

Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022

EXPLANATORY STATEMENT

Issued by the Australian Pesticides and Veterinary Medicines Authority

INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (**APVMA**) is a statutory authority continued in existence under section 6 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*. Its functions and powers include administering the national system for regulation of agricultural and veterinary chemicals, and exercising the powers and functions conferred on it by the Agricultural and Veterinary Chemicals Code, as scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (**Code**).

Under section 6E(1)(b) of the Code, APVMA may make standards for chemical products by legislative instrument. Section 87(2)(a) of the Code prohibits a person from supplying, or causing or permitting to be supplied, a product where a standard is prescribed in respect of that product unless the product conforms to the standard. Regulation 42(3) of the *Agricultural and Veterinary Chemicals Code Regulations 1995* (**Regulations**) provides a cascade of standards for products or constituents contained in products, with step 2 of the cascade (regulation 42(3)(b)) being a standard made under section 6E of the Code.

This Instrument establishes a standard under section 6E of the Code for agricultural chemical products.

PROCESS BEFORE INSTRUMENT WAS MADE

Regulatory impact analysis

A Regulatory Impact Statement has not been prepared. The Office of Best Practice Regulation (**OBPR**) was consulted about this Instrument and related instruments for specifying allowable variation in products and active constituents which may be established in the future (OBPR ID OBPR22-02871).

On the basis of the information provided, OBPR considered that a Regulatory Impact Statement is not required for this Instrument (or other related instruments) as the making of this Instrument is likely to have no more than minor regulatory impacts on business, community organisations or individuals and is not being considered by Cabinet.

Consultation before making

Prior to making the Instrument under section 6E of the Code to create the standard specifying the prescribed extent of the variation from the concentration on the Register allowed for concentrations of constituents in agricultural chemical products, the proposed standard was consulted on via a formal process via the APVMA website and by targeted consultation with key stakeholders.

Statement of compatibility with human rights obligations

A statement of compatibility has been prepared and is at [Attachment A](#).

OTHER ISSUES

Matter incorporated by reference

The Instrument incorporates by reference the matters contained in the document, *Validation of analytical methods for active constituents and agricultural products* (Validation Guidance Document) for the purposes of the Validated Analytical Methods defined in subsection 4(2) of Part 1 of the Instrument.

Subsection 6E(2) of the Code provides that a standard made under subsection (1) may apply, adopt or incorporate, with or without modification, any matter contained in any instrument or other writing as in force at a particular time or as in force from time to time. In accordance with subsection 6E(2) of the Code, the Validation Guidance Document is incorporated as in force from time to time.

The Validation Guidance Document sets out procedures for validating analytical methods used to generate analytical results provided by applicants as scientific evidence in support of their applications to the APVMA. This guidance document assists applicants to demonstrate that the nominated method, when correctly applied, produces results that are fit for purpose when providing evidence to the APVMA that certain required statutory criteria are met under the Code as part of the APVMA's assessment of the application.

The Validation Guidance Document may be viewed or downloaded free of charge from the APVMA's website (<https://www.apvma.gov.au>).

Sunsetting

The Instrument is not subject to sunseting as the Code facilitates the operation of a scheme involving the Commonwealth and one or more States or Territories and authorises the Instrument to be made by the APVMA under section 6E for the purposes of the scheme, namely the national regulatory system for agricultural and veterinary chemicals.

More information

A provision-by-provision explanation of the Instrument is provided in Attachment B.

STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS ATTACHMENT A

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

AGRICULTURAL AND VETERINARY CHEMICALS CODE (ALLOWABLE VARIATION IN CONCENTRATIONS OF CONSTITUENTS IN AGRICULTURAL CHEMICAL PRODUCTS) STANDARD 2022

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 Instrument is to establish a standard for prescribing under section 6E of the Code the extent to which the measured concentrations of constituents of registered agricultural chemical products may vary from the concentrations recorded in the Register.

Human rights implications.

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

Conclusion

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

Part 1**Item 1 – Preamble**

This item provides that the Instrument is made under section 6E of the Code, following the procedure in regulation 8AF of the Regulations. It also states that under regulation 42(3) of the Regulations, a standard made under section 6E of the Code is a prescribed standard for a chemical product for the purposes of section 87(1)(a) of the Code.

Item 2 – Name of instrument and authority

This item provides for the Instrument to be named as the *Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022* and confirms that the authority for making it is section 6E(1) of the Code.

Item 3 – Commencement

This item provides for the Instrument to commence on the day after the day it is registered.

Item 4 – Definitions

This item describes the definitions used in the Instrument.

Part 2**Item 1 – Prescribed extent of allowable variation for concentrations of active constituents in agricultural chemical products**

This item specifies the extent to which the concentration of an active constituent in a registered agricultural chemical product may, when measured, differ from the concentration declared and recorded in the Register for that active constituent in the product.

Item 2 – Prescribed extent of allowable variation for concentrations of non-active constituents in agricultural chemical products

This item specifies the extent to which the concentration of a non-active constituent in a registered agricultural chemical product may, when measured, differ from the concentration declared and recorded in the Register for that non-active constituent in the product.