



# **Agricultural and Veterinary Chemicals Code (Application Requirements) Instrument 2014**

made under section 8B of the Agricultural and Veterinary Chemicals Code, as scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

## **Compilation No. 2**

**Compilation date:** 18 August 2020

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## About this compilation

### **This compilation**

This is a compilation of the *Agricultural and Veterinary Chemicals Code (Application Requirements) Instrument 2014* that shows the text of the law as amended and in force on 18 August 2020 (the *compilation date*).

The notes at the end of this compilation (the *endnotes*) include information about amending laws and the amendment history of provisions of the compiled law.

### **Uncommenced amendments**

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register ([www.legislation.gov.au](http://www.legislation.gov.au)). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

### **Application, saving and transitional provisions for provisions and amendments**

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

### **Modifications**

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

### **Self-repealing provisions**

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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## Part 1—Preliminary

### 1 Name of Instrument

This Instrument is the *Agricultural and Veterinary Chemicals Code (Application Requirements) Instrument 2014*.

### 2 Commencement

This Instrument commences on the commencement of Schedule 1 to the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*.

### 3 Definitions

- (1) Unless the contrary intention appears:
  - (a) words and expressions that are used in the Code have the same meaning in this Instrument; and
  - (b) words and expressions that are used in the Regulations have the same meaning in this Instrument.
- (2) In this Instrument:

*ACN* has the same meaning as in the Corporations Act 2001.

***applicant declaration*** means a declaration, made by or on behalf of the applicant, that the information contained in, and accompanying, an application is complete and correct (except that if the particular approved form for the application sets out an alternative form of words for the declaration, the declaration is to use that form of words). If the holder or the proposed holder of an approval or registration is not a resident of, and does not carry on business in, Australia, the declaration must be made on behalf of the applicant by an approved person or nominated agent who is a resident of, or carries on business in, Australia.

***applicant details*** means the following information:

- (a) the name of the applicant;
- (b) if the applicant has an ACN – the ACN;
- (c) if the applicant is an overseas company and has a number equivalent to an ACN – that number;
- (d) if the applicant is not an individual – the name of an individual whom the APVMA may contact in relation to the application;
- (e) the telephone number of the applicant;
- (f) the facsimile number of the applicant;
- (g) the street address of the applicant;
- (h) the postal address of the applicant.
- (i) the email address of the applicant.

**CAS number** means a number assigned by the Chemical Abstracts Service, a division of the American Chemical Society. **chemical abstracts name** means a name assigned by the Chemical Abstracts Service, a division of the American Chemical Society.

**Code** means the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

**constituent standard** means any standard (however described) applicable to an active constituent, including feed standards, manufacturer standards, pharmacopoeial standards and standards made under section 6E of the Code.

**formulation information**: see section 4.

**IUPAC name** means a name assigned by the International Union of Pure and Applied Chemistry.

**Regulations** means the *Agricultural and Veterinary Chemicals Code Regulations 1995*.

**safety criteria information**: see section 5.

**Standard for the Uniform Scheduling of Medicines and Poisons** means Schedule 1 to the Poisons Standard, as in force at the time this Instrument is made.

#### 4 Formulation information

- (1) The following information is the formulation information in relation to a chemical product:
  - (a) for each active or other constituent in relation to the chemical product:
    - (i) the name of the constituent; and
    - (ii) the CAS number of the constituent; and
    - (iii) the applicable constituent standard (if any); and
    - (iv) the concentration of the constituent; and
    - (v) the purpose of the constituent in the formulation of the product;
  - (b) the total weight or volume of the product (as applicable);
  - (c) if the product is a liquid –the specific gravity of the product;
  - (d) the formulation type of the product;
  - (e) whether the product contains any ingredients that have a risk of transmitting agents of animal spongiform encephalopathies;
  - (f) whether the product contains any genetically modified organism or any product derived from a genetically modified organism;
  - (g) whether the product contains any ingredients intentionally engineered to be less than 100 nanometres in one or more dimensions and, if so, those ingredients.

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- (2) Where this Instrument requires an application to contain, or be accompanied by, formulation information:
- (a) the information need not be provided by the applicant (for example, it may be provided by a manufacturer of the product); and
  - (b) the person providing the information must state the persons, if any, to whom the information may be disclosed; and
  - (c) the information must be accompanied by a declaration, signed by the person providing the information, that the information is complete and correct.

## 5 Safety criteria information

- (1) For an active constituent, safety criteria information means information relevant to whether the constituent would meet the safety criteria. Where this Instrument requires the provision of safety criteria information, the requirement includes the provision of the following information:
- (a) information about the toxicity of the constituent and its residues, including metabolites and degradation products, in relation to relevant organisms and ecosystems, including human beings;
  - (b) the method by which the constituent is, or is proposed to be, manufactured;
  - (c) information about the extent to which the constituent will contain impurities;
  - (d) whether an analysis of the chemical composition of the constituent has been carried out and, if so, the results of the analysis.
- (2) For a chemical product, safety criteria information means information relevant to whether the product would meet the safety criteria. Where this Instrument requires the provision of safety criteria information, the requirement includes the provision of the following information:
- (a) information about the toxicity of the chemical product and its residues, including metabolites and degradation products, in relation to relevant organisms and ecosystems, including human beings;
  - (b) the relevant poison classification of the product under the law in force in this jurisdiction;
  - (c) the method of analysis (if any) of the chemical composition and form of the constituents of the chemical product;
  - (d) if paragraph 8AB(1)(b) of the Regulations applies – information about whether each step in the manufacture of the product complies, or will comply, with the manufacturing principles and the Australian GMP Code;
  - (e) if paragraph 8AB(1)(c) of the Regulations applies – information about whether each step in the manufacture of the product complies, or will comply, with a standard that the APVMA has determined for the purposes of that paragraph;

Note: Paragraphs 8AB(1)(b) and (c) of the Regulations do not apply in the circumstances set out in subregulation 8AB(2) (for example, when the product is an exempt product pursuant to regulation 59).

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- (f) for a molluscicide in the form of a bait and of which the active constituent is metaldehyde, information about:
  - (i) whether the product contains sufficient green pigment or dye to colour the bait a distinctive green colour; and
  - (ii) whether the product contains, in the bait, any bone meal or other product of animal origin;
- (g) for a molluscicide in the form of a bait and of which the active constituent is methiocarb, information about:
  - (i) whether the product contains sufficient blue pigment or dye to colour the bait a distinctive blue colour; and
  - (ii) whether the product contains, in the bait, any bone meal or other product of animal origin;
- (h) for a product to be applied to seeds to be stored before planting or sowing – information about whether the product contains sufficient pigment or dye to colour the seed to enable the seed to be readily distinguished from seed to which the product has not been applied;
  - (i) whether any trials or laboratory experiments have been carried out to determine the residues of the product and, if so, the results of those trials or experiments and whether those results show that the residues of the product will not be greater than limits that the APVMA has approved or approves;
- (j) unless the application is for a research permit—information about:
  - (i) the stability of the product; and
  - (ii) the specifications for containers for the product.

## Part 2—Active constituents – applications for approval or variation

### 6 Information in the application

- (1) An application for approval of an active constituent for a proposed or existing chemical product, or to vary the particulars or conditions of an approved active constituent, must contain the following information:
  - (a) the following names of the constituent:
    - (i) the common name;
    - (ii) the IUPAC name (if applicable);
    - (iii) the chemical abstracts name (if applicable);
  - (b) the CAS number of the constituent (if applicable);
  - (c) the minimum purity or constituent standard of the constituent;
  - (d) whether the application relates to a not previously endorsed active constituent or a new manufacturer or site of manufacture for an active constituent, or is to vary the particulars or conditions of an approved active constituent;
  - (e) whether the active constituent is for use in:
    - (i) agricultural chemical products only; or

- (ii) veterinary chemical products only; or
  - (iii) agricultural and veterinary chemical products;
  - (f) if the application is a timeshift application (which may include an international joint review or workshare arrangement);  
Note: A timeshift application must include a project plan: see regulation 8AG of the Regulations.
  - (g) whether the active constituent contains any ingredients intentionally engineered to be less than 100 nanometres in one or more dimensions;
  - (h) whether the constituent is a genetically modified organism or is manufactured using genetically modified materials;
  - (i) the following information about the manufacturer of the constituent:
    - (i) the manufacturer's name;
    - (ii) if the manufacturer has an ACN – the ACN;
    - (iii) if the manufacturer is an overseas company and has a number equivalent to an ACN – that number;
    - (iv) the name and street address of the site at which the active constituent is manufactured;
    - (v) the country in which the active constituent is manufactured;
  - (j) the applicant details;
  - (k) the applicant declaration;
  - (l) whether the applicant considers that there is information, the use of which is limited by the Code, that can be used by the APVMA in determining the application, and if so, the nature of that information;
  - (m) whether that information can be used by the APVMA pursuant to consent or agreement (for example, the consent of the relevant authorising party).
- (2) If there is consent or agreement for the purposes of paragraph (1)(m), the application must be accompanied by the written consent or agreement for the use of the information by the APVMA.

## 7 Safety criteria

The application must contain, or be accompanied by, the safety criteria information.

## 8 Other information

- (1) The application must contain, or be accompanied by, a short description of each item of information contained in, or accompanying, the application.  
Note: This short description is commonly known as a data list.
- (2) Unless the application is to vary the particulars or conditions of an approved active constituent, the application must contain, or be accompanied by, information about any approvals (or similar) of the active constituent, or chemical products containing the active constituent, in overseas countries, where those details are known to the applicant.

- (3) If the active constituent:
  - (a) is a genetically modified organism or is manufactured using genetically modified materials; or
  - (b) contains any ingredients intentionally engineered to be less than 100 nanometres in one or more dimensions;  
the application must contain, or be accompanied by, details of that matter.
- (4) For an application for approval of an active constituent, if the applicant is not a resident of, and does not carry on business in, Australia, the application must contain, or be accompanied by, an application under section 8M of the Code.

## **Part 3—Chemical products – applications for registration and label approval**

### **Division 1—General information**

#### **9 Basic information**

- (1) An application for the registration of a chemical product and the approval of a label for that product, or an application only for the approval of a label for a chemical product, must contain the following information:
  - (a) the name of the chemical product;
  - (b) if the application is a timeshift application (which may include an international joint review or workshare arrangement);  

Note: A timeshift application must include a project plan: see regulation 8AG of the Regulations.
  - (c) the applicant details;
  - (d) the applicant declaration;
  - (e) whether the applicant considers that there is information, the use of which is limited by the Code, that can be used by the APVMA in determining the application, and if so, the nature of that information;
  - (f) whether that information can be used by the APVMA pursuant to consent or agreement (for example, the consent of the relevant authorising party).
- (2) If there is consent or agreement for the purposes of paragraph (1)(f), the application must be accompanied by the written consent or agreement for the use of the information by the APVMA.
- (3) If the applicant is not a resident of, and does not carry on business in, Australia, the application must contain, or be accompanied by, an application under section 8M of the Code (for a person to be a nominated agent).

#### **10 Label**

The application must contain, or be accompanied by, the following information:

- (a) the particulars prescribed for paragraph 21(a) of the Code that are appropriate to be stated on the label;
- (b) any instructions proposed to be stated on the label;
- (c) any information required by regulation 18E of the Regulations to be stated on the label.

## **Division 2—Technical information**

### **11 Application of Division**

- (1) This Division does not apply if:
  - (a) the application is for the registration of a chemical product that contains an approved active constituent; and
  - (b) the chemical product is the same as a registered chemical product; and
  - (c) the chemical product is to be registered with a different name.

Note: Division 4 will apply to such applications.

- (2) This Division does not apply if the application is for registration of a listed chemical product and approval of a label where the product and label comply with an established standard made under section 8U of the Code.

Note: Division 5 will apply to such applications.

- (3) This Division does not apply if the application is only for the approval of a label.

### **12 General technical information**

- (1) The application must contain the following information:
  - (a) for each active constituent of the product:
    - (i) the name of the constituent; and
    - (ii) if the active constituent has been approved – its distinguishing number; and
    - (iii) the name of the manufacturer of the constituent and the street address of the site at which it is manufactured;
  - (b) the following information about each manufacturer of the product:
    - (i) the name of the manufacturer (if the manufacturer is a company, the company's name);
    - (ii) if the manufacturer has an ACN – the ACN;
    - (iii) if the manufacturer is an overseas company and has a number equivalent to an ACN – that number;
    - (iv) the street address of each site at which steps in the manufacturing process are undertaken by the manufacturer;
    - (v) the steps in the manufacturing process which take place at that site;
  - (c) if the product is a veterinary chemical product—the licence number of each person who performs a step in the manufacture of the product in Australia;

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- (d) if the product is a veterinary chemical product—the name, street address and licence number (for facilities in Australia) of the person who performs release for supply of the product, whether the manufacture of the product occurs in Australia or overseas;
- (e) the following information about the containers of the product:
  - (i) the proposed size of the containers;
  - (ii) a description of the containers, including an explanation of the extent to which the containers are in direct contact with the product;
  - (iii) the method by which the approved label will be attached to the containers; and
  - (iv) details of the presentation of the product;
- (f) the proposed shelf life expiry period for the product (if applicable);
- (g) the proposed in-use shelf life for the product (if applicable);
- (h) the proposed storage conditions for the product;
- (i) if the product is a veterinary immunobiological product – for each of the product’s active constituents:
  - (i) its common name and reference; and
  - (ii) its source or history of isolation; and
  - (iii) its identity (strain, genus, species and serotype or biotype); and
  - (iv) its unique identifier or descriptor; and
  - (v) its master seed code and passage level; and
  - (vi) its working seed code and passage level.

### 13 Formulation information

The application must contain, or be accompanied by, the formulation information in relation to the chemical product.

### 14 Overseas manufacturers

- (1) For a veterinary chemical product, the application must contain, or be accompanied by, 1 or more of the following in relation to each person who performs a step in the manufacture of the product outside Australia:
  - (a) an original or notarised certificate of good manufacturing practice, issued by an authority recognised by the APVMA, that the performance of that step complies with the manufacturing principles or a comparable good manufacturing practice code;
  - (b) an original or notarised copy of an audit report on good manufacturing practice from an auditor from an authority recognised by the APVMA, and evidence that any identified non-conformances have been addressed and that the person’s facility complies with the manufacturing principles or a comparable good manufacturing practice code;
  - (c) other evidence demonstrating the person’s good manufacturing practice.

- (2) A document referred to in paragraph (1)(a) or (b) may be provided electronically, but if it is, the applicant must retain a hard copy of the document for provision upon the APVMA's request.

### **15 Information accompanying the application – other**

- (1) The application must contain, or be accompanied by, a short description of each item of information contained in, or accompanying, the application.

Note: This short description is commonly known as a data list.

- (2) The application must also contain, or be accompanied by, an estimate of the volume of the chemical product expected to be manufactured in the first 2 years of the registration sought.
- (3) The application must contain, or be accompanied by, information about any registrations (or similar) of the chemical product in overseas countries, where those details are known to the applicant.
- (4) For a veterinary chemical product—if there is an approved active constituent for the product, the application must contain, or be accompanied by:
- (a) the distinguishing number for the active constituent (if known to the applicant); and
  - (b) the relevant standards or specifications for the active constituent; and
  - (c) the results of an analysis of a batch of the active constituent performed no more than 2 years before the date of the application.
- (5) If the chemical product is a veterinary chemical product and contains ingredients of a biological origin that have been, or are to be, imported into Australia, the application must contain, or be accompanied by, a copy of the relevant permits (or similar) for the importation of the product for the purposes of the *Quarantine Act 1908* or a copy of any applications for such permits.

## **Division 3—Supporting technical data**

### **16 Application of Division**

- (1) This Division does not apply if:
- (a) the application is for the registration of a chemical product that contains an approved active constituent; and
  - (b) the chemical product is the same as a registered chemical product; and
  - (c) the chemical product is to be registered with a different name.

Note: Division 4 will apply to such applications.

- (2) This Division does not apply if the application is for registration of a listed chemical product and approval of a label where the product and label comply with an established standard made under section 8U of the Code.

Note: Division 5 will apply to such applications.

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- (3) This Division does not apply if the application is only for the approval of a label.

### 17 Safety criteria

The application must contain, or be accompanied by, the safety criteria information.

### 18 Efficacy criteria

- (1) The application must contain, or be accompanied by, information relevant to whether the chemical product meets the efficacy criteria.
- (2) The application must contain, or be accompanied by, the results of any trials or laboratory experiments that have been carried out to determine the efficacy of the product, but only if the APVMA is required by subsection 5B(2) of the Code to have regard to that matter.

### 19 Trade criteria

- (1) The application must contain, or be accompanied by information relevant to whether the chemical product meets the trade criteria.
- (2) The application must also contain, or be accompanied by:
  - (a) information to enable the APVMA to identify any potential risks to Australia's export trade associated with the use of a chemical product; and
  - (b) proposals to mitigate any identified export trade risks; and
  - (c) information to demonstrate that when the chemical product is used as proposed and relevant residue-management strategies are followed, residues in exported commodities will not unduly prejudice trade or commerce between Australia and places outside Australia.

## Division 4—Repacked products

### 20 Application of Division

This Division applies to an application for the registration of a chemical product and the approval of a label for the product if:

- (a) the relevant chemical product (the repacked product) contains an approved active constituent; and
- (b) the chemical product is the same as a registered chemical product (the original product); and
- (c) the repacked product is to be registered with a different name.

### 21 Information in the application

The application must contain the following information:

- (a) the name of the repacked product;

- (b) the name and distinguishing number of the original product that is the same as the repacked product.

Note: Section 10 also requires information about the repacked product's label.

## 22 Manufacturer's declaration

The application must contain, or be accompanied by, a declaration by or on behalf of each manufacturer for the product, to the effect that, as between the original product and the repacked product:

- (a) the sites of manufacture will be the same (including that the equipment used will be the same); and
- (b) the formulation information will be the same (the same ingredients of the same standards at the same concentrations); and
- (c) the manufacturing processes will be the same (including quality assurance and test procedures); and
- (d) the formulation type or dose form, physico-chemical properties (including pH, particle size, crystal form and, where applicable, dissolution profile, payout rate and payout period), and product specifications (release and expiry limits and test methods) will be the same; and
- (e) the containers will be the same (including packaging materials and closure systems) and that there is no additional pack size.

## 23 Additional declaration

The application must contain, or be accompanied by, a declaration that the use pattern (including host crop or animal species, application or dose rates, application method or route of administration, and withholding periods), label claims and use instructions (including precautionary or safety instructions) for the repacked product are all the same as those of the original product.

## Division 5—Listed chemical products

### 24 Application of Division

This Division applies to an application for registration of a listed chemical product and approval of a product label where the product and label comply with an established standard made under section 8U of the Code.

### 25 Information required

The following information must be contained in the application:

- (a) the established standard with which the applicant seeks to demonstrate that the product complies;
- (b) for each active or other constituent of the product:
  - (i) the name of the constituent; and
  - (ii) the CAS number of the constituent; and

- (iii) the relevant constituent standard; and
- (iv) the concentration of the constituent; and
- (v) the purpose of the constituent in the formulation of the product;
- (c) the following information about each manufacturer of the product:
  - (i) the name of the manufacturer (if the manufacturer is a company, the company's name);
  - (ii) if the manufacturer has an ACN – the ACN;
  - (iii) if the manufacturer is an overseas company and has a number equivalent to an ACN – that number;
  - (iv) the street address of each site at which steps in the manufacturing process are undertaken by the manufacturer;
  - (v) the steps in the manufacturing process which take place at that site.

## **Part 4—Variation applications – registered chemical products and approved labels**

### **26 Application of this Part**

This Part applies to an application to vary the relevant particulars or conditions of the registration of a chemical product or the approval of a label, except if the application is made under section 26B of the Code.

### **Division 1—Information generally required**

#### **27 Information in the application – general**

- (1) The application must contain the following information:
  - (a) the name of the registered chemical product to which the application relates and its distinguishing number;
  - (b) if the application seeks to change the name of the product – the proposed name;
  - (c) the distinguishing number for the existing approved label and the pack size;
  - (d) a statement of the purpose of the application and a description of the use of the chemical product;
  - (e) the applicant details;
  - (f) the applicant declaration;
  - (g) whether the applicant considers that there is information, the use of which is limited by the Code, that can be used by the APVMA in determining the application, and if so, the nature of that information;
  - (h) whether that information can be used by the APVMA pursuant to consent or agreement (for example, the consent of the relevant authorising party);
  - (i) the following information about each manufacturer of the product, to the extent that the proposed variation would affect the information, or if there is a new manufacturer:

- (i) the name of the manufacturer (if the manufacturer is a company, the company's name);
  - (ii) if the manufacturer has an ACN – the ACN;
  - (iii) if the manufacturer is an overseas company and has a number equivalent to an ACN – that number;
  - (iv) the street address of each site at which steps in the manufacturing process are undertaken by the manufacturer;
  - (v) the steps in the manufacturing process which take place at that site;
  - (j) for a veterinary chemical product – the name, street address and licence number of the person who performs release for supply of the product;
  - (k) for a veterinary chemical product – the licence number of each person who performs a step in the manufacture of the product in Australia;
  - (l) if the application is of a kind that requires the provision of data or a technical assessment – for each active constituent of the product:
    - (i) the name of the constituent; and
    - (ii) if the active constituent has been approved – its distinguishing number; and
    - (iii) the name of the manufacturer of the constituent and the street address of the site at which it is manufactured;
  - (m) the following information about the containers of the product, but only if those details would change in accordance with the variation proposed:
    - (i) the proposed size of the containers;
    - (ii) a description of the containers, including an explanation of the extent to which the containers are in direct contact with the product;
    - (iii) the method by which the approved label will be attached to the containers;
    - (iv) details of the presentation of the product;
  - (n) the proposed shelf life expiry period for the product (if applicable, and only if that period would change in accordance with the variation proposed);
  - (o) the proposed in-use shelf life for the product (if applicable, and only if the shelf life would change in accordance with the variation proposed);
  - (p) the proposed storage conditions for the product, but only if those conditions would change in accordance with the variation proposed;
  - (q) if the variation affects an approved label – the distinguishing number for the approved label, the pack size, and a statement as to whether the applicant seeks for the approval to be cancelled and the reason why the applicant seeks for the approval to be cancelled.
- (2) If there is consent or agreement for the purposes of paragraph (1)(h), the application must contain, or be accompanied by, the written consent or agreement for the use of the information by the APVMA.

## 28 Formulation information

If the variation proposed in the application affects the formulation of the chemical product, the application must contain, or be accompanied by, the formulation information in relation to the chemical product.

## 29 Overseas manufacturers

For a veterinary chemical product the manufacturers of which would change if the particulars or conditions are varied in accordance with the application, the application must, for each person who manufactures the chemical product outside Australia, contain or be accompanied by 1 or more of the following:

- (a) an original or notarised certificate of good manufacturing practice, issued by an authority recognised by the APVMA, that all steps of the manufacture undertaken at that site comply with the manufacturing principles or a comparable good manufacturing practice code;
  - (b) an original or notarised copy of an audit report on good manufacturing practice from an auditor from an authority recognised by the APVMA, and evidence that any identified non-conformances have been addressed and that the person's facility complies with the manufacturing principles or a comparable good manufacturing practice code;
  - (c) other evidence demonstrating the person's good manufacturing practice.
- (2) A document referred to in paragraph (1)(a) or (b) may be provided electronically, but if it is, the applicant must retain a hard copy of the document for provision upon the APVMA's request.

## 30 Other information

- (1) If the application is of a kind that requires the provision of data, the application must contain, or be accompanied by, a short description of each item of information contained in, or accompanying, the application.  
Note: This short description is commonly known as a data list.
- (2) If the application proposes a new kind of use for the chemical product, the application must contain, or be accompanied by, an estimate of the volume of the chemical product expected to be manufactured in the first 2 years of that use.
- (3) The application must contain, or be accompanied by, information about any approvals (or similar) of the chemical product in overseas countries, where those details are known to the applicant.
- (4) If the chemical product is a veterinary chemical product and contains ingredients of a biological origin that have been, or are to be, imported into Australia, the application must contain, or be accompanied by, a copy of the relevant permits (or similar) for the importation of the product for the purposes of the *Quarantine Act 1908* or a copy of any applications for such permits.

### **31 Label**

- (1) If the variation proposed affects an approved label, the application must contain, or be accompanied by, the following information to the extent that the information is affected by the variation:
  - (a) the particulars prescribed for paragraph 21(a) of the Code that are appropriate to be stated on the label; and
  - (b) any instructions proposed to be stated on the label;
  - (c) any information required by regulation 18E of the Regulations to be stated on the label.
- (2) The information must be presented in a way that shows how the variation affects the information (for example, all additions and deletions must be clearly identified).

## **Division 2—Additional data when full assessment required**

### **32 Application of Division**

This Division applies to an application where a full assessment of the relevant chemical product is required.

### **33 Active constituent information**

For a veterinary chemical product, if there is an approved active constituent for the product, the application must contain, or be accompanied by:

- (a) the distinguishing number for the constituent (if known to the applicant); and
- (b) the relevant standards or specifications for the constituent; and
- (c) the results of an analysis of a batch of the constituent performed no more than 2 years before the date of the application.

### **34 Safety criteria**

The application must contain, or be accompanied by, the safety criteria information, but only to the extent that the variation proposed affects whether the product would meet the safety criteria.

### **35 Efficacy criteria**

- (1) The application must contain, or be accompanied by, information relevant to whether the chemical product meets the efficacy criteria, but only to the extent that the variation proposed affects whether the product meets the efficacy criteria.
- (2) The application must contain, or be accompanied by, the results of any trials or laboratory experiments that have been carried out to determine the efficacy of the product, but only if the APVMA is required by subsection 5B(2) of the Code to

have regard to that matter and only if the variation proposed affects whether the product meets the efficacy criteria.

## Part 4A—Requirements for applications for prescribed variations

### 35A Application of this Part

This Part applies to applications for one or more prescribed variations of the relevant particulars of an approval or registration made under section 26B of the Code.

### 35B Application requirements for prescribed variations

- (1) This section specifies, for subsection 8B(1) of the Code, that an application for a prescribed variation of the kind set out in item 2 of the table in the *Agricultural and Veterinary Chemicals Code Act (Prescribed Variations) Instrument 2019* must include a statement that the applicant holds:
  - (a) evidence that each secondary step in the manufacture of the chemical product by the manufacturer at the site of manufacture conforms to a standard that the APVMA has determined is comparable to the manufacturing principles and the Australian GMP Code
- (2) This section specifies, for subsection 8B(1) of the Code, that an application for a prescribed variation of the kind set out in item 3 of the table in the *Agricultural and Veterinary Chemicals Code Act (Prescribed Variations) Instrument 2019* must include a statement that the applicant holds:
  - (a) evidence that at the time of the holder's application, the site of manufacture is entered in the Register as a site for another chemical product of the holder, and the manufacturer conducts the same steps of manufacture in relation to the other chemical product; and
  - (b) evidence that each primary step in the manufacture of the chemical product by the manufacturer at the site of manufacture conforms to a standard that the APVMA has determined is comparable to the manufacturing principles and the Australian GMP Code
- (3) This section specifies, for subsection 8B(1) of the Code, that an application for a prescribed variation of the kind set out in item 4 of the table in the *Agricultural and Veterinary Chemicals Code Act (Prescribed Variations) Instrument 2019* must include a statement that the applicant holds:
  - (a) evidence that the physical properties and storage stability of the product, as varied and relevant to the product's formulation type or dosage form, are the same as the product's existing physical properties and storage stability, when measured using the same methodology used for the product before being varied; and

- (b) if the application relates to a veterinary chemical product—the following evidence about the product, as varied:
  - (i) a dissolution profile (if relevant) of at least 2 pilot scale batches that is comparable to the formulation of the product immediately before the application is made;
  - (ii) at least 3 consecutive months of data on the storage stability of the product.

## **Part 5—Permit applications**

### **36 Application of this Part**

This Part applies to an application for a permit or the extension of a permit.

### **Division 1—General information**

#### **37 Information in the application – general**

- (1) The following information must be contained in the application:
  - (a) whether the application is for a permit in respect of an active constituent or for a permit in respect of a chemical product;
  - (b) the applicant details;
  - (c) the applicant declaration;
  - (d) if the permit is in respect of a chemical product – the name of the product;
  - (e) whether paragraph 112(4)(b) of the Code applies in relation to any of the persons mentioned in subparagraphs 112(4)(b)(i) to (iii).
- (2) However, if the application is for a permit to do, or omit to do, any thing which would, apart from the permit, be an offence against subsection 121(4A) or (5A) of the Code or a contravention of the civil penalty provision set out in subsection 121(4) or (5) of the Code, the application must contain the following information:
  - (a) the applicant details;
  - (b) the applicant declaration;
  - (c) whether paragraph 112(4)(b) of the Code applies in relation to any of the persons mentioned in subparagraphs 112(4)(b)(i) to (iii);
  - (d) the particulars of any relevant licence issued to the applicant under the Code;
  - (e) the steps in the manufacturing process to be carried out pursuant to the permit;
  - (f) the street address of each premises at which those steps will be carried out;
  - (g) the duration of the permit sought and the day on which the applicant seeks to have the permit commence;

## Part 5 Permit applications

**Division 2** Export permits – non-approved or non-registered constituents or products where no technical data required

### Item 38

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- (h) a statement of the exceptional circumstances that the applicant claims justify issuing the permit;
- (i) if the applicant holds a relevant licence issued under the Code—a statement of the extent to which the steps in the manufacturing process to be carried out pursuant to the permit would be undertaken consistently with the conditions of the licence;
- (j) the types of products manufactured at the primary, secondary and tertiary premises (see paragraphs 57(d), (e) and (f));
- (k) evidence of how the applicant will comply with the manufacturing principles (made under section 23 of the *Agricultural and Veterinary Chemicals Act 1994*);
- (l) nominations of a person to be responsible for production, and a person to be responsible for quality control, pursuant to the permit, and in each case information about their qualifications and experience.

## **Division 2—Export permits – non-approved or non-registered constituents or products where no technical data required**

### **38 Application of this Division**

This Division applies to an application where the relevant permit is 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, where no data of a technical nature is required.

### **39 Information in the application – general**

The following information must be contained in the application:

- (a) whether the permit is to export 1 active constituent or chemical product or multiple active constituents or chemical products;
- (b) declarations (using the words set out in the relevant approved form) as to whether:
  - (i) the permit is for a single export; and
  - (ii) the applicant manufactures agricultural or veterinary active constituents or chemical products for export on an ongoing basis; and
  - (iii) if the application is for a permit in respect of an active constituent – the active constituent is not an approved active constituent; and
  - (iv) if the application is for a permit in respect of a chemical product – the chemical product is not a registered chemical product;
- (c) a declaration that the manufacture, possession or export of the active constituent or chemical product would not contravene:
  - (i) the *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade*; or

- (ii) the *Stockholm Convention on Persistent Organic Pollutants (POPs)*.

#### **40 Information for active constituents**

If the application relates to an active constituent, the application must contain, or be accompanied by, the following information:

- (a) the name of the relevant chemical product for the active constituent;
- (b) the following names of the constituent:
  - (i) the common name;
  - (ii) the IUPAC name (if applicable);
  - (iii) the chemical abstracts name (if applicable);
- (c) the CAS number of the constituent (if applicable);
- (d) the minimum purity or pharmacopoeial standard of the constituent;
- (e) the following information about the manufacturer of the constituent:
  - (i) the manufacturer's name;
  - (ii) if the manufacturer has an ACN—the ACN;
  - (iii) if the manufacturer is an overseas company and has a number equivalent to an ACN—that number;
  - (iv) the name and street address of the site at which the active constituent is manufactured;
  - (v) the country in which the active constituent is manufactured.

#### **41 Information for chemical products**

If the application relates to a chemical product, the application must contain, or be accompanied by, the following information:

- (a) the name of the chemical product;
- (b) the following information about each manufacturer of the product:
  - (i) the name of the manufacturer (if the manufacturer is a company, the company's name);
  - (ii) if the manufacturer has an ACN – the ACN;
  - (iii) if the manufacturer is an overseas company and has a number equivalent to an ACN – that number;
  - (iv) the street address of each site at which steps in the manufacturing process are undertaken by the manufacturer;
  - (v) the steps in the manufacturing process which take place at that site;
- (c) the name of each active constituent of the product;
- (d) if the product is a veterinary immunobiological product – for each of the product's active constituents:
  - (i) its common name and reference; and
  - (ii) its source or history of isolation; and
  - (iii) its identity (strain, genus, species and serotype or biotype); and

## Part 5 Permit applications

### Division 3 Application covered by a previous assessment – no technical data required

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- (iv) its unique identifier or descriptor; and
- (v) its master seed code and passage level; and
- (vi) its working seed code and passage level;
- (e) the formulation information for the product;
- (f) if the chemical product is a veterinary chemical product and contains ingredients of a biological origin that have been, or are to be, imported into Australia—a copy of the relevant permits (or similar) for the importation of the product for the purposes of the *Quarantine Act 1908* or a copy of any applications for such permits.

#### 42 Label

If the application is in respect of a chemical product, the application must contain, or be accompanied by, a copy of the label for the product.

### Division 3—Application covered by a previous assessment – no technical data required

#### 43 Application of this Division

This Division applies to an application for which there is a previous assessment that remains valid and no data of a technical nature is required.

#### 44 Information in the application – general

The following information must be contained in the application:

- (a) the distinguishing number for the relevant existing or previous permit;
- (b) a statement of the reasons why the applicant seeks a permit or the extension of an existing permit;
- (c) the period for which the applicant seeks a permit or the extension of an existing permit.

### Division 4—Application for a permit (minor or emergency use)

#### 45 Application of this Division

This Division applies to an application in respect of a chemical product, where the applicant proposes that the use pursuant to the permit would be a minor use or an emergency use.

#### 46 Information in the application – general

The following information must be contained in the application:

- (a) the following information, to the extent that the information is applicable to the chemical product and the proposed use:
  - (i) the name of the product;

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- (ii) the active constituents for the product and their weight or volume;
  - (iii) the crop, animal or situation for which the product is to be used;
  - (iv) if the product is to be used on a crop—whether the crop is grown in a field, undercover, or both;
  - (v) the disease, pest or other purpose for which the product is intended (both common and scientific names);
  - (vi) information about when, and how much of, the product is administered (including, where applicable, spray rate or dosage rate, frequency, duration and volume);
  - (vii) the wetters or other proposed additives or mixtures to be added to the product, and their volume;
  - (viii) the end users of the product, identified as ‘persons generally’ or specified persons or classes of persons;
  - (ix) the timing for the product’s application (for example, the phase of growth of the crop at which the product is applied);
  - (x) the maximum number of applications of the product per crop or animal and season or year;
  - (xi) the minimum interval between applications of the product to the crop or animal;
  - (xii) the method of application of the product (including, for veterinary chemical products, the route of administration);
  - (xiii) an estimate of the extent to which the product will be used (for example, the number of hectares or tonnage of produce or the number of animals);
  - (xiv) the equipment used to apply the product;
  - (xv) the time between the last application of the product and the harvest of the relevant crop or grazing and cutting for livestock, the slaughter or milking of the relevant animal, the collection of eggs or honey, or the harvesting of wool or fibre;
  - (xvi) any other information regarding special precautions or critical use for the product;
- (c) a statement of the reasons why the proposed use of the chemical product is a minor or emergency use, including an explanation of why no currently registered chemical product would be suitable or effective for that use;
  - (d) the first date of the proposed use of the product, the annual timing of the proposed use and the proposed duration of the permit;
  - (e) the States and Territories in which the proposed use would occur or, if the use would only be in one location, that location;
  - (f) for a veterinary chemical product manufactured pursuant to a licence issued under the Code—the number given to that licence by the APVMA;
  - (g) if an application has been made for the registration of the product—a statement as to why the applicant needs a permit before the application is determined;

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### Division 4 Application for a permit (minor or emergency use)

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- (h) if no application has been made for the registration of the product—a statement as to why no application has been made.

#### 47 Registered chemical products

If the chemical product is a registered chemical product, the application must contain, or be accompanied by, the following information:

- (a) whether the rate and method of application is similar to the rate and method approved for other purposes in respect of the product and, if not, an explanation as to how the proposed use for the product will not pose unacceptable risks to persons or the environment;
- (b) the details of any Australian efficacy or safety trials or studies that have been conducted;
- (c) whether the product has been registered (or similar) in countries other than Australia in relation to the proposed use and, if so, the name of the countries and, if available, copies of the relevant labels for the product;
- (d) in relation to each holder of the registration under the Code:
  - (i) whether the holder is aware of the application; and
  - (ii) any data provided by the holder that would support the application;
- (e) safety criteria information for the product and information relevant to whether the product would meet the efficacy criteria.

#### 48 Unregistered chemical products

- (1) If the chemical product is not a registered chemical product, the application must contain, or be accompanied by, the following information:
  - (a) whether the product has been registered (or similar) in countries other than Australia in relation to the proposed use and, if so, the name of the countries and, if available, copies of the relevant labels for the product;
  - (b) in relation to each manufacturer of the product in Australia:
    - (i) whether the manufacturer is aware of the application; and
    - (ii) any data provided by the manufacturer that would support the application;
  - (c) the formulation information for the product;
  - (d) if the product is imported into Australia – details of the importation and evidence of any consent provided by the APVMA for the purposes of subsection 69B(1B) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*;
  - (e) the name and address of each supplier of the chemical product;
  - (f) the following information about each manufacturer of the product:
    - (i) the name of the manufacturer (if the manufacturer is a company, the company's name);
    - (ii) if the manufacturer has an ACN – the ACN;
    - (iii) if the manufacturer is an overseas company and has a number equivalent to an ACN – that number;

- (iv) the street address of each site at which steps in the manufacturing process are undertaken by the manufacturer;
- (v) the steps in the manufacturing process which take place at that site;
- (g) for a veterinary chemical product – the name, street address and licence number of the person who performs release for supply of the product;
- (h) for a veterinary chemical product – the licence number of each person who performs a step in the manufacture of the product in Australia;
- (j) for a veterinary chemical product – in relation to each person who performs a step in the manufacture of the product outside Australia:
  - (i) an original or notarised certificate of good manufacturing practice, issued by an authority recognised by the APVMA, that the performance of that step complies with the manufacturing principles or a comparable good manufacturing practice code; and
  - (ii) an original or notarised copy of an audit report on good manufacturing practice from an auditor from an authority recognised by the APVMA, and evidence that any identified non-conformances have been addressed and that the person's facility complies with the manufacturing principles or a comparable good manufacturing practice code; and
  - (iii) other evidence demonstrating the person's good manufacturing practice;
- (k) for each active constituent of the product:
  - (i) the name of the constituent; and
  - (ii) if the active constituent has been approved – its distinguishing number; and
  - (iii) the name of the manufacturer of the constituent and the street address of the site at which it is manufactured;
- (l) the following information about the containers of the product:
  - (i) the proposed size of the containers;
  - (ii) a description of the containers, including an explanation of the extent to which the containers are in direct contact with the product;
  - (iii) the method by which the approved label will be attached to the containers;
  - (iv) details of the labelling of the product;
- (m) the proposed shelf life expiry period for the product (if applicable);
- (n) the proposed storage conditions for the product;
- (o) safety criteria information for the product and information relevant to whether the product would meet the efficacy criteria;
- (p) if the chemical product is a veterinary chemical product and contains ingredients of a biological origin that have been, or are to be, imported into Australia—a copy of the relevant permits (or similar) for the importation of the product for the purposes of the *Quarantine Act 1908* or a copy of any applications for such permits.

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- (2) A document referred to in subparagraph (1)(j)(i) or (ii) may be provided electronically, but if it is, the applicant must retain a hard copy of the document for provision upon the APVMA's request.

## Division 5—Application for a research permit

### 49 Application of this Division

This Division applies to an application in relation to a chemical product where the applicant proposes that the use of the product pursuant to the permit would be for the purpose of research.

### 50 Information in the application – general

The following information must be contained in the application:

- (a) details of the nature of the research purposes for which the permit is sought;
- (b) whether the relevant product is a registered chemical product;
- (c) the following information, to the extent that the information is applicable to the chemical product and the proposed use:
  - (i) the name of the product;
  - (ii) the active constituents for the product and their weight or volume;
  - (iii) the crop, animal or situation for which the product is to be used;
  - (iv) if the product is to be used on a crop—whether the crop is grown in a field, undercover, or both;
  - (v) the disease, pest or other purpose for which the product is intended (both common and scientific names);
  - (vi) information about when, and how much of, the product is administered (including, where applicable, spray rate or dosage rate, frequency, duration and volume);
  - (vii) the wetters or other proposed additives or mixtures to be added to the product, and their volume;
  - (viii) the end users of the product, identified as 'persons generally' or specified persons or classes of persons;
  - (ix) the timing for the product's application (for example, the phase of growth of the crop at which the product is applied);
  - (x) the maximum number of applications of the product per crop or animal and season or year;
  - (xi) the minimum interval between applications of the product to the crop or animal;
  - (xii) the method of application of the product (including, for veterinary chemical products, the route of administration);
  - (xiii) an estimate of the extent to which the product will be used (for example, the number of hectares or tonnage of produce or the number of animals);

- (xiv) the equipment used to apply the product;
- (xv) the time between the last application of the product and the harvest of the relevant crop or grazing and cutting for livestock, or the slaughtering or milking of the relevant animal;
- (xvi) any other information regarding special precautions or critical use for the product;
- (d) identification of the end users of the product, either by reference to 'persons generally' or a specified persons or classes of persons;
- (e) details of the persons involved in the proposed research and, if the proposed research will involve animals, whether those persons hold licences (or similar) to undertake research that involves animals;
- (f) if the proposed research will involve animals:
  - (i) the States or Territories, and licence numbers, of the relevant animal investigators; and
  - (ii) the names of the animal ethics committees consulted, or to be consulted, by the applicant in relation to the research; and
  - (iii) if approval by such a committee has been obtained – the relevant application name and identification number; and
  - (iii) if approval by such a committee has been obtained – the relevant application number;
- (g) whether the proposed research will produce food, and if so, whether the produce will be available for consumption by humans or animals;
- (h) if the proposed research will produce food that will be available for consumption by humans or animals, a statement that:
  - (i) the maximum residue limit will not be exceeded when the produce is used as proposed; or
  - (ii) that a temporary maximum residue limit is proposed for the use; or
  - (iii) that the proposed research will not result in any detectable or quantifiable residues;
- (i) whether the produce of the proposed research will be exported;
- (j) if the chemical product is a registered chemical product – the name of the product and its distinguishing number;
- (k) if the chemical product is not a registered chemical product and is imported into Australia – details of the importation and evidence of any consent provided by the APVMA for the purposes of subsection 69B(1B) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*;
- (l) if the product is not a registered chemical product – the following information about each manufacturer of the product:
  - (i) the name of the manufacturer (if the manufacturer is a company, the company's name);
  - (ii) if the manufacturer has an ACN – the ACN;
  - (iii) if the manufacturer is an overseas company and has a number equivalent to an ACN – that number;

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- (iv) the street address of each site at which steps in the manufacturing process are undertaken by the manufacturer;
- (v) the steps in the manufacturing process which take place at that site;
- (m) if the product is not a registered chemical product – the name and address of the supplier of the chemical product;
- (n) for a veterinary chemical product manufactured pursuant to a licence issued under the Code—the number given to that licence by the APVMA;
- (o) for an unregistered chemical product:
  - (i) if an application has been made for the registration of the product—a statement as to why the applicant needs a permit before the application is determined; and
  - (ii) if no application has been made for the registration of the product—a statement as to why no application has been made;
- (p) for an unregistered product—the following information about the containers of the product:
  - (i) the proposed size of the containers;
  - (ii) a description of the containers, including an explanation of the extent to which the containers are in direct contact with the product;
  - (iii) the method by which the product's label will be attached to the containers;
  - (iv) details of the label;
- (q) whether the chemical product is intended to be applied to a genetically modified crop.

### 51 Formulation and other information

- (1) If the chemical product is not a registered chemical product, the application must contain, or be accompanied by, the formulation information in relation to the chemical product.
- (2) If the chemical product is not a registered chemical product or an agricultural chemical product, and is imported into Australia, the application must contain, or be accompanied by, evidence of the manufacturer's good manufacturing practice.
- (3) The application must contain, or be accompanied by, the safety criteria information for the product and information relevant to whether the product meets the efficacy criteria.
- (4) If the chemical product is a veterinary chemical product and contains ingredients of a biological origin that have been, or are to be, imported into Australia, the application must contain, or be accompanied by, a copy of the relevant permits (or similar) for the importation of the product for the purposes of the *Quarantine Act 1908* or a copy of any applications for such permits.

## **52 Produce**

- (1) If the proposed research will produce food that is not available for consumption by humans or animals, the application must contain, or be accompanied by, a description of the method by which the produce will be disposed of.
- (2) If the proposed research will produce food that is available for consumption by humans or animals, the application must contain, or be accompanied by, information supporting the statement made for the purposes of paragraph 50(h).
- (3) If produce of the proposed research will be exported, the application must contain, or be accompanied by, information about the countries to which the produce will be exported and the relevant residue or tolerance limits of those countries.

## **Division 6—Supply of batch or oversticker for label**

### **53 Application of this Division**

This Division applies to an application for a permit to:

- (a) supply 1 or more batches of a registered chemical product that do not comply with product specifications; or
- (b) place a sticker over the approved label for a registered chemical product;

but only if none of Divisions 2 to 5 apply to the application.

### **54 Information in the application – general**

The following information must be contained in the application:

- (a) whether the application for a permit is to:
  - (i) supply 1 or more batches of a registered chemical product that do not comply with product specifications; or
  - (ii) place a sticker over the approved label for a registered chemical product;
- (b) the name and distinguishing number of the relevant registered chemical product;
- (c) the following information about the relevant batches of the product:
  - (i) the batch number;
  - (ii) the date of manufacture;
  - (iii) the current expiry date;
  - (iv) if applicable—the proposed expiry date.

### **55 Other information**

- (1) The application must contain, or be accompanied by, the safety criteria information in relation to the chemical product and information relevant to whether the product would meet the efficacy criteria.

- (2) If the permit sought would involve an extension to the shelf life of 1 or more batches of a registered chemical product, the application must contain, or be accompanied by:
  - (a) a statement of the purpose of the application; and
  - (b) information about the batches, including the location and conditions of their storage; and
  - (c) a summary of any supporting stability, analytical or validation data provided in support of the application.
- (3) If the permit sought concerns 1 or more batches that do not comply with assessed release specifications, the application must contain, or be accompanied by, a summary of any data provided in support of the application.

## Part 6—Manufacturing licences

### 56 Application of this Part

This Part applies to an application for a licence under Part 8 of the Code.

### 57 Information in the application

The application must contain the following information:

- (a) the applicant details;
- (b) if the applicant already holds a licence – the number assigned to that licence by the APVMA;
- (c) the reason for the application;
- (d) the street address of the primary premises at which the steps in the manufacture of chemical products to which the application relates would be carried out;
- (e) the street addresses of any other premises controlled by the applicant (*secondary premises*) at which those steps would be carried out;
- (f) the street addresses of any other premises controlled by the applicant (*tertiary premises*) at which starting materials, work in progress or manufactured products to which the application related would be stored;
- (g) the types of products manufactured at the primary premises, secondary premises and tertiary premises, in the manner provided for by the relevant approved form;
- (h) the steps in the manufacture of chemical products to be carried out at the primary premises and each of the secondary and tertiary premises (in the manner provided for by the relevant approved form);
- (i) if the application relates to the manufacture of biological or immunobiological veterinary chemical products – a list of the organisms used in the production areas or for production purposes;
- (j) for each chemical product manufactured or proposed to be manufactured (wholly or partly):

- (i) the name of the product; and
  - (ii) any distinguishing number for the registration of the product or permit in relation to the product; and
  - (iii) the person who is, or is proposed to be, the holder of the product's registration; and
  - (iv) the steps in the manufacture of the product which the applicant proposes to carry out; and
  - (v) the status of the product under the Code (for example, whether it is registered, awaiting a decision on registration, or is supplied pursuant to a permit);
- (k) whether any of the chemical products to which the application relates contain penicillins, cephalosporins, other antibiotics, cytotoxic medicines, hormones, steroids, or chemicals to which any schedule to the Standard for the Uniform Scheduling of Medicines and Poisons applies;
- (l) if the application relates to veterinary chemical products – any chemical products that are not veterinary chemical products and are manufactured at the primary, secondary or tertiary premises, and whether those other products are manufactured using the same equipment used for the veterinary chemical products;
- (m) for each laboratory or manufacturer involved in the analysis and testing of any of the chemical products to which the application relates – the following information:
- (i) the name and address of the laboratory or manufacturer;
  - (ii) the number assigned by the APVMA to any relevant licence held by the laboratory or manufacturer;
  - (iii) the products dealt with by the laboratory or manufacturer;
  - (iv) the analysis or testing, or assaying, performed by the laboratory or manufacturer;
- (n) for each manufacturer who, under contract with the applicant, carries out or would carry out steps in the manufacture of a chemical product to which the application relates:
- (i) the name and address of the manufacturer; and
  - (ii) the number assigned by the APVMA to any relevant licence held by the manufacturer; and
  - (iii) the products dealt with by the manufacturer pursuant to the contract; and
  - (iv) the steps in the manufacture of those products carried out pursuant to the contract;
- (o) for each person other than the applicant who performs release for supply of a chemical product to which the application relates:
- (i) the name and address of the person; and
  - (ii) the number assigned by the APVMA to any relevant licence held by the person; and
  - (iii) the products dealt with by the person;

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- (p) if a primary, secondary or tertiary premises is licenced or certified (or similar) for compliance with good manufacturing practice or relevant recognised quality standard by the Therapeutic Goods Administration or the National Association of Testing Authorities, Australia:
  - (i) whether the holder of that licence or certification is the same as the proposed holder of the licence being applied for; and
  - (ii) the extent to which the relevant products, and steps in the manufacture of those products, to which the application relates are the same as the products and steps covered by that licence or certification and have been the subject of inspections by the relevant licensing or certifying authority;
- (q) whether the applicant consents to the Therapeutic Goods Administration providing the APVMA with information relevant to their inspections of premises to which paragraph (p) applies;
- (r) the number of permanent and casual employees, and their shifts per day, engaged in production, in quality control, in storage and distribution, and in technical and engineering support services;
- (s) nominations of a person responsible for production and a person responsible for quality control pursuant to the licence sought and, in each case, information about their qualifications and experience;
- (t) the applicant declaration;
- (u) whether paragraph 123(1)(e) of the Code applies in relation to any of the persons mentioned in subparagraphs 123(1)(e)(i) to (iii);
- (v) whether paragraph 123(1)(f) of the Code applies in relation to any of the persons mentioned in subparagraphs 123(1)(f)(i) to (iii).

### 58 Information accompanying the application

- (1) The application must contain, or be accompanied by, a diagram of the applicant's organisational reporting structure for manufacturing and for quality control.
- (2) The application must also contain, or be accompanied by:
  - (a) a diagram of the buildings on the primary, secondary and tertiary premises and their functions, and the activities carried out on adjacent premises; and
  - (b) diagrams of the buildings to be used for manufacture, storage and quality control, identifying major plant items and equipment, the activities carried out in each room, and all entrances and exits, and explaining the various steps in the manufacturing process; and
  - (c) a description of, and the specifications for, each controlled air system at the manufacturing premises; and
  - (d) details of each cleanroom at the premises (including their grade, number of air changes per hour and pressure gradients).
- (3) If a primary, secondary or tertiary premises is licenced or certified (or similar) for compliance with good manufacturing practice or relevant recognised quality standard by the Therapeutic Goods Administration or the National Association of

Testing Authorities, Australia, the application must contain, or be accompanied by:

- (a) a copy of the licence or certification (or similar), including any schedules or attachments; and
- (b) a copy of the most recent inspection report and closure advice.

## **Part 7—Changing the holder of an approval or registration**

### **59 Application of this Part**

This Part applies to an application to change the holder of an approval or registration (see section 8L of the Code).

### **60 Information required**

- (1) The application must contain the following information:
  - (a) the applicant details for the proposed holder of the approval or registration (meaning the applicant details as if the proposed holder were the applicant);
  - (b) the distinguishing number of the approved active constituent, registered chemical product or approved label to which the application relates;
  - (c) if the application relates to an approved active constituent or registered chemical product—the name of the constituent or product;
  - (d) if the application relates to an approved label—the name of the relevant registered chemical product;
  - (e) an applicant declaration, made by or on behalf of the existing holder.
- (2) The application must contain or be accompanied by:
  - (a) the written consent of the proposed holder to being the holder; and
  - (b) if the proposed holder is not a resident of, and does not carry on business in, Australia—an application under section 8M of the Code; and
    - Note: Section 8N of the Code requires overseas applicants to have nominated agents. Applications for nominated agents are made under section 8M.
  - (c) a declaration by or on behalf of the proposed holder that the proposed holder understands the requirements of the Code (the declaration is to be in the form of words set out in the approved form); and
  - (e) a statement from the current holder as to the extent to which the current holder consents to the APVMA providing information relating to the approval or registration to the proposed holder.

## **Part 8—Nominating an agent**

### **61 Application of this Part**

This Part applies to an application for a person to be the nominated agent for an approval or registration (see section 8M of the Code).

### **62 Information required**

The application must contain, or be accompanied by, the following information:

- (a) the distinguishing number of the approved active constituent, registered chemical product or approved label to which the application relates;
- (b) if the application relates to an approved active constituent or registered chemical product—the name of the constituent or product;
- (c) if the application relates to an approved label—the name of the relevant registered chemical product;
- (d) the applicant details for the proposed nominated agent (as if the proposed nominated agent were the applicant);
- (e) evidence that the proposed nominated agent is a resident of, or carries on business in, Australia;
- (f) the written consent of the proposed nominated agent to being the nominated agent; and
- (g) an applicant declaration, made by or on behalf of the holder.

## **Part 9—Changing a nominated agent**

### **63 Application of this Part**

This Part applies to an application to change the nominated agent for an approval or registration (see section 8P of the Code).

### **64 Information required**

- (1) The application must contain the following information:
  - (a) the applicant details for the proposed nominated agent (meaning the applicant details as if the proposed nominated agent were the applicant);
  - (b) the applicant details for the existing nominated agent;
  - (c) the distinguishing number of the approved active constituent, registered chemical product or approved label to which the application relates;
  - (d) if the application relates to an approved active constituent or registered chemical product—the name of the constituent or product;
  - (e) if the application relates to an approved label—the name of the relevant registered chemical product;
  - (f) an applicant declaration, made by or on behalf of the holder.

- (2) The application must contain or be accompanied by:
- (a) the written consent of the proposed nominated agent to being the nominated agent; and
  - (b) evidence that the proposed nominated agent is a resident of, or carries on business in, Australia.

## **Part 10—Renewals of registrations**

### **65 Application of this Part**

This Part applies to an application for the renewal, or further renewal, of the registration of a chemical product (see section 48 of the Code).

### **66 Information required**

The application must contain the following information:

- (a) the distinguishing number of the registered chemical product to which the application relates;
- (b) the name of that product.

## **Part 11—Transitional**

### **67 Effect of instrument on certain transitional applications under the Code**

This Instrument does not apply in relation to an application lodged with the APVMA before the commencement of this Instrument.

Note: In some cases, pre-commencement applications will be dealt with under the Code as amended by the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*: see item 47 of Schedule 6 to that Act. This Instrument will not apply in those cases.

## Endnotes

Endnote 1—About the endnotes

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## Endnotes

### Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

### Abbreviation key—Endnote 2

The abbreviation key sets out abbreviations that may be used in the endnotes.

### Legislation history and amendment history—Endnotes 3 and 4

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

### Misdescribed amendments

A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation “(md)” added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation “(md not incorp)” is added to the details of the amendment included in the amendment history.

**Endnote 2—Abbreviation key**

ad = added or inserted	o = order(s)
am = amended	Ord = Ordinance
amdt = amendment	orig = original
c = clause(s)	par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)
C[x] = Compilation No. x	pres = present
Ch = Chapter(s)	prev = previous
def = definition(s)	(prev...) = previously
Dict = Dictionary	Pt = Part(s)
disallowed = disallowed by Parliament	r = regulation(s)/rule(s)
Div = Division(s)	
exp = expires/expired or ceases/ceased to have effect	reloc = relocated
F = Federal Register of Legislation	renum = renumbered
gaz = gazette	rep = repealed
LA = <i>Legislation Act 2003</i>	rs = repealed and substituted
LIA = <i>Legislative Instruments Act 2003</i>	s = section(s)/subsection(s)
(md) = misdescribed amendment can be given effect	Sch = Schedule(s)
(md not incorp) = misdescribed amendment cannot be given effect	Sdiv = Subdivision(s)
mod = modified/modification	SLI = Select Legislative Instrument
No. = Number(s)	SR = Statutory Rules
	Sub-Ch = Sub-Chapter(s)
	SubPt = Subpart(s)
	<u>underlining</u> = whole or part not commenced or to be commenced

## Endnotes

Endnote 3—Legislation history

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### Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
F2020L01022	17 August 2020	18 August 2020	—

**Endnote 4—Amendment history**

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<b>Provision affected</b>	<b>How affected</b>
<b>Part 4A</b>	
item 35A.....	ad F2019L00359
item 35B.....	ad F2019L00359; F2020L01022

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