subsection **(1)** requires the NRA to publish a notice of each listed registration of a chemical product that it grants, unless the NRA thinks it is unnecessary in the circumstances to publish such a notice.

Subsection **(2)** requires the notice is to be published in the *Gazette* or in any other manner that the NRA thinks appropriate. It must state that the product has been granted listed registration, the date of the listed registration. Additionally by subsection **(3)**, the notice must also contain a brief statement of the conditions of the listed registrations that directly regulate the use of the product.

Clause 56ZP - Publication of notice of variations of listed registration of chemical product

Subsection **(1)** requires the NRA, when it varies the relevant particulars (*refer section 3 Definitions*) or any of the conditions of a listed registration of a chemical product, to publish a notice of that variation as soon as practicable, unless the NRA thinks it is unnecessary in the circumstances to publish such a notice.

Subsection **(2)** provides that the notice must be published in the *Gazette* or in any other manner that the NRA thinks appropriate. It must state that the relevant particulars or the conditions of a listed registration of a chemical product have been varied, the date of the variation, and contain a brief statement of the nature of, and reasons for, the variation.

Clause 56ZQ - Publication of notice of end of listed registration of chemical product

This clause closely mirrors section **54** (as amended) of the Agvet Code.

As discussed under in section **45A**, it is reasonable in risk management terms, to provide for appropriate possession, custody, use or otherwise dealing with chemicals whose registration has ended, where they can be used safely to exhaust existing stocks and avoid the potential of subsequent effects arising from long term storage.

Specifically, subsection **56ZS(1)** provides that the NRA must publish a notice in the *Gazette* of the end of listed registration of any chemical product. The notice must contain:

a statement that the listed registration has ended (paragraph **56ZS(1)(a)**);

instructions for possessing, having custody of, using or otherwise dealing with the product (paragraph **56ZS(1)(b)**);

a warning of the consequence if a person fails to comply with the instruction (paragraph **56ZS(1)(c)**). Such warnings must include a statement of the consequences if a person fails to comply with the instructions, and a statement advising the period after which an offence against the Agvet Code arises;

any other warning or explanations in relation to the product that the NRA thinks desirable (paragraph **56ZS(1)(d)**);

Setting out the date on which the listed registration ends; (paragraph **56ZS(1)(e)**); and

Containing any other information that the NRA thinks appropriate (paragraph **56ZS(1)(f)**).

Subsection (2) provides that if, after publication of a notice stating that listed registration of a chemical product has ended, a person possesses, has custody of, uses or otherwise deals with the product in accordance with the instructions in the notice, then that person is taken to have been issued with a permit to so possess, have custody of, use or otherwise deal with the product in accordance with those instructions for 2 years (after the day on which listed registration ends); or the NRA publishes a notice in the *Gazette* declaring that this provision ceases to apply to the product.

Subsection (3) provides that, subject to subsection (5), if the NRA has published a notice under subsection (1) stating that the listed registration of a chemical product has ended, and a person has possession or custody with the intention of supply, then that person may only possess, have custody of, or otherwise deal with that product if the possession, custody or dealing is in accordance with the instructions contained in the notice. The penalty for an individual convicted of an offence against this subsection is 300 penalty units.

Subsection (4) provides that, in paragraph (3)(a), strict liability applies to the physical element of circumstance that the person knows that the publishing of the notice was under this section.

Subsection (5) provides that the offence provision of subsection (3) does not apply to any possession, custody, or other dealing with the chemical product by a person if, when the possession, custody, or other dealing with took place the product was a registered product, a registered listed chemical product, or a reserved chemical product because of its having been registered or granted listed registration, or having become reserved after its previous registration had ended.

Subsection (6) provides that, if the NRA publishes a notice under subsection (1) stating that the listed registration of a chemical product has ended, then the NRA must cause a copy of the notice to be given any person who, in the opinion of the NRA, should be given notice. The latter part of the provision ensures that the NRA must give a copy of the notice to major user groups.

Clause 56ZR - Publication of notice of suspension or cancellation of listed registration

This clause closely mirrors section 55 of the Agvet Code (as amended). As noted in section 45A, it is reasonable in risk management terms, to provide for appropriate possession, custody, use or otherwise dealing with chemicals whose registration has been suspended or cancelled, where they can be used safely to exhaust existing stocks and avoid the potential of subsequent effects arising from long term storage.

Subsection (1) provides that, if the NRA suspends or cancels the listed registration of a chemical product, it must publish in the *Gazette* (and in any other manner that it thinks appropriate) a notice of the suspension or cancellation containing any information that it thinks relevant.

Subsection (2) provides if the reason(s) for the suspension or cancellation was that the continued use of the product might not meet the standard assessment criteria; i.e. that the product might be an undue occupational health or safety hazard and residue hazard (subsection (2)(a)), might be likely to have a harmful effect to humans (subsection (2)(b)), might be likely to harm target animals/plants or the environment (subsection (2)(c)), or might not be effective (subsection (2)(d)), the notice issued under subsection (2)(1) must contain:

a statement to that effect (subsection (2)(e));

instructions for possessing, having custody of, using or otherwise dealing with the product (subsection (2)(f));

a warning of the consequences if a person fails to comply with the above instructions; including a statement as to when it will be an offence against the Agvet Code to possess or have custody of with the intention of supply, or supply the product (subsection (2)(g)); and

any other warnings or explanations in relation to the product that the NRA thinks desirable (subsection (2)(h)).

Subsection (3) provides that if, after publication under the section of a notice stating that listed registration of a chemical product has been suspended or cancelled, a person possesses, has custody of, uses or otherwise deals with the product in accordance with the instructions in the notice, then that person is taken to have been issued with a permit to so possess, have custody of, use or otherwise deal with the product in accordance with those instructions for 2 years (after the day on which listed registration was suspended or cancelled); or the NRA publishes a notice in the *Gazette* declaring that this provision ceases to apply to the product.

Subsection (4) provides that, subject to subsection (6), if the NRA has published a notice under subsection (1) stating that the listed registration of a chemical product has been suspended or cancelled, and a person has possession or custody with the intention of supplying the product, then that person may only possess, have custody of, or otherwise deal with that product if the possession, custody or dealing is in accordance with the instructions contained in the notice. The penalty for an individual convicted of an offence against this subsection is 300 penalty units.

Subsection (5) provides that, consistent with other offence provisions in the Agvet Code, strict liability applies to the physical element of circumstance that the person knows that the publishing of the notice was under this section.

Subsection (6) provides that the offence provision of subsection (4) does not apply to any possession, custody, or other dealing with the chemical product by a person if, when the possession, custody, or other dealing with took place the product was a registered product, a registered listed chemical product, or a reserved chemical product because of its having been registered or granted listed registration, or having become reserved after its previous registration had been cancelled.

Subsection (7) provides that, if the NRA publishes a notice under subsection (1) stating that the listed registration of a chemical product has been suspended or cancelled, then the NRA must cause a copy of the notice to be given any person who, in the opinion of the NRA, should be given notice. The latter part of the provision ensures that the NRA must give a copy of the notice, including the instructions and warnings, to major user groups.

Clause 56ZS - Notice of revocation of suspension or cancellation

This clause provides that if the NRA revokes the suspension or cancellation of the listed registration of a chemical product, then it must publish in the *Gazette* (and in any other manner that it thinks appropriate) a notice of the revocation containing any information that it thinks relevant.

Clause 56ZT - Publication of instrument varying established standard for listable chemical product

This clause provides that if, after publication in the *Gazette* of a notice of the variation of the established standard for a listable chemical product, a person possesses, has custody of, uses or otherwise deals with any part of stock of the product that complies with the standard that was established for the product immediately before the variation, then that person is taken to have been issued with a permit to so possess, have custody of, use or otherwise deal with that part of the stock of the product in accordance with the instructions contained in the standards as in force immediately before the variation for 2 years after the day of publication of the notice of variation; or the NRA publishes a notice in the *Gazette* declaring that this provision ceases to apply to the product.

Part 2B Reserved chemical products

Part 2B provides for an even more simplistic system of approval of a chemical product than listing under Part 2A above. This Part provides that an agricultural or veterinary chemical product may be merely reserved by being specified on a schedule to the Agvet Code Regulations (with certain

conditions), provided the Minister has accepted a written explanation from the NRA that it is satisfied that the use of the product in accordance with those conditions would not be a hazard.

The effect will almost be to exclude such products from any form of regulation or control although, if they were declared not to be an Agvet chemical product as provided for in the Agvet Code Regulations and thus completely excluded from the operation of the Agvet Code, they would fall within the ambit of the *Industrial Chemicals (Notification and Assessment) Act 1989*.

It is envisaged that reserved chemical products under Part 2B would apply only to products such as agricultural lime (calcium oxide) when used as a fungicide.

Reserved chemical products are however, by these amendments, excluded from the main offence provisions of Part 4 (Control of chemical products), Division 2 (Control generally) of the Agvet Code, so that it will not be an offence to have possession or custody of with intent to supply, or to supply, a reserved chemical product.

Clause 56ZU - Regulations may contain schedule of reserved chemical products

Subsections (1) and (2) provide that the regulations may contain a schedule specifying chemical products (or classes of chemical products) that are reserved chemical products for the purposes of the Agvet Code. Restricted chemical products, which are known to be relatively hazardous and are only available for supply to, or use by, persons having specialised knowledge or skill, are not eligible to be declared reserved chemical products.

Subsection (3) provides that the regulations containing a schedule of reserved chemical products must state the conditions imposed on the possession, custody of, use of, or other dealing with, each of the products (or each class of products).

Subsection (4) provides that before regulations are made specifying a reserved chemical product, the reservation must have been recommended to the Minister by the NRA. Further, the NRA, in making the recommendation, must have given to the Minister written particulars of the product (subparagraph (4)(b)(i)) and a draft of the conditions proposed by the NRA (subparagraph (4)(b)(ii)).

Subsection (4)(c) also requires the NRA to provide a written explanation to the Minister as to why the NRA is satisfied that use of the product, in accordance with the proposed conditions, would meet the standard assessment criteria i.e. that the product would not be an undue occupational health or safety hazard and residue hazard (subparagraph 4(c)(i)), would not be likely to have a harmful effect to humans (subparagraph 4(c)(ii)), would not be likely to harm target animals/plants or the environment (subparagraph 4(c)(iii)), would not unduly prejudice trade or commerce (subparagraph 4(c)(iv)) and would be effective (subparagraph 4(c)(v)).

Additionally, subsection 4(d) provides that the NRA must have given to the Minister a written statement identifying consultations held by, and the advice given to, the NRA in relation to the proposed reservation of each chemical product.

Agvet Code Part 3 - Compensation for provider of certain information in respect of continued registration of certain chemical products

Clause 107 - The Schedule (subsection 59(1))

107 This clause omits the reference to subsection (2) and replaces it with a reference to subsections (1A) and (2).

Clause 108 - The Schedule (after subsection 59(1))

108.1 Section 59 of the Agvet Code provides for the right of compensation to the originator of *protected information* (refer *Definitions Section 3*) if the NRA is required to use that protected information in determining other applications. Unless an agreement on compensation is reached by

the relevant two applicants, the NRA must not use protected information given to it in relation to an active constituent or a chemical product in determining whether to approve or register or to continue the approval or registration of another active constituent or chemical product.

108.2 Subsection **1(A)**, provides that subsection **(1)** does not apply if the information in question is the same information as previously given to the NRA, otherwise than in compliance with a requirement referred to in subsection **(1)**.

Part 4 - Control of Chemical Products

Clause 109 - The Schedule (paragraph 72(2)(c))

109.1 Section **72** is the explanatory part of the Agvet Code for Division 1 Part 4 - Control of chemical products. This part regulates the supply of active constituents for chemical products and the supply of chemical products by, for example, prohibiting the possession for supply purposes of unapproved constituents and unregistered products.

109.2 Paragraph **(2)(c)** is repealed and substituted so as to include reference to registered listed products and reserved products. This amendment ensures that the NRA is able to restrict the supply of an extended range of chemical products, including both registered listed chemical products or products which are reserved following the inclusion of Parts 2A and 2B in the Agvet Code.

Clause 110 - The Schedule (subsections 75(1) and (3))

110.1 The heading to section **75** is replaced and substituted with a new heading Possession or custody of chemical products with the intention of supply other than registered, registered listed or reserved products. Though not part of the Agvet Code, this amended heading assists in the better understanding of the division and ensures that the newly proposed registered listed chemicals and reserved chemicals are captured in the intent of the section.

110.2 This clause also amends subsection **(1)** and **(3)** by inserting a reference to a registered listed chemical product or a reserved chemical product. This amendment ensures that, in line with the inclusion of Parts 2A and 2B, the integrity of the Agvet Code is maintained as a person must not have possession of or custody of, with intent to supply, a chemical product that is not registered chemical products, a registered listed chemical product or a reserved chemical product unless authorised.

Clause 111 - The Schedule (subsection 78(1))

111.1 The heading to section **78** is replaced and substituted with a new heading Supply of chemical products that are not registered products, registered listed products or reserved products. Though not part of the Agvet Code, the amended heading assists in the recognition of the structure within the Agvet Code by referencing chemical products, registered products, registered listed products and reserved products.

111.2 This clause inserts reference to a registered listed chemical product or a reserved chemical product in to subsection **(1)**. This amendment ensures that, in line with the inclusion of Parts 2A and 2B, the integrity of the Agvet Code is maintained as a person must not supply, or permit to be supplied, a chemical product that is not registered chemical products, a registered listed chemical product or a reserved chemical product unless authorised.

Clause 112 - The Schedule (subparagraphs 78(1)(c)(i) to (iii))

112.1 This clause repeals and substitutes subparagraphs **(1)(c)(i)** to **(iii)**, for the purpose of clarification and as a consequential effect of the introduction of Part 2A (Registered Listed Products) and Parts 2B (Reserved Chemical Products) by adding references to registered listed products and reserved products, to each of the subparagraphs.

112.2 The effect of paragraph **78(1)(c)** is to have an exception to the general offence of subsection **78(1)** that a person must not supply a chemical product that is not registered, listed or reserved. The exception must meet all the requirements of the subparagraphs **(i)** to **(vi)** the first three of which require that when the relevant supply of the chemical product took place (that would, but for this paragraph, be an offence against this section) the product had at some previous time been registered, granted listed registration, or had been reserved; and the relevant supply was made within a period of time (usually two years), determined by the NRA in relation to the product, after that registration, listed registration or reserved registration actually ceased; and the supply was part of a stock of product that came into the persons possession before that registration, listed registration or reserved registration ceased.

112.3 The overall effect is that a person does not commit an offence of supplying unregistered or unlisted or unreserved chemical product, if the product supplied was previously registered or listed or reserved, and the supply was part of a stock of product that came into the persons possession before registration ceased, and the supply was within the period after registration did cease that was determined by the NRA.

Clause 113 - The Schedule (subparagraph 78(1)(c)(vi))

113.1 This clause amends subsection **(1)(c)(vi)** as a consequential effect of the introduction of Part 2A (Registered Listed Products) and Parts 2B (Reserved Chemical Products) by adding a reference to listed registration in subsection **(1)(c)(vi)**.

113.2 As noted in the clause above, the effect of paragraph **78(1)(c)** is to have an exception to the general offence of subsection **78(1)** that a person must not supply a chemical product that is not registered, listed or reserved. The exception must meet all the requirements of subparagraphs **(i)** to **(vi)** inclusive. Subparagraph **(vi)** provides that any such supply must be in accordance with any conditions imposed on the registration or listed registration.

Clause 114 - The Schedule (at the end of subsection 78(3))

114.1 It is a defence to a prosecution for the commission of an offence against subsection **78(1)** - that a person must not supply a chemical product that is not registered, listed or reserved - that the person did not know and could not reasonably be expected to know that the product was not a registered chemical product when the chemical product was supplied. This defence to a prosecution for the commission of an offence is extended to include reference to a registered listed chemical product or a reserved chemical product.

Clause 115 - The Schedule (after section 79)

115.1 Two new section relating to the offence of supplying registered listed chemical products (section **79A**) and reserved chemical products (section **79B**) are inserted. Both new clauses mirror the existing section **79** provisions for registered chemical products.

115.2 The new section **79A** provides that a registered listed chemical product may only be supplied in accordance with the conditions, if any, which are attached to the listed registration or where the supply is authorised by a permit. A breach of this section incurs a penalty of 300 penalty units.

115.3 The new section **79B** provides that the supply of reserved chemical products contrary to conditions specified in the regulations is an offence. The supply of such chemical products may occur only in compliance with regulations made for the purpose of section **56ZW** (which provides that the regulations may contain a schedule specifying chemical products - or class of chemical products - that are reserved chemical products. The regulations must state the conditions attached to the possession of, custody of, use of, or other dealing with reserved chemical products); or if the supply is authorised by a permit.

115.4 There is a penalty of 300 penalty units for a breach of this section. The offence of strict liability will apply to the physical element of circumstance that the conditions relating to the chemical product were specified in regulations made for section **56ZW**.

Clause 116 - The Schedule (subsection 80(1))

116.1 The intent of sections **80** and **81** were not fully achieved in the original Agvet Code in 1994. It had been intended to make it an offence (under section **80**) to supply a chemical product without a label. However, section **80** was enacted with a reference to approved label. Section 81 makes it an offence to supply a chemical product with a label that is not the approved label. The inclusion of the word approved in section **80** was unnecessary and made the intent of the section unclear. This amendment restores the original intention and is a technical adjustment only.

116.2 Section **80** as amended, clarifies that it is now an offence to supply a chemical product without a label.

116.3 The heading of section **80** is replaced by the heading Supply of chemical products without a label.

Clause 117 - The Schedule (subsection 80(2))

117 In line with the intention of the amendment to section **80**, the reference to an approved label will be omitted and replaced with a label in subsection **80(2)**. It will be a defence to an offence against subsection (1) if the person did not know, and could not reasonably be expected to have known, that the container did not have a label attached to it.

Clause 118 - The Schedule (subsection 81(1) excluding the penalty)

118.1 The supply of a registered chemical product in a container may only occur when the label on the container is identical in all material respects (except for batch number, date of manufacture and expiry date) to the approved label or in circumstances when the supply is authorised by a permit. A breach of this provision will carry a penalty of 300 penalty units.

118.2 The heading of this section will be replaced by the heading Supply of registered chemical products with unapproved label.

Clause 119 - The Schedule (at the end of section 81)

119 At the end of this section, a new subsection (**3**) will be added which provides an additional exemption to the provisions of subsection (1) that prohibits the supply of a registered chemical product in a container with an unapproved label. The new exemption is, if the label attached to the container is identical in all material respects to an earlier label that was approved; and the NRA decides that the provisions of this subsection are to apply to the earlier approved label; and the supply takes place not later than 2 years, or such time that the NRA allows, after the earlier approved label ceased to be approved.

Clause 120 - The Schedule (after section 83)

120.1 This clause inserts a new provision (section **83A**) which mirrors section 83 relating to the control of the supply of a substance (or mixture of substances) in a container having a label containing the name of a registered chemical product whose constituents differ from the constituents of a registered chemical product. The new section **83A** contains the same provision in relation to registered listed chemical products.

120.2 The supply of such a substance (or mixture) must not take place if the constituents of the substance (or mixture) differ by more than the prescribed extent from the constituents of the registered listed chemical product listed in the Register of Chemical Products (paragraph **(a)**); or the concentration of the constituents of the substance (or mixture) differ by more than the prescribed

extent from the concentration of the constituent of the registered listed chemical product shown in the particulars in the Register (paragraph **(b)**); or the purity or composition of any constituent of the substance (or mixture) differs by more than the prescribed extent from the composition or purity of the corresponding constituent of the registered listed chemical product shown in the Register (paragraph **(3)**). A breach of this provision carries a penalty of 300 penalty units.

Clause 121 - The Schedule (subsection 84(1))

121.1 Section **84** generally prohibits a person making, or attempting to make, a claim in relation to a chemical product that is inconsistent with the approved label for containers for that product.

121.2 This clause inserts a reference to registered listed chemical product after registered chemical product to ensure the provision also applies to registered listed chemical products established under Part 2A.

Clause 122 - The Schedule (at the end of subsection 84(1))

122 This clause extends the protection of section 84 to a claim that is inconsistent with any instruction required by an established standard for the registered listed chemical product to be on a label for that registered listed chemical product.

Clause 123 - The Schedule (subsection 86(1))

123 This clause extends the prohibition on a person detaching, removing, altering or destroying any matter on the approved label attached to a container of a chemical product, to the detaching, removing, altering or destroying of any matter required by an established standard for a registered listed chemical product (the product in this section) to be included on a label for a registered listed chemical product.

Clause 124 - The Schedule (subsection 87(1))

124 Listable chemical products will be excluded from the provisions of this section that prevents registered chemical products from being supplied except in accordance with any standard prescribed for the product or the constituents of the product. Standards for listable chemical products are provided for in Division 3 of new Part 2A.

Clause 125 - The Schedule (after section 87)

125 This clause inserts new section 87A to prohibit the supply of registered listed chemical product that do not conform to established standards. The supply of a registered listed chemical product is not permitted unless the product conforms to the established standard or the supply is authorised by permit.

Clause 126 - The Schedule (subsection 88(1))

126.1 Subsection **88(2)** prohibits the publication of notices offering to sell or inviting offers to buy chemical products that are not registered chemical products unless an application has been made to the NRA for registration of the chemical product and the notice states that the product is not registered and such an application has been made. Subsection **88(3)** provides a defence that when the notice was published the defendant did not know, and could not reasonably be expected to have known, that the product was not a registered chemical product.

126.2 The inclusion of the definition of chemical product expands the prohibition, and the defence in section 88, to include registered listed chemical products but not reserved chemical products.

126.3 This clause inserts in this section only a definition of chemical product to confirm that chemical product does not include a reserved chemical product.

Clause 127 - The Schedule (paragraph 88(2)(b))

127 Consistent with the intent of the amendment to subsection **88(2)**, this clause omits not a registered chemical product and substitutes neither a registered chemical product nor a registered listed chemical product.

Clause 128 - The Schedule (paragraph 88(2)(c))

128 Consistent with the intent of the amendment to subsection **88(2)**, this clause inserts or listed registration after registration.

Clause 129 - The Schedule (subparagraph 88(2)(d)(i))

129 Consistent with the intent of the amendment to subsection **88(2)**, this clause omits not a registered chemical product and substitutes neither a registered chemical product nor a registered listed chemical product.

Clause 130 - The Schedule (at the end of paragraph 88(3)(b))

130 Consistent with the intent of the amendment to the defence in subsection **88(3)**, this clause omits not a registered chemical product and substitutes neither a registered chemical product nor a registered listed chemical product.

Clause 131 - The Schedule (before section 90)

131 This clause inserts a new section 89A, which provides that Division 3 relating to date controlled chemical products does not apply to either a chemical product that is a listable chemical product nor is a reserved chemical product.

Agvet Code Part 5 - Analysis

Part 5 of the Agvet Code establishes the procedures by which samples or substances are to be analysed and how the evidence of the results of the analysis may be used under the terms of the Agvet Code. The intent is that Part 5 will also apply to registered listed chemical products.

Clause 132 The Schedule - (paragraph 97(4)(b))

132.1 Section 97 provides that if the NRA obtains an analysis of a chemical substance it must be given a certificate of analysis. Upon payment of the prescribed fee, the NRA must give a copy of the certificate of analysis to the owner of the substance analysed or to an applicant for approval or registration of that substance as an active constituent or chemical product.

132.2 This amendment extends the obligation to give a copy of the certificate of analysis to an applicant for a listed registration of that substance as a registered listed chemical product. This clause inserts or listed registration after registration.

Clause 133 - The Schedule (subsection 99(2))

133.1 Section **99** provides for circumstances whereby a person, in possession of a substance (or mixture of substances) that is intended for supply as a registered chemical product under a particular name, may be required by the NRA to obtain an analysis of the substance (or mixture).

133.2 This clause provides that the provisions of section **99** also apply to a registered listed chemical product.

Clause 134 - The Schedule (subsection 99(3))

134.1 Subsection **99(3)** provides that the NRA, following the advice of an inspector, may require a person to have the substance or mixture analysed to find out whether it complies with any prescribed

standard or other prescribed requirement, in circumstances where it is suspected that the mixture or substance does not comply with any prescribed standards. A prescribed standard applies in respect of registered chemical products (refer section **87**).

134.2 This clause inserts established standard after prescribed standard. An established standard applies in respect of registered listed chemical products (new section **56C**). The addition therefore, expands the provision of the section to registered listed chemical products established by new Part 2A.

Agvet Code Part 6 - Recall Notices

Clause 135 - The Schedule (subsection 101(1))

135.1 Section **101** enables the NRA to give a written notice to any person (the notified person) requiring the person to stop supplying or to recall chemical products that are unregistered or under reconsideration under Division 4 of Part 2, or to destroy or otherwise deal with unregistered chemical products.

135.2 Subsection **101(1)** is repealed and substituted by these amendments which extend the provisions of this subsection to unregistered listed chemical products or chemical products for which the listed registration is under reconsideration under new Division 6 of Part 2A. Note: It is not the intent that reserved chemical products are captured by this clause.

135.3 The heading to section **101** is changed to Recall of products that are not registered and do not have listed registration or whose registration or listed registration is being reconsidered.

Clause 136 - The Schedule (paragraph 101(2)(c))

136 This clause inserts and has not been granted listed registration after the word registered. This ensures that products which are not yet granted listed registration are destroyed (or dealt with) in accordance with the notice issued by the NRA under subsection 101(1).

Clause 137 - The Schedule (paragraph 102(1)(a))

137.1 Section **102** provides that, if it appears to the NRA that the continued use of a registered chemical product in accordance with the instructions on an approved label for containers for the product, may not satisfy the basic criteria for the registration of chemical products set out in section **14** or certain other matters, then the NRA may issue a written notice to any person who has, or had, possession or custody of stocks of the product to stop supplying the products, or to recall them, to destroy or otherwise deal with them, or to take other action as stated in the notice to prevent or reduce any harmful effects that may result from the use of the product.

137.2 These amendments extend the provisions of this section to registered listed chemical products.

137.3 This clause inserts a provision so that if it appears to the NRA that, having regard to the matters in subsection **56D(2)**, the continued use of a registered listed chemical product in accordance with the established standard for the product, may no longer satisfy the basic criteria of subsection **56D(1)** - that the NRA must take into account in preparing a standard for a listable chemical product - then the NRA may issue the written notice of recall in accordance with the provision of the section.

Clause 138 - The Schedule (paragraph 102(1)(b))

138.1 Paragraph **102(1)(b)** provides that if the constituents of stocks or a particular batch of a registered chemical product differ by more than the prescribed extent as stated in the Register of Chemical Products, then the NRA may also issue a recall notice under the provisions of section 102.

138.2 This clause inserts new paragraph (ba) which provides that if the constituents of stocks or a particular batch or a registered listed chemical product differ by more than the prescribed extent as

stated in the Register of Chemical Products, then the NRA may also issue a recall notice under the provisions of section 102.

Clause 139 - The Schedule (after paragraph 102(1)(c))

139.1 Paragraph **102(1)(c)** provides that if the concentration of the constituents of stocks or a particular batch of a registered chemical product differ by more than the prescribed extent as stated in the Register of Chemical Products, then the NRA may also issue a recall notice under the provisions of section **102**. (refer also Clauses 137 - 138 & 140)

139.2 This clause inserts new paragraph **(ca)** which provides that if the concentration of the constituents of stocks or a particular batch or a registered listed chemical product differ by more than the prescribed extent as stated in the Register of Chemical Products, then the NRA may also issue a recall notice under the provisions of section **102**.

Clause 140 - The Schedule (paragraph 102(1)(d))

140.1 Paragraph **102(1)(d)** provides that if the composition or purity of any constituent of stocks or a particular batch of a registered chemical product differ by more than the prescribed extent as stated in the Register of Chemical Products, then the NRA may also issue a recall notice under the provisions of section **102**. (refer also Clauses 137-139)

140.2 This clause inserts new paragraph **(e)** which provides that if the composition or purity of any constituent of stocks or a particular batch or a registered listed chemical product differ by more than the prescribed extent as stated in the Register of Chemical Products, then the NRA may also issue a recall notice under the provisions of section **102**.

Clause 141 The Schedule - subsection 103(1)

141.1 Section **103** provides that, if it appears to the NRA that the labels attached to the containers of stocks or a particular batch of a registered chemical product differ from the approved label for the product, then the NRA may issue a written notice to any person who has or had possession or custody of the stocks of the product to stop supplying the offending stocks of the products, or to recall them, or to destroy or otherwise deal with them, or to attach labels to the containers that are the same as the approved label.

141.2 These amendments extend the provisions of this section to registered listed chemical products.

141.3 Subsection **103(1)** is repealed and substituted to additionally provide that if it appears to the NRA that the labels attached to containers of stocks or a particular batch of a registered listed chemical product differ from the label required by the relevant standard for the product, then the NRA may give written notice of recall in accordance with the provision of the section.

141.4 The heading to this section is repealed and replaced with the following heading which states that the Recall of products with labels that are not approved or are not authorised by an established standard.

Clause 142 - The Schedule (paragraph 103(2))

142 These amendments extend the provisions of this subsection to registered listed chemical products by inserting in paragraph **103(2)(c)** relating to attaching labels to containers that are the same as the approved label, the words or the label required by the established standard for the product, as the case may be after the word file.

Part 7 - Permits

This Part provides for a system under which a person, who wants to do something in respect of an active constituent or chemical product that would otherwise be prohibited by certain provisions of the

Agvet Code or State control-of-use laws, may obtain a permit from the NRA authorising the person to do that thing.

Clause 143 - The Schedule (subsections 108(2) and (3))

143.1 Section **108** is an explanation of Part 7 and the circumstances in which permits may be required and sought.

143.2 Subsections **(2)** and **(3)** are repealed and substituted by new subsection **108(2)** which also takes account of registered listed chemical products or reserved chemical products established by Parts 2A and 2B. Additionally, one of the examples of the circumstances (old subsection **108(3)(a)**) in which a permit could previously have been sought has been removed, as in fact a permit could not be obtained in those particular circumstances.

Clause 144 - The Schedule (section 109, paragraph (a) of the definition of permit)

144. Paragraph (a) of the definition of permit is repealed and substituted. The new paragraph extends the circumstances in which a permit may be issued to also include the offence provisions of sections **79A**, **79B** and **87A** which have been added to take account of the provisions of Parts 2A and 2B establishing registered listed chemical products and reserved chemical products.

Clause 145 - The Schedule (paragraph 111(1)(b))

145.1 Section **111** of the Agvet Code specifies the functions of State co-ordinators in relation to the issue of permits under Part 7. The NRA must, unless it thinks it inappropriate to do so, give the co-ordinator a copy of the application and of any accompanying documents received by it.

145.2 In this co-operative scheme for Agvet chemicals the intention of the legislative scheme, which includes the complementary Acts of the States was to rationalise administrative law matters, that is, even though the Agvet Code operated as State law in each of the States, Commonwealth administrative law provisions would apply to decisions made under the State Agvet Code. It is considered that the provisions of subsection **111(1)(b)** could result in administrative problems as conduct or decisions taken by co-ordinators would not be decisions of Commonwealth officers and authorities. A co-ordinator is not an officer of the Commonwealth. Should an applicant challenge the decision of a co-ordinator made under the provision of section **111** on the grounds that the decision had not been made properly then, contrary to Commonwealth policy on judicial review in cooperative schemes, an applicant would have to proceed under common law, or State statute where it exists, to a state Supreme Court.

145.3 This proposed amendment ensures that in circumstances where the NRA has given a copy of the application and any accompanying documents to the co-ordinator and the co-ordinator requires additional information, the NRA must request the information from the applicant and give the information to the co-ordinator as soon as practicable after receipt. The NRA may refuse the request from the co-ordinator for this additional information if the NRA has reasonable grounds for refusing. The co-ordinator will not be permitted to seek the information directly from the applicant. A request for information must go through the NRA, which may request the information.

Clause 146 - The Schedule (subsection 112(2)(b))

146 In line with the amendment to paragraph **111(1)(b)** [clause 145 above], this clause amends paragraph **112(2)(b)** to add that any requirement made by a co-ordinator has to be made to the NRA.

Clause 147 - The Schedule (paragraph 112(2)(i))

147.1 In circumstances where an application for a permit is made in relation to an active constituent for which an application has not been made or determined, or chemical product for which an application has not been made or determined, then the NRA can only grant the permit application if it

is satisfied that there are reasonable grounds for the active constituent or product application not having been made or for issuing a permit pending determination of the application.

147.2 This amendment adds the circumstance where an application for a permit is made in relation to a chemical product that has not been granted listed registration.

Agvet Code Part 8 - Manufacture of chemical products

Clause 148 - The Schedule (after section 120)

148 This clause inserts a new section **120A**. The new section ensures that Part 8 does not apply to chemical products that are listable chemical products or are reserved chemical products.

Clause 149 - The Schedule (at the end of subsection 122(1)(d))

149 Section **122** provides for the method by which an application for a licence is to be made, stipulating, amongst other requirements, that the application must be in writing in or to the effect of the approved form, signed by an approved person and accompanied by the appropriate fee. This new subsection (e) provides that the form must be lodged with the NRA. This removes any ambiguity as to where the appropriate application should be lodged.

Clause 150 - The Schedule (subsection 122(2))

150.1 The manufacture of certain chemical products is prohibited unless the manufacturer of those chemical products has been issued with a licence by the NRA. The NRA may require further information in relation to an application for a licence.

150.2 In line with the intent that the NRA is empowered to deal with persons other than an applicant in certain circumstances, subsection **122(2)** is amended to allow the NRA to issue a written notice seeking further information to an approved person (*refer Definitions section 3*).

Clause 151 - The Schedule (paragraph 124(1)(a))

151 In line with the intent that the NRA is empowered to deal with persons other than an applicant in certain circumstances, paragraph **124(1)(a)** is amended to allow the NRA to issue a written notice of the refusal of an application for a licence to an approved person (*refer Definitions section 3*).

Clause 152 - The Schedule (subsection 127(1))

152 In line with the intent that the NRA is empowered to deal with persons other than an holder of a licence in certain circumstances, subsection **127(1)** is amended to allow the NRA to issue a written notice of the suspension or cancellation of a licence to an approved person (*refer Definitions section 3*).

Clause 153 - The Schedule (paragraph 127(2)(a))

153 In line with the intent that the NRA is empowered to deal with persons other than an holder of a licence in certain circumstances, paragraph **127(2)(a)** is amended to allow the NRA to issue a written notice of the NRAs proposal to suspend or cancel a licence to an approved person (*refer Definitions section 3*).

Agvet Code Part 9 - Enforcement

Clause 154 - The Schedule (section 145)

154.1 The offence of providing false information to the NRA in section 145 of the Agvet Code previously incurred a fine of 30 penalty units. This was considered to be too low a penalty for the

gravity of the offence. This clause amends the penalty unit for that offence and distinguishes the gravity of certain offences of providing false information to the NRA.

154.2 New subsection **145(1)** provides for particular offences to which the maximum penalty of 300 penalty units attaches (subsection **145(2)**). A person who gives information, orally or in writing, knowing the information to be false or misleading in a material fact, or produces a document knowing it to be false or misleading, to the NRA when it is considering matters relating to:

- subsections **14(4)**, **(5)** or **(6)** providing for the grant or refusal of an application; or
- subsection **56K(1)** being an application in relation to listable chemical products; or
- paragraph **123(1)(a)** providing for the issue of a licence, and

does not disclose that the information or document is false, is guilty of an offence.

154.3 New subsection **145(3)** provide for a second range of offences to which a lower penalty of up to 60 penalty units attaches (new subsection **145(4)**). It is intended that this second range of offences will be all offences against the Agvet Code other than those identified in subsection (1).

Clause 155 - The Schedule (subsection 149(1))

155.1 Section **149** provides that the NRA may provide a certificate that states certain matters. The matters that can be stated broadly relate to details held in the Records and Registers kept by the NRA or other matters within the exclusive knowledge of the NRA. A matter stated in a certificate under section **149** is evidence of that matter for purposes relating to a court, tribunal or an authority having power to require production of documents or answer questions.

155.2 As previously constructed, the operation of section **149** was limited to providing certificates for the purposes of the Agvet Code only. The intention of the new provision is to facilitate the NRA in assisting the States in their control-of-use functions, by overcoming the previous limitations in section **149**. In addition to the provision of evidentiary certificates for the purposes of the Agvet Code, this amendment enables the NRA to provide evidentiary certificates for the purpose of State eligible law.

155.3 Offences directly punishable by imprisonment are excluded from the matters that can be stated in an evidentiary certificate.

Clause 156 - The Schedule (paragraph 149(3)(b))

156.1 Subsection **149(3)** identifies those matters that may be included in an evidentiary certificate. Such matters include, but are not limited to, whether or not, at a particular time, a chemical product referred to in the evidentiary certificate was a registered chemical product (paragraph **(b)**); that a label referred to in the evidentiary certificate was or was not, at a particular time, an approved label (paragraph **(c)**); or that matter appearing on an approved label or in a permit referred to in the evidentiary certificate is identical to matter set out in the certificate (paragraph **(g)**).

156.2 Paragraph **149(3)(b)** ensures that as well as registered chemical products, registered listed chemical products are also included as matters for which the NRA may issue evidentiary certificates.

Clause 157 - The Schedule (at the end of paragraph 149(3)(c))

157 In line with the intent of subsection **149(3)**, this clause ensures that as well as approved labels for registered chemical products, labels required by an established standard for a registered listed chemical product are also included as matters for which the NRA may issue evidentiary certificates.

Clause 158 - The Schedule (paragraph 149(3)(g))

158 In line with the intent of subsection **149(3)**, this clause ensures that as well as matters appearing on an approved label for registered chemical products, matters appearing on a label required by an established standard for a registered listed chemical product are also included as matters for which the NRA may issue evidentiary certificates.

Clause 159 - The Schedule (subsection 152(2))

159 In subsection **152(2)** dealing with the liability of persons acting on behalf of non-residents the words or listed registration are inserted after registration wherever occurring.

Agvet Code Part 10 - Miscellaneous

Clause 160 - The Schedule (subsection 159(1))

160.1 Section **159** is a commonly used provision that underpins the NRAs ability to acquire additional information beyond that which was supplied with the initial application in respect of applications for active constituents, chemical products and labels. This provision is extremely important to the NRA, as without an express provision such as section 159, the NRA would be severely constrained in making any request other than an initial request for deficient information. The provision allows the NRA to raise genuine questions about an application and, indeed, to have a chain of further queries flowing on from responses and data submitted in response to earlier requests for additional material. Currently, section 159 provisions do not fully cover all of the NRAs needs.

160.2 The heading of this section is replaced by a new heading that states that the NRA or other authority may require, or require additional, information, report or sample in certain circumstances.

160.3 This clause repeals the words and paragraphs before paragraph (e) and substitutes them to provide for a clearer and more precise separation of the situations in which the NRA, or any other prescribed authority, may request additional information.

Specifically, this clause:

structurally and more clearly separates an application for approval of a label from an application for registration for registration of a chemical product;

provides for the making of an application for a permit for an active constituent or chemical product;

additionally provides for the listed registration of a chemical product in relation to the reconsideration of an approval for an active constituent, the registration of a chemical product, or the approval of a label;

expands the existing provision in relation to a decision whether to suspend or cancel a permit (in respect of an active constituent or a chemical product) to also include a decision whether to suspend or cancel an approval of an active constituent, the registration of a chemical product, the approval of a label and the listed registration of a chemical product.

Clause 161 - The Schedule (paragraph 159(1)(g))

161 The words or further sample are omitted to accommodate the inclusion of subsection **159(1A)**.

Clause 162 - The Schedule (after subsection 159(1))

162.1 There is some confusion with section **159** in the use of the word further. The word appears in the section heading, which is not strictly part of legislation, but is not in the actual body of the legislation. Nonetheless, the word further is of significant assistance in the proper interpretation of the section. The intent of the section is that the NRA may make a request for further information in the sense of being information *additional* to any information provided with the original application.

162.2 This clause adds a new subsection (**1A**) which clarifies that the power of the NRA under subsection **159(1)** to require a person to give to the NRA a report or information or sample includes a power to require the person to give to the NRA such information, report or sample in addition to any information, report or sample previously given by the person to the NRA under any other provision of the Agvet Code other than this section.

162.3 It is essential to the operation of the application review procedures in the NRA that the NRA and other prescribed authorities have the facility to require a person to give to the NRA or another authority information, a report or sample in addition to any information, report or sample which may have been given previously by the person to the NRA or to the authority under any provision of the Agvet Code. This new subsection will provide for such circumstances.

Clause 163 - The Schedule (paragraph 160(c))

163.1 Section **160** allows the NRA, for the purposes of an application for an active constituent, a chemical product (including an application for approval of a label for a chemical product), a reconsideration by the NRA, or the NRA deciding whether to suspend or cancel a permit, to take account of assessments made by overseas authorities which have similar functions to the NRA.

163.2 This clause inserts a reference to listed registration after registration to ensure the provisions of the section also apply to listed registrations established under new Part 2A.

Clause 164 - The Schedule (after section 160)

164.1 A new section, **160A**, is inserted to provide for the notification of new information to the NRA in situations where applications are pending. The new section requires applicants to provide any new relevant information to the NRA during the period from when an application is made from when it is determined.

164.2 The new section applies in relation to the approval of an active constituent; the registration or listed registration of a chemical product; the approval of a label; a permit in respect of an active constituent or a chemical product; a reconsideration by the NRA; or a suspension or cancellation of an approval or registration by the NRA.

164.3 If the appropriate person becomes aware of relevant information, the information must be given to the NRA as soon as practicable. An appropriate person is stated to be either an interested person (*refer Definitions section 3*) or the person who made the application. Failure to provide the relevant information to the NRA as soon as practicable will incur a penalty of 300 penalty units.

164.4 Relevant information is defined as any information which contradicts any information already given to the NRA; demonstrates that the use of or dealing with the chemical product may be hazardous to the safety of people; harmful to humans, or have unintended effect harmful to animals, plants, things or the environment. Any information which demonstrates that the use of the chemical in accordance with the proposed instructions for its use, but which use may be ineffective according to criteria determined by the NRA for the product is also relevant information. Information which the applicant would have given to the NRA if the applicant was aware of the information at the time of lodging the application, is also relevant information which must be provided to the NRA.

164.5 To ensure that a corporation cannot hide behind a related, or overseas parent, corporation and not provide relevant information to the NRA, a corporation is taken to be aware of any information if a related corporation is aware of the information. To determine if there is a relationship between two corporations recourse will be had to the *Corporations Act 2001*.

164.6 Information that a person gives to the NRA must be in writing and signed by the person.

Clause 165 - The Schedule (paragraph 161(1)(a))

165.1 Section **161** imposes an obligation on the interested person (*refer Definitions section 3*) in relation to approvals or registrations, and on permit holders, to provide any new information of which they become aware after the approval, registration or permit has been granted.

165.2 This clause inserts a reference to a registered listed chemical product after registered chemical product to ensure the provisions of the paragraph also apply to registered listed chemical products established under new Part 2A.

Clause 166 - The Schedule (paragraphs 161(2)(b) and (c))

166 In line with the intent for greater consistency with the language used throughout the Agvet Code, this clause omits the word recommendations and substitutes it with instructions (*refer section 14*).

Clause 167 - The Schedule (paragraph 161(2)(d))

167 This clause inserts a reference to a listed registration after registration to ensure the provisions of the paragraph also apply to listed registrations established under new Part 2A.

Clause 168 - The Schedule (subsection 161(2))

168. Consistent with the relevant part of new section **160A** above, (clause 164), a person obliged to give new information to the NRA in accordance with section **161** is taken to be aware of that information in circumstances where a related corporation is aware of the information. This will ensure that a corporation cannot hide behind a related, or overseas parent, corporation and not provide relevant information to the NRA. To determine if there is a relationship between two corporations recourse will be had to the *Corporations Act 2001*.

Clause 169 - The Schedule (subparagraph 162(3)(a)(ii))

169.1 Section **162** generally prohibits the disclosure of confidential commercial information except in the circumstances provided for by the section.

169.2 One of the exceptions to this general prohibition on the disclosure of confidential commercial information is that the particulars of an active constituent may be disclosed for the purposes of a reconsideration by the NRA under Division 4 of Part 2 (subparagraph **162(3)(a)(ii)**).

169.3 This clause inserts the words the relevant to clarify that it is only the relevant particulars (Refer Definitions Section 3) that may be disclosed.

Clause 170 - The Schedule (subparagraph 162(3)(b)(i))

170.1 Additional to the exception in subparagraph **162(3)(a)(ii)**, another exception to the general prohibition on the disclosure of confidential commercial information, is that, for chemical products containing new active constituents, a summary of the NRAs assessment (made under section **14**) may be disclosed (for the purposes of section **13**).

170.2 This clause inserts a reference to listed registration after registration to ensure the provisions of this subparagraph also apply to listed registrations established under new Part 2A.

Clause 171 - The Schedule (subparagraph 162(3)(b)(ii))

171.1 One of the exceptions to the general prohibition on the disclosure of confidential commercial information is that the particulars of a registered product may be disclosed for the purposes of a reconsideration by the NRA under Division 4 of Part 2.

171.2 This clause adds a reference to the reconsideration of the listed registration of a chemical product under Division 6 of new Part 2A, and inserts the words the relevant to clarify it is only the relevant particulars (*refer Definitions Section 3*) that may be disclosed.

Clause 172 - The Schedule (subsection 162(13))

172 This clause inserts a new subsection to section **162**. The effect of the new subsection is to add that a reference in section **162** to information about an active constituent, a chemical product, any of the constituents of the chemical product, or the label for containers of the chemical product includes a reference to information about anything that was, at any time, such an active constituent, a chemical product, a constituent of the chemical product, or a label for containers of the chemical product.

Clause 173 - The Schedule (paragraph 167(1)(a))

173.1 Many of the decisions of the NRA are subject to merits review by the Administrative Appeals Tribunal (AAT). The decisions of the NRA that may be reviewed on their merits are set out in subsection **167(1)**.

173.2 These amendments insert a number of matters in the Agvet Code that give the NRA discretionary powers, which should be subject to merits, review by the AAT.

173.3 This clause inserts, at the beginning of subsection **167(1)**, four additional decisions of the NRA that are to be subject to a merits review by the AAT. The five decisions are:

a decision of the NRA under paragraph 11A that the application does not comply with subsection 11(1) (paragraph **(aa)**);

a decision under section 11A to defer consideration of an application for registration of a chemical product, approval of a label for containers for a chemical product or to treat such application as having been withdrawn (paragraph **(ab)**);

a decision under section 11A to reject an application for approval of an active constituent for a proposed or existing chemical product for registration of a chemical product or approval of a label for a container for chemical product (paragraph **(ab)**);

a decision under subparagraph 11A(3)(a)(iii) refusing to extend a period;

Clause 174 - The Schedule (after paragraph 167(1)(f))

174.1 Many of the decisions of the NRA are subject to merits review by the Administrative Appeals Tribunal (AAT). The decisions of the NRA that may be reviewed on their merits are set out in subsection **167(1)**.

174.2 These amendments insert a number of matters in the Agvet Code that give the NRA discretionary powers, which should be subject to merits, review by the AAT.

174.3 This clause inserts, after paragraph 167(1)(f), six additional decisions of the NRA relating to the listed registration of a chemical products (Part 2A), that are to be subject to a merits review by the AAT. The six decisions are refusal to grant an application for listed registration of a chemical product; refusal to grant listed registration of a chemical product subject to particular conditions; refusal to vary the relevant particulars of the listed registration of a chemical product; refusal to vary the conditions of the listed registration of a chemical product; a decision to vary the conditions of the listed registration of a chemical product; and a decision to suspend or cancel the listed registration of a chemical product.

Clause 175 - The Schedule (paragraph 167(1)(g))

175 Paragraph **167(1)(g)** makes the decision of the NRA under subsection 48(3) to refuse to accept a late application for the renewal of the registration of a chemical product, subject to merits review. This clause extends the provision in paragraph **167(1)(g)** to include decisions, under the proposed section **56ZN(3)**, to refuse to accept a late application for the renewal of the listed registration of a chemical product, as being NRA decisions which are reviewable.

Clause 176 - The Schedule (after paragraph 167(1)(i))

176 This clause includes the decision of the NRA under proposed subsection 81(3) shortening or extending or refusing to shorten or extend a period as a reviewable decision. Subsection **81(3)** provides, in circumstances specified in the subsection but for a period of time of 2 years or such shorter or longer period that the NRA allows, an exemption to the section 81 offence of supplying a registered chemical product in a container that is not identical to the approved label.

Agvet Code Part 11 - Transitional provisions

Clause 177 - The Schedule (subsection 178(2))

177.1 This Part contains provisions to continue in force under the Agvet Code certain approvals, registrations and permits, granted by the States under previous arrangements as well as certain pending applications that may have been previously made to the States.

177.2 The Part contains two provisions whereby a label for a chemical product granted by a State under previous arrangements is taken to have been approved under the Agvet Code - namely, paragraphs **174(1)(c)** and **176(1)(d)**.

177.3 If a label for a chemical product was taken to have been approved under Part 11, then by subsection **178(2)**, the NRA was required to give a distinguishing number to the label and record the relevant particulars in the relevant NRA file. This requirement of subsection **178(2)** however, only applied in respect of labels taken to have been approved under section 176. This amendment corrects this minor error and adds paragraph 174(1)(c) after taken by.

Schedule 2 - Amendment of the Agricultural And Veterinary Chemicals (Administration) Act 1992

Clause 1 Paragraph 7(1A)(b)

1.1 Section 7 of the Agvet Admin Act outlines the powers and functions of the NRA. Paragraph **7(1A)(b)** includes the power to provide information to the Governments and various authorities of the Commonwealth and the States and Territories.

1.2 This clause broadens the scope of the information that can be provided to also include registered listed chemical products and reserved chemical products established by new Parts 2A and 2B of the amendments to the Agvet Code (refer Schedule 1).

Clause 2 Subsection 7A(2) - definition of protected commodity

2 The substantial definition of protected commodity is repealed and substituted with a definition which has the same meaning as in the Agvet Code: see section 3.

Clause 3 Subparagraphs 8A(2)(a)(ii), (b)(ii) and (c)(ii)

3.1 Section **8A** requires the NRA to consult with the Gene Technology Regulator in certain circumstances.

3.2 This clause add to the circumstances where the NRA must consult the Gene Technology Regulator by including in subparagraphs **8A(2)(a)(ii)**, **(b)(ii)** and **(c)(ii)** a reference to listed registration in addition to registration.

Clause 4 Paragraph 43(5)(b)

4 This clause corrects an error whereby the word which was inserted into the section rather than the correct word with. The amendment will follow the intent of the provision.

Clause 5 Subsection 50(1)

5.1 The subsection is repealed and substituted with new provisions to synchronise the production of the NRAs Corporate Plan and its Annual Operating Plan (AOP) and to provide that a Corporate Plan does not have to be prepared every year.

5.2 Part 6 of the Agvet Admin Act requires the NRA to prepare both a Corporate Plan and an Annual Operating Plan and submit these business plans to the Minister for approval, unless the Minister directs otherwise. By virtue of section 50, the Corporate Plan had to be submitted by 1 May each year and the Annual Operating Plan by 1 June.

5.3 The two plans substantially interconnect and the requirement to submit these plans to the Minister at different times has proved to be impractical and, each year, both plans have in fact been submitted together in June. Each year a direction from the Minister, has had to be sought in respect of the late delivery of the Corporate Plan.

5.4 It is proposed that the date on which both the Corporate Plan is required to be submitted to the Minister be changed from 1 May to 1 June in line with the requirement for the NRAs Annual Operating plan.

5.5 Furthermore, the NRAs Corporate Plan must extend for at least three years but may, at the NRAs discretion, extend for up to five years. To date, the NRA has chosen to prepare Corporate Plans for no more than three years. It is also proposed that the NRA would have a discretion, if it so chooses and the Minister approves, of not producing a Corporate Plan each year. Instead, where the NRA has produced a Corporate Plan extending for three, four or five years, then it would not have to produce a revised Corporate Plan until 1 June in the last year of the life of that Corporate Plan.

5.6 This amendment provides for the NRA to give to the Minister a corporate plan on or before 1 June, or as directed by the Minister, in each calendar year. The Minister may determine that the provision of the corporate report is not required in a relevant calendar year (defined to be a particular calendar year).

5.7 In circumstances where the NRA does not give the Minister a corporate plan in a particular year, the NRA must, nonetheless inform the Minister of any proposed strategy changes. Changes to strategy must not be undertaken without approval by the Minister.

Clause 6 Application

6 The amendment put in place by clause 5 above will apply for the calendar year beginning 1 June 2003 and all calendar years.

Clause 7 Subsection 55(1)

7 This clause provides that the NRA must on or before 1 June each year, or any other date as directed by the Minister, give an annual operational plan to the Minister. This plan will relate to the 12 month period beginning on 1 July in that calendar year.

Clause 8 - Application

8 The amendment put in place by clause 7 above will apply for the calendar year beginning 1 June 2003 and all calendar years.

Part 7A importation, manufacture and exportation of chemicals

The main provision of this Division (subsection 69B(1)) creates the offence that a person must not import into Australia an active constituent that is not an approved active (or is an exempt active constituent for the purposes of the subsection) or a chemical product that is not a registered chemical product (or is an exempt chemical product for the purposes of the subsection).

Clause 9 Subparagraph 69B(1)(a)(ii)

9 This subparagraph is repealed and substituted to provide that a person must not import into Australia a chemical product that is not a registered product, a registered listed chemical product, a reserved chemical product or an exempt chemical product. Registered listed and reserved chemical products are established by Parts 2A and 2B of the amendments to the Agvet Code (refer Schedule 1).

Clause 10 Section 69EO

10.1 The offence of providing false information to the NRA in section 69EO of the Agvet Admin Act previously incurred a fine of 30 penalty units. This is considered to be too low a penalty for the gravity of the offence. This clause raises the penalty for the offence and distinguishes the gravity of certain offences of providing false information to the NRA. This clause repeals the section and substitutes it.

10.2 Subsection **69EO(1)** provides for a particular offence to which the maximum penalty of 300 penalty units attaches. When the NRA is deciding whether to consent to the importation into Australia of a chemical product that is not a registered product, a registered listed product, a reserved chemical product or an exempt chemical product, a person who gives either oral or written information to the NRA, knowing it to be false or misleading in a material particular; or who produces a document to the NRA knowing the document to be false or misleading in a material particular without indicating the deficiencies of the document to the NRA or correcting the information (if in possession of, or can reasonably acquire, the correct information), is guilty of an offence.

10.3 In circumstances where a person, in complying with any provision of Part 7A (other than section **69EO**) or a requirement from an inspector in connection with this Part, provides information to the NRA or to an inspector knowing it to be false or misleading in a material particular; or who produces a document to the NRA or to an inspector knowing it to be false or misleading in a material particular without indicating the errors in the document or without correcting the information (if in possession of, or can reasonably acquire, the correct information) then that person is guilty of an offence. The penalty for an offence by an individual against this provision is a fine not exceeding 60 penalty points.

Clause 11 Subsection 69ES(1)

11.1 Similar to the provisions of section 149 of the Agvet Code, section 69ES provides that the NRA may provide a certificate that states certain matters. A matter stated in a certificate under section 69ES is evidence of that matter for the purposes of any legal or administrative proceeding under or for the purposes of the Agvet Admin Act. The matters that can be stated broadly relate to details held in the Records and Registers kept by the NRA or other matters within the exclusive knowledge of the NRA.

11.2 The intention of the new section is to facilitate the NRA in assisting the States in their control-of-use functions, or other persons who may need to prove a matter kept on the NRAs Records or Registers, by overcoming the previous limitation in section 69ES.

11.3 Subsection 69ES(1) is repealed and substituted with a provision that allows the NRA to issue evidential certificates for the purposes of any proceeding before a court or tribunal or an authority or person having power to require the production of documents or the answering of questions, other than a proceeding for an offence that is directly punishable by imprisonment.

Clause 12 Paragraph 69ES(3)(d)

12 This clause will omit the expression Part. but substitutes it with Part; to demonstrate continuation of the paragraph.

Clause 13 At the end of subsection 69ES(3)

13 This clause extends the existing list of matters for which an evidential certificate may be given by the NRA to include any matter that could be included in a certificate provided in accordance with section 149 of the Agvet Code as amended. This ensures that the ability of the NRA to certify certain matters is as complete as possible and operates in union with the Agvet Code.

Clause 14 - Paragraph 69H(1)(b)

14.1 Subsection 69H(1) provides that no proceedings, suit or action lies against the Commonwealth, the NRA or any other parties or persons mentioned in the section, as a result of certain acts, events, uses or inability to use, amongst other things, an active constituent, or a registered chemical product.

14.2 This clause clarifies that the protection of subsection 69H(1) is extended to circumstances involving the handling of a registered listed chemical product or a reserved chemical product which are established by new Parts 2A and 2B of the amendments to the Agvet Code (refer Schedule 1).

Clause 15 - Paragraph 69H(1)(e)

15.1 The protection afforded to the parties mentioned in subsection 69H(1) also applies to situations where there is an inability to use, or use in a particular manner, a chemical product because a registration, permit or exemption has been refused by the NRA or if already granted, has been suspended or cancelled.

15.2 This clause clarifies that the protection of subsection 69H(1) is extended to registered listed and reserved chemical products established by new Parts 2A and 2B of the amendments to the Agvet Code (refer Schedule 1).

Clause 16 and 17 -After paragraph 69H(2)(b) and subsection 69H(2)

16.1 Subsection 69H(2) provides that, in any action, suit or other proceeding brought against a person responsible for the importation, manufacture, supply or handling of an approved active constituent, a registered chemical product, a permit or exemption or a manufacturing licence, in relation to any loss or injury suffered, it is not a defence that the NRA approved the active constituent, registered the product, issued the permit, or granted the exemption or licence.

16.2 The subsection is amended to add an appropriate reference to registered listed chemical products established by new Part 2A of the amendments to the Agvet Code (refer Schedule 1), as a new paragraph 69H(2)(ba) and in subsection 69H(2).

Clause 18 - Subsection 70(1)

18.1 The NRA can issue a certificate (signed by a director, the Chief Executive Officer, or an authorised person) under section 70 stating that the NRA has done any act or thing or formed any opinion.

18.2 This clause repeals paragraph (b) and omits all the words after it and includes words to the effect that a certificate that states any of the following:

that the NRA has done any act or thing, or formed any opinion;

that a substance referred to in a certificate was, or was not, at any particular time, an active constituent or an approved active constituent; or

that a chemical product referred to in the certificate was, or was not, at any particular time, a chemical product, a registered chemical product, a registered listed chemical product or a reserved chemical product;

is upon mere production, to be taken as *prima facie* evidence of the matters stated in the certificate.

18.3 Registered listed and reserved chemical products are established by new Parts 2A and 2B of the amendments to the Agvet Code (refer Schedule 1).

Schedule 3 - Amendment of the Agricultural And Veterinary Chemical Products (Collection of Levy) Act 1994

Clause 1 - Subsection 3(1) (definition of offence against this Act).

1 This clause repeals the definition of offence against this Act, which included a reference to the *Crimes Act 1914* and the *Criminal Code*.

Clause 2 - Subsection 3(1) (definition of registered)

2 This clause repeals and substitutes the definition of registered, in relation to a jurisdiction, to mean registered under a registration law of the jurisdiction and, where such a registration law is an Agvet Code of the jurisdiction, to clarify that the application of the word registered includes a listed registration under Part 2A of the Agvet Code established by the amendments to the Agvet Code (refer Schedule 1).

Clause 3 - Subsection 3(1) (paragraph (a) of the definition of registration law)

3 This clause repeals and substitutes the first part of the definition of registration law to also include a reference to Part 2A of the Agvet Code established by the amendments to the Agvet Code (refer Schedule 1).

Clause 4 - After subsection 11(1)

4.1 Subsection **11(1)** provides that the levy payable to the NRA by the interested person (*refer Definitions section 3 Schedule 1*) in respect of a chemical product in a particular calendar is the total value of the leviable disposals of the chemical product multiplied by the rate of levy. The rate of levy is the percentage figure prescribed by the regulations.

4.2 This clause inserts a new subsection (**1A**) to provide that the regulations may prescribe a lower rate of levy for chemical products having a listed registration under Part 2A of the Agvet Code than the rate of levy prescribed in respect of chemical products registered under Part 2 of the Agvet Code. Part 2A is established by the amendments to the Agvet Code (refer Schedule 1). The intention is that, as the level of assessment by the NRA for products that are granted listed registration will be lower, a lower rate of levy should be paid in respect of such products.

Clause 5 - After subsection 12(1)

5.1 Subsection **12(1)** provides that the levy payable to the NRA by the interested person (refer Definitions section 3 Schedule 1) in respect of a chemical product during the first six months of a particular calendar is the total value of the leviable disposals of the chemical product for those six months multiplied by the rate of levy. The rate of levy is the percentage figure prescribed by the regulations.

5.2 As with clause 4 above which amends section 11, this clause creates a new subsection, (**1A**), to provide that the regulations may prescribe a lower rate of levy for chemical products having a listed registration under Part 2A of the Agvet Code than the rate of levy prescribed in respect of chemical products registered under Part 2 of the Agvet Code. Part 2A is established by the amendments to the Agvet Code (refer to Schedule 1). The intention is that, as the level of assessment by the NRA for products which are granted listed registration will be lower, a lower rate of levy should be paid in respect of such products.