Agricultural and Veterinary Chemicals Code (Manufacturing Principles) Determination 2014

Agricultural and Veterinary Chemicals Code

I, Kareena Arthy, Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority:

a) make this Determination for the purposes of subsection 23(1) of the *Agricultural and Veterinary Chemicals Act 1994*; and
b) repeal the *Agricultural and Veterinary Chemicals Instrument No. 1 (Manufacturing Principles) 2007* with effect from the commencement of this Determination.

Kareena Arthy
Chief Executive Officer

Dated this 25th day of June 2014

Part 1 Preliminary

1 Name of Standard

This Determination is the *Agricultural and Veterinary Chemicals (Manufacturing Principles) Determination 2014*.

2 Commencement

This Determination commences on the commencement of Schedules 1 to 6 to the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*.

3 Object

The object of this Determination is to set out written principles to be observed in the manufacture of veterinary chemical products, unless the products are exempt from the requirement to be manufactured in licensed facilities under the Agvet Regulations.

4 Interpretation

(1) Unless the contrary intention appears, an expression used in the Agvet Code or the Agvet Regulations and in this Determination has the same meaning in this Determination as in the Agvet Code or the Agvet Regulations.

(2) In this Determination, unless the contrary intention appears:

Agvet Code means the Agricultural and Veterinary Chemicals Code, scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

Agvet Regulations means the *Agricultural and Veterinary Chemicals Code Regulations 1995*.

Code of Good Manufacturing Practice means the Australian Code of Good Manufacturing Practice for Veterinary Chemical Products (including its Annexes) published by the Australian Pesticides and Veterinary Medicines Authority on 29 March 2007.

specified biological process means a process of manufacture of a veterinary chemical product involving one or more of the following:

(a) microbial, cell or tissue culture, including fermentation;

(b) extraction from biological tissues, including animal and plant tissues;

(c) derivatives from blood and body fluids;

(d) genetic manipulation, including recombinant DNA and hybridoma techniques;

(e) biotechnological processes;

(f) propagation in embryos or animals;

(g) formation or isolation of protein fragments or their derivatives.

relevant approval means an administrative decision permitting the supply of a chemical product, whether the decision is made in Australia or overseas, and whether it is made by the APVMA or an overseas authority.

Part 2 Manufacturing principles for veterinary chemical products

5 Compliance with Code of Good Manufacturing Practice

Subject to this Determination, veterinary chemical products must be manufactured in compliance with the Code of Good Manufacturing Practice.

6 Quality management

(1) Manufacturers of veterinary chemical products must have in place a quality assurance system to ensure that finished products are fit for their intended use, are manufactured in accordance with the manufacturing information mentioned in subsection 12(1) of this Determination, and do not place treated animals or users at risk due to inadequate quality, safety or efficacy.

(2) The quality assurance system must ensure that:

(a) appropriate procedures are in place to ensure that the required quality standards – meaning the quality standards on which the relevant approvals of a chemical product are based – are met;

(b) all materials involved in the manufacturing process comply with required quality standards before they are released for use in manufacture;

(c) there are measures designed to prevent cross-contamination;

(d) there are safeguards and controls in place designed to prevent the occurrence of foreseeable errors or process failures; and

(e) finished products have been made and stored correctly, and comply with required quality standards before they are released for supply.

(3) The quality assurance system must be relevant to the nature and intended use of the product. It must be fully documented, monitored for effectiveness and provide for continuous improvement.

7 Personnel and training

(1) Veterinary chemical products must be manufactured under the management and supervision of appropriately qualified, trained or experienced persons who:

(a) understand the specialised technical, quality and legal requirements relating to the manufacture of veterinary chemical products for which they have responsibility; and

(b) have their duties and responsibilities clearly defined by the manufacturer.

(2) Manufacturing staff must be trained to a satisfactory level of competency in:

(a) the basic principles of good manufacturing practice; and

(b) the specific duties, in connection with the manufacture of veterinary chemical products, that they are required to perform.

(3) There must be a sufficient number of competent personnel to carry out all required tasks.

8 Buildings and grounds

(1) Veterinary chemical products must be manufactured in buildings that are located, designed, constructed, maintained and utilised to:

(a) suit the operations carried out in them;

(b) ensure protection of the veterinary chemical products from contamination;

(c) permit effective cleaning and maintenance, including cleaning after processes have been completed; and

(d) minimise the risk of manufacturing error.

(2) The products must also be manufactured in an environment, or in equipment fitted with precautionary measures, that:

(a) ensures a standard of hygiene appropriate to the class of veterinary chemical product being manufactured;

(b) minimises the risk of cross-contamination of the finished product, or of materials or components that are used or manufactured at the premises; and

(c) ensures the safety of operators and protects the outside environment.

9 Equipment

(1) Equipment used in the manufacture of veterinary chemical products must be suitable for its intended purpose and appropriately operated, maintained and cleaned. Equipment must be correctly installed and operated in accordance with written instructions that are appropriate for the equipment.

(2) The design and layout of equipment must be such that:

(a) the risk of manufacturing error is minimised; and

(b) effective cleaning and maintenance are possible, in order to avoid cross-contamination of either intermediate materials or the finished product, the build-up of dust or dirt and, in general, to avoid any adverse environmental effect on the quality of the product.

10 Documentation

Manufacturers of veterinary chemical products must establish and maintain a system of documentation, document control and record keeping that:

(a) provides precise specifications for starting materials, intermediate materials and finished products, manufacturing formulae and instructions, and operating procedures for associated manufacturing and quality control activities;

(b) provides a complete history of each item, batch, or quantity manufactured in a specified timeframe, of veterinary chemical product manufactured at the premises; and

(c) establishes a traceable connection between raw materials and the finished product.

11 Computer systems

(1) Where, in any step in the manufacture of a veterinary chemical product, a computer is used for any activity that may affect the quality, safety or efficacy of the product, then the computer system must be subject to the principles of quality system management to ensure operational suitability.

(2) The introduction of computer systems into any manufacturing process, including materials control, processing control, quality control and product distribution, must not adversely affect product quality or quality assurance processes.

12 Production

(1) Veterinary chemical products must be manufactured to specifications in accordance with manufacturing information supplied as part of their application for a relevant approval, and as part of any subsequent variation of the particulars or conditions of such an approval.

(2) Production operations must follow documented procedures that have been clearly defined by the manufacturer.

(3) Any critical manufacturing process and any change to that manufacturing process, must be validated and formally approved by the holder of the licence or a person authorised by the holder for that purpose. Where a change in the manufacturing process affects the specifications of the product such that the product no longer complies with the particulars or conditions of a relevant approval, formal approval of such changes must be obtained from the relevant authority before the affected product is released for supply.

13 Quality control

(1) Manufacturers of veterinary chemical products must have in place an effective quality control system that is designed to ensure that, before products are released from manufacture for supply, they meet the specifications for the product on which any relevant approval of the product is based, and have been manufactured in accordance with the manufacturer's documented procedures.

(2) The person responsible for quality control must be sufficiently independent of other aspects of the manufacturing operation to allow effective implementation of the quality control function.

Federal Register of Legislative Instruments F2014L00859

(3) Manufacturers must ensure that analytical laboratories and animal testing facilities used in a step in the manufacture of a veterinary chemical product follow the principles of good laboratory practice.

14 Contracting out steps in the manufacture of a veterinary chemical product

(1) Where a licensed manufacturer contracts all or some of the steps in the manufacture of a veterinary chemical product to another person, the licensed manufacturer must ensure that, before manufacture commences, it has entered into a signed written 'GMP Agreement' with the other person that clearly specifies each party's responsibility in relation to every aspect of the manufacturing process, assurance of product quality and consistency with the specifications for the product on which any relevant approval of the product is based.

(2) Arrangements for contracting out steps in the manufacture of a veterinary chemical product must not compromise the quality of the product.

(3) Where a person is permitted to carry out a step in the manufacture of a veterinary chemical product under the licence of another manufacturer (pursuant to regulation 59A of the Agvet Regulations), the licence holder must exert direct control over and maintain oversight of the quality management of the step.

15 Internal audits

Manufacturers of veterinary chemical products must regularly and systematically carry out internal audits of all aspects of their manufacturing operations, as well as of their quality assurance system, in order to monitor compliance with their authorised procedures, standards and requirements and to ensure product quality. Steps must be taken to assess the outcomes of the internal audits and to implement any necessary corrective and preventive action identified by those internal audits.

16 Complaints and product recalls

(1) Manufacturers of veterinary chemical products must have in place a system of handling complaints regarding products they have manufactured on the licensed premises. There must be a documented system of recording, investigating and, where appropriate, acting upon all complaints that may be related to product quality.

(2) Manufacturers must also have in place a documented and effective procedure for recalling from the marketplace product that is known to be defective, or is suspected of being defective.

17 Sterile products

(1) Veterinary chemical products that are required to be, or are represented as being, sterile, must be manufactured:

(a) in separate, controlled areas in the premises that have:
  (i) high standards of hygiene; and
  (ii) a system of controlling particulate contaminants that is appropriate to the class of veterinary chemical product being manufactured;
(b) with special care and attention to detail; and
(c) in accordance with procedures established and validated by the manufacturer.

(2) The manufacturer must establish procedures and have equipment available (or in the case of bioburden, have access to equipment) to adequately monitor:
(a) the microbiological status of the environment in production areas; and
(b) the microbial load of the veterinary chemical products that are to be sterilised.

18 Immunobiologicals and other products of biological origin

Veterinary immunobiological products and other chemical products of biological origin, including those that are manufactured using a specified biological process, must be manufactured:
(a) using biological starting materials that are, or are derived from, biological materials demonstrated to be as free as practicable from adventitious contamination;
(b) in premises designed, constructed and maintained so as to provide an appropriate level of containment of the biological or microbiological agents being handled and to permit effective decontamination from these agents or from toxic residues by procedures that:
  (i) are established and validated by the manufacturer; and
  (ii) maintain the safety of personnel; and
(c) in cases where uniformity of product depends on deriving batches from a seed lot:
  (i) by maintaining the lots in secure and protective storage; and
  (ii) by keeping detailed and comprehensive records of their origin and disposition.