EXPLANATORY STATEMENT

Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014

Section 5B(1) of the Agricultural and Veterinary Chemicals Code (Agvet Code), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, provides that the Australian Pesticides and Veterinary Medicines Authority (APVMA) may, by legislative instrument, determine criteria against which the efficacy of chemical products is to be assessed.

Section 32(1) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* provides that the Chief Executive Officer of the APVMA may exercise any of the powers and functions of the APVMA.

The Commonwealth and all States and Territories have agreed to a National Registration Scheme for Agricultural and Veterinary Chemicals. The National Scheme sets out the regulatory framework for the management of pesticides and veterinary medicines in Australia by a single agency. The APVMA is the current name for the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) established in 1993 as an independent statutory authority responsible for the Commonwealth's regulatory functions under the Scheme.

The National Registration Scheme also provides for a national, uniform and cooperative legislative regime throughout Australia administered by the APVMA. The centrepiece of the legislation is the Agvet Code, which has been applied to all Australian states and territories. Under the Agvet Code, the APVMA is responsible for the registration, quality assurance and compliance of pesticides and veterinary medicines up to and including the point of retail sale in Australia.

One of the changes brought about by the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* is to require chemical products to meet 3 substantive tests for registration: a product must meet the 'safety criteria', meet the 'trade criteria' and meet the 'efficacy criteria' (see section 14(1)(c)(i) of the Agvet Code). Listed chemical products can, in the alternative, be registered if they demonstrate compliance with the relevant established standard (see section 14(1)(c)(ii)).

This Determination concerns the third of the substantive tests: the 'efficacy criteria'. Section 5B of the Agvet Code explains how a product meets the efficacy criteria. Broadly speaking, meeting the efficacy criteria requires the use of the chemical product, in accordance with instructions approved, or to be approved, by the APVMA, to be effective according to criteria determined by the APVMA (or, alternatively, contained in an established standard). The role of this Determination is to determine these criteria.

The Determination sets out different criteria for agricultural chemical products (Part 2) and veterinary chemical products (Part 3). For each type of product there are two alternative criteria.

The first criterion (sections 3 and 5) is based on the type of product. This criterion is designed to treat certain kinds of low-risk products as being effective without the need to supply evidence to demonstrate that the products are effective. For the product types

listed, the efficacy criteria can be met if the product has equivalent use to a product currently registered for use in Australia. Equivalent use means that the amount of active constituent applied, the frequency and method of application are the same for the same host and pest/purpose as the registered product.

Importantly a product cannot be treated as effective pursuant to this criterion if it contains a new active constituent or there is no other APVMA registered chemical product with an equivalent use. For such a product, it will fall within the second criterion as efficacy information is required to establish the lowest effective rate (LER). The LER defines the exposure threshold which determines whether there is an undue hazard and is therefore used in determining whether the proposed use satisfies the safety criteria.

One type of product within the first criterion is an autogenous vaccine which is the subject of an application for a permit (section 5(a)(iv)). This type of product will only be treated as effective if it and its use complies with, or would comply with, the guidelines issued by the APVMA in relation to autogenous vaccines under section 6A of the Agvet Code. These guidelines are incorporated as of the day the Determination commences (as opposed to from time to time) and will be available from the APVMA's website at that time.

The second criterion (sections 4 and 6) is based on the *evidence* that is provided in support of the effectiveness of a product. The key test is whether the use of the product would, to a reasonable degree, achieve one or more of the fundamental characteristics of an agricultural or veterinary chemical product, as set out in sections 4(2) and 5(2) of the Agvet Code.

The criterion lists the ways in which the achievement of these characteristics must be demonstrated. Further guidance as to the appropriate evidence to demonstrate effectiveness in a particular case will be set out in the APVMA's data and regulatory guidelines.

No Regulatory Impact Statement has been prepared for the Instrument. The Office of Best Practice Regulations was consulted about this Instrument and has advised that no further analysis (in the form of a Regulatory Impact Statement) is required (OBPR ID: 17109).

Public Consultation

This Determination was released for public consultation from 30 April 2014 to 21 May 2014. Industry and community stakeholder groups were informed of the release. Comments were provided with respect to the content of the Determination. These comments were taken into account in preparing the Determination.

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 (Efficacy Criteria) Determination 2014

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

This Determination sets out criteria against which the effectiveness of chemical products is assessed for the purposes of the efficacy criteria in s 5B of the Agvet Code.

Human rights implications

The Determination does not engage any applicable rights or freedoms.

Conclusion

The Determination is compatible with human rights.