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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

AGRICULTURAL AND VETERINARY CHEMICALS CODE AMENDMENT BILL 2010

EXPLANATORY MEMORANDUM

(Circulated by authority of the Minister for Agriculture, Fisheries and Forestry, the Hon. Tony Burke MP)

AGRICULTURAL AND VETERINARY CHEMICALS CODE AMENDMENT BILL 2010

GENERAL OUTLINE

The Agricultural and Veterinary Chemicals Code Amendment Bill 2010 (the Bill) consists of two measures and will amend the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code). The Bill seeks to improve the efficiency of the registration processes of the Australian Pesticides and Veterinary Medicines Authority (APVMA), without jeopardising human health or the environment.

The Bill provides for:

- the APVMA being effectively exempted from the general prohibition on using confidential commercial information when registering a permit for minor use or emergency use; and
- trade issues being considered when addressing the adequacy of product labels by extending the definition of "adequate".

Confidential commercial information

The Bill provides for an exemption to the general prohibition on the disclosure of confidential commercial information (CCI) in relation to consideration of minor use or emergency use permits. Currently, all matters about a permit application, including the fact that an application has been made, are considered CCI. This means the APVMA cannot discuss the permit application with the product registrant, or any other person who might be able to provide relevant information, without first obtaining the permit applicant's consent and operating within the parameters of section 162 of the Agvet Code. This arrangement is administratively cumbersome.

Any person can make a permit application to extend the use of an existing registered product. Permit applications are often made by individual farmers or grower organisations. In some cases several persons or organisations may make an application for a permit to use the same product. Under the current legislation, it is very difficult for the APVMA to disclose that it has received multiple applications and streamline the application process.

The amendments would enable the APVMA to efficiently liaise with all applicants with a view to combining the requests into a single application. The amendments will also enable the APVMA to contact the registrant, or consult with any person who is likely to have information (scientific data or otherwise) that would be relevant to the APVMA's assessment to decide whether to grant the permit. Without this information the APVMA may not have sufficient information on which to assess the application and ultimately to issue the permit. This would increase the efficiency of the APVMA's process for assessing and issuing permits.

Applications for minor use or emergency use permits do not ordinarily contain commercially valuable information. However, in the event that such information is included, the Bill foreshadows regulations which will specify the types of information

that APVMA needs to release in relation to undertaking its assessment of the application. Other information will remain CCI.

The regulations would mirror a subset of the disclosure requirements for product applications currently set out in regulations 8C, 8D and 8E of the *Agricultural and Veterinary Code Regulations 1995* (the Regulations).

The amendments would only apply to minor use or emergency use permits. Details of research permits—which are commonly used by chemical companies during product development—including the fact that they have been made, would rightfully remain protected, as this is commercially sensitive information.

Trade issues

The Bill also seeks to include trade issues as a consideration when deciding on the adequacy of product labels—which include instructions for proper use—by extending the definition of "adequate" to include trade aspects. The APVMA is currently required to consider trade when determining whether to grant or refuse an application, but not when approving a label.

Instructions (specified on the product label) ensure that proper use of the product will not adversely affect Australia's exports. However, over time issues may arise that require changes to the label to update the instructions. For example, trade concerns can arise where an importing country reduces its maximum residue limit or establishes a zero tolerance. If this happens the use of the product in accordance with the label will result in a residue violation in that country. This sort of trade concern can be addressed by an instruction on the label. Currently, to update the label instructions to address a trade-only issue, the APVMA must take regulatory action against the product registration. Only then can it update the label as a related action. The APVMA lacks the power to directly take action against the source of the concern, namely the product label.

The Bill seeks to address this problem by enabling the APVMA to focus the regulatory action upon the label approval when concerns about trade issues arise without unnecessarily affecting the registration of the product.

The Bill does not include consequential amendments to other Acts.

FINANCIAL IMPACT STATEMENT

The amendments have been assessed as having no significant financial impact on the Australian Government and affected parties.

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NOTES ON CLAUSES

Clause 1: Short title

This clause is a formal provision specifying the short title of the Act as the *Agricultural and Veterinary Chemicals Code Amendment Act 2010*.

Clause 2: Commencement

This clause provides that the Act will commence on the day after it receives the Royal Assent.

Clause 3: Schedule(s)

This clause provides that each Act that is 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—Amendment of the *Agricultural and Veterinary Chemicals Code Act 1994*

Item 1: Section 3 of the Schedule

This item splits section 3 into two subsections.

Item 2: Section 3 of the Schedule (at the end of the definition of *adequate*)

This item amends the definition of "adequate" by adding paragraph (d) so that it extends to trade concerns. Paragraph (b) mirrors the statutory criterion relating to trade in subparagraph 14(3)(e)(iv) of the Agvet Code and other provisions in the Agvet Code which require the APVMA to have regard to trade concerns when considering and reconsidering product registrations.

The purpose and intention of the new paragraph (d) is to enable the APVMA to have regard to trade concerns when assessing or taking other regulatory action such as a reconsideration under section 34 or 34A or a suspension or cancellation under section 41 in respect of label approvals.

Item 3: Section 3 of the Schedule (at the end of the definition of *confidential commercial information*)

This item inserts two new paragraphs into the definition of "confidential commercial information". Paragraph (d) excludes from that definition the fact that an application has been made for a permit for the use of an active constituent for a proposed or existing chemical product, or for the use of a chemical product if the proposed use of the product is a minor use or emergency use.

Paragraph (e) excludes from the definition of "confidential commercial information" prescribed information relating to the making of a minor use or emergency use permit application.

By implication, a permit for an active constituent for a proposed or existing chemical product, or for the use of a chemical product if the proposed use is for the purposes of research will continue to come within the definition of "confidential commercial information". This extends to the fact of an application having been made for such a permit.

Paragraphs (d) and (e) are intended to exclude certain information from the operation of section 162 of the Agvet Code which governs the disclosure of confidential commercial information. Without those constraints, the APVMA will be able to disclose certain information about such permits, including the fact of the application having been made, to the person in whose name the product is registered or other persons who could inform the APVMA's assessment of that process.

Item 4: Section 3 of the Schedule

This item inserts into section 3 a definition of 'emergency use' by reference to the definition in the Regulations.

Item 5: Section 3 of the Schedule

This item inserts into section 3 a definition of 'minor use' by reference to the definition in the Regulations.

Item 6: At the end of section 3 of the Schedule

This item inserts a new subsection 3(2) providing that a regulation prescribing information for the purposes of paragraph (1)(c) of the definition of "confidential commercial information" is a legislative instrument.

Item 7: Subsection 162(13) of the Schedule

This item repeals and substitutes subsection 162(13).

Paragraph (a) of the new subsection 162(13) clarifies that a reference in that section to information about an active constituent for a proposed or existing chemical product, or about a chemical product, includes a reference to the fact of an application having been made.

Paragraph 162(13)(a) operates in conjunction with subsection 162(1), so that the information described in paragraph (a) remains confidential. That confidentiality can, however, be lost upon the application passing preliminary assessment when certain information about the application must be published in accordance with section 11B or 28B of the Agvet Code as appropriate to the application.

Paragraph (b) of the new subsection 162(13) provides that a reference in that section to information about an active constituent for a proposed or existing chemical product,

or about a chemical product, includes a reference to the fact of an application having been made.

The intention of paragraph (b) is to operate in conjunction with the amended definition of "confidential commercial information" to exclude from the operation of section 162 the fact of a permit application having been made where the proposed use of the product is a minor use or emergency use. It is also intended to exclude from the operation of section 162 prescribed information about the making of such a permit.

The purpose of the new paragraph (b) is to enable the APVMA to disclose some details about the permit application, including the fact of an application having been made, to the product registrant and others who might have relevant information to inform the assessment of the permit application. It is intended that such disclosure be able to occur outside the constraints of section 162 which require obtaining the permit applicant's consent as well as ensuring that the recipient continues to protect the confidentiality of the information in accordance with subsection 162(6) of the Agvet Code.

Item 8: Application

This item confirms that the amendment to the definition of "adequate" in item 2 applies to applications for approval for containers for a chemical product made under section 10 of the Agvet Code and applications to vary the relevant particulars or conditions of label approval for containers for a chemical product under section 27 of the Agvet Code made on or after the commencement of this amendment.

The item also confirms that the amendment in item 2 applies to a reconsideration of a label approval under section 34 if at least one of the actions described in subparagraphs (i) – (iii) has occurred, to a reconsideration under section 34A of the Agvet Code that began before commencement of the amendment, and to a standard for a chemical product already submitted to the Minister under section 56D of the Agvet Code on or after commencement of this amendment.

This item also confirms that the amended definition of "confidential commercial information", which excludes certain information relating to permits for minor use and emergency use as set out in items 3 to 7, applies whether the application is made on or after the commencement of these amendments.