EXPLANATORY STATEMENT

Agricultural and Veterinary Chemicals (Manufacturing Principles) Determination 2014

Section 23(1) of the *Agricultural and Veterinary Chemicals Act 1994* provides that the Australian Pesticides and Veterinary Medicines Authority (APVMA) may, by legislative instrument, determine for the purposes of Part 8 of the Agricultural and Veterinary Chemicals Code (Agvet Code) scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* principles to be observed in the manufacture of chemical products that are consistent with the Agvet Code, the *Agricultural and Veterinary Chemicals Code Regulations 1995* and the laws of any jurisdiction that relate to occupational health or safety.

Subsection 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.

Part 8 of the Agvet Code provides for the licensing of manufacturers of veterinary medicines by the APVMA, where the manufacturer complies with the APVMA's manufacturing principles.

The APVMA has made a new Determination of Manufacturing Principles (Determination), to replace the existing *Agricultural and Veterinary Chemicals Instrument No. 1 (Manufacturing Principles) 2007* determined by the then Chief Executive Officer of the APVMA on 2 April 2007 (2007 Determination). The Determination, which repeals the 2007 Determination, will commence on the commencement of Schedules 1 to 6 to the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (see clause 2).

Generally speaking, the Manufacturing Principles determined under the Determination are in substance the same as those in force under the 2007 with mainly minor changes made to improve the drafting. The substantive changes effected by the Determination are as follows:

- **Section 3 (Object):** this is a new objects clause, providing that the object of the Determination is to set out written principles to be observed in the manufacture of veterinary chemical products.
- **Section 4 (Interpretation), definition of 'manufacture':** this definition has been removed as there is a new definition of 'manufacture' in section 3 or the Agvet Code.

- **Section 4 (Interpretation), definition of 'relevant approval':** a definition of 'relevant approval' is inserted. This term is inserted in sections 6, 12, 13 and 14 as a shorthand expression to refer to both Australian and overseas approvals. These amendments aid clarity and make drafting improvements.
- **Section 6 (Quality management):** section 6(1) contains a new cross-reference to section 12(1), requiring manufacturers of veterinary chemical products to have in place a quality assurance system to ensure that finished products are manufactured in accordance with the manufacturing information mentioned in that section. Section 6(2)(a) specifies that the 'required quality standards' mentioned in that provision are the quality standards on which the registration of a chemical product is based.
- **Section 11 (Computer systems):** section 11(1) is amended to clarify that this provision regulates a step in the manufacture of a veterinary chemical product.
- **Section 12 (Production):** section 12(1) is amended to clarify that the manufacturing information in accordance with which veterinary chemical products must be manufactured includes information supplied as part of any variation of the relevant particulars or conditions of the relevant product's registration. Section 12(3) provides that any critical manufacturing process or change to that process must be validated and formally approved by the holder of the licence or a person authorised by the holder for that purpose.
- **Section 14 (Contracting out steps in the manufacture of a veterinary chemical product):** for clarity, changes have been made to the expression in section 14(1). Section 14(3) provides that, where a person is permitted to carry out a step in the manufacture of a veterinary chemical product under another manufacturer's licence (pursuant to regulation 59A of the Agvet Regulations), the licence holder must exert direct control over and maintain oversight of the quality management of that step.
- **Section 15 (Internal audits):** minor changes have been made to the expression in this section.

The Determination is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

No Regulatory Impact Statement has been prepared for the Determination, given that it effects no significant changes to the Manufacturing Principles under the 2007 Determination. The Office of Best Practice Regulations was consulted about this Determination and has advised that no further analysis (in the form of a Regulatory Impact Statement) is required (OBPR ID: 17109).

Documents incorporated by reference

The Determination incorporates by reference the Australian Code of Good Manufacturing Practice for Veterinary Chemical Products, published by the APVMA on 29 March 2007, which is readily available on the internet.

Public Consultation

The Determination was released for public consultation from 30 April 2014 to 21 May 2014. Industry and community stakeholder groups were informed of the release. There were no comments provided with respect to this 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 (Manufacturing Principles) 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

The purpose of this Determination (Determination) is to set out written principles to be observed in the manufacture of veterinary chemical products. The Determination will replace the existing *Agricultural and Veterinary Chemicals Instrument No. 1 (Manufacturing Principles) 2007* (2007 Determination). Generally speaking, the Manufacturing Principles determined under this Determination (Manufacturing Principles) are in substance the same as those in force under the 2007 Determination.

The Manufacturing Principles require compliance with the *Australian Code of Good Manufacturing Practice for Veterinary Chemical Products* (published by the APVMA on 29 March 2007), and prescribe certain requirements for the manufacture of veterinary chemical products. These requirements cover the topics of quality management, personnel and training, buildings and grounds, equipment, documentation, computer systems, production, quality control, contracting out manufacturing steps, internal audits, complaints and product recalls, sterile products, and immunobiologicals and other products of biological origin.

Human rights implications

To the extent that the Manufacturing Principles require manufacturers to take measures to ensure the safety of personnel involved in the manufacture of veterinary chemical products, and to protect the outside environment (see clauses 8(2)(c) and 18(b)(ii)), the Determination engages and promotes the right to health and to a healthy environment recognised in article 12 of the *International Covenant on Economic, Social and Cultural Rights*. The United Nations Committee on Economic, Social and Cultural Rights has interpreted article 12 to extend to the underlying determinants of health, including a healthy environment.

The Determination does not otherwise engage any of the applicable rights or freedoms.

Conclusion

The Determination is compatible with human rights as it promotes the right to health, and does not otherwise raise any human rights issues.