



SECTION 67A AMENDMENT OF APP201613

21 December 2017

Summary

Substance	Plant & Food Research Experimental Plant Protection Compounds
Amendment application number	APP203818
Type	Minor or technical amendments to approvals under Section 67A of the Hazardous Substances and New Organisms Act 1996 ("the Act")
Purpose	To make a minor or technical amendment to approval HSC100088 "To import or manufacture Plant & Food Research Experimental Plant Protection Compounds in containment"
Consideration date	07 March 2019
Considered by	The General Manager ¹ of the Hazardous Substances and New Organisms group of the Environmental Protection Authority ("the EPA")
Decision	The approval is amended
Original application number	APP202019
Approval number	HSC100112

¹ The General Manager of the HSNO 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. A containment approval, HSC100112 was granted on 11 March 2014 to The New Zealand Institute for Plant and Food Research Limited. The purpose of that application was to import or manufacture Plant & Food Research Experimental Plant Protection Compounds in containment for field trials (approval number HSC100112).
- 1.2. The Environmental Protection Authority (EPA) is seeking to amend the decision document and one of the controls for the original approval HSC100112. The amendment proposes to extend the approval expiry date from 11 March 2019 to 31 May 2019 in paragraph 7.4 of the original decision document and control 1 of Appendix A: Controls applying to Plant & Food Research Experimental Plant Protection Compounds.

2. Eligibility

- 2.1. According to section 67A of the HSNO Act, the EPA may amend any approval it has granted if it considers that the alteration is minor in effect or corrects a minor or technical error.
- 2.2. The alteration of the expiry date is considered to be minor in effect as it will not change the risks associated with Plant & Food Research Experimental Plant Protection Compounds, and will not affect the containment of the substances.

3. Amendment

- 3.1. The decision document and the controls for application APP202019, approval number HSC100112, are modified in the following ways:
 - “11 March 2019” is replaced with “31 May 2019” in paragraph 7.4 of the original decision document
 - “11 March 2019” is replaced with “31 May 2019” in Control 1 of Appendix A: Controls applying to Plant & Food Research Experimental Plant Protection Compounds.

4. Consideration

- 4.1. Pursuant to section 67A of the Act, I have considered the proposal to amend the containment approval for Plant & Food Research Experimental Plant Protection Compounds (HSC100112), which was issued under application APP202019.
- 4.2. I am satisfied that the amendment is minor in effect and I have therefore amended the approval.



Dr Fiona Thomson-Carter

Date: 7 March 2019

General Manager, HSNO, EPA



DECISION

Amended under section 67A on 15 January 2016

11 March 2014

1. Summary

Substance	Plant & Food Research Experimental Plant Protection Compounds
Application code	APP202019
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	The New Zealand Institute for Plant & Food Research
Purpose of the Application	To import and manufacture Plant & Food Research Experimental Plant Protection Compounds in containment for use in field trials to evaluate their use as pesticides and plant protection compounds on various crops
Unique identifier of substance	Plant & Food Research Experimental Plant Protection Compounds
Date application received	27 January 2014
Consideration date	11 March 2014
Considered by	The Chief Executive ¹ of the Environmental Protection Authority ("the EPA")
Decision	Approved with controls
Approval code	HSC100112

¹ The Chief Executive of the EPA has made the decision on this application under delegated authority in accordance with section 19 of the Act.

2. Background

- 2.1. The New Zealand Institute for Plant & Food Research is a Crown Research Institute which conducts research to improve the production of fruit, vegetable, crop and food products. This includes research with new plant protection products and methods, including biopesticides and semiochemicals.
- 2.2. A containment approval is required to conduct studies with experimental substances that are not currently approved for use in New Zealand, or which are not yet approved for some purposes. A generic containment approval allows a company to test unapproved substances without having to apply for an approval each time. Such approvals are time limited and are assigned controls that must be complied with.
- 2.3. In this application *Plant & Food Research Experimental Plant Protection Compounds* refers to a number of experimental substances that are intended to regulate plant growth; activate plants' natural defence mechanisms; control weeds, pests and diseases in agricultural and horticultural crops and seeds; act as insect semiochemicals (insect signalling or attractant chemicals) and/or be used for biosecurity purposes.
- 2.4. The purpose of this application is to import or manufacture limited quantities of experimental hazardous substances in containment for research and development. The substances will be trialled in New Zealand with the intention of gaining full approval under the Act and registration under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997. The applicant has stated that the trials are intended to be conducted on private land, although trials of semiochemicals may be conducted on publicly accessible land such as parks or reserves.

3. Eligibility and consultation

- 3.1. The purpose of the application (see Appendix D for the application form) is to conduct 'research and development on any hazardous substance', therefore, I consider that the application qualifies for consideration as a containment approval under section 30(ba) of the Act.
- 3.2. The staff of the EPA ("the staff") have reviewed the application, the draft ACVM Operating Plan, and the proposed containment system. The staff have advised me that the information is sufficient to understand what is proposed, and to assess the risks involved.
- 3.3. Worksafe New Zealand², the Ministry for Primary Industries (ACVM Group), and Department of Conservation were advised of the application and invited to comment. No comments were received.

² Formerly the Department of Labour, (and most recently) the Labour group of the Ministry of Business and Innovation

4. Hazardous properties

- 4.1. The staff have advised me that the hazard information available on the substances is limited because the substances are experimental and not yet commercialised. However, it is assumed that *Plant & Food Research Experimental Plant Protection Compounds* have the potential to cause adverse effects to human health and the environment. Therefore, controls have been assigned to *Plant & Food Research Experimental Plant Protection Compounds* to mitigate the potential effects of those substances and ensure that they are adequately contained.

5. Potential risks

- 5.1. The applicant has identified and assessed the potential risks posed by *Plant & Food Research Experimental Plant Protection Compounds* and has provided detailed proposals to manage those risks. The staff have assessed the risks to the environment, human health and Māori cultural issues as set out below.
- 5.2. Based on the considerations below and presuming compliance with the controls imposed, I consider that *Plant & Food Research Experimental Plant Protection Compounds* can be adequately contained.

Risks to the environment

- 5.3. The staff have advised me that adverse effects on the environment could arise from:
- an accident during manufacture, storage, application or transportation of a *Plant & Food Research Experimental Plant Protection Compound*, resulting in their release. For example, a spill could contaminate a waterway.
 - spray drift (droplet and/or vapour drift) beyond the boundary of the trial site, which could adversely affect beneficial plants and insects.
 - failure to follow procedures in Section 4 of the application (see Appendix D) and the draft ACVM Operating Plan (see Appendix C), resulting in the release of the substances beyond containment, which may result in the destruction of beneficial plants and insects.
- 5.4. The controls in Appendix A are set to reduce the likelihood of these adverse effects occurring. These controls relate to the packaging, storage, handling, transport, use, emergency management and disposal of *Plant & Food Research Experimental Plant Protection Compounds*. They also set requirements for field trials to ensure that *Plant & Food Research Experimental Plant Protection Compounds* are kept contained.
- 5.5. After taking into account the containment regime proposed by the applicant, the containment controls in Appendix A and controls in place under other legislation, I consider that the risks to the environment are negligible.

Risks to human health

- 5.6. The staff have advised me that adverse effects on human health could arise from:
- an accident during storage, transportation, application or disposal of a *Plant & Food Research Experimental Plant Protection Compound*, resulting in its release. For example, a spill could result in a worker being exposed.
 - removal of a substance, or sprayed produce, from the trial site by unauthorised visitors; or removal of sprayed produce by livestock that enter the site and consume produce sprayed with the substance.
 - exposure of people to volatile or semi-volatile substances used to attract insects to traps and/or which are released into the air to kill insects.
 - exposure to micro-organisms (as biopesticides) which people are not normally exposed to, or where exposure is normally very small, or where people are exposed via a different exposure route than when they are exposed to the same microorganism in the natural environment (e.g. respiratory exposure to a soil organism that people are normally only exposed to via the skin).
 - failure to follow procedures in Section 4 of the application (see Appendix D) and the draft Operating Plan (see Appendix C) resulting in the release of the substances from containment and people being exposed to the substance. For example, people could be exposed to *Plant & Food Research Experimental Plant Protection Compounds* if they do not use the personal protective equipment specified in the trial management plan.
- 5.7. The controls in Appendix A are set to reduce the likelihood of adverse effects occurring. These controls relate to the packaging, application, emergency management and disposal of *Plant & Food Research Experimental Plant Protection Compounds*. They also set requirements for field trials to ensure that *Plant & Food Research Experimental Plant Protection Compounds* are kept contained.
- 5.8. After taking into account compliance with the containment regime proposed by the applicant, the containment controls in Appendix A and controls in place under other legislation, I consider that the risks to human health are negligible.

Risks to the relationship of Māori to the Environment

- 5.9. The staff have considered the potential Māori cultural effects of this application in accordance with sections 6(d) and 8 of the Act.
- 5.10. From the information provided, and considering that the application is for containment, the staff have advised me that *Plant & Food Research Experimental Plant Protection Compounds* are unlikely to have an impact on the relationship between Māori culture and their traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga. This is

on the condition that the substances are used in accordance with the controls established for this application, and in accordance with any other relevant controls applying under other legislation.

- 5.11. The trial of these substances does not involve significant community exposure or significant exposure to the environment; therefore the staff have advised me that it is not necessary to consult with Māori on this application.
- 5.12. There is no evidence to suggest that the controlled application of *Plant & Food Research Experimental Plant Protection Compounds* by individuals with relevant qualifications and training will breach the duties of the EPA to protect taonga and improve Iwi/Māori participation in Hazardous Substances decision making in alignment with the principles of the Treaty of Waitangi as expressed in the Act.
- 5.13. However, should the application, transport or disposal of the substances result in the contamination of waterways, the approval user must notify iwi authorities within 24 hours, to minimise any potential effect on traditional practises, such as food gathering. This should include advising iwi of the nature of the contamination and the measures taken in response.

6. Controls

- 6.1. Under section 32 of the Act, a containment approval must include controls for each of the applicable matters specified in Schedule 3 of the Act and may include controls that provide for any other matters in order to give effect to the purpose of the Act.
- 6.2. The purpose of the controls is to ensure that the substances can be adequately contained.
- 6.3. Schedule 3 requires that the following matters be addressed:
 - preventing the escape of the contained hazardous substance and preventing the contamination of the facility
 - excluding unwanted organisms from the facility or controlling organisms within the facility
 - excluding unauthorised people from the facility
 - preventing unintended release of the substance by experimenters
 - controlling the effects of any accidental release of the substance, and
 - inspection and monitoring requirements of the containment facility
- 6.4. The applicant has indicated how the Schedule 3 matters will be addressed in the application form and confidential information provided with the application. They have also supplied an Draft ACVM Operating Plan (see Appendix C) which sets out management standards for the field trials.
- 6.5. Taking the Schedule 3 requirements and the applicant's containment and trial plans into account, the Staff have prepared a set of controls that they consider should be applied to *Plant*

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& *Food Research Experimental Plant Protection Compounds* to ensure containment of the substances. The controls to be imposed on this approval are listed in Appendix A.

- 6.6. The applicant was given an opportunity to comment on the proposed controls as set out in this decision. The applicant provided feedback which staff addressed including where appropriate making amendments to the proposed controls.

7. Decision

- 7.1. Pursuant to section 32 of the Act, I have considered this application to import or manufacture hazardous substances in containment made under section 31 of the Act and have applied the relevant sections of the Act and clauses of the Hazardous Substances and New Organisms (Methodology) Order 1998 (“the Methodology”) as detailed in the decision path and explanatory notes available from the EPA website³.
- 7.2. Having considered the risks associated with *Plant & Food Research Experimental Plant Protection Compounds*, I am satisfied that the controls imposed will result in the substances being adequately contained.
- 7.3. The application to import or manufacture in containment *Plant & Food Research Experimental Plant Protection Compounds* for the purpose of research and development is **approved with controls** as set out in Appendix A and in accordance with the relevant provisions of the Act and the Methodology.
- 7.4. This approval expires on the 11 March 2019.

Rob Forlong

Date: 11 March 2014

Chief Executive, EPA

³<http://www.epa.govt.nz/publications/er-pr-02-decision-paths.pdf>

Amendment: December 2015

The original decision required the following:

1. Any person handling a *Plant & Food Experimental Plant Protection Compound* to be an approved handler or work under the direct supervision of an approved handler; and
2. That the approval user notify the EPA of all trials 10 working-days before the substance is applied in a trial. The applicant requested that these aspects of the approval be changed because they made it difficult to conduct research on semiochemical efficiently; and they proposed that semiochemicals pose a lower risk than other substances covered by the approval.

The proposed amendments were considered minor in effect because the approval is only applicable to one organisation, i.e. the applicant. Therefore, the following amendments are proposed under section 67A of the HSNO Act:

Vary control 32

1. To vary control 32 of approval HSC100112 to allow people handling experimental semiochemicals to complete a course of approved in-house training, as detailed in Appendix A, rather than approved handler training.

2. Current wording of the control:

Any person handling or applying a Plant & Food Experimental Plant Protection Compound must either be an approved handler or work under the direct supervision of an approved handler.

3. Revised wording:

Any person handling or applying a Plant & Food Experimental Plant Protection Compound must either:

- a. *be an approved handler; or*
- b. *work under the direct supervision of an approved handler; or*
- c. *have completed the in-house semiochemical handlers training prescribed in Appendix E within the five years prior to handling semiochemicals.*

Reduction of the trial notification timeframe

- Semiochemical trials need to be notified to the EPA to “before the substance is applied in a trial”, instead of notifying the EPA “10 working-days” before the substance is applied in a trial.

Re-ordering of the controls

- The controls have been re-ordered to clearly identify which controls apply only to semiochemicals, and which controls apply only to other substances covered by the approval

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(i.e. pesticides and biopesticides). The reason for re-ordering the controls is to make the controls easier to understand.

Therefore, the proposed amendments are approved in accordance with section 67A of the HSNO Act, and I confer the revised controls, as specified in Appendix A, on this substance.



Environmental
Protection Authority
Whana Rauwhānui

Dr Allan Freeth

Date: 15 January 2016

Chief Executive, Environmental Protection Authority

Appendix A: Controls applying to Plant & Food Experimental Plant Protection Compounds

General

1. This approval expires on 11 March 2019.
2. This approval is limited to substances being studied by or on behalf of The New Zealand Institute for Plant & Food Research which is referred to in the controls as the “approval user”.
3. For the purposes of this approval the term *Plant & Food Experimental Plant Protection Compound* includes any chemical pesticide, biopesticide, plant growth regulator, plant activator or semiochemical; or any combination of these, which is used as a plant protection product; but excludes:
 - a. any vertebrate toxic agent, including any substance that is intended to kill or deter any vertebrate animal.
 - b. any substance, or microbial active ingredient of a substance (including biopesticides) which contains a new organism, as defined by the Act. If the new organism status of a substance or the microbial active ingredient in a substance is in doubt, then it should be considered a new organism and is not covered by this approval.
4. This approval applies only to the ground based application of *Plant & Food Experimental Plant Protection Compounds*. This approval excludes any aerial application of the substances and excludes any application of the substances directly to water⁴.
5. ⁵Controls listed under heading “semiochemicals only” (Conditions 40 – 50) only apply to semiochemicals, controls listed under the heading “non-semiochemicals” do not apply to semiochemicals (Conditions 32 – 39).
6. This approval does not apply to substances which trigger any hazardous property thresholds in classes 1, 2, 3.2, 4 or 5.2.
7. The approval user may import or manufacture a maximum of 250 L or 250 kg of each *Plant & Food Experimental Plant Protection Compound* over the term of this approval.

Manufacture

8. The approval user must ensure that *Plant & Food Experimental Plant Protection Compounds*, which are manufactured in New Zealand, are only manufactured in a secure laboratory (i.e. a laboratory accessible only by a swipe-card or similar security access system).

⁴ Water means any fresh water or geothermal water in a river, lake, stream, pond, wetland, or aquifer, or any part thereof.

⁵ Added by amendment, December 2015

Packaging and Information

9. The approval user must ensure that when each *Plant & Food Experimental Plant Protection Compound* enters New Zealand, or after it is manufactured, it is securely packed in containers that comply with the Hazardous Substances (Packaging) Regulations 2001.
10. The approval user must ensure that packages containing a *Plant & Food Experimental Plant Protection Compound* are:
 - a. labelled in accordance with the Hazardous Substances (Identification) Regulations 2001; and
 - b. that the label includes an instruction that the substance is the subject of a trial, and that any of the substance remaining after the trial must be returned to The New Zealand Institute for Plant & Food Research in the original container.
11. The approval user must ensure that information on safety precautions necessary to provide safeguards against any of the substance's physical, toxic and ecotoxic properties accompanies each substance at all stages of its lifecycle in New Zealand. This must include, but not be limited to, information on the protective clothing that is to be used when handling the substance and first aid measures.
12. The approval user must ensure that a safety data sheet accompanies each *Plant & Food Experimental Plant Protection Compound* throughout its lifecycle in New Zealand.

Storage

13. The approval user must ensure that each *Plant & Food Experimental Plant Protection Compound* is kept in locked storage when not in use. Locked storage includes, but is not limited to, a secure laboratory.

Transport

14. No person may transport a *Plant & Food Experimental Plant Protection Compound* on a passenger service vehicle⁶.

Field trial sites selection

15. The approval user must designate an area (or areas) as the trial site (or sites) for each trial, which may be all or part of a property or facility.
16. The trial site must include all of the following:
 - 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; and
 - d. any area on which any excess mixture of the substance (tank mix) will be sprayed.

⁶ As defined in section 2(1) of the Land Transport Act 1998.

Field trials

17. The approval user must ensure that the trials are undertaken in accordance with the application form, attached to and forming part of this approval as Appendix D, and the project plan (see Appendix B) which accompanies the notification of each substance.
18. The approval user must ensure that the trials do not result in any residential building or workplace, which is not related to the research, being exposed to a *Plant & Food Experimental Plant Protection Compound*.
19. The approval user must ensure that produce treated with a *Plant & Food Experimental Plant Protection Compound* is not eaten by people or animals, sold, or otherwise distributed unless that use has been authorised under the Agricultural Compounds and Veterinary Medicines Act 1997.
20. The approval user must take measures to ensure that livestock do not enter the trial site; except where grazing by livestock is permitted by control 29 and is included in the trial plan submitted as part of the notification of the trial.

Records

21. The approval user must keep a record of each application of a *Plant & Food Experimental Plant Protection Compound*. This record must include, but is not limited to, the details representing all matters referred to in Regulation 6(1) of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001. Each record of application must be kept for three years from the date on which the final trial is completed under this approval.
22. The approval user must make all records kept under this approval are made available to the EPA or a HSNO enforcement officer within 48 hours of receiving a written request for those records.

Emergency Management

23. The approval user must ensure that the storage, use, transport or disposal of *Plant & Food Experimental Plant Protection Compounds* complies with the emergency management provisions as prescribed by the Hazardous Substances (Emergency Management) Regulations 2001.
24. The person with overall responsibility for each trial must ensure that the trial site and trial activities comply with the emergency management provisions as prescribed by the Hazardous Substances (Emergency Management) Regulations 2001.
25. Any person handling a *Plant & Food Experimental Plant Protection Compound* must ensure that any spill, and any material contaminated by a spill, is collected and placed in a sealed container, and then returned to the New Zealand Institute for Plant & Food Research for disposal.

Disposal

26. The approval user must ensure that any unused *Plant & Food Experimental Plant Protection Compounds*, and any containers which held a *Plant & Food Experimental Plant Protection Compound*, are disposed of in a manner compliant with the Hazardous Substances (Disposal) Regulations 2001.
27. The approval user must ensure that any produce sprayed with *Plant & Food Experimental Plant Protection Compounds*, which is not permitted to be used as food under clause 29, is disposed of by mulching, ploughing in, composting, or by burial at the trial site or by disposal at a landfill.
28. The approval user must ensure that at the expiry of this approval all *Plant & Food Experimental Plant Protection Compounds*:
 - a. have been used
 - b. have been disposed of
 - c. are contained in a laboratory with HSNO exempt status; or
 - d. are covered by a new approval under the Act.

Breach of containment

29. If for any reason a breach of containment occurs, the approval user must notify the EPA within 24 hours of the breach being detected.
30. If a breach in containment results in contamination of a waterway, the approval user must notify the relevant regional council and local iwi authorities within 24 hours. Contact details for iwi authorities are available from the relevant regional council.
31. Each notification of a breach of containment must include information about the nature of the breach and the measures taken in response to the breach.

Controls that apply to non-semiochemicals

Trial site

32. The trial site must not include any area that the public have legal access to (public place)

Notification

33. The approval user must notify the EPA of each substance imported or manufactured under this approval. The information specified in the Project Plan (Appendix B) must be notified to the EPA in writing at least 10 working days before the start of the trial.
34. The trial location and the date that the substance is first applied or administered in the trial must be notified to the EPA in writing no later than 48 hours after the substance is applied or administered for the first time. This notification must include:
 - a. Application number: APP202019
 - b. HSNO approval number: HSC100112

- c. Unique Identifier of the substance (product name or code)
- d. Address of the trial location
- e. Identification of the trial location within the trial sites (e.g. whole property, field number, description)
- f. Date (day/month/year) that the substance was applied or administered

Trial site

35. The approval user must take measures to ensure that no person enters a trial site without the express permission of the approval holder's representative on site.
36. The approval user must ensure that signs are displayed at each entrance to each trial site. The signs must state that an *Plant & Food Experimental Plant Protection Compound* is in use at the site and:
 - a. that the site is subject to a field trial of a hazardous substance
 - b. that unauthorised access to the site is not permitted; and
 - c. must display a telephone number of the approval holder's representative on site.

Handling and personal protective equipment

37. The approval user must ensure that each person handling or using a *Plant & Food Experimental Plant Protection Compound* has read, understood, and complies with:
 - a. the controls in this approval; and
 - b. the project plan which accompanies the notification of the substance, or substances, which that person will be handling.
38. Any person handling or applying a Plant & Food Experimental Plant Protection Compound must either be an approved handler or work under the supervision of an approved handler.
39. Any person applying⁷ a *Plant & Food Experimental Plant Protection Compound*, which is, or contains, a biopesticide must wear respiratory protection (mask or respirator) when preparing, spraying or disposing of the spray mix, in addition to any other PPE that is specified for that substance.

⁷ This should be taken to include people in the immediate vicinity of the application activity who may be observing or taking notes as well as people physically handling the substance.

Controls that apply to semiochemicals only

Trial site

40. The trial site must not include any area that the public have legal access unless the substance being trialled:
 - a. is a semiochemical, and
 - b. does not contain any biocidal active ingredients; and
 - c. is used in or with a trap, lure or dispenser (i.e. the substance may not be sprayed).

Field trial sites on private land

41. Conditions 42-43 apply to field trials in places that the public cannot legally access (e.g. on private land).
42. The approval user must take measures to ensure that no person enters a trial site without the express permission of the approval holder's representative on site.
43. The approval user must ensure that signs are displayed at each entrance to each trial site. The signs must state that an *Plant & Food Experimental Plant Protection Compound* is in use at the site and:
 - a. that the site is subject to a field trial of a hazardous substance
 - b. that unauthorised access to the site is not permitted; and
 - c. must display a telephone number of the approval holder's representative on site.

Field trial sites in areas that the public can legally access

44. Controls 45-48 apply to field trials in places that the public can legally access (e.g. public land).
45. The approval user must obtain written permission for the trial from the relevant local authority, government department or organisation that administers the site.
46. The approval user must ensure that the traps/lures/dispensers are placed in locations that minimise the likelihood of the public coming into contact with the traps/lures/dispensers.
47. The approval user must ensure that the following information is displayed (e.g. as a label) on each trap, lure or dispenser used:
 - a. an indication that the trap, lure or dispenser (or other appropriate description) is part of a field trial of a hazardous substance
 - b. the statement "Please do not touch"
 - c. a trial name or reference number
 - d. the telephone number of the approval holder's representative who is responsible for the trial.

48. The approval user must ensure that signs are displayed at each entrance to each trial site. The signs must state that an *Plant & Food Experimental Plant Protection Compound* is in use at the site and:
- that the site is subject to a field trial of a hazardous substance, and
 - the phrase “Please do not touch or remove traps”⁸, and
 - must display a telephone number of the approval holder’s representative on site.

Notification

49. The approval user must notify the EPA of each substance imported or manufactured under this approval in writing before the start of the trial it is used in. The notification must include the information specified in the Project Plan (Appendix B).

Handling and personal qualifications

50. Any person handling or applying a Plant & Food Experimental Plant Protection Compound that is a semiochemical must either:
- be an approved handler; or
 - work under the direct supervision of an approved handler; or
 - have completed the in-house semiochemical handlers training prescribed in Appendix E within the five years prior to handling semiochemicals.

Interpretation

51. In these controls, unless otherwise specified below, a word has the same meaning as it is defined in the HSNO Act (if any).
52. Unless the context otherwise requires, the words/phrases listed below have the following meaning:

Term	Description
Semiochemical	Semiochemical is a chemical substance or mixture that carries a message between organisms e.g. pheromones.

⁸ The term ‘traps’ may be substituted for lure, dispenser or a similar word or phrase that describes the type of trap/lure/dispenser that is being used for the study.

Appendix B: Contents of Project Plan

The project plan to be supplied for each substance must contain information on the following points:

1. Project title
- 1a⁹ Application number: APP202019
- 1b⁹ HSNO approval number: HSC100112
2. Name, position and contact details of the person with overall responsibility for the trial
3. Purpose or objectives of the trial
4. Trial dates (earliest start date and latest completion date) (day/month/year)
5. Unequivocal identification of the substance (product name or code)
6. The name, CAS number or (systematic chemical name) and % of the active ingredient/s of each substance.
7. Species and strain of microbe used if the substance is, or contains a biopesticide
8. Quantity of substance manufactured
9. Quantity of substance applied at each application
10. Address of the trial location(s) (or a map if an address is not applicable to the area)
11. Identification of the trial site(s) within the trial location(s) (e.g. description, diagram, map)
12. Total treated area
13. Application method
14. Application rate
15. Steps taken to ensure that any bees are not adversely affected by the trial (if the effects on bees is part of the trial this should be indicated)
16. The security systems and containment provisions specific to the location
17. Intended method for disposing of treated produce (where applicable)
18. A copy of the provisional registration under the ACVM Act, or an ACVM approved operating plan or other ACVM documentation that permits the substance to enter the food chain (only required if produce sprayed with the substance is used as food for humans or animals)

⁹ Added by amendment December 2015

Confidential Appendix C: Trial Management Plan

This section contains the confidential appendices submitted as part of the application form.

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Appendix D: Application Form

Appendix E: Semiochemical handlers training curriculum

Introduction

1. This training program is a substitute for approved handlers training for staff using semiochemicals only, other substances covered by this approval e.g. experimental pesticides and biopesticides are not covered by this training and require an approved handler's certificate.

The trainer

2. The training must be delivered by someone who is experience at using semiochemicals in the field and is familiar with the requirements of the containment approval and HSNO requirements covered in the training.

Frequency of training

3. This training can be completed by staff as required but must be completed at least every five years. i.e. this training is considered to expire five years from the date of completion.

Handouts and reference materials

4. Inform trainees of the location of the training booklet so they can reference it at any stage
5. Inform trainees about how to access the containment approval for future reference.

Testing competence

6. Trainees' competence will be tested by a quiz or written test and an assessment of their practical skills by the trainer or someone who has completed this training or approved handler training.

Training records

7. A record of training must be kept until the training qualification expires (e.g. five years) or until the trainee is no longer employed by Plant & Food.

Topics covered in the training

Overview of relevant regulations and the responsibilities the regulators {P8&9}

- HSE (Worksafe), health and safety
- HSNO (EPA), manages hazardous properties of substances {P13-15}
- What the legislation means {P29}

The containment approval HSR100112

- Containment approval for Experimental Plant Protection Compounds (APP202019)
- ensure staff are familiar with the controls of this approval, including what to do in the event of a breach in containment
- ensure staff are familiar with the ACVM operating plan

Notifying trials

- Need to notify EPA before putting out trials
- What is included in this
- Need to notify land owner that you are putting out trial on their land

Safety data sheets (SDS)

- What an SDS is
- Pictograms {P41}
- How to find toxicological information
- How to find ecological information
- Explain chemical classes, what they mean and where they are on MSDS {P16-18}
- LD₅₀, ~<2000 is dangerous {P42-43}
- Definition of risk {P44}
- PPE, {P45-47}

Understanding the risks of semiochemicals

- Hazards of semiochemicals to human health and the environment.
- Precautions to minimise risks

Management of experimental semiochemicals

8. Packaging-
 - How semiochemicals will be packaged?
9. Storage
 - Chemicals must be stored safely and securely, away from unauthorised people {P54-56}
10. Transport –
 - It will say on SDS how much can be transported before needing “D” on license and
 - If transporting bulk chemicals, must be securely tied down, not in the cab with you etc {P50-51}
11. Keeping Records - Each trial needs to be recorded
 - Working in public places and signage requirements
12. Emergency management
 - Eliminate, isolate, minimise {P27}
 - Emergency response plan {P22-23}, and whereabouts
 - Risks associated

Application for approval to import or manufacture Plant & Food Experimental Plant Protection Compounds in containment (APP202019)

- Safe, responsible, effective {P5}
13. Tracking chemicals {P21}
- All info on the movement of tracked substances must be recorded
14. Disposal
- Excess chemical to be disposed of in waste containers in lab, which are taken away and dealt with by chemical company.
 - Empty chemical/solvent containers – leave in fume hood until contents evaporate, throw away in sharps container.
 - Used lures are brought in from the field and disposed of with the normal waste. The quantities used are small enough that by the time they come in from the field the majority of the semiochemical has evaporated, and is ok to be disposed of normally.