REPLACEMENT EXPLANATORY STATEMENT

Issued by Authority of the Minister for Agriculture and Northern Australia

Agricultural and Veterinary Chemicals Code Act 1994

Agricultural and Veterinary Chemicals Code (Conditions of Approval or Registration) Order 2021

Legislative Authority

Section 7 of the *Agricultural and Veterinary Chemicals Code Act 1994* (the Code Act) provides that the Minister may, by legislative instrument, make orders with respect to a matter that are consistent with the regulations if:

- provision may be made by the regulations for or in relation to a matter; and
- the regulations declare that this section applies to that matter.

Regulation 2 of the *Agricultural and Veterinary Chemicals Code Regulations 1995* (the Code Regulations) in turn states that the matters covered by subsections 6(1), (2) and (3) of the Code Act (other than paragraph 6(2)(i)) are matters to which section 7 of the Code Act applies. This generally authorises the making of orders for anything that could be done in regulations except for the prescribing of penalties (paragraph 6(2)(i) of the Code Act allows regulations to prescribe penalties up to 50 penalty units).

Purpose

The purpose of the *Agricultural and Veterinary Chemicals Code (Conditions of Approval or Registration) Order 2021* (the Order) is to ensure that the Australian Pesticides and Veterinary Medicines Authority (the APVMA) can respond appropriately should it establish (for example through an overseas official determination) that registered agricultural chemical products (or approved active constituents for such products) are not compliant with any licencing requirement (however described, for example manufacturing permits, certificates or authorisations) in the country of manufacture. Appropriate action by the APVMA may include (but is not limited to) cancelling or suspending the registration or approval.

The Order will protect the credibility and reputation of Australia's regulatory controls for agricultural chemicals. The reputation of Australia's regulatory controls for veterinary chemical products is already sufficiently protected by the existing system (Good Manufacturing Practice).

Background

Agricultural and veterinary (agvet) chemicals (active constituents and products) are regulated through a cooperative National Registration Scheme (the NRS). The NRS is a partnership between the Commonwealth and the states and territories, with an agreed division of responsibilities. It is implemented through an applied law scheme, supported by an intergovernmental agreement.

The APVMA is established by the Commonwealth under the *Agricultural and Veterinary Chemicals (Administration) Act 1992*. It assesses, registers and approves agvet chemicals for use in Australia. The APVMA is responsible for regulating these chemicals up to and including the point of supply – for example, retail sale. The control of use of agvet chemicals after supply is the responsibility of individual states and territories.

The NRS is implemented, in part, through the Code Act. The Code Act contains, as a Schedule, the Agricultural and Veterinary Chemicals Code (Agvet Code). The Agvet Code provides for the APVMA to evaluate, approve, register and reconsider active constituents and agvet chemical products and their associated labels. It also allows the APVMA to issue permits for supply and use and to licence the manufacture of agvet chemical products. Other provisions allow the APVMA to regulate the supply of agvet chemical products; and ensure compliance with (and enforce) the Agvet Code – including suspending and cancelling registrations and approvals.

Previous agvet chemicals legislation did not require any evidence to show that agvet chemicals (active constituents or chemical products) were legally manufactured in the country of manufacture. This meant, where a company had imported agvet chemicals into Australia for the purposes of Australian approval (of an active constituent) or registration (of a chemical product), the APVMA had no ability to check if the manufacture was compliant with any manufacturing licence authorisation requirement in the country of the manufacture. There was no evidence this situation raised any agvet chemical safety concerns as safety requirements were already addressed under the APVMA's existing requirements. However, the lack of evidentiary requirements did create a risk of undermining the credibility and robustness of Australia's regulatory controls for agricultural chemicals. This situation poses little reputational risk for veterinary chemicals as the existing 'Good Manufacturing Practice (GMP)' system requires overseas veterinary product manufacturers to comply with at least equivalent standards to the Australian GMP system.

Impact and Effect

The Order will reassure the public, agvet chemical stakeholders and international trading partners that the APVMA can respond appropriately should it establish that the manufacture of a registered agricultural chemical product (or of an active constituent for such a product) contravenes, or fails to comply with, any law in the country of manufacture that provides for the licensing (however described) of the manufacture of such products or active constituents. To ensure the APVMA has the appropriate information to assess compliance with this condition, it is expected that relevant information requirements will also be included in the legislative instrument that deals with the APVMA's application requirements (the *Agricultural and Veterinary Chemicals Code (Application Requirements) Instrument 2014*). This instrument allows the APVMA to request the information necessary to complete its assessment of an application to register an agricultural chemical product or to approve an active constituent for such a product.

Consultation

The department consulted key industry stakeholders on this Order through peak industry bodies throughout April and May 2021. A consultation paper describing the measure in the Order was made available for targeted consultation from 27 April 2021 to 14 May 2021. Stakeholders consulted included CropLife Australia (CropLife), Animal Medicines Australia,

the Veterinary Manufacturers and Distributors Association, ACCORD, Chemistry Australia and the Swimming Pool & Spa Association of Australia Ltd. These bodies collectively represent the vast majority of individuals and businesses that may be affected by this Order. A targeted consultation process also allowed the Order to be progressed quickly to address the identified need. This targeted consultation was supported by a consultation paper describing the measure, which was open for comment from these key stakeholders and relevant state and territory agencies from 27 April 2021 to 14 May 2021. Eight submissions were received in response to the consultation paper. These submissions identified two issues:

- The original proposal included veterinary chemical products (and actives for such products) – this was unnecessary as the existing system (compliance with at least an equivalent standard to the Australian GMP Code) already provides strong reputational safeguards.
- The language of the proposed conditions was too open to interpretation and could potentially have included peripheral laws such as employment or tax requirements.

These issues have been addressed in the final version of the Order. The Order was also developed in close consultation with the APVMA.

In accordance with subsection 7(6) of the Code Act, which sets out matters the minister must consider when making an order, the minister has considered the effect that the Order would have for the purposes of the Agvet Code of each jurisdiction. This will be minimal since under the split of responsibilities in the NRS, conditions of registration and approval are routinely enforced by the APVMA as a supply issue.

The Office of Best Practice Regulation (OBPR) was consulted in the preparation of the Order (ID 44022). The OBPR advised a Regulation Impact Statement was not required as the measures in the Order are unlikely to have more than a minor regulatory impact.

Details/Operation

Details of the Order are set out in Attachment A.

Other

Subsection 7(3) of the Code Act also provides that, despite subsection 44(1) of the *Legislation Act 2003*, section 42 (disallowance) of that Act applies to the Order. That the Order is disallowable is another matter under subsection 7(6) of the Code Act that the minister considered when making the Order.

Sunsetting does not apply to the order due to paragraph 54(1)(a) of the *Legislation Act 2003.* This is because the enabling legislation for the Order (which also authorises the creation of the Order) facilitates the establishment or operation of an intergovernmental body or scheme (the NRS).

The Order 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.

The Order is a legislative instrument for the purposes of the *Legislation Act 2003*.

ATTACHMENT A

Details of the *Agricultural and Veterinary Chemicals Code (Conditions of Approval or Registration) Order 2021*

Part 1 – Preliminary

Section 1 – Name

This section provides that the name of the Order is the *Agricultural and Veterinary Chemicals Code (Conditions of Approval or Registration) Order 2021*.

Section 2 – Commencement

This section provides for the Order to commence the day after the end of the period of 3 months beginning on the day it is registered.

Section 3 – Authority

This section provides that the Order is made under the *Agricultural and Veterinary Chemicals Code Act 1994*. The note to this section states that section 7 of that Act permits the Minister to make orders with respect to most matters that may be dealt with by regulations under section 6 of that Act.

Section 4 – Definitions

This section defines *manufacturing law* to be, in relation to a country, or part of a country, a law that provides for the licensing (however described) of the manufacture of agricultural chemical products or active constituents for agricultural chemical products.

This is a consequential amendment to sections 5 and 6 of Part 2 below, which set out the conditions of approval of active constituents for agricultural chemical products and the conditions of registration of agricultural chemical products.

Part 2 – Conditions of approval or registration

Section 5 – Conditions of approval of active constituents for agricultural chemical products

This section prescribes, for the purposes of paragraph 23(1)(a) of the Code, two conditions to which the approval of an active constituent for a proposed or existing agricultural chemical product is subject.

The first condition is that the active constituent must not be supplied if the manufacture of the active constituent contravenes, or fails to comply with, any manufacturing law (defined in section 4) of the country, or part of the country, in which it is manufactured.

The second condition is that the holder of the approval must, on written request by the APVMA and within 28 days after the request is given, provide the APVMA with written evidence that the manufacture of the active constituent complies with the first condition. Where the country of manufacture does not have any relevant manufacturing law

requirements, in lieu of providing written evidence, the APVMA may merely request the holder to make a declaration to this effect.

To give just one example, if the APVMA becomes aware of an overseas official determination, such as the findings of an agency, tribunal or court which indicates that an approval holder has not complied with a relevant overseas manufacturing law, it may then make a request under subsection 5(3).

These conditions will also apply in the rare circumstance where an active constituent is approved for use in both an agricultural chemical product and a veterinary chemical product (for the purposes of section 19(c) of the Agvet Code). It is important to note that 'approved' refers to the unique approval of each active constituent. The same chemical can have separate approvals. For example, while some chemicals (such as abamectin) can be used in both agricultural and veterinary chemical products, it is usual for the APVMA to have established separate 'approvals' of the active constituent, ones where the APVMA recorded the use as 'only for use in an agricultural chemical product' and others as 'only for use in a veterinary chemical product'. Rarely, however, an approval will be granted for use in both.

This section also includes three notes. The first note alerts the reader to the existing requirements under sections 130 and 159 of the Agvet Code for persons to provide information and documents to the APVMA. The second note highlights the existing authority, under section 36 of the Agvet Code, for the APVMA to suspend or cancel an approval of an active constituent for a proposed or existing chemical product for a contravention of a condition of the approval. The third note alerts the reader to the penalty provision under section 77 of the Agvet Code for the supply of an approved active constituent in contravention of conditions of approval.

Section 6 – Conditions of registration of agricultural chemical products

This section prescribes, for the purposes of paragraph 23(1)(a) of the Code, two conditions to which the registration of an agricultural chemical product is subject.

The first condition is that the chemical product must not be supplied if the manufacture of the chemical product contravenes, or fails to comply with, any manufacturing law (defined in section 4) of the country, or part of the country, in which it is manufactured.

The second condition is that the holder of the registration must, on written request by the APVMA and within 28 days after the request is given, provide the APVMA with written evidence that the manufacture of the chemical product complies with the first condition. Where the country of manufacture does not have any relevant manufacturing law requirements, in lieu of providing written evidence, the APVMA may merely request the holder to make a declaration to this effect.

To give just one example, if the APVMA becomes aware of an overseas official determination, such as the findings of an official agency, tribunal or court which indicates that an approval holder has not complied with a relevant overseas manufacturing law, it may then make a request under subsection 6(3).

This section also includes three notes. The first note alerts the reader to the existing requirements under sections 130 and 159 of the Agvet Code for persons to provide information and documents to the APVMA. The second note highlights the existing authority, under section 36 of the Agvet Code, for the APVMA to suspend or cancel the registration of a chemical product for a contravention of a condition of the registration. The third note alerts the reader to the penalty provision under section 79 of the Agvet Code for the supply of registered chemical products in contravention of conditions of registration.

Part 3 – Application and transitional provisions

Section 7 – Application of this instrument

This section provides that the Order applies in relation to an agricultural chemical product (or active constituent for such a product), that is supplied on or after the commencement of this instrument.

The effect of this section is that the conditions of approval of active constituents for agricultural chemical products (set out in section 5 above) and the conditions of registration of agricultural chemical products (set out in section 6 above) apply only to an agricultural chemical product that is supplied on or after the commencement of the Order. The conditions do not apply to agricultural chemical products, or active constituents for agricultural chemical products, that were supplied before commencement.

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 Code (Conditions of Approval and Registration) Order 2021

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 *Agricultural and Veterinary Chemicals Code (Conditions of Approval and Registration) Order 2021* (the Order) ensures that the Australian Pesticides and Veterinary Medicines Authority can respond appropriately should it establish that registered agricultural chemical products (or approved active constituents for such products) are not compliant with any licencing requirement (however described, for example manufacturing permits, certificates or authorisations) in the country of manufacture.

The Order will protect the credibility and reputation of Australia's regulatory controls for agricultural chemicals. The reputation of Australia's regulatory controls for veterinary chemical products is already sufficiently protected by the existing system (Good Manufacturing Practice) requiring APVMA issued licenses to manufacture veterinary chemicals.

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. David Littleproud MP
Minister for Agriculture and Northern Australia