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## DECISION

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16 February 2018

### Summary

Substance name	FSN+TCM OD 80
Application code	APP203515
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	Bayer New Zealand Limited
Purpose of the Application	To import FSN+TCM OD 80 into containment for use in small-scale field trials
Date application received	8 December 2017
Consideration date	16 February 2018
Considered by	The Chief Executive <sup>1</sup> of the Environmental Protection Authority ("the EPA")
Decision	<b>Approved with controls</b>
Expiry date of approval	<b>19 February 2021</b>
Approval code	<b>HSC100168</b>

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<sup>1</sup> The Chief Executive 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. Bayer New Zealand Limited sought approval under section 32 of the Act to import FSN+TCN OD 80 ("the substance") into containment.
- 1.2. The substance is a herbicide and is intended to be used in small-scale field trials for weed control in fodder beet. The purpose of these trials is to generate data on the efficacy, crop safety, and residue profile of the substance.

## 2. Process and notification

### Application receipt

- 2.1. The application was formally received on 8 December 2017 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
  - EPA staff advice memorandum.
- 2.3. The available information is sufficient to assess the application.

### Notification to government departments

- 2.4. The Ministry for Primary Industries (Agricultural Compounds and Veterinary Medicines group) and WorkSafe New Zealand were advised of the application and invited to comment. No comments were received.

## 3. Hazardous properties

- 3.1. The applicant submitted information on the hazards of the substance for which approval is sought. Based on this information, the substance has the potential to cause significant adverse effects to human health and the environment.
- 3.2. The potential adverse effects are expected to be similar to other herbicides 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 issues below:
  - methods for preventing the escape of the contained hazardous substance and preventing the contamination of the facility
  - methods for excluding unwanted organisms from the facility or to control organisms within the facility

- methods for excluding unauthorised people from the facility
- methods for preventing unintended release of the substance by experimenters
- methods for controlling the effects of any accidental release of the substance
- Inspection and monitoring requirements of the containment facility

4.2. With this containment system in place, the applicant has identified the remaining risks that the substance may pose to human health and the environment. The EPA considered the applicant's assessment and determined that the substance 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 import, storage, transport, application or disposal of the substance. The risk of an incident occurring with the proposed controls in place is 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 complied with. These measures include the use of personal protective equipment (PPE), and qualification requirements for people preparing and handling the substance.
- 4.6. Members of the public may be exposed to the substance. This is mitigated by controls that limit access to the field-trial sites to authorised personnel only. Also, field trials are limited to sites that do not include land or facilities that the public can legally access without permission.
- 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 posed to human health and the environment by the importation of the substance into containment are negligible.
- 4.9. There are also requirements in the Health and Safety at Work (Hazardous Substances) Regulations 2017 under the Health and Safety at Work Act 2015. 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 the 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 of the substance into 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 likely 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 the substance into containment.

## New Zealand's international obligations

- 4.14. None of New Zealand's international obligations were identified as being impacted by importing the substance into 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 30(ba) 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 (Part 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 Schedule 3 requirements and 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. No comments were received within the specified timeframe.
- 5.7. Having considered all the applicable matters, the EPA has determined that the substance can be imported into 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 a hazardous substance into 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 FSN+TCM OD 80 can be adequately contained with the controls in Appendix A.
- 6.3. Therefore, this application to import FSN+TCM OD 80 into containment is granted until **19 February 2021**.



Environmental  
Protection Authority  
Te Mana Rauhi Tairā

**Dr Allan L Freeth**

**Date:** 16 February 2018

Chief Executive, EPA

## Appendix A: Controls applying to the importation of FSN+TCM OD 80 into containment

### General

1. In these controls, “approval holder” refers to Bayer New Zealand Limited.
2. In these controls, “substance” refers to, and is limited only to FSN+TCM OD 80.

### Accountability

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

### Requirement for containment

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

### Limitations

5. This approval expires on **19 February 2021**.
6. The approval holder must ensure that the nature of the field trials are in accordance with the activities proposed in application APP203515, unless otherwise specified by the controls on this approval.
7. Over the term of this approval, the approval holder may import up to 25 kilograms or 25 litres, of FSN+TCM OD 80.

### General requirements

8. The substance must be correctly packaged. The substance is correctly packaged if it is packed in accordance with the Hazardous Substances (Packaging) Notice 2017 and the packaging complies with the same notice.
9. The substance must be correctly labelled. The substance is correctly labelled if it is packed in a container that is labelled in accordance with the Hazardous Substances (Labelling) Notice 2017. The label must include the name and contact details for Bayer New Zealand Limited, including a 24-hour emergency service telephone number.
10. A safety data sheet (SDS) must accompany the substance at all stages of its life cycle 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

11. Clauses 39 to 42 of the Hazardous Substances (Hazardous Property Controls) Notice 2017 apply to this approval, as if the substance were class 9.1A.

## Field-trial site

12. Each field trial of the 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.
13. The field-trial site must include:
  - a. all preparation, storage and operational areas related to the study
  - b. all necessary buffer zones
  - c. any area used for cleaning equipment or disposing of rinse water
  - d. any area on which any excess mixture of the substance is applied.
14. The field-trial site must not include land or facilities that the public can legally access without permission of the owner or legal occupier.
15. Unauthorised people must be excluded from the field-trial site.
16. Signs must be displayed at every vehicular and pedestrian entrance to the field-trial site 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 the substance that is being trialled
  - c. the immediate response action to be taken in an emergency
  - d. that unauthorised access to the site is not permitted
  - e. a 24-hour emergency service telephone number
17. The management of the signs referred to in Control 16 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 16 of this approval.
18. Field-trial sites that are at risk of entry by grazing animals must be secured by stock-proof fencing to exclude grazing animals for the duration of the trial.

## Use

19. The substance must only be used in a workplace.
20. The substance must only be applied using ground-based methods.
21. The substance must not be applied directly to, or enter into water or a waterway.
22. The substance must not be used outdoors as bait, or part of a bait, to target vertebrate species.
23. Any crop or produce to which the substance is applied must not be used for food by people or animals, unless that use is specifically permitted by the Agricultural Compounds and Veterinary Medicines group of the Ministry for Primary Industries.

24. The use of the substance must be compliant with clause 46 of the Hazardous Substances (Hazardous Property Controls) Notice 2017, as if the substance were a class 9 pesticide.
25. The use of the substance must be compliant with clause 47 of the Hazardous Substances (Hazardous Property Controls) Notice 2017, as if the substance were a class 9 pesticide.
26. The field trials must not result in exposure of any of the substance to a place in which people or organisms may be significantly adversely affected by the substance.
27. All reasonable steps must be taken to ensure that non-target species are not adversely affected by the use of the substance.
28. The use of the substance as a seed treatment must be compliant with clause 54 of the Hazardous Substances (Hazardous Property Controls) Notice 2017, as if the substance were a class 9.3 pesticide.
29. The use of the substance in a granular form must be compliant with clause 55 of the Hazardous Substances (Hazardous Property Controls) Notice 2017, as if the substance were a class 9.3 pesticide.
30. The use of the substance must be compliant with clause 58 of the Hazardous Substances (Hazardous Property Controls) Notice 2017, as if the substance were a class 9.4 pesticide.
31. 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.

### **Storage**

32. The substance must be held in a locked container when not in use.

### **Transport**

33. No person may transport the substance on a passenger service vehicle<sup>2</sup>.

### **Disposal**

34. The disposal of the substance must be in compliance with the Hazardous Substances (Disposal) Notice 2017.
35. 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.

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<sup>2</sup> As defined in section 2(1) of the Land Transport Act 1998.



36. Any crop or produce to which the substance is applied, and is not permitted to be used as food by Control 23, must be disposed of by mulching, ploughing-in, composting or burial at the field-trial site or by disposal at an approved landfill.
37. At the expiry of this approval, the substance must:
  - a. have been used up, or
  - b. have been disposed of, or
  - c. be contained in a laboratory compliant with Part 18 of the Health and Safety at Work (Hazardous Substances) Regulations 2017, or
  - d. be covered under a new approval.

### Personnel qualifications

38. The qualification of a person that mixes, loads, or otherwise handles the substance in preparation for application 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 were a class 9.1A, 9.2A, 9.3A, or 9.4A pesticide or plant growth regulator.
39. 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

40. Written records must be kept of the amount of the substance imported under this approval.
41. 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.
42. All records kept under this approval must be held by the approval holder for not less than three years after the date on which this approval expires.
43. The approval holder must provide any records kept under this approval to the EPA or WorkSafe New Zealand within 5 working days of the approval holder receiving a written request from the EPA or WorkSafe New Zealand.
44. The approval holder must notify the EPA in writing of the location of each field trial before the substance is first applied at that location. For each efficacy trial this must occur no later than five working days before the substance is first applied and for each residue field trial no later than 10 working days before the substance is first applied. The notification must include:
  - a. the application number: **APP203515**
  - b. the HSNO approval number **HSC100168**
  - 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 quantity of the substance that will be applied.

### Emergency management

- 45. 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.
- 46. Any facility that contains the substance must be able to be readily decontaminated in the event of a spill.

### Breach of containment

- 47. If 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.
- 48. If for any reason a breach of containment occurs, other than those specified in Control 47, the approval holder must report the nature of the incident to the EPA within 24 hours of the incident occurring.

### Interpretation

- 49. 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 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.