EXPLANATORY STATEMENT

Select Legislative Instrument 2013 No. 108

Issued by the Authority of the Parliamentary Secretary for Agriculture, Fisheries and Forestry

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

AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT (2013 MEASURES NO. 1) REGULATION 2013

Legislative Authority

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

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

Other provisions in the Code Act or Levy Act include specific authorities for matters to be prescribed in regulations and these are specified in the particular regulation amendment.

Purpose

The Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No.1) Regulation 2013 (Amendment Regulation) amends the Agricultural and Veterinary Chemicals Code Regulations 1995 (Principal Code Regulations) and the Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995 (Principal Levy Regulations).

The Amendment Regulation commences on 1 July 2013 and:

- updates fees and levies consistent with the approved Cost Recovery Impact Statement (CRIS) for the reasons described in the CRIS
- refines the scope of the regulation of agricultural chemical products and veterinary chemical products to implement a Council of Australian Governments reform, as well as addresses an anomaly with the current definition of ‘excluded organism’
- amends licence conditions for manufacturers to more efficiently and transparently apply these conditions in the regulations.

Background

Agricultural chemicals and veterinary medicines (together, agvet chemicals) are regulated through a cooperative National Registration Scheme for Agricultural and Veterinary Chemicals (NRS). The NRS was agreed on by the Australian Agriculture Council (now the Standing Council on Primary Industries) in 1991 and is described in a ministerial level intergovernmental agreement that was signed in September 1995.

The NRS is a partnership between the Commonwealth and 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.

Under the NRS, the Agvet Code operates, together with the Agvet Code of each state and 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 chemical products (and their associated labels). The provisions also allow the APVMA to issue permits and to licence the manufacture of chemical products.

Legislative Instruments Act 2003

The Amendment Regulation is a disallowable legislative instrument for the purposes of the *Legislative Instruments Act 2003* (LI Act). Section 54 of the LI Act means that the Amendment Regulation is not subject to sunsetting as the amendments to regulations in the Amendment Regulation are enabled by legislation which facilitates the establishment and operation of a scheme involving the Commonwealth and one or more states.

Cost Recovery Impact Statement and Regulatory Impact Analysis

In mid-2011 independent consultants undertook an Activity Based Costing (ABC) study which provided an analysis of the costs associated with the APVMA's various activities. A Cost Recovery Discussion Paper, which included the data generated by the ABC study was released for public comment in December 2011. A further Supplementary Discussion Paper proposing alternate arrangements for the cost recovery of monitoring compliance with manufacturing requirements for veterinary chemical products was released for public comment in May 2012. A subsequent Cost Recovery Impact Statement (CRIS) was developed and approved for the period from 1 July 2013 to 30 June 2015 and is accessible at <http://www.apvma.gov.au/about/work/cost_recovery.php>.

The Amendment Regulation only includes the fees and levies matters from the CRIS that are to apply from 1 July 2013. In relation to the additional measures in the Amendment Regulations (for example, licence conditions and NRS exclusions), the Office of Best Practice Regulation was consulted and advised that the measures were machinery and that no further regulatory impact analysis was required (ID 15005).

Public Consultation

The details of the regulations (including some draft regulations) were released for public consultation from 25 September 2012 to 21 December 2012. Industry and community stakeholder groups were informed of the release. The APVMA was consulted over the requirements for and content of the Amendment Regulation. Relevant state and territory

agencies were also consulted on the regulations as part of the public consultation, as required under the NRS agreement. Comments provided were taken into account in preparing the Amendment Regulation.

Documents incorporated by reference

The Amendment Regulation incorporates the Australian Code of Good Manufacturing Practice for Veterinary Chemical Products into the Principal Code Regulations. This reference was published on 29 March 2007 and is available from the APVMA website at <http://www.apvma.gov.au/supply/veterinary/licensing.php>.

DETAILS OF THE AMENDMENT REGULATIONS

The details of the Amendment Regulation, including the impact and effect of the amending regulations are at Attachment A.

HUMAN RIGHTS COMPATIBILITY ASSESSMENT

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

ATTACHMENT A

Details of the Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 1) Regulation 2013

Section 1 – Name of Regulation

This section provides that the title of the regulation is the Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 1) Regulation 2013 (Amendment Regulation).

Section 2 – Commencement

This section provides that the Amendment Regulation commences on 1 July 2013.

Section 3 – Authority

This section specifies that the Amendment Regulation is made under the authority in the *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act) and the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (Collection Act).

Section 4 – Schedule(s)

This section provides that each instrument in a Schedule of the Amendment Regulation is amended as described in the Schedule. In Schedule 1:

- items 1 to 5 amend the Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995 (Principal Levy Regulations);
- items 6 to 29 amend the Agricultural and Veterinary Chemicals Code Regulations 1995 (Principal Code Regulations).

Schedule 1 – Amendments to the Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995 (Principal Levy Regulations)

Items 1 and 2 - Regulations 4, 5, 6 and subregulation 6A(1)

These items repeal spent provisions in the Principal Levy Regulations (regulations 4, 5, 6 and subregulation 6A(1)). These regulations are redundant as they dealt with the rate of the levy in financial years 1994 to 2006.

Items 3 to 5 – Subregulation 6A(2)

For the authority in section 12C of the Collection Act and consistent with the approved Cost Recovery Impact Statement, these items amend subregulation 6A(2) of the Principal Levy Regulations to reduce the rates of the levies payable for chemical products in the 2013–2014 financial year and subsequent financial years. The reduction in these levy rates is a consequence of changes to application fees and new cost recovery arrangements for monitoring compliance with good manufacturing practice (GMP) requirements for veterinary chemical products.

Schedule 1 – Amendments to the Agricultural and Veterinary Chemicals Code Regulations 1995 (Principal Code Regulations)

Good manufacturing practice and licences for the manufacture of chemical products

Good manufacturing practice is the part of quality assurance that ensures that products are consistently manufactured to the standards appropriate for their intended veterinary use and in accordance with the particulars of their registration. GMP is concerned with both production and quality control.

Australian GMP Code definition

Item 6 – Subregulation 3(1)

Item 6 inserts a new definition of 'Australian GMP Code' into the Principal Code Regulations. The APVMA routinely imposes compliance with the manufacturing principles and the Australian GMP Code as a licence condition each time it issues a licence to manufacture veterinary chemical products under Part 8 of the Agvet Code. The manufacturing principles are the Agricultural and Veterinary Chemicals Instrument No. 1 (Manufacturing Principles) 2007 (a legislative instrument available on the Federal Register of Legislative Instruments). Following consultation, the Australian Code of Good Manufacturing Practice for Veterinary Chemical Products was published on 29 March 2007 and is available from the Australian Pesticides and Veterinary Medicines Authority (APVMA) website at <http://www.apvma.gov.au/supply/veterinary/licensing.php>.

Categories of licences

Item 6 also inserts new definitions into the Principal Code Regulations for categories of licences to manufacture veterinary chemical products. The definitions for licence categories 1, 2, 3 and 4 align with the definitions that were previously in regulation 72A. For the new licence category 6 definition, the definition is similar to the single step manufacturing exemption in current regulation 59A but includes other activities associated with certain steps in the manufacture of chemical products. Category 5 is a reserved category.

Item 6 inserts a definition of a 'category 1 licence' so that it includes the steps in the manufacture of any other veterinary chemical product in addition to those veterinary chemical products specified in the definition (sterile products, immunobiological products). Item 6 also inserts a 'category 2 licence' definition which is a licence to manufacture a veterinary chemical product other than as specified in the category 1, category 3, category 4 and category 6 definitions.

Item 6 inserts a 'category 3 licence' definition, which is to apply to the steps in the manufacture of a veterinary chemical product that is an externally applied ectoparasiticide. The Australian GMP Code specifies that 'ectoparasiticides are those products applied externally to animals to control only external parasites'. An ectoparasiticide product that requires an internal dosage would be required to be manufactured in a category 2 licensed facility because of the manufacturing and quality principles required around an internal dosage product. The inclusion of the words 'externally applied' in the category 3 licence definition reflects current practice and clarifies a distinction between a category 2 licence and a category 3 licence.

Item 6 inserts a 'category 4 licence' definition, which is to apply to the steps in the manufacture of a veterinary chemical product that is a premix or a stockfood supplement.

Item 6 inserts a new definition of a 'category 6 licence' and provides that this is a licence to manufacture a veterinary chemical product, which only allows certain steps in the manufacture of a chemical product and may include a combination of some of these steps.

Item 6 inserts a definition for a 'multi-category licence', which is a licence to manufacture products in more than one licence category (other than licence categories 1 or 6) at the same premises. For example, a licence to manufacture products in licence category 2 at the same premises at which another product in licence category 3 or 4 is manufactured.

[Item 7 is explained below alongside explanations about items 23 to 28]

GMP requirements for products manufactured outside Australia

Item 8 – New Regulation 14A

For the authority in paragraph 14(5)(i) of the Agvet Code, item 8 inserts new regulation 14A into the Principal Code Regulations. This regulation prescribes new requirements for applications to register a veterinary chemical product. These requirements apply to applications for registration of a veterinary chemical product where a step in the manufacture of the chemical product occurs outside of Australia. It requires that the product must comply with a standard of manufacture that the APVMA has determined is comparable to the manufacturing principles and the Australian GMP Code (together, the GMP requirements). The Australian GMP Code is defined in subregulation 3(1), see item 6. The requirements in regulation 14A formalise those currently applied by the APVMA in determining whether it is satisfied of the matters in subsection 14(3) of the Agvet Code for a veterinary chemical product manufactured outside of Australia.

The requirement in new regulation 14A does not apply for chemical products, which are exempt from the manufacturing licence provisions in Part 8 of the Agvet Code. These exempt products are listable chemical products, reserved chemical products and the products described in regulation 59 (including all agricultural chemical products). Similarly, regulation 14A does not apply where all the steps in the manufacture of a chemical product occur in Australia because compliance with GMP requirements in these cases is dealt with as part of the licensing arrangements for manufacturers in Australia.

As regulation 14A is prescribed for the authority in paragraph 14(5)(i) of the Agvet Code, it also applies for applications to vary relevant particulars or conditions (Division 3 of Part 2 of the Agvet Code).

GMP requirements for licences

Item 9 – New Regulation 59E

Item 9 inserts a new regulation 59E into the Principal Code Regulations to prescribe a new requirement for the issue of a licence to manufacture a veterinary chemical product under Part 8 of the Agvet Code. The purpose of the new regulation is to prescribe that the APVMA must be satisfied that a manufacturer complies with licence conditions, including any conditions that are to be imposed by the APVMA. These are the conditions specified or imposed under sections 126(1) and (4) of the Agvet Code. The requirements in regulation 59E mirror those licence conditions that the APVMA already imposes when it issues a licence to manufacture a chemical product.

For paragraph 123(1)(a) of the Agvet Code, the APVMA must issue a licence to a person unless the APVMA is satisfied that the person will be unable to comply with the manufacturing principles or the particular premises in which the product is to be

manufactured are not satisfactory for the manufacture of chemical products. An audit is the means by which the APVMA determines whether a person can comply with the manufacturing principles and that the premises are satisfactory.

The audit mentioned in paragraph 59E(a) is at the direction of the APVMA CEO (a function that may be delegated). This allows the APVMA flexibility in applying the audit requirement to account for a situation where an audit may have already been undertaken and a further audit is not necessary. For example, an applicant might apply for a licence in relation to premises for which a Therapeutic Goods Administration audit has been completed and it is not necessary to duplicate audits.

Items 10 to 13 – Regulation 61

Conditions imposed on licences - manufacture

For the authority in paragraph 126(4)(b) of the Agvet Code, items 10 to 13 amend regulation 61 of the Principal Code Regulations to incorporate conditions imposed on the manufacture of chemical products into the regulations. This measure promotes transparency and equity in the imposition of licence conditions and improves efficiency as the APVMA no longer needs to continue to impose these conditions each time it issues a licence. The licence conditions do not apply to the manufacture of chemical products which are exempt from the manufacturing requirements in Part 8 of the Agvet Code. These exempt products are listable chemical products, reserved chemical products and the products described in regulation 59 (including all agricultural chemical products).

Item 10 replaces the previous subregulation 61(8) that included an out of date reference to an Australian Standard. However, new paragraph 61(3)(e) still requires a licence holder to maintain records about complaints and product failures and any actions taken in relation to these complaints or failures.

Item 11 inserts a new subregulation 61(3A) that requires a licence holder to manufacture a chemical product in accordance with the manufacturing principles and the Australian GMP Code to ensure products manufactured in Australia meet the requirements and are acceptable.

Item 12 inserts a new subregulation 61(7A) to ensure that a licence holder only sub-contracts steps out to manufacturers and laboratories that are licensed by the APVMA. Paragraph (b) of new subregulation 61(7A) ensures that, where a manufacturer or laboratory is located outside of Australia, the APVMA has determined the manufacturer or laboratory complies with a standard that the APVMA determines is comparable to that which applies to manufacturing in Australia.

Conditions imposed on licences - audits

Assessing an audit report is the means by which the APVMA determines whether a licence holder is complying with conditions imposed on the licence, including that chemical product manufacture is in accordance with the manufacturing principles and the Australian GMP Code.

Item 13 inserts new subregulations 61(8) to (8C) to require licence holders to undergo good manufacturing practice audits (GMP audits) as a condition of holding a licence. These new subregulations also specify other obligations of licence holders about the conduct of GMP audits. These conditions are routinely imposed by the APVMA each time it issues a licence.

The condition in subregulation 61(8) requires a holder of a licence to undergo an audit on the direction of the APVMA CEO (a function that may be delegated) to demonstrate to the

APVMA that the holder complies with the licence conditions. Current APVMA work procedures provide for dispute resolution in relation to audit report findings. Sections 166 and 167 of the Agvet Code provide for internal reconsideration of decisions and Administrative Appeal Tribunal review of decisions that relate to audit findings (for example, licence cancellation).

To conduct an effective audit, it is essential that the APVMA inspectors or APVMA authorised auditors have access to all relevant information and premises. The licence condition in new subregulation 61(8A) requires that this access be provided.

The identification and communication of non-conformances and corrective action to address these non-conformances are an essential means of ensuring that only products of acceptable quality are manufactured in Australia. The completion of the audit is what triggers the auditor telling the holder of any critical non-conformances. The conditions in new subregulations 61(8B) and (8C) require these non-conformances to be reported and require appropriate corrective action to be taken.

APVMA assessment of GMP audits

Item 14 – New Regulation 61A

For the authority in paragraph 6(2)(c) of the Code Act, item 14 inserts a new regulation 61A into the Principal Code Regulations. New regulation 61A provides that the APVMA must assess the audit related information in new subregulation 61(8C) and determine if a licence holder is complying with the manufacturing licence conditions for the manufacture of veterinary chemical products.

[Items 15 and 16 are explained below alongside explanations about other fees matters]

GMP compliance for veterinary chemical products manufactured overseas

Item 17 – Regulation 71A

For the authorities in subsections 164(1) and (2) of the Agvet Code, item 17 amends subregulation 71A(2) of the Principal Code Regulations to require payment of an annual fee of $1000 in relation to the registration of a veterinary chemical product for assessment of overseas GMP compliance for each site outside of Australia at which the chemical product is manufactured. Subregulation 71A(3) provides for this fee to be payable once during each financial year if the interested person has already paid an overseas GMP compliance assessment fee in relation to another chemical product manufactured at the same site – that is where the interested person is the interested person for multiple products manufactured at the one site. This additional fee is for monitoring compliance with a condition of registration that requires a veterinary chemical product to be manufactured in accordance with GMP requirements and is consistent with the approved Cost Recovery Impact Statement. ‘Interested person’ is defined in section 3 of the Agvet Code.

Item 18 – Regulation 71B

At the time of registering a chemical product, the APVMA may apply conditions of registration that require compliance with the Agvet Code, the manufacturing principles, the Australian GMP Code and any applicable standards. For a product manufactured overseas, this includes a standard that APVMA determines is comparable to the manufacturing principles and the Australian GMP Code. These conditions may also include conditions that require an interested person to provide evidence to the APVMA of compliance with these requirements. ‘Interested person’ is defined in section 3 of the Agvet Code.

Item 18 inserts a new regulation 71B into the Principal Code Regulations. This new regulation requires the APVMA to assess evidence of compliance (including audit reports, non-conformances and any corrective action taken) with a condition of registration that relates to the manufacture of a veterinary chemical product outside of Australia. The regulation also requires the APVMA to determine whether it is satisfied that the condition is being complied with.

The regulation applies where the registration of a product is subject to a condition that the manufacture of the product complies with the Agvet Code, the manufacturing principles, the Australian GMP Code and any applicable standards. It mirrors the requirements that apply for the APVMA assessment of GMP audit information for licence holders in regulation 61A.

Licence fees

Item 19 – New regulation 72A

Item 19 replaces regulation 72A with a regulation prescribing a new fee structure for licences to manufacture veterinary chemical products. This structure is consistent with the approved Cost Recovery Impact Statement.

The new fee structure provides for recovery of the entire cost of monitoring compliance with GMP requirements for licences. New regulation 72A institutes an annual fee for holders of licences to manufacture veterinary chemical products in Australia and provides for the APVMA assessment of GMP compliance as required by new regulation 61A (see item 14).

The new fee is authorised by subsection 164(1) of the Agvet Code which provides for the regulations to prescribe the fees to be paid for the doing of any thing by the APVMA under the Agvet Code or the Principal Code Regulations. Subsection 164(2) of the Agvet Code provides for fees in subsection 164(1) to be due and payable in the manner and at times that are prescribed.

Licence fees – applications

New subregulation 72A(2) specifies that from 1 July 2013 the fee payable for an application for a licence is $900.

As a transitional measure, subregulation 72A(9) provides that the APVMA must waive all outstanding licence fee instalments that remain payable on 1 July 2013. This provision ends all licence fee instalment liabilities that were established under the previous licence fee structure.

Licence fees – annual fees

Paragraph 72A(3)(a) prescribes that the annual fee for a category 1 licence is $7500. Paragraph 72A(3)(b) prescribes an annual fee of $5000 for a category 2 licence, a category 3 licence or a category 4 licence. Paragraph 72A(3)(c) prescribes an annual fee of $1800 for a category 6 licence. Paragraph 72A(3)(d) prescribes an annual fee of $7500 for a multi-category licence.

Subregulation 72A(4) specifies that the fee for the issue of the first licence is calculated by the APVMA on a *pro rata* basis taking into account the completed full months that the licence will run prior to the next first of July. Subregulation 72(5) provides that annual licence fees are to be reduced by 50 per cent if the holder of the licence provides evidence to the APVMA that the total notional wholesale value (as detailed in subregulations 72A(10) and (11)) of the chemical products is less than $50 000 in a financial year. The concession for licence fees

applies for the licence fee payable in the following financial year (that is, based on sales in the preceding year).

Subregulation 72A(6) provides that no licence fee is payable if a licence is suspended for a financial year. If a suspension is revoked during a financial year, subregulation 72A(6) also provides that a *pro rata* annual licence fee is payable for the remainder of that financial year. This fee does not apply if the holder has already paid the annual licence fee for the financial year. Any *pro rata* annual licence fee is to be calculated by the APVMA on the basis of the completed full months that the licence will run prior to the next first of July.

Subregulation 72A(7) provides that the annual licence fee is payable when the APVMA issues an invoice for the fee.

Licence fees – variations

Subregulation 72A(8) provides that an additional fee of $1800 is payable if a licence holder requests a variation to a licence and the APVMA determines that a GMP audit is required to ensure that veterinary chemical products (as provided for by the varied licence) are manufactured in compliance with GMP requirements. There is no fee prescribed for where the APVMA determines that an audit is not required for a licence variation. Like in regulation 61A, the fee in subregulation 72A(8) is for the APVMA to assess the GMP audit information where the licence variation requires a GMP audit and the assessment of GMP audit information.

The fee is to be paid at the time an audit is directed by the APVMA. Subregulation 61(8) provides for the APVMA to direct that a licence holder must undergo an audit when directed by the APVMA CEO. Subregulation 72A(10) specifies that a reference to a GMP audit in regulation 72A has the same meaning as in the licence condition in paragraph 61(8)(a).

Other fees matters

Items 15, 16, 20, 21, 22 and 29 – Regulations 70, 71, 73, 78 and 78A, Schedules 6 and 7

For the authority in subsection 164(1) of the Agvet Code, item 15 amends subregulations 70(4) and 70(5) of the Principal Code Regulations to increase the fee to be paid at the time of making applications that are subject to a modular assessment fee and to increase the amount that is not repayable if the APVMA refuses an application. Items 16, 21 and 22 amend notes to subregulations 71(4), 78(3) and 78A(2) as a consequence of changes to regulation 70.

Consistent with the approved Cost Recovery Impact Statement, item 20 amends subregulation 73(2) of the Principal Code Regulations to increase the initial fee and hourly rate to $95 for the APVMA to make copies and extracts available from the records specified in subregulation 73(1). These records include the Record of Approved Active Constituents and the Register of Agricultural and Veterinary Chemical Products, as well as copies of permits, certificates of analysis and where relevant confidential commercial information. The authority for this fee is subsection 164(1) of the Agvet Code.

Consistent with the approved Cost Recovery Impact Statement and for the authority in subsection 164(1) of the Agvet Code, item 29 amends Part 2 of Schedule 6 and Schedule 7 of the Principal Code Regulations to increase fees for some applications and some application modules.

Definitions of 'agricultural chemical product' and 'veterinary chemical product

Item 7 – Regulation 5

Item 7 amends the Principal Code Regulations to remove the regulation that deals with the definition of excluded organism. This is no longer required because of amendments to the exclusions prescribed for the definitions of 'agricultural chemical product' and 'veterinary chemical product' (see items 23 to 28).

Items 23 to 28 – Schedule 3 and 3AA

Item 23 inserts new definitions into Schedule 3 of the Principal Code Regulations to ensure that the exclusions for certain biocides (in item 25) can be properly applied. These definitions are for 'air conditioning', 'cooling tower', 'open water cooling system', 'ore extraction and processing', 'sewage', 'sewage treatment', 'water cooling system' and 'wastewater'.

Vertebrate animals

It is not intended that the APVMA regulate whole vertebrate animals but, as parts of these animals may be used in chemical products, there is a need to ensure that parts of vertebrate animals are regulated where they are used for an agricultural or veterinary chemical product purpose. This approach of excluding the whole vertebrate animal but including parts of these animals as agricultural or veterinary chemical products is a more effective means of capturing the substances or things that should be regulated under the NRS.

For the authorities in subsection 4(3) and paragraph 5(3)(b) of the Agvet Code, items 24 and 26 insert new entries in Part 2 of Schedules 3 and 3AA respectively of the Principal Code Regulations. The amendments clarify that an agricultural chemical product or veterinary chemical product includes parts of a vertebrate animal if that material is represented, supplied or used for an agricultural or veterinary chemical purpose as described in subsections 4(2) and 5(2) of the Agvet Code.

These amendments are related to those done by items 25 and 28, which exclude whole vertebrate animals from the definitions of agricultural chemical product (new item 24 in Part 3 of Schedule 3) and veterinary chemical product (new item 12 in Part 3 of Schedule 3AA). The purpose of these amendments and the repeal of regulation 5 is to exclude whole vertebrate animals but not parts of them from the application of the Agvet Code and the National Registration Scheme (NRS).

Water sanitisers

For the authority in paragraph 4(4)(b) of the Agvet Code, item 25 also inserts new entries into Part 3 of Schedule 3 of the Principal Code Regulations to exclude certain biocides (water sanitisers) from the definition of 'agricultural chemical product' and therefore the application of the Agvet Code. These products will no longer be regulated by the APVMA.

In early 2008 a number of 'early harvest' reforms were developed through the Ministerial Taskforce on Chemicals and Plastics Regulation Reform that could be progressed in conjunction with any recommendations arising from the 2008 Productivity Commission study of Chemicals and Plastics Regulation. In consultation with the APVMA, selected industry experts and industry bodies, these reforms identified a number of water sanitiser product classes that could be excluded from regulation under the NRS and from the application of the Agvet Code. These product classes included water sanitisers used in cooling towers, sewage treatment, ore processing and coal seam gas extraction.

State and territory regulation controls the water standards applicable to different water uses (for example, water quality standards for environmental discharge/disposal) and the potential human health hazards associated with the use (for example, regulations for cooling tower water). The states and territories also regulate standards for water destined for human consumption and also oversee recycled water, including on-site wastewater and sewage. The additional layer of regulation of products previously used to manage water quality by the APVMA was unnecessary and duplicative. Removing this additional layer of regulation does not pose undue hazards to human health or the environment as there is appropriate regulation in place. This reform is achieved by excluding these sanitisers (biocides) from the definition of 'agricultural chemical product' and therefore the application of the Agvet Code so that these products are no longer regulated by the APVMA. These exclusions implement a reform of the Council of Australian Governments.

One of the exclusions is biocides that are used to control organisms in water, for the purpose of maintaining equipment associated with the extraction of coal seam gas in serviceable condition. The biocides in this product class are used in coal seam gas mining for maintaining equipment, for example, to clean microbial growth on reverse osmosis membranes during water treatment. This class of industrial water sanitisers does not include sanitisers in continual use in coal seam gas wastewater, rather it relates to biocides used periodically to clean equipment that is used in wastewater treatment in coal seam gas mining.

Other exclusions

Item 27 clarifies an existing exclusion and ensures that the current exclusion of 'blood and stem cell products' encompasses blood, blood products, stem cells and stem cell products.

For the authority in paragraph 5(4)(b) of the Agvet Code, item 28 also amends Part 3 of Schedule 3AA of the Principal Code Regulations to exclude certain material from the application of the Agvet Code and clarify an existing exclusion.

New item 10 in Part 3 of Schedule 3AA clarifies the topical applications that are excluded from the definition of 'veterinary chemical product' and therefore the application of the Agvet Code. The APVMA will not regulate these products.

New Item 11 in Part 3 of Schedule 3AA excludes semen, ova and embryos when represented supplied or used for the purpose of reproduction. The APVMA will not regulate these products. The definition of a veterinary chemical product includes 'modifying the physiology of the animal so as to alter its natural development, productivity, quality or reproductive capacity'. It is not intended to capture semen, ova and embryos when used for reproduction (e.g. artificial insemination) as veterinary chemical products and the new item in Part 3 of Schedule 3AA excludes these substances from the definition of a veterinary chemical product.

ATTACHMENT B

STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS

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

Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 1) Regulation 2013

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

Overview of the Legislative Instrument

The Amendment Regulation commences on 1 July 2013. The Amendment Regulation updates fees and levies consistent with an approved Cost Recovery Impact Statement and amends licence conditions for manufacturers to more efficiently and transparently apply these conditions in the regulations. The Amendment Regulation also refines the scope of regulation of agricultural chemical products and veterinary chemical products. These amendments implement Council of Australian Governments reforms by excluding certain types of products from agricultural and veterinary chemical legislation, as well as addressing an anomaly with the current definition of 'excluded organism'.

Human rights implications

This Legislative Instrument does not engage any of the applicable rights or freedoms.

Conclusion

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

The Hon. Peter Douglas Sidebottom MP
Parliamentary Secretary for Agriculture, Fisheries and Forestry