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HOUSE OF REPRESENTATIVES

AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT (REMOVING RE-APPROVAL AND RE-REGISTRATION) BILL 2014

EXPLANATORY MEMORANDUM

(Circulated by authority of the Minister for Agriculture
the Hon. Barnaby Joyce MP)

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GLOSSARY

The following abbreviations and acronyms are used throughout this explanatory memorandum.

Abbreviation	Definition
APVMA	Australian Pesticides and Veterinary Medicines Authority
Admin Act	*Agricultural and Veterinary Chemicals (Administration) Act 1992*
agvet chemicals	Agricultural chemicals and veterinary medicines
Agvet Act	*Agricultural and Veterinary Chemicals Act 1994*
Amendment Act	*Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*
Agvet Code	The Schedule to the Code Act (see below)
Bill	Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014
CEO	Chief Executive Officer of the APVMA
Code Act	*Agricultural and Veterinary Chemicals Code Act 1994*
Collection Act	*Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*
consultation paper	*Proposed Agricultural and Veterinary Chemicals Legislation Amendments: Consultation Paper*, released 18 December 2013
FOI Act	*Freedom of Information Act 1982*
FSANZ	Food Standards Australia New Zealand
FSANZ Act	*Food Standards Australia New Zealand Act 1991*
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
LI Act	*Legislative Instruments Act 2003*
Minister	Minister for Agriculture
NRS	National Registration Scheme for Agricultural and Veterinary Chemicals
reconsideration	A reconsideration of an active constituent or label approval or chemical product registration under Division 4 of Part 2 of the Agvet Code, known widely as a chemical review
Record	Record of Approved Active Constituents for Chemical Products
Register	Register of Agricultural and Veterinary Chemical Products
re-registration	The periodic re-approval of active constituents and re-registration of chemical products introduced by the Amendment Act.

AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT (REMOVING RE-APPROVAL AND RE-REGISTRATION) BILL 2014

GENERAL OUTLINE

The Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014 (the Bill) amends the *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act), the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (Amendment Act), the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (Collection Act) and the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

Objectives of the Bill

The Bill implements the Australian Government's 2013 election commitment to remove the requirement for agricultural chemicals and veterinary medicines (together, agvet chemicals) re-registration by removing end dates for approvals and last renewal dates for registrations so that approvals will no longer end after a particular period and registrations may be renewed perpetually, and removing redundant provisions that allow applications to re-approve and re-register active constituents and chemical products.

The Bill also introduces reforms that:

- reduce red tape by providing for less frequent registration renewals
- improve the APVMA's ability to secure information about the safety of chemicals supplied in the market
- introduce further simple reforms to agvet chemicals regulation to reduce red tape and improve efficiency
- oblige the APVMA to provide access to information about approvals and registrations in its files to persons eligible to receive it
- address some minor implementation issues identified in existing reform legislation.

Overview of amendments

Implementing the election commitment to remove re-registration

The Amendment Act introduced the re-approval of active constituents and re-registration of chemical products (re-registration) by amending the Agvet Code (the Schedule to the Code Act). Re-registration requires periodic examination (every seven to 15 years) of active constituents and products. Without changes to the Agvet Code, re-registration will come into force on 1 July 2014.

While the government has committed to remove re-registration, it will retain the existing comprehensive powers the APVMA has that ensure any newly identified risks about the safety, efficacy or trade impact of a chemical are examined. The APVMA also retains powers to recall unsafe chemical products or suspend or cancel the registration of a chemical product if they may no longer meet criteria for registration. These provisions were recently strengthened and streamlined by the Amendment Act.

Schedule 1 of the Bill amends the Agvet Code to:

- implement the election commitment to remove re-registration, by:
  - preventing the expiry of active constituent approvals and preventing the application of dates after which a registration cannot be renewed
  - removing provision for applications to be made to re-approve active constituents or re-register chemical products
  - make additional consequential amendments to the Agvet Code, Collection Act and Amendment Act
- reduce red-tape by allowing for less frequent renewal of registrations

Addressing concerns with chemical product quality

Removing re-registration removes an opportunity for the APVMA to confirm that chemical products supplied to the market are the same as the product evaluated and registered by the APVMA. This can be addressed in part by improving the ability of the APVMA to require a person who supplies an agvet chemical product in Australia to provide information (for example, a chemical analysis) about the product they are supplying.

Schedule 2 of the Bill amends section 99 of the Agvet Code to provide that the APVMA may, by written notice, require a person to provide information about substances supplied or intended for supply as a chemical product (or an active constituent for a chemical product) if they have, will have, or have had possession of the substance. The information that may be required includes details of the composition of the substance, manufacturing details, packaging, labelling and advertising information and about conformance of the substance with any relevant standard.

Reducing red-tape by allowing for simpler variations to approvals and registrations

The previous section 26A in Division 2A of Part 2 of the Agvet Code allowed for applications to be made for variations to certain particulars of an approval or registration. The particulars that could be varied under this section were to be set out in a legislative instrument the APVMA made. The section was intended to streamline applications for simple variations to an approval or registration.

The Bill amends Division 2A of Part 2 and inserts a new Division 2AA to improve the effectiveness of the Agvet Code and increase efficiency in dealing with these simple variations of approvals and registrations. The Bill substantially revises the existing provisions in Division 2A for applications for simple variations of registrations or approvals. The amendments to Division 2A provide that prescribed variations are taken to have been made after a set period, where the application meets the application requirements. The Bill also inserts a new Division 2AA that provides for variations of approval and registration to be made by notification to the APVMA. Prescribed variations and notifiable variations will be set out in the regulations or in a legislative instrument the APVMA makes.

These simplified application processes will greatly reduce the supporting information required and industry time taken to make a variation to a registration or approval. Without these amendments to the Agvet Code, the APVMA would have to complete a more onerous technical assessment of these variations with no real benefit to improving chemical safety.

Obliging access to information about chemicals that the APVMA holds

Currently, the APVMA is often asked by companies to provide information relating to their own registered chemical products (including about the formulation and details of manufacturing). This information is then provided under the *Freedom of Information Act 1982* (FOI Act).

These requests often occur because companies do not keep adequate records about applications they

make to the APVMA, or because records are not transferred between companies when responsibility for a chemical changes hands. Payments for information sought under the FOI Act are not recovering the costs of providing the information. As a result, companies that maintain accurate records are subsidising the records costs of those that do not.

Schedule 2 of the Bill amends the Agvet Code to allow persons to apply to the APVMA for copies of documents it holds about a chemical and for a copy to be provided for a fee. These amendments are intended to 'turn off' access under the FOI Act (by relying on an existing exemption in paragraph 12(1)(b) of that Act) for these documents while still ensuring access to the information.

Other amendments consequential to existing reforms

In preparing for implementation of the Amendment Act, the Department of Agriculture and the APVMA found some issues with that Act and the Agvet Code that should be addressed:

- the Amendment Act inadvertently undid 2010 amendments to the FSANZ Act. The 2010 amendments were an efficiency measure to allow the APVMA to amend the Maximum Residue Limit Standard of the Australia New Zealand Food Standards Code. The FSANZ Act will be amended to correct an incorrect reference to part of the Agvet Code in the FSANZ Act. Schedule 2 of the Bill addresses these amendments.
- several minor technical amendments are required to the Agvet Code to improve the readability of the legislation and reduce the possibility of difficulties in implementing it. Schedules 1 and 2 of the Bill address these miscellaneous amendments as appropriate.

Public Consultation

The reforms have been informed by extensive stakeholder consultation. Chemical industry groups, environmental organisations, primary producer associations, Commonwealth, state and territory agencies were all involved in discussions about the Bill.

Submissions were sought between 18 December 2013 to 7 March 2014 about an exposure draft of the legislation and an associated consultation paper, *Proposed Agricultural and Veterinary Chemicals Legislation Amendments: Consultation Paper*. Forty-two submissions were received and considered. Teleconferences and face to face meetings with interested stakeholders occurred over January and February 2014.

The Bill was revised to address some issues raised during the consultation.

Policy context

Agricultural chemicals and veterinary medicines

Agricultural chemicals (also known as pesticides) include a wide range of products that protect crops from a wide range of weeds, insects and pathogens. These chemicals are used in agricultural and forestry industries to ensure pest control is effective and so to aid industry productivity. In other contexts, agricultural chemicals are important in the protection of buildings, parks and infrastructure, as well as in households for the control of a range of pests.

Agricultural chemicals are also used in human health for protecting against disease vectors such as mosquitoes and rodents. Agricultural chemicals also play a role in protecting the environment from pests such as locusts, foxes and weeds.

Veterinary medicines, such as vaccines, antibiotics, worm treatments, lice treatments and some vitamins and minerals are important for the protection of livestock from pests and to treat a wide

range of diseases and illnesses. These products are also essential for maintaining the health and wellbeing of companion animals, including domestic pets and service animals.

National Registration Scheme

Agvet chemicals are regulated through a cooperative National Registration Scheme for Agricultural and Veterinary Chemicals (NRS). The NRS was first agreed to by the Australian Agriculture Council (subsequently the Standing Council on Primary Industries) in 1991 and is described in a ministerial level intergovernmental agreement that was signed in September 1995. In mid-2013 ministers confirmed their commitment to a new NRS agreement.

The NRS is a partnership between the Commonwealth and all the states and territories, with a shared division of responsibilities. Assessment and registration of agvet chemicals, as well as control of supply activities up to the point of retail sale, is undertaken by the APVMA (a Commonwealth authority). Control of use of agvet chemicals after sale is the responsibility of individual states and territories.

The Code Act contains as a schedule to it, the Agvet Code. Under the NRS, the Agvet Code operates in the Australian Capital Territory, together with the Agvet Code of each participating territory (that is, each state and the Northern Territory) to constitute a single national Agvet Code applying throughout Australia.

The Agvet Code, among other things, contains the detailed provisions allowing the APVMA to evaluate, approve or register and reconsider active constituents and agricultural and veterinary chemical products (and their associated labels). The provisions also allow the APVMA to issue permits and to licence 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.

Roles and responsibilities of the APVMA

The APVMA is responsible for administering and managing the parts of the NRS that oversee registration, quality assurance and compliance of agvet chemicals up to and including the point of retail sale.

With input from other government agencies, the APVMA approves active constituents and agvet chemical products, undertakes reviews of existing approvals and registrations and monitors the compliance of approvals and registration up to and including the point of retail sale. The APVMA's processes provide assurance, through rigorous science based risk assessments, that the use of agvet chemical according to the label instructions is safe for human and animal health and the environment. They also provide assurance that agvet chemicals will be effective to the extent relevant and will not adversely affect Australia's ability to trade agricultural produce. Australia currently has around 11 700 separate agvet chemical products registered (approximately 8 350 agricultural and 3 350 veterinary), each of which contains one or more of around 2 230 approved active constituents, of which around 782 are unique.

The APVMA's regulatory functions are defined by the Admin Act which established the APVMA; and the Code Act, together with its scheduled Agvet Code, which provides detailed operational procedures on the registration and management of agvet chemicals.

Reform context

The *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (Amendment Act) was passed by parliament in June 2013. The Act reformed the approval, registration and reconsideration (review) of agvet chemicals to improve the effectiveness of the regulatory system and reduce

inefficiency at the APVMA, while making processes more predictable, clearer and less unwieldy for industry. The reforms were intended to improve community's confidence that chemicals approved for use in Australia are safe.

The reforms of the Amendment Act (including provisions for re-approval of active constituents and re-registration of chemical products, or re-registration) commence on 1 July 2014.

This Bill builds on earlier progress made through the legislative changes in the Amendment Act.

Election commitment

The Bill delivers on an election commitment made during the 2013 election to deliver further reforms to the regulation of agricultural and veterinary chemicals in Australia.

The Australian Government committed to 'easing the burden imposed on the Australian economy and agricultural sector by reducing red and green tape on business by at least $1 billion per year'.

Specifically, the government has committed to remove re-registration and to work with industry to implement further improvements through legislation and administrative change.

The government considers that, prior to the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*, existing chemical review mechanisms provided sufficient basis for the examination of newly discovered risks about the safety, efficacy or trade impact of a chemical. New mechanisms (the re- registration scheme) duplicating the existing system and impose additional costs on industry are not required.

FINANCIAL IMPACT STATEMENT

This Bill, itself, has no financial impact for the Budget.

STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS

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

Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014

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

Overview of the Bill

The Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014 amends the Schedule (Agvet Code) to the *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act) and the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (Collection Act) (collectively called agvet chemical legislation). The Bill also amends the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* and the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

The Bill removes the requirement for agvet chemical re-registration by removing end dates for approvals and last renewal dates for registrations so that approvals will no longer end after a particular period and registrations may be renewed indefinitely, and removing redundant provisions that allow applications to re-approve and re-register active constituents and chemical products.

The Bill also introduces reforms that:

- reduce red tape by providing for less frequent registration renewals
- improve the APVMA's ability to secure information about the safety of chemicals supplied in the market
- introduce further simple reforms to agvet chemicals regulation to reduce red tape and improve efficiency
- oblige the APVMA to provide access to information about approvals and registrations in its files to persons eligible to receive it
- address some minor implementation issues identified in existing reform legislation.

Human rights implications

The Bill engages the following rights:

- the right to health and a healthy environment (Article 12) in the *International Covenant on Economic, Social and Cultural Rights* (ICESCR)
- fair trial and fair hearing rights including the right to be free from self-incrimination and the right to presumption of innocence in Article 14 of the *International Covenant on Civil and Political Rights* (ICCPR).

The right to health and a healthy environment

This Bill engages and promotes the right to health in Article 12 of the ICESCR by providing that the first priority of the system for regulating agvet chemicals is the health and safety of human beings, animals and the environment. The United Nations Committee on Economic, Social and Cultural Rights has interpreted Article 12 to extend to the underlying determinants of health, including a healthy environment.

The existing section 99 of the Agvet Code allows the APVMA to require a person who has possession or custody of a substance intended for supply as a chemical product to provide an analysis

of the substance's composition and quality. However, this provision is not effective as it applies only if the APVMA has a reasonable suspicion that the product does not meet APVMA requirements.

It is not feasible for APVMA to develop this suspicion while the person still has possession of the substance, due to changes in the way chemicals are manufactured and sold since the Agvet Code was drafted. This provision was drafted at a time when domestic manufacturing dominated the chemicals market and there was very limited import of finished product. Now, just-in-time imports of finished product dominate the market and direct supply of product from overseas manufacturer to customer means an importer has possession of the product for only a very small time.

Removing re-registration removes an opportunity for the APVMA to confirm that chemical products supplied to the market are the same as the product evaluated and registered by the APVMA. This can be addressed in part by improving the ability of the APVMA to require a person who supplies an agvet chemical product in Australia to provide information (for example, a chemical analysis) about the product they are supplying.

The Bill amends section 99 of the Agvet Code to provide that the APVMA may, by written notice, require a person to provide information about substances supplied or intended for supply as a chemical product (or an active constituent for a chemical product) if they have, will have, or have had possession of the substance. The information that may be required includes details of the composition of the substance, manufacturing details, packaging, labelling and advertising information and about conformance of the substance with any relevant standard.

The APVMA is to be able to require a chemical analysis of the product to provide the required information and for the results of the analysis to be provided to the APVMA.

The power is to apply only if the APVMA considers the information is necessary to protect human, animal and environmental health and safety or protect trade.

The offence for failing to provide the required information is unchanged.

In addition, the APVMA is bound by the *Privacy Act 1988* (Cwlth) in collecting, handling and disclosing personal information and this Act confers rights designed to protect privacy. These rights and obligations are set out in 13 Australian Privacy Principles (APPs) contained within the Privacy Act.

The amendments to section 99 promote the protection of the right to heath and a healthy environment (through the confirmation of information about substances, which may include chemical analysis).

The right to a fair trial and fair hearing rights, including the privilege against self-incrimination and the right to the presumption of innocence

The Bill also engages the right to be free from self-incrimination. The Bill reintroduces self-incrimination to be a reasonable excuse for non-compliance with a requirement at section 146A of the Agvet Code.

Item 47 of Schedule 2 of the Bill reinstates a section inadvertently omitted from the Agvet Code by the Amendment Act. Consistent with the Office of Parliamentary Counsel's Drafting Direction 3.5 (at 61 and 62), this section reinstates the section 146 confirmation that provisions which require an individual to give information, produce a document or do any other thing, unless the individual has a reasonable excuse, are not intended to abrogate the privilege against self-incrimination.

Article 14(3)(g) of the ICCPR protects the right to be free from self-incrimination by providing that anyone may not be compelled to testify against themselves or to confess guilt.

The reinstatement of this privilege provides that it is a reasonable excuse for an individual to refuse or fail to give information, produce a document or do any other thing required under the Agvet Code

if providing the information or document or doing the thing would tend to incriminate the individual. The reinstatement of this privilege promotes the protection of the right to a fair trial and fair hearing rights and the right to the presumption of innocence.

Other provisions

The Bill also includes amendments to remove redundant provisions and amend out of date provisions in all Commonwealth agricultural and veterinary chemical legislation. These provisions do not make any substantive change to the law and do not engage any rights.

Conclusion

The Bill is compatible with human rights because it is promoting the right to health and a healthy environment through amendments to section 99, and promoting the right to be free from self-incrimination with the reinstatement of requirements at section 146A of the Agvet Code.

The Hon. Barnaby Joyce MP, Minister for Agriculture

AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT (REMOVING RE-APPROVAL AND RE-REGISTRATION) BILL 2014

NOTES ON ITEMS

Clause 1: Short Title

Clause 1 is a formal provision specifying the short title of the Act and that it may be cited as the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014*.

Clause 2: Commencement

Clause 2 provides for the commencement of the Act as follows:

- Clauses 1 to 3 commence upon Royal Assent.
- Schedules 1 and 2 commence on the later of:
    (a) upon Royal Assent; and
    (b) immediately after the commencement of Schedule 1 to the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (the Act that introduces re-registration).

Clause 3: Schedule(s)

Clause 3 provides that each Act specified in a Schedule to the Act is amended or repealed as set out in the applicable items of the Schedule concerned, and any other item in a Schedule to the Act has effect according to its terms.

SCHEDULE 1 – REMOVING RE-APPROVAL AND RE-REGISTRATION

Summary

Schedule 1 amends the Schedule to the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code), the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* and the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013.* These amendments remove re-approval of active constituents and re-registration of chemical products (re-registration) and makes consequential amendments to address other changes made in 2013 to accommodate re-registration.

The *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* introduced re-registration by amending the Agvet Code. Re-registration requires periodic examination (every seven to 15 years) of active constituents and products. Without changes to the Agvet Code, re-registration will come into force on 1 July 2014.

While the Australian Government has committed to remove re-registration, it will retain the existing comprehensive powers the APVMA has that ensure any newly identified risks about the safety, efficacy or trade impact of a chemical are examined. The APVMA also retains powers to recall unsafe chemical products or suspend or cancel the registration of a chemical product if they may no longer meet criteria for registration. These provisions were recently strengthened and streamlined by the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*.

Schedule 1 of the Bill amends the Agvet Code to:

- prevent the expiry of active constituent approvals and prevent the application of dates after which a registration cannot be renewed. Active constituent approvals are to continue in force so long as they are not cancelled. Registrations are to continue in force so long as they are not cancelled, subject to renewal of the registration.
- remove provision for applications to be made to re-approve active constituents or re-register chemical products.

Additional amendments include the following consequential changes as discussed above to address other changes made in 2013 to accommodate re-registration:

- item 1 amends the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* to remove the requirement that applicants keep records of re-registration of chemical products
- item 71 removes a transitional provision in the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* that relates to re-approval and re-registration, entitled ‘Existing approvals and registrations must be given end date etc.’.

Reducing red-tape by allowing for less frequent renewal of registrations

Currently, chemicals registration must be renewed annually and renewal fees paid each year. Longer renewal periods will require less frequent applications for renewal and reduce the red-tape burden of these applications.

Amendments to the Agvet Code will provide for less frequent renewal of registration. Amendments will require APVMA to use a method set out in the regulations to work out the next renewal date for a chemical product. The renewal date could be up to seven years from the initial registration or last renewal. If no period is set in the regulations then the default period will be the existing one year.

Detailed Explanation

The detailed explanation is provided according to reform measure and then by item to group related amendments for ease of reading.

Part 1 - Amendments

Implementing the election commitment to remove re-registration

Agricultural and Veterinary Chemicals Code Act 1994

Item 20 – subsection 9(5) of the Code set out in the Schedule

Item 20 removes the explanation about Division 3A (re-approval and re-registration of active constituents and chemical products) from the explanation of Part 2 as Division 3A is omitted (item 30).

Items 22 to 25 – section 19 of the Code set out in the Schedule

Items 22 to 25 remove provisions that required the APVMA to work out and record the date an approval ends. Item 24 removes paragraph 19(1)(e) that required an end date to be recorded. Item 25 removes subsections 19(2), (3) and (4) that dealt with working out the date an approval ends. Items 22 and 23 reformat the remaining words. The amendments mean that approvals no longer end after a particular period.

Item 26 – paragraphs 20(1)(f) and (g) of the Code set out in the Schedule

Item 26 together with item 27 (see below under '*Reducing red tape by allowing for less frequent renewal of registration*') remove provisions that require the APVMA to work out and record the last renewal date for a product registration but retain the requirements to work out and record when a registration ends. The amendments mean registrations may be renewed indefinitely.

Item 30 – Division 3A of Part 2 of the Code set out in the Schedule

Item 30 removes Division 3A of Part 2 of the Code which dealt with applications for re-approval and re-registration. This amendment means that applications for re-approval of active constituents and re-registration of chemical products are not required.

Item 32 – subsections 34A(5) and (6) of the Code set out in the Schedule

Item 32 is a consequential amendment to remove provisions that require the APVMA to enter or remove last renewal dates from the Register where relevant particulars or conditions are amended for chemical products. These are redundant provisions as last renewal dates are to be removed as part of the removing the re-registration related provisions.

Item 39 – subsection 47(1) of the Code set out in the Schedule

Item 39 provides that an approval of an active constituent continues in force unless it is cancelled. Approvals no longer end after a particular period.

Item 40 – subsection 47(3) of the Code set out in the Schedule

Item 40 amends provisions that deal with registration of a chemical product ending if the approval of an active constituent for the product ends (consequential to item 39). The provisions are not necessary as approvals no longer end after a particular period.

Item 41 – subsection 47(6) of the Code set out in the Schedule

Item 41 removes unnecessary provisions that specified that section 47 does not limit the power to suspend or cancel an approval or registration.

Item 42 – section 47A of the Code set out in the Schedule

Item 42 removes section 47A that dealt with triggers for re-approval and re-registration applications based on certain decisions of overseas regulators. This section is no longer necessary as re-approval and re-registration applications are no longer required.

Item 43 – subdivision C of Division 6 of Part 2 of the Code set out in the Schedule (heading)

Item 43 amends the heading of subdivision C of Part 2 so that the heading more accurately reflects the subject matter of the amended subdivision.

Item 44 – section 47B of the Code set out in the Schedule

Item 44 removes section 47B that dealt with advance notice of end of approval or registration and the details of this advance notice. This section is no longer necessary as approvals no longer end after a particular period and registrations may be renewed indefinitely.

Item 58 – subsection 48(2) of the Code set out in the Schedule

Item 58 amends section 48 which deals with applications to renew registration of chemical products. The amendments provide that applications to renew registration may be made three months before a registration ends and sets a two month window for renewal applications. Subsection 48(3) provides for late renewal applications for a further prescribed fee. The amendments also remove reference to the day after which the registration cannot be renewed as registrations may be renewed indefinitely.

Item 59 – subsection 48(4) of the Code set out in the Schedule

Item 59 removes the redundant subsection that refers to a re-registration application. This is no longer necessary following removal of re-registration related provisions.

Item 60 – subsection 48(5) of the Code set out in the Schedule

Item 60 removes the redundant word 'renewal' from subsection 48(5). It is unnecessary given that section 48 only deals with renewal applications.

Item 61 – subsection 49(1) of the Code set out in the Schedule

Item 61 simplifies subsection 49(1) by specifying that the APVMA must renew a product registration if the application for the renewal meets the application requirements. This amendment aligns the requirements for renewal applications with other applications in the Agvet Code.

Agricultural and Veterinary Chemicals Legislation Amendment Act 2013

Item 71 – item 51 of Schedule 6

Item 71 removes a redundant transitional provision that dealt with the APVMA determining end dates for approvals and last renewal dates for registrations. Approvals no longer end after a particular period and registrations may be renewed indefinitely.

Reducing red tape by allowing for less frequent renewal of registration

Agricultural and Veterinary Chemicals Code Act 1994

Items 27 and 62 to 64 – subsections 20(2), (3) and (4), and section 50 of the Code set out in the Schedule

Items 27 and 62 to 64 amend sections 20 and 50, respectively, to provide for the period of registration to be up to seven years. The period of registration is to be worked out according to a method set out in the regulations.

These amendments increase flexibility in renewing products and provide for a potential reduction in the red tape associated with renewing product registrations (for example, by allowing a holder of registration to choose annual or (say) five yearly renewal). If no method is set out in the regulations the current period of one year is set as a default period.

Clarifying listed chemical product

Item 5 – section 3 of the Code set out in the Schedule (definition of *listed chemical product*)

Item 5 amends the definition of *listed chemical product* to introduce that a listed chemical product is a chemical product that also complies with the established standard for the product.

Listed chemical products that comply with the established standard for the product were previously identified through the absence of a last renewal date in the Register. This approach is no longer practical as the removal of the re-registration related provisions mean that all last renewal dates are to be removed from the Register.

After the amendment, products listed by the regulations under section 8T are only listed chemical products if they comply with the established standard for the product. Listed chemical products may be registered by a simpler pathway as they need not be assessed against the safety, trade and efficacy criteria (see paragraph 14(1(c) of the Agvet Code).

Item 21 – paragraph 15(2)(b) of the Code set out in the Schedule

Item 21 removes a redundant reference to the established standard for a listed chemical product and is consequential to item 5.

Items 28 and 29 – subsections 26D(2) and (3) and subsections 29B(2) and (3) of the Code set out in the Schedule

Items 28 and 29 provide that where the relevant particulars or conditions for listed chemical products are varied so they no longer comply with the established standard for the product, the APVMA must vary the Register to identify that these products are no longer recorded as listed chemical products. Consistent with the amended definition of *listed chemical product*, a listed chemical product must comply with the established standard. These items are complementary to the item 5 amendments.

Consequential amendments to remove references to 're-approve' or 're-register' (and similar terms) and to the re-registration related provisions in Division 3A of Part 2 of the Agvet Code

Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994

Item 1 – subsection 36(1) of the Collection Act

Item 1 removes references to re-approval and re-registration applications as these applications are no longer required. Active constituent approvals are to continue in force so long as they are not cancelled. Registrations are to continue in force so long as they are not cancelled, subject to the periodic renewal of the registration.

Agricultural and Veterinary Chemicals Code Act 1994

Items 2 and 3 – section 3 of the Code set out in the Schedule (definition of *approval*)

Items 2 and 3 remove the reference to re-approval from the definition of *approval* as re-approval no longer applies.

Item 4 – section 3 of the Code set out in the Schedule (definition of *determine*)

Item 4 removes references to re-approval, re-registration and section 29H of Division 3A of Part 2, as re-approval and re-registration no longer apply and Division 3A is removed from the Agvet Code. Item 4 also includes 'renew' in the definition of *determine* so that the determination of applications for renewal of registration are included with all other applications.

Item 6 – section 3 of the Code set out in the Schedule (definition of *re-approval*)

Item 6 removes the unnecessary definition of *re-approval* in its entirety.

Item 7 – section 3 of the Code set out in the Schedule (definition of *registration*)

Item 7 removes the reference to re-registration from the definition of *registration* as re-registration no longer applies.

Item 8 – section 3 of the Code set out in the Schedule (definition of *relevant particulars*)

Item 8 removes the reference to section 29G (varying relevant particulars and conditions to allow re-approval or re-registration) from the definition of *relevant particulars* as this section is removed as part of the removal of Division 3A of Part 2 of the Agvet Code.

Item 9 – section 3 of the Code set out in the Schedule (definition of *re-registration*)

Item 9 removes the unnecessary definition of *re-registration* in its entirety.

Item 10 – subsection 8B(2) of the Code set out in the Schedule

Item 10 amends subsection 8B(2) to remove reference to section 29D (applications for re-approval or re-registration) as this section is removed as part of the removal of Division 3A of Part 2 of the Agvet Code.

Item 11 – subparagraph 8E(2)(c)(i) of the Code set out in the Schedule

Item 11 removes the reference to section 29D (applications for re-approval or re-registration) from the subparagraph as this section is removed as part of the removal of Division 3A of Part 2 of the Agvet Code.

Item 12 – subparagraph 8E(2)(c)(ii) of the Code set out in the Schedule

Item 12 removes the reference to section 29G (varying relevant particulars and conditions to allow re-approval or re-registration) as this section is removed as part of the removal of Division 3A of Part 2 of the Agvet Code.

Items 13 and 14 – paragraphs 8F(1)(a) and(b) of the Code set out in the Schedule

Item 13 removes unnecessary references to re-approval and re-registration from the paragraphs.

Item 15 – subparagraph 8F(2)(a)(iii) of the Code set out in the Schedule

Item 15 removes the reference to the date the approval or registration ends.

Item 16 – subparagraph 8F(2)(b) and (c) of the Code set out in the Schedule

Item 16 removes reference to the date after which registration cannot be renewed and replaces it with the date the current registration ends. Item 16 also introduces for the renewal of registration that the notice to holder of approval, registration or variation must also include the date the registration ends (as renewed).

Item 17 – subparagraphs 8F(2)(d)(iii) and (iv) of the Code set out in the Schedule

Item 17 removes reference to approval end dates and the date after which registration cannot be renewed from paragraph 8F(2)(d).

Item 18 – paragraph 8H(2)(c) of the Code set out in the Schedule

Item 18 removes the unnecessary reference to re-approval and re-registration from the subsection.

Item 19 – paragraph 8S(1)(b) of the Code set out in the Schedule

Item 19 removes the unnecessary reference to re-approval and re-registration from subsection 8S(1).

Item 31 – subsection 29L(10) of the Code set out in the Schedule

Item 31 removes references to re-approval of active constituents and re-registration of chemical products and section 29H as this section is removed as part of the removal of Division 3A of Part 2 of the Agvet Code.

Item 33 – paragraphs 34AC(2)(c), (d) and (e) of the Code set out in the Schedule

Item 33 removes references to the date an approval ends and removes references to the date after which a registration cannot be renewed under Division 6, as these dates no longer apply.

Item 34 – sections 34AD and 34AE of the Code set out in the Schedule

Item 34 removes sections 34AD and 34AE which respectively dealt with 'Affirmation leading to re-approval or re-registration' and 'Varying duration of approval or registration'. These provisions no longer apply with the removal of Division 3A of Part 2 of the Agvet Code (which dealt with re-approval of active constituents and re-registration of chemical products).

Item 35 – 34AF(4) of the Code set out in the Schedule

Item 35 removes the unnecessary reference to section 34AE as item 34 removes section 34AE from the Code.

Item 36 – subsection 34G(1A) of the Code set out in the Schedule

Item 36 removes the unnecessary reference to section 29G as this section is removed as part of the removal of Division 3A of Part 2 (which dealt with re-approval of active constituents and re-registration of chemical products – see item 30).

Item 37 – subsection 43(2) of the Code set out in the Schedule

Item 37 removes the unnecessary reference to section 29D as this section is removed as part of the removal of Division 3A of Part 2.

Item 38 – subsections 46A(3) to (6) of the Code set out in the Schedule

Item 38 amends the explanation of Division 6 of the Agvet Code (which deals with the durations of approvals and registrations). Item 39 amends section 46A to reflect the changes made to Division 6 by items 39 to 44 and 58 to 61 that remove references to the date an approval ends and the date after which registration cannot be renewed. Item 39 also removes the requirement to publish at least 12 months' advance notice of the end of approval and the date after which a registration cannot be renewed. As re-approval applied to constituents, reference to 'constituent' has also been removed from section 46A.

The item also removes reference to section 47A as item 42 removes this section.

Item 65 – subsection 59(1) of the Code set out in the Schedule (note)

Item 65 removes the note that contains redundant references to re-approval of active constituents and re-registration of chemical products and their definitions.

Item 66 – paragraph 59(2)(e) of the Code set out in the Schedule

Item 66 removes reference to information provided as part of a re-approval or re-registration application as these applications are no longer provided for with the removal of Division 3A of Part 2 of the Agvet Code.

Item 67 – paragraph 59(6)(a) of the Code set out in the Schedule

Item 67 removes references to Division 3A of Part 2 for re-approval of active constituents and re-registration of chemical products, as this division no longer applies.

Item 68 – paragraph 165(2)(a) of the Code set out in the Schedule

Item 68 removes the paragraph that relates to working out the period within which re-approval and re-registration applications have to be determined. This is no longer necessary with the removal of Division 3A of Part 2.

Item 69 – paragraph 166(1A)(b)(i) of the Code set out in the Schedule

Item 69 omits reference to subsection 29E(3) as this subsection is removed as part of the removal of Division 3A of Part 2.

Item 70 – paragraphs 167(1)(da) and (db) of the Code set out in the Schedule

Item 70 removes these paragraphs as they relate to subsections 29D(3) and 29G(1) which are removed as part of the removal of Division 3A of Part 2.

Consequential amendments relating to notices of the end of a registration should it not be renewed and for the sell-out of stocks where registration has ended

Agricultural and Veterinary Chemicals Code Act 1994

Item 45 – section 47C of the Code set out in the Schedule (heading)

Item 45 replaces the heading 'Notice of end of approval or registration' with the new heading 'Notice of end of registration' that reflects the subject matter of section 47C.

Item 46 – subsection 47C(1) of the Code set out in the Schedule

Item 46 amends section 47C(1) to remove reference to the end of an approval of an active constituent. The section continues to provide for notice to be given following the end of a chemical product registration (for example, should a registration not be renewed).

Item 47 – paragraphs 47C(2)(a), (b) and (c) of the Code set out in the Schedule

Item 47 removes references to the end of an approval as approvals no longer end after a particular period (see item 39).

Item 48 – paragraphs 47C(2)(d), (e) and (f) of the Code set out in the Schedule

Item 48 removes reference to 'constituent or' wherever occurring as approvals no longer end after a particular period.

Item 49 – subsection 47C(3) of the Code set out in the Schedule

Item 49 amends subsection 47C(3) to also provide that subsection 47C(1)(notice that a registration ends) does not apply if the registration of the chemical product ends because it is cancelled. This item also adds a note referring to section 45A for the notice of the cancellation of the registration.

Item 50 – paragraph 47C(4)(a) of the Code set out in the Schedule

Item 50 replaces 'the holder' with 'the person who was the holder of the registration' to clarify the application of this paragraph.

Item 51 – paragraph 47C(4)(b) of the Code set out in the Schedule

Item 51 removes the reference to the ending of the approval of an active constituent.

Item 52 – section 47D of the Code set out in the Schedule

Item 52 replaces section 47D so the section only refers to the end of a product registration (no longer refers to an approval ending, as approvals no longer end after a particular period). Section 47D has also been simplified to improve its readability. Section 47D continues to provide for a permit to dispose of products one year after a registration ends, unless the APVMA declares that subsection 47D(2) does not apply (and publishes a notice in the Gazette to that effect). Subsection 47D(3) retains the restriction that the permit does not authorise the person to manufacture or import the product.

Items 53 to 57 – section 47E of the Code set out in the Schedule

Items 53 to 57 amend section 47E to remove reference to constituent and an approval of a constituent in the provision. The amended section 47E continues to apply to a person who has possession or custody of a product with the intention of supplying it after the end of the registration of a chemical product (for example, where the registration is not renewed).

Part 2 – Transitional provisions

Item 72 – end dates

Item 72 specifies that if the APVMA has entered the date an approval ends or date after which a registration cannot be renewed in the Record or Register then the APVMA must remove these dates, as active constituent approvals are to continue in force so long as they are not cancelled and registrations are to continue in force so long as they are not cancelled, subject to the periodic renewal of the registration.

SCHEDULE 2 – MISCELLANEOUS AMENDMENTS

Summary

Addressing concerns with chemical product quality

The previous section 99 of the Agvet Code allows the APVMA to require a person who has possession or custody of a substance intended for supply as a chemical product to provide an analysis of the substance's composition and quality. However, this provision was not effective as it applied only if the APVMA had a reasonable suspicion that the product does not meet APVMA requirements.

It is not feasible for APVMA to develop this suspicion while the person still has possession of the substance, due to changes in the way chemicals are manufactured and sold since the Agvet Code was drafted. This provision was drafted at a time when domestically manufactured product was more prominent in the chemicals market and there was limited import of finished product. Now, just-in-time imports of finished product dominate the market and direct supply of product from overseas manufacturer to customer means an importer has possession of the product for only a very short time.

Removing re-registration removes an opportunity for the APVMA to confirm that chemical products supplied to the market are the same as the product evaluated and registered by the APVMA. This can be addressed in part by improving the ability of the APVMA to require a person who supplies an agvet chemical product in Australia to provide information (for example, a chemical analysis) about the product they are supplying.

The Bill amends section 99 of the Agvet Code to provide that the APVMA may, by written notice, require a person to provide information about substances supplied or intended for supply as a chemical product (or an active constituent for a chemical product) if they have, will have, or have had possession of the substance. The information that may be required includes details of the composition of the substance, manufacturing details, packaging, labelling and advertising information and about conformance of the substance with any relevant standard.

The APVMA is to be able to require a chemical analysis of the product to provide the required information and for the results of the analysis to be provided to the APVMA.

The power is to apply only if the APVMA reasonably believes that the information is necessary to protect human, animal and environmental health and safety or prevent prejudice to trade.

The penalty in section 99 for failing to provide the required information is unchanged.

Reducing red-tape by allowing for simpler variations to approvals and registrations

The previous section 26A in Division 2A of Part 2 of the Agvet Code allowed for applications to be made for variations to certain particulars of an approval or registration. The particulars that could be varied under this section were to be set out in a legislative instrument the APVMA made.

The section was intended to streamline applications for simple variations to an approval or registration. However, the provisions are not yet active as the APVMA has not made the required legislative instrument and in examining these provisions the Department of Agriculture has found that it is not likely to be as effective in its current form. The Bill therefore amends Division 2A of Part 2 and inserts a new Division 2AA in Part 2 to provide for certain variations to approvals or registrations to be made more simply. These amendments improve the effectiveness of the Agvet Code and increase efficiency in dealing with these simple variations. The provisions replace the previous arrangement where the APVMA must individually assess the appropriateness of a variation.

New Division 2AA provides for notifiable variations to approvals or registrations that the APVMA will have to make if the variation is a prescribed notifiable variation and the notification meets the

notification requirements. No further assessment of the suitability of the variation would be required and the variation would take effect on the day that a valid notification is lodged with the APVMA. The simple notification process will improve efficiency in dealing with simple changes to a registration or approval.

The Bill also amends Division 2A to provide for prescribed variations to approvals and registrations to be made more simply. These variations may be made by application and will be taken to have been made after a period that is prescribed in the regulations has elapsed.

The notifiable variations and prescribed variations will be set out in the regulations or legislative instruments the APVMA makes. The APVMA would not be able to set out a variation in its legislative instruments unless it has considered whether the variation would be unsafe or would adversely affect efficacy or trade. The APVMA may also provide advice before regulations are made prescribing variations to ensure that, again, the variation would not be unsafe or adversely affect trade or efficacy.

The kinds of variations could be permitted under these simplified approaches include simple variations to the name or packaging of a product or limited changes to product formulation. Without these amendments to the Agvet Code, the APVMA would have to complete a more onerous technical assessment of these variations with no benefit to improved chemical safety.

Obliging access to information about chemicals that the APVMA holds

Currently, the APVMA is often asked by companies to provide information relating to their own registered chemical products (including about the formulation and details of manufacturing). This information is then provided under the *Freedom of Information Act 1982* (FOI Act).

These requests often occur because companies do not keep adequate records about applications they make to the APVMA. As well, records may not be transferred when responsibility for a chemical is transferred (for example, if a company changes hands). Payments for information sought under the FOI Act are not recovering the costs of providing the information. As a result, companies that maintain accurate records are subsidising the records costs of those that do not.

The Bill amends the Agvet Code to allow persons to apply to the APVMA for copies of documents it holds about a chemical and for a copy to be provided for a fee. Such a provision is intended to 'turn off' access under the FOI Act for these documents (as is provided for by the exemption at paragraph 12(1)(b) of the FOI Act) but not prevent access to the information.

This provision will not allow release of confidential commercial information unless the recipient was entitled to the information (for example, because they were the person that provided the information).

Other amendments consequential to existing reforms

In preparing for implementation of the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*, the Department of Agriculture and the APVMA have found some issues with that Act and the Agvet Code that should be addressed.

The *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* inadvertently undid 2010 amendments to the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The 2010 amendments are an efficiency measure that allows the APVMA to amend the Maximum Residue Limits Standard in the Australia New Zealand Food Standards Code.

The Bill includes several minor technical amendments to the Agvet Code to improve the readability of the legislation and reduce the possibility of difficulties in implementing it.

Detailed Explanation

The detailed explanation is provided according to reform measure and then by item to group related amendments for ease of reading.

Part 1 – Amendments

Miscellaneous amendments

Agricultural and Veterinary Chemicals Code Act 1994

Items 1 and 2 – section 3 of the Code set out in the Schedule (paragraph (a) of the definition of *agvet law* and paragraph (a) of the definition of *agvet penalty provision*)

Items 1 and 2 ensure that the definitions of *agvet law* and *agvet penalty provision* (which are relevant for the investigative and enforcement parts of the Agvet Code) include reference to the regulations made under the Code Act.

Items 3 and 4 – section 3 of the Code set out in the Schedule (definition of *approved active constituent* and *approved label*)

Items 3 and 4 replace these definitions to clarify that an approved active constituent or label is a currently approved active constituent or label. This is necessary to promote effective enforcement of compliance with the Agvet Code.

Item 5 – section 3 of the Code set out in the Schedule (definition of *continue*)

Item 5 improves readability and operability of the legislation and reduces the possibility of difficulties in implementing it.

Item 6 – section 3 of the Code set out in the Schedule (second definition of *limitation period*)

Item 6 removes the second occurrence of the definition to address an error in the Amendment Act.

Item 11 – section 3 of the Code set out in the Schedule (definition of *registered chemical product*)

Item 11 replaces the definition to clarify that a registered chemical product is a currently registered chemical product. This is necessary to promote effective enforcement of compliance with the Agvet Code.

Item 13 – section 3 of the Code set out in the Schedule (first and second definitions of *secondary applicant*)

Item 13 removes the first and second definitions of *secondary applicant* to address an error in the Amendment Act as that Act did not specify which definition should be repealed.

Item 14 – section 6B of the Code set out in the Schedule

Item 14 replaces section 6B to clarify that the APVMA's ability to vary conditions of approvals or registration includes the ability to add or remove conditions.

Items 20 to 22 – paragraphs 8S(1)(b), (1)(c), and (2)(b) of the Code set out in the Schedule

Items 20 to 22 remove unnecessary provisions in relation to applications to vary relevant particulars of approvals or registrations (under Divisions 2A and 3 of Part 2). The APVMA cannot vary particulars other than as set out in the application, so there is no need to require a notice under section 8S about variations proposed to be made other than in accordance with the application.

Applications may be altered with the consent of the applicant to allow for variations to be made different to those in the original variation application. See, for example, subsection 26B(3).

Item 20 reformats the subsection as item 21 removes paragraph 8S(1)(c) in its entirety. Item 22 removes paragraph 8S(2)(b) in its entirety.

Item 28 – subsection 23(2) of the Code set out in the Schedule

Item 28 amends this subsection to improve readability and operability of the legislation and reduce the possibility of difficulties in implementing it.

Items 35 and 36 – subsections 32(1) and 33(1) of the Code set out in the Schedule

Items 35 and 36 amend these subsections to improve readability and operability of the legislation and reduce the possibility of difficulties in implementing it.

Item 39 – subsection 59(6) of the Code set out in the Schedule

Consistent with item 5, item 39 amends subsection 59(6) to improve readability and operability of the legislation and reduces the possibility of difficulties in implementing it.

Item 40 – subsection 86(4) of the Code set out in the Schedule

Item 40 replaces references to subsections (1) and (2) with the correct references to subsections (1A) and (2A) and addresses errors in the Amendment Act.

Item 41 – section 89A of the Code set out in the Schedule

Item 41 amends section 89A to provide for the regulations to exclude products from provisions for date-controlled chemical products (Division 3 of Part 4 of the Agvet Code). The regulations may exclude products or a product included in a class of chemical products. A date-controlled chemical product is a product declared by the regulations to be a date-controlled chemical product.

Item 44 – subsection 116(3C) of the Code set out in the Schedule (note)

Item 44 removes a typographical error (an additional full stop).

Item 45 – section 120A of the Code set out in the Schedule

Item 45 amends section 120A to provide for the regulations to exclude products from the requirements to be produced by a licensed manufacturer. The regulations may exclude a chemical product, or a product included in a class of chemical products, prescribed by the regulations. A transitional provision is included to ensure existing excluded products continue to be excluded (see item 63) until such time as regulations are made for the authority in section 120A.

Item 46 – paragraph 121(4)(a) of the Code set out in the Schedule

Item 46 removes reference to exempt products, as exclusions from Part 8 of the Agvet Code will now be dealt with under the authority in section 120A (see item 45 above). This approach promotes greater transparency in the legislation about these exclusions. A transitional provision is included to ensure existing excluded products continue to be excluded until such time as regulations are made for the authority in section 120A (see item 63).

Item 47 – after section 146 of the Code set out in the Schedule

Item 47 reinstates in the Agvet Code the privilege against self-incrimination for individuals, which was inadvertently omitted from the Agvet Code by the Amendment Act. Consistent with the Office of Parliamentary Counsel's Drafting Direction 3.5, this section provides that it is a reasonable excuse for an individual to refuse or fail to give information, produce a document or do any other thing

required under the Agvet Code if providing the information or document or doing the thing would tend to incriminate the individual.

Item 48 –at the end of subsection 159(1) of the Code set out in the Schedule

Item 48 adds a new paragraph 159(1)(h) to the end of subsection 159(1) to clarify that the power for the APVMA to gather information to inform consideration of an application or decision to suspend or cancel includes the power to require a person to undertake trials or experiments and then provide the results to the APVMA.

Food Standards Australia New Zealand Act 1991

Items 56 to 62 – section 80, paragraphs 81(1)(a) and 81(1)(b) and subsections 81(2), 84(1) and 84(2)

Items 56 to 60 amend the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) to replace references to section 13A with references to section 8E of the Agvet Code. The Amendment Act replaced section 13A in the Agvet Code with section 8E. These are consequential amendments that were inadvertently missed and are required to correct an incorrect Agvet Code reference in the FSANZ Act. Items 61 and 62 amend subsections 84(1) and 84(2) of the FSANZ Act to include missing references in that Act.

Reducing red-tape by allowing for simpler variations to approvals and registrations

Agricultural and Veterinary Chemicals Code Act 1994

Items 7 to 9 and item 12 – section 3 of the Code set out in the Schedule

Items 7 to 9 amend the definition of *lodged* and includes new definitions of *meets the notice requirements* and *notifiable variation* which are expressions used and described in new Division 2AA of Part 2 of the Agvet Code. New Division 2AA provides for certain variations to approval and registration to be varied by a notification to the APVMA (see item 29 below). Item 12 updates the definition of *relevant particulars* to include reference to variations made under the new Division 2AA.

Item 10 – section 3 of the Code set out in the Schedule

Item 10 introduces the definition of *prescribed variation* which points to the variations described in section 26B(4). These variations are those variations that may be made by simple applications under Division 2A of Part 2 of the Agvet Code. These variations will be prescribed in regulations or determined by the APVMA by legislative instrument.

Item 15 – section 8A of the Code set out in the Schedule

Item 15 amends subparagraph 8A(a)(v) to provide for regulations to prescribe information that may be contained in an application or accompany an application. This will be in addition to any information that the APVMA specifies by legislative instrument for subsection 8B.

This amendment complements those that provide for prescribed variations by allowing for the regulations to specify the information that must accompany an application for a prescribed variation. As an example, the amendment would enable the regulations to set out that an application for variation of a formulation under Division 2A of part 2 of the Agvet Code must be accompanied by a certificate of analysis.

Item 16 – section 8A of the Code set out in the Schedule

Item 16 amends paragraph 8A(e) of the Agvet Code to clarify that an application would not *meet the application requirements* if an amount was payable and due. The provision applies in situations

where an amount payable is outstanding beyond the due date for payment of the amount. This ensures that applications may proceed even though an applicant may have another application under consideration but may not yet have made a payment because the payment is not yet due, or if a levy amount is to be paid but the due date for payment has not arrived.

Item 17 – section 8F of the Code set out in the Schedule

Item 17 is a consequential amendment to paragraph 8F(1)(e) of the Agvet Code to require notice of variation for variations done under new Division 2AA of Part 2 of the Agvet Code. Section 8F deals with notices to be provided to holders of approval or registration and the content of these notices and the amendment means that these notice requirements apply to notifications as if the notification was an application.

Items 25 and 26 – section 9 of the Code set out in the Schedule

Items 25 and 26 are consequential amendments to the explanation of Part 2 of the Agvet Code. The amendments include an explanation of new Division 2AA of the Agvet Code and update an existing explanation to refer to variations that may be prescribed in regulations.

Item 29 – new Division 2AA of Part 2 of the Code set out in the Schedule

Item 29 inserts a new Division 2AA in Part 2 of the Agvet Code to provide for holders of approval or registration to notify the APVMA of certain variations to relevant particulars of an approval or registration. These notifiable variations are to be of a kind either set out in a legislative instrument made by the APVMA or prescribed by the regulations (new subsection 26AB(3)). These variations will not include those variations prescribed under Division 2A. The purpose of these notifications is to provide for a simplified means of making certain limited variations to the relevant particulars of an approval or registration.

New section 26AC provides that the variation of the relevant particular is done when the notification is lodged with the APVMA under section 26AB. The APVMA must record the variation and the date on which the variation was done in the Record or Register or relevant APVMA file within 14days of lodgement of the notification, including where a variation results in a listed chemical product no longer complying with the established standard for the product.

These notifications are not applications but as provided for by new section 26AD, they must meet the notice requirements in that they must be made in writing in the approved form, signed by the holder, accompanied by the prescribed fee and lodged with the APVMA. The notifications must contain, or be accompanied by, any information specified for the notification.

A holder may only notify the APVMA of notifiable variations. Notification of a variation that is not a notifiable variation will not result in the variation of the relevant particulars of an approval or registration. As provided for by subsection 26AB(6), the APVMA must notify a holder where a notification does not meet the notice requirements and provide reasons why it considers that it does not meet the requirements.

As provided for by section 6A the APVMA may make guidelines about Division 2AA notifications. Section 8J provides for published notice of variations of approval and registration.

Item 30 – Division 2A of Part 2 of the Code set out in the Schedule (heading)

Item 30 replaces the heading of Division 2A of Part 2 of the Code with ‘Prescribed variations of relevant particulars’ which better describes the content of the division.

Item 31 – sections 26A to 26C of the Code set out in the Schedule

Item 31 replaces sections 26A to 26C with revised provisions which improve processes for applications for simple variations of registrations or approvals. Variations which may be applied for

under this Division will be prescribed in the regulations or determined by the APVMA by legislative instrument. The APVMA is prevented from setting out the variation in the legislative instrument unless it has considered whether the variation would be safe or would not unduly affect efficacy or trade.

Under Division 2A APVMA must, within a period prescribed in the regulations, make the variation if the variation is a prescribed variation and the application meets the application requirements. If the APVMA does not make the variation in the prescribed period then the variation is taken to have been made.

These amendments are anticipated to allow industry to effectively make simple variations to the formulation or packaging of their product or to sources of ingredients. Without these changes, APVMA would have to complete a more rigorous technical assessment of the variation.

Item 32 – section 26D of the Code set out in the Schedule (heading)

Item 32 replaces the heading of section 26D with 'How prescribed variation takes place'.

Item 33 – subsection 26D(1) of the Code set out in the Schedule

Item 33 replaces subsection 26D(1) to allow for variation of multiple relevant particulars instead of only a single relevant particular.

Item 34 – subsection 27(4) of the Code set out in the Schedule

Item 34 removes unnecessary subsection 27(4) in its entirety. This provision provided for the fee associated with an application for a variation made under Division 2A to be offset against any subsequent application under Division 3, where the application under Division 2A was refused because the variation was not of a kind specified in the legislative instrument. As an application under Division 2A could not be accepted if it was not of a kind specified in the instrument or regulations, no fee would be payable for such an application and there is therefore no need to provide for any subsequent fee reduction for an application under Division 3.

Items 49 to 52 – section 164 of the Code set out in the Schedule

Items 49 to 52 amend section 164 (which deals with fees) to include the notifications under new Division 2AA of Part 2 of the Agvet Code. The amendments mean that fees can be applied in relation to these notifications and that these notifications are taken not to have been made unless any fee for the notification has been paid. The amendments also provide for notifications under new Division 2AA to be treated as if the notification was an application under the Agvet Code and therefore treated in a similar and consistent manner as for applications.

Items 53 and 54 – subsection 166(1A) of the Code set out in the Schedule

Item 53 is a consequential amendment to subsection 166(1A) of the Agvet Code to update the provision where a decision is made under section 26C on a variation of approval or registration (this decision is now made under 26C(1)(b)). Item 54 provides for a decision under new Division 2AA of Part 2 to be internally reviewed by the APVMA where the decision relates to a notice not meeting the notice requirements.

Obliging access to information about chemicals that the APVMA holds

Agricultural and Veterinary Chemicals Code Act 1994

Item 18 – at the end of subsection 8F(2) of the Code set out in the Schedule

Item 18 inserts a note at the end of subsection 8F(2) clarifying that release of confidential commercial information is not authorised by subsection 8F(2) if it would otherwise be prevented by section 162 (which deals with disclosure of confidential commercial information).

Item 19 – section 8K of the Code set out in the Schedule

Item 19 removes section 8K as this subject matter is now dealt with in section 8X (refer to item 24).

Item 23 – at the end of subsection 8S(2) of the Code set out in the Schedule

Item 23 inserts a note at the end of subsection 8S(2) clarifying that release of confidential commercial information is not authorised subsection 8S(2) if it would otherwise be prevented by section 162.

Item 24 – at the end of Part 1 of the Code set out in the Schedule

Item 24 inserts new Division 7 which deals with access to certain documents and information and contains new sections 8W and 8X. Section 8W is a new provision that allows a person to apply for copies or extracts of documents the APVMA holds in relation to approved active constituents or registered chemical products. The APVMA must provide the copy or extract of the document if the person pays the prescribed fee. This does not apply to documents in any part of the Record or Register. Existing subsections 17(4) and (5) and 18(4) and (5) of the Agvet Code provide for access to documents in the Record and Register.

Currently, this information (for example, information about the formulation of a registered product) is often requested under the *Freedom of Information Act 1982* by companies that are responsible for the product. This occurs because companies may keep poor records or fail to arrange the transfer of records when responsibility for a chemical is transferred (for example, if a company changes hands). Payments for information sought under the FOI Act are not recovering the costs of providing the information. As a result, companies that maintain accurate records are subsidising the records costs of those that do not. New section 8W allows for more cost-effective and efficient access to this information.

New section 8W, along with subsections 17(4) and (5) and 18(4) and (5) engages the exemption provided at paragraph 12(1)(b) of the FOI Act for access to 'a document that is open to public access, as part of a public register or otherwise, in accordance with another enactment, where that access is subject to a fee or other charge'. The effect of the amendments in the Bill is that persons will need to apply under section 8W for information that the APVMA holds and the provision in the FOI Act will no longer be available.

These amendments do not reduce or limit access to information. The amendments change the mechanism by which the information must be provided.

New section 8W does not allow release of confidential commercial information unless the applicant was entitled to that information (for example, because they were the person that provided the information).

Section 8X is the same as the previous section 8K (see item 19).

Item 27 – subsections 17(4) and (5) and 18(4) and (5) of the Code set out in the Schedule (note)

Item 27 amends notes to subsections 17(4) and (5) and 18(4) and (5) of the Agvet Code as a result of the renumbering of section 8K to 8X (see item 19).

Items 37 and 38 – at the end of subsections 34AB(2) and 34AC(2) of the Code set out in the Schedule

Items 37 and 38 insert a note at the end of subsections 34AB(2) and 34AC(2) clarifying that release of confidential commercial information is not authorised by these provisions if it would otherwise be prevented by section 162 of the Agvet Code.

Addressing concerns with chemical product quality

Agricultural and Veterinary Chemicals Code Act 1994

Item 42 – section 99 of the Code set out in the Schedule (heading)

Item 42 replaces the heading of section 99 with 'Information and documents about, and analysis of, substances supplied as active constituents or chemical products' to better reflect the content of the section (see item 43).

Item 43 – subsections 99(1) to (5) of the Code set out in the Schedule

Item 43 replaces subsections 99(1) to (5).

The previous section 99 allowed the APVMA to require a person who has possession or custody of a substance intended for supply as a chemical product to provide an analysis of the substance's composition and quality. However, this provision was not effective as it applied only if the APVMA had a reasonable suspicion that the product did not meet APVMA requirements. It is not feasible for APVMA to develop this suspicion during the short time that a person has possession of the substance.

The previous section 99 was drafted at a time when domestically manufactured product was more prominent in the chemicals market and there was limited import of finished product. Now, just-in-time imports of finished product dominate the market and direct supply of product from an overseas manufacturer to a customer means an importer has possession of the product for only a very short period of time.

Removing re-registration removes an opportunity for the APVMA to confirm that chemical products supplied to the market are the same as the product evaluated and registered by the APVMA. . The new subsection 99(2) therefore allows the APVMA to, by written notice, require a person to provide information about substances intended for supply as a chemical product (or an active constituent for a chemical product) if they have, will have, or have had possession of the substance.

The new subsection (1) provides that the power is to apply only if the APVMA reasonably believes that the information is necessary to protect human, animal and environmental health and safety or prevent prejudice to trade.

The new subsection (3) lists the matters that might be included in the notice requiring information or documents. The information that may be required includes details of the composition of the substance, manufacturing details, packaging, labelling and advertising information and about conformance of the substance with any relevant standard.

The new subsection (4) provides that the notice may specify that the person have the substance analysed and the results and analyst's certificate be provided to the APVMA.

The new subsection (4A) provides that the notice may require (as stated) the manner in which samples must be taken or the analysis must be carried out.

The new subsection (4B) provides that the information or results must be provided to the APVMA in writing (and also refers to section 156A, relating to giving information electronically to the APVMA).

The new subsection (5) provides that the person to whom the notice under subsection (2) is given must not fail to comply with the requirements listed in the notice.

The penalty in section 99 for failing to provide the required information is unchanged. Section 99 also includes a reasonable excuse defence for failing to provide the required information.

Item 55 – paragraph 167(1)(j) of the Code set out in the Schedule

Item 55 replaces paragraph 167(1)(j), consequential to changes done by item 43, to provide for merits review of a decision to issue a notice under section 99.

Part 2 – Transitional provisions

Item 63 – exempt products for the purposes of paragraph 121(4)(a) of the Code

Item 63 introduces a transitional provision to ensure that products currently excluded from Part 8 of the Agvet Code (Manufacture of chemical products) continue to be excluded until such time as regulations are made for the authority in section 120A (which deals with products that are excluded from the manufacturing requirements in Part 8 of the Agvet Code).