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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT BILL 2012

SUPPLEMENTARY EXPLANATORY MEMORANDUM

Amendments and new clauses to be moved on behalf of the government

(Circulated by authority of the Minister for Agriculture, Fisheries and Forestry, Senator the Hon. Joe Ludwig)
AMENDMENTS TO THE AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT BILL 2012

OUTLINE

The proposed government amendments to the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 (the Bill) make technical amendments and corrections to the Bill and make minor changes to some reform measures that the Australian Government considers either necessary or desirable to achieve the government’s aims for reform.

The amendments to the Bill amend the Agricultural and Veterinary Chemicals (Administration) Act 1992 and the Agricultural and Veterinary Chemicals Code Act 1994 to, among other things:

- insert a missing reference to ‘reconsideration of approvals and registrations’ in the list of those guidelines for principles and processes that APVMA must make
- provide that a person may apply to the Australian Pesticides and Veterinary Medicines Authority (APVMA) for copies of any information in the Record or Register that a person is entitled to (instead of a subset of the information, as at present) and clarify arrangements for authorised disclosure of confidential commercial information
- fix an omission in amendments to do with listed chemical products where the product and each label of the product comply with the established standard by no longer requiring separate approval of the active constituents in these listed chemical products
- address concerns with current provisions around standards for constituents, products and labels and for regulations about standards
- correct amendments dealing with internal and Administrative Appeals Tribunal merits review of decisions to remove inconsistencies, increase opportunities for review, clarify standing for seeking review, and apply timeframes for internal reviews
- allow for reduction in red tape associated with providing annual returns of information about chemical manufacture, exports and imports

The amendments to the Bill implement changes agreed to be made to the Bill in the government’s response to the Australian Greens’ minority report of the Senate Rural and Regional Affairs and Transport Legislation Committee inquiry into the Bill.

FINANCIAL IMPACT STATEMENT

These amendments have no financial impact.

REGULATION IMPACT STATEMENT

No regulation impact statement is required for these amendments.

STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS


Amendments to the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012

These amendments do not engage any human rights beyond those already engaged by the Bill. As they do not raise any additional human rights issues, the amendments remain 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.
NOTES ON INDIVIDUAL AMENDMENTS

Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012

Schedule 1—Approvals, registrations, permits and licences

Amendment (1)—new item 17A

This amendment inserts a definition of “lodged” for the purposes of an application under the Agvet Code, the Schedule to the Agricultural and Veterinary Chemicals Code Act 1994. This provides for the regulations to specify when an application is taken to be lodged for the Agvet Code or the regulations.

This amendment provides flexibility by allowing the regulations to prescribe that components of an application may be provided at different times in a specified window of time rather than requiring all application components at the same time. It is anticipated that this will allow for electronic submission of application forms while large amounts of published information supporting the application can be provided in hard copy. Over time, the meaning of lodged can be changed as the Australian Pesticides and Veterinary Medicines Authority’s (APVMA’s) ability to deal with electronic submission of information develops.

Relevant particulars for constituents, products and labels

Amendments (2) and (18)—items 26 and 43

Amendment (18) inserts “any other particulars prescribed by the regulations” at new subparagraph 21(c)(iva) in relation to particulars for labels. The purpose of this amendment is to provide for the regulations to specify particulars that must recorded for a label approval even though these particulars are not required on the label.

Amendment (2) is consequential to amendment (18) and ensures all information recorded in the relevant file for a label approval for paragraph 21(c) are relevant particulars.

Safety criteria and efficacy criteria

Amendments (3) and (5)—item 27

These amendments insert the phrase “including metabolites and degradation products” into the definition of meets the safety criteria (new section 5A). This amendment ensures the APVMA must have regard to the toxicity of active constituent and chemical product metabolites and degradation products in being satisfied about whether a constituent or product meets the safety criteria.

Amendment (3) implements the government response to recommendation 2 of the Australian Greens’ minority report of the Senate Rural and Regional Affairs and Transport Legislation Committee inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012.

Amendment (7)—item 27

This amendment makes a technical correction to the definition of meets the efficacy criteria by replacing subsection 5B(1). A chemical product meets the efficacy criteria if the use of the product, in accordance with either the instructions approved (or to be approved) or the established standard, would be effective according to criteria determined by the APVMA in a legislative instrument.
Standards for constituents, products and labels

Amendments (4), (6) and (8) to (10)—item 27

These amendments insert new subparagraphs in the definitions of meets the safety criteria, meets the trade criteria, meets the efficacy criteria, and meets the labelling criteria (new sections 5A to 5D) to codify that the APVMA must have regard to the conformance of a constituent, product or label with any standard made by the APVMA under new section 6E (see amendment (12)) to the extent that the standard relates to the matters set out in subsection (1) of each definition.

Amendment (12)—item 28

This amendment provides an explicit power for the APVMA to make standards by inserting new section 6E into the Agvet Code. Section 6E removes any doubt about the authority for the APVMA to make standards and specifies that these standards are legislative instruments.

By virtue of new section 163A (item 44 of Schedule 6), standards made under section 6E are disallowable legislative instruments.

Consistent with the current regulation-making power in the Agricultural and Veterinary Chemicals Code Act 1994, the amendment provides that standards made by the APVMA may incorporate rules, codes, specifications or methods of any association, body or institution, as amended from time to time or in force at a particular time. This approach to making regulations and other instruments is justified by the need to preserve consistency with international standards and developments, for example, the Food and Agriculture Organization Specifications for Pesticides. While some material incorporated in standards may be available for a fee, this material is already incorporated under existing regulations and is in extremely common use within industry. It is expected that all entities affected by this legislation would already have access to this material as part of their normal business operations.

It is intended that standards for constituents for chemical products or standards for chemical products made for section 6E be prescribed by the regulations for section 87.

Amendment (34)—new item 34A of Schedule 6

This amendment updates the regulations-making power to allow the Governor-General to make regulations for or in relation to the development and approval of standards for constituents of chemical products, for chemical products and for labels for containers of chemical products.

This amendment is related to amendment (12) above.

Corrections, technical and miscellaneous amendments

Amendment (11)—item 28

This amendment inserts reference to the reconsideration of approvals and registrations at subsection 6A(3). This ensures APVMA guidelines for performing functions and exercising powers include guidelines for principles and processes for reconsiderations done under Division 4 of Part 2 of the Agvet Code.

Amendment (14)—item 32

This amendment inserts a new provision in section 14A to require that the APVMA is to be entered in the Record as the holder of the approval if the APVMA approves an active constituent under this section without an application having been made for the approval.

Amendment (15)—new item 41A

This amendment amends subsection 15(2) of the Agvet Code to specify that the APVMA is not prevented from registering a listed chemical product if the APVMA has not approved each active
constituent for the product, so long as the product complies with the established standard for the product. This is appropriate as the risks associated with the use of the active constituent in the product are to be managed through the provisions of the established standard.

Amendment (19)—item 44
This amendment provides for prescribed requirements for constituents, products or labels to be complied with where the APVMA varies the relevant particulars or conditions of an approval or registration under section 29A on its own initiative but with the holder’s consent. The provision ensures that the same requirements may apply for applications for variations of relevant particulars or conditions (as per paragraph 8A(d)) as well as for variations done by the APVMA on its own initiative.

Disclosure of confidential commercial information

Amendments (13)—item 29
Amendment (13) replaces section 8K to clarify that the disclosure of confidential commercial information is not authorised where that information would otherwise be required in notices given to holders of approval or registration for the provisions listed at paragraphs 8K(1)(a) to (g). Confidential commercial information is a term defined in section 3 of the Agvet Code.

Amendments (16) and (17)—new items 42A to 42H
These amendments provide for a person to apply to the APVMA for any information in the Record or Register (maintained by the APVMA for sections 17 and 18) and for this to be provided to the person for a prescribed fee. However, the amendments do not permit a person to be provided with confidential commercial information that would otherwise be prohibited by section 162, and notes to this effect have been included to clarify this.

Amendments (20) and (21) to (24)—new item 201A and items 202 to 205
Amendment (20) ensures that a person authorised by the APVMA to disclose confidential commercial information may disclose this information to the authorising party for the information. The term authorising party is a term defined in section 3 of the Agvet Code.

Like amendment (20), amendments (21) to (24) clarify to whom a person authorised by the APVMA may disclose confidential commercial information about an active constituent or chemical product. These amendments replace the words “applicant or holder” or “applicant or holder concerned” with the phrase “authorising party for the information”.

Internal review of decisions

Amendment (25)—item 221 and new item 221A
Amendment (25) amends item 221 to make clear who has standing to request internal reconsideration of an APVMA decision that is not reviewable by the Administrative Appeals Tribunal (AAT). If a decision listed at new paragraph 166(1A)(b) were reviewable by the Administrative Appeals Tribunal, a person who would be entitled to apply to the AAT for review of the decision may request APVMA reconsider the decision. Without amendment to item 221, subsection 166(2) would be ambiguous about who has standing to request reconsideration of an APVMA decision.

Amendment (25) also inserts new item 221A which provides that persons who wish to request a reconsideration under section 166 are able to do so only within 42 days of the original decision being made. This period was chosen as the APVMA has 14 days to notify persons of a decision and it would be reasonable for a person to have 28 days to decide if they wish to request a reconsideration of the decision.
Amendment (26)—new item 223

This amendment provides that a person who requests that the APVMA reconsider a decision may notify the APVMA that it is to treat the original decision as confirmed if the APVMA has not notified the person of the decision on the reconsideration (under subsection 166(4)) within 90 days of the request being made (under subsection 166(2)). Effectively, this places a 90 day period for the APVMA to complete an internal review of a decision.

Review of decisions by Administrative Appeals Tribunal

Amendments (27) and (28)—new items 232A and 233A

Amendments (27) and (28) provide that a decision to refuse an application to extend a permit or to issue a licence is not to be reviewable by the AAT if the decision to refuse the application was based only on the administrative application requirements in paragraphs 8A(a) or (b) or subsection 122(1).

These decisions are internally reviewable under subparagraphs 166(1A)(b)(ii) and (iii) (see amendment (25) above).

These amendments are consistent with the approach taken for other applications which may similarly be refused because the application does not meet administrative application requirements, see amendments to paragraphs 167(1)(b) to (d) (see item 225 of Schedule 1).

Amendment (29)—new item 235A

This amendment provides for the regulations to specify decisions that may be reviewed by the Administrative Appeals Tribunal.

Schedule 3—Enforcement

Annual returns

Amendments (30) and (31)—new item 58A and item 59

These amendments provide for regulations to specify certain substances that need not be included in annual returns about imports, manufacture and exports of active constituents and chemical products, such as innocuous substances. The purpose is to prescribe the substances to which subsection 69(E)(1) of the Agricultural and Veterinary Chemicals (Administration) Act 1992 (Admin Act) does not apply and provides for a reduction in the regulatory burden for those importers, manufacturers and exporters of low risk chemical products.

Amendment 31 corrects a typographical error in note 1 to section 69E(2A) of the Admin Act.

Technical amendments and removing spent provisions

Amendment (32)—item 142

This amendment replaces the previous item that referred to subsection 77(4) of the Agvet Code with subsection 77(3) to ensure sequential numbering of the subsections in section 77.

Amendment (33)—new item 263

This amendment replaces the previous item to remove all spent provisions in section 121 of the Agvet Code.