



Australian Government

**Australian Pesticides and
Veterinary Medicines Authority**

Enforceable Undertaking

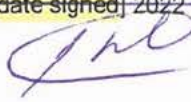
*Agricultural and Veterinary Chemicals Code Act 1994
(Cth)*

**CTS CHEMICALS PTY LTD
ACN 605 759 644**


The commitments in this undertaking are offered to the
Administering Authority by the above person or entity

Details

Date

27th of January 2023
~~[insert date signed] 2022~~


Parties

Name	CTS CHEMICALS Pty Ltd ACN 605 759 644 (CTS)
Address	
Name	Australian Pesticides and Veterinary Medicines Authority (Administering Authority)
Address	102 Taylor Street, Armidale NSW 2350

Background

- A The Administering Authority is a government body and has primary responsibility for the administration and enforcement of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) (**Agvet Code**)
- B CTS is alleged to have contravened provisions of the Agvet Code as set out in this Undertaking
- C CTS has offered, and the Administering Authority has agreed to accept, an undertaking in connection with the supply of relevant agricultural chemical products on the terms and conditions set out in this Undertaking

Agreed Terms

1 INTERPRETATION

1.1 Definitions

In this Undertaking, unless the context requires otherwise

Agvet Code means the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth),

Administering Authority means the Australian Pesticides and Veterinary Medicines Authority (APVMA),

Agricultural Chemical Products has the meaning given by section 4 of the Agvet Code,

Proceedings means a legal or other action,

Register means the Register of Agricultural and Veterinary Chemical Products kept under section 18 of the Agvet Code,

Related Body Corporate has the meaning given to it by sections 9 and 50 of the *Corporations Act 2001* (Cth);

Relevant Information has the meaning given to it by section 161 of the Agvet Code; and

Undertaking means this enforceable undertaking made pursuant to section 145E of the Agvet Code, given by CTS and accepted by the Administering Authority.

1.2 Interpretation

In this Undertaking, unless the context requires otherwise:

- (a) reference to a person includes any other entity recognised by law and vice versa;
- (b) the singular includes the plural and vice versa;
- (c) one gender includes every gender;
- (d) reference to a party includes their executors, administrators or permitted assigns or, being a company, its successors or permitted assigns;
- (e) an agreement, representation or warranty in favour of two or more persons is for the benefit of each and all of them;
- (f) clause headings are for reference purposes only; and
- (g) reference to a statute, ordinance, code or other law includes regulations and other instruments under it and consolidations, amendments, re-enactments or replacements of it.

2. COMMENCEMENT AND DURATION OF UNDERTAKING

This Undertaking takes effect on the day that the Administering Authority signs the Undertaking. It ceases 12 months from the day it takes effect.

3. CONTRAVENTIONS OF THE AGVET CODE

- (a) CTS is a company that supplies Agricultural Chemical Products within the Australian marketplace.
- (b) CTS imported four Agricultural Chemical Products being:
 - (i) Trio Bromoxynil 250 Diflufenican 25 EC herbicide – APVMA Registration No: 90709, Label No: 129854, Batch No: HB20210320 and HB20210130; and
Trio Bromoxynil 200 EC herbicide – APVMA Registration No: 90777, Label No: 130001, Batch No: HB20210125 and HB20210126 (together, **Bromoxynil Products**); and
 - (ii) Trio Glyphosate 450 Herbicide – APVMA Registration No: 64397, Label No: 1109, Batch No: FH20200331, FH20200508, FH20200509, XF20200915, XF20200925, XF20201003 and FH20210108 (**Glyphosate Product**); and
 - (iii) Trio MCPA LVE EC Herbicide – APVMA Registration No: 89725, Label No: 125902 Batch No: MP2020006010001, MP202012100001 and MP202012100002 (**MCPA Product**).

- (c) The Bromoxynil Products, Glyphosate Product and MCPA Product were supplied to consumers in the Australian marketplace.
- (d) The Bromoxynil Products, Glyphosate Product and MCPA Product did not comply with the APVMA's conditions of registration because:
- (i) The Bromoxynil Products were not manufactured in accordance with the particulars entered for the chemical product in the Register.
 - (ii) The Glyphosate Product was not manufactured by a manufacturer whose name is entered for the chemical product in the Register.
 - (iii) The Glyphosate Product was not manufactured at a site of manufacture entered for the chemical product in the Register.
 - (iv) The Glyphosate Product was not manufactured in accordance with the particulars entered for the chemical product in the Register.
 - (v) The MCPA Product was not manufactured in accordance with the particulars entered for the chemical product in the Register.
- (e) As a consequence of the above, CTS:
- (i) Initiated a voluntary recall of the Bromoxynil Products 16 June 2021.
 - (ii) Notified the APVMA of the intention of voluntary recall for the MCPA Product and Glyphosate Product on 28 September 2021.
 - (iii) Commenced an internal audit of products in its inventory, being those products imported into Australia by CTS or its Related Body Corporates.
 - (iv) During the internal audit, it was determined that CTS imported 10 Agricultural Chemical Products into the Australian marketplace, which did not comply with the APVMA's conditions of registration issued under section 23 of the Agvet Code.
- (f) As a result of the matters referred to above, the Administering Authority has identified that CTS has likely contravened sections 79 and 83 of the Agvet Code.
- (g) CTS has offered to the Administering Authority this Undertaking to take specified actions in order to comply with particular provisions of the Agvet Code relating to the supply of Agricultural Chemical Products.
- (h) The Administering Authority has agreed to accept this Undertaking.

4. KEY OBJECTIVES OF THIS UNDERTAKING

4.1 Binding Document

This Undertaking is a binding document with the primary objective of securing compliance with the Agvet Code, and furthering the objectives of the Agvet Code to ensure the protection of the health and safety of human beings, animals, the environment and trade.

4.2 Improve Regulatory Compliance

This Undertaking aims to improve CTS's regulatory compliance by implementing systemic changes that will reduce the likelihood of non-compliance with the Agvet Code occurring in the future.

4.3 Improve Industry Compliance

This Undertaking aims to assist in improving the regulatory compliance of the relevant industry more broadly.

5. ASSURANCE ABOUT FUTURE CONDUCT

By completing the undertakings set out below, CTS is demonstrating its commitment to ensuring their supply of Agricultural Chemical Products complies with the Agvet Code.

6. UNDERTAKINGS

Under section 145E of the Agvet Code, CTS has offered and the Administering Authority has agreed to accept undertakings by CTS on the following terms:

- (a) CTS will, within 14 days of the date the Undertaking takes effect, provide to the Administering Authority a list of all Agricultural Chemical Products imported into Australia by it or its Related Body Corporates. The list must include all CTS registered and unregistered Agricultural Chemical Products, quantity imported, pack sizes, APVMA approval numbers, batch numbers and site of manufacture for the last 12 months.
- (b) CTS will, within 21 days of the date the Undertaking takes effect, conduct an internal audit of its inventory (excluding any inventory that is in the process of being destroyed, re-worked or returned and which is already subject of a recall notified to the APVMA prior to the date of the Undertaking), of Agricultural Chemical Products registered by CTS with the Administering Authority by it or its Related Body Corporates as at the commencement of this Undertaking, to ensure that the formula complies with the formula in the Register and provide this information to the Administering Authority.
- (c) CTS will, within 5 days of the date the Undertaking takes effect, cease to supply any Bromoxynil Products, Glyphosate Product and MCPA Product, until the formulation of each of the relevant product has undergone the internal audit, referred to above. For the avoidance of doubt, CTS may recommence supply of a product so long as CTS has determined that the formula for that product conforms with the Register and irrespective of whether CTS has completed the audit for any other products referred to above at clause 6(b).
- (d) CTS will comply with any obligation which may exist under section 161 of the Agvet Code relating to the notification of Relevant Information to the Administering Agency. CTS will ensure Relevant Information is provided to the Administering Authority as soon as it becomes aware of the information. CTS will also provide the following information as soon as reasonably practicable:
 - (i) all Relevant Information, including any variations to the registered formulation so that the Administering Authority can assess any potential safety, efficacy or quality risks;
 - (ii) batch reconciliation data to trace each affected lot; and
 - (iii) any actions to be taken, and the anticipated timeline for completion.
- (e) Where required, CTS agrees to undertake recall action promptly and acknowledges that failure to notify the Administering Authority in accordance with the provisions of section 106 of the Agvet Code may lead to further action by the Administering Authority. If voluntary recall actions are required, CTS will:
 - (i) notify the Administering Authority using the approved form as published on the APVMA website within two days of taking recall action;

- (ii) provide updates on recall progress to the Administering Authority as per an agreed schedule; and
 - (iii) provide the Administering Authority with an investigation report for each recalled product, and this will include identification of the root cause and the immediate, corrective and preventative actions implemented to prevent recurrence.
- (f) CTS undertakes to provide compliance training to its Australian staff directly involved in the supply of, including conditions of registration issued under section 23 of the Agvet Code applicable to Agricultural Chemical Products on:
 - (i) the intent and purpose of Part 4 Division 2 of the Agvet Code regarding the control of chemical products;
 - (ii) relevant CTS policies and procedures relevant to ensuring compliance with the Agvet Code;
 - (iii) the requirements of this Undertaking; and
 - (iv) implications of non-compliance with the Agvet Code,within 12 months of the date on which this Undertaking commences.
- (g) CTS will also make the compliance training referred to in clause 6(f) above available to new Australian staff, who are directly involved in the supply of Agricultural Chemical Products, as part of their induction.
- (h) CTS undertakes, during the 12 month period after the date the Undertaking takes effect, to provide monthly reports to the Administering Authority. The monthly report will include:
 - (i) a summary update for batches subject to voluntary recall action
 - (ii) sufficient evidence to provide assurance that all CTS registered Agricultural Chemical Products in the Australian marketplace comply with the Administering Authority's conditions of registration under the Agvet Code. This may include certificates of conformance, certificates of analysis, and batch records.
- (i) Reports must be provided to the Administering Authority by the 7th of each month. The first monthly report must include a full product list as an Annexure to the report, of the inventory specified at paragraph 6(b) of this Undertaking.
- (j) A meeting with the Administering Authority is to occur no later than one week from the 7th of each month, or such later date approved in writing by the Administering Authority, to discuss the monthly reports provided by CTS. This meeting is to be organised by the Administering Authority.
- (k) In addition to the monthly reports referred to above, CTS will provide a final report at the end of the 12 month period which sets out the information required in (h) above.
- (l) Prior to re-commencing supply of any recalled product, and without limiting any other obligation to ensure that the supply of an Agricultural Chemical Product complies with the requirements of the Agvet Code, CTS undertakes to submit to the Administering Authority via the appropriate application method any required variations, identified in the course of the internal audit referred to in clause 6(b), to ensure that the registration of the relevant product is accurate.

- (m) CTS undertakes to implement corrective and preventative actions reasonably necessary to address issues that are identified in the internal audit referred to in clause 6(b), including making changes or enhancements to CTS's internal systems for monitoring compliance.
- (n) The Administering Authority may undertake its own compliance monitoring activities to verify evidence of compliance with this Undertaking. CTS agrees to cooperate with any reasonable request by the Administering Authority.

7. ACKNOWLEDGMENTS

CTS acknowledges that:

- (a) The Administering Authority has accepted this Undertaking on the reasonable belief that the Undertaking will secure CTS's compliance with the Agvet Code.
- (b) The Administering Authority has accepted this Undertaking in reliance upon the information provided to it by CTS, and on the understanding that the information provided is not false or misleading.
- (c) Pursuant to section 146 of the Agvet Code, it is an offence to provide information to the Administering Authority that a person knows to be false or misleading in a material particular.
- (d) Pursuant to Division 137 of the *Criminal Code Act 1995* (Cth), it is an offence to give information or documents to a person exercising powers or functions under a law of the Commonwealth that a person knows is false or misleading in a material particular.
- (e) This Undertaking will be published on the Administering Authority's website as required by section 145E(6) of the Agvet Code.
- (f) Any variation or withdrawal of this Undertaking will also be published on the Administering Authority's website.
- (g) This Undertaking only applies to the conduct and offences specified above and cannot be varied to provide for a different alleged contravention of the Agvet Code.
- (h) The Administering Authority may, under section 145EA of the Agvet Code, commence court proceedings against CTS for contravening any of the terms of this Undertaking.
- (i) The acceptance of this Undertaking does not affect the Administering Authority's power to:
 - (i) bring Court proceedings;
 - (ii) issue penalty notices; or
 - (iii) take other enforcement action,in relation to any subsequent contraventions or alleged contraventions of the Agvet Code that are not the subject of this Undertaking.
- (j) Demonstration of compliance with this Undertaking is the sole responsibility of CTS.

8. WARRANTIES

(a) CTS warrants that:

- (i) the information provided to the Administering Authority in negotiating and giving this Undertaking, both orally and in writing, has not been false or misleading in any material particular;
- (ii) it is duly incorporated and validly exists under the laws of its jurisdiction of incorporation and has full corporate power and lawful authority to enter into this Undertaking;
- (iii) it is not in liquidation;
- (iv) no action has been taken by or against CTS which could lead to the winding up of the corporation;
- (v) the corporation is not under official management;
- (vi) an administrator, controller or managing controller has not been appointed to the corporation;
- (vii) a compromise or arrangement has not been proposed between the corporation and its members or creditors, not agreed to by the members or creditors sanctioned by the Court; and
- (viii) it has the financial capacity to fully comply with all of the terms of this Undertaking.

9. ADMINISTRATIVE PROVISIONS

9.1 Severability

If any part of this Undertaking becomes illegal, invalid or unenforceable in any relevant jurisdiction, the legality, validity or enforceability of the remainder of the Undertaking will not be affected and this Undertaking will be read as if the part had been deleted in that jurisdiction only.

9.2 Entire Understanding

- (a) This Undertaking contains the entire understanding and undertaking between the parties as to the subject matter of this Undertaking.
- (b) All previous negotiations, understandings, representations, warranties, memoranda or commitments in relation to, or in any way affecting, the subject matter of this Undertaking are merged in and superseded by this Undertaking and will be of no force or effect and no party will be liable to any other party in respect of those matters.
- (c) No oral explanation or information provided by any party to another will affect the meaning or interpretation of this Undertaking or constitute any collateral agreement, warranty or understanding between any of the parties.

9.3 Execution by Counterparts

This Undertaking may consist of one or more counterpart copies and all counterparts will, when taken together, constitute the one Undertaking.

Signing page

SIGNED and unconditionally given
as an undertaking under section 145E of
the Agvet Code

SIGNED by **CTS Chemicals Pty. Limited.**
(ACN 605 759 644)
in accordance with section 127(1) of the
Corporations Act 2001 (Cth) by

Name of Director
(print)

Signature of Director

1/20/2023

Date

Name of Director/~~Company Secretary~~ (print)

Signature of Director/~~Company Secretary~~

1/20/2023

Date

SIGNED for and on behalf of the
**Australian Pesticides and Veterinary
Medicines Authority** (ABN 19 495 043
447) by a duly authorised representative

Name of authorised representative
(print)

Signature of authorised representative

Date

27th January 2023

Name of witness (print)

Signature of witness

Date

27 January 2023

Signing page

SIGNED and unconditionally given
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(print)

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Signature of witness

Date