

## EXPLANATORY STATEMENT

### *Agricultural and Veterinary Chemicals Code (Listed Chemical Product – Joint Health Products for Dogs and Horses) Standard 2014*

The *Agricultural and Veterinary Chemicals Code Act 1994* (Act) provides, within a Code set out in the Schedule to the Act (Agvet Code), a low regulatory scheme for agricultural and veterinary chemicals. This scheme was amended by the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (Amending Act). Relevantly, the Amending Act repealed Part 2A of the Act (dealing with the registration of low regulatory concern chemical products) and replaced it with new provisions in Part 1 Division 6 that simplify the arrangements for listing and developing established standards for listed chemical products.

New section 8T of the Agvet Code as amended allows for the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Regulations) to contain a schedule specifying chemical products or classes of chemical products that are listed chemical products under the Agvet Code. Regulation 8AR of the Regulations provides that the products specified in Schedule 3B of the Regulations are listed chemical products under the Agvet Code. Among a number of other products, products to improve the health of joints in dogs or horses that contain any one or more of the following as an active constituent are listed chemical products:

- chondroitin;
- glucosamine.

Section 8U(2) provides that the APVMA must, by legislative instrument, make a standard for each listed chemical product. This provision aligns with the former section 56D(2) of the Agvet Code, but removes the requirement in that former provision for the Minister to approve the standard.

This Standard, the *Agricultural and Veterinary Chemicals Code (Listed Chemical Product – Joint Health Products for Dogs and Horses) Standard 2014* (Standard), is made in accordance with section 8U of the Agvet Code. It replaces the *Listable Chemical Product (Joint Health Products for Dogs and Horses) Standard 2007* (Former Standard) made under the former section 56D of the Agvet Code, and specifies the following requirements in relation to the listed chemical products:

- formulation requirements;
- additional constituents;
- package limits;
- labels and formats.

The Standard contains the following changes from the Former Standard:

- Section 9 of the Former Standard which dealt with site of product manufacture has been omitted from this Standard for consistency with changes to the Agvet Code that come into effect on 1 July 2014;
- The note at the beginning of the label format in Schedule 1 which states ‘[Insert S5 signal heading applicable]’, has been replaced with the requirement to include the following on the front panel of the label:

CAUTION

KEEP OUT OF REACH OF CHILDREN

- Disposal instructions have also been included in the ancillary panel of the label format in Schedule 1 to the Standard.

Otherwise the Standard is substantially the same as the Former Standard, with only minor changes made to the Standard to improve the drafting.

Clause 7 of the Standard refers to the following documents in relation to determining additional constituents in listed chemical products:

- the ‘SUSMP’ which means the *Standard for the Uniform Scheduling of Medicines and Poisons* in Schedule 1 to the Poisons Standard, as in force at the time this Standard is made. This is available at: <http://www.comlaw.gov.au>
- the *Agricultural and Veterinary Chemicals Code Act (Excluded Stockfood Non-active Constituents) Order 2014* which is available at: <http://www.comlaw.gov.au>
- ‘Handbook of Pharmaceutical Excipients’ published by the British Pharmaceutical Society and the American Pharmaceutical Association.

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

The Standard commences immediately on the commencement of Schedules 1 to 6 to the Amendment Act (see clause 2).

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

### **Public Consultation**

This Standard was released for public consultation from 20 April 2014 to 21 May 2014. Industry and community stakeholder groups were informed of the release. No comments were provided with respect to the Standard.

## **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 (Listed Chemical Product – Joint Health Products for Dogs and Horses) Standard 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 Standard (Standard) is to set out requirements in relation to a chemical product or class of chemical products to which the Standard applies, including in relation to the formulation, labelling and handling of the product or products. The Standard will replace the existing *Listable Chemical Product (Joint Health Products for Dogs and Horses) Standard 2007* (Former Standard). The Standard is substantially the same as the Former Standard.

#### **Human rights implications**

This Standard does not engage any of the applicable rights or freedoms.

#### **Conclusion**

The Standard is compatible with human rights as it does not raise any human rights issues.