BILLS DIGEST

No. 8 1994

Agricultural and Veterinary Chemicals Code Bill 1993
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Caution:

Unless otherwise stated, each Bills Digest reflects the provisions of the legislation as initially presented. Digests should not be read as a complete guide to the relevant legislation and do not constitute legal advice.

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Agricultural and Veterinary Chemicals Code Bill 1993

Date Introduced: 16 December 1993
House: House of Representatives
Portfolio: Primary Industries and Energy

Commencement: On the same day as the Agricultural and Veterinary Chemicals Bill 1993. (The Agricultural and Veterinary Chemicals Bill 1993 will commence on a day to be fixed by Proclamation, or if it does not commence within 12 months of receiving the Royal Assent, it will commence on the first day after that period.)

Purpose

To provide for the evaluation, approval, registration and control and supply of agricultural and veterinary chemicals in the Australian Capital Territory and prescribed Territories.

Background

This Bill forms part of a package of seven Bills. The other Bills in this package include the Agricultural and Veterinary Chemicals Bill 1993, Agricultural and Veterinary Chemicals (Consequential Amendments) Bill 1993, Agricultural and Veterinary Chemical Products (Collection of Levy) Bill 1993, Agricultural and Veterinary Chemical Products Levy Imposition (General) Bill 1998, Agricultural and Veterinary Chemical Products Levy Imposition (Excise) Bill 1998 and Agricultural and Veterinary Chemical Products Levy Imposition (Customs) Bill 1993. An outline of the background to this package of Bills is contained in the Digest (No. 3 of 1994) for the Agricultural and Veterinary Chemicals Bill 1993.

Collectively, this package provides a scheme for the evaluation, registration and control of agricultural and veterinary chemicals in the Australian Capital Territory and prescribed Territories. This Bill applies only to the Australian Capital Territory and prescribed Territories by virtue of clause 7 of the Agricultural and Veterinary Chemicals Bill 1993. It is the Government's intention that the Agricultural and Veterinary Chemicals Code (Agvet Code), set out in the Schedule to this Bill, will be adopted by the enactment of complementary legislation by each State and the Northern Territory. Were this to occur, the evaluation, approval, registration and control and supply of agricultural and veterinary chemicals would be administered uniformly across Australia by the National Registration Authority for Agricultural and Veterinary Chemicals (NRA).

Main Provisions

Preamble: The recitals set out at the start of this Bill give the reasons for this Bill, including:

- that the furthering of Australia's international trade and commerce, and the present and future economic viability and competitiveness of primary industry and domestic industry for manufacturing and formulating agricultural and veterinary chemical products, are essential for the well-being of the economy and require a cost-effective, efficient, predictable, adaptive and responsible regulatory system;
- that the system should, as far as is practicable, be uniform throughout Australia; and
- that uniformity could best be achieved by enacting Commonwealth legislation as a law for the Australian Capital Territory and the adoption of that legislation by the States and the Northern Territory.
Commencement: This Bill will commence on the same day as the Agricultural and Veterinary Chemicals Bill 1993 (clause 2). That Bill will commence on a day to be fixed by Proclamation, or if it does not commence within 12 months of receiving the Royal Assent, it will commence on the first day after that period.

Application of Schedule: The effect of clause 4, in conjunction with the Agricultural and Veterinary Chemicals Bill 1993, will be to give the Agvet Code contained in the Schedule to this Bill force of law in the Australian Capital Territory and prescribed Territories.

Regulations: The Governor-General may make regulations prescribing matters:

* required or allowed by the Agvet Code to be prescribed; or
* necessary or convenient to be prescribed for carrying out or giving effect to the Agvet Code [subclause 6(1)].

Orders: The Minister may:

* where the regulations provide for, or in relation to, a matter and declare that this clause applies to the matter;

make orders, consistent with the regulations, with respect to the matter [subclause 7(1)]. Orders will not be able to prescribe a penalty, and will be disallowable by Parliament [subclauses 7(2) and 7(3)].

Compensation: Where the operation of, or the NRA does an act under, the Agvet Code which results in the acquisition of property from a person, the Commonwealth will be liable to pay him/her such compensation as is agreed between them, or where no agreement is reached, as determined by the Supreme Court of the Australian Capital Territory or a prescribed Territory court (clause 8). The term 'acquisition of property' is defined as having the same meaning as in paragraph 51(xxxi) of the Constitution. Paragraph 51(xxxi) of the Constitution accords the Parliament an express power to legislate with respect to the 'The acquisition of property on just terms from any State or person for any purpose in respect of which the Parliament has power to make laws'.

Agvet Code

The Agvet Code is structured with the definitions at the front. Page 13 of this Bill contains a list of terms defined by clause 3 of the Agvet Code. (Note: For the purposes of this Digest, important terms are defined as they first occur.)

Part 1 - Preliminary

Object of Agvet Code: The objects of the Agvet Code are contained in clause 1, and include:

* the evaluation, approval, control and supply, of active constituents for proposed or existing agricultural and veterinary chemical products; and
* the evaluation, registration and control of the manufacture and supply, of agricultural and veterinary chemical products. (Note: The terms 'agricultural chemical product' and 'veterinary chemical product' are defined in clauses 4 and 5.)

The term 'active constituent' is defined in clause 3 as the substance that is, or one of the substances that together are, primarily responsible for the biological or other effect identifying the product as an agricultural chemical product or a veterinary chemical product.

Relationship of Agvet Code to Other Laws: Laws of this jurisdiction which are inconsistent with the Agvet Code are excluded by subclause 2(1).

The term 'jurisdiction' is defined in clause 3 of this Bill as a State/Northern Territory, or the Australian Capital Territory or prescribed Territory.
Laws of this jurisdiction which can operate concurrently with the Agvet Code will not be taken to be inconsistent with the Agvet Code [subclause 2(2)].

Definition of `Agricultural Chemical Product`: A agricultural chemical product is defined by subclause 4(2) as a substance or mixture of substances that is represented, imported, manufactured, supplied or used directly or indirectly for certain purposes, including:

* destroying, stupefying, repelling, inhibiting the feeding of, or preventing infestation by or attacks of, any pest in relation to a plant, a place or thing;
* modifying the physiology of a plant or pest to alter its natural development, productivity, quality or reproductive capacity; or
* attracting a pest for the purpose of destroying it.

An agricultural chemical product does not include:

* a veterinary chemical product; or
* a substance or mixture of substances declared by the regulation not to be an agricultural chemical product [subclause 4(4)].

Definition of `Veterinary Chemical Product`: A `veterinary chemical product` is defined by subclause 5(2) as a substance or mixture of substances represented as being suitable for, or manufactured, supplied or used for, administration or application to an animal by any means, or consumption by an animal, directly or indirectly for certain purposes, including:

* preventing, diagnosing, curing or alleviating a disease or condition in an animal or an infestation of an animal by a pest;
* curing or alleviating an injury suffered by an animal; or
* modifying the physiology of an animal so as to alter its natural development, productivity, quality or reproductive capacity, or to make it more manageable.

A veterinary chemical product does not include:

* a substance or mixture of substances prepared by a pharmacist, or veterinary surgeon in his/her professional capacity; or
* a substance or mixture of substances declared by the regulations not to be a veterinary chemical product [subclause 5(4)].

Part 2 - Approvals and Registration

Division 2 - Applications for Approval or Registration

Applications that may be made: Applications for approval of an active constituent for a proposed or existing chemical product, registration of a chemical product, or approval of a label for containers for a chemical product may be made to the NRA (clause 10).

Public Notice Before NRA Determination of Application for New Active Constituent: The NRA is required by clause 12, before determining an application for approval of an active constituent not previously contained in a chemical product registered under an Agvet Code, or a corresponding previous law, to publish a notice detailing certain matters about the new active constituent, including:

* the fact that an application has been made;
* particulars of the constituent, other than confidential commercial information;
• any other matter the NRA thinks appropriate; and

• inviting any person who wishes to do so, to make a written submission, within 28 days of the notice appearing in the Gazette, as to whether the application should be granted [subclause 12(1)].

The grounds on which a submission for non-approval is to be based, must be grounds relating to matters that the NRA is required to take into account in determining whether to grant an application. These grounds are set out in clause 14. Where a submission is made, the NRA has to take it into account when making a determination [subclause 12(2)].

Public Notice Before NRA Determination of Application for Registration of Chemical Product Containing New Active Constituent: The public notice requirements applicable under clause 12 will also apply to an application for registration of a chemical product containing an active constituent not previously contained in a chemical product registered under an Agvet Code, or a corresponding previous law (clause 13).

Grant or Refusal of Application: The NRA must grant an application for approval of an active constituent for a proposed or existing chemical product, registration of a chemical product, or approval of a label for containers for a chemical product, if all the matters specified in subclause 14(3) are satisfied [subclause 14(1)]. The matters specified in subclause 14(3) include:

• compliance with subclause 11(1) [Subclause 11(1) provides that an application must be in the approved form; contain, or be accompanied by, any information that the NRA requires; be signed by an approved person; and be accompanied by the prescribed fee (if any)];

• any requirements with respect to the giving of samples for analysis, or samples/copies of labels; and

• where an application is for approval of an active constituent or registration of a chemical product, the use of the constituent or product in accordance with the recommendations for its use would not:
  • be an undue hazard to the safety of people exposed to it during handling, or people using anything containing its residues;
  • be likely to have an effect harmful to human beings;
  • be likely to have an unintended effect harmful to animals, plants or things or to the environment; and
  • unduly prejudice Australia’s foreign trade or commerce.

Restriction on Power of NRA to Grant Approvals: The NRA is not to grant an application for registration of a chemical product unless:

• the active constituent, or each active constituent of the product, is an approved active constituent (unless the active constituent has been exempted by the NRA), and it grants an application for approval of a label for containers for the product; or

grant an application for approval of a label for containers for a chemical product unless:

• it also grants or has granted an application for registration of the product (clause 15).

NRA Record of Approved Active Constituents: The NRA, for the purposes of this Agvet Code, is to keep a record to be known as the Record of Approved Active Constituents for Chemical Products (the Record) [subclause 17(1)]. The Record is to comprise two parts, one containing confidential commercial information, and the other non-confidential commercial information [subclause 17(3)]. The non-confidential part of the Record will be open to public inspection [subclause 17(4)]. Approval of an active constituent for a proposed or existing chemical product will be effected by giving a distinguishing number to the active constituent and entering that number and any other prescribed particulars in the Record (clause 19).
NRA Register of Agricultural and Veterinary Chemical Products: The NRA, for the purposes of this Agvet Code, is required to keep a register to be known as the Register of Agricultural and Veterinary Chemical Products (the Register) [subclause 18(1)]. The Register is to comprise two parts, one containing confidential commercial information, and the other information [subclause 18(3)]. The non-confidential part of the Register will be open to public inspection [subclause 18(4)]. Registration of a chemical product will be effected by giving a distinguishing number to the product and entering that number and any prescribed particulars in the Register (clause 20).

Notice of Refusal to Grant an Application: Where an application for approval of an active constituent for a proposed or existing chemical product, registration of a chemical product, or approval of a label for containers for a chemical product is refused by the NRA, it must:

* give the applicant written notice of the refusal [subclause 25(1)];
* provide brief reasons for the refusal (subclause 25(1)); and
* inform the applicant that he/she may apply to the Administrative Appeals Tribunal for a review of the decision [subclause 25(2) and clause 168].

Offence for not Notifying NRA of Incorrectly Recorded or Registered Particulars: It will be an offence, punishable by a maximum penalty of 60 penalty units (currently $6000), for an interested person to not notify the NRA of a reasonable belief of incorrect information in the Record, the Register, or the relevant NRA file in relation to a constituent, product or label [subclause 26(1)]. Where the NRA is satisfied that information entered in the Record, Register or file is incorrect, it must change the entry [subclause 26(2)].

In effect, the term 'interested person' is defined by clause 3 as the person who applied for approval of an active constituent, registration of a chemical product, or approval of a label, or their legal successor.

Division 4 - Reconsideration of Approval or Registration

NRA Invitation to Public to Propose Approved Active Constituents or Registered Chemical Products for Reconsideration: The NRA may invite the public to nominate active constituents for proposed or existing chemical products, or chemical products, whose approval or registration the NRA might reconsider [subclause 30(1)]. A proposal made by a person must contain reasons, based on criteria stated in the NRA invitation, in support of his/her proposal [subclause 30(3)].

NRA may Reconsider Approval or Registration: The NRA may, at any time, reconsider the approval of an active constituent for a proposed or existing chemical product, the registration of a chemical product, or the approval of a label for containers for a chemical product [subclause 31(1)]. The basis of a reconsideration is whether the NRA is satisfied the prescribed requirements for continued approval or registration are complied with [subclause 31(1)].

Notice of Proposed Reconsideration: The NRA may, before reconsidering the approval of an active constituent for a proposed or existing chemical product, or registration of a chemical product, if it thinks it desirable, publish a notice:

* stating that it proposes a reconsideration and setting out particulars of the constituent or product; and
* inviting any person to make a submission to the NRA on whether the approval or registration should be continued [subclause 32(1)].

The NRA must give notice to an interested person, in relation to the constituent or product:

* telling them of the matter(s) it proposes to reconsider and reasons for doing so;
* requiring them to provide any information of which they were aware that is relevant to the reconsideration (Note: Failure to not provide such information will constitute an offence, punishable by a maximum penalty of 120 penalty units (currently $12 000) [subclause 32(3)]; and
inviting them to make a submission about the matter(s) it proposes to reconsider [subclause 32(2)].

Where the NRA seeks public comment, or gives notice to an interested person, in relation to a reconsideration, the minimum period for comment is 28 days [paragraphs 32(1)(b) & 32(2)(b)].

NRA May Require Trial or Laboratory Experiment: The NRA may require, for the purposes of a reconsideration of an approval, that an interested person, within a reasonable period,:

* conduct, or cause to be conducted, trials or laboratory experiments in relation to the constituent or product; and

* give the results of the trials or experiments to the NRA [subclause 33(1)]. (Note: Failure to comply with such a requirement will constitute an offence, punishable by a maximum penalty of 120 penalty units (currently $12 000) [subclause 33(2)].

Division 5 - Suspension or Cancellation of Approval or Registration:

Clauses 35-42 set out the circumstances in which the NRA may suspend or cancel an approval of an active constituent for a proposed or existing chemical product, the approval of a label for containers for a chemical product, or the registration of a chemical product. The circumstances include:

* a breach of a condition of an approval or registration (clause 36);

* a failure to provide subclause 32(2) information, or under subclause 33(1), a failure to conduct trials or experiments, or provide results of such trials or experiments (clause 37);

* the NRA, in the course of a reconsideration, is not satisfied the conditions of the approval or registration can be varied so that the prescribed requirements for continued approval or registration will be complied with (clause 40); and

* at the request of an interested person (clause 42).

Notice of Proposed Suspension or Cancellation: The term 'co-ordinator' is defined by clause 3 as a person designated by a State, the Australian Capital Territory or a prescribed Territory to perform the functions of a co-ordinator under the relevant Agvet Code. The functions of a co-ordinator are set out in clause 111.

The NRA must not suspend or cancel an approval or registration unless:

* it has given notice of the proposed suspension or cancellation to each co-ordinator; and

* ten days, or any other period the NRA thinks appropriate, has passed since the notice was given (clause 35).

Division 7 - Publication of Notices by NRA

Publication of Notice of Approval or Registration: The NRA must, where it approves an active constituent for a proposed or existing chemical product:

* give notice of the approval in the Gazette and in any other way it thinks appropriate;

* state in the notice that the constituent has been approved and the date of the approval; and

* provide in the notice a brief statement of the conditions attaching to the approval that directly regulate the use of the constituent [subclauses 52(1) & 52(3)].

In relation to the registration of a chemical product, notice of the registration is only required where the NRA thinks it necessary. Where the NRA does thinks it necessary, the notice is subject to the same content and form requirements as apply to an approval [subclauses 52(2) & 52(3)].

Publication of Notice of Suspension or Cancellation: Where the NRA suspends or cancels an approval of an active constituent for a proposed or existing chemical product, the approval of a label for
containers for a chemical product, or the registration of a chemical product, it is to have published in the *Gazette* and in any other way it thinks appropriate, notice of the suspension or cancellation containing and information it thinks relevant [subclause 55(1)].

Subclause 55(2) requires a notice of suspension or cancellation to contain particular information in certain circumstances, including where the reason, or one of the reasons, for the suspension or cancellation was that the continued use of, or other dealing with the constituent or product might:

* be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues;
* be likely to have a harmful effect on humans; or
* be likely to have an unintended harmful effect to animals, plants or the environment.

In such circumstances, the notice must contain information, including:

* instructions for using or dealing with the constituent or product; or
* a warning of the consequences of failing to comply with the instructions.

It will be an offence, punishable by a maximum penalty of 300 penalty units (currently $30,000), for a person, who has possession of a constituent or product for supply, to not deal with that constituent or product in accordance with instructions contained in a notice of suspension or cancellation [subclause 55(4)]. It will be defence to a prosecution under subclause 55(4) if the defendant can prove that he/she, when dealing with constituent or product, did not know, or could not reasonably be expected to have known, of the existence of the notice or that the dealing did not comply with the instructions contained in the notice [subclause 55(6)].

Where the NRA publishes a notice of the suspension or cancellation of the approval of a label for a container, it must:

* as soon as practicable, provide a copy of the notice to the interested person in relation to the chemical product; and
* provide a copy of the notice to any other person who, in the NRA's opinion, should be given notice of the suspension or cancellation and of the instructions, warnings and explanations contained in the notice [subclause 55(8)].

**Part 3 - Compensation for use of Protected Registration Information**

**Division 2 - Right to Compensation**

**Right of Originator of Protected Registration Information to Compensation for its Use in Relation to other Applications:**

The term 'protected registration information' is defined by clause 3 as information in relation to a chemical product that has been obtained through laboratory experiments or trials and relates to the interaction between the product and the environment, living organisms or naturally occurring populations in ecosystems. Protected registration information does not include information obtained only to assess the performance of a product for its proposed use.

The term 'protected chemical product' is defined by clause 3 as a registered chemical product that is, or includes, an invention for which a patent was granted, and the term of which has ended, or will end during the protection period applicable to protected registration information about the product (Note: The 'protection period' is defined by clause 3 as the specified period or seven years.). A protected chemical product does not include a chemical product for which instructions on the approved label, or each of the approved labels, state the product should only be used for a particular class of animals that are not a food-producing species.

The term 'primary applicant' is defined by clause 3 as the person who gave protected registration information to the NRA in respect of a primary chemical product.

Basically, a 'secondary applicant', a term which is defined by clause 3, is a person who has applied to the NRA for the registration of a secondary chemical product, or, in the case of a reconsideration of the product, their legal successors.
Subclause 59(1) provides that the NRA must, subject to the exemptions set out in subclause 59(2) (see below), not use protected registration information relating to a protected chemical product (the primary chemical product) in determining whether to register, or continue the registration of, another chemical product (the secondary chemical product). The exceptions to this proposed rule include:

* where the primary and secondary applicant have agreed on the terms of compensation to be paid by the secondary applicant to the primary applicant for the information to be used in relation to the secondary chemical product, and have notified the NRA that they have so agreed and the terms of the compensation;

* an NRA appointed arbitrator has determined the compensation payable and the secondary applicant has notified the primary applicant and NRA that he/she agrees to comply with the determination;

* the protection period has lapsed since the information was given to the NRA; or

* the NRA is satisfied, having regard to any prescribed criteria, that it is in the public interest for the information to be so used.

Division 3 - Mediation or Arbitration as to Terms of Compensation

**Mediation:** The NRA must appoint a person as mediator to help parties to negotiations reach agreement as to the terms of compensation to be paid by the secondary applicant to the primary applicant [subclause 63(1)]. A mediation will cease where:

* the parties reach agreement as to the terms of compensation;

* the mediator, or either party, tells the NRA the mediation has not been successful; or

* 14 days have passed since the appointment of the mediator.

**Arbitration:** Where mediation fails, the NRA must appoint an arbitrator to determine the terms of compensation in accordance with any reasonable proposals made in the course of negotiations between the parties, including during the mediation [subclause 64(1)]. A proposal as to the terms of compensation will be taken to be reasonable only if the arbitrator is satisfied that:

* it provides for an amount/s to be paid by the secondary applicant to the primary applicant; and

* the amount/s represent a fair proportion of:

(i) the cost incurred by the primary applicant in obtaining the protected registration information (excluding the cost of obtaining the information from a Government or public authority); or

(ii) where the protected registration information was obtained by the primary applicant before the NRA required him/her to give that information to it - a lesser amount where than under (i) above, having regard to the time between when the information was obtained and when it was given to the NRA [subclause 69(1)].

Part 4 - Control of Supply of Chemical Products

This Part regulates the supply of active constituents for chemical products and the supply of chemical products.

Division 1 - Preliminary

**Non-application to Veterinary Surgeons:** Part 4 of this Bill, clauses 72-95, does not apply to a veterinary surgeon, or person acting under the instructions of such a person, in respect of any action of his/her allowed by another law, other than the Agvet Code [subclause 73(1)].
Divisions 2-4 - Control Generally/Date-controlled Chemical Product/Registered Chemical Products:

Divisions 2-4 of Part 4 of this Bill, clauses 74-95, establish offences relating to: the supply of active constituents and chemical products; the manufacture and supply of date-controlled chemical products; and the supply of restricted chemical products. It is not within the scope of this Digest to provide an outline of all the offences established under Division 2-4. Set out below are certain of these offences:

* Supply of Unapproved Active Constituents: It will be an offence, punishable by a maximum penalty of 300 penalty units (currently $30 000), for a person to supply, or allow to be supplied, an active constituent for a proposed or existing chemical product that is not an approved active constituent, unless certain exceptions apply, including:

- the constituent is exempted by the NRA; or
- the supply is authorised by a permit [subclause 76(1)].

It will be a defence to a prosecution if the defendant can prove that when he/she supplied the active constituent, or allowed it to be supplied, he/she did not know, and could not reasonably be expected to have known, that the constituent was not an approved active constituent [subclause 76(3)];

* Supply of Chemical Products Without Approved Label: It will be an offence, punishable by a maximum penalty of 300 penalty units (currently $30 000), for a person to supply, or allow to be supplied, a chemical product in a container that does not have an approved label attached. No offence will have been committed if the supply is authorised by a permit [subclause 80(1)].

It will be a defence to a prosecution if the defendant can prove that when the chemical product was supplied, or allowed to be supplied in the container, he/she did not know, and could not reasonably be expected to have known, that the container did not have an approved label attached to it [subclause 80(2)];

* Manufacture or Import of Date-controlled Chemical Product: It will be an offence, punishable by a maximum penalty of 120 penalty units (currently $12 000), for a person who manufactures or imports a date-controlled chemical product, without a reasonable excuse either not to:

- as soon as practicable, record in the prescribed manner the date of manufacture, or date of manufacture and import, of the product and any other particulars required by the regulations to be inserted in the record; or
- keep that record for the prescribed period (clause 90) (Note: The term ‘date-controlled chemical product’ is defined by clause 3 as a chemical product declared by the regulations as a date-controlled chemical product.); and

* Restricted Chemical Products: It will be an offence, punishable by a maximum penalty of 120 penalty units (currently $12 000), for a person, without reasonable excuse, to supply a restricted chemical product, or cause or allow such a product to be supplied to someone who is not authorised to use it under another law (clause 94). (Note: Clause 93 provides that the regulations may declare a chemical product to be a restricted chemical product. Such a declaration may only be made where the NRA has certified that it is in the public interest for the product to be so declared. In deciding whether to certify a chemical product as restricted, the NRA has to have regard to certain matters, including whether it may have a harmful effect on humans and whether any special equipment is required to use it safely.)

Part 6 - Recall Notices

Recall Notices: Part 6 of this Bill (clauses 100-107) sets out the circumstances in which the NRA may issue a recall notice. The circumstances include:

* where a chemical product is unregistered, or its registration is being reconsidered by the NRA [subclause 101(1)];
where it appears to the NRA that the continued use of a registered chemical product in accord
with instructions on an approved label for containers for the product may be an undue hazard
to people exposed to it during handling, or using anything containing its residues [subclause
102(1)]; and

where it appears to the NRA that labels attached to containers of stocks of a registered
chemical product, or particular batch of a registered chemical product, differs from the
approved label kept on file by the NRA in relation to the product [subclause 103(1)].

In issuing a recall notice, the NRA may require the recipient to do a number of things, including:

* not supply the chemical product;
* recover stocks of the chemical product; or
* destroy the chemical product [subclauses 101(2), 102(2) & 103(2)].

A notice issued by the NRA under subclauses 101(1), 102(1) & 103(1), is to include a statement that
an application may be made by, or on behalf of, a person whose interests are affected by the NRA’s
decision to issue the notice, to the Administrative Appeals Tribunal, for a review of the decision
[subclauses 101(3), 102(3) & 103(3)].

Notice of Recall to be Published: Where the NRA issues a recall notice, it must, as soon as practicable,
have a notice published in the Gazette and in any other way it thinks appropriate, of the issue of the
recall notice [subclause 104(1)]. Each notice has to contain a brief statement of the matters to which
the recall notice relates [subclause 104(2)].

Non-compliance with Recall Notice: It will be an offence, punishable by a maximum penalty of 120
penalty units (currently $12 000), for a person to fail, without reasonable excuse, to comply with a
recall notice (clause 105).

Part 7 - Permits

Definition of ‘Permit’: The term ‘permit’ is defined by clause 109 as a permit to do, or omit to do,
an act in respect of an active constituent for a proposed or existing chemical product, or a chemical
product, which otherwise would constitute an offence under clauses 74-81, 84, 85, 87, 91, or an
eligible law of this jurisdiction.

NRA may Grant or Refuse Permit Application: The NRA must consider an application for a permit
and take into account any recommendations made by a co-ordinator [subclause 112(1)]. (Note: The
functions of a co-ordinator are set out in clause 111, and include the making of recommendations to
the NRA in relation to the granting of permits.)

The NRA must grant a permit if it is satisfied of certain matters, including:

* the applicant is a suitable person to hold the permit;
* the use of, or any other dealing with, the constituent or product as proposed in the application
  for the permit, would not be an undue hazard to the safety of people exposed to it during its
  handling, or people using anything containing its residues; and
* the use of, or any other dealing with, the constituent or product as proposed in the application
  for the permit would not prejudice Australia's foreign trade or commence [subclause 112(2)].

Where the NRA is not satisfied that an application for a permit meets all the criteria set out in
subclause 112(2), it must refuse the application [subclause 112(3)]. Where a refusal occurs, notice of
the refusal must be given to the applicant and to each co-ordinator to whom a copy of the application
was given. The notice of refusal has to include brief particulars of the reasons for the refusal and that
an application may be made to the Administrative Appeals Tribunal for a review of the decision
[subclauses 112(4) & 112(5)].
Record of Permits: The NRA is to keep a record of permits, which is to be known as the Record of Permits [subclause 113(1)]. The Record of Permits is to comprise two parts. One part is to contain confidential commercial information, and the other part non-confidential commercial information. The NRA must allow any person to inspect the non-confidential part of the Record of Permits [subclauses 113(3)-113(5)].

Issue of Permit: The NRA may, on its own initiation or on application, issue a permit to a person [subclause 114(1)]. Permits may be unconditional or subject to any condition the NRA thinks appropriate [subclause 114(3)].

A permit must contain certain information, including:
* the name of the active constituent or chemical product in respect of which it was issued;
* the matters authorised by it to be done, or omitted to be done; and
* any conditions attaching to it [subclause 114(4)].

Cancellation of Permit: The NRA is accorded by subclause 119(1) the power to cancel a permit. The conditions under which this discretionary power may be exercised include:
* where the continued use of, or any other dealing with, an active constituent for a proposed or existing chemical product, or a chemical product, in accordance with the permit, might be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues, or may unduly prejudice Australia's foreign trade or commerce [subclause 119(1)];
* where a permit is suspended (Note: Clause 118(2) accords the NRA the power to suspend a permit) and information or samples required are not provided to the NRA within a reasonable time after the suspension occurs [subclause 119(2)]; and
* the permit holder has been convicted of an offence against this Agvet Code, the Agvet Code of another jurisdiction, another law of this or another jurisdiction relating to active constituents for proposed or existing chemical products, or chemical products [subclause 119(4)].

Part 8 - Manufacture of Chemical Products

Offences Relating to Manufacture of Certain Chemical Products and Licensing of Manufacturers of other Chemical Products: It will be an offence, punishable by a maximum penalty of 240 penalty units (currently $24 000), for a person, without reasonable excuse, to carry out a step in the manufacture of a prohibited chemical product in this jurisdiction [subclause 121(3)].

The term "prohibited chemical product" is defined by clause 3 as a chemical product declared by the regulations to be a prohibited chemical product.

Subclause 121(4) make it an offence, punishable by a maximum penalty of 240 penalty units (currently $24 000), for a person, without reasonable excuse, to carry out a step in the manufacture of a chemical product in this jurisdiction unless:
* the products are exempt products, or the person is an exempt person, under the regulations;
* the person has a licence which allows him/her to carry out that step; or
* the person was already engaged in the manufacture of the products at the commencement of this Agvet Code, and before the commencement of this clause had applied for a licence allowing him/her to carry out the manufacture, but the NRA has not dealt with the application.
Issue of Licence: The NRA must issue a licence to carry out steps in the manufacture of chemical products (other than prohibited chemical products) at particular premises where the applicant has complied with clause 122 application conditions unless:

(i) the NRA is satisfied the person will be unable to comply with the manufacturing principles (See clause 23 of the Agricultural and Veterinary Chemicals Bill 1998), or the premises are not satisfactory for the manufacture of the products;

(ii) a licence previously issued to the person was cancelled, other than at the request of the licensee;

(iii) the person has been convicted of an offence against the Agvet Code of this or another jurisdiction, or another law relating to chemical products; or

(iv) the person has failed on more than two occasions in any 12 months to observe any of the manufacturing principles, whether the failures relate to the same manufacturing principle or to different manufacturing principles [subclause 123(1)].

Even where a person fails to meet conditions (ii)-(iv) above, the NRA may issue him/her with a licence if in its opinion special circumstances make it appropriate to do so [subclause 123(2)].

Where the NRA issues a licence, it must, as soon as is practicable, publish in the Gazette, and in any other manner it thinks fit, particulars of the licence [subclause 123(5)].

Refusal of Application: Where the NRA refuses a licence, it must notify the applicant of the refusal, give brief particulars of the reasons for the refusal and that an application may be made to the Administrative Appeals Tribunal for a review of the decision [clause 124].

Conditions of Licences: The conditions to which a licence may be subject include:

* conditions imposed by the NRA for the purpose of ensuring the licence holder manufactures the chemical products in accordance with the manufacturing principles and any standards that apply to the products; and

* any other conditions relating to the manufacture of the products that the NRA thinks appropriate [subsection 126(1)].

In addition to the above conditions which `may' be imposed, each licence is, except as otherwise stated in the licence, subject to the condition that the licence holder will ensure the chemical products conform to any standard that applies to them, and comply with any prescribed conditions [subclause 126(4)].

Where a new condition is imposed on a licence, or an existing condition is varied, under subclause 126(3), the notice required to be given by the NRA to the licence holder notifying him/her of the new condition/s or variation, must indicate that an application may be made to the Administrative Appeals Tribunal for a review of the decision [subclause 126(5)].

Suspension or Cancellation of Licences: The circumstances under which the NRA may, by written notice to a licence holder, suspend or cancel his/her licence to manufacture chemicals are contained in clause 126. The circumstances, include:

* if the licence holder has been convicted of an offence against the Agvet Code of this or another jurisdiction, or an offence against another law of this or another jurisdiction relating to chemical products;

* the licence holder has breached a licence condition;

* the licence holder has asked that the licence be suspended or cancelled; or

* a prescribed fee in relation to the licence has not been paid [subsection 127(1)].

Where the NRA proposes to suspend or cancel a licence, except where asked to do so by the licence holder, the NRA must, unless it thinks a failure to suspend or cancel the licence immediately would
create an imminent risk to public health or occupational health or safety, or to Australia's foreign trade or commerce:

* give written notice to the licence holder, telling him/her of the action it proposes to take and reasons for so doing; and

* except where the proposed action is because of the non-payment of a prescribed fee, give the licence holder a chance to make, within a reasonable time stated in the notice, a written submission to it relating to the proposed action [subclause 127(2)].

A notice suspending or cancelling a licence to manufacture chemicals must include brief particulars of the reasons for the suspension or cancellation and that an application may be made to the Administrative Appeals Tribunal for a review of the NRA's decision [subclauses 127(5) & 127(6)].

Part 9 - Enforcement

Division 2 - Injunctions

Injunctions: Where a person has engaged, or is proposing to engage, in any act that was or would be an offence under this Agvet Code, a court of competent jurisdiction (See clause 20 of the Agricultural and Veterinary Chemicals Bill 1993) may, on application from any person, grant an injunction:

* restraining the offender from engaging in the conduct; and

* if in the court's opinion it is desirable, requiring the offender to do a particular thing [subclause 130(1)].

Where a court of competent jurisdiction considers it desirable, it may issue an interim injunction, pending determination of an application for an injunction under subclause 130(1) [subclause 130(2)].

An injunction, or interim injunction, may be discharged or varied by the court [subclause 130(3)].

Division 3 - Powers of Entry, Search and Seizure

Division 3 of this Bill, clauses 131-145, contain standard compliance monitoring provisions, relating to the powers of inspectors to search premises, seize things and require the giving of information and production of documents.

Division 4 - Miscellaneous Enforcement Provisions:

Self-incrimination to be a Reasonable Excuse for Non-compliance with a Requirement: A person may refuse or fail to give information, produce a document, or do any other thing that he/she is required to do by this Agvet Code, where that information, production or doing would tend to incriminate him/her (clause 146).

Time for Bringing Prosecutions: A prosecution for an offence against this Agvet Code may be started at any time within two years of the commission of the offence (clause 147).

Forfeiture: Where a person is convicted of an offence against this Agvet Code in respect of a thing the court finds to be the property of that person, the court may order all, or any part of, that thing to be forfeited to the NRA [subclause 150(1)].

Part 10 - Miscellaneous

How to Make a Single Application Under Agvet Code of Each Jurisdiction: Clause 156 allows a single application to be made under the Agvet Codes (rather than under the Agvet Code of a particular jurisdiction), so that it has effect as an application under the Agvet Code of each State and Territory.
Fees: The regulations may prescribe, or prescribe the way to work out, fees to be paid for making an application to the NRA, or the doing of anything by the NRA or an inspector under this Agvet Code [subclause 164(1)]. A prescribed fee must not exceed $20,000 [subclause 164(3)], and two or more fees may be prescribed for the same matter [subclause 164(4)].

A fee will not be payable for the making of an application to the NRA, doing of anything by the NRA or by an inspector, in relation to an active constituent for a proposed or existing chemical product, chemical product, or label for containers for a chemical product under this Agvet Code, if a corresponding fee has already been paid for the same thing under a corresponding provision of another State or Territory's Agvet Code [subclause 164(5)].

The NRA may, on its own initiative, or on application by a person, waive or remit all or part of a fee payable under this Agvet Code:

* if the fee is payable or was paid for an applicant that is or was withdrawn; or
* in any other prescribed circumstances [subclause 164(8)].

Review of NRA Decisions by the NRA: NRA decisions in respect of which an application may be made to the Administrative Appeals Tribunal for a review are set out in clause 167. Reviewable NRA decisions include:

* an NRA decision refusing an application for approval of an active constituent for a proposed or existing chemical product, or the approval of a label for containers for a chemical product, or the registration of a chemical product;

* an NRA decision to suspend or cancel the approval of an active constituent for a proposed or existing chemical product, or the approval of a label for containers for a chemical product, or the registration of a chemical product; and

* an NRA decision refusing an application for a permit or a licence.