Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

26 May 2021

Summary

Substance Name	Experimental Pesticides - Development Trials 3
Application code	APP204207
Application type	To import or manufacture a hazardous substance in containment under section 31 of the Hazardous Substances and New Organisms Act 1996 (“the Act”)
Applicant	Corteva Agriscience New Zealand Limited
Purpose of the Application	To import or manufacture in containment[1]
Date application received	15 April 2021
Consideration date	24 May 2021
Considered by	The General Manager[2] of the Environmental Protection Authority (“the EPA”)
Decision	**Approved with controls**
Expiry date of approval	26 May 2024
Approval code	**HSC100295**

[1] Manufacturing is described as making, preparing, producing, labelling or packaging a hazardous substance, this also includes relabelling and repackaging. For the purpose of this application, the term “subsampling” of substances is considered manufacturing.
[2] The General Manager of the Hazardous Substances and New Organisms group of the EPA has made the decision on this application under delegated authority in accordance with section 19 of the Act.

1. Background

1.1. Corteva Agriscience New Zealand Limited ('the applicant") sought approval under section 32 of the Act to import or manufacture one hazardous substance ("the substance") in containment.

1.2. The substance is an agricultural chemical intended to be used as a herbicide.

1.3. The applicant intends to use the substance in field trials (e.g. horticultural crops, arable, pasture and forestry), glasshouse (small plots or pots) and laboratory studies (e.g. resistance testing, insect or disease bioassays and spray drift investigation) in order to evaluate the efficacy, crop safety, residue profile, good agricultural practice (GAP) use patterns and pre-plant interval of the substance.

1.4. The applicant stated that they may export the substance upon completion of the trial project or expiry of the containment approval.

2. Process

Application receipt

2.1. The application was formally received on 15 April 2021 under section 31 of the Act.

Information available for consideration

2.2. The information available for the consideration includes the:

- application form
- confidential appendices to the application, including information on the substance
- EPA staff advice memorandum.

2.3. The available information is sufficient to assess the application.

3. Hazardous properties

3.1. The applicant submitted information on the hazards of the substance for which approval is sought. It is noted that this is experimental substance, and as such there is insufficient information available for the hazard classifications of the substance to be determined.

3.2. Based on the available information, this substance may cause adverse effects to human health and the environment. The potential adverse effects are expected to be similar to other plant protection substances that are already approved under the Act for import or manufacture with controls.

4. Assessment of risks

4.1. The applicant has proposed a containment system and information on how they intend to address the risks from the following:

- To limit the likelihood of escape of any contained hazardous substances or contamination of the facility by hazardous substances
- To exclude organisms from a facility or to control organisms within a facility
- To exclude unauthorised people from a facility
- To prevent unintended release of the substance by experimenters working with a substance
- To control the effects of an accidental release of the substance
- Inspection and monitoring requirements of the containment facility

4.2. The EPA considered the applicant's assessment and determined that the substances may pose risks such as, but not limited to, those detailed below.

Risks to human health and the environment

4.3. The substance may cause adverse effects to human health and the environment if people or non-target organisms are exposed to the substance.

4.4. The substance could potentially contaminate waterways, groundwater, soil or neighbouring properties. These potential exposures could result from an incident during importation, manufacture, storage, transport, application, or disposal of the substance. The risk of an incident occurring with the proposed controls in place is considered negligible.

4.5. The likely route for human exposure is through oral or dermal contact while handling the substance. However, it is unlikely that people using the substance will be exposed in this way provided that risk mitigation measures are in place. These measures include the use of personal protective equipment (PPE), and qualification requirements for people preparing and handling the substance.

4.6. There is also a risk that members of the public may be exposed to the substance. This is mitigated by controls that limit access to the field trial sites and manufacturing site to authorised personnel only. Field trials are limited to sites that do not include land or facilities that the public can legally access without permission. The manufacturing site is a secure site with measures in place to prevent access from unauthorised people.

4.7. Non-target animals foraging within the field trial site may be exposed to the substance either via contact with or consumption of treated produce or vegetation. This is mitigated by a control that specifies that trial sites that are at risk of entry by grazing animals must be secured by stock-proof fencing. The approval holder is also required to ensure that non-target species are not adversely affected by the use of the substance.

4.8. With the controls in Appendix A and restrictions under other relevant legislation, the risks to human health and the environment posed by the importation or manufacture of the substance (in containment) are negligible.

4.9. There are also requirements under the Health and Safety at Work Act 2015 and associated regulations. Note: the Health and Safety at Work Requirements are not set under this approval but apply in their own right.

Risks to the relationship of Māori to the environment

4.10. The potential effects of the substance on the relationship of Māori to the environment have been assessed in accordance with sections 5(b), 6(d) and 8 of the Act. Under these sections all persons exercising functions, powers and duties under this Act shall recognise and provide for the maintenance and enhancement of people and communities to provide for their cultural well-being, and; take into account the relationship of Māori and their culture and traditions with their ancestral lands, water, taonga and the principles of the Treaty of Waitangi (Te Tiriti o Waitangi).

4.11. It is unlikely that the importation or manufacture of the substance in containment will impact on Māori culture or traditional relationships with the environment.

4.12. If the substance is managed in accordance with the controls in Appendix A, it would be likely to be consistent with the principles of the Treaty of Waitangi, particularly the principle of active protection.

Assessment of risks to society, the community and the market economy

4.13. No risks to society, communities or the market economy were identified from importing or manufacturing the substance in containment.

New Zealand's international obligations

4.14. None of New Zealand's international obligations were identified as being impacted by importing or manufacturing the substance in containment.

5. Assessment of containment

Purpose of the approval

5.1. Under section 32 of the Act, a containment approval may only be granted if the application is for one of the purposes specified in section 30 of the Act.

5.2. The applicant notes that the purpose of this application is to conduct research and development on the substance, in accordance with section 30(b) and section 30(ba) of the Act. The applicant also indicates that the substances may be exported after completion of a project or expiry of the containment approval in accordance with section 30(ca) of the Act. The application is therefore eligible for consideration under section 32 of the Act.

Adequacy of containment

5.3. Section 32(1) of the Act requires that the substance can be adequately contained. The potential for the substance to escape from containment was assessed by taking into account the

containment system proposed by the applicant and the potential pathways for release of the substance.

5.4. Section 32(2) of the Act specifies that a containment approval for a hazardous substance must include controls for each of the applicable matters specified in Schedule 3. The approval may also include controls that provide for any other matters in order to give effect to the purpose of the Act.

5.5. Applying the Schedule 3 requirements and using the information provided by the applicant, a set of controls was developed to ensure adequate containment of the substance.

5.6. The applicant was provided with the proposed controls and given an opportunity to comment. The applicant suggested to:

- remove Control 34 (use of the substance as a seed treatment) as it was not relevant to this application
- remove Control 35 (use of the substance as a granular form) as it was not relevant to this application
- amend the wording for Control 41, now Control 39 (any crop or produce to which the substance is applied to is not to be permitted to be used as a food) to remove reference of the Agricultural Compounds and Veterinary Medicines (ACVM) group, as the use of treated produce for food or feed is permitted under certain circumstances of the operating plan, ACVM do not expressly permit each substance as the operating plan is generic to all research trials. Projects, including the intended fate of the treated produce are notified to ACVM separately.

These comments were acknowledged and the EPA agreed to these changes.
No other concerns with the controls were raised.

5.7. Having considered all the applicable matters, the EPA has determined that the substance can be imported or manufactured in containment, provided that the controls in Appendix A are complied with.

6. Decision

6.1. Pursuant to section 32 of the Act, I have considered this application for an approval to import or manufacture Experimental Pesticides - Development Trials 3 in containment. I have applied the relevant sections of the Act and clauses of the Hazardous Substances and New Organisms (Methodology) Order 1998.

6.2. I am satisfied that Experimental Pesticides - Development Trials 3 can be adequately contained with the controls in Appendix A.

6.3. Therefore, the application to import or manufacture Experimental Pesticides - Development Trials 3 in containment is granted until **26 May 2024**.

Environmental Protection Authority
Te Mana Rauhī Taiao

Dr Christopher Hill **Date:** 26 May 2021

General Manager, HSNO, EPA

Appendix A: Controls applying to the importation or manufacture of Experimental Pesticides - Development Trials 3

General

1. In these controls, “approval holder” refers to Corteva Agriscience New Zealand Limited.
2. In these controls, “substance” refers to, and is limited only to, Experimental Pesticides - Development Trials 3.
3. Experimental Pesticides - Development Trials 3 consists of one formulation declared with application APP204207. This substance is summarised in confidential Appendix B below.
4. This containment approval is granted to the listed approval holder and is not transferable to any other party.

Accountability

5. The approval holder must ensure compliance with all the controls in this approval.

Requirement for containment

6. The substance must be in containment at all stages of its life cycle in New Zealand.

Limitations

7. This approval expires on **26 May 2024**.
8. The approval holder must ensure that the nature of the field trials, manufacture and laboratory testing of the substance are in accordance with the activities proposed in application APP204207, unless otherwise specified by the controls on this approval.
9. Ownership of the substance cannot be transferred from the approval holder while the substance remains in New Zealand for any purpose other than those specified in Control 39.
10. Over the term of this approval, the approval holder may import or manufacture up to 100 kilograms or litres, of the substance covered under this approval.

General requirements

11. The substance must be correctly packaged. The substance is correctly packaged if they are packed in accordance with the Hazardous Substances (Packaging) Notice 2017 and their packaging complies with the same Notice.
12. The substance must be correctly labelled. The substance are correctly labelled if they are packed in a container that is labelled in accordance with the Hazardous Substances (Labelling) Notice 2017. The label must include a 24-hour emergency contact phone number.

13. A safety data sheet (SDS) must accompany the substance at all stages of its life cycles in New Zealand. The SDS must comply with the relevant requirements of the Hazardous Substances (Safety Data Sheets) Notice 2017.

Workplace site and storage requirements

14. Clauses 39 to 42 of the Hazardous Substances (Hazardous Property Controls) Notice 2017 apply to this approval, as if the substance has a hazard classification of hazardous to the aquatic environment acute Category 1 or hazardous to the aquatic environment chronic Category 1.

15. The substance, when not in use, must be held in secured storage.

Containment facility

16. The approval holder must only import, subsample[3] or conduct laboratory studies for the substances at the facility described by the approval holder in the confidential appendix provided with this application. This facility is described as the “containment facility”.

17. Unauthorised persons must be excluded from the containment facility.

18. The containment facility must, as far as is reasonably practical, be managed so as to exclude unwanted organisms.

Field trial sites

19. Each field trial of a substance must be undertaken in containment within an area specifically designated as a ‘field trial site’. This site may be all or part of a property or facility.

20. The field trial sites must include:
    a. all necessary buffer zones
    b. any area used for cleaning equipment or disposing of rinse water
    c. any area on which any excess mixture of the substance is applied.

21. The field trial sites must only be land or facilities that the public cannot legally access without permission of the owner or legal occupier.

22. Unauthorised people must be excluded from the field trial sites.

23. Signs must be displayed at every vehicular and pedestrian entrance to the field trial sites for the duration of the trials. The signs must state :
    a. that the site is subject to the trial of a hazardous substance
    b. the general type of hazards of each substance that is being trialled
    c. the immediate response action to be taken in an emergency, including a 24-hour emergency contact phone number
    d. that unauthorised access to the site is not permitted

[3] Manufacturing is described as making, preparing, producing, labelling or packaging a hazardous substance, this also includes re-labelling and re-packaging. For the purpose of this application, the term “sub-sampling” of substances is considered manufacturing.

24. The management of the signs referred to in Control 23 must be compliant with regulation 2.5(2) of the Health and Safety at Work (Hazardous Substances) Regulations 2017, as if references to regulation 2.6 in those regulations were references to Control 23 of this approval.

25. Field trial sites that are at risk of entry by unwanted grazing animals must be secured by stock-proof fencing to exclude grazing animals for the duration of the trial.

Use

26. The substance must only be used in a workplace.

27. The substance must only be applied using ground-based methods.

28. The substance must not be applied directly to, or enter into water or a waterway.

29. The substance must not be used outdoors as bait, or part of a bait, to target vertebrate species.

30. The use of the substance must be compliant with clause 46 of the Hazardous Substances (Hazardous Property Controls) Notice 2017, as if the substance was an agrichemical with a hazard classification in the hazard grouping environmental hazards.

31. The use of the substance must be compliant with clause 47 of the Hazardous Substances (Hazardous Property Controls) Notice 2017, as if the substances was an agrichemical with a hazard classification in the hazard grouping environmental hazards.

32. The field trials must not result in exposure of the substance to a place in which people or non-target organisms may be significantly adversely affected by the substance.

33. All reasonable steps must be taken to ensure that non-target species are not adversely affected by the use of the substance.

34. The use of the substance must be compliant with clause 58 of the Hazardous Substances (Hazardous Property Controls) Notice 2017, as if the substance was an agrichemical with the hazard classification hazardous to terrestrial invertebrates.

35. Any person that handles the substance must use personal protective clothing or equipment that is designed, constructed, and operated to ensure that the person:

    a. does not come in contact with the substance

    b. is not exposed to a concentration of the substance that may cause an adverse effect to the person.

Transport

36. No person may transport the substance on a passenger service vehicle[4].

[4] As defined in section 2(1) of the Land Transport Act 1998.

Disposal

37. The disposal of the substance must be in compliance with the Hazardous Substances (Disposal) Notice 2017.

38. Any equipment used to prepare or apply the substance must be cleaned after use, and the rinsate either sprayed within the field trial site or disposed of in compliance with the Hazardous Substances (Disposal) Notice 2017.

39. Any crop or produce to which the substance is applied, and is not permitted to be used as food, must be disposed of by mulching, ploughing-in, dropping on the ground under the tree or vine, composting or burial at the field trial site or by disposal at an approved landfill.

40. At the expiry of this approval, the substance must:
    a. have been used up, or
    b. have been disposed of, or
    c. have been exported, or
    d. be contained in a laboratory compliant with Part 18 of the Health and Safety at Work (Hazardous Substances) Regulations 2017, or
    e. be covered under a new approval.

Personnel qualifications

41. The qualification for a person that mixes, loads, or otherwise handles, or applies the substance must be compliant with the relevant qualification requirements in clauses 60, 63 and 64 of the Hazardous Substances (Hazardous Property Controls) Notice 2017 as if the substance was an agrichemical with the hazard classification hazardous to the aquatic environment acute Category 1 or hazardous to the aquatic environment chronic Category 1.

42. Any person entering the field trial site must have received sufficient instruction on the containment regime to enable the person to meet their responsibilities under this approval.

Record keeping and notification

43. Written records must be kept for each time the substance is trialled. These records must include the information specified in clause 48(3) of the Hazardous Substances (Hazardous Property Controls) Notice 2017.

44. All records kept under this approval must be held by the approval holder for not less than three (3) years after the date on which this approval expires.

45. The approval holder must provide any records kept under this approval to the EPA or WorkSafe New Zealand within five (5) working days of the approval holder receiving a written request from the EPA or WorkSafe New Zealand.

46. The approval holder must keep a record of the substance that is imported/manufactured or exported under this approval. The record must include:

a. the unequivocal identification of the substance;
b. the approval number for this containment (**HSC100295**);
c. the composition of the substance;
d. the dates of substance imported/manufactured or exported; and
e. the total quantity of the substance imported/manufactured or exported;
f. the physical address of the field trial location, including the area of land or property that is designated as the field trial site; and
g. the date and by whom the substance was applied.

47. The approval holder must notify the EPA in writing before the start of any field trial under this approval. The notification must include:

a. the application number: APP204207
b. the HSNO approval number **HSC100295**
c. the name and contact information for the person responsible for the trial
d. the physical address of the field trial location
e. the area of land or property that is designated as the field trial site
f. the date on which the trial will commence and the expected duration of the trial, and
g. the name (as given with APP204207) and total quantity of each substance that will be applied.

Emergency management

48. Any spillage of the substance must be contained, prevented from entering into any waterway, and absorbed with an appropriate material. This material must then be disposed of in compliance with the Hazardous Substances (Disposal) Notice 2017.

49. Any facility that contains the substance must be able to be readily decontaminated in the event of a spill.

Breach of containment

50. If any of the substance is applied other than in the intended application area, or are lost or spilt, the approval holder must report the nature and quantity of the substance within 24 hours of this incident to the EPA and the Regional Council or councils in whose area the incident occurred.

51. If for any reason a breach of containment occurs, other than those specified in Control 52, the approval holder must report the nature of the incident to the EPA within 24 hours of the incident occurring.

Interpretation

52. Unless defined below, terms used in the controls have the same meaning as defined in the Act or Notices made under the Act.

Term	Definition
Ground-based application methods	These methods include, but are not limited to, application by ground-boom, airblast or knapsack, and do not include aerial application methods.
Passenger service vehicle	As defined in section 2(1) of the Land Transport Act 1998.
waterway	Includes every river, stream, passage, and channel on or under the ground, whether natural or not, through which water flows, whether continuously or intermittently.

Appendix B (Confidential): Substances covered under this approval (HSC100295)

The identity of the substances covered by this approval are confidential to the applicant, and are therefore removed from the publicly available documents.