



Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014

Agricultural and Veterinary Chemicals Code

I, Kareena Arthy, Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority, make this Determination for subsection 5B(1) of the Agricultural and Veterinary Chemicals Code (the Agvet Code), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

Kareena Arthy
Chief Executive Officer

Dated this 25th day of June 2014

Part 1 Preliminary

1 Name of instrument

This instrument is the *Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014*.

2 Commencement

This Determination commences on the commencement of the *Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 2) Regulation 2013*.

Part 2 Agricultural chemical products

3 Criteria based on type of product

- (1) The use of an agricultural chemical product, in accordance with instructions approved, or to be approved, by the APVMA for the product, is, or would be, effective if:
 - (a) the use is as:
 - (i) a domestic or home garden product (see subsection (2)); or
 - (ii) an adjuvant, wetter or surfactant; or
 - (iii) a drift retardant; or
 - (iv) a plant growth regulator; or
 - (v) a semiochemical-based mating disruptor or semiochemical lure; or
 - (vi) a defoliant; or
 - (vii) a spray-marker dye; or
 - (viii) a mosquito coil or candle; and
 - (b) each active constituent of the product is used in 1 or more other registered chemical products for an equivalent use (that is, for an equivalent pest or purpose at equivalent rates of active constituent application).
- (2) For subparagraph (1)(a)(i), a ***domestic or home garden product***:
 - (a) includes products developed only for use for domestic or home garden purposes and available to the general public via normal retail outlets, but only where those products are insecticides, herbicides, fungicides, miticides and nematocides, molluscicides, rodenticides or dog and cat repellents; and
 - (b) does not include products used to sanitise swimming pools or spas.

4 Criteria based on demonstrated effectiveness

The use of an agricultural chemical product, in accordance with instructions approved, or to be approved, by the APVMA for the product, is also taken to be effective if:

- (a) it would, to a reasonable degree, achieve one of the effects listed in paragraphs 4(2)(a) to (e) of the Agvet Code; and
- (b) this is evidenced or demonstrated by:
 - (i) results from efficacy trials or experiments; or
 - (ii) valid scientific argument; or
 - (iii) demonstrated history of sale and effective use in equivalent uses; or
 - (iv) full results from overseas efficacy trials or experiments and the associated assessment reports by an overseas regulator that are relevant to the proposed product and use; or
 - (v) a combination of 2 or more of the above.

Note: The APVMA will consider, on a case by case basis, which of the above matters are necessary to demonstrate effectiveness in a particular case. The APVMA also takes into account other relevant matters: see subsection 5B(2) of the Code. The APVMA's data guidelines and regulatory guidelines made under section 6A of the Code, published on the APVMA's website, set out information about the kind of data considered sufficient to demonstrate effectiveness in particular cases.

Part 3 Veterinary chemical products

5 Criteria based on type of product

The use of a veterinary chemical product, in accordance with instructions approved, or to be approved, by the APVMA for the product, is, or would be, effective if:

- (a) the use is as:
 - (i) a counterirritant, rubifacient or poultice; or
 - (ii) an enzyme, direct-fed microbial, or probiotic; or
 - (iii) a pet food containing enzymes or direct-fed microbials; or
 - (iv) an autogenous vaccine which is the subject of an application for a permit, so long as the product 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 and as in force on the day this Determination commences; or
 - (v) a sheep branding substance; and
- (b) each active constituent of the product is used in 1 or more other registered veterinary chemical products that contain similar amounts of the active constituent and have similar claims and use patterns.

6 Criteria based on demonstrated effectiveness

The use of a veterinary chemical product, in accordance with instructions approved, or to be approved, by the APVMA for the product, is also taken to be effective if:

- (a) it would, to a reasonable degree, achieve one of the effects listed in paragraphs 5(2)(a) to (d) of the Agvet Code; and
- (b) this is evidenced or demonstrated by:

- (i) target animal efficacy studies, including dose determination studies, dose confirmation studies or confirmatory clinical or field studies; or
- (ii) pharmacological studies, such as *in vivo* or *in vitro* bioequivalence studies in target animals, pharmacokinetic studies or pharmacodynamic studies; or
- (iii) other relevant studies or data, such as clinical case studies, compatibility studies or palatability studies; or
- (iv) full results from overseas efficacy trials or experiments and the associated assessment reports by an overseas regulator that are relevant to the proposed product and use; or
- (v) valid scientific argument; or
- (vi) a combination of 2 or more of the above.

Note: The APVMA will consider, on a case by case basis, which of the above matters are necessary to demonstrate effectiveness in a particular case. The APVMA also takes into account other relevant matters: see subsection 5B(2) of the Code. The APVMA's data guidelines and regulatory guidelines made under section 6A of the Code, published on the APVMA's website, set out information about the kind of data considered sufficient to demonstrate effectiveness in particular cases.