REVISED EXPLANATORY STATEMENT

Issued by Authority of the Minister for Agriculture

Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994
Agricultural and Veterinary Chemicals (Administration) Act 1992
Agricultural and Veterinary Chemicals Code Act 1994

Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2019

Legislative Authority

Subsection 39(1) of the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (the Levy Act) provides that the Governor-General may make regulations prescribing matters required or permitted by this Act to be prescribed; or necessary or convenient to be prescribed for carrying out or giving effect to this Act; and, in particular, prescribing the way in which notices may be given by or to the Australian Pesticides and Veterinary Medicines Authority (APVMA) (a Commonwealth authority) under the Levy Act. Section 12C of the Levy Act provides specific authority to prescribe rates of levy in regulations.

Section 73 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (the Administration Act) provides that the Governor-General may make regulations prescribing all matters required or permitted by this Act to be prescribed; or necessary or convenient to be prescribed for carrying out or giving effect to this Act.

Subsection 6(1) of the *Agricultural and Veterinary Chemicals Code Act 1994* (the Code Act) provides that the Governor-General may make regulations prescribing matters required or permitted by the Agvet Code (a Schedule to the Code Act) to be prescribed by regulations within the meaning of the Agvet Code; or necessary or convenient to be prescribed by such regulations for carrying out or giving effect to the Agvet Code.

The legislation above also includes other provisions for certain matters to be prescribed in regulations. These provisions are described for each of the relevant amending items in Attachment A.

The Administration Act, Code Act and Levy Act, and any regulations or legislative instruments made under these laws, are collectively referred to as agricultural and veterinary (agvet) chemical legislation throughout this explanatory statement.

ACRONYMS, ABBREVIATIONS AND COMMONLY USED TERMS

Term	Meaning
Administration Act	*Agricultural and Veterinary Chemicals (Administration) Act 1992*
Administration Regulations	Agricultural and Veterinary Chemicals (Administration) Regulations 1995
agvet	agricultural and veterinary
Agvet Code	the Agricultural and Veterinary Chemicals Code, as set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*
APVMA	Australian Pesticides and Veterinary Medicines Authority
Code Regulations	Agricultural and Veterinary Chemicals Code Regulations 1995
Code Act	*Agricultural and Veterinary Chemicals Code Act 1994*
Criminal Code	*Criminal Code Act 1995*
the department	The Department of Agriculture
Food Standards Code	the Australia New Zealand Food Standards Code as defined in section 4 of the *Food Standards Australia New Zealand Act 1991*
Guide to Framing Commonwealth Offences	Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers
HGP	Hormonal Growth Promotant
Levy Act	*Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*
Levy Regulations	Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995
minister	the minister administering the Administration Act
NRS	National Registration Scheme for Agricultural and Veterinary Chemicals
Record	the Record of Approved Active Constituents for Chemical Products, kept under section 17 of the Agvet Code

Purpose

The purpose of the Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2019 (the Regulations) is to improve the efficient and effective regulation of agricultural chemicals and veterinary medicines (agvet chemicals). They amend regulations made under the agvet chemical legislation to:

- extend the range of application types that can be assessed as timeshift applications, to provide more flexibility for the Australian Pesticides and Veterinary Medicines Authority (APVMA) and applicants
- provide for greater use of ministerial orders, which are disallowable, so the government can be more responsive
- declare certain substances to not be agricultural chemical products or veterinary chemical products, so they are not regulated by the APVMA
- simplify the legislation for notifiable and prescribed variations and consolidate related requirements into instruments made by the APVMA
- modernise hormonal growth promotant requirements, including introducing civil penalties and infringement notices for non-compliance, to allow the APVMA to respond more proportionately to alleged contraventions of existing legal requirements
- address a policy anomaly about advertising in agvet chemical legislation
- clarify some matters about when the APVMA can use information provided by another party to support the registration of a proposed chemical product
- allow for approvals (in certain circumstances) to be dealt with simultaneously as part of an application for registration of a chemical product
- deal with a number of minor and consequential changes, including updating some outdated references and removing unnecessary provisions.

Documents incorporated by reference

The Regulations includes new, and updates to existing, measures that incorporate documents by reference. Incorporated documents are referred to in:

- item 49 (the monograph or compendial standards in the British Pharmacopoeia, British Pharmacopoeia (Veterinary), European Pharmacopoeia or United States Pharmacopeia) in Part 8 of Schedule 1 to the Regulations`
- item 64 (the *Handbook of First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for Agricultural and Veterinary Chemicals*)
- items 69 and 71 (the United States Pharmacopeia).

Consistent with subregulation 3(2) of the Agricultural and Veterinary Chemicals Code Regulations 1995 (the Code Regulations), the manner in which each of the aforementioned documents are incorporated is ‘as modified or amended from time to time’. This is authorised under paragraphs 6(2)(c) and 6(3)(a)) of the Code Act.

The Australia New Zealand Food Standards Code (the Food Standards Code)—including subordinate standards—is incorporated through items 93 and 94 in Part 9 of Schedule 1 to the Regulations. The manner in which this material is incorporated is as ‘in force from time to time’. Section 10 of the *Acts Interpretation Act 1901* (as applied by paragraph 13(1)(a) of the *Legislation Act 2003*) has the effect that references to Acts or Commonwealth disallowable

legislative instruments can be taken to be references to those instruments as in force from time to time, unless otherwise specified.

The definitions, as set out in Regulation 3 of the Code Regulations, provide the full title for these documents. This material is available as follows:

- the British Pharmacopoeia is available (for a fee) from the British Pharmacopoeia Commission (accessible at pharmacopoeia.com)
- the British Pharmacopoeia (Veterinary) is available (for a fee) from the British Pharmacopoeia Commission (accessible at pharmacopoeia.com)
- the European Pharmacopoeia is available (for a fee) from the European Pharmacopoeia Commission (accessible at edqm.eu/en/European-pharmacopoeia-commission)
- the United States Pharmacopeia is available (for a fee) from the United States Pharmacopeia National Formulary (accessible at uspnf.com)
- the Handbook of First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for Agricultural and Veterinary Chemicals is available free of charge from the APVMA (accessible at apvma.gov.au)
- the Food Standards Code is available free of charge from the Federal Register of Legislation (accessible at legislation.gov.au).

The British Pharmacopoeia, British Pharmacopoeia (Veterinary), European Pharmacopoeia and United States Pharmacopeia set out international standards for the manufacture of veterinary (and in some cases agricultural) chemicals. They are, in effect, internationally accepted and peer-reviewed 'recipes' for these chemicals. Although there are fees associated with accessing this material, this material is commonly used by those persons—such as agvet chemical manufacturers—who apply to register chemical products they manufacture based on those standards. Accordingly, the entities affected by this regulation would generally already have access to this material as part of their normal business operations. Additionally, the references to these documents inserted by Part 8 of the Regulations benefit those affected by the incorporation of the material. This is because incorporating these standards will enable more applicants to make a single application to the APVMA for approval of an active constituent, registration of a chemical product and approval of a label for containers for a chemical product. Previously, it was not possible for the APVMA to approve an active constituent as part of an application to register a chemical product for applications of a type described in items 5 and 6 of the table at clause 2.1 of Schedule 6 to the Code Regulations. Accordingly, if an applicant wished to register a new chemical product while seeking approval of a new active constituent, two separate applications were required (with associated costs and administrative overheads).

Background

Agvet chemicals are regulated through a cooperative National Registration Scheme (the NRS). The NRS is a partnership between the Commonwealth and the states and territories with an agreed division of responsibilities.

The APVMA (established by the Commonwealth) assesses, registers and approves agvet chemicals for use in Australia. The APVMA is also responsible for regulating these chemicals up to, and including, the point of supply—for example, retail sale. The control of use of agvet chemicals after supply is the responsibility of individual states and territories.

The APVMA is established under section 6 of the Administration Act, which sets out its role as the independent regulator for the supply of agvet chemical products under the NRS.

The NRS is implemented, in part, through the Code Act. The Code Act contains, as a schedule, the Agvet Code. The Agvet Code operates in each state, the Northern Territory and each participating territory (the Australian Capital Territory and Norfolk Island, as provided for by section 4 of the *Agricultural and Veterinary Chemicals Act 1994*) to constitute a single national Agvet Code applying throughout Australia. The Agvet Code includes detailed provisions allowing the APVMA to evaluate, approve, register and reconsider active constituents and agvet chemical products and their associated labels. The provisions in the Agvet Code also allow the APVMA to issue permits for supply and use and to issue licences for the manufacture of chemical products. Other provisions in the Agvet Code provide for controls to regulate the supply of chemical products and ensure compliance with, and enforcement of, the Agvet Code, including suspending and cancelling registration of chemical products.

The Levy Act contains measures that allow for levies to be assessed, calculated and collected on the sale of agvet chemical products registered for use in Australia.

Impact and Effect

These regulations will improve the efficiency and effectiveness of agvet chemical regulation, while maintaining health and trade safeguards. It will do this, for example, by reducing unnecessary regulation, increasing flexibility and modernising penalties for non-compliance with hormonal growth promotants.

Consultation

The department consulted the affected industries on these regulation amendments through peak industry bodies throughout 2018. These included CropLife Australia (CropLife), Animal Medicines Australia, the Veterinary Manufacturers and Distributors Association and the National Farmers' Federation (NFF). Teleconferences and meetings were held to ensure industry awareness of the proposed changes. A consultation paper describing these amendments and an exposure draft of the proposed Regulations was made available for public consultation from 12 December 2018 to 20 February 2019. Five submissions were received. These submissions largely supported the measures in the proposed Regulation. The NFF and CropLife suggested that more products could be removed from the agvet legislation's scope, while the Australian Competition & Consumer Commission noted that products being removed from the APVMA's purview would not be subject to the same level of regulatory scrutiny. The appropriateness of other products being included within agvet chemical legislation will continue to be explored by the government and stakeholder views will be sought ahead of future regulations changes.

The Regulations were also developed in close consultation with the APVMA. Relevant state and territory agencies were also consulted.

The Office of Best Practice Regulation (OBPR) was consulted in the preparation of the Regulations (ID 23790). The OBPR advised a Regulation Impact Statement was not required as the proposed measures appear to have only minor regulatory impacts on business, community organisations or individuals.

The Code, Administration and Levy Acts do not specify any conditions that need to be satisfied before the power to make the Regulations may be exercised.

Details/ Operation

Details of the Regulations are set out in Attachment A.

Other

The Regulations are compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011.* A full statement of compatibility is set out in Attachment B.

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

ATTACHMENT A

Details of the *Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2019*

Section 1 – Name

This section provides that the name of the Regulations is the *Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2019*.

Section 2 – Commencement

This section provides for the Regulations to commence on the day after the instrument is registered.

Section 3 – Authority

This section provides that the Regulations are made under the following Acts:

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

Section 4 – Schedules

This section provides that the Regulations are amended or repealed as set out in the applicable items in the Schedule.

Schedule 1 – Amendments

Part 1–Timeshift applications

Part 1 of these Regulations amends the Agricultural and Veterinary Chemicals Code Regulations 1995 (Code Regulations) to extend the range of applications that can be assessed as timeshift applications, to provide more flexibility for the APVMA and applicants to plan and assess complex applications.

Prior to these Regulations, the Code Regulations provided only for certain complex applications for registration or approval to be considered using a 'timeshift' approach.

Timeshift applications—which are assessed according to a project plan agreed to by the applicant and the APVMA—provide greater flexibility than other types of application. This is because they allow the applicant to submit information while the assessment is underway, according to the timing agreed by the applicant and the APVMA in the project plan. This is not the case with other types of applications, which require the applicant to provide all the information required to assess the application at the time of lodgement. This flexibility allows applications to be made before all information (for example, information relating to a laboratory trial) is finalised. Timeshift applications also provide flexibility around the period during which the application must be assessed by the APVMA.

While timeshift applications provide more flexibility than other types of applications, they are a greater administrative burden for the APVMA and applicant. As such, timeshift was previously only available for the most complex applications. However, it is apparent that the scope of application types that could previously be assessed using timeshift was too restrictive.

Accordingly, Part 1 of these Regulations extends the kinds of applications that can be considered using a timeshift approach. The additional kinds of applications are those for chemical product registrations and variations that, although complex, are less so than those for which timeshift was previously available. That is, timeshift is being extended to those kinds of application for which the benefits of a timeshift approach may offset the additional administrative burden on the APVMA and applicant.

Specifically, the Regulations make amendments to enable timeshift to be extended to applications of the kind described in items 5, 10, 11 and 14 (in the table in Part 2 of Schedule 6 to the Code Regulations). The amendments in Part 1 of the Regulations would also allow applications of the kind mentioned in items 10 or 14, which apply a modular approach.

Modular applications allow the fee and assessment period for an assessment to be tailored to the specific needs of an individual application. The different modules, which are described in the table in Schedule 7 to the Code Regulations, apply to different aspects of an assessment such as chemistry or toxicology. Different levels of fee and assessment are provided for within the different aspects of an assessment—e.g $9,220 and 13 months for 'Chemistry—level 1', '$3,075 and 9 months for Chemistry—level 2' and $1,580 and 6 months for 'Chemistry—level 3'.

However, in keeping with the policy that timeshift be restricted to more complex applications, timeshift is only available for those applications of a kind mentioned in items 10 or 14, if the APVMA determines that at least two of the modules at items 2 to 10 of the table in Schedule 7 to the Code Regulations are necessary for the assessment.

Additionally, Schedule 7 currently includes timeshift-specific modules with associated charges that the APVMA uses to calculate the total modular assessment fee for timeshift applications. Currently, the fees for each of the timeshift-specific modules are the same as those for the most expensive module for each type of an assessment (for example the most expensive module relating to the toxicology or residues component of an assessment), which relate to the most complex assessment. These timeshift-specific modules are no longer required, as the amendments allow any level of module to apply to a timeshift application (specifically, the level that most appropriately reflects the costs of the APVMA's assessment effort).

Code Regulations

Item 1 amends the definition of 'modular assessment period' in subregulation 3(1) of the Code Regulations. It now references the entirety of regulation 77 (which describes how the modular assessment period is set), rather than the previous reference to subregulation 77(2).

Items 2 and 3 amends the Code Regulations to broaden the previous definition of 'timeshift application'. Item 2 repeals and substitutes a new definition of 'timeshift application', which defines the term by reference to new regulation 3BA.

Item 3 inserts a new definition of 'timeshift application' in new subregulation 3BA. This new definition of provides that an application is a timeshift application if: (a) it is covered by subregulation 3BA(2), and (b) the applicant and the APVMA have agreed that it will be assessed in accordance with assessment periods set out in a project plan for the application, agreed to by the applicant and the APVMA. New subregulation 3BA(2) specifies that applications of the kind described in column 1 of items 1, 2, 3, 4, 5, 10, 11, 14 or 15 of the table in clause 2.1 of Schedule 6 to the Code Regulations may be timeshift applications. However, in the case of applications of a kind mentioned in items 10 or 14, this is limited to circumstances where the APVMA has determined that at least two of the modules at items 2 to 10 of the table in Schedule 7 are necessary for the application.

Item 3 also includes a note that explains that the table in clause 2.1 of Schedule 6 sets out the assessment periods and fees applicable to applications. It also notes that for timeshift applications, item 27 of that table applies.

Item 4 repeals and substitutes regulation 77 of the Code Regulations. It replaces the definition of 'modular assessment period' (which describes how the modular assessment period is set) with a new definition that incorporates any assessment period set out in the project plan for a timeshift application. This reflects that Schedule 7 to the Code Regulations (which sets out the fees and periods for completion of modules) will no longer include a reference to assessment periods for timeshift applications.

Item 5 repeals all the items in the table in Schedule 7 to the Code Regulations that exclusively related to timeshift applications—items 2.4, 3.4, 4.2, 5.6, 6.4, 7.4, 8.4 and 10.4. These timeshift-specific modules are no longer required as the amendments allow timeshift

applications to apply to any level of module (specifically, the level that most appropriately reflects the costs of the APVMA's assessment effort).

Note that item 49, discussed in Part 8, amends the items of the table in clause 2.1 of Schedule 6 to the Code Regulations, that previously applied to timeshift applications. In addition, item 75, discussed in Part 9, includes consequential amendments relating to the fees payable for a timeshift application.

Part 2–Ministerial orders

Part 2 of these Regulations amends the Code Regulations to provide for greater use of ministerial orders.

Ministerial orders made under the Code Act are disallowable legislative instruments. They allow the government to be more responsive to agvet chemical issues, as they can be made more quickly than regulations and are less administratively burdensome to make.

Consultation requirements relating to legislative instruments under section 17 of the *Legislation Act 2003* would apply to Ministerial orders as they do to regulations.

Section 7 of the Code Act confers power on the minister to make orders about matters that the regulations can prescribe, other than prescribing a penalty. However, the power in section 7 is only triggered if a regulation is made that operates to declare that the minister can make an order about that matter. Before the commencement of these Regulations, the minister could only make orders that dealt with the following matters:

- standards for chemical products and a constituent contained in a chemical product (regulation 42)
- tests for the analysis of samples of substances or mixtures of substances (regulation 55).

Examples of matters that could be covered by the orders include:

- adopting an international standard, such as a pharmacopoeial quality specification
- exempting particular persons, substances or products from the operation of a provision of the Agvet Code
- declaring a substance to be, or not to be, an agricultural or veterinary chemical product
- clarifying the information that must be included in a specific notice.

Allowing for ministerial orders to deal with a broad range of matters provides more flexibility for regulating agvet chemicals. It also allows the government to respond more quickly on matters that must otherwise be addressed through regulations.

Code Regulations

Item 6 inserts new Division 1.1B into the Code Regulations, which comprises regulation 2. Regulation 2 provides that the matters covered by subsections 6(1), (2) and (3) of the Code Act, other than the matters covered by paragraph 6(2)(i) (prescribing penalties of not more than 50 penalty units for offences against the regulations) are the matters to which section 7 of the Act applies. The result is that regulation 2 essentially provides a single authority to the minister to make orders in relation to any matter that may be prescribed in regulations, other than prescribing penalties (which is already beyond the scope of the order making power in section 7).

Item 7 makes a consequential amendment to paragraph 15(1)(b) of the Code Regulations. It substitutes a reference to regulation 42 (which deals with standards for chemical products) in paragraph 15(1)(b) with a reference to standards made for the purposes of paragraph 87(1)(a) of the Agvet Code. This reflects that the order-making power in relation to prescribed standards in regulation 42 is replaced by the general order-making power that is provided for by item 6.

Item 8 repeals subregulations 42(2) and 55(1) of the Code Regulations. Previously, subregulations 42(2) and 55(1) provided for ministerial orders to be made specifically in relation to prescribed standards for chemical products and analysis of chemical products, respectively. These are made redundant by item 6.

Item 9 makes a consequential amendment. It reflects the need to renumber regulation 55 of the Code Regulations (which deals with the analysis of chemical products) following the repeal of subregulation 55(1).

Part 3–Chemical product declarations

Part 3 of these Regulations amends the Code Regulations to declare certain substances to not be agricultural chemical products or veterinary chemical products, so they are no longer regulated by the APVMA.

The Agvet Code provides for the regulations to declare substances or mixtures of substances to not be an agricultural chemical product (paragraph 4(4)(b)) or a veterinary chemical product (paragraph 5(4)(b)). Substances that are declared to not be either an agricultural or veterinary chemical product are not regulated by the APVMA. These substances are set out in the table at Part 3 of Schedule 3 to the Code Regulations.

Conversely, the Agvet Code also provides for the regulations to declare that particular substances (or mixtures) are agricultural chemical products (subsection 4(3), which provides authority for Part 2 of Schedule 3 to the Code Regulations) or veterinary chemical products (paragraph 5(3)(b), which provides authority for Part 2 of Schedule 3AA of the Code Regulations).

Consistent with the above regulation making powers, Part 3 of these Regulations declares that the following substances are not agricultural chemical products:

- carbon dioxide or nitrogen used as fumigants
- citronella oil, including in candles and sticks, unless the citronella oil is used as an insect repellent on human beings or as an insect repellent on food producing species or food crops.

Part 3 of these Regulations also amends the Code Regulations to remove sheep branding substances from the list of declared veterinary chemical products.

The low risks associated with these substances can be sufficiently addressed under other laws controlling chemicals in Australia (such as the workplace safety, poisons scheduling, consumer protection, environment, food and public health laws) without need for additional specific controls under agvet legislation.

Code Regulations

Item 10 amends paragraph (c) of item 1 of the table in Part 3 of Schedule 3 to the Code Regulations. It substitutes the term ‘pesticide’ (which is not defined in the Agvet Code and may lead to confusion about requirements) with the term ‘agricultural chemical product’ (which is defined). Part 3 of Schedule 3 sets out substances or mixtures declared not to be agricultural chemical products.

Item 11 amends the table in Part 3 of Schedule 3 to the Code Regulations. It adds the following to the list of substances or mixtures of substances declared not to be agricultural chemical products:

- carbon dioxide or nitrogen used as a fumigant
- citronella oil, including in candles and sticks, unless the citronella oil is used as an insect repellent on human beings or as an insect repellent on food producing species or food crops.

Item 12 amends the table under clause 2 in Part 2 of Schedule 3AA to the Code Regulations (substances or mixtures declared to be veterinary chemical products). It removes sheep branding substances (item 6 in the table) from the list of substances or mixtures of substances declared to be veterinary chemical products.

Part 4–Notifiable variations and prescribed variations

The Agvet Code provides for certain kinds of variations to approvals and registrations to be made by notification (Division 2AA of Part 2 of the Agvet Code) or as a prescribed variation (Division 2A of Part 2 of the Agvet Code). Notifiable and prescribed variations are simple mechanisms for varying approvals or registrations, where minimal or no assessment by the APVMA is required. Examples include a variation to the distinguishing name of a chemical product or a variation of the name of a manufacturer of a chemical product. Previously, notifiable variations and prescribed variations were prescribed in both the regulations and in a legislative instrument made by the APVMA.

Part 4 of these Regulations simplifies the scheme relating to notifiable variations and prescribed variations by repealing regulations related to the scheme. This requires the APVMA to make legislative instruments for these variations. The legislative authority in the Code Act to prescribe a regulation for notifiable variations and prescribed variations remains unchanged.

Code Regulations

Item 13 makes a consequential amendment. It repeals regulation 8AFB of the Code Regulations. Regulation 8AFB dealt with the information that was required to accompany an application for a prescribed variation. This regulation applied only to 'a prescribed variation of the kind set out in item 3 of the table in regulation 19AF' (item 3 of this table relates to variation of constituents of a chemical product). As regulation 19AF of the Code Regulations has been repealed (by item 16), regulation 8AFB is no longer needed. The information requirements previously prescribed in regulation 8AFB can be specified by the APVMA in a legislative instrument as authorised by section 26B of the Agvet Code, should the APVMA consider this to be appropriate.

Item 14 makes a consequential amendment. It substitutes the existing heading for subdivision 2.2.2 of the Code Regulations ('notifiable variations') with the heading 'interchangeable constituent determinations'. Interchangeable constituent determinations are the only remaining matters that are dealt with in subdivision 2.2.2 following repeal of regulation 19AE of the Code Regulations (by item 15).

Item 15 repeals regulation 19AE of the Code Regulations. Regulation 19AE sets out types of notifiable variations. Instead, these kinds of variations will be left to the APVMA to specify in a legislative instrument made under section 26AB of the Agvet Code, as the APVMA considers appropriate.

Item 16 repeals Subdivision 2.2.3 of the Code Regulations. Subdivision 2.2.3 only comprised of regulation 19AF, which set out the types of variations that were prescribed. Instead, these will be left to the APVMA to specify in a legislative instrument made under section 26B of the Agvet Code, as the APVMA considers appropriate.

Item 17 is a consequential amendment. It repeals and substitutes regulation 69AA of the Code Regulations to reflect the repeal of regulation 19AE of the Code Regulations (by item 15). New subregulation 69AA(1) prescribes a $50 fee for lodging a notice under Division 2AA of Part 2 of the Agvet Code. This maintains the fee for this activity that was previously prescribed in regulation 69AA as repealed by this item (as inserted by the

Agricultural and Veterinary Chemicals Code Amendment (Removal of Re-approvals and Re-registrations) Regulation 2014 [F2014L01115] which was subject to public consultation in 2013 and 2014). That is, this item does not impose a new fee, nor change to the amount of the existing fee. The fee is calculated on the basis of cost-recovery.

Regulation 69AA did not previously set a fee for a notifiable variation of a kind mentioned in items 6 or 8 of the table in subregulation 19AE(1) of the Code Regulations, which was repealed by item 15.

New subregulation 69AA(2) and 69AA(3) effectively provides that there will continue to be no prescribed fee for these kinds of notices.

Part 5–Hormonal growth promotants

Part 5 of these Regulations amends the Code Regulations to modernise hormonal growth promotant (HGP) requirements and introduce civil penalties and infringement notices for non-compliance. This allows the APVMA to respond more proportionately to alleged contraventions of existing legal requirements.

Regulation 3 of the Code Regulations defines HGPs, which are veterinary chemical products containing a substance, or mixture of substances, responsible for certain hormonal activities to enhance growth or production in cattle or buffalo.

The European Union requires continued assurance from Australia that the beef and beef products that its member states import have not been treated with HGPs. The national monitoring system provides this assurance by enabling Australian authorities to account for the importation, supply and use of HGPs. The APVMA plays a significant role in the national monitoring system by authorising importers and resellers. The APVMA also requires that accurate records of supply be kept, which account for every dose of HGP supplied.

Prior to the commencement of the amendments in Part 5 of these Regulations, regulations 47 to 54 of the Code Regulations imposed requirements on persons who supplied or intended to supply HGPs. Those requirements are summarised in Table 1.

Table 1 Summary of Code Regulation provisions for hormonal growth promotants

Regulation	Summary of the provision
47	Provide for persons to be issued with a unique notification number by the APVMA for each premises that a person intends to supply a HGP (for a fee)
47A	Allow the APVMA to withdraw or replace a notification number in certain circumstances
47AB	Provide that withdrawal of a notification number is subject to review by the Administrative Appeals Tribunal
47B	Require that a notification number must be renewed annually
47C	Require that a person may only supply a hormonal growth promotant if the person has been assigned a unique notification number and that number has not been withdrawn or ceased to have effect
48, 49, 50, 51 and 52	Impose requirements on persons to provide declarations and keep records if those persons supply, import or manufacture hormonal growth promotants
53	Require persons who make records to provide a copy of those records to the APVMA within 14 days after the end of the month in which the record was made
54	Require persons to keep records and require persons receiving declarations to keep those records and declarations for two years

These regulations also prescribed certain offences for supplying HGPs without an APVMA issued notification number and for failing to keep the necessary records. These offences previously carried a maximum penalty of 10 penalty units (the value of a penalty unit is set

out in section 4AA of the *Crimes Act 1914* at $210). This is not an adequate sanction for the conduct in the offences—see the Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers (Guide to Framing Commonwealth Offences).

In addition, there were no corresponding civil penalty provisions. The previous legislation, therefore, limited the APVMA's ability to respond proportionately to non-compliance for these offences. For example, the APVMA could not issue infringement notices but instead had to pursue criminal proceedings against alleged offenders should it have deemed that this was required.

Part 5 of these Regulations amends regulations 47C and 48 to 54 of the Code Regulations (see Table 1) to increase the penalties from 10 penalty units to 30 or 50 penalty units (see Table 2) and provides for these criminal offences to be civil penalty provisions. The penalties set out in these regulations are the maximum amounts that a court may impose for a conviction of a criminal offence against these regulations. These amounts are consistent with those in the Guide to Framing Commonwealth Offences and the power in paragraph 6(2)(i) of the Code Act to prescribe penalties of not more than 50 penalty units for offences against the regulations. These amendments also provide for infringement notices to be issued against a person in the event that a person contravenes one of these new civil penalty provisions (see section 145DA of the Agvet Act).

Table 2 Maximum offence, civil penalty and infringement notice amounts for individuals and bodies corporate, in penalty units

Category	**Regulations 47C, 48 and 53**	**Regulations 49, 50, 51 and 54**
Criminal penalty—individual	50	30
Criminal penalty—body corporate	250	150
Civil pecuniary penalty—individual	150	90
Civil pecuniary penalty—body corporate	1,250	750
Infringement notice—individual	30	18
Infringement notice—body corporate	250	150

Subsection 170(5) of the Agvet Code provides that the maximum monetary penalty for a body corporate that a court may impose for an offence is five times the amount it may impose on an individual for the same offence.

Paragraph 6(2)(j)) of the Code Act authorises the regulations to declare provisions of the regulations to be civil penalty provisions. Subsections 145AA(1) and (2) of the Agvet Code provide (respectively) that the pecuniary penalty for a contravention of a civil penalty provision:

- by a body corporate must not exceed five times the amount that could be imposed for conviction of the equivalent offence
- by an individual must not exceed three times the amount that could be imposed for conviction of the equivalent offence.

Providing for infringement notices for alleged contraventions is authorised by subsection 145DA(1) of the Agvet Code. Subsection 145DB(2) of the Agvet Code provides that the amount stated in an infringement notice must not exceed one-fifth of the maximum penalty that a court could impose for the contravention (in this case, the civil pecuniary penalties described in Table 2).

Infringement notice provisions supplement offence and civil penalty provisions to provide an alternative to prosecution for an offence or litigation of a civil matter. An infringement notice is a notice issued by an authority setting out the particulars of an alleged contravention of a civil penalty provision. The infringement notice will give the person to whom the notice is issued the option to pay the penalty amount specified in the notice, in order to prevent the matter from being pursed in Court.

Consistent with the Guide to Framing Commonwealth Offences, Part 5 also modernises the Code Regulations to remove the reasonable excuse defences from all the offences in subregulations 47C(1A), 48(2), 49(2), 51(3), 53(3) and 54(4) (these offences all relate to the supply and record keeping requirements for HGPs). Persons that may be subject to these offences will still be able to rely on the defences in the Criminal Code, including the defence of honest and reasonable mistake of fact (section 9.2 of the Criminal Code). This modernises the provisions so they operate like contemporary offence provisions. For regulation 53, the privilege against self-incrimination would not be abrogated in relation to giving a copy of a record under regulations 49, 50 or 51 (as per section 146A of the Agvet Code).

Code Regulations

Items 18 and 22 modernise the language in subregulations 47C(1) and 48(1) to ensure that these offences attract the operation of subsection 4D(1) of the *Crimes Act 1914* (which refers to a contravention of a section or subsection).

Items 19, 23 and 34 increase the pecuniary penalties for contraventions of regulations 47C, 48 and 53 of the Code Regulations from 10 penalty units to 50 penalty units.

Items 20, 24, 27, 32, 35 and 38 amend the Code Regulations to remove the reasonable excuse defences from all the offences by repealing subregulations 47C(1A), 48(2), 49(2), 51(3), 53(3) and 54(4).

Items 21, 25, 28, 30, 33, 36 and 39 make all the criminal offences in regulations 47C, 48, 49, 50, 51, 53 and 54 of the Code Regulations civil penalty provisions.

Items 26, 29, 31 and 37 increase the pecuniary penalties for the contraventions of regulations 49, 50, 51 and 54 of the Code Regulations from 10 penalty units to 30 penalty units.

Item 40 adds items 57 to 63 to the table in Schedule 5A to the Code Regulations. This is to make the civil penalty provisions in subregulations 47C(1), 48(1), 49(1), 50(1), 51(2), 53(2) and 54(3) prescribed civil penalty provisions against which infringement notices can be issued under subsection 145DA of the Agvet Code. These new items also specify the infringement notices amounts that apply for alleged contraventions of these civil penalty provisions as authorised by subsection 145DB(3) of the Agvet Code.

Part 6–Section 88 exemption

Part 6 of these Regulations amends the Code Regulations to address a policy anomaly in the Agvet Code whereby persons were prevented from publishing notices offering to sell or inviting offers to buy certain chemical substances, despite the APVMA having authorised the supply and use of those substances.

The prohibition on publishing notices included advertising and captured any means of publication, including through broadcasting or televising. This was because section 88 of the Agvet Code prevents the publication of notices offering for sale, or inviting offers to buy, an unregistered chemical product or unapproved active constituent unless an application for registration or approval has been made to the APVMA.

Part 6 of these Regulations ensures that the general constraint on the advertising of an unregistered chemical product or unapproved active constituent does not apply in circumstances where possession, custody and supply is authorised by the APVMA. To achieve this outcome, the amendments exempts three classes of substances or chemical products from the operation of section 88 of the Agvet Code.

The first class exempted includes active constituents or chemical products for which the APVMA has issued a permit in respect of possession, custody or supply. Specifically, the exemption applies to permits that authorise an act or omission which would otherwise be an offence or contravention of a civil penalty provision mentioned in sections 74, 75, 76 or 78 of the Agvet Code (these provisions relate to permits for the possession, custody or supply of unapproved active constituents or unregistered chemical products). Provided that the permit relates to one or more of these, section 88 does not apply. If an APVMA permit does not relate to sections 74, 75, 76 or 78 of the Agvet Code, then the unapproved active constituent or unregistered chemical product supplied under the permit would remain subject to the restrictions on advertising through section 88 of the Agvet Code.

The second class for which section 88 of the Agvet Code does not apply are those unapproved active constituents that the APVMA has exempted under paragraph 15(2)(a) of the Agvet Code from the operation of subparagraph 15(1)(a)(i) of the Agvet Code (which requires that the APVMA must not register a chemical product unless it also approves each active constituent for the product).

The third class for which section 88 of the Agvet Code does not apply are those unapproved active constituents that are part of a listed chemical product (see paragraph 15(2)(b) of the Agvet Code).

Code Regulations

Item 41 inserts new regulation 42A in the Code Regulations. Regulation 42A exempts certain substances from the operation of section 88 of the Agvet Code (section 88 provides that certain notices, including advertisements, are not to be published). This exemption is authorised by paragraph 6(3)(c) of the Code Act, which provides for regulations to exempt particular substances or chemical products from the operation of any provision of the Agvet Code. The relevant substances are:

- active constituents exempted by the APVMA from the operation of subparagraph 15(1)(a)(i) of the Agvet Code

- active constituents for listed chemical products
- active constituents for a proposed or existing chemical product, or chemical product, in respect of which the APVMA has issued a permit of the kind described in subregulation 42A(2). That is, a permit that authorises an act or omission in relation to the active constituent or product that would otherwise be an offence against, or contravention of a civil penalty provision mentioned in, sections 74, 75, 76 or 78 of the Agvet Code.

Item 41 also inserts a note that states that sections 74, 75, 76 and 78 of the Agvet Code generally prohibit the supply of unapproved active constituents or unregistered chemical products, and related acts or omissions.

Note that item 108 in Part 10 of these Regulations clarifies that the exemption in regulation 42A will apply to active constituents or chemical products covered by regulation 42A(1)(a), (b), (c) or (d) irrespective of whether it met the requirements of the paragraph before, on or after the commencement day. This is because there is no detriment to permit holders or other relevant persons (such as persons who use chemical products under permit) if this exemption also applies to active constituents or chemical products covered by established permits, or active constituents already exempted from the operation of subparagraph 15(1)(a)(i) of the Agvet Code, or in listed chemical products.

Part 7–Restricted information

Part 7 of these Regulations amends the Code Regulations to clarify some matters about when the APVMA can use information provided by another party, to support the registration of a proposed product. Specifically, Part 7 amends Schedule 6 to the Code Regulations to:

- introduce the term 'restricted' information in place of the term 'protected information'. This is because the term 'protected information' is defined differently in the Agvet Code and it is confusing to use the same expression in the Code Regulations with a separate (and different) meaning
- clarify that the use of information is 'restricted' only if the APVMA is restricted by Division 4A of Part 2, or Part 3, of the Agvet Code, from using the information in determining the application.

Schedule 6 of the Code Regulations sets out when a proposed chemical product can be taken to be 'closely similar', 'similar' or 'the same' as a reference chemical product. Previously, Part 1 of Schedule 6 provided that a proposed chemical product is taken to not be 'closely similar', 'similar' or 'the same' as a reference product if information about the reference chemical product is 'protected information', within the meaning of Schedule 6.

Part 7 of these Regulations substitutes clause 1.5(1) of Schedule 6 to provide that despite the operation of clauses 1.2, 1.3 and 1.4, a proposed chemical product or reference chemical product are only 'closely similar', 'similar' or 'the same' as a reference chemical product if:

- the APVMA is required to use the information in determining an application in respect of the proposed chemical product, and
- the use of the information by the APVMA in determining that application is restricted.

(The concepts of 'closely similar', 'similar' or 'the same' are also mentioned in items 5, 6, 7 or 8 of the table in clause 2.1 of Schedule 6 to the Code Regulations.)

Subclause 1.5(2) sets out when the use of information by the APVMA is restricted. Where the authorising party has given consent for the APVMA to use information then that specific use of the information will not meet the definition of 'restricted information'.

Code Regulations

Items 42 and 43 amend clause 1.1 of Schedule 6 to the Code Regulations to repeal the definition of 'protected information' and insert the definition 'restricted', in relation to the use of information by the APVMA in determining an application. The term 'restricted' in this context is defined by reference to the meaning that is given to that term by subclause 1.5(2) (see item 44).

Item 44 substitutes a new clause 1.5 of Schedule 6 to the Code Regulations. Subclause 1.5(2) introduces the concept of the use of information being 'restricted'. The use of information by the APVMA in determining an application is 'restricted' if the APVMA's use of the information in determining the application is restricted by Division 4A of Part 2 of the Agvet Code (which limits the use the APVMA can make of certain information that is given to it) or by Part 3 of the Agvet Code (which relates to the provision of compensation for providers of certain information in respect of continued registration of certain chemical products).

Subclause 1.5(1) clarifies that despite the operation of clauses 1.2, 1.3 and 1.4, a proposed chemical product and a reference chemical product are not 'closely similar', 'similar' or 'the same' if:

- the APVMA is required to use information in determining an application in respect of the proposed chemical product; and
- the use of the information by the APVMA in determining that application is restricted (e.g. no consent from the authorising party to use the secured information has been given).

Items 45 to 48 make consequential amendments to clause 1.6 of Schedule 6 to the Code Regulations. These substitute previous references to 'protected information' with references to the use of information that is 'restricted'.

Part 8–Assessment periods and fees

Part 8 of these Regulations amends the Code Regulations to allow for some active constituent approvals to be dealt with simultaneously as part of an application for registration of a chemical product in certain circumstances. This enables more applicants to make one application to the APVMA for approval of an active constituent, registration of a chemical product and approval of a label for containers for a chemical product.

Applications to the APVMA are classified on the basis of item numbers and descriptors set out in the table in clause 2.1 of Schedule 6 to the Code Regulations. Previously, except for applications of a type described in items 1 and 2, it was not possible for the APVMA to approve an active constituent as part of an application to register a chemical product. Accordingly, if an applicant wished to register a new chemical product while seeking approval of a new active constituent, two separate applications were required.

The amendments made by Part 8 of these Regulations set out additional circumstances when the APVMA may consider an application to both approve an active constituent and register a chemical product. Part 8 amends the descriptions of the application kinds referred to in items 5, 6 and 10 of the table in clause 2.1 of Schedule 6 to the Code Regulations to provide that the APVMA can consider applications to simultaneously approve certain new active constituents and register a chemical product.

The amendments made by Part 8 of these Regulations allow the fully modular applications of a type described by item 10 to include registration of a chemical product and approval of an active constituent that will deal with more complex active constituent than items 5 or 6. Accordingly, there is no constraint on which active constituent applications could be considered under item 10.

Joint assessment of active constituents and products has not been extended to applications of a type described in items 3, 4, 7, 8 or 9, as it is likely that the APVMA would require additional resources to do this.

The amendments made by Part 8 of these Regulations also extend items 5, 6 and 10 to include a chemical product registration and approval of the product label where an application for approval of an active constituent has already been separately lodged. This provides for situations, for example, where an applicant may be seeking to register a range of new products that all have the same new active constituent, so the company would only seek one active constituent approval (either separately or as part of a single application of a type described in items 5, 6 or 10).

Code Regulations

Item 49 repeals and substitutes the table of assessment periods and fees in Part 2 of Schedule 6 of the Code Regulations. In so doing, the descriptions of the kinds of applications specified in items 5, 6 and 10 were amended to provide that the APVMA can also—in certain circumstances—assess an active constituent at the same time that it considers an application to register a chemical product and product label. These items also now provide for chemical product registration and approval of the product label where an application for approval of an active constituent has been separately lodged. These constraining circumstances are outlined in Table 3.

Table 3 Constraints on approval of a new active constituent as part of the consideration of a registration application

Item	Scenario 1: Active constituent already approved	Scenario 2: Approval of active constituent as part of registration application	Scenario 3: Separate application for active constituent approval has been lodged
5	• the chemical product must be similar to a registered chemical product • chemistry and manufacture, efficacy or target species safety data must be the only data required to demonstrate this similarity	The active constituent must also comply with a monograph or compendia standard in the British Pharmacopoeia, British Pharmacopoeia (Veterinary), European Pharmacopoeia or United States Pharmacopeia.	No additional constraint
6	• the chemical product must be closely similar to a registered chemical product • chemistry and manufacture data must be the only data required to demonstrate this similarity		
10	For all situations other than those described in items 1 to 9.		

Item 49 changes the description of item 6, employing a more concise description of the data requirements. Item 49 also amends the description of item 17 to clarify that this item is not applicable when items 5, 6 or 10 apply.

Item 49 also removes column 5 of the table in clause 2.1 of Schedule 6, which dealt with fees from 1 July 2014 to 31 December 2014.

Item 49 further removes the previous references to 'other than a timeshift application' in the previous descriptions of items 1, 2 3, 4 and 15 of the table in clause 2.1 of Schedule 6 and amends item 27 of the table to include a new reference to the definition of 'timeshift application (see regulation 3BA)'. New regulation 3BA is inserted by item 3 of these Regulations.

The fees prescribed table in clause 2.1 of Schedule 6, as inserted by item 49, are unchanged from those that were previously prescribed in the table in Part 2 of Schedule 6, as repealed by this item. That is, the item does not add or change any of the fees relating to the kinds of applications described in the table. The fees are all calculated on the basis of cost-recovery. They reflect those in APVMA's 2012 Cost Recovery Impact Statement (available at apvma.gov.au), which was subject to consultation in 2011 and 2012.

Part 9–Consequential and other amendments

Part 9 of these Regulations amends the Levy Regulations, Administration Regulations and Code Regulations to deal with a number of minor and consequential changes, including updating some outdated references and removing unnecessary provisions.

The changes to the Levy Regulations remove redundant provisions and make minor amendments to improve accuracy and clarity.

The changes to the Administration Regulations clarify the fee that applies in circumstances when an applicant requires the APVMA to request the performance of a consular act (in relation to a certificate) for which a fee is imposed under the *Consular Fees Act 1955*. The amount of the fee is an amount equal to the amount of the consular fee payable by the APVMA for the consular act.

The remaining amendments are all changes to the Code Regulations to:

- insert new definitions into the Code Regulations ('assessment period' and 'extended assessment period')
- repeal definitions from the Code Regulations that are no longer used ('biological pesticide', 'pool or spa hypochlorite' and 'total leviable value')
- correct the reference in the Code Regulations to the legislative authority to issue several notices
- clarify the requirements for the APVMA to issue a notice when a person applies for a technical assessment or lodges an application to:
    - make an interchangeable constituent determination
    - make or vary an ingredient determination
- recast a number of regulations to reflect modern drafting requirements or correct inconsistencies
- remove redundant references and update references to the 'United States Pharmacopeia' and the 'FAISD Handbook – Handbook of First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for Agricultural and Veterinary Chemicals'.

Additional changes to the Code Regulations prescribe the information that must be included in certain notices about protected information for active constituents and updates references following the recent restructuring of provisions in the Australia New Zealand Food Standards Code (the Food Standards Code).

<u>Protected information</u>

Provisions in Part 3 of the Agvet Code provide for a person who has provided protected information to the APVMA to negotiate compensation from other parties who want to use that information. Section 60 of the Agvet Code sets out information that must be in notices given to certain persons if the APVMA would have to use protected information to register another chemical product—this includes information prescribed in regulations.

These notices allow the holder (or holders) of a registered chemical product (primary holder(s)) and the prospective holder of the proposed registration of a second chemical product (secondary holder) to negotiate compensation for access to protected information. Regulations 24 and 25 of the Code Regulations prescribe the type of information that must be

included in the notices to the primary and secondary holder, respectively. Previously, these regulations only prescribed information for chemical products. However, notices about protected information may also relate to active constituents.

Part 9 of these Regulations amends the Code Regulations to prescribe the information to be included in notices that allow the holder (or holders) of a currently approved active constituent (primary holder(s)) and the prospective holder of the second active constituent (secondary holder) to negotiate compensation for access to protected information. Additionally, Part 9 amends the headings of regulations 24 and 25, to refer to prescribed information rather than 'protected registered information'. This is because the undefined term 'protected registered information' may be misleading.

Food Standards Code

Part 9 of these Regulations updates references to provisions in the Food Standards Code in previous items 1 and 2 of the table in clause 5 of Schedule 3AA to the Code Regulations. These updates are necessary following the restructuring of provisions in the Food Standards Code. Specifically:

- For previous item 1 of the table, which dealt with generally permitted processing aids, these substances are now specified in:
    - section S18—2 of Schedule 18 to the Food Standards Code ('Processing aids')
    - the food additives permitted at good manufacturing practice (with respect to the addition of substances used as food additives and substances used as processing aids to food) in section S16—2 of Schedule 16 to the Food Standards Code ('Types of substances that may be used as food additives').
- For previous item 2 of the table, which dealt with permitted flavouring substances and colours, these substances are now defined in section 1.1.2—2 of Standard 1.1.2 of the Food Standards Code ('Definitions used throughout the Food Standards Code'). Permitted colours are specified in sections S16—3 and S16—4 of Schedule 16 to the Food Standards Code ('Types of substances that may be used as food additives').

Given the changes to the Food Standards Code, Part 9 of these Regulations consolidates previous items 1 and 2 of the table in clause 5 of Schedule 3AA into a provision that authorises these ingredients, as authorised by the Food Standards Code, as existing at the time of supply:

- permitted flavouring substances
- generally permitted processing aids
- food additives (including colourings) specified in Schedule 16 to the Food Standards Code.

Levy Regulations

Item 50 repeals regulation 6A of the Levy Regulations and substitutes a new regulation 6A. Repealed subregulations 6A(2) and (3) are no longer required as they related to rates of levy from before the 2012–13 financial year. Repealed subregulation 6A(4) has been renumbered to become regulation 6A. It has also been amended:

- to take into account that it is the 'percentage' that is to be prescribed rather than the 'rate' (as per section 12C of the Levy Act)
- to clarify that the amounts prescribed are the 'total leviable values' (as defined at section 3 of the Levy Act) in respect of the products in a given financial year.

The levy to which the rates prescribed in item 50 relate is a cost-recovery levy charged to the agvet chemicals industry. The levy is a tax imposed by the Levy Act, which is a taxation Act. The rates prescribed are the same as those that were previously prescribed in regulation 6A, as repealed by this item. That is, the item does not add or change the levy rates. They reflect those in APVMA's 2012 Cost Recovery Impact Statement (available at apvma.gov.au), which was subject to consultation in 2011 and 2012.

Administration Regulations

Item 51 repeals subregulation 3.550(3) of the Administration Regulations and substitutes a new subregulation 3.550(3). It clarifies the fee that applies in circumstances when an applicant requires the APVMA to request the performance of a consular act (in relation to a certificate) for which a fee is imposed under the *Consular Fees Act 1955*. The amount of the fee is an amount equal to the amount of the consular fee payable by the APVMA for the consular act.

Code Regulations

Items 52 and 54 insert new definitions into subregulation 3(1) of the Code Regulations for 'assessment period' and 'extended assessment period'. Definitions are required as these terms are used in later parts of the Code Regulations.

Items 53 and 55 amend subregulation 3(1) of the Code Regulations to repeal the definitions of 'biological pesticide', 'pool or spa hypochlorite' and 'total leviable value'. These definitions are no longer used in the Code Regulations.

Items 56, 79, 81, 82 and 89 amend references in the Code Regulations to reflect the correct legislative authority to issue a notice (by referencing subsection 11(2), 28(2) or 110A(2) of the Agvet Code, or subregulations 8AP(1) or 8AQ(2) of the Code Regulations rather than the previous incorrect reference to '8AO, 8AP or 8AQ'). The updated references are in:

- regulation 8AH
- subregulation 70(7)
- subparagraph 72(2)(b)(i)
- subregulation 72(5)
- paragraphs 78(1)(a) and (b).

Items 57, 75, 76, 77, 80, 83, 84, 85 and 90 make consequential amendments to subparagraphs 8AO(2)(e)(i) and 70B(1)(a)(i) and subregulations 70(2), 70(4), 70(5), 76(1), 76(1A), 76(2), 76A(2) and 78(2) of the Code Regulations to update cross-references so that they refer to the new table in clause 2.1 of Schedule 6.

Items 58 and 60 repeal and substitute paragraphs 8AO(2)(m) and 8AQ(2)(i) to clarify the matters that must be included in certain notices. These matters relate to the authority under which an applicant may apply for a review, should the APVMA not determine the application within the assessment period.

Item 59 repeals and substitutes regulation 8AP of the Code Regulations. It extends the previous requirements for the APVMA to issue a notice when a person applies for a technical

assessment under regulation 8AS. The requirements will now also apply when a person lodges an application to:

- make an interchangeable constituent determination (under regulation 19AEB)
- make or vary an ingredient determination (under clause 10 of Schedule 3AA).

Item 59 also alters the construction of the notice requirements in subregulation 8AP(2) to reflect modern drafting conventions. In addition, new paragraph 8AP(2)(g) clarifies matters relating to the authority under which an applicant may apply for a review, should the APVMA not determine the application within the assessment period.

Item 61 makes a minor amendment to the examples listed in regulation 8AS of the Code Regulations to remove the reference to 'Assessment of a trial protocol'. Such assessments are not undertaken by the APVMA under this regulation.

Items 62 and 63 make minor amendments to subparagraph 18(2)(e)(i) and subregulation 23H(2) of the Code Regulations so that the conditions for containers for reserved chemical products are expressed in the same way as the conditions for registered chemical products. This is done by aligning:

- subparagraph 18(2)(e)(i) with subparagraph 23H(1)(e)(i)
- subregulation 23H(2) with subregulation 18(3).

Item 64 updates the handbook referred to in subregulation 23I(2) of the Code Regulations to the 'FAISD Handbook – Handbook of First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for Agricultural and Veterinary Chemicals' which is now published by the APVMA on its website (not the Therapeutic Goods Administration, as previously stated).

Item 65 repeals and substitutes regulations 24 and 25 to prescribe, for the purposes of subparagraphs 60(3)(a)(i) and 60(3)(a)(ii) of the Agvet Code, information about secondary active constituents and primary active constituents, respectively that must be included in notices. In addition to the previously prescribed information for the primary and secondary chemical product, further information about primary and secondary active constituents is now prescribed by these amendments. The key additional information that has been prescribed is set out in Table 4.

Table 4 Information in relation to active constituents, prescribed by amendments to regulations 24 and 25 of the Code Regulations

Type of information	Notice to Primary Holder (Regulation 24)	Notice to Secondary Holder (Regulation 25)
Name and business address	For an approved active constituent, the name and address of the secondary holder of approval in the Record of Approved Active Constituents for Chemical Products (the Record) For an unapproved active constituent, the name and address of the prospective holder in the application for approval	The name and address of each primary holder entered in the Record
Particulars from the Record	Particulars of the approved secondary active constituent No details for an unapproved active constituent	Particulars of each primary active constituent

For notices to either primary or secondary holders that require particulars from the Record, these particulars are those prescribed in regulation 15 of the Code Regulations for paragraph 19(c) of the Agvet Code.

Item 65 also amends the headings for regulations 24 (notice to primary holder) and 25 (notice to secondary holder) to refer to 'prescribed information' rather than 'protected registered information'.

Items 66, 67, 68 and 73 amend paragraph 35(1)(a), the heading of regulation 36, paragraphs 36(a), (c) and (d) and subregulations 66(2) and (3) of the Code Regulations. These amendments replace the previous references to 'protected registration information' and 'protected registered information' so that they now refer to 'protected information'.

Items 69 and 71 amend subparagraphs 42(3)(e)(iv) and 55(2)(c)(vi) of the Code Regulations to omit 'Pharmacopoeia' and 'US Pharmacopoeia' and substitute 'Pharmacopeia' and 'United States Pharmacopeia'. This ensures that the correct names are used and those names align with the definitions in subregulation 3(1) of the Code Regulations.

Item 70 modernises the language in subregulation 46(1) of the Code Regulations for the reasons described in relation to items 18 and 22 above (that is, to ensure that these offences attract the operation of subsection 4D(1) of the *Crimes Act 1914*, which refers to a contravention of a section of subsection).

Item 72 repeals and substitutes the definition of 'XP' (the extended assessment period) in subregulation 65A(2). This is a variable in a mathematical formula used to calculate the period for giving additional information for certain applications. The amendment updates cross references so that they refer to the table in clause 2.1 of Schedule 6 (previously at Part 2 of Schedule 6).

Item 74 repeals and substitutes subregulation 66(5) of the Code Regulations. These amendments amend the previous reference to 'compensatable protected registration information' to 'compensatable protected information' and clarifies that compensation is

payable for ‘use’ of the information (previously this subregulation referred to ‘provision’ of the information).

Item 78 repeals and substitutes subregulation 70(6) of the Code Regulations. This removes redundant references to fees that were required to be paid at the time of making an application in the period from 1 July 2014 to 31 December 2014.

Item 86 repeals a redundant note in subregulation 76A(3). This note referred to an application for re-approval or re-registration. This type of application no longer exists.

Item 87 repeals and substitutes subregulation 76A(4) of the Code Regulations. The term ‘extended assessment period’ is bolded and italicised as it is a definition provision. Item 87 also updates a cross-reference so that it refers to the table in clause 2.1 of Schedule 6 (previously at Part 2 of Schedule 6).

Item 88 removes the reference to item 26 in subregulation 78(1) of the Code Regulations—item 26 was repealed from Part 2 of Schedule 6 to the Code Regulations, by the Agricultural and Veterinary Chemicals Code Amendment (Removal of Re-approvals and Re-registrations) Regulation 2014. Item 88 also updates a cross reference so that it refers to the table in clause 2.1 of Schedule 6 (previously at Part 2 of Schedule 6).

Item 91 inserts subregulation 78C(caa) of the Code Regulations. This paragraph clarifies that a decision by the APVMA to refuse an application for a technical assessment (as defined by regulation 8AS of the Code Regulations) is reviewable by the Administrative Appeals Tribunal.

Item 92 repeals Part 9A of the Code Regulations, which dealt with prescribed reviews. Previous regulation 80C of the Code Regulations provided that Part 9A ceases to have effect 5 years after the day the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (Amendment Act) receives the Royal Assent. The Amendment Act received the Royal Assent on 29 June 2013. The repeal of Part 9A of the Code Regulations allows the reference to be removed from the statute book.

Item 93 repeals items 1 and 2 of the table in subclause 5(3) of Schedule 3AA to the Code Regulations and substitutes a new item 1. This updates the ingredients authorised for use by certain standards, rules, codes, specifications or methods so they accurately reference the Food Standards Code. Specifically, it references the following ingredients authorised by the Food Standards Code, as existing at the time of supply:

- permitted flavouring substances
- generally permitted processing aids
- food additives (including colourings) specified in Schedule 16 to the Food Standards Code.

Item 94 repeals and substitutes paragraph 7(3)(c) of Schedule 3AA. It updates the references to provisions in the Food Standards Code. References are now to sections 1.2.4—3, 1.2.4—4, 1.2.4—6, 1.2.4—7 and 1.2.4—8 instead of clauses 3, 4, 6, 7, 8, 9, and 10 of Standard 1.2.4 of the Food Standards Code.

Items 95, 96 and 97 make minor amendments to the definitions of ‘closely similar’, ‘similar’ and ‘the same’ in clause 1.1 of Schedule 6 to the Code Regulations. This is to correctly

reference *clauses* 1.2, 1.3 and 1.4 instead of *sections*. It also adds a reference to new subclause 1.5(1), which describes specific circumstances when chemical products are not 'closely similar', 'similar' or 'the same'.

Items 98 to 107 make consequential amendments to clauses 1.2, 1.3 and 1.4 of Schedule 6 to the Code Regulations (which detail when a proposed and reference chemical product are 'closely similar', 'similar' or 'the same' as a reference product) to refer to clause 1.5 (which describes specific circumstances when chemical products are not 'closely similar', 'similar' or 'the same'). Subclauses 1.2(2), 1.2(4), 1.3(2), 1.3(4) and 1.4(2) are omitted—these previously dealt with the circumstance where information about the reference chemical product was 'protected information' within the meaning of Schedule 6 (a concept that has been removed from Schedule 6).

Part 10–Transitional provisions

Part 10 provides for transitional and application provisions that are necessary to allow the smooth implementation of the changes in Parts 1 to 9.

In keeping with drafting conventions, transitional and application provisions relating to the amendments of the Agvet Code are kept together and have been inserted into the Code Regulations as a new Division.

Code Regulations

Item 108 inserts new Division 10.4 into Part 10 of the Code Regulations for the transitional and application provisions associated with the amendments made by these Regulations. Specifically this item:

- inserts definitions for 'amending regulations' and 'commencement day' that apply to the new Division 10.4
- provides that the amendments apply in relation to applications made on or after the commencement day
- provides that new regulation 42A (the new exemption from the operation of section 88 of the Agvet Code inserted by item 41 under Part 6) applies to a relevant substance or chemical product, whether the substance or chemical product first meets the requirement of paragraph 42A(1)(a), (b), (c) or (d) on or after the commencement day.

ATTACHMENT B

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2019

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The Legislative Instrument makes amendments to the Agricultural and Veterinary Chemicals (Administration) Regulations 1995 (the Administration Regulations), the Agricultural and Veterinary Chemicals Code Regulations 1995 (the Code Regulations) and the Agricultural and Veterinary Chemicals (Collection of Levy) Regulations 1995 (the Levy Regulations).

The Legislative Instrument will improve the efficient and effective regulation of agricultural chemicals and veterinary medicines (agvet chemicals). They amend regulations made under the agvet chemical legislation to:

- extend the range of application types that can be assessed as timeshift applications, to provide more flexibility for the Australian Pesticides and Veterinary Medicines Authority (APVMA) and applicants
- provide for greater use of ministerial orders, which are disallowable, so the government can be more responsive
- declare certain substances to not be agricultural chemical products or veterinary chemical products, so they are not regulated by the APVMA
- simplify the legislation for notifiable and prescribed variations and consolidate related requirements into instruments made by the APVMA
- modernise hormonal growth promotant requirements, including introducing civil penalties and infringement notices for non-compliance, to allow the APVMA to respond more proportionately to alleged contraventions of existing legal requirements
- address a policy anomaly about advertising in agvet chemical legislation
- clarify some matters about when the APVMA can use information provided by another party to support the registration of a proposed chemical product
- allow for approvals (in certain circumstances) to be dealt with simultaneously as part of an application for registration of a chemical product
- deal with a number of minor and consequential changes, including updating some outdated references and removing unnecessary provisions.

Human rights implications

Some parts of the Legislative Instrument engage, or have the potential to engage, Articles 14, 15 and 17 of the International Covenant on Civil and Political Rights (ICCPR). These are identified and assessed below for each part of the Legislative Instrument.

Part 1–Timeshift
Part 1 of Schedule 1 to the Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

Part 2–Ministerial orders
Part 2 of Schedule 1 to the Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

Importantly, ministerial orders are legislative instruments that must be registered on the Federal Register of Legislation. They are subject to parliamentary scrutiny and disallowance and cannot prescribe a penalty. Furthermore, ministerial orders cannot be inconsistent with the regulations or the Agvet Code (that is, a ministerial order cannot 'override' a regulation or any provision of the Agvet Code).

Part 3–Chemical product declarations
Part 3 of Schedule 1 to the Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

Part 4– Notifiable variations and prescribed variations
Part 4 of Schedule 1 to the Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

Part 5–Hormonal Growth Promotants
Amendments to regulations 47C to 51, and 53 to 54 of the Code Regulations increase the existing penalties in relation to supply and record-keeping for hormonal growth promotants (HGPs) from 10 penalty units to 30 or 50 penalty units, and provide for them to be civil penalties in addition to being criminal offences. The amendment to Schedule 5 of the Code Regulations also prescribes regulations 47C to 51 and 53 to 54 of the Code Regulations, which in turn will allow the APVMA to issue infringement notices.

The inappropriate supply of HGPs has the potential to negatively affect Australia's trade reputation and reduce market access for meat products exported from Australia. The penalty for contravening these requirements is therefore commensurate with this potential impact. Furthermore, inadequate record keeping prevents the regulator from taking proportionate actions when monitoring compliance, as traceback procedures can be frustrated by a lack of records about the supply of HGPs.

Increasing penalties and Article 15
The penalty amounts for an individual for a contravention of regulation 47C, 48, 49, 50, 51, 53 or 54 of the Code Regulations is either 30 or 50 penalty units—previously this was 10 penalty units.

Subsection 170(5) of the Agvet Code states that, where a body corporate is convicted of an offence against the Agvet Code, a court may, if the court thinks fit, impose a monetary penalty not greater than five times the amount of the maximum monetary penalty that could be imposed by the court on an individual convicted of the same offence. Accordingly, the

corresponding maximum penalty for a body corporate for the criminal contravention of regulation 47C, 48, 49, 50, 51, 53 or 54 of the Code Regulations will be either 150 (30 x 5) or 250 (50 x 5) penalty units. Previously this was 50 penalty units.

These increased penalties are consistent with the Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers, which provides that regulations should not impose fines for individuals exceeding 50 penalty units and 250 penalty units for bodies corporate. A penalty for an individual in the upper range of 50 penalty units is appropriate given the potential impact to Australia's trade reputation and reduced market access for meat products exported from Australia for contravening these requirements.

Article 15 of the ICCPR prohibits the retrospective application of criminal laws. As the amendments to the Code Regulations by Part 5 of Schedule 1 to the Legislative Instrument will only apply in relation to actions taken on or after the commencement of Part 5—being the day after the instrument is registered—Article 15 of the ICCPR is not engaged.

Civil penalties and Articles 14 and 15

Prescribing conduct that is subject to a civil penalty could engage criminal process rights if the imposition of a civil penalty is classified as 'criminal' under international human rights law. *Guidance Note 2: Offence provisions, civil penalties and human rights* (December 2014), which is published by the Parliamentary Joint Committee on Human Rights, states that civil penalty provisions may engage criminal process rights under Articles 14 and 15 of the ICCPR, regardless of the distinction between criminal and civil penalties in domestic law. When a provision imposes a civil penalty, an assessment is required as to whether it amounts to a 'criminal' penalty for the purposes of the ICCPR.

Determining whether penalties could be considered to be criminal under international human rights law requires consideration of the classification of the penalty provisions under Australian domestic law, the nature and purpose of the penalties, and the severity of the penalties.

Items 21, 25, 28, 30, 33, 36 and 39 of the Legislative Instrument, which amend regulations 47C, 48, 49, 50, 51, 53 and 54 of the Code Regulations, also inserts a note a to direct the reader to Division 2 of Part 9A of the Agvet Code. Division 2 of Part 9A of the Agvet Code creates a framework for the use of civil penalties to enforce civil penalty provisions of the Agvet Code.

Subsection 145AA(1) of the Agvet Code provides that the pecuniary penalty for a contravention of a civil penalty provision by a body corporate must not exceed five times the amount of the maximum monetary penalty that could be imposed by a court if the body corporate were convicted of an offence constituted by conduct that is the same as the conduct constituting the contravention.

Subsection 145AA(2) of the Agvet Code provides that the pecuniary penalty for a contravention of a civil penalty provision by an individual must not exceed three times the amount of the maximum monetary penalty that could be imposed by a court if the person were convicted of an offence constituted by conduct that is the same as the conduct constituting the contravention.

Subsection 170(5) of the Agvet Code states that, where a body corporate is convicted of a criminal offence against the Agvet Code, a court may, if the court thinks fit, impose a monetary penalty not greater than five times the amount of the maximum monetary penalty that could be imposed by the court on an individual convicted of the criminal offence.

The applicable criminal pecuniary penalty for an individual for a contravention of regulations 47C, 48, 49, 50, 51, 53 or 54 of the Code Regulations is either 30 or 50 penalty units. Accordingly, the corresponding criminal pecuniary penalty for a body corporate for a contravention of regulations 47C, 48, 49, 50, 51, 53 or 54 will be either 150 (30x5) or 250 (50x5) penalty units.

In compliance with section 145AA and subsection 170(5) of the Agvet Code, the civil penalty for a contravention of regulations 47C, 48, 49, 50, 51, 53 or 54 will be either 90 (30x3) or 150 (50x3) penalty units for individuals and 750 (150x5) or 1,250 (250x5) penalty units for bodies corporate.

The penalty provisions for a contravention of regulations 47C, 48, 49, 50, 51, 53 and 54 of the Code Regulations are also expressly classified as civil penalties. A civil penalty is payable as a debt in the event a court orders that a person pay the Commonwealth the penalty (see section 145AB of the Agvet Code). These penalty provisions do not seek to impose criminal liability and do not lead to the creation of a criminal record. The penalties will only apply to those persons who supply HGPs. That is, the penalty does not apply to the public in general, it only applies to persons who would reasonably be expected to be aware of their obligations in relation to the supply of HGPs. Further, the imposition of these civil pecuniary penalties is not dependent on a finding of guilt, and section 145AG of the Agvet Code expressly states that the contravention of a civil penalty provision is not an offence. The applicable penalties are also reflective of the seriousness of the conduct and the risk contravening behaviour may pose to negatively impact on Australia's trade reputation and reduce market access for meat products exported from Australia.

These factors all support that the new civil penalties for a contravention of regulations 47C, 48, 49, 50, 51, 53 and 54 of the Code Regulations are civil penalties rather than criminal penalties for the purposes of Australia's human rights obligations. Accordingly, the criminal process rights provided for by Articles 14 and 15 of the ICCPR are not engaged.
Article 15 of the ICCPR prohibits the retrospective application of criminal laws. As the amendments to the Code Regulations made by Part 5 of Schedule 1 to the Legislative Instrument will only apply in relation to actions taken on or after the commencement of Part 5—being the day after the instrument is registered—Article 15 of the ICCPR is not engaged.

The reasonable excuse defence
Consistent with the Guide to Framing Commonwealth Offences, the Legislative Instrument removes the reasonable excuse defences from all the offences in subregulations 47C(1A), 48(2), 49(2), 51(3), 53(3), and 54(4) of the Code Regulations (these offences all relate to the supply and record keeping requirements for HGPs). Persons that may be subject to these offences will continue to be able to rely on the defences in the Criminal Code, including the honest and reasonable mistake of fact defence (section 9.2 of the Criminal Code). This will modernise the provisions so they operate like contemporary offence provisions.

Summary
Part 5 of Schedule 1 to the Legislative Instrument is compatible with the criminal process rights provided for by Articles 14 and 15 of the ICCPR because amended regulations 47C, 48, 49, 50, 51, 53 or 54, as well as amended Schedule 5A, of the Code Regulations do not engage those rights.

Part 6–Section 88 exemption
Part 6 of Schedule 1 to the Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

Transitional provisions related to new regulation 42A created by the amendments in Part 6 are set out in Part 10 of Schedule 1 to the Legislative Instrument. These include a retrospective, but positive, aspect which is dealt with under this human rights statement's discussion about Part 10.

Part 7–Restricted information
Part 7 of Schedule 1 to the Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

Part 8—Allowing certain actives to be approved as part of a product registration
Part 8 of Schedule 1 to the Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

Part 8 includes measures to allow the APVMA to make a decision about approving an active constituent while assessing a broader range of chemical product applications than previously allowed. This does not affect the circumstances in which a person may request an internal review or apply for AAT review in relation to a decision on approving an active constituent.

Part 9—Consequential and other amendments
Part 9 of Schedule 1 to the Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

Right to privacy
Article 17 of the ICCPR prohibits arbitrary or unlawful interference with an individual's privacy, family, home or correspondence, and protects a person's honour and reputation from unlawful attacks. The right to privacy can be limited to achieve a legitimate objective where the limitations are lawful and not arbitrary. In order for an interference with the right to privacy to be permissible, the interference must be authorised by law, be for a reason consistent with the ICCPR and be reasonable in the circumstances. The United Nations Human Rights Committee has interpreted the requirement of 'reasonableness' as implying that any interference with privacy must be proportionate to a legitimate end and be necessary in the circumstances.

Provisions in Part 3 of the Agvet Code provide for a person who has provided protected information to the APVMA to negotiate compensation from other parties who want to use that information. Section 60 of the Agvet Code sets out information that must be in notices given

to certain persons if the APVMA would have to use protected information to register another chemical product—this includes information to be prescribed in regulations.

These notices allow the holder (or holders) of a registered chemical product (primary holder(s)) and the prospective holder of the proposed registration of a second chemical product (secondary holder) to negotiate compensation for access to protected information.

Regulations 24 and 25 of the Code Regulations prescribe the type of information that must be included in the notices to the primary and secondary holder, respectively. Previously, these regulations only prescribed information for chemical products. However, notices about protected information may also relate to active constituents.

Part 9 amends the Code Regulations to prescribe the information to be included in notices that will allow the holder of an approved active constituent (primary holder) and the holder of the second approved active constituent (secondary holder) to negotiate compensation for access to protected information. These notices require the APVMA to share information between the parties.

For notices to either primary or secondary holders that require particulars from the Record of Approved Active Constituents for Chemical Products (the Record), these particulars are those prescribed in regulation 15 of the Code Regulations, which include (if readily available to the APVMA):

- name of the active constituent
- composition and purity active constituent
- name of the manufacturer(s) and the address of each site at which the active constituent is manufactured by the manufacturer
- identifying information for the holder(s) of the approval
- the date of entry of these particulars in the Record of Approved Active Constituents
- identifying information for any nominated agent for the approval.

To the extent that expanding the disclosure of information (to facilitate compensation negotiations) in regulations 24 and 25 to include information about active constituents may limit the right to privacy, any limitation is reasonable, necessary and proportionate to the achievement of a legitimate objective of an effective compensation scheme to protect property rights of affected parties.

The potential disclosure of information has been limited to only those details necessary to ensure that potential parties in a compensation negotiation are sufficiently informed to be able to progress any such negotiations.

Summary

Part 9 of Schedule 1 to the Legislative Instrument is compatible with human rights because, to the extent that amended regulations 24 and 25 of the Code Regulations may limit the right to privacy in Article 17 of the ICCPR, that limitation is reasonable, necessary and proportionate to the achievement of a legitimate outcome of promoting an effective compensation scheme to protect property rights of affected parties.

Part 10–Transitional provisions
Part 10 of Schedule 1 to the Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

Retrospective right to advertise and Article 15
Article 15 of the ICCPR prohibits the retrospective application of criminal laws. As set out under item 107, the exemption in new regulation 42A of the Code Regulations (item 41 in Part 6 of Schedule 1) will apply to certain substances or chemical products regardless of whether they meet certain requirements before, on, or after the commencement date—being the day after the instrument is registered. However, as regulation 42A operates as an exemption from the advertising restrictions imposed by section 88 of the Agvet Code, and does not itself impose new restrictions, there is no detriment to any relevant persons (e.g. persons who use chemical products under permit) from the retrospective aspect of this amendment so Article 15 of the ICCPR is not engaged.

Conclusion
This Legislative Instrument is compatible with human rights as it does not raise any human rights issues.

Senator the Hon. Bridget McKenzie
Minister for Agriculture