Australian Government
Department of Agriculture and Water Resources

Proposed changes to timeshift applications and other measures, and to support operational efficiency

Agricultural and Veterinary Chemicals Legislation Amendment Regulations 2018

Cataloguing data

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Department of Agriculture and Water Resources
GPO Box 858 Canberra ACT 2601
Telephone 1800 900 090
Web agriculture.gov.au

Contents

Tables

Submissions

The Department of Agriculture and Water Resources (the department) is seeking submissions on proposed changes to the:

- Agricultural and Veterinary Chemicals (Administration) Regulations 1995
- Agricultural and Veterinary Chemicals Code Regulations 1995
- Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995.

The department is consulting on two sets of measures. The first set is a group of new proposed changes (Timeshift Applications and Other Measures). These would:

- 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
- provide for greater use of disallowable ministerial orders, so the government can be more responsive to agricultural and veterinary (agvet) chemical issues
- declare a limited range of substances to not be agricultural chemical products or veterinary chemical products, so they are no longer 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 and introduce some new penalties for non-compliance, to allow the APVMA to respond more proportionately to alleged contraventions of existing legal requirements
- address an anomaly about advertising in agvet legislation
- clarify the handling of some aspects of protected information
- reduce red tape for some active constituent approvals by allowing 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- deal with a number of machinery changes, including updating some outdated references and removing unnecessary provisions
- clarify new requirements introduced in the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, which is before parliament:
  - clarify when the APVMA is required to publish a notice about a voluntary recall and allow for a full suite of compliance options by introducing infringement notices
  - prescribe the information that the APVMA may consider during the assessment of an application without triggering extensions to the assessment period
- better allocate the costs that arise when the APVMA chooses to work with an applicant to remedy applications containing incorrect information, by charging those applicants a fee.

The second set of proposed changes (Operational Efficiency Regulations measures) amend regulations that deal with annual returns, record-keeping for these returns and infringement notices, to reflect the amendments in the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017. This Bill is also before parliament.

Collectively, the measures would improve the effectiveness and efficiency of the national system for regulating agvet chemical products, while retaining protections for the health and safety of humans, animals and the environment.

Your submissions will help us assess how well these proposals meet stakeholders' needs.

How to have your say

Submissions must be received by 5 pm on 20 February 2019.

The department will consider all relevant material provided in submissions. While there is no set format for a submission, please make sure you include at least:

- the title of this consultation document
- your name and title
- your organisation's name if submitting on behalf of an organisation
- your contact details.

Please ensure your comments can be clearly read as copies may be made to help with assessment and evaluation. We would appreciate your assistance by identifying the relevant section of this paper and/or the draft regulation amendments when making a comment on a specific section of this consultation document.

You can return your submission by post or email.

Post to:
Regulation of Agricultural and Veterinary Chemicals
Agvet Chemicals Branch
Department of Agriculture and Water Resources
GPO Box 858
Canberra ACT 2601

Email: agvetreform@agriculture.gov.au

If submitted by email (the department's preferred method), a hard copy of your submission is not needed. The department will endeavour to formally acknowledge receipt of submissions within three business days.

We may not be able to consider submissions received after the closing date of 20 February 2019. However, suggestions for additional reform measures received after the submission deadline can be considered as part of future regulatory amendments.

Privacy: The department will only use the personal information collected about you to enable us to contact you about your submission and may (where the disclosure is consistent with relevant laws, in particular the *Privacy Act 1988*) disclose it to specialists; other Commonwealth government agencies; state and territory government agencies or foreign government departments.

The department requests that, at minimum, you provide your name and contact details with your submission. Please indicate if you do not wish to have identifying information published with your submission or disclosed to third parties.

The department will use and store all personal information it collects in accordance with the Australian Privacy Principles as outlined in the department's Privacy Policy available on the department's website.

Confidentiality: Subject to the *Freedom of Information Act 1982* and the *Privacy Act 1988*, the content of submissions may be made public, unless you state you want all or part of your submission to be treated as confidential material. A claim for confidentiality must be justified and provided as an attachment, marked 'Confidential'. Confidential' material will not be made public. No breach of confidence will occur if the department shares your submission with a third party referred to under 'Privacy' in seeking advice in response to your submission.

Publishing of submissions

All non-confidential submissions will be published on the department's website, although the department may redact parts of submissions. We will not publish confidential material but will record that such information is held. Confidential submissions may be subject to release under the provisions of the *Freedom of Information Act 1991* (FOI Act). Submissions will be published as soon as possible after the end of the public comment period.

If you are making a confidential submission, you may wish to indicate any grounds for withholding information it contains. Reasons could include that the information is commercially sensitive or that you wish personal information, such as names and contact details, to be withheld. An automatic confidentiality disclaimer from your IT system will not be considered as grounds for withholding information if the department receives an FOI Act request.

We will take your indications into account when determining whether to release information under an FOI Act request. Any decisions to withhold information requested under the FOI Act may be reviewed by the Commonwealth Ombudsman.

The department reserves the right not to publish submissions.

Next steps

After the consultation period has closed, the department will assess all submissions and consider whether further amendments are necessary in light of the issues raised.

The department will then recommend the finalised policy for regulation amendments to the Minister for Agriculture and Water Resources.

Why we are consulting

The department is developing regulation amendments to improve the regulation of agvet chemical products.

The first tranche of proposed amendments, which is the focus of this document, would deliver operational efficiencies for the Australian Pesticides and Veterinary Medicines Authority (APVMA), clarify ambiguities and remove unnecessary and redundant provisions. These amendments would also support measures in the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017 (the Operational Efficiency Bill).

These proposed changes are detailed in this document. Consultation on these measures is supported by exposure drafts of two sets of regulation changes:

- the Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2018 (Timeshift and Other Measures Regulations)
- the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Regulations 2018 (Operational Efficiency Regulations).

We are also consulting on a number of proposed changes that are not supported by drafted regulations. This includes some early consultation on two measures that relate to the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 (the Streamlining Regulation Bill) recently introduced into parliament. Consulting on these now will help refine our policy, ahead of drafting of the regulations.

The government anticipates that further regulatory amendments will follow, including those relating to other measures in the Streamlining Regulation Bill. Priority among these will be the data protection incentives measure (Part 3 of the Streamlining Regulation Bill—'Limits on use of information'). The department expects to consult on these in the first half of 2019.

Context

The Australian Government is committed to improving agvet chemical regulation. The government wants to further reduce red tape, which can unnecessarily impede user access to safe and effective chemicals. This is important, for example, for the many farmers who depend on chemical access to manage their commercial competitiveness, sustainability and farm gate returns.

The 2016–17 budget included a $17.1 million measure, over four years, to streamline agvet chemical regulation under the *Agricultural Competitiveness White Paper*. This funding has supported operational changes within the APVMA and changes to legislation.

The operational changes by the APVMA are being made to improve efficiency and reduce regulatory burden. This includes work to fast-track registration for products of low regulatory concern and its guidance on the use of international data, standards and assessments to support registration.

The department is working with the APVMA, and consulting the farm industry, chemicals sector and government agencies, to identify further priority changes to agvet chemical legislation.

National regulatory framework

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.

This scheme is given effect through agvet chemical legislation that includes the:

- *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act)
- *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act)
- *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (Levy Act)
- Agricultural and Veterinary Chemicals (Administration) Regulations 1995 (Administration Regulations)
- Agricultural and Veterinary Chemicals Code Regulations 1995 (Code Regulations)
- Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995 (Levy Regulations).

The APVMA assesses and registers agvet chemicals for use in Australia and is 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) 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 and collected on the sale of agvet chemical products registered for use in Australia.

The Administration, Levy and Code Acts, including the Agvet Code and any regulations or legislative instruments made under these laws, are collectively described as agvet legislation.

Glossary

Term	Definition
Administration Act	*Agricultural and Veterinary Chemicals (Administration) Act 1992*
Administration Regulations	Agricultural and Veterinary Chemicals (Administration) Regulations 1995
active	active constituent
agvet	agricultural and veterinary
Agvet Code	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*
CRIS	Cost Recovery Implementation Statement
Criminal Code	*Criminal Code Act 1995*
department	the Department of Agriculture and Water Resources
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
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
Operational Efficiency Bill	Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017
Operational Efficiency Regulations	Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Regulations 2018
Record	the Record of Approved Active Constituents for Chemical Products, kept under section 17 of the Agvet Code
Streamlining Regulation Bill	Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018
Timeshift and Other Measures Regulations	Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2018

Changes to timeshift applications and other measures

Proposal 1: Timeshift applications

Background

The Code Regulations currently provide 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 timeshift applications allow the applicant to submit information while the assessment is underway, according to the timing in the project plan. This is not the case with other types of applications, which require the applicant to provide all information 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—for example, the (non-timeshift) assessment period for full assessment of a new active constituent is 14 months, whereas for timeshift it is the period specified in the agreed project plan.

All timeshift applications are made under item 27 (of the table at Part 2 of Schedule 6 to the Code Regulations). Where timeshift is available, the applicant can choose to either make a timeshift application under item 27 or under the application item number corresponding to the relevant type of assessment. For example, an applicant may decide to apply for approval of an active constituent requiring a full assessment under either item 27 (timeshift) or item 15 (approval of an active constituent)—see Table 1.

A 'timeshift application' is currently defined in regulation 3 of the Code Regulations as meaning an application for:

- approval of an active constituent that is not a previously-endorsed active constituent (new active constituent)
- registration of a chemical product which contains a previously-endorsed active constituent and for which a full assessment is required
- registration of a chemical product containing an active constituent that is not an active constituent contained in any other registered chemical product.

Timeshift currently applies to applications that are equivalent to those described in items 1, 2, 3, 4 and 15 of the table at Part 2 of Schedule 6 to the Code Regulations (see Table 1).

Table 1 Types of application

Item	Description of application
1	Application for approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring a full assessment of the active constituent and chemical product
2	Application for approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring less than full assessment of the active constituent and chemical product
3	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) there is no registered chemical product containing the active constituent; and (b) a full assessment of the chemical product is required
4	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) there is a registered chemical product containing the active constituent; and (b) a full assessment of the chemical product is required; and (c) there are no relevant maximum residue limits; and (d) poison schedule classification is required
5	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical product is similar to a registered chemical product; and (b) chemistry and manufacture, efficacy or target species safety data is the only data required to demonstrate the similarity of the chemical product to the registered chemical product
10	Application for registration of a chemical product containing an approved active constituent (or an active constituent for which the APVMA has received an application for approval) and approval of the product label for all situations other than those described in items 3 to 9
11	Application to vary particulars or conditions of registration or label approval where a full assessment of the chemical product is required
14	Application to vary particulars or conditions of registration or label approval if the application is not of a kind described in any of items 11 to 13A
15	Application for approval of an active constituent requiring a full assessment
27	Timeshift application

Note: Selected descriptions of items from the table in Part 2 of Schedule 6 to the Code Regulations (which sets out the different types of application that may be made to the APVMA). Timeshift is currently available for applications that are equivalent to those described in items 1–4 and 15. The government is proposing to extend the availability of timeshift to applications that are equivalent to those described in items 5, 10, 11 and 14. These do not incorporate changes to the descriptions of items 5 and 10 being proposed in proposal 8.

While timeshift applications provide greater flexibility than other corresponding application types, they involve more administrative burden for the APVMA and applicant. The restrictions on the types of application that apply a timeshift approach were implemented to reflect where this additional burden was most likely to be offset by the benefits of timeshift's flexibility. As such, timeshift is currently available for only the most complex applications, such as those for approval or registration of innovative new active constituents and chemical products.

Proposed approach

Extended scope of timeshift applications

Stakeholders and the APVMA have told us that—while it is appropriate that the timeshift approach be reserved for more complex application types—the scope of application types that can currently be assessed using timeshift is too restrictive.

Accordingly, the government is proposing to extend the kinds of applications that can be considered using a timeshift approach. The additional kinds of applications would be those for chemical product registrations that, although complex, are less so than those for which timeshift is presently available. This is proposed where the benefits of a timeshift approach may offset the additional administrative burden for the APVMA and applicant.

Specifically, the government proposes that the Code Regulations be amended to provide that timeshift may be extended to applications of a kind described in items 5, 10, 11 and 14 (in the table at Part 2 of Schedule 6 to the Code Regulations; see Table 1).

Applications may be 'fixed' or 'modular'. Fixed application types have a defined assessment period and fee that reflects the average effort needed to assess that type of application. Modular applications, on the other hand, allow the fee and assessment period to be better tailored to individual assessments. Different modules are prescribed for the various aspects of an assessment (for example chemistry, toxicology or residues assessments) and have multiple levels (for example, chemistry level 1, 2 or 3), each with a different fee and assessment period. The assessment fee and timeframe for an application is determined by the sum of all the fees and timeframes for each individual module that comprises an assessment. The various modules are provided for in the table in Schedule 7 to the Code Regulations.

The government proposes that applications of a kind mentioned in items 10 or 14 (which apply a modular approach) may also be assessed using a timeshift application. However, in keeping with the policy that timeshift still be restricted to more complex applications, this would only be available where the APVMA has determined 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 application. These modules cover:

- chemistry
- toxicology (requiring poison scheduling)
- toxicology (not requiring poison scheduling)
- residues
- work health and safety
- environment
- efficacy and safety
- non-food trade
- special data.

Extending the definition of timeshift to complex applications for variation to chemical product registrations and additional complex applications for chemical product registrations would:

- increase flexibility for applicants
- facilitate earlier submission of applications where the full information requirements (such as trial results) may not be available when the application is lodged
- enable products to enter the market with fewer delays.

The government invites comment on this proposal.

Fees for timeshift applications

The fees for the extended range of timeshift applications should match the regulatory effort the APVMA expends in considering them. The Code Regulations (item 27 in the table at Part 2 of Schedule 6; see the example in Table 2) already specify that the fee for a timeshift application is the modular assessment fee. The modular fees are set out in Schedule 7 to the Code Regulations.

Currently, Schedule 7 has specific timeshift modules that the APVMA uses to calculate the modular assessment fee for timeshift applications. The fees for the timeshift modules are the same as those for level 1 modules (the most expensive module, which relates to the most complex assessment). For example, the timeshift application fee for a residue assessment (module 5.6) is the same as that for the Residues—level 1 module (module 5.1); see Table 2.

Table 2 Fees and periods for residues modules, levels and types of assessments

Item	Module, level or type	Period for completion	Fee ($)
5.1	Residues—level 1	13 months	18,170
5.2	Residues—level 2	8 months	10,525
5.3	Residues—level 3	8 months	8,200
5.4	Residues—level 4	4 months	7,465
5.5	Residues—level 5	4 months	2,000
5.6	Residues—timeshift application	As set out in the project plan	18,170

Note: Extract of the table at Schedule 7 of the Code Regulations, showing the different levels of the prescribed residues modules. The $18,170 fee prescribed for the timeshift module (module 5.6) is the same as that for a level 1 residues module (module 5.1).

The current fees in Schedule 7 reflect that only the most complex types of applications can be considered as timeshift applications. To reflect the extended range of timeshift applications, and to ensure the fees for these applications better reflect the APVMA regulatory effort, the government proposes to provide that any of the levels of the relevant modules in Schedule 7 can apply to a timeshift application. This will allow the APVMA to apply the modular assessment fee appropriate to the level of assessment required for the timeshift application. The modular assessment fees for timeshift applications would be calculated in the same way as other applications with a modular assessment fee.

The government invites comment on this proposal.

While the timeshift approach provides stakeholders and the APVMA with additional flexibility, it requires the APVMA to work with the applicant to develop and maintain (and potentially vary) a project plan. This administrative burden may require some additional charges which would be determined (and consulted on) when the APVMA updates its Cost Recovery Implementation Statement (CRIS).

In addition, stakeholders and the APVMA have raised the possibility of introducing a new, 'lower level' chemistry module, similar to module 2.4 ('Chemistry–Level 4') in the APVMA's 2013 Cost Recovery Impact Statement. This would apply to simple chemistry assessments—which might include such things as updating an established stability data analysis for a date-controlled product. While setting the appropriate levels for modules is essentially a matter for the APVMA, it may be something that it could consult on when a new CRIS is developed.

Exposure draft explanatory notes

Part 1 of the Timeshift and Other Measures Regulations exposure draft deals with broadening the definition of a timeshift application. This part would commence the day after registration.

Item 1 would make minor amendments to the definition of modular assessment in subregulation 3(1) of the Code Regulations to correctly reference the entirety of regulation 77 (which describes how the modular assessment period is set), rather than the current incomplete reference to subregulation 77(2).

Items 2 and 3 would amend the Code Regulations to broaden the existing definition of 'timeshift application' in subregulation 3(1). Item 2 replaces the current definition with a reference to new regulation 3BA (created by item 3)—this reflects the increased complexity of the definition.

New subregulation 3BA(1) would create a new definition of 'timeshift application'. New subregulation 3BA(2) would specify that applications of the kind described in column 1 of items 1, 2, 3, 4, 5, 10, 11, 14 or 15 in the table in clause 2.1 of Schedule 6 to the Code Regulations (see Table 1) 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 4 would replace the current definition of modular assessment period in regulation 77 (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. Currently, Schedule 7 provides that the 'period for completion' for timeshift applications is 'as set out in the project plan' (see Table 2, in relation to the timeshift residues module—module 5.6).

Item 5 would make a consequential amendment to remove all the items in the table under Schedule 7 to the Code Regulations (items 2.4, 3.4, 4.2, 5.6, 6.4, 7.4, 8.4 and 10.4) that exclusively relate to timeshift applications. These timeshift-specific modules are no longer required as the amendments would allow timeshift applications to apply to any level of module (specifically, the

level that most appropriately reflects that APVMA's assessment requirements). That is, timeshift would no longer be restricted to the specific modules with the 'highest' associated fee (for example, any of the fees associated with residues modules 5.1 to 5.5 could be used for a timeshift application, rather than just the fee for module 5.6— see Table 2).

Item 75, discussed in Part 9 of the Timeshift and Other Measures Regulations exposure draft, also includes a minor clarification about the fee payable for a timeshift application.

Proposal 2: Ministerial orders

Background

Section 7 of the Code Act provides for the minister to make orders about any matters–other than a penalty–for which regulations may be prescribed (these matters are set out at section 6 of the Code Act). Currently, orders can only be made about a matter if the regulations declare that the minister may make an order about that matter.

Currently, ministerial orders are specifically authorised in the Code Regulations for:

- standards for chemical products (regulation 42)
- tests for the analysis of samples of substances or mixtures of substances (regulation 55).

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.

While Ministerial Orders have rarely been used under the Agvet Code, these types of orders and other delegated legislation are common in Commonwealth legislation. For example, the Export Control (Orders) Regulations 1982 provide that the minister may make orders with respect to any matter for which regulations may be made under the *Export Control Act 1982*. Orders have been made under this regulation in relation to a broad range of matters, including fees for service (Export Control (Fees) Order 2015), the registration of establishments (Export Control (Prescribed Goods—General) Order 2005), live animal exports (Export Control (Animals) Order 2004) and to regulate the export of a broad range of commodities (such as milk, meat, eggs, plants and poultry).

Proposed approach

Similar to the approach used in the Export Control (Orders) Regulations 1982, the government proposes that the Code Regulations be amended to provide a single authority for the minister to make orders about any of the matters that may be prescribed in regulations, except prescribing a penalty. This is in contrast to the current approach whereby the authority must be separately provided in individual regulations (in respect to the particular matter covered by that regulation).

Examples of matters that could be prescribed 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 would provide more flexibility for regulating agvet chemicals and simplify the regulations. It would also allow the

government to respond more quickly on matters that must otherwise be addressed through regulations.

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 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).

The government invites comment on this proposal.

Exposure draft explanatory notes

Part 2 of the Timeshift and Other Measures Regulations exposure draft deals with the ability of the minister to make an order. This part would commence the day after registration.

Item 6 would insert new Division 1.1B into the Code Regulations that would provide a single authority to make ministerial orders for any matter—except prescribing a penalty—that may be prescribed in regulations (instead of requiring the authority to be prescribed repeatedly in individual regulations).

Item 7 would make a consequential amendment to paragraph 15(1)(b) of the Code Regulations to replace a reference to regulation 42 (which deals with standards for chemical products) with 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 would be replaced by the general order-making power proposed at item 6.

Item 8 would make a consequential amendment to repeal subregulations 42(2) and 55(1) of the Code Regulations. Currently, subregulations 42(2) and 55(1) provide for ministerial orders to be made specifically in relation to prescribed standards for chemical products and analysis of chemical products, respectively. These will become unnecessary following the broadening of the authority for ministerial orders, as provided for at item 6.

Item 9 would make a minor consequential amendment to reflect renumbering of regulation 55 of the Code Regulations (which deals with analysis of chemical products) following the repeal of subregulation 55(1).

Proposal 3: Chemical product declarations

Background

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)). Substance 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. Currently carbon dioxide, nitrogen and citronella fall within the general definition of agricultural chemical products in the Agvet Code, when used to control pests.

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). For example, sheep branding substances are currently declared to be veterinary chemical products (item 6 of the table to clause 2 of Part 2 of Schedule 3AA to the Code Regulations).

Proposed approach

The government proposes that carbon dioxide and nitrogen do not need to be regulated as agricultural chemical products when used as fumigants.

The government similarly proposes that citronella oil (including citronella oil incorporated into candles or sticks) used for a purpose other than as an insect repellent for use on a human being, does not need to be regulated as an agricultural chemical product.

In addition, the government proposes that sheep branding substances do not need to be regulated as 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.

The government invites comment on this proposal.

The government also invites comment from stakeholders as to whether there are other categories of substances that should be, or should not be, regulated as agricultural or veterinary chemicals.

Exposure draft explanatory notes

Part 3 of the Timeshift and Other Measures Regulations exposure draft deals with chemical products declarations. This part would commence the day after registration.

Item 10 would be an editorial amendment to Part 3 of Schedule 3 to the Code Regulations (paragraph (c) of table item 1) to replace the word ‘pesticide’ (which is not defined in the Agvet

Code) 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 would amend the table under Part 3 of Schedule 3 to the Code Regulations (substances or mixtures declared not to be agricultural chemical products) to add carbon dioxide or nitrogen (when used as a fumigant), and citronella oil (other than as an insect repellent for use on human beings).

Item 12 would amend the table under clause 2 of Schedule 3AA to the Code Regulations (substances or mixtures declared to be veterinary chemical products) to remove sheep branding substances (item 6 in the table).

Proposal 4: Notifiable variations and prescribed variations

Background

The Agvet Code currently provides for certain kinds of variations to approval and registration 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). These kinds of variations may be both set out in a legislative instrument made by the APVMA and prescribed in the regulations.

Notifiable and prescribed variations are simple mechanisms for varying approvals or registrations, when minimal or no assessment by the APVMA is required. Examples of these types of variations include a variation to the distinguishing name of a chemical product or a variation of the name of a manufacturer of a chemical product.

Currently, regulation 19AE of the Code Regulations prescribes which variations to relevant particulars are notifiable variations for the purposes of the Agvet Code. Regulation 19AF of the Code Regulations prescribes which variations to relevant particulars are prescribed variations. The APVMA also has a legislative instrument, the Agricultural and Veterinary Chemicals Code (Notifiable Variations) Instrument 2016, specifying certain kinds of notifiable variations.

Proposed approach

The government considers that the legislation for notifiable variations and prescribed variations could be simplified by repealing regulations 19AE and 19AF of the Code Regulations and relying solely on the APVMA to make legislative instruments for these variations.

This would consolidate these variations and avoid the unnecessary and confusing duplication where *both* regulations and APVMA legislative instruments can be used concurrently to deal with the same or similar matters.

The APVMA has committed to making legislative instruments to encompass the existing notifiable and prescribed variations before the regulations are repealed.

Exposure draft explanatory notes

Part 4 of the Timeshift and Other Measures Regulations exposure draft deals with simplifying how the types of variations that are notifiable or prescribed are specified. This part would commence the day after registration.

Item 15 would repeal regulation 19AE of the Code Regulations, which sets out types of variations which are notifiable. These would instead be incorporated in the APVMA legislative instrument authorised by section 26AB of the Agvet Code (notice of notifiable variations).

Item 16 would repeal subdivision 2.2.3 of the Code Regulations. Subdivision 2.2.3 only comprises regulation 19AF, which sets out the types of variations which are prescribed. This would instead be specified by the APVMA in a legislative instrument as authorised by section 26B of the Agvet Code (application for prescribed variations).

Item 13 would be a consequential amendment to remove regulation 8AFB of the Code Regulations. Regulation 8AFB deals with information that must accompany an application for a

prescribed variation. This regulation applies 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 would be repealed (by item 16), regulation 8AFB would no longer be needed. The information requirements currently 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 would be a consequential amendment to replace the existing heading for subdivision 2.2.2 of the Code Regulations ('notifiable variations') with 'interchangeable constituent determinations'. Interchangeable constituent determinations would be the only remaining matters in subdivision 2.2.2 once regulation 19AE of the Code Regulations is repealed (by item 15).

Item 17 would be a consequential amendment to regulation 69AA of the Code Regulations to reflect the repeal of regulation 19AE of the Code Regulations (by item 15). In particular, regulation 19AE currently sets out that no fee is prescribed for a notifiable variation mentioned in items 6 or 8 of the table in subregulation 19AE(1) of the Code Regulations. A new subregulation 69AA(2) would be inserted to provide that these kinds of notices will have no fee prescribed even if they are specified by the APVMA in a legislative instrument when regulation 19AE(1) is repealed (this would not preclude the APVMA from consulting on a charge for these items under a CRIS at some point in the future). This item would also include some editorial amendments:

- The current regulation 69AA provides that the fee is prescribed for the purposes of paragraph 26AD(1)(c) of the Agvet Code (which sets the requirements for a notice to the APVMA about a notifiable variation). However the power to prescribe the fee for the lodging of the notice is actually at subsection 164(1) of the Agvet Code (which sets out how fees may be set for the doing of any thing under the Code). This would be amended in new subregulation 69AA(1).
- The current wording 'for a notice of a notifiable variation' in regulation 69AA would be amended to 'for lodging a notice under Division 2AA of Part 2 of the Code' to better reflect the wording in subsection 164(1) of the Agvet Code. All notices of notifiable variations are made under Division 2AA and that Division does not deal with the making of any other notices.

Proposal 5: Hormonal growth promotants

Background

Hormonal growth promotants (defined at regulation 3 of the Code Regulations) 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 hormonal growth promotants (in 2017–18, beef and veal exports to the European Union were valued at $249.6 million). 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 hormonal growth promotant applied.

Regulations 47 to 54 of the Code Regulations impose these requirements on persons who supply or intend to supply hormonal growth promotants. These requirements are summarised in Table 3.

Table 3 Regulations 47 to 54 of Code Regulations covering hormonal growth promotants

Regulation	Summary of the provision
47	Provide for persons to be issued with a unique notification number by the APVMA (for a fee)
47A	Allow the APVMA to withdraw or replace a notification number in certain circumstances
47AB	Withdrawal of a notification number is subject to review by the Administrative Appeals Tribunal
47B	A notification number must be renewed annually
47C	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 prescribe certain offences for supplying hormonal growth promotants without an APVMA issued notification number and for failing to keep the necessary records. These offences currently carry 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 appropriate sanction for the conduct in the offences—see the Guide to Framing Commonwealth Offences.

In addition, there are no corresponding civil penalty provisions. The legislation, therefore, limits the APVMA's ability to respond proportionately to non-compliance for these offences. For

example, the APVMA cannot issue infringement notices but must rather pursue criminal proceedings against alleged offenders should it deem that this is required.

The legislation is also unreasonably restrictive in the range of administrative actions available in relation to hormonal growth promotants, including in response to non-compliance.

Proposed approach

Strengthening the regulation of hormonal growth promotant supply

The government is proposing changes to enhance the deterrent effect of the existing penalties in relation to supply and record-keeping for hormonal growth promotants. The inappropriate supply of these substances has the potential to negatively impact on Australia's trade reputation and reduce market access for meat products exported from Australia. The penalty for contravening these requirements should be commensurate with this potential impact. Furthermore, inadequate record-keeping prevents the regulator from taking proportionate actions when monitoring compliance, as trace-back procedures could be frustrated if there was a lack of records about the supply of hormonal growth promotants.

The proposal involves amending regulations 47C and 48 to 54 of the Code Regulations (see Table 3) to increase the penalties from 10 penalty units to 30 or 50 penalty units (see Table 4), provide for them to be civil penalties and provide for infringement notices to be issued.

Table 4 Proposed 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

The penalties set out in regulations 47C and 48 to 54 of the Code Regulations are the maximum amount that a court may impose for a conviction of a criminal offence against these regulations, as authorised by paragraph 6(2)(i) of the Code Act (see Table 4). These court-imposed amounts are consistent with those in the Guide to Framing Commonwealth Offences.

Subsection 170(5) of the Agvet Code provides that the maximum 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 declaration of civil penalty provisions in the regulations. 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
- 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–see Table 4).

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 specified in the notice in full, or elect to have the offence heard by a court.

Consistent with the Guide to Framing Commonwealth Offences, the government also proposes to modernise 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 hormonal growth promotants). Persons that may be subject to these offences will still be able to rely on the defences in the Criminal Code, including the mistake of fact defence (section 9.2 of the Criminal Code). This will modernise the provisions so they operate like contemporary offence provisions. For subregulation 53(3), 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).

The government invites comment on these proposals to modernise and improve the supply and record keeping requirements for hormonal growth promotants.

Administrative actions for hormonal growth promotants

The government is also considering providing the APVMA with the ability to take administrative action to deal with non-compliance with the supply and record-keeping requirements for hormonal growth promotants. Administrative actions would be appropriate in some circumstances and may represent an additional deterrent to non-compliance.

Proposed administrative actions include providing for the APVMA to withdraw a non-compliant supplier's unique notification number (which is needed to supply hormonal growth promotants) or being compelled to not issue such a number. Specifically, this could involve the following amendments to regulations 47 and 47A of the Code Regulations (see Table 3 for a summary of these regulations):

- Amend regulations (for example, regulation 47) to prevent the APVMA assigning a notification number to a person if, in the previous 10 years, any of the following apply:
  - the person has been convicted of an offence against an agvet law or other relevant law

  - the person has been ordered by a court to pay a pecuniary penalty for the contravention of an agvet penalty provision or other relevant penalty provision
  - the person has been convicted of an offence, or ordered by a court to pay a pecuniary penalty for the contravention of a civil penalty provision, of any Australian jurisdiction involving fraud or dishonesty
  - the person has held a unique notification number that was previously withdrawn for these reasons
  - the person has been a business manager, or a major interest holder, of a body corporate in respect of which any of the above applies in that 10 year period, if the conduct occurred when the person was a manager or major interest holder of the body corporate.

- Amend regulations (for example, regulation 47A) to provide that the APVMA may withdraw a notification number if ,in the previous 10 years, any of the following apply:
  - the person has been convicted of an offence against an agvet law or other relevant law
  - the person has been ordered to pay a pecuniary penalty for the contravention of an agvet penalty provision or other relevant penalty provision
  - the person has been convicted of an offence, or ordered to pay a pecuniary penalty for the contravention of a civil penalty provision, of any Australian jurisdiction involving fraud dishonesty
  - the person has provided the APVMA with information that is false or misleading in a material particular, including (but not limited to) in a notice of intention to supply a HGP (regulation 47) or in copies of records given to the APVMA (regulation 53)
  - the person has held a unique notification number that was previously withdrawn for these reasons
  - the person has been a business manager, or a major interest holder, of a body corporate in respect of which any of the above applies in that 10 year period, if the conduct occurred when the person was a manager or major interest holder of the body corporate.

Before taking the administrative action, the APVMA would be required to issue a notice setting out its reasons for doing so. Internal and Administrative Appeals Tribunal review would be available in relation to these decisions.

This approach is similar to that already used for permits (sections 112 and 119) and licences (sections 123 and 127) in the Agvet Code. It would enhance the APVMA's ability to promote compliance with the supply and record keeping requirements for hormonal growth promotants, and thus reduce the potential for prejudice to Australia's trade. They would also ensure that only fit and proper persons are issued with, or can continue to have, unique identification numbers for the supply of hormonal growth promotants.

The measure would not be applied retrospectively. For example, the requirement to withdraw a notification number would not apply to a person convicted of an offence or ordered to pay a pecuniary penalty before the amendments commence. Similarly, the requirement preventing the

APVMA from issuing a unique notification number in certain circumstances would only apply to application for a notification number made after the amendment commences.

The government invites comment on these proposals.

Exposure draft explanatory notes

Part 5 of the Timeshift and Other Measures Regulations exposure draft deals with hormonal growth promotants. This part would commence the day after registration. Amendments have not been prepared in respect of the proposal to expand the scope of administrative actions, as the department wishes to first hear the views of stakeholders before these provisions are drafted.

Items 19, 23 and 34 would increase the pecuniary penalties for the criminal offences in regulations 47C, 48 and 53 of the Code Regulations from 10 penalty units to 50 penalty units, as provided for by paragraph 6(2)(i) of the Code Act. (Paragraph 6(2)(i) provides for regulations to prescribe penalties of not more than 50 penalty units for offences against the regulations.)

Items 26, 29, 31 and 37 would increase pecuniary penalties for the criminal offences in regulations 49, 50, 51 and 54 of the Code Regulations from 10 penalty units to 30 penalty units, as provided for by paragraph 6(2)(i) of the Code Act.

Items 21, 25, 28, 30, 33, 36 and 39 would provide that all the criminal offences in regulations 47C, 48, 49, 50, 51, 53 and 54 of the Code Regulations are also civil penalty provisions, as authorised by paragraph 6(2)(j) of the Code Act.

Items 20, 24, 27, 32, 35 and 38 would amend 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). The removal of this defence does not mean that the privilege against self-incrimination is abrogated.

Items 18 and 22 would be editorial amendments to recast subregulations 47C(1) and 48(1) into modern form. The offence provisions in regulations 47C and 48 use the formulation ‘a person may do X only if’. Modern drafting style holds that these expressions should be avoided in creating an offence. This is because there is some doubt as to whether these forms attract the operation of subsection 4D(1) of the *Crimes Act 1914* (which refers to a contravention of a section or subsection). See paragraph 16 of the OPC Drafting Direction No. 3.5.

Item 40 would amend Schedule 5A to the Code Regulations to include new items that prescribe that the civil penalty provisions for regulations 47C, 48, 49, 50, 51, 53 and 54 are provisions for which an inspector may give a person an infringement notice for an alleged contravention (as authorised by subsection 145DA(1) of the Agvet Code).

Proposal 6: Section 88 exemption (allowing advertising)

Background

There is an anomaly in the Agvet Code whereby persons are 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. This occurs where supply is:

- authorised under permit
- the substance is exempted from needing to be an approved active constituent
- where the substance is an active constituent of a listed chemical product.

The prohibition on publishing notices includes advertising and captures any means of publication, including through broadcasting or televising. This is 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.

Permits authorise persons to do, or omit to do things that would otherwise be an offence or contravene a civil penalty provision. They may only be issued if the APVMA is satisfied that, among other things, an active constituent meets the safety criteria, or a chemical product meets the safety, efficacy and trade criteria in the Agvet Code.

A general constraint on advertising of a chemical product or active constituent is unnecessary, where possession, custody, use and supply is authorised by a permit. Indeed, such a constraint could be contrary to the point of issuing the permit. For example, a product may be needed to address a biosecurity emergency but, because of section 88, no one can legally publish a notice about the product unless an application for registration is made. This could undermine the emergency response that the permit is intended to address. Similarly, some substances are legitimately supplied under a permit because their registration is not economically viable. The prohibition on publishing notices about these substances undermines the legitimate supply of a product.

Section 88 of the Agvet Code also prevents advertising about the sale or purchase of active constituents of listed chemical products as well as those active constituents that are exempt from the operation of subparagraph 15(1)(a)(i) of the Agvet Code (which states the APVMA must not register a chemical product unless it also approves each active constituent for the product). This is because they are not approved active constituents, as required by section 88. This represents an unnecessary restriction on the advertising of these legitimate substances.

Proposed approach

The government proposes to amend the regulations to exempt certain substances or chemical products from the operation of section 88 of the Agvet Code.

These include active constituents or chemical products for which the APVMA has issued a permit in respect of possession, custody or supply. Specifically, the exemption would apply to permits that authorise an act or omission which would otherwise be an offence or contravention of a

civil penalty provision in sections 74, 75, 76 or 78 of the Agvet Code (these sections are summarised in Table 5). Provided that the permit related to one or more of these, section 88 would not apply.

Table 5 Provisions in the Agvet Code relevant to permits for the possession, custody or supply of unapproved active constituents or unregistered chemical products

Section	Summary of section
74	Possession or custody of unapproved active constituents with the intention of supply
75	Possession or custody of chemical products, other than registered or reserved products, with the intention of supply
76	Supply of unapproved active constituents
78	Supply of chemical products that are not registered products or reserved products

Note: The government proposes to exempt unapproved active constituents or unregistered chemical products from the operation of section 88 of the Agvet Code, if they are the subject of permit relating to one or more of the sections in this table.

However, if the permit did not relate to sections 74, 75, 76 or 78 of the Agvet Code, then the active constituent or chemical product supplied under the permit would remain subject to the restrictions on advertising. That is, publication of notices would continue to be prohibited unless the permit related to an approved active constituent or registered chemical product (or for which an application for approval or registration had been made). For example a permit relating solely to supply of a chemical product in a container that does not have an approved label attached (section 80 of the Agvet Code) would not be covered by the proposed exemption. The government does not foresee the need to advertise substances or products solely related to any such permits.

The government also proposes to amend the regulations to exempt these substances from the operation of section 88 of the Agvet Code:

- an active constituent that the APVMA has exempted from the operation of subparagraph 15(1)(a)(i) of the Agvet Code (which states the APVMA must not register a chemical product unless it also approves each active constituent for the product)
- an active constituent that is part of a listed chemical product.

This measure will allow the advertising of these legitimate substances.

The government invites comment on this proposal.

In addition, it would be possible to prescribe that the proposed exemption to section 88 of the Agvet Code only applies subject to certain conditions, listed in the regulations. The government also invites comment on whether there may be value in prescribing such conditions, and if so, what these additional conditions might be.

Exposure draft explanatory notes

Part 6 of the Timeshift and Other Measures Regulations exposure draft deals with advertising of substances supplied under permit. This part would commence the day after registration.

Item 41 would insert new regulation 42A in the Code Regulations. Regulation 42A would exempt 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 Agvet Code, which provides for regulations to exempt particular substances or chemical products from the operation of any provision of the Code. The relevant substances are:

- active constituents exempted from the operation of subparagraph 15(1)(a)(i) of the Agvet Code, or in listed chemical products
- active constituents or chemical products for which the APVMA has issued a permit that authorises an act or omission 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 (see Table 5 for a summary of these sections).

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

Item 108 in Part 10 of the Timeshift and Other Measures Regulations exposure draft (proposal 10) clarifies that the exemption that would be created in item 41 is proposed to apply to active constituents or chemical products irrespective of whether it met the requirements of a relevant permit (or to be considered an active constituent exempted from the operation of subparagraph 15(1)(a)(i) of the Agvet Code or a listed chemical product) before, on or after the commencement day of item 41. 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 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).

Proposal 7: Restricted information

Background

Part 7 proposes amendments to 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.

'Protected information' is certain kinds of information (defined in section 3 of the Agvet Code) provided to the APVMA:

- as part of a reconsideration (sometimes referred to as a chemical review)
- in response to a request (under paragraph 159(1) of the Agvet Code) from the APVMA when deciding whether to suspend or cancel an approval, registration or permit.

The information must have been obtained because of a trial or laboratory experiment and relate to either an active constituent that has been approved or a chemical product that has been registered.

The term 'protected information' is defined separately (and differently to that in section 3 of the Agvet Code) in Part 1 of Schedule 6 to the Code Regulations. In this case, the term describes information that the APVMA is prevented from using to approve another active constituent or register another chemical product. In this context, it encompasses protected information as defined in section 3 of the Agvet Code *as well as* information with limits on its use under Division 4A of Part 2 of the Code (information given in connection with an application for approval or registration, or variation of approval or registration, that is subject to a limitation period, as described at section 34M of the Agvet Code).

The term, as defined in the regulations, is used to prevent the APVMA from dealing with applications of a kind mentioned in items 5, 6, 7 or 8 of the table at Part 2 of Schedule 6 to the Code Regulations—products that are similar, closely similar or the same as a registered chemical product (a reference product) if:

- the APVMA would have to use protected information to determine the application
- there is no consent from the authorising party to use the protected information.

Part 1 of Schedule 6 provides that a proposed chemical product is taken to *not* be similar, closely similar or the same as a reference product if information about the reference chemical product is protected information. Therefore, where protected information exists in relation to the reference product, the registration of the proposed chemical product cannot be dealt with as an item 5, 6, 7 or 8 application. However, the regulations are silent about whether this is the case only if the APVMA would have to use the protected information to register a proposed product.

Proposed approach

The government proposes to amend the regulations to:

- introduce the term 'restricted information' in Part 1 of Schedule 6 as the term 'protected information' is defined differently in the Agvet Code and it is not appropriate for the same expression to be used in the Code Regulations with a separate meaning
- clarify that the constraints on the use of 'restricted information' (in Part 1 of Schedule 6) only apply if the APVMA would have to use the information to register a proposed product

A new term 'restricted information'

As the term 'protected information' is defined in the Agvet Code, the term cannot be defined to mean something different in the regulations. The government proposes to amend the Code Regulations to introduce a concept of the use of information being 'restricted', and proposes that the relevant regulations make it clear that the use of information is restricted in respect of an application, and not generally.

As the word 'restricted' is only currently used in the Agvet Code and the Code Regulations in the phrase 'restricted chemical products', there should be no confusion over its use here.

Clarifying where information can be used

There may be restricted information for a reference product but this information may only relate to some uses of the product. For example, information for a use on goats may be restricted information whereas information for a use on sheep may not be restricted. In this circumstance it would be possible for a proposed product to rely on the existing information to support an application to register a use on sheep but not on goats. The government proposes that this should be more clearly provided for in the Code Regulations.

This would clarify that the proposed product could only be 'closely similar', 'similar' or 'the same' (in an application of a kind mentioned in items 5, 6, 7 or 8 of the table at Part 2 of Schedule 6 to the Code Regulations) if the APVMA would not have to use restricted information to register the proposed product.

The government invites comment on this proposal.

Exposure draft explanatory notes

Part 7 of the Timeshift and Other Measures Regulations exposure draft deals with restricted information. This part would commence the day after registration.

Items 42 and 43 would amend clause 1.1 of Schedule 6 to the Code Regulations to replace the term 'protected information' with the term 'restricted information' (in relation to the use of information by the APVMA in determining an application) by reference to the new definition of 'restricted information' in subclause 1.5(2) created by item 44.

Item 44 would substitute a new clause 1.5 of Schedule 6 to the Code Regulations to introduce the concept of the use of information being 'restricted' and make clear that a proposed product cannot be 'closely similar', 'similar' or 'the same' (in an application of a kind mentioned in items 5, 6, 7 or 8 of Part 2 of Schedule 6 to the Code Regulations) if:

- the APVMA would have to use restricted information to register the proposed product
- no consent from the authorising party to use the secured information has been given.

Items 45 to 48 would make consequential amendments to clause 1.6 to reflect the replacement of previous references to where information is 'protected information' to now refer to where use of information is 'restricted'.

Proposal 8: Assessment periods and fees (active approval as part of registration)

Background

Part 8 proposes amendments to the Code Regulations to allow active constituents to be approved as part of a product registration in certain circumstances.

Applications to the APVMA are classified on the basis of item numbers and descriptors set out in the table at Part 2 of Schedule 6 to the Code Regulations (the item descriptors relevant to the registration of a chemical product—items 1 to 10—are set out in Table 6). Except for applications of a type described in items 1 and 2, these do not provide for the APVMA to approve an active constituent as part of an application to register a chemical product.

In addition, section 29A of the Agvet Code provides that the APVMA may vary an approval of an active constituent with the holder's consent, as part of an application for registration of a chemical product. However, there is currently no means for the APVMA to approve an active constituent on its own initiative without becoming the holder of the approval (section 14A of the Agvet Code).

Accordingly, if an applicant wishes to register a new chemical product while seeking approval of a new active constituent, two separate applications are usually required.

There are several additional types of application under which the APVMA could efficiently approve an active constituent at the same time that it registers a chemical product. This would reflect the approach for items 1 and 2. It also reflects the approach taken for approval of a label for a chemical product, which is generally done as part of the application for chemical product registration.

Table 6 Selected descriptions of items from Part 2 of Schedule 6 to the Code Regulations

Item	Description of application
1	Application for approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring a full assessment of the active constituent and chemical product
2	Application for approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring less than full assessment of the active constituent and chemical product
3	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) there is no registered chemical product containing the active constituent; and (b) a full assessment of the chemical product is required
4	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) there is a registered chemical product containing the active constituent; and (b) a full assessment of the chemical product is required; and (c) there are no relevant maximum residue limits; and (d) poison schedule classification is required
5	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical product is similar to a registered chemical product; and (b) chemistry and manufacture, efficacy or target species safety data is the only data required to demonstrate the similarity of the chemical product to the registered chemical product
6	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical product is closely similar to a registered chemical product; and (b) efficiency and safety data are not required to demonstrate the similarity of the chemical product to the registered chemical product; and (c) chemistry and manufacture data are required
7	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical product is closely similar to a registered chemical product; and (b) efficiency and safety data are not required to demonstrate the similarity of the chemical product to the registered chemical product; and (c) chemistry and manufacture data are not required
8	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical product is the same as a registered chemical product; and (b) the chemical product is to be registered with a different name
9	Application for registration of a listed chemical product and approval of a product label where the product and label comply with an established standard that has been approved in accordance with section 8U of the Code.
10	Application for registration of a chemical product containing an approved active constituent (or an active constituent for which the APVMA has received an application for approval) and approval of the product label for all situations other than those described in items 3 to 9.

Note: This table sets out the different types of application for registration of a chemical product that may be made to the APVMA.

Proposed approach

The government proposes to reduce the red tape associated with approving certain active constituents where the approval can efficiently be sought in connection with the application for registration of a chemical product. This will enable more applicants to make one application to the APVMA for approval of an active constituent, registration of a chemical product and approval label for containers for a chemical product.

To implement this measure, the government proposes to amend the descriptions of the application kinds in items 5, 6 and 10 of the table to Part 2 of Schedule 6 to the Code Regulations (see Table 6) to provide that the APVMA can approve certain new active constituents at the same time that it registers a chemical product.

Items 5 and 6 require similarity or close similarity to an already-registered chemical product, and provide for the APVMA to consider chemistry and manufacture data (which means the APVMA will have the information it needs to assess a new active constituent). Where these actives also comply with a well-recognised quality standard, it is anticipated that the APVMA would be able to approve the active with few or no additional resources beyond those required for the product assessment. Relying on compliance with a monograph or compendial standard is the same approach used for listed chemical products in Schedule 3B of the Code Regulations.

It is proposed that a suitable quality standards would be monographs or compendial standards in the British Pharmacopoeia, British Pharmacopoeia (Veterinary), European Pharmacopoeia or United States Pharmacopeia. This would essentially restrict this pathway to veterinary active constituents, although a small number of pharmacopoeial actives, such as some ectoparasiticides, also have agricultural application.

The government invites stakeholder comment on whether there could be other standards that might be appropriate in this context.

As applications of a type described by item 10 allow for fully modular fees and assessment periods, they can deal with more complex active constituents than items 5 or 6. Accordingly, there is no need to constrain which active constituents can be considered under this application type.

Joint assessment of active constituents and products are not proposed for 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.

It is further proposed that, like existing item 10, items 5 and 6 would apply in situations where the product registration being sought involves an active constituent for which an application for approval has been separately lodged. For example, a company 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 an item 5 or 6 application).

The government invites comment on this proposal, including whether there might be other types of active constituents which could be suitable for joint assessments.

Exposure draft explanatory notes

Part 8 of the Timeshift and Other Measures Regulations exposure draft deals with allowing certain active constituent approvals to be made in connection with an application for registration of a chemical product. This part would commence the day after registration.

Item 49 would amend the descriptions of the application kinds described in items 5, 6, 10 and 17 in the table in Part 2 of Schedule 6 of the Code Regulations 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. These proposed constraining circumstances are set out in Table 7:

Table 7 Proposed 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	Scenario 3: Separate application for active constituent approval has been lodged
5	(a) the product must be similar to a registered product (b) 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	(a) the chemical product must be closely similar to a registered chemical product (b) chemistry and manufacture, efficacy or target species safety data must be the only data required to demonstrate this similarity		
10	For all situations other than those described in items 1 to 9.		

*Note: The British Pharmacopoeia (Veterinary) would be added to the final draft of the regulation amendments. Item refers to the item number in the table in Part 2 of Schedule 6 of the Code Regulations.

Item 49 also simplifies the description of item 6 (which currently indicates that efficacy and safety data are not required to demonstrate the similarity of the chemical product to the registered chemical product; and that chemistry and manufacture data are required). Instead, item 6 now employs a more concise description: 'chemistry and manufacture data is the only data required to demonstrate the similarity of the chemical product to the registered chemical product' to achieve the same outcome. This clearer construction is similar to that already used for item 5 in the table in Part 2 of Schedule 6 to the Code Regulations.

Item 49 also makes a minor editorial amendment to item 27 in the table in Part 2 of Schedule 6 of the Code Regulations. This item would also make an editorial amendment to remove existing column 5 from this table (which dealt with fees from 1 July 2014 to 31 December 2014). This is no longer necessary.

Proposal 9: Consequential and other amendments

The government has identified some regulations that need to be amended to remove provisions that are no longer necessary, correct errors or deal with minor inconsistencies.

The proposed changes to the Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995 (the Levy Regulations) would remove redundant provisions. The proposed changes to the Administration Regulations are to include a more correct reference to consular acts for which a fee is imposed under the *Consular Fees Act 1955*.

The remaining amendments are all proposed 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 head of power to issue a number of 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 are proposed to prescribe the information that must be included in certain notices about protected information for active constituents and to update the Code Regulations following the recent restructuring of provisions in the Australia New Zealand Food Standards Code (the Food Standards Code).

Protected information

The government wishes to prescribe the information that must be included in certain notices about protected information for active constituents.

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. Currently, these regulations only prescribe information for chemical products. However, notices about protected information may also relate to active constituents. The government therefore proposes to amend the Code Regulations to prescribe the information to be included in notices that would 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.

The government also proposes to change the headings of regulations 24 and 25, to refer to prescribed information rather than 'protected registered information'. This is because the undefined term of 'protected registered information' may be misleading.

Food Standards Code

Changes to the Code Regulations are necessary following the restructuring of provisions in the Australia New Zealand Food Standards Code (the Food Standards Code). This involves updating the references to provisions in the Food Standards Code in items 1 and 2 of the table in clause 5 of Schedule 3AA to the Code Regulations. Specifically:

- For item 1 of the table, which deals 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 item 2 of the table, which deals 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, the regulations amendments would consolidate 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.

Amendments are also required to update the references to provisions in the Food Standards Code in paragraph 7(3)(c) of Schedule 3AA.

Exposure draft explanatory notes

Part 9 of the Timeshift and Other Measures Regulations exposure draft deals with consequential and other amendments. This part would commence the day after registration.

Item 50 would omit subregulations 6A(2) and (3) of the Levy Regulations as these provisions are no longer required (they relate to rates of levy from before the 2012–13 financial year). Regulation 6A would also be 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 leviable disposals of the products in a given year.

Item 51 would amend subregulation 3.550(3) of the Administration Regulations to replace the specific references to fees for a consular act set out under the Consular Fees Regulations 1990 with a more correct reference to consular acts for which a fee is imposed under the *Consular Fees Act 1955*.

Items 52 and 54 would 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 would amend subregulation 3(1) of the Code Regulations to repeal unnecessary 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 would amend referencing in the Code Regulations to reflect the correct source of power 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 current incorrect reference to '8AO, 8AP or 8AQ'). These references would be updated:

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

Items 57, 75, 76, 77, 80, 83, 84, 85 and 90 would amend subparagraph 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 correct the references to the table in clause 2.1 of Schedule 6. Item 75 and 77 also remove redundant references in subregulations 70(2) and 70(5) of the Code Regulations to existing column 5 from this table (which dealt with fees from 1 July 2014 to 31 December 2014). This column would be removed through item 49 in Part 8 of the Timeshift and Other Measures Regulations exposure draft).

Items 58 and 60 would make consequential amendments to paragraph 8AO(2)(m) and 8AQ(2)(i) to mirror the correction in new paragraph 8AP(2)(g) (item 59) for the reference 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 would amend regulation 8AP of the Code Regulations to extend the current requirements for the APVMA to issue a notice when a person applies for a technical assessment under regulation 8AS. The requirements would also apply when a person lodges an application to:

- make an interchangeable constituent determination (under regulation 19AEB)
- make or vary an ingredient determination (under subclause 10(1) of Schedule 3AA).

Item 59 would also amend the construction of the notice requirements in subregulation 8AP(2) to reflect modern drafting conventions. In addition, new paragraph 8AP(2)(g) corrects the reference to the authority (to subsection 167(1) of the Agvet Code) under which an applicant may apply for a review by the Administrative Appeals Tribunal should the APVMA not determine the application within the assessment period. Previously this reference was to subsection 165(3) of the Agvet Code.

Item 61 would make a minor amendment to the examples listed in Regulation 8AS to remove 'assessment of a trial protocol'. Such assessments are not undertaken by the APVMA under this regulation.

Items 62 and 63 would make minor amendments so that the conditions for containers for reserved chemical products are expressed in the same way as the conditions for registered chemical products. It will do this by aligning:

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

Item 64 would update 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 (not the Therapeutic Goods Administration) and reflect that the handbook is now published on the APVMA website.

Item 65 would recast regulations 24 and 25 to prescribe information about secondary active constituents and primary active constituents, respectively. The proposed information to be prescribed by these amendments is set out in Table 8.

Table 8 Proposed information to be 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 secondary holder of approval in the Record For an unapproved active constituent, the prospective holder's details in the application for approval	For each primary holder entered in the Record
Particulars from the Record	For the approved secondary active constituent No details for an unapproved active constituent	For each primary active constituent

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
- composition and purity
- 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

Item 65 would also change 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 and 73 would amend paragraph 35(1)(a), the heading of regulation 36, and subregulations 66(2) and (3) of the Code Regulations to replace the current reference to 'protected registration information' with the more accurate 'protected information'.

Item 68 would amend paragraphs 36(a), (c) and (d) of the Code Regulations to replace the current reference to 'protected registered information' with the more accurate 'protected information'.

Items 69 and 71 would amend subparagraphs 42(3)(e)(iv) and 55(2)(c)(vi) of the Code Regulations to replace 'United States Pharmacopoeia' and 'US Pharmacopoeia' with 'United States Pharmacopeia' to ensure the correct name is used and to align with the definition in subregulation 3(1) of the Code Regulations.

Item 70 would be an editorial amendment to recast subregulation 46(1) of the Code Regulations into modern form, similar to the recasting of regulations 47C and 48 of the Code Regulations in items 18 and 22 in Part 5 of the Timeshift and Other Measures Regulations exposure draft.

Item 72 would recast the definition of 'XP' (the extended assessment period) in subregulation 65A(2). This is a variable used to calculate the period for giving additional information for certain applications. The recast definition in subregulation 65A(2) clarifies the references to the table in clause 2.1 of Schedule 6.

Item 74 would repeal and substitute existing subregulation 66(5) of the Code Regulations to replace the current reference to '***compensatable registration information*** means protected registration information' with '***compensatable information*** means protected information'. The new subregulation 66(5) also clarifies that compensation is payable for 'use' of the information (currently this subregulation refers to 'provision' of the information).

Item 78 would recast subregulation 70(6) of the Code Regulations, which deals with the minimum portion of the application fee that is required to be paid at the time of making an application, to remove redundant references that dealt with fees from 1 July 2014 to 31 December 2014.

Item 86 would remove the redundant note in subregulation 76A(3). This note refers to an application for re-approval or re-registration. This type of application no longer exists.

Item 87 would recast subregulation 76A(4) of the Code Regulations to amend the formatting of 'extended assessment period' in subregulation 76A(4) of the Code Regulations to be in bold and italics as it is a definition provision. Item 87 also corrects a reference to the table in clause 2.1 of Schedule 6.

Item 88 would remove 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 corrects a reference to the table in clause 2.1 of Schedule 6.

Item 91 would insert new subregulation 78C(caa) of the Code Regulations to clarify that a decision by the APVMA to refuse an application for a technical assessment is reviewable by the Administrative Appeals Tribunal (see regulation 8AS of the Code Regulations).

Item 92 would repeal Part 9A of the Code Regulations, which deals with prescribed reviews. Regulation 80C of the Code Regulations provides that Part 9A 'ceases to have effect 5 years after the day the Amendment Act receives the Royal Assent'. The *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* received the Royal Assent on 29 June 2013. This amendment will repeal the Part so that it can be removed from the statute book.

Item 93 would replace items 1 and 2 of the table in subclause 5(3) of Schedule 3AA to the Code Regulations with a consolidated new item 1. This would update the ingredients authorised for use in this table to accurately reference the Food Standards Code. Specifically, it references these 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 would update the references to provisions in the Food Standards Code in paragraph 7(3)(c) of Schedule 3AA to the Code Regulations. These references should refer 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 would make minor editorial amendments to the definitions of 'closely similar', 'similar' and 'the same' in clause 1.1 of Schedule 6 to the Code Regulations to correctly reference *clauses* 1.2, 1.3 and 1.4 (the current references to *section* 1.2, 1.3 and 1.4 are incorrect). It also adds an additional reference to subclause 1.5(1) (recrafted by item 44 to describe specific circumstances when chemical products are not closely similar, similar or the same).

Items 98 to 107 would 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). These will now refer to substituted clause 1.5. Subclauses 1.2(2), 1.2(4), 1.3(2), 1.3(4) and 1.4(2) would be omitted—these deal with the circumstance where information about the reference chemical product was protected information.

Proposal 10: Transitional provisions

A number of transitional and application provisions are necessary to allow the smooth implementation of the changes in proposals 1 to 9.

In keeping with current drafting conventions, it is proposed that all the application provisions relating to the amendments of the Agvet Code will be kept together and inserted in the Code Regulations as a new Division.

Exposure draft explanatory notes

Part 10 of the Timeshift and Other Measures Regulations exposure draft deals with transitional arrangements needed to implement proposals 1 to 9. This part would commence the day after registration.

Item 108 would insert a new Division 10.4 into Part 10 of the Code Regulations for the transitional and application provisions associated with the amendments made by the Timeshift and Other Measures Regulations. Specifically this item:

- inserts definitions for 'amending regulations' and 'commencement day' that would apply to the new Division 10.4.
- sets out that the amendments of these regulations apply in relation to applications made on or after the commencement day
- clarifies that new regulation 42A (the new exemption from the operation of section 88 of the Agvet Code inserted by item 41 under proposal 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.

Additional undrafted regulation changes

Proposal 11: Voluntary recalls

Background

Notification

Part 6 of Schedule 1 to the Streamlining Regulation Bill would amend section 106 of the Agvet Code to include new provisions about voluntary recalls. The amendments require persons to inform the APVMA when they have undertaken certain voluntary recalls and requires the APVMA to publish information about such recalls.

The measures in the Streamlining Regulation Bill will ensure that the APVMA must be informed if certain voluntary recalls are conducted. The amendments would provide that a person conducting a voluntary recall must notify the APVMA if it appears to the person that either:

- the chemical product does not meet the safety, trade or efficacy criteria, or the label does not meet the labelling criteria
- the chemical product is not a registered chemical product (for example, where the concentration, composition or purity of constituents in a batch of the chemical product varies by more than the prescribed extent set out in the Register of Agricultural and Veterinary Chemical Products, as required under section 18 of the Agvet Code).

The notification to the APVMA must be made in an approved form within two days of this recall. The approved form will be a form that the APVMA has approved or a form prescribed in the regulations.

The Bill also provides that the regulations may prescribe circumstances where a person does not need to notify the APVMA of the voluntary recall.

Publication

The Streamlining Regulation Bill requires that the APVMA must publish a copy of voluntary recall notices on its website within three working days, and in the Gazette within 14 days, of receiving the notice. It also provides for the APVMA to publish the recall notice in any other manner it thinks appropriate.

Not all notices submitted to the APVMA about voluntary recalls need to be published. For example, there is limited value in publicising recalls of products that have only been distributed to a limited range of persons or have not been distributed to users (for example, through the retail chain). For this reason, the measures in the Streamlining Regulation Bill provide that the publication requirements do not apply in circumstances prescribed by the regulations.

Proposed approach

Notification

The government proposes that there should be no exemptions from the requirement in the Streamlining Regulation Bill (new section 106(1) of the Agvet Code) to notify the APVMA of a voluntary recall where a person has conducted such a recall because it appears to the person that either:

- the chemical product does not meet the safety, trade or efficacy criteria, or the label does not meet the labelling criteria
- the chemical product is not a registered chemical product.

It is appropriate that the APVMA is always informed where a person is voluntarily recalling products for these reasons.

Publication

The government proposes that the Code Regulations be amended to provide that the APVMA is not required to publish a notice about a voluntary recall of a chemical product if the chemical product has not been supplied to either:

- premises where a person that may purchase the chemical product (such as retail premises)
- a product user.

The regulations may also prescribe other circumstances in which the APVMA will not be required to publish notices about a voluntary recall of a chemical product. The government invites comment on whether there are any such additional circumstances.

Compliance sanctions

The Streamlining Regulation Bill includes an offence and civil penalty provision for contravening the requirement to notify the APVMA of a voluntary recall. To provide the APVMA with a graduated suite of compliance options, the government proposes to authorise infringement notices for contravening the civil penalty provision. This would allow the APVMA to issue an infringement notice, instead of pursuing criminal or civil proceedings in the courts.

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 sets out the particulars of an alleged contravention of an offence or civil penalty provision. The infringement notice will give the person to whom the notice is issued the option to pay the fine specified in the notice in full, or elect to have the offence heard by a court.

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 civil pecuniary penalty that a court could impose for the contravention (which is 180 penalty units for a person or 1500 penalty units for a body corporate). Therefore, the maximum amount that could be prescribed for an infringement notice for allegedly contravening the civil penalty provision is 36 penalty units for an individual and 300 penalty units for a body corporate. The value of a penalty unit is set in subsection 4AA(1) of the *Crimes Act 1914* and is $210.

The government proposes that the prescribed amount for the infringement notice be 36 penalty units for an individual and 300 penalty units for a body corporate. These amounts would be consistent with existing amounts prescribed for infringement notices in the Code Regulations (see Schedule 5A to the Code Regulations).

The government invites comment on this proposal.

Exposure draft explanatory notes

An exposure draft of these proposed regulations has not been prepared, as the government is seeking comment on the details of the exemptions before preparing them.

Proposal 12: Determining applications

Background

Part 2 of Schedule 1 to the Streamlining Regulation Bill amends the Agvet Code to provide the APVMA and industry with more flexibility to deal with certain kinds of information given to the APVMA while it is determining an application, without triggering a compulsory extension to the statutory assessment period. These kinds of information are to be prescribed in the regulations.

Prior to 2014, applicants could provide information to the APVMA while an assessment was underway—for example, information to support registration of additional uses or the results of additional field trials. This resulted in the APVMA having to manage sub-standard or incomplete applications and would sometimes require it to undertake additional technical assessments that were not foreseen when the application was made. This is not appropriate for a cost-recovered agency.

Changes to the Agvet Code in 2014 prevent the APVMA from considering new information provided by an applicant after an application has been made, except in very limited circumstances. Specifically, section 8C of the Agvet Code prevents the APVMA from considering new information provided by, or on behalf of, the applicant during the assessment period unless the information was requested by the APVMA or is specifically required by legislation (for example, section 160A of the Agvet Code requires an applicant to provide information if they become aware that the active constituent or product may not meet the safety, efficacy or trade criteria).

The mechanism for the APVMA to seek additional information about an application (at its discretion), is by issuing a notice to an applicant under section 159 of the Agvet Code. Under the Agvet Code, the first such notice issued during the course of an assessment triggers a mandatory one-off extension to the statutory time period in which the application must be assessed. This extension is typically equivalent to one third of the statutory assessment period for the original application (rounded up to the nearest whole month) plus an additional month.

Apart from responding to a notice given under section 159 (or other, very limited circumstances), applicants may choose to provide new information to the APVMA through a variation application made after the active constituent or label has been approved or the product has been registered. However, this can add to the costs and increase the time required to bring a chemical product to market.

The 2014 amendments help the APVMA efficiently perform its role as a regulator by ensuring that it receives quality applications containing all the information required for an assessment and that this information is correct. However, since the implementation of these amendments, it has become evident that these mechanisms may be too restrictive in some circumstances.

The Streamlining Regulation Bill provides for the regulations to prescribe certain, limited kinds of information that the APVMA may consider during the assessment period for an application. This would remove the need for a notice under section 159 of the Agvet Code in some circumstances, and avoid the associated extension of the assessment period (proposal 12 relates to those circumstances where the APVMA uses the section 159 notice mechanism).

Proposed approach

The government proposes that the kinds of information to be prescribed in the Code Regulations, as information the APVMA may consider during the assessment period for an application, are:

- in relation to overseas manufacturers, information about whether a person holds an instrument authorising the manufacture of a chemical product in compliance with a standard that the APVMA has determined is comparable to manufacturing principles (F2014L00859) and the Australian Code of Good Manufacturing Practice for Veterinary Products (GMP Code)
- information that clarifies information the applicant has already provided and which is provided in these circumstances:
  - the APVMA requests the information from the applicant
  - the applicant provides the information within 28 days of the APVMA request.

These are minor information deficiencies that can be reasonably incorporated by the APVMA with minimal likely need for additional assessment time—certainly less than the existing fixed extension period triggered if the APVMA were to request this information under section 159 of the Agvet Code.

Information requiring technical assessment

Some stakeholders have told us that for date-controlled products, it is often impractical to provide a full package of stability data at the time of making an application—particularly where the data must be collected in real-time. The only alternatives in such cases are to delay submission of the original application, or to make a variation application after the original application has been determined. Both of these can considerably delay entry of the product to market which can adversely impact both users and chemical suppliers.

Proposal 1 in this consultation document (increasing the availability of timeshift applications) may go some way to addressing this problem, by allowing the applicant and the APVMA to agree on a project plan that sets out when stability data will be provided.

However, the proposed amendment at Part 2 of Schedule 1 to the Streamlining Regulation Bill—which amends the Agvet Code to provide the APVMA and industry with more flexibility to deal with certain kinds of information given while an application is being assessed—does not preclude the regulations from prescribing certain types of technical data that may be provided.

Relevantly, existing provisions in the Agvet Code allow the regulation to prescribe appropriate fees and extensions to the assessment period associated with assessing such data (for clarity, the government is not proposing, at this time, to prescribe additional fees or extensions to the assessment period for information that does not require a technical assessment).

The APVMA has indicated a strong preference that information requiring technical assessment—such as stability data—not be prescribed through this mechanism. Accordingly, the government is not proposing that such data be prescribed. We are, however, interested in stakeholders' views on the matter—particularly those with contemporary (post-2014)

experience with seeking registration of date controlled products requiring stability data that was collected in real-time.

General

Importantly, the government intends that the types of data that can be prescribed through this mechanism remain strictly limited. It is not the government's intention that this mechanism be used to substantially 'wind back' the effect of the 2014 amendments. For example, it is not intended that applicants be provided with the ability to correct significant defects in their applications.

The government invites comment on this proposal. In particular, the government seeks stakeholder feedback about any other kinds of information that could (and should) be given to the APVMA while it is determining an application, using this mechanism.

Exposure draft explanatory notes

An exposure draft of these proposed regulations has not been prepared, as the government is seeking comment on the details of the information before preparing them.

Proposal 13: Improving application quality

Background

When an application is lodged with the APVMA, it may contain incorrect or inadequate information. Dealing with this diverts the APVMA's resources, places timeframe pressure on the agency and disadvantages those applicants that provide quality applications. Legislative changes in 2014 sought to address this problem by restricting the ability of applicants to provide new information to the APVMA after an application has been lodged. Nevertheless, the APVMA may, at its discretion, seek additional information from an applicant (including information to replace incorrect information in an application) by issuing a notice under section 159 of the Agvet Code (see also proposal 12).

Section 11 of the Agvet Code requires the APVMA to complete a preliminary assessment of an application. This assessment determines whether the application appears to meet the application requirements (set out at section 8A of the Agvet Code). If the application does not pass preliminary assessment (that is, it does not appear to meet the prescribed application criteria) the APVMA must refuse it.

The preliminary assessment is purely administrative in nature—it is not a technical assessment of the information provided (section 14 of the Agvet Code).). Requiring the APVMA to refuse applications that appear deficient at preliminary assessment means that it only needs to assess applications that are of the required standard.

If an application passes preliminary assessment, the APVMA may alter it with the written consent of the applicant (subsection 11(4) of the Agvet Code). This provision allows the APVMA to alter an application, when appropriate, rather than refuse it. The APVMA is expected to only use the flexibility afforded by this provision where it is efficient to do so. The APVMA cannot be compelled to amend an application.

It has become evident that where minor errors are concerned, the intent of the 2014 amendments, which brought in provisions that require the APVMA to refuse an application (so the applicant must then make a new application), may be disproportionately burdensome for industry and time consuming for the APVMA in certain circumstances.

As a consequence, the Operational Efficiency Bill contains amendments to enable the APVMA, to notify an applicant of minor errors identified in their application during preliminary assessment, and provide one opportunity to address the errors or submit missing information where this can be reasonably rectified. Providing applicants with an opportunity to address errors or submit missing information was intended, for example, to overcome situations where the applicant failed to attach a document, or attached the wrong piece of information, to the application.

However, not all minor deficiencies and errors are detected through preliminary assessment. As discussed in proposal 12, the Streamlining Regulation Bill also provides for the regulations to prescribe kinds of information that the APVMA may consider during the assessment period for an application (that is, after preliminary assessment).

The APVMA can continue to issue a notice requiring information from the applicant to address certain other deficiencies under section 159 of the Agvet Code. Importantly, the APVMA's use of notices issued under section 159 should remain strictly limited. It is not the government's intention that this mechanism be used to substantially 'wind back' the effect of the 2014 amendments. For example, it is not the government's policy intent to provide applicants with the ability to submit ostensibly flawed applications that require substantial correction. The APVMA can most efficiently perform its role as a regulator of agvet chemicals if the legislation and its operational approach encourage applicants to provide quality applications containing all relevant, and correct, information.

The costs of the APVMA's regulatory activities are recovered from industry. Diverting resources to deal with deficient applications, or those requiring remedial action through notices under section 159 of the Agvet Code, costs all industry participants. As a result, those applicants lodging good applications are cross-subsidising applicants lodging poor quality applications.

Proposed approach

The government is seeking stakeholder views about introducing fees for the APVMA to assess information required by a notice (under section 159 of the Agvet Code) when dealing with deficient applications. This would support better use of the APVMA's resources, and complement measures introduced in the Operational Efficiency Bill and Streamlining Regulation Bill.

Charging a fee for this service would result in better apportionment of the costs that arise when the APVMA chooses to work with an applicant to remedy applications containing incorrect or inadequate information, and may incentivise higher quality applications.

The approach would prescribe a fee where the APVMA has been required to issue a section 159 notice during the assessment of an application. A fee could also be imposed in relation to the time taken by the APVMA to take steps to alter applications, with the written consent of the applicant, pursuant to subsections 11(4), 26B(3), 28(4), 48(5) and 110A(5) of the Agvet Code.

A regulation that imposed such a fee would be authorised by section 164 of the Agvet Code.

The fee should reflect the effort of the APVMA to deal with deficient applications. There are two potential approaches for setting this fee: a fixed flat amount or an amount based on an hourly rate (such as the fee of $95 an hour for providing records in subregulation 73(2) of the Code Regulations). The government proposes that an hourly rate fee would be the appropriate approach to ensure that costs are commensurate with the APVMA's effort, as this acknowledges different applicants may need different levels of remediation. The exact amount of the fee would be determined when the APVMA updates its CRIS, and would be subject to consultation during that process.

Applicants could avoid these fees by:

- lodging a quality application
- withdrawing the application and lodging a new one that addresses the issues
- using pre-application assistance to help ensure their application is of sufficient quality.

Applicants and the APVMA may not agree in relation to the quality of an application or issues in an application. To ensure the merits of each case can be considered where a party is dissatisfied with the initial decision, the decision to issue a section 159 notice that attracts a charge (requiring information to fill a gap or correct an error in an application) would be reviewable, both internally and by the Administrative Appeals Tribunal. This will allow applicants to contest these decisions and ensure the decision is a correct and preferable one.

The expectation remains that the APVMA would only use notices under section 159 to correct errors or information gaps that can be dealt with within the statutory assessment timeframe. Where significant deficiencies are detected, the requirement that the APVMA must refuse these deficient applications would stand.

The APVMA will retain the ability to waive or remit fees, as provided for in subsection 164(8) of the Agvet Code. In addition, a person can apply under this subsection for a fee to be waived or remitted.

Encouraging applicants to provide better quality applications has the potential to free up the APVMA's resources for assessing applications.

The government invites comment on this proposal. Stakeholder views are also invited on whether this approach (prescribing a fee) should be considered for other activities the APVMA undertakes to encourage better quality applications, such as issuing a notice about (and determining its satisfaction with any applicant response) rectifying defects detected as part of a preliminary assessment (section 11 of the Agvet Code through the Operational Efficiency Bill) or after preliminary assessment (as set out in proposal 11).

Exposure draft explanatory notes

Amendments have not been prepared in respect of this proposed approach as we wish to first hear stakeholder's views.

Changes to support measures in the Operational Efficiency Bill

Proposal 14: Annual returns reporting and false or misleading information

Background

The Operational Efficiency Bill reduces the regulatory burden on industry by simplifying reporting requirements for annual returns about import, export and manufacture of active constituents (both active constituents in, and those for, chemical products). The Bill simplifies the red tape burden for industry by aligning the annual returns reporting requirements with levy reporting on product disposals. It also ensures the ongoing availability of information about active constituents in the marketplace, to support appropriate levels of risk management.

The Operational Efficiency Bill inserts new sections 35 and 37 into the Levy Act. These include civil penalty provisions for contravening the simplified annual return reporting and record-keeping requirements in those sections, respectively. These are the same as the existing offences and civil penalty provisions in sections 69E and 69EA of the Administration Act (the Operational Efficiency Bill repeals section 69E and amends section 69EA of the Administration Act as a result of the new Levy Act requirements).

The Operational Efficiency Bill also inserts civil penalty provisions in the Administration Act and the Agvet Code for providing false or misleading information to the APVMA (subsections 69ER(3) and (4) of the Administration Act and subsections 146(3) and 146(4) of the Agvet Code). These complement existing criminal offence provisions for similar conduct.

Proposed approach

Annual returns reporting

The government proposes to maintain the APVMA's ability to issue infringement notices for contravening annual returns reporting requirements.

This would be achieved by amending the Administration Regulations to provide for infringement notices to be issued for alleged contraventions of the civil penalty provisions in sections 35(1) and 37(1) of the Levy Act (as inserted by the Operational Efficiency Bill). The amounts for the infringement notices would be 15 penalty units for an individual and 125 penalty units for a body corporate. (The value of a penalty unit is set in subsection 4AA(1) of the *Crimes Act 1914* and is $210.)

These are the same amounts for contravening the existing corresponding requirements in sections 69E and 69EA in the Administration Act, which currently deal with annual return reporting and record-keeping requirements in those sections. They are half the maximum amount that could be prescribed under the legislation.

By providing for infringement notices for allegedly contravening these provisions, the APVMA will maintain access to a graduated suite of compliance measures in relation to annual return reporting requirements.

As the Operational Efficiency Bill repeals section 69E from the Administration Act, regulation amendments will repeal regulation 4.10 from the Administration Regulations (which relies on section 69E). This will ensure the legislation remains current.

These amendments would commence on either the commencement of Part 1 of Schedule 1 to the Operational Efficiency Bill or registration of the regulation (whichever is later), and would apply to leviable disposals that take place in the 2018–19 and later financial years.

The government invites comment on this proposal.

False or misleading information

Section 69ER of the Administration Act and section 146 of the Agvet Code provide that a person commits an offence if that person knowingly gives false or misleading information or produces false or misleading documents. New subsections 69ER(3) and (4) of the Administration Act and subsections 146(3) and (4) of the Agvet Code (as proposed by the Operational Efficiency Bill) introduce civil pecuniary penalties for persons engaging in this type of conduct. These provisions relate to false and misleading information or documents given in respect to:

- subsection 69ER(3) of the Administration Act—information given in respect to a consent to import an unapproved active constituent or unregistered chemical product
- subsection 69ER(4) of the Administration Act—information given to an inspector in relation to Parts 7A (import, manufacture or export of chemicals—other than consents to import), 7AA (investigative powers) or 7AB (enforcement)
- subsection 146(3) of the Agvet Code—information given in respect to the safety, efficacy, trade or labelling criteria (at sections 5A, 5B, 5C or 5D of the Agvet Code) or a licence to manufacture (section 112 of the Agvet Code)
- subsection 146(4) of the Agvet Code—information given in respect to the APVMA's performance of functions and exercise of powers.

The government proposes to provide for the APVMA to issue infringement notices for alleged contraventions of these new civil penalty provisions.

This will ensure the APVMA has a graduated suite of compliance tools to allow it to take proportionate action if a person knowingly provides false or misleading information. It would authorise the APVMA to issue an infringement notice, in those circumstances where this is a more appropriate sanction than prosecution of the offence or civil proceedings.

The government proposes to provide for infringement notices to be issued for these amounts, which are authorised under the Administration Act (sections 69EJA, 69EK and 69EKA) and the Agvet Code (sections 145AA, 145DA and 145DB):

- 90 penalty units for an individual for an alleged contravention of subsections 69ER(3) and 146(3)

- 18 penalty units for an individual for an alleged contravention of subsections 69ER(4) and 146(4)
- 750 penalty units for a body corporate for an alleged contravention of subsections 69ER(3) and 146(3)
- 150 penalty units for a body corporate for an alleged contravention of subsections 69ER(4) and 146(4).

These are half the maximum amount that could be prescribed under the legislation but are consistent with the amounts set for similar alleged contraventions of agvet legislation (see the table in Schedule 5A of the Code Regulations).

The government invites comment on this proposal.

Exposure draft explanatory notes

Part 1 of the Operational Efficiency Regulations exposure draft deals with annual returns and record-keeping. This part would commence on the start of the day after registration, provided that Part 1 of Schedule 1 to the Operational Efficiency Bill has commenced.

Items 4 and 5 amend the table in Schedule 5 of the Administration Regulations to provide for infringement notices to be issued for alleged contraventions of the civil penalty provisions in sections 35(1) and 37(1) of the Levy Act (as proposed by the Operational Efficiency Bill).

Item 3 is a consequential amendment to remove item 8 in the table in Schedule 5 of the Administration Regulations. Item 8 relies on section 69E of the Administration Act which is proposed to be repealed by the Operational Efficiency Bill (because proposed new section 35 of the Levy Act will provide for a new, simplified annual return reporting system).

Item 1 is a consequential amendment to the Administration Regulations to remove regulation 4.10. Regulation 4.10 relies on section 69E of the Administration Act which is proposed to be repealed by the Operational Efficiency Bill.

Item 2 would insert a new Part 5 to deal with transitional matters relating to the removal of regulation 4.10.

Part 2 of the exposure draft for the Operational Efficiency Regulations deal with false and misleading information. This part would commence on the start of the day after registration, provided that Part 5 of Schedule 1 to the Operational Efficiency Bill has commenced.

Items 6 and 7 amend the Administration Regulations and the Code Regulations to provide for the APVMA to issue infringement notices for alleged contraventions of the proposed new civil penalty provisions in the Operational Efficiency Bill.