



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

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I, Sheila Logan, Delegate of the Australian Pesticides and Veterinary Medicines Authority, make the following instrument.

Dated            9 August 2022

Sheila Logan  
Delegate

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# Part 1 Introduction

## 1 Preamble

Section 5AA(1) of the Code states that a registered chemical product must comply with the relevant particulars entered into the Register for the product. Section 5AA(3) further states that the concentration of the constituents of a chemical product must not differ from the concentrations entered into the Register by more than the extent prescribed by regulations in force for the purposes of section 83(1)(b) of the Code.

Regulation 41(2) of the Regulations, made for the purposes of section 83(1)(b) of the Code, states that the prescribed extent of the variation in the concentrations of constituents is the extent permitted by the standards prescribed by Regulation 42 of the Regulations.

Regulation 42(3) of the Regulations states that a standard made under section 6E(1) is prescribed for a constituent in a chemical product or for a chemical product, provided that it is not already dealt with in an order under section 7 of the *Agricultural and Veterinary Chemicals Code Act 1994*.

This Instrument prescribes the extent to which the concentrations of constituents, including both active constituents, and non-active constituents (commonly referred to as excipients) in registered agricultural chemical products may differ from the concentrations entered into the Register when measured using a suitable validated analytical method. It is made under section 6E of the Code following the procedures set out in regulation 8AF of the Regulations.

This Instrument does not permit the deliberate variation of the nominal or 'target' concentrations of the constituents in a registered agricultural chemical product without recourse to an appropriate application to the APVMA for variation of the relevant particulars, even where such a change of the nominal concentration is within the tolerances defined within the Instrument. This Instrument manages variations in concentrations from the nominal value that arise from normal variability in manufacturing processes and/or analytical methods.

Further, this Instrument does not in itself provide any guidance or prescription on changes or differences in concentrations in constituents in agricultural chemical products that meet the definition of 'closely similar' as set out in Clause 1.2(1) of Schedule 6 of the Regulations.

## 2 Name of instrument and power

This Instrument is the *Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022* and is made under section 6E of the Code.

## 3 Commencement

This Instrument commences on the day after the day it is registered.

## 4 Definitions

(1) Unless the contrary intention appears:

- (a) words and expressions that are used in the Code have the same meaning in this Instrument; and
  - (b) words and expressions that are used in the Regulations have the same meaning in this Instrument.
- (2) In this Instrument:

**Active constituent** has the meaning given in section 3 of the Code and for the purpose of this Instrument means the constituent, or one of the constituents, of an agricultural chemical product that is, or are together, responsible for the biological or other effect identifying the product as an agricultural chemical product.

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

**Declared content, declared concentration, nominal content or nominal concentration** all refer to the expected, mean, or target concentration of a constituent stated or referred to in the appropriate section of an application form for registration or variation of an agricultural chemical product by an applicant for a constituent in their product. In addition, for active constituents or constituents included in a Schedule of the Poisons Standard, declared content refers to the concentration listed in a constituent statement on a product label.

**Heterogeneous formulation** means formulation types with a higher degree of spatial variability of particle size and chemical composition, as determined by the APVMA from time to time. It includes as examples, but is not limited to, the water dispersible granule (WG) and granular (GR) formulation types.

**Homogeneous formulation** means formulation types with a lower degree of spatial variability of particle size and chemical composition, as determined by the APVMA from time to time. It includes as examples, but is not limited to, the soluble concentrate (SL) and emulsifiable concentrate (EC) formulation types.

**Non-active constituent** means any constituent of a registered chemical product other than an active constituent. Non-active constituents are also commonly referred to as excipients.

**Poisons Standard** means the legislative instrument published by the Therapeutic Goods Administration and containing the decisions made by the Scheduling Delegate regarding the classification of medicines and chemicals into Schedules for inclusion in relevant legislation of the states and territories. It is also known as the Standard for the Uniform Scheduling of Medicines and Poisons.

**Register** has the meaning given in the Code.

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

**Relevant particulars** has the meaning given in the Code. For the purposes of this Instrument, relevant particulars generally means the concentration of a constituent in an agricultural chemical product.

**Validated analytical method** means an analytical method validated in accordance with the APVMA guidance document on validation of analytical methods, which is incorporated by reference into this Instrument as in force from time to time.

Note: The document, *Validation of analytical methods for active constituents and agricultural products*, is able to be viewed or downloaded free of charge from the APVMA's website (<https://apvma.gov.au/>).

## Part 2 Allowable variations for concentrations of constituents in agricultural chemical products

### 1 Prescribed extent of allowable variation for concentrations of active constituents in agricultural chemical products

- (a) The standard allowable variations from the concentration declared and recorded in the Register for active constituents in agricultural chemical products are given in the table below.

Declared content g/kg or g/L	Allowable variation
Up to 25	±15% of the declared content for homogeneous formulations or ±25% for heterogeneous formulations
Above 25 up to 100	±10% of the declared content
Above 100 up to 250	±6% of the declared content
Above 250 up to 500	±5% of the declared content
Above 500	±25 g/kg or g/L

Note: In each range the upper limit is included.

- (b) Applicants may propose alternative allowable variations from those in the table at 1(a) above, provided an appropriate scientific justification is provided, and the APVMA is satisfied that the alternative allowable variation would still ensure that the product complied with the safety, efficacy and trade criteria as defined in sections 5A, 5B and 5C of the Code.

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

- (a) The standard allowable variations from the concentration declared and recorded in the Register for non-active constituents in agricultural chemical products are given in the table below.

Nominal concentration g/kg or g/L	Allowable variation
Up to 10	±10% of the declared content
Above 10 up to 200	±5% of the declared content
Above 200 up to 1000	±3% of the declared content

- (b) Applicants may propose alternative allowable variations from those in the table at 2(a) above, provided an appropriate scientific justification is provided, and the APVMA is satisfied that the alternative allowable variation would still ensure that the product complied with the safety, efficacy and trade criteria as defined in sections 5A, 5B and 5C of the Code.
- (c) For constituents used as solvents or carriers in liquid chemical products or as fillers or carriers in solid chemical products and the quantities of these ingredients may be adjusted to balance variable amounts of other ingredients, tolerances may instead of a percentage tolerance as defined by (a) or (b) be declared as q.s. 1 L or q.s. 1 kg as appropriate.
- (d) For constituents including but not limited to pH adjusters, salt-forming acids or bases, buffers, antifoams, or viscosity modifiers, whose concentrations may be adjusted to bring a parameter such as pH, persistent foam level or viscosity within a desired range, tolerances may instead of a percentage tolerance as defined by (a) or (b) be declared as, for example, q.s. pH 4.0-5.0, or q.s. 200-300 mPa.s.
- (e) For any ingredient as described at (c) or (d), a nominal (mean expected or target) concentration must still be provided, for the purpose of placing the product in the correct Schedule of the Poisons Standard.

Note: The Code provides for standards to be made in respect of chemical products. This Instrument makes standards in respect of concentrations of constituents contained in agricultural chemical products as defined in the Code.