

Agricultural and Veterinary Chemicals Code (Interchangeable Constituent) Determination 2024

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)*.

For an agricultural and veterinary (agvet) chemical product to legally be manufactured, imported, supplied, sold, or used in Australia, it must be registered by the APVMA (unless otherwise authorised or exempted by the Code). Applications are made to the APVMA to approve, register or vary active constituents, products, or labels. The registration process involves scientifically evaluating the product to determine whether the APVMA is satisfied that the product meets the applicable statutory criteria (safety, efficacy, trade and labelling criteria).

Once an agvet chemical product is registered, the holder may apply for relevant particulars or conditions to be varied. Variations may include changes to the product formulation. The APVMA will assess whether the product continues to meet all the statutory criteria once varied.

Under Regulation 19AEA of the *Agricultural and Veterinary Chemicals Code Regulations 1995 (Regulations)*, the APVMA may, by legislative instrument, determine that one or more constituents of a chemical product or a class of chemical products may be interchanged with another constituent if the requirements specified in the determination are met. This means that specific non-active constituents (excipients) may be substituted for one another without assessment.

This Determination is an Interchangeable Constituent Determination made under Regulation 19AEA that allows Tersperse 4896 to be interchanged with Tersperse 4894 if the requirements specified in Column 3 of the Table at Item 5 are met.

The APVMA is satisfied that all requirements specified in Regulation 19AEA for this Determination have been met, including that after the constituents are interchanged the chemical product would continue to meet the safety, efficacy and trade criteria.

Once made, holders may lodge a notice with the APVMA under section 26AB of the Code to vary the relevant particulars of a registration if the criteria in the *Agricultural and Veterinary Chemicals Code (Notifiable Variations) Instrument 2019* and this Interchangeable Constituent Determination are met.

PROCESS BEFORE INSTRUMENT WAS MADE

Regulatory impact analysis

The Office of Impact Analysis (OIA) was consulted on 9 April 2024 about this Determination (OIA reference OIA24-07378).

On the basis of the information provided, the OIA determined that detailed analysis is not required under the Australian Government's Policy Impact Analysis Framework. This assessment was

informed by the understanding that the Determination will (only) allow Tersperse 4896 to be interchanged with Tersperse 4894 if the requirements specified in the Determination are met.

Consultation before making

Prior to making the Interchangeable Constituent Determination under Regulation 19AEA of the Regulations, the proposed Determination was consulted on under a formal process via the APVMA website. The consultation was open from 10 April 2024 to 8 May 2024. A total of one submission was received. The submission was supportive of the proposed Determination. The respondent asked for this submission to remain confidential and the APVMA responded directly to this submission. No changes were made to the proposed Determination as a result of the consultation.

Statement of compatibility with human rights obligations

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

Disallowance and Sunsetting

Although the *Agricultural and Veterinary Chemicals Code (Interchangeable Constituent) Determination 2024* is a legislative instrument for the purposes of the *Legislation Act 2003*, pursuant to subsection 54(1) of that Act it is not subject to sunsetting.

This is because the Code is:

- (a) facilitates the establishment and operation of a co-operative scheme involving the Commonwealth and all States and Territories; and
- (b) the Code authorises the *Agricultural and Veterinary Chemicals Code (Interchangeable Constituent) Determination 2024* to be made for the purposes of the scheme.

This Determination is subject to disallowance pursuant to section 42 of the *Legislation Act 2003*, because of the operation of section 163A of the Code.

OTHER ISSUES

Matter incorporated by reference

This Determination does not incorporate any matter by reference.

More information

A provision-by-provision explanation of the Determination 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 (Interchangeable Constituent) Determination 2024

This Determination 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 is to establish an Interchangeable Constituent Determination that authorises a constituent being substituted with another constituent in certain circumstances.

The APVMA is satisfied that all requirements specified in Regulation 19AEA of the *Agricultural and Veterinary Chemicals Code Regulations 1995 (Regulations)* for this Determination have been met, including that after the constituents are interchanged the chemical product would continue to meet the safety, efficacy and trade criteria.

Following commencement, holders may lodge a notice with the Australian Pesticides and Veterinary Medicines Authority under section 26AB of the *Agricultural and Veterinary Chemicals Code Act 1994 (Code)* to vary the relevant particulars of a registration if the criteria in the *Agricultural and Veterinary Chemicals Code (Notifiable Variations) Instrument 2019* and this Interchangeable Constituent Determination are met.

Notifiable variations are minor variations of relevant particulars, which are made through a simplified application process rather than the technical assessment process under Division 3 of Part 2 of the Code.

Human rights implications.

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

Conclusion

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

Item 1 – Name of instrument

This item provides for the Determination to be named as the *Agricultural and Veterinary Chemicals Code (Interchangeable Constituent) Determination 2024*.

Item 2 – Commencement

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

Item 3 – Authority

This item provides that the Determination is made under Regulation 19AEA of the *Agricultural and Veterinary Chemicals Code Regulations 1995*.

The power to make a legislative instrument under Regulation 19AEA is given to the APVMA, however, section 32 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* provides, inter alia, that the Chief Executive Officer may exercise any of the powers and perform any of the functions of the APVMA.

Item 4 – Definitions

This item defines the term ‘non-active constituent’ for the purposes of the Determination. It also includes a note to the effect that words and expressions used in the Determination have the same meaning as in the Code and the Regulations.

Item 5 – Interchangeable constituent determination

This item determines that the constituent Tersperse 4896 in a chemical product may be interchanged with the constituent Tersperse 4894 if the following requirements are met.

- The chemical product must be a registered chemical product, and
- Tersperse 4896 must be a non-active constituent of the chemical product, and
- Tersperse 4896 must be used as a surfactant, and
- The registered chemical product must be a suspension concentrate or flowable concentrate formulation type, and
- The concentration of Tersperse 4894 to be interchanged must be the same as the concentration of Tersperse 4896 in the registered chemical product.