Statutory Rules 1995 No. 27

AGRICULTURAL AND VETERINARY CHEMICALS CODE REGULATIONS

TABLE OF PROVISIONS

93R485, 5/1/95, 9:47 AM 93383254

TABLE OF PROVISIONS—continued

TABLE OF PROVISIONS—continued

TABLE OF PROVISIONS—continued

9323R485, 5/1/95, 10:16 AM 93383254

TABLE OF PROVISIONS—continued

Statutory Rules 1995 No. 27₁

Agricultural and Veterinary Chemicals Code Regulations

I, THE GOVERNOR-GENERAL of the Commonwealth of Australia, acting with the advice of the Federal Executive Council and under section 4 of the *Acts Interpretation Act 1901*, make the following Regulations under the *Agricultural and Veterinary Chemicals Code Act 1994*.

Dated 21 February 1995.

BILL HAYDEN
Governor-General

By His Excellency's Command,

BOB COLLINS
Minister for Primary Industries and Energy

93R485, 5/1/95, 9:47 AM 93383254

PART 1—PRELIMINARY

Citation

1. These Regulations may be cited as the Agricultural and Veterinary Chemicals Code Regulations.

Commencement

2. These Regulations commence on the same day as the *Agricultural and Veterinary Chemicals Code Act 1994*.

Interpretation

3. (1) In these Regulations, unless the contrary intention appears:

"**Act**" means the *Agricultural and Veterinary Chemicals Code Act 1994*;

"approved active constituent" means an active constituent approved under Part 2 of the Code;

"biological pesticide" means an agricultural chemical product containing, or derived from, a living organism, whether or not the organism is genetically modified;

"block" or **"lick"** means a blend or mixture of one or more stockfood ingredients compressed or poured into a solid block form for voluntary consumption by livestock;

"British Pharmacopoeia" means the book of that name published for the British Pharmacopoeia Commission;

"British Pharmacopoeia (Veterinary)" means the book of that name published on the recommendation of the Medicines Commission of the United Kingdom;

"Code" means the Agvet Code of this jurisdiction;

"CSIRO" means the Commonwealth Scientific and Industrial Research Organization established by the *Science and Industry Research Act 1949*;

"direct-fed microbial product" means a chemical product that:

(a) contains viable micro-organisms; and

(b) is intended for oral administration to animals;

"emergency use", in relation to a chemical product or an active constituent, means a use of the product or constituent arising from an

93R485, 5/1/95, 9:47 AM 93383254

emergency in which there is a genuinely believed need for the use of the product or constituent;

"European Pharmacopoeia" means the book of that name published for the European Pharmacopoeia Commission;

"FAO Specifications for Plant Protection Products" means the publications of that name published by the Food and Agriculture Organization of the United Nations;

"formulation change", in relation to a chemical product, means:

(a) a change in the source of any active constituent of the product; or

(b) a variation in the amount or concentration of one or more of the active constituents, or other constituents, of the product; or

(c) the addition to the product, or removal from the product of one or more of the active constituents, or other constituents, of the product;

"hormonal growth promotant" means a veterinary chemical product containing a substance that is, or a mixture of substances that are, responsible for oestrogenic, androgenic or gestagenic activity to enhance growth or production in bovines or bubalines;

"immunobiological product" means a chemical product which, when administered to a vertebrate or invertebrate living creature, provides, induces or changes an immune response to a particular chemical or biological entity in that creature;

"legal practitioner" means a person who is admitted, and entitled to practise, as a barrister or solicitor in a State or Territory;

"medical practitioner" means a person registered or licensed as a medical practitioner under a law of a State or Territory;

"medicated block or lick" means a block or lick incorporating a veterinary chemical product;

"medicated premix" means a premix that incorporates one or more veterinary chemical products for the purpose of:

(a) preventing or treating disease; or

(b) enhancing growth, production, work or performance; or

(c) altering reproductive physiology;

"medicated stockfood" means a ready-to-use stockfood that incorporates one or more veterinary chemical products for the purpose of:

(a) preventing or treating disease; or

(b) enhancing growth, production, work or performance; or

93R485, 5/1/95, 9:47 AM 93383254

(c) altering reproductive physiology;

"minor use", in relation to a chemical product or an active constituent, means a use of the product or constituent that would not produce sufficient economic return to an applicant for registration of the product to meet the cost of registration of the product, or the cost of registration of the product for that use, as the case requires (including, in particular, the cost of providing the data required for that purpose);

"modular assessment fee" has the meaning given in regulation 71;

"modular assessment period" has the meaning given in regulation 77;

"NATA" means the National Association of Testing Authorities, Australia, a company having the Australian Company Number 004379748;

"notification number", means a notification number assigned to a person under regulation 47;

"nutritional ingredient" includes, but is not limited to, the following:

(a) protein meals (as a protein source);
(b) fermentation products from human foods, (including brewer's grains, yeasts and yeast extracts);
(c) hay, including lucerne hay and peanut hay;
(d) chaff;
(e) straw;
(f) grains, other similar seeds and the products of those grains or seeds;
(g) vitamins, minerals and amino acids at normal nutritional levels;
(h) salt, limestone and inorganic phosphorus sources;
(i) fats and oils;
(j) milk by-products;
(k) non-protein nitrogen sources;
(l) molasses;

"poison schedule classification", in relation to a chemical product, means classification of the product or any of its constituents in the Standard for the Uniform Scheduling of Drugs and Poisons;

"premix" means a mixture that:

(a) contains vitamins, minerals, amino acids or other substances; and

(b) is intended to be added to stockfood to form a finished feed for feeding to a group of animals;

"purchaser declaration number" means a distinguishing number issued in respect of premises by a State or Territory or by an authority of a State or Territory, for the purpose of identifying those premises as premises where animals to be treated with a hormonal growth promotant are, or are to be, kept;

"Standard for the Uniform Scheduling of Drugs and Poisons" means the publication of that name published by the Department of Human Services and Health;

"stockfood" means a basic food or food mixture that:

(a) contains one or more nutritional ingredients; and

(b) is intended to be fed to animals for the maintenance of life, normal growth, production, work, reproduction or performance;

"stockfood non-active constituent" means any organic acid, antioxidant, pellet binding product, mould inhibitor, preservative, feed handling improver, colouring agent, anticaking agent, deodorising agent or other substance or mixture of substances intended to be added to stockfood for continuous, long-term administration to animals for a purpose other than:

(a) preventing or treating disease; or

(b) enhancing growth, production, work or performance; or

(c) altering reproductive physiology;

"stockfood supplement" means any substance or mixture of substances in the form of tablets, sachets or measures added to stockfood for administration to animals individually in order to supplement or balance that stockfood, but does not include a substance or mixture of substances in an injectable dose form, an intraruminal bolus, a block or a lick;

"supply", in relation to any product or thing, includes cause or permit the supply of the product or thing;

[NOTE: Section 3 of the Code provides that "supply" includes do, or cause or permit the doing of, any of the following:

(a) sell;

(b) expose for sale;

(c) send or deliver for sale or on sale;

(d) dispose of under a hire purchase agreement;

(e) exchange;

(f) give;

(g) offer to do an act that would be a supply (including an act referred to in any of the above paragraphs).]

"total leviable value" has the same meaning as in the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*;

"United States Pharmacopoeia" means the book of that name published by the United States Pharmacopoeia Convention.

(2) Unless the contrary intention appears, a reference in these Regulations to a book or other publication is a reference to the latest edition of that book or publication as modified or amended from time to time, and includes any addendum or other addition to the book or publication.

Definition of "date-controlled chemical product"—section 3 of the Code

4. For the purposes of the definition of "date-controlled chemical product" in section 3 of the Code, the following are declared to be date-controlled chemical products:

(a) each veterinary chemical product;

(b) an agricultural chemical product specified in Schedule 1.

Definition of "excluded organism"—section 3 of the Code

5. For the purposes of the definition of "excluded organism" in section 3 of the Code, a vertebrate animal is an excluded organism.

Definition of "protection period"—section 3 of the Code

6. (1) Subject to this regulation, the period, in years, in relation to protected registration information of a kind specified in columns 2 and 3 of an item in Schedule 2 is the period worked out in accordance with the formula:

$$2 + 5\frac{A}{B}$$

where:

A is the number, or the total number, as the case requires, of points allocated to that item in column 4 of Schedule 2; and

B is 600.

(2) If the period worked out in accordance with subregulation (1) in relation to an item is not a whole number, it is to be rounded to the nearest whole number.

(3) If the period worked out in accordance with subregulations (1) and (2) in relation to an item is more than 7 years, the period is taken to be 7 years.

Definition of "agricultural chemical product"—section 4 of the Code

7. (1) For the purposes of subsection 4 (3) of the Code, a substance or mixture of substances included in any of the following classes of substances or mixtures of substances is declared to be an agricultural chemical product:

(a) dairy cleansers for on-farm use;

(b) any substance used in conjunction with an agricultural chemical product to identify areas treated with that product;

(c) insect repellents for use on human beings.

(2) For the purposes of paragraph 4 (4) (b) of the Code, a substance or mixture of substances included in a class of substances or mixtures of substances specified in Column 2 of an item in Schedule 3 is declared not to be an agricultural chemical product.

Definition of "veterinary chemical product"—section 5 of the Code

8. (1) For the purposes of paragraph 5 (3) (b) of the Code, a substance or mixture of substances included in any of the following classes of substances or mixtures of substances is declared to be a veterinary chemical product:

(a) allergenic substances supplied or used for administration to an animal by any means, or for consumption by an animal;

(b) medicated blocks or licks;

(c) enzymes supplied or used for administration to an animal by any means, or for consumption by an animal;

93R485, 5/1/95, 9:47 AM 93383254

(d) stockfood non-active constituents except stockfood non-active constituents excluded from this class by an order under section 7 of the Act;
(e) direct-fed microbial products;
(f) sheep branding substances.

(2) Section 7 of the Act (which deals with the power to make orders) applies to the prescription of stockfood non-active constituents excluded from the class described in paragraph (1) (d).

(3) For the purposes of paragraph 5 (4) (b) of the Code, a substance or mixture of substances included in any of the following classes of substances or mixtures of substances is declared not to be a veterinary chemical product:
(a) stockfoods;
(b) medicated stockfoods to which subregulation (4) applies;
(c) medicated premixes to which subregulation (4) applies;
(d) blocks and licks (other than medicated blocks or licks) to which subregulation (5) applies;
(e) premixes to which subregulation (5) applies;
(f) stockfood supplements to which subregulation (5) applies;
(g) colour intensifiers for aviary birds.

(4) This subregulation applies to a medicated stockfood or medicated premix if:
(a) any veterinary chemical product that is incorporated in the medicated stockfood or medicated premix:
(i) is a registered chemical product; and
(ii) is incorporated at a rate of use in accordance with the approved label for containers for that registered chemical product; and
(b) the container for the medicated stockfood or medicated premix is labelled in accordance with the directions on the approved label for that registered chemical product.

(5) This subregulation applies to a block, lick, premix or stockfood supplement:
(a) for which the only claim on the label consists of the words "to supplement diets where levels may be low", or words to that effect; and

93R485, 5/1/95, 9:47 AM 93383254

(b) that incorporates, in respect of any vitamin, mineral or amino acid listed on the label, not less than 25% of the daily requirement of that vitamin, mineral or amino acid for the species for which the premix or stockfood supplement is intended.

(6) For the purposes of paragraph (5) (b), the daily requirement of a vitamin, mineral or amino acid is the amount of the vitamin, mineral or amino acid specified as the daily requirement by:

(a) if the species is a dog, cat or horse—the US National Research Council of the US National Academy of Sciences; or

(b) if the species is a ruminant, a pig or poultry—the relevant feeding standard.

(7) In paragraph (6) (b), **"the relevant feeding standard"** means:

(a) in the case of a ruminant—the standard "Feeding Standards for Australian Livestock: Ruminants Standing Committee on Agriculture, Ruminants Subcommittee East Melbourne 1990", published by CSIRO; or

(b) in the case of a pig—the standard "Feeding Standards for Australian Livestock: Pigs Standing Committee on Agriculture, Pig Subcommittee East Melbourne c1987", published by CSIRO; or

(c) in the case of poultry—the standard "Feeding Standards for Australian Livestock: Poultry Standing Committee on Agriculture, Poultry Subcommittee East Melbourne c1987", published by CSIRO.

PART 2—APPROVALS AND REGISTRATION

Certain agricultural products must contain dye or pigment

9. (1) For the purposes of paragraph 14 (3) (d) of the Code (which deals with the grant or refusal of applications), an agricultural chemical product of a kind specified in subregulation (2), (3) or (4) must comply with the requirements prescribed by this regulation in relation to that product.

(2) A molluscicide in the form of a bait and of which the active constituent is metaldehyde:

93R485, 5/1/95, 9:47 AM 93383254

(a) must contain sufficient green pigment or dye to colour the bait a distinctive green colour; and

(b) must not contain, in the bait, any bone meal or other product of animal origin.

(3) A molluscicide in the form of a bait and of which the active constituent is methiocarb:

(a) must contain sufficient blue pigment or dye to colour the bait a distinctive blue colour; and

(b) must not contain, in the bait, any bone meal or other product of animal origin.

(4) An agricultural chemical product that is to be applied to seeds that are to be stored before planting or sowing must contain sufficient pigment or dye to colour the seed to which the product is applied so as to enable that seed to be readily distinguished from seed to which the product has not been applied.

Certain veterinary chemical products must contain dye marker, etc.

10. (1) For the purposes of paragraph 14 (3) (d) of the Code (which deals with the grant or refusal of applications), a veterinary chemical product for bovine intramammary infusion that contains any antibiotic substance must comply with this regulation.

(2) The veterinary chemical product must contain:

(a) the dye marker Brilliant Blue FCF (Index number 42090 in the third edition, 1971, of the Society of Dyers and Colourists Colour Index); or

(b) another dye marker approved by the NRA.

(3) The quantity of dye marker contained in the veterinary chemical product must be sufficient:

(a) to colour the milk of an animal infused with the product; and

(b) to enable the applicant to satisfy the NRA:

(i) that the dye marker will remain in the milk for the duration of the withholding period in respect of the milk; and

(ii) that, at the visual end-point, 95 per cent of the antibiotic substance has been excreted.

93R485, 5/1/95, 9:47 AM 93383254

(4) Each dose of the product for bovine intramammary infusion must not exceed 10 mL.

(5) In this regulation, **"antibiotic substance"** includes sulfonamides, trimethoprim and any anti-microbial substance, but does not include any immunobiological substance.

Labels to contain certain information

11. (1) For the purposes of paragraph 14 (3) (d) of the Code (which deals with the grant or refusal of applications), a label for containers for a chemical product must comply with the requirements of subregulation (2).

(2) A label must contain the following information:

(a) the appropriate signal heading in accordance with the Standard for the Uniform Scheduling of Drugs and Poisons;

(b) the name of the chemical product;

(c) the name of each active constituent of the product;

(d) the proportion of each active constituent of the product;

(e) the name of each other constituent classified as a poison in the Standard for the Uniform Scheduling of Drugs and Poisons;

(f) the proportion of any other constituent referred to in paragraph (e);

(g) provision for a batch number;

(h) provision for an expiry date, if applicable;

(j) provision for a date of manufacture, if applicable;

(k) the name and address of the person who is primarily responsible for marketing the product;

(l) the net contents of the product;

(m) the distinguishing number of the product;

(n) any other particulars of the product that the NRA thinks appropriate.

Labels to contain additional instructions

12. For the purposes of subparagraph 14 (3) (g) (x) of the Code (which deals with the grant or refusal of applications), a label must contain adequate instructions relating to the following:

93R485, 5/1/95, 9:47 AM 93383254

(a) if the chemical product is a veterinary chemical product—the duration of any treatment using the product;

(b) any matter, other than a matter referred to in paragraph 14 (3) (g) (ix) of the Code, that, in the opinion of the NRA, requires a warning or other precautionary instructions.

Assessment of use of an active constituent as an undue hazard

13. For the purposes of paragraph 14 (4) (e) of the Code (which deals with the grant or refusal of applications), the NRA must have regard to the method of analysis (if any) of the chemical composition of the active constituent concerned.

Assessment of use of a chemical product as an undue hazard

14. For the purposes of paragraph 14 (5) (i) of the Code (which deals with the grant or refusal of applications), the NRA must have regard to the method of analysis (if any) of the chemical composition and form of the constituents of the chemical product concerned.

Particulars of approved active constituents to be recorded

15. For the purposes of subsection 19 (2) of the Code (which deals with approval of an active constituent), the following particulars must be entered in the Record of Approved Active Constituents in relation to the approval of an active constituent:

(a) if a name is given to the active constituent by the International Union of Pure and Applied Chemistry—that name;

(b) if no name is given to the active constituent by the International Union of Pure and Applied Chemistry—the name given to the active constituent in an order, publication or approval referred to in regulation 42 that specifies the standard for the active constituent for the purposes of that regulation;

(c) the common name for the active constituent proposed by the applicant and accepted by the NRA;

(d) the composition and purity of the active constituent;

(e) the name of the manufacturer of the active constituent;

93R485, 5/1/95, 9:47 AM 93383254

(f) the address of each site at which the active constituent is manufactured by the manufacturer;
(g) the name and business address of the applicant;
(h) the date of entry of these particulars in the Record of Approved Active Constituents;
(j) the date (if any) on which the approval ends;
(k) any conditions of the approval under section 23 of the Code, other than a condition specifying the date on which the approval ends.

Particulars of registered chemical products to be recorded

16. For the purposes of subsection 20 (2) of the Code (which deals with registration of a chemical product), the following particulars must be entered in the Register of Chemical Products in relation to the registration of a chemical product:

(a) the distinguishing name of the chemical product proposed by the applicant and accepted by the NRA;
(b) the constituents of the chemical product;
(c) the concentration of each constituent of the chemical product;
(d) the composition and purity of each constituent of the chemical product;
(e) the name and business address of the applicant;
(f) the name of each State or Territory in respect of which the chemical product is registered;
(g) the name of the manufacturer of the chemical product;
(h) the address of each site at which the chemical product is manufactured by the manufacturer;
(j) the date of entry of these particulars in the Register of Chemical Products;
(k) the date on which the registration ends;
(l) any conditions of the registration under section 23 of the Code, other than a condition specifying the date on which the registration ends.

Particulars of approved labels to be recorded

17. For the purposes of subsection 21 (2) of the Code (which deals with approval of a label), the following particulars must be

93R485, 5/1/95, 9:47 AM 93383254

recorded in the relevant NRA file in relation to the approval of a label:

(a) the date of recording the relevant distinguishing number of the label in the file;

(b) any conditions of the approval under section 23 of the Code.

Containers for the supply of registered chemical products

18. (1) For the purposes of paragraph 23 (2) (a) of the Code (which deals with additional conditions of registration relating to containers), a container for a chemical product must:

(a) be impervious to, and incapable of chemical reaction with, its contents when under conditions of temperature and pressure that are likely to be encountered in normal service; and

(b) have sufficient strength and impermeability to prevent leakage of its contents during handling, transport and storage under normal handling conditions; and

(c) if it is intended to be opened more than once—be able to be securely and readily closed and reclosed; and

(d) have sufficient excess capacity to prevent it from breaking if its contents expand during handling, transport or storage; and

(e) enable all or any part of its contents to be removed or discharged in such a way that, with the exercise of no more than reasonable care, the contents cannot:

(i) harm any person; or

(ii) have an unintended effect that is harmful to the environment.

(2) Nothing in subregulation (1) is intended to affect the operation of any other law that applies in relation to containers for chemical products.

Information to be given in notice to the applicant of approval or registration

19. (1) For the purposes of subsection 24 (2) of the Code, the following information must be contained in a notice to the applicant of the approval of an active constituent:

93R485, 5/1/95, 9:47 AM 93383254

(a) the particulars of the active constituent entered in the Record of Approved Active Constituents;
(b) the date (if any) on which the approval ends;
(c) any conditions of the approval under section 23 of the Code, other than a condition specifying the date on which the approval ends;
(d) particulars of the notice of the approval to be published under subsection 52 (1) of the Code;
(e) the date on which the notice to the applicant is issued.

(2) For the purposes of subsection 24 (2) of the Code, the following information must be contained in a notice to the applicant of the registration of a chemical product:

(a) a copy or sample of an approved label for containers for the chemical product;
(b) the date of its registration under section 22 of the Code;
(c) the date on which the registration ends;
(d) any conditions of the registration under section 23 of the Code, other than a condition specifying the date on which the registration ends.

(3) For the purposes of subsection 24 (2) of the Code, the following information must be contained in a notice to the applicant of the approval of a label for containers for a chemical product:

(a) the name of the chemical product;
(b) a copy or sample of the approved label, including the distinguishing number given to the label under subsection 21 (2) of the Code;
(c) the date of the label's approval under section 22 of the Code;
(d) any conditions of the approval under section 23 of the Code.

Continued approval of an active constituent

20. For the purposes of subsection 31 (2) of the Code (which deals with reconsideration of approval or registration), the requirement for continued approval of an active constituent is that the continued use of, or any other dealing with, the constituent in accordance with the recommendations for its use or for such a dealing that the NRA has approved:

93R485, 5/1/95, 9:47 AM 93383254

(a) 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

(b) would not be likely to have an effect that is harmful to human beings; and

(c) would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and

(d) would not unduly prejudice trade or commerce between Australia and places outside Australia.

Continued registration of a chemical product

21. For the purposes of subsection 31 (2) of the Code (which deals with reconsideration of approval or registration), the requirements for continued approval of the registration of a chemical product are:

(a) that the continued use of, or any other dealing with, the product in accordance with the recommendations for its use or for such a dealing that the NRA has approved:

(i) 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

(ii) would not be likely to have an effect that is harmful to human beings; and

(iii) would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and

(iv) would not unduly prejudice trade or commerce between Australia and places outside Australia; and

(b) that the continued use of the product in accordance with the recommendations for its use that the NRA has approved would be effective according to criteria determined by the NRA for the product; and

(c) if regulation 9 or 10 applies to the product—that the product complies with that regulation.

93R485, 5/1/95, 9:47 AM 93383254

Continued approval of a label

22. For the purposes of subsection 31 (2) of the Code (which deals with reconsideration of approval or registration), the requirements for continued approval of a label for containers for a chemical product are that the label:

(a) will contain adequate instructions about such of the matters set out in paragraph 14 (3) (g) of the Code (which sets out matters relating to the use, handling etc. of the product) as the NRA thinks appropriate; and

(b) will comply with regulations 11 and 12.

Late applications for renewal of registration of chemical product

23. (1) For the purposes of subsection 48 (3) of the Code, the NRA may accept a late application for the renewal of the registration of a chemical product:

(a) if:

(i) before the end of the period for making an application referred to in subsection 48 (2) of the Code, the applicant requests in writing that the NRA accept a late application; and

(ii) the NRA agrees to that request; or

(b) in any other case—if the NRA thinks it would be unreasonable not to accept the late application.

(2) Subject to subregulation (3), the fee payable for acceptance of a late application for the renewal of the registration of a chemical product is:

(a) $50—if the fee prescribed under regulation 70 in respect of the application is not more than $600; or

(b) $100—if the fee prescribed under regulation 70 in respect of the application is more than $600.

(3) No fee is payable for acceptance of a late application for the renewal of the registration of a chemical product if the application is one to which paragraph (1) (a) applies.

93R485, 5/1/95, 9:47 AM 93383254

PART 3—COMPENSATION FOR PROVIDER OF CERTAIN INFORMATION IN RESPECT OF CONTINUED REGISTRATION OF CERTAIN CHEMICAL PRODUCTS

Division 1—Notices

Protected registered information—notice to primary applicant

24. For the purposes of subparagraph 60 (3) (a) (i) of the Code, a notice to a primary applicant must contain the following information about the secondary applicant and the secondary chemical product:

(a) if the secondary chemical product is a registered chemical product:

(i) the name and business address of the secondary applicant entered in the Register of Chemical Products; and

(ii) the particulars of the secondary chemical product entered in the Register of Chemical Products or, if the primary applicant so requests, the particulars of the approved active constituent entered in the Record of Approved Active Constituents; and

(iii) a copy of the approved label for a container for the secondary chemical product;

(b) if the secondary chemical product is not a registered chemical product—the name and business address of the secondary applicant contained in the application for registration of the secondary chemical product.

Protected registered information—notice to secondary applicant

25. For the purposes of subparagraph 60 (3) (a) (ii) of the Code, the information about each primary applicant and primary chemical product that must be contained in a notice to the secondary applicant is:

(a) the name and business address of each primary applicant; and

(b) the particulars of each primary chemical product, entered in the Register of Chemical Products or, if the secondary

93R485, 5/1/95, 9:47 AM 93383254

applicant so requests, the particulars of each approved active constituent, entered in the Record of Approved Active Constituents; and

(c) a copy of the approved label for a container for each primary chemical product.

Division 2—Conduct of Arbitration

Rules governing the conduct of an arbitration

26. (1) For the purposes of section 71 of the Code (which deals with the conduct of an arbitration), regulations 27 to 39 apply to an arbitration under Division 3 of Part 3 of the Code.

(2) A law that relates to the conduct of commercial arbitration, to the extent that it is inconsistent with any regulation mentioned in subregulation (1), does not apply to an arbitration under Division 3 of Part 3 of the Code.

Notice of appointment of arbitrator

27. (1) When an arbitrator is appointed for a purpose of the Code, the NRA must give notice in writing of the appointment, stating the arbitrator's name and address, to:

(a) each primary applicant in the matter to be arbitrated; and

(b) the secondary applicant in the matter; and

(c) the mediator in the matter.

(2) The notice must be given within a reasonable period after the appointment.

Parties to give information to arbitrator

28. As soon as practicable after being notified of the arbitrator's appointment, an applicant must tell the arbitrator in writing about any proposal as to the terms of compensation that was made by the applicant in the course of negotiations.

93R485, 5/1/95, 9:47 AM 93383254

Mediator to submit report

29. As soon as practicable after being notified of the arbitrator's appointment, the mediator must give a written report to the arbitrator:

(a) setting out the proposals and counter proposals (if any) made by the applicants during the mediation; and

(b) summarising the issues raised during the mediation.

Arbitrator to conduct a hearing

30. Before determining the terms of compensation (if any), the arbitrator must conduct a hearing.

Arbitrator to give the applicants notice of the hearing

31. (1) The arbitrator must give written notice of a hearing to each party to the arbitration, at least 14 days before the hearing.

(2) The notice must specify the date, time and place of the hearing.

Arbitrator's powers if applicant does not attend the hearing

32. If the arbitrator has given a party to the arbitration notice of a hearing in accordance with regulation 31, the arbitrator may determine terms of compensation in accordance with Division 3 of Part 3 of the Code even if the applicant does not attend the hearing.

Procedure at the hearing

33. The arbitrator may determine the procedure to be observed at a hearing.

Representation at the hearing

34. (1) Subject to subregulation (2), a party to an arbitration must not be represented by a legal practitioner at the hearing.

93R485, 5/1/95, 9:47 AM 93383254

(2) Subject to subregulation (3), the arbitrator may permit a party to be represented by a legal practitioner if, in the opinion of the arbitrator:

(a) legal representation is likely to shorten the proceedings or reduce costs; or

(b) the party would be unfairly disadvantaged if the party were not represented.

(3) The arbitrator must not permit an applicant to be represented by a legal practitioner if, in the opinion of the arbitrator, another party would be unfairly disadvantaged as a result.

Arbitrator may require information etc.

35. (1) If the arbitrator reasonably believes that a person is able to give information or produce a document that may be used for the purpose of determining:

(a) an amount referred to in subparagraph 69 (1) (b) (i) or (ii) of the Code (each of which deals with the amount of the cost of obtaining protected registration information); or

(b) what, for the purposes of paragraph 69 (1) (b) of the Code, is a fair proportion of that amount; or

(c) any other matter relevant to the determination of what is a reasonable proposal as to the terms of compensation;

the arbitrator may give notice in writing to the person in accordance with subregulation (2).

(2) A notice under subregulation (1) may require the person:

(a) to give the information to the arbitrator within the time and in the manner specified in the notice; or

(b) to attend before the arbitrator at a specified time and place and answer any question; or

(c) to produce the document to the arbitrator in accordance with the notice.

(3) A person must not without reasonable excuse fail to comply with a notice given to the person under subregulation (1).

Penalty: 5 penalty units.

(4) An arbitrator may require evidence to be given on oath or affirmation, and for that purpose, the arbitrator may administer an oath or affirmation.

Fair proportion of cost of providing protected registration information

36. For the purposes of subsection 69 (2) of the Code, the matters to which the arbitrator must have regard in determining what is a fair proportion of an amount of the cost incurred by a primary applicant are as follows:

(a) the time that has elapsed since the protected registered information was obtained by the primary applicant;

(b) the value of sales of the primary chemical product concerned since the registration of the product;

(c) whether the primary applicant has already received compensation for the use of the protected registered information by the NRA;

(d) the cost of obtaining the protected registered information if it were to be compiled at the time of the arbitration.

Arbitrator's costs

37. (1) The parties to an arbitration are jointly and severally liable to pay any costs reasonably incurred by the arbitrator in relation to the arbitration.

(2) The NRA may elect to pay the arbitrator's costs mentioned in subregulation (1).

(3) If the NRA pays the arbitrator's costs, the NRA may recover the costs from all or any of the applicants as a civil debt in a court of competent jurisdiction.

Applicants' costs of arbitration

38. Each party to an arbitration must bear the party's own costs relating to the arbitration.

93R485, 5/1/95, 9:47 AM 93383254

Arbitrator exonerated from liability

39. No action lies against an arbitrator for anything done in the course of an arbitration, if it is done in accordance with the Code and these Regulations.

PART 4—CONTROL OF CHEMICAL PRODUCTS

Division 1—General

Supply of substances for research etc. for chemical products

40. (1) Subsections 74 (1) and 75 (1) of the Code (which deal with the possession of chemical products and active constituents for supply) do not apply to a person in relation to an amount of:

(a) a substance that is likely to be used as an active constituent for a chemical product; or

(b) an active constituent for a chemical product; or

(c) a chemical product;

to which subregulation (2) applies.

(2) This subregulation applies to a substance, constituent or chemical product in the possession or custody of a person if:

(a) the substance, constituent or product is to be used only for the purposes of research in connection with a chemical product; and

(b) the amount of the substance, constituent or product does not exceed the amount specified in subregulation (5); and

(c) the person complies with subregulations (6) and (8) in respect of the substance, constituent or product.

(3) Subsections 76 (1), 77 (1), 78 (1) and 79 (1) of the Code (which deal with the supply of chemical products and active constituents) do not apply to a person in relation to an amount of:

(a) a substance that is likely to be used as an active constituent for a chemical product; or

(b) an active constituent for a chemical product; or

(c) a chemical product;

93R485, 5/1/95, 9:47 AM 93383254

to which subregulation (4) applies.

(4) This subregulation applies to a substance, constituent or chemical product supplied by a person if:

(a) the substance, constituent or product is to be used only for the purposes of research in connection with a chemical product; and

(b) the amount of the substance, constituent or product supplied in any 12 month period does not exceed the amount specified in subregulation (5); and

(c) the person complies with subregulations (7) and (8) in respect of the substance, constituent or product.

(5) For the purposes of subregulations (2) and (4), the amount of the substance, constituent or chemical product is:

(a) in the case of a substance or constituent—3 kilograms; or

(b) in the case of a chemical product—6 kilograms.

(6) A person referred to in subregulation (2) must make a record stating the amount of the substance, constituent or chemical product in the person's possession or custody at any time.

(7) A person referred to in subregulation (4) must make a record that shows, at any time, the amount of the substance, constituent or chemical product supplied by the person in the preceding 12 month period.

(8) A record made under subregulation (6) or (7):

(a) must be in a form that is readily accessible for the purposes of Part 9 of the Code (which deals with enforcement); and

(b) must be kept at the business premises of the person who made it for at least 2 years after it is made.

Supply etc. of substances with constituents differing from registered particulars

41. (1) This regulation has effect for the purposes of the following provisions of the Code:

(a) section 83 (which deals with the supply of substances);

(b) section 99 (which deals with the analysis of substances);

(c) section 102 (which deals with recall of registered chemical products).

(2) For the purposes of paragraphs 83 (a), 99 (2) (a) and 102 (1) (b) of the Code, the prescribed extent, in the case of an active constituent of a registered chemical product, is nil.

(3) For the purposes of paragraphs 83 (b), 99 (2) (b) and 102 (1) (c) of the Code, the prescribed extent, for a constituent of a registered chemical product:

(a) that is an active constituent; and

(b) in respect of which a standard is prescribed under section 87 of the Code;

is the extent (if any) of variation of concentration permitted by that standard.

Prescribed standards for chemical products

42. (1) For the purposes of section 87 of the Code (which deals with standards for chemical products), all chemical products are prescribed.

(2) Section 7 of the Act (which deals with the power to make orders) applies to the specification of standards in respect of:

(a) a chemical product; and

(b) a constituent contained in a chemical product.

(3) The standard for a chemical product, or a constituent contained in a chemical product, is:

(a) the standard specified in respect of the chemical product or the constituent in an order under section 7 of the Act; or

(b) in the case of a constituent (not being a constituent referred to in paragraph (a)) in respect of which a standard is specified in Appendix L of the Standard for the Uniform Scheduling of Drugs and Poisons—that standard; or

(c) in the case of a veterinary chemical product or of a constituent (not being a chemical product or constituent referred to in paragraph (a) or (b)), in respect of which a standard is specified in:

(i) the British Pharmacopoeia; or

93R485, 5/1/95, 9:47 AM 93383254

(ii) the British Pharmacopoeia (Veterinary); or

(iii) the European Pharmacopoeia; or

(iv) the United States Pharmacopoeia;

the standard specified in the first of those publications, in the order set out in this paragraph, that applies to the product or constituent; or

(d) in the case of a chemical product or constituent (not being a product or constituent referred to in paragraph (a), (b) or (c)), in respect of which a standard is specified in any of the FAO Specifications for Plant Protection Products—that standard; or

(e) in the case of a chemical product or constituent (not being a product or constituent referred to in paragraph (a), (b), (c) or (d))—the standard (if any) approved by the NRA in respect of the product or constituent.

(4) If no standard is prescribed under subregulation (3) in respect of the concentration of an active constituent of a particular chemical product, the standard in respect of the concentration of that active constituent is the standard set out in the following table:

Concentration of each active constituent as specified on the product label (g/kg or g/L at 20°C)	Standard (allowable variation)
500 or more	± 25 g/kg or g/L of the active constituent
From 250 up to but not including 500	± 5% of the content of the active constituent
From 100 up to but not including 250	± 6% of the content of the active constituent
Less than 100	± 10% of the content of the active constituent

When statements about chemical products can be made or reported

43. (1) For the purposes of subsection 89 (3) of the Code, a person is not prevented from making or reporting a statement about a chemical product if the statement is not made for the purpose of

promoting the product and is one of the following kinds of statement:

(a) a statement made:

(i) in a scientific paper or other scientific literature, or in a scientific report or presentation; or

(ii) at a conference or seminar, or in an address, meeting or discussion, concerning chemical products;

being a statement based on data published in a reputable, refereed scientific journal or of a standard publishable in such a journal;

(b) a statement made on radio or television or in a newspaper, journal or newsletter, as fair comment on any material:

(i) published for the purposes of a conference or seminar; and

(ii) based on data referred to in paragraph (a).

(2) Nothing in subregulation (1) is taken to permit a statement that would, apart from that subregulation, contravene section 84 of the Code.

Record of manufacture or import of date-controlled chemical product

44. (1) For the purposes of paragraph 90 (a) of the Code, a record in relation to a date-controlled chemical product:

(a) must be made:

(i) in written or electronic form; and

(ii) in such a way as to ensure that the record is readily accessible for the purposes of Part 9 of the Code (which deals with enforcement); and

(b) must include the following particulars:

(i) the name and business address of the manufacturer;

(ii) if the product is imported—the name and business address of the importer;

(iii) the distinguishing name of the product;

(iv) if the product is a registered chemical product—the distinguishing number given to the product under section 20 of the Code;

93R485, 5/1/95, 9:47 AM 93383254

(v) the volume or quantity manufactured or imported;
(vi) the batch number.

(2) For the purposes of paragraph 90 (b) of the Code, the period for keeping a record of a date-controlled chemical product is the period that begins when the record is made and ends 12 months after the expiry date of the product to which it relates.

Restricted chemical products

45. For the purposes of subsection 93 (1) of the Code (which deals with restricted chemical products), a chemical product specified in Column 2 of Schedule 4 is declared to be a restricted chemical product, the NRA having certified in writing, in respect of the product, under subsection 93 (2) of the Code, that it is in the public interest for the product to be so declared.

Supply of chemical product—batch number or record of supply

46. (1) A person must not, without reasonable excuse, supply a chemical product unless:

(a) the container for the product has attached to it a label containing a batch number, in a form approved by the NRA, that enables the NRA to identify the batch of that chemical product from which the contents of the container were taken; or
(b) the person makes a record, in respect of the supply, in accordance with subregulation (2).

Penalty: 10 penalty units.

(2) For the purposes of paragraph (1) (b), a person who supplies a chemical product must make, as soon as practicable, a record:

(a) in a form approved by the NRA; and
(b) in such a way as to ensure that the record is readily accessible for the purposes of Part 9 of the Code (which deals with enforcement); and
(c) including the following particulars:
(i) the name and address of the person who supplied the product;

93R485, 5/1/95, 9:47 AM 93383254

(ii) the name and address of the person to whom the product was supplied;

(iii) the date of supply;

(iv) the quantity of the product supplied or, if the product is supplied as part of a mixture of chemical products, the quantity of the mixture of products supplied;

(v) the identification number of the container in which the product was transported or stored for the purpose of supply or, if the container is a bulk tank, the location of the container;

(vi) the distinguishing name of the product supplied or, if the product is supplied as part of a mixture of chemical products, the distinguishing name of each of those products;

(vii) if the batch number of the product supplied or, if the product is supplied as part of a mixture of chemical products, the batch number of each of those products supplied, is known to the person who supplied the product—that batch number, or as the case requires, those batch numbers.

(3) A person who makes a record under subregulation (2) must keep the record for 3 years after it is made, unless the person has a reasonable excuse for not doing so.

Penalty: 10 penalty units.

Division 2—Supply of hormonal growth promotants

Supplier of hormonal growth promotant to have notification number

47. (1) A person must not, without reasonable excuse, supply a hormonal growth promotant unless:

(a) a distinguishing number (the **"notification number"**) has been assigned to that person; and

(b) the notification number has not been replaced or withdrawn under subregulation (4).

Penalty: 10 penalty units.

93R485, 5/1/95, 9:47 AM 93383254

(2) A person may give notice in writing to the NRA of his or her intention to supply a hormonal growth promotant.

(3) On receipt of a notice under subregulation (2), and of a fee of $200, the NRA must assign a notification number to a person for the purposes of subregulation (1).

(4) The NRA may, at any time:

(a) without payment of a fee, assign to a person a notification number in place of a notification number previously assigned to that person; or

(b) if it appears to the NRA that a person to whom a notification number has been issued no longer supplies a hormonal growth promotant—by notice in writing to the person, withdraw the notification number.

(5) A person who, immediately before the commencement of these Regulations, was authorised under a corresponding previous law of this jurisdiction to supply a hormonal growth promotant, is taken to have notified the NRA under subregulation (2) and to have paid the prescribed fee under subregulation (3).

Supply of hormonal growth promotant—purchaser's declaration

48. (1) A person must not, without reasonable excuse, supply a hormonal growth promotant to another person (**"the purchaser"**) unless the purchaser gives to the supplier, at the time of purchase, a declaration in the form, and containing the particulars, required by subregulation (3).

Penalty: 10 penalty units.

(2) Subregulation (1) does not apply in relation to a purchaser if a notification number has been assigned to the purchaser under regulation 47 and has not been replaced or withdrawn.

(3) For the purposes of subregulation (1), a declaration must:

(a) be in a form approved by the NRA; and

(b) be made and signed by the purchaser; and

(c) state:

(i) the total quantity and type of the hormonal growth promotant to be purchased; and
(ii) the batch number of the hormonal growth promotant; and
(iii) the manner of identifying the animals to be treated with the hormonal growth promotant; and
(iv) the relevant purchaser declaration number.

Record of supply of hormonal growth promotant—manufacturer and supplier

49. (1) A person who manufactures and supplies a hormonal growth promotant must, on the occasion of each supply of the hormonal growth promotant to another person (**"the purchaser"**), make a record in accordance with regulation 52 and containing the following particulars:

(a) the distinguishing name of the hormonal growth promotant entered in the Register of Chemical Products;
(b) the name and address of the manufacturer;
(c) the date of manufacture of the hormonal growth promotant;
(d) the quantity of the hormonal growth promotant manufactured;
(e) the batch number;
(f) the date of supply;
(g) the name and address of the purchaser;
(h) the purchaser's notification number or the relevant purchaser declaration number;
(j) the total quantity of the hormonal growth promotant supplied.

(2) A person must not, without reasonable excuse, fail to comply with subregulation (1).

Penalty: 10 penalty units.

Record of supply of hormonal growth promotant—importer and supplier

50. (1) A person who imports and supplies a hormonal growth promotant must, on the occasion of each supply of the hormonal growth promotant to another person (**"the purchaser"**),

make a record in accordance with regulation 52 and containing the following particulars:

(a) the distinguishing name of the hormonal growth promotant entered in the Register of Chemical Products;
(b) the name and address of the importer;
(c) the date of importation of the hormonal growth promotant;
(d) the quantity of hormonal growth promotant imported;
(e) the batch number;
(f) the date of supply;
(g) the name and address of the purchaser;
(h) the purchaser's notification number or the relevant purchaser declaration number;
(i) the total quantity of the hormonal growth promotant supplied.

(2) A person must not, without reasonable excuse, fail to comply with subregulation (1).

Penalty: 10 penalty units.

Record of supply of hormonal growth promotant—other suppliers

51. (1) A person (**"the supplier"**), not being a person who is required to make a record under regulation 49 or 50, who:

(a) receives a hormonal growth promotant from another supplier (**"the previous supplier"**); and
(b) supplies that hormonal growth promotant to another person (**"the purchaser"**);

must, on the occasion of each supply of that hormonal growth promotant, make a record in accordance with regulation 52 and containing the particulars set out in subregulation (2).

(2) For the purposes of subregulation (1), the particulars are as follows:

(a) in respect of the receipt of the hormonal growth promotant from the previous supplier:
    (i) the distinguishing name of the hormonal growth promotant entered in the Register of Chemical Products;

(ii) the name, address and notification number of the supplier;
(iii) the name, address and notification number (if any) of the previous supplier;
(iv) the date of supply by the previous supplier;
(v) the total quantity of hormonal growth promotant supplied by the previous supplier;
(vi) the batch number;

(b) in respect of supply of the hormonal growth promotant to the purchaser:
(i) the name and address of the purchaser;
(ii) the purchaser's notification number, or the relevant purchaser declaration number;
(iii) the date of supply;
(iv) the total quantity of the hormonal growth promotant supplied;
(v) the total quantity of the hormonal growth promotant remaining in the supplier's possession after supply.

(3) A person must not, without reasonable excuse, fail to comply with subregulation (1).

Penalty: 10 penalty units.

Record of supply of hormonal growth promotant—general requirements

52. For the purposes of regulations 49, 50 and 51, a record must be made:

(a) in written or electronic form; and
(b) in such a way as to be readily accessible for the purposes of Part 9 of the Code (which deals with enforcement).

Copy of records to be given to NRA

53. (1) A person who makes a record under regulation 49, 50 or 51 must give a copy of the record to the NRA within 14 days after the end of the month in which it was made.

(2) A person must not, without reasonable excuse, fail to comply with subregulation (1).

93R485, 5/1/95, 9:47 AM 93383254

Penalty: 10 penalty units.

Copy of records etc. to be kept

54. (1) A person who makes a record under regulation 49, 50 or 51 must keep the record for 2 years after it is made.

(2) A person to whom a declaration is given under subparagraph 48 (1) (b) must keep the declaration for 2 years after it is given.

(3) A person must not, without reasonable excuse, fail to comply with subregulation (1) or (2).

Penalty: 10 penalty units.

PART 5—ANALYSIS

Analysis of chemical products—tests

55. (1) Section 7 of the Act (which deals with the power to make orders) applies to prescribing tests for the analysis of samples of substances or mixtures of substances for the purposes of the Code.

(2) For the purposes of Part 5 of the Code, a sample of a substance or mixture of substances must be analysed by means of any of the following tests that apply to the substance or mixture:

(a) a test prescribed in an order made under section 7 of the Act;

(b) if the substance or mixture is a chemical product in respect of which a test is accepted by the NRA for the purposes of registration of that chemical product—that test;

(c) if the substance or mixture is an agricultural chemical product—a test specified for that product in:

(i) the CIPAC Handbook and Addenda published by the Collaborative International Pesticides Analytical Council Limited; or

(ii) the AOAC Manual and Addenda published by the Association of Official Analytical Chemists;

(d) if the substance or mixture is a veterinary chemical product—a test specified for that product in:

93R485, 5/1/95, 9:47 AM 93383254

(i) the British Pharmacopoeia; or
(ii) the British Pharmacopoeia (Veterinary); or
(iii) the European Pharmacopoeia; or
(iv) the US Pharmacopoeia;

(e) any other test approved by the NRA as equivalent to a test specified in paragraph (a), (b), (c) or (d).

Analysis at an accredited laboratory

56. For the purposes of paragraph 99 (4) (c) of the Code (which deals with requirements for analysis), a prescribed laboratory, in relation to the analysis of a substance or mixture of substances, is a laboratory accredited by NATA, or approved by the NRA, to carry out an analysis of that kind.

PART 6—PERMITS

Additional requirement for the issue of a permit

57. For the purposes of paragraph 112 (2) (h) of the Code (which deals with the grant and refusal of permit applications), in the case of an application for a permit in respect of the use of:

(a) a chemical product that is not a registered chemical product; or
(b) an active constituent for a proposed or existing chemical product that is not an approved active constituent; or
(c) a registered chemical product or approved active constituent for a proposed or existing chemical product, otherwise than in accordance with any conditions on the approved label for containers for that product;

the use of the product as proposed in the application must be:

(d) a minor use; or
(e) an emergency use; or
(f) for the purpose of research.

93R485, 5/1/95, 10:09 AM 93383254

PART 7—MANUFACTURE OF CHEMICAL PRODUCTS

Coming into force of section 121 of the Code

58. For the purposes of subsection 120 (3) of the Code, the date on which section 121 of the Code (which deals with offences relating to manufacture and licences) comes into force is the date of commencement of the Code.

Manufacture of chemical products—exempt products

59. **(1)** For the purposes of paragraph 121 (4) (a) of the Code (which deals with exempt products and persons in relation to manufacture), the following are exempt products:

(a) any agricultural chemical product;

(b) an ingredient used in the manufacture of a chemical product if the ingredient:

(i) does not have a therapeutic or biological effect on a plant or animal; or

(ii) is a herb, or an oil extracted from a herb, the sole use of which is as a starting material for use in the manufacture of a chemical product;

(c) any product prepared in a research facility or pilot plant solely for experimental use;

(d) any veterinary homeopathic preparation that:

(i) is more dilute than a one thousandfold dilution of a mother tincture; and

(ii) is not required to be sterile.

(2) In paragraph (1) (d):

"mother tincture" means a liquid prepared by the process of solution, extraction or trituration;

"veterinary homeopathic preparation" means a preparation:

(a) formulated for use on the principle that it is capable of producing in a healthy animal symptoms similar to those which it is administered to alleviate; and

(b) prepared according to the practices of homeopathic pharmacy using the method of:

(i) serial dilution and succussion of a mother tincture in water, ethanol, aqueous ethanol or glycerol; or

(ii) serial trituration in lactose.

93R485, 5/1/95, 9:47 AM 93383254

Licence condition—holder to give information about manufacture

60. For the purposes of paragraph 126 (4) (b) of the Code (which deals with additional conditions of a licence), it is a condition of each licence that the holder of the licence must give the NRA on or before each anniversary of the day on which the licence comes into force:

(a) the name, qualifications and details of the relevant experience of any person nominated by the holder of the licence as the person having control of:

(i) the production of the chemical products manufactured by or on behalf of the holder of the licence; and

(ii) the quality control measures that are, or are to be, employed in the manufacture of the chemical products; and

(b) if the NRA so requests—details of chemical products manufactured by or on behalf of the holder of the licence during the previous 12 months.

Licence conditions—general

61. (1) For the purposes of paragraph 126 (4) (b) of the Code (which deals with conditions in licences), the following subregulations set out conditions to which each licence to manufacture chemical products is subject.

(2) A holder of a licence must display publicly, at the premises to which the licence relates, a copy of the licence and of any notice issued by the NRA imposing, varying or removing the conditions applicable to the licence.

(3) A holder of a licence must make records showing:

(a) the materials used in the manufacture of the chemical products, the supplier and quantities of the materials used and details of the tests performed on those materials; and

(b) the procedures and controls employed in the manufacture of the chemical products, including the results of tests carried out during the processing of the chemical products; and

93R485, 5/1/95, 9:47 AM 93383254

(c) details of the tests performed on the chemical products and the results of those tests; and

(d) the stability studies (if any) that validate the recommended shelf life and appropriate storage conditions of the chemical products.

(4) If the chemical products are produced in identifiable batches, the holder of the licence must assign a batch number to each batch of the finished products.

(5) A holder of a licence must keep at the premises to which the licence relates:

(a) the records specified in subregulation (3); and

(b) if it is not unreasonable in the circumstances—a sample from each batch of the finished products;

for at least 12 months after the expiry date of the products to which they relate or, if there is no expiry date, for at least 6 years after the date on which the manufacture of the products was completed.

(6) The holder of the licence must ensure that a person nominated by the holder as having control of the production of the chemical products or of the quality control measures that are to be employed in the manufacture of the products maintains that control.

Licence condition—naming persons in control of production etc.

62. For the purposes of paragraph 126 (4) (b) of the Code (which deals with conditions in licences), if:

(a) an applicant for a licence to manufacture chemical products nominates a person as the person having control of the production of chemical products or of the quality control measures to be employed in the manufacture of the chemical products; and

(b) the licence is granted; and

(c) the applicant wishes to replace the nominated person with another person;

it is a condition of the licence that the licence holder must inform the NRA as soon as practicable of the name, qualifications and experience of that other person.

93R485, 5/1/95, 9:47 AM 93383254

PART 8—ENFORCEMENT

Method of securing samples

63. An inspector who takes a sample of any substance or mixture of substances for the purposes of section 131 or 132 of the Code (which deal with powers of search and seizure) must ensure that:

(a) the sample is contained and sealed in an appropriate vessel or package; and

(b) the vessel or package is so marked as to clearly identify the sample; and

(c) the vessel or package cannot be opened, or the identification of the sample removed, without breaking the seal; and

(d) the sample is stored and transported in such a way that the composition of the sample is not altered.

Form of search warrant

64. For the purposes of subsection 133 (2) of the Code (which deals with the form of a search warrant), the form of warrant in Schedule 5 is prescribed.

PART 9—MISCELLANEOUS

Prescribed authorities that may require further information

65. For the purposes of subsection 159 (1) of the Code (which deals with notices to give further information), each of the following authorities is prescribed:

(a) the Department of Human Services and Health of the Commonwealth;

(b) the Department of the Environment, Sport and Territories of the Commonwealth;

(c) the National Occupational Health and Safety Commission established by the *National Occupational Health and Safety Commission Act 1985;*

93R485, 5/1/95, 9:47 AM 93383254

(d) an authority in this jurisdiction having any function or power in relation to a matter referred to in paragraph 159 (a), (b), (c) or (d) of the Code.

Disclosure of confidential commercial information about toxicity etc.

66. (1) For the purposes of subparagraphs 162 (3) (a) (iii) and 162 (3) (b) (iii) of the Code, this regulation prescribes the conditions under which confidential commercial information of a kind described in those subparagraphs may be disclosed by the authorised person about a chemical product or any of its constituents.

(2) Information about a protected chemical product that is compensatable protected registration information may be disclosed to a person (**"the requesting person"**) on request if the requesting person signs and gives to the NRA, before the information is disclosed, a declaration stating that the information will not be used in connection with an application for registration, in Australia or elsewhere, of another chemical product, except with the consent of the interested person in relation to the protected chemical product.

(3) Information about a chemical product that is not compensatable protected registration information, may be disclosed to a person on request by making it available to that person, for the purpose of reading only, at the premises of the NRA or, if the NRA thinks it appropriate, at other premises.

(4) Despite subregulations (2) and (3), information about a constituent of a chemical product other than an active constituent may be disclosed to a medical practitioner, in connection with his or her professional duties.

(5) In this regulation, **"compensatable protected registration information"** means protected registration information in respect of which compensation for provision of the information would be payable under Part 3 of the Code.

93R485, 5/1/95, 9:47 AM 93383254

Disclosure of confidential commercial information about chemical products not yet registered etc.

67. For the purposes of subparagraph 162 (3) (c) (iii) of the Code a prescribed person is:

(a) in the case of a chemical product in respect of which an application for registration has been made—a person who is expressly authorised to obtain the information by the applicant for registration; or

(b) in the case of an active constituent in respect of which an application for approval has been made—a person who is expressly authorised to obtain the information by the applicant for approval.

Disclosure of confidential commercial information to international organisations

68. For the purposes of subparagraph 162 (3) (d) (ii) of the Code, the following organisations are prescribed:

(a) the World Health Organization;

(b) the Food and Agriculture Organization of the United Nations;

(c) the International Labour Organization;

(d) the United Nations Environment Programme;

(e) the United Nations International Programme on Chemical Safety;

(f) the Organization for Economic Co-operation and Development;

(g) any international organisation established jointly by 2 or more of the international organisations mentioned in paragraphs (a), (b), (c), (d), (e) and (f);

(h) any international organisation that is an agency or committee of an international organisation mentioned in paragraph (a), (b), (c), (d), (e), (f), or (g).

93R485, 5/1/95, 9:47 AM 93383254

Disclosure of confidential commercial information—records

69. **(1)** The NRA must make a record, on each occasion on which confidential commercial information is disclosed, of:

(a) the name and address of the person to whom the information is disclosed; and

(b) the nature of the information disclosed; and

(c) the date on which the information was disclosed.

(2) A record made under subregulation (1) must be kept for a period of 10 years.

(3) Except with the permission in writing of the Minister or a person authorised under subregulation (4), a person must not, without reasonable excuse, disclose any information contained in a record made under subregulation (1) to a person who is not a member of the staff of the NRA.

Penalty: 10 penalty units.

(4) The Minister may, in writing, authorise a person for the purposes of subregulation (3).

(5) In this regulation **"the Minister"** means the Minister for Primary Industries and Energy.

Fees for applications

70. **(1)** For the purposes of section 164 of the Code, this regulation provides for the fees payable in respect of applications under the Code.

(2) Subject to subregulation (6), the fee payable in respect of an application of a kind specified in Column 2 of an item in Schedule 6 is the fee (if any) specified for the item in Column 4 of that Schedule.

(3) A reference in Column 4 of an item in Schedule 6 to a modular assessment fee, is a reference to the modular assessment fee in respect of the application to which that item refers, worked out in accordance with regulation 71.

93R485, 5/1/95, 9:47 AM 93383254

(4) The fee payable in respect of an application for the renewal of the registration of a chemical product, if the registration is one to which subsection 47 (2) of the Code applies, is:

(a) $600—if the total leviable value in respect of the product for the calendar year immediately preceding the year in which the registration ends is not more than $25,000; or

(b) $1,000—if the total leviable value in respect of the product for the calendar year immediately preceding the year in which the registration ends is more than $25,000.

(5) No fee is payable in respect of an application for the renewal of the registration of a chemical product, if the registration is one to which subsection 47 (3) of the Code applies.

(6) No fee is payable in respect of an application for a permit:

(a) if the applicant is:

(i) a person primarily engaged in the growing of an agricultural or horticultural product; or

(ii) an officer or employee of the Commonwealth, a State or a Territory, or of an authority of the Commonwealth, a State or a Territory; or

(b) in respect of an emergency use of a chemical product.

Modular assessment fee

71. (1) The fee payable for a module of assessment specified in Column 2 of an item in Schedule 7 is the fee specified for the item in Column 4 of that Schedule.

(2) The modular assessment fee in respect of an application is the sum of the fees payable for each module of assessment necessary to determine the application.

Remission of fees for applications

72. (1) For the purposes of paragraph 164 (8) (b) of the Code, a circumstance in which the NRA may remit the whole or part of a fee paid:

(a) in respect of an application under the Code, other than an application:

93R485, 5/1/95, 9:47 AM 93383254

(i) for the renewal of the registration of a chemical product; or

(ii) for a permit; or

(b) for a module of assessment;

is that:

(c) in the case of an application—the application is not determined within the period specified or worked out in respect of that application under regulation 76; or

(d) in the case of a module of assessment specified in Schedule 7—the module is not completed within the time specified for the module in that Schedule.

Fees for copies and extracts

73. **(1)** Subject to subregulation (3), the fee payable:

(a) under subsection 17 (5) of the Code—for a copy of, or extract from, a part of the Record of Approved Active Constituents in respect of an active constituent; or

(b) under subsection 18 (5) of the Code—for a copy of, or extract from, a part of the Register of Agricultural and Veterinary Chemical Products in respect of a chemical product; or

(c) under subsection 21 (5) of the Code—for a copy of an approved label; or

(d) under subsection 97 (4) of the Code—for a copy of a certificate in respect of an analysis; or

(e) under subsection 113 (6) of the Code—for a copy of a permit; or

(f) under section 162 of the Code—for the disclosure of confidential commercial information:

(i) of a kind described in subparagraphs 162 (3) (a) (iii) or 162 (3) (b) (iii) of the Code, other than to a medical practitioner referred to in subregulation 66 (4); or

(ii) to a person referred to in subparagraph 162 (3) (c) (ii);

is the fee worked out in accordance with subregulation (2).

(2) For the purposes of subregulation (1), the fee is the sum of the following:

(a) $20; and

(b) $20 for each additional hour or part of an hour, after the first hour, of work done by the NRA to make the copy or extract available; and

(c) 10 cents for each photocopied page; and

(d) $4.40 for each page of a copy, other than a photocopy, of a document; and

(e) $4.40 for each page of a transcript of:

(i) a sound recording ; or

(ii) a document in shorthand.

(3) No fee is payable:

(a) for a copy or extract referred to in paragraph (1) (a), (b) or (c)—by the person who applied for registration or approval of the constituent, product or label; or

(b) for a copy referred to in paragraph (1) (e)—by the person who applied for the permit; or

(c) in respect of any matter referred to in subregulation (1)—by an authority in this jurisdiction having any function or power in relation to a matter referred to in paragraph 159 (a), (b), (c) or (d) of the Code.

Payment of fees

74. A fee payable under these Regulations is payable to the NRA.

Notification that application has been received

75. Within 10 days of receiving an application under the Code, the NRA must notify the applicant that the application has been received.

Period within which NRA is to determine application

76. (1) For the purposes of section 165 (1) of the Code, the NRA must determine an application of a kind specified in Column 2 of an item in Schedule 6 within the period (if any) specified for the item in Column 3 of that Schedule.

(2) A reference in Column 3 of an item in Schedule 6 to a modular assessment period, is a reference to the modular assessment

93R485, 5/1/95, 9:47 AM 93383254

period in respect of the application to which that item refers, worked out in accordance with regulation 77.

(3) For the purposes of this regulation and Schedule 6, an application for registration of a chemical product is a secondary application if:

(a) it is made at the same time as, or after, another application for registration of a chemical product (**"the primary application"**); and

(b) the active constituents of the chemical product are the same as the active constituents of the chemical product that is the subject of the primary application; and

(c) the application is connected with, and dependent on, the primary application.

(4) Despite subregulation (1), if:

(a) the NRA receives an application for a permit in respect of a chemical product; and

(b) the application is in respect of an emergency use of the chemical product;

the NRA must determine the application as soon as is practicable in the circumstances of the case.

[NOTE: 1. Subsection 165 (2) of the Code provides that in working out a period for the purposes of an application, no regard is to be had to certain periods that would otherwise be part of that period, including any period during which a requirement made by the NRA has not been complied with.

2. For the period within which an application for the renewal of the registration of a chemical product must be granted, see subsection 49 (4) of the Code.]

Modular assessment period

77. (1) The period within which a module of assessment specified in Column 2 of an item in Schedule 7 must be completed is the period (if any) specified for the item in Column 3 of that Schedule.

(2) If more than 1 module of assessment is necessary to determine an application, the modular assessment period in relation to that application is the longer or longest of the periods within

which each module of assessment necessary to determine the application must be completed, as the case requires.

Commencement of period for determining applications

78. (1) In the case of an application of a kind specified in item 8, 9, 10, 11, 16, 17, 19, 20, 21, 24, 25, 26, 27, 30, 33, 37, 38, 39, 40, 41, 42, 47, 49, or 50 in Schedule 6, the period specified for that item in the Schedule commences:

(a) if the prescribed fee in respect of the application is paid on the same day as the application is received—immediately after that day; or

(b) in any other case—immediately after the later of:

(i) the day on which the application is received; and

(ii) the day on which the prescribed fee in respect of the application is paid.

(2) In the case of an application of a kind specified in an item in Schedule 6, other than an item mentioned in subregulation (1), the period specified for that item in the Schedule commences:

(a) if the prescribed fee in respect of the application is paid on the same day as notification occurs under subregulation (4)—immediately after that day; or

(b) in any other case—immediately after the later of:

(i) the day on which notification occurs under subregulation (4); and

(ii) the day on which the prescribed fee in respect of the application is paid.

(3) The modular assessment period for an application commences:

(a) if the prescribed fee in respect of the application is paid on the same day as notification occurs under subregulation (4)—immediately after that day; or

(b) in any other case—immediately after the later of:

(i) the day on which notification occurs under subregulation (4); and

(ii) the day on which the prescribed fee in respect of the application is paid.

93R485, 5/1/95, 9:47 AM 93383254

(4) The NRA must, within 1 month after receiving an application to which subregulation (2) or (3) applies, notify the applicant in writing:

(a) that the NRA will proceed with consideration of the application; or

(b) that the NRA makes or intends to make a requirement in connection with the application, and will suspend consideration of the application until the requirement is complied with.

93R485, 5/1/95, 9:47 AM 93383254

SCHEDULE 1 Regulation 4

DATE-CONTROLLED AGRICULTURAL CHEMICAL PRODUCTS

Column 1 **Item**	**Column 2** **Agricultural Chemical product**
1.	An agricultural chemical product the active constituent of which consists of organisms (including, in particular, nematodes, bacteria, viruses, fungi, algae or protozoa)
2.	Bacillus thuringiensis
3.	Mancozeb
4.	Zineb
5.	Diazinon

SCHEDULE 2 Regulation 6

PROTECTED REGISTRATION INFORMATION— ALLOCATED POINTS

Column 1 Item	Column 2 Study	Column 3 Species	Column 4 Points
	TOXICOLOGY Acute Studies		
1.	Acute oral (technical)	rabbit, rodent, dog	3
2.	Acute dermal (technical)	rabbit, rodent	5
3.	Acute inhalation (technical)	rabbit, rodent	9

93R485, 5/1/95, 9:47 AM 93383254

SCHEDULE 2—continued

Column 1 Item	Column 2 Study	Column 3 Species	Column 4 Points
4.	Eye irritation (technical)	rabbit, rodent	3
5.	Dermal irritation (technical)	rabbit, rodent	3
6.	Dermal sensitization (technical)	rabbit, rodent	2
7.	Acute oral (formulated)	rabbit, rodent	3
8.	Acute dermal (formulated)	rabbit, rodent	5
9,	Acute inhalation (formulated)	rabbit, rodent	9
10.	Eye irritation (formulated)	rabbit, rodent	1
11.	Dermal irritation (formulated)	rabbit, rodent	1
12.	Dermal sensitisation (formulated)	rabbit, rodent	4
	Short Term		
13.	Oral (90 day)	rabbit, rodent, dog	100
14.	Dermal (90 day)	rabbit, rodent	100
15.	Inhalation (90 day)	rabbit, rodent	200
16.	Dermal (21 day)	rabbit, rodent	25
17.	Inhalation (21 day)	rabbit, rodent	50

SCHEDULE 2—continued

Column 1 Item	Column 2 Study	Column 3 Species	Column 4 Points
	Long Term		
18.	1 year chronic feeding	rabbit, rodent, dog	425
19.	Lifetime oncogenicity	rabbit, rodent	600
20.	Combined chronic and oncogenicity	rabbit, rodent	825
	Special Studies		
21.	Multi-generation reproduction	rabbit, rodent	270
22.	Teratogenicity	rabbit, rodent	70
23.	In vitro mutagenicity Point mutation	microbial mammalian	20 20
24.	Chromosome aberration		15
25.	DNA repair		15
26.	Delayed neurotoxicity	bird	45
27.	Exposure studies		150 (each study)
28.	In vivo genotoxicity		30
29.	Other		30
	METABOLISM		

SCHEDULE 2—continued

Column 1 Item	Column 2 Study	Column 3 Species	Column 4 Points
30.	Metabolism (labelled)	rabbit, rodent, bird, cattle, goat	100 100
31.	Metabolism (labelled)	plants	100
32.	Pharmacokinetic (unlabelled)		80
33.	Other		30
	ENVIRONMENTAL CHEMISTRY		
34.	Hydrolysis		15
35.	Vapour pressure		15
36.	Photodegradation	soil aqueous air	80 25 15
37.	Solubility in water		25
38.	Octanol/water partition coefficient		5
39.	Mobility: absorption/desorption		35
40.	Leaching lab study (cold) field (labelled)		 40 150

SCHEDULE 2—continued

Column 1 Item	Column 2 Study	Column 3 Species	Column 4 Points
41.	Soil metabolism	aerobic/anaerobic	40
42.	Soil dissipation study or crop rotation study		60
43.	Soil accumulation		60
44.	Pond study (run-off)		75
45.	Aquatic degradation and persistence	aerobic	30
46.	Other		30
	ENVIRONMENTAL TOXICOLOGY		
47.	Acute oral	bird	5
48.	Sub-acute oral	bird	5
49.	Avian reproduction study		15
50.	Acute toxicity	fish	5
51.	Acute toxicity	insect	10
52.	Toxicity	insect	5
53.	Toxicity: non-target terrestrial invertebrate		20
54.	Toxicity: non-target	plant/algal inhibition test	30

SCHEDULE 2—continued

Column 1 Item	Column 2 Study	Column 3 Species	Column 4 Points
55.	Other		30
	RESIDUES		
56.	Residue Trials		50 (per trial or test)
	OTHER		
57.	Other		30

SCHEDULE 3 Subregulation 7 (2)

SUBSTANCES OR MIXTURES DECLARED NOT TO BE AGRICULTURAL CHEMICAL PRODUCTS

Column 1 Item	Column 2 Class of substance or mixture of substances
1.	Any mould inhibitor for use in the manufacture of paper, glue, plywood, carpets, or any surface coating (including paint), if: (a) the mould inhibitor is incorporated into the product during manufacture as part of the manufacturing process; and (b) the manufactured product is not claimed to have any effect as a pesticide
2.	Any fungicide, bactericide or deodorant for use in footwear and clothing
3.	Any soil ameliorant, conditioner or fertiliser if the product is not claimed to have any effect as a regulator of plant growth
4.	Any invertebrate pest management lure based on food and not containing any active constituent, and any vertebrate pest management lure
5.	Any disinfectant, mould inhibitor, air freshener or sanitiser sold by retailers, or presented or promoted primarily through retailers, to consumers for domestic use, except any sanitiser for use in swimming pools or spa water
6.	Cyanuric acid for use in swimming pools as a chlorine stabiliser

93R485, 5/1/95, 9:47 AM 93383254

SCHEDULE 3—continued

Column 1 Item	Column 2 Class of substance or mixture of substances
7.	Any cut flower preservative
8.	Any hay inoculant, silage inoculant or legume inoculant, if the product is based on bacteria or enzymes, or both
9.	Any predatory insect, predatory mite or macroscopic parasite
10.	The nematode *Deladenus siricidicola* for the control of *Sirex* species wood wasps in pine plantations
11.	Any industrial biocide used in the manufacture of paper pulp
12.	Any head lice or body lice treatment for human beings

93R485, 5/1/95, 9:47 AM 93383254

SCHEDULE 4 Regulation 45

RESTRICTED CHEMICAL PRODUCTS

Column 1 Item	Column 2 Chemical product
1.	Ethylene dibromide (also known as EDB)
2.	Chlordane
3.	Heptachlor
4.	Sodium monofluoroacetate (also known as 1080)
5.	Acrolein

SCHEDULE 5 Regulation 64

AGVET CODE OF
[NAME OF JURISDICTION]

SEARCH WARRANT UNDER SUBSECTION 133 (2)

TO *(name and address of inspector)*, an inspector within the meaning of section 3 of the Agvet Code of *[name of jurisdiction]* ("the Code"):

1. This warrant is issued on the basis that:
   (a) I am satisfied, by information on oath, that there are reasonable grounds for suspecting that there is, or may be within the next 72 hours, at the premises mentioned below, a particular thing that may be evidence of the commission of an offence against the Code; and
   (b) I have been given, either orally or by affidavit, the further information (if any) that I required about the grounds on which the issue of this warrant is being sought.

2. The nature of the offence in relation to which this warrant is issued is *(state the nature of the suspected offence)*.

3. The purpose for which this warrant is issued is set out in clause 4.

4. This warrant authorises you, with any help, and using any force, that is necessary and reasonable, * at any time of the day or night / * during the following hours of the day or night *(specify the hours)*:
   (a) to enter the premises at *(address)*; and
   (b) exercise the powers referred to in paragraphs 132 (1) (c), (d) and (e) of the Code in respect of the particular thing, namely *(specify the particular thing)*.

[NOTE: Paragraphs 132 (1) (c), (d) and (e) of the Code empower an inspector to:
"(c) search the premises for the thing; and

SCHEDULE 5—continued

(d) if the thing is found, take photographs (including video recordings) of the premises or thing, take samples of the thing, seize the thing or undertake more than one of those activities; and

(e) give any directions for, or with respect to, the detention of a thing that has been seized under paragraph (d)."]

THIS WARRANT CEASES TO HAVE EFFECT ON *(date not later than 7 days after the day of issue of the warrant).*

Issued by me *(full name and designation of magistrate).*

On *(date)*

(signature of magistrate)

* Omit whichever is inapplicable.

SCHEDULE 6 Regulations 70, 76 & 78

TABLE OF FEES AND ASSESSMENT PERIODS

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
	APPLICATION FOR REGISTRATION		
1.	Application for registration of a chemical product if: (a) one or more of the active constituents of the product have not been approved; and (b) the application is not of a kind referred to in any of items 2 to 8; and (c) the product is for use on food-producing species, or on both food-producing species and animals other than food-producing species, but is not for use solely on animals other than food-producing species	15 months	$10,000
2.	Application for registration of a chemical product, if: (a) one or more of the active constituents of the product have not been approved; and (b) the application is not of a kind referred to in any of items 3 to 8; and	The period specified for the primary application	$ 1,000

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
	(c) the product is not for use on animals other than food-producing species; and (d) the application is a secondary application		
3.	Application for registration of a chemical product, if: (a) one or more of the active constituents of the product have not been approved; and (b) the product is for use on a dog, cat or horse	15 months	$ 3,000
4.	Application for registration of a chemical product, if: (a) one or more of the active constituents of the product have not been approved; and (b) the product is for use on a dog, cat or horse; and (c) the application is a secondary application	The period specified for the primary application	$ 500

93R485, 5/1/95, 9:47 AM 93383254

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
5.	Application for registration of a chemical product, if: (a) one or more of the active constituents of the product have not been approved; and (b) the product is for use on an animal other than a food-producing species (not being a dog, cat or horse)	The modular assessment period	The modular assessment fee
6.	Application for registration of a chemical product, if: (a) one or more of the active constituents of the product have not been approved; and (b) the product is for use on an animal other than a food-producing species (not being a dog, cat or horse); and (c) the application is a secondary application	The period specified for the primary application	$ 300
7.	Application for registration of a chemical product, if: (a) one or more of the active constituents of the product have not been approved; and (b) the product is an immunobiological product	8 months	$ 2,000

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
8.	Application for registration of a chemical product, if: (a) the product is a direct-fed microbial product or an enzyme; and (b) an assessment of the efficacy of the product is required	8 months	$ 2,000
9.	Application for registration of a chemical product, if: (a) the product is a direct-fed microbial product or an enzyme; and (b) the product is for use on a food-producing species; and (c) an assessment of the efficacy of the product is not required	5 months	$ 1,000
10.	Application for registration of a chemical product, if: (a) the product is a direct-fed microbial product or an enzyme; and (b) the product is for use on a dog, cat or horse; and (c) an assessment of the efficacy of the product is not required	5 months	$ 500

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
11.	Application for registration of a chemical product, if: (a) the product is a direct-fed microbial product or an enzyme; and (b) the product is for use on a species other than a food-producing species (not being a dog, cat or horse); and (c) an assessment of the efficacy of the product is not required	5 months	$ 300
12.	Application for registration of a chemical product if: (a) the active constituents of the product have been approved; and (b) the particular combination of the active constituents has not been approved; and (c) the application is not of a kind referred to in any of items 13 to 26	8 months	$ 6,000

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
13.	Application for registration of a chemical product, if: (a) the active constituents of the product have been approved; and (b) the particular combination of the active constituents has not been approved; and (c) the application is not of a kind referred to in any of items 14 to 26; and (d) the application is a secondary application	The period specified for the primary application	$ 500
14.	Application for registration of a chemical product if: (a) the active constituents of the product have been approved; and (b) the product is to be used on a crop or food-producing species, or in a situation, in respect of which the product is not registered; and (c) there is no change in the pattern of use requiring poison schedule classification or major environmental assessment of the product	8 months	$ 6,000

93R485, 5/1/95, 9:47 AM 93383254

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
15.	Application for registration of a chemical product if: (a) the active constituents of the product have been approved; and (b) the product is to be used on a crop or food-producing species, or in a situation, in respect of which the product is not registered; and (c) there is a change in the pattern of use requiring poison schedule classification or major environmental assessment of the product	13 months	$ 6,000
16.	Application for registration of a chemical product if: (a) the active constituents of the product have been approved; and (b) the product is for use on a dog, cat or horse; and (c) the application is not of a kind referred to in item 17 or any of items 19 to 26	8 months	$ 500

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
17.	Application for registration of a chemical product if: (a) the active constituents of the product have been approved; and (b) the product is for use on a dog, cat or horse; and (c) the application is a secondary application	The period specified for the primary application	$ 300
18.	Application for registration of a chemical product if: (a) the active constituents of the product have been approved; and (b) the product is for use on an animal other than a food-producing species (not being a dog, cat or horse); and (c) a toxicology assessment of the product is required	The modular assessment period	The modular assessment fee

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
19.	Application for registration of a chemical product if: (a) the active constituents of the product have been approved; and (b) the product is for use on an animal other than a food-producing species (not being a dog, cat or horse); and (c) a toxicology assessment of the product is not required	5 months	$ 300
20.	Application for registration of a chemical product if: (a) the active constituents of the product have been approved; and (b) the product is a medicated lick or block; and (c) the product is to be assessed by a person other than a member of the staff of the NRA	8 months	$ 1,500

93R485, 5/1/95, 9:47 AM 93383254

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
21.	Application for registration of a chemical product if: (a) the active constituents of the product have been approved; and (b) the product is a medicated lick or block; and (c) the product is to be assessed by a member of the staff of the NRA	5 months	$ 800
22.	Application for registration of a chemical product if: (a) the active constituents of the product have been approved; and (b) the product is for use by a householder in the home or the home garden, or in a swimming pool or spa; and (c) the application is not of a kind referred to in any of items 23 to 27	8 months	$ 3,000

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
23.	Application for registration of a chemical product if: (a) the active constituents of the product have been approved; and (b) the product is for use by the householder in the home or the home garden, or in a swimming pool or spa; and (c) the application is not of a kind referred to in any of items 24 to 27 ; and (d) the application is a secondary application	The period specified for the primary application	$ 500
24.	Application for registration of a chemical product if: (a) the active constituents of the product have been approved; and (b) the product is closely similar to a registered chemical product; and (c) data is required to demonstrate the similarity of the product to the registered chemical product	5 months	$ 1,500

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
25.	Application for registration of a chemical product if: (a) the active constituents of the product have been approved; and (b) the product is closely similar to a registered chemical product; and (c) data is required to demonstrate the similarity of the product to the registered chemical product; and (d) residues data is required in respect of the product	The modular assessment period	$ 1,500
26.	Application for registration of a chemical product if: (a) the active constituents of the product have been approved; and (b) the product is closely similar to a registered chemical product; and (c) data is not required to demonstrate the similarity of the product to the registered chemical product	3 months	$ 500

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
27.	Application for registration of a chemical product if: (a) the product is the same as a registered chemical product; and (b) the product is to be marketed under a different brand name	3 months	$ 300
28.	Application for registration of a chemical product if: (a) the active constituents of the product have been approved; and (b) the product is an agricultural chemical product, or is for use on a food-producing species; and (c) there is to be a major formulation change to the product	8 months	$ 6,000

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
29.	Application for registration of a chemical product if: (a) the active constituents of the product have been approved; and (b) the product is for use on an animal other than a food-producing species; and (c) there is to be a major assessment of the product	8 months	$ 2,500
30.	Application for registration of a chemical product if: (a) the active constituents of the product have been approved; and (b) there is to be a formulation change to the product from a wettable powder, a suspension concentrate or a water dispersible or dry flowable granule, to another of those forms; and	3 months	$ 500

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
	(c) no assessment (other than an assessment by a member of the staff of the NRA) is required of the toxicity of the product, of the residues which result from the use of the product or of the efficacy of the product		
APPLICATION FOR APPROVAL OF AN ACTIVE CONSTITUENT			
31.	Application for approval of an active constituent	12 months	$ 3,000
APPLICATION TO VARY AN APPROVAL OR REGISTRATION			
32.	Application to vary a particular or condition of registration of a chemical product if: (a) the variation is to permit the use of the product on a crop, or in a situation, not specified in the particular or condition, or to permit a method of application substantially different from a method of application specified in the particular or condition; and	8 months	$ 5,000

93R485, 5/1/95, 9:47 AM 93383254

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
	(b) the application is not of a kind referred to in item 33		
33.	Application to vary a particular or condition of registration of a chemical product if: (a) the variation is to permit the use of the product to control a pest or disease not specified in the particular or condition, or to permit the use of the product in a jurisdiction not specified in the particular or condition; and (b) no assessment is required of the toxicity of the product or of the residues which result from the use of the product	5 months	$ 1,000

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
34.	Application to vary a particular or condition of registration of a chemical product if: (a) the product is to be used on a food-producing species or in a situation in respect of which the product is not registered; and (b) there is no change in the pattern of use requiring poison schedule classification or major additional assessment of the product of a technical nature; and (c) the product is a registered veterinary chemical product	8 months	$ 5,000

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
35.	Application to vary a particular or condition of registration of a chemical product if: (a) the product is to be used on a food-producing species or in a situation in respect of which the product is not registered; and (b) there is a change in the pattern of use requiring poison schedule classification or major additional technical assessment of the product; and (c) the product is a registered veterinary chemical product	13 months	$ 6,000
36.	Application to vary a particular or condition of registration of a chemical product if: (a) the product is an immunobiological product; and (b) the variation is to permit a change of use of the product or a formulation change to the product	5 months	$ 1,500

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
37.	Application to vary a particular or condition of registration of a chemical product if: (a) the variation is to permit a minor formulation change to the product; and (b) no assessment of the product of a technical nature is required; and (c) the application is not of a kind referred to in item 36	3 months	$ 500
38.	Application to vary a particular or condition of approval of a label to permit one or more of the following changes of an administrative nature to the label (and no other change): (a) a change to the company name or address on the label; or (b) a change to the label due to a change in the pack size; or (c) the addition of a statement about disposal of the product or container; or (d) a specific change requested in writing by the NRA	3 months	Nil

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
39.	Application to vary a particular or condition of approval of a label to permit a change of an administrative nature (other than a change referred to in item 30), including: (a) a change to the layout or wording of the label; (b) updating of the label to conform to current labelling codes	3 months	$ 300
40.	Application to vary a particular or condition of approval of a label to permit a change of a technical nature, including a change to a warning, or safety direction statement on the label	8 months	$ 1,000
41.	Application to vary a particular or condition of approval of an active constituent if the variation is to permit the active constituent to be obtained from a source from which it has not previously been obtained	8 months	$ 1500

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
	APPLICATION FOR A PERMIT		
42.	Application for a permit in respect of a chemical product or active constituent if: (a) the proposed use of the chemical product or active constituent is a minor use; and (b) no assessment of a technical nature is required	3 months	$ 300
43.	Application for a permit in respect of a chemical product or an active constituent if the proposed use of the chemical product or active constituent is an emergency use	Not applicable	Nil
44.	Application for a permit in respect of a chemical product or an active constituent if: (a) the proposed use of the chemical product or active constituent is a minor use; and (b) an assessment of a technical nature is required	The modular assessment period	The modular assessment fee

SCHEDULE 6—continued

Column 1 Item.	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
45.	Application for a permit in respect of a chemical product or an active constituent to conduct a field trial if: (a) residue evaluation is required to allow the sale of produce from plants or animals treated during the course of the trial; and (b) the active constituent, or the active constituent of the product, as the case requires, has not been approved	12 months	$ 1,000
46.	Application for a permit in respect of a chemical product or an active constituent to conduct a field trial if: (a) residue evaluation is required to allow the sale of produce from plants or animals treated during the course of the trial; and (b) the active constituent, or the active constituent of the product, as the case requires, has been approved	6 months	$ 500
47.	Application for a permit in respect of a chemical product or an active constituent to conduct experimental trials, not being an application of a kind referred to in item 45 or 46	3 months	$ 300

SCHEDULE 6—continued

Column 1 Item	Column 2 Description of Application	Column 3 Assessment Period	Column 4 Fee
48.	Application for a permit in respect of a chemical product or an active constituent to possess or supply, other than for use in Australia, an active constituent that is not an approved active constituent or a chemical product that is not a registered chemical product	Not applicable	Nil
49.	Application for a permit in respect of a chemical product or an active constituent if the application is not of a kind referred to in any of items 42 to 48	3 months	$ 300
	OTHER APPLICATIONS		
50.	Application for a trial protocol in connection with an application for approval, registration or a permit	3 months	$ 500

93R485, 5/1/95, 9:47 AM 93383254

SCHEDULE 7 Regulations 71, 72 & 77

MODULES—FEES AND ASSESSMENT PERIODS

Column 1 Item	Column 2 Module	Column 3 Assessment Period	Column 4 Fee
1.	Application[1]		$ 300
2.	Chemistry Assessment[2]	5 months	$ 500
3.	Toxicology (Full Package)[3]	15 months	$ 4,700
4.	Toxicology (Partial Package)[4]	12 months	$ 2,900
5.	Toxicology (Acute Studies only)[5]	8 months	$ 1,200
6.	Residues Assessment[6]	8 months	$ 1,200
7.	Occupational Health and Safety Assessment[7]	5 months	$ 500
8.	Environmental Assessment[8]	12 months	$ 1,500
9.	Efficacy Review (Category 1)[9]	6 months	$ 1,500
10.	Efficacy Review (Category 2)[10]	5 months	$ 1,000
11.	Efficacy Review (Category 3)[11]	5 months	$ 500
12.	Minor Use—Requiring one or more MRL's[12]	8 months	$ 300

93R485, 5/1/95, 9:47 AM 93383254

SCHEDULE 7—continued

Column 1 Item	Column 2 Module	Column 3 Assessment Period	Column 4 Fee
13.	Any other assessment	5 months	$ 300

[NOTES:

1. This module covers the administrative processes of receiving, recording, reading and handling the application.

2. This module covers an assessment of the chemical identity, properties, formulation details, manufacturing processes and methods of analysis of active and non-active constituents, impurities and the end use product.

3. This module covers an assessment of the full range of acute studies, short-term repeat dose studies, sub-chronic toxicity studies, long-term toxicity studies, reproduction studies, developmental studies, genotoxicity studies, human toxicological data, special toxicity data (for example, neurotoxicity), first aid and safety directions and any other additional data required to make a full assessment of the toxicity of the product.

4. This module covers an assessment of data additional to, and including, the data required for acute studies, but which is not as extensive as the data required for the full toxicology package.

5. This module covers an assessment of acute toxicological data including, but not limited to data on acute oral, ocular, dermal and inhalation toxicities.

6. This module covers an assessment of data showing the nature, level and safety of residues and metabolites resulting from the proposed use-pattern, and the effect of any major variables needed to determine the need for and, if necessary, the establishment of, maximum residue limits (MRLs).

7. This module covers a comprehensive assessment, undertaken by Worksafe Australia, of occupational health and safety data and issues relating to the product. It addresses all potential occupational exposure to both the active constituent and the end-use product, including any residues, within Australia.

93R485, 5/1/95, 9:47 AM 93383254

SCHEDULE 7—continued

NOTES—continued

8. This module covers an assessment, undertaken by The Environmental Protection Agency of the Commonwealth, of information provided by the applicant, together with information available from other sources, to determine, in relation to the product:

(a) the degree of environmental exposure of the product; and

(b) the toxicity of the product to aquatic organisms, terrestrial organisms, birds, and desirable vegetation, as applicable; and

(c) the overall environmental hazard constituted by the product, taking into account both exposure and toxicity.

9. This module covers an efficacy review carried out by more than one jurisdiction but with only one jurisdiction being identified as the primary reviewer. The review is carried out:

(a) on all agricultural, veterinary, industrial and household chemical products containing a new active constituent; and

(b) on chemical products with either or both of the following:

(i) new combinations of active constituents;

(ii) significant new formulations not included in a Category 2 review; and

(c) on major extensions of use of the product.

10. This module covers an efficacy review carried out by a nominated expert in one State only or by an external specialist where appropriate. The review is carried out:

(a) on agricultural chemical products if a Category 1 review is not justified (for example, an extension of use within the same food group), and on such products as swimming pool chemicals and vermin destroyers; and

(b) on veterinary chemical products:

(i) used on animals other than food-producing species—if the NRA does not have the appropriate expertise for the review; or

(ii) used on food-producing species—if a Category 1 review is not justified (for example, an extension of use on the same species or a formulation change in respect of an immunobiological product).

93R485, 5/1/95, 9:47 AM 93383254

SCHEDULE 7—continued

NOTES—continued

11. This module covers an efficacy review carried out by the NRA.

12. This module covers an assessment of an application for a permit for the use of a chemical product or for the variation of a particular or condition of registration of a chemical product if:

(a) the cost of registration (including the cost of research to provide the necessary data), of the chemical product would exceed the economic return to the manufacturer or distributor; and

(b) in the opinion of the NRA, it is necessary to establish maximum residue limits (MRLs) for the product.]

NOTE

1. Notified in the *Commonwealth of Australia Gazette* on 28 February 1995.

93R485, 5/1/95, 9:47 AM 93383254