Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

22 March 2019

Summary

Substance Name	Cholecalciferol extruded pellet bait and 1080 extruded pellet bait
Application code	APP203788
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	Invasive Pest Control Limited
Purpose of the Application	To manufacture Cholecalciferol extruded pellet bait and 1080 extruded pellet bait in containment to carry out cage trials on rats and possums to generate efficacy data that will be used to register these formulations for use on rats and possums in New Zealand
Date application received	14 February 2019
Consideration date	22 March 2019
Considered by	The General Manager[1] of the Hazardous Substances and New Organisms group of the Environmental Protection Authority ("the EPA")
Decision	**Approved with controls**
Expiry date of approval	**22 March 2020**
Approval code	**HSC100195**

[1] 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. Invasive Pest Control Limited (“the applicant”) sought approval under section 32 of the Act to manufacture two hazardous substances (“the substances”) in containment.

1.2. These substances are vertebrate toxic agents (VTAs). The active ingredients for Cholecalciferol extruded pellet bait and sodium monofluoroacetate (1080) extruded pellet bait have individual approvals in New Zealand.

1.3. The purpose of the application was to manufacture the substances in containment to carry out cage trials on rats and possums to generate efficacy data that will be used to register these formulations for use on rats and possums in New Zealand.

2. Process and notification

Application receipt

2.1. The application was formally received on 14 February 2019 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 substances
- EPA staff containment evaluation report.

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

Notification to government departments

2.4. The Ministry for Primary Industries (ACVM group) and the Department of Conservation (DOC) were advised of the application and invited to comment. No comments were received by ACVM.

2.5. General comments were provided by DOC regarding other similar substance approvals granted by the EPA and that they may relate to this application.

3. Hazardous properties

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

3.2. Based on the available information, these substances may cause adverse effects to human health and the environment. The potential adverse effects are expected to be similar to other VTAs 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 substances may cause adverse effects to human health and the environment if people or non-target organisms are exposed to the substances.

4.4. The substances could potentially contaminate waterways, groundwater, soil or neighbouring properties. These potential exposures could result from an incident during transport or disposal of the substances. If exposure occurs, the substance may pose a risk to aquatic organisms or non-target vertebrates. The likelihood 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 substances. However, it is unlikely that people using the substances 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 substances.

4.6. There is also a risk that members of the public may be exposed to the substances. This is mitigated by controls that limit access to the cage-trial facilities to authorised personnel only. The application areas do not include land or facilities that the public can legally access without permission.

4.7. Non-target animals may be exposed to the substances via consumption of any uneaten or unused substances and/or treated rat or possum carcasses. This is mitigated by limiting the use of the substances to cages during the trial period and by adding a control that specifies the substances and rat and possum carcasses must be disposed of in accordance with the Hazardous Substances (Disposal) Notice 2017. The approval holder is also required to ensure that non-target species are not adversely affected by the use of the substances.

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 manufacture of the substances (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 substances 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 manufacture of the substances in containment will impact on Māori culture or traditional relationships with the environment.

4.12. If the substances are 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 manufacturing the substances in containment.

New Zealand's international obligations

4.14. None of New Zealand's international obligations were identified as being impacted by 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 substances, in accordance with section 30(b) and section 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 substances can be adequately contained. The potential for the substances 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 substances.

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 substances.

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

5.7. Having considered all the applicable matters, the EPA has determined that the substances can be 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 manufacture Cholecalciferol extruded pellet bait and 1080 extruded pellet bait 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 Cholecalciferol extruded pellet bait and 1080 extruded pellet bait can be adequately contained with the controls in Appendix A.

6.3. Therefore, the application to manufacture Cholecalciferol extruded pellet bait and 1080 extruded pellet bait in containment is granted until **22 March 2020**.

Environmental Protection Authority
Te Mana Rauhī Taiao

Dr Fiona Thomson-Carter	**Date: 22 March 2019**
General Manager, HSNO, EPA	

Appendix A: Controls applying to the manufacture of Cholecalciferol extruded pellet bait and 1080 extruded pellet bait in containment

General

1. In these controls, “approval holder” refers to Invasive Pest Control Limited.
2. In these controls, “substances” refers to, and is limited only to, the specified Cholecalciferol extruded pellet bait and 1080 extruded pellet bait.
3. Cholecalciferol extruded pellet bait and 1080 extruded pellet bait consists of two (2) formulations declared with application APP203788. These substances are summarised in confidential Appendix B.

Accountability

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

Requirement for containment

5. The substances must be in containment at all stages of their life cycle in New Zealand.

Limitations

6. This approval expires on **22 March 2020**.
7. This approval applies exclusively to substances that are manufactured and studied by, or on behalf of, the approval holder.
8. The approval holder must ensure that the nature of the cage trials are in accordance with the activities proposed in application APP203788, unless otherwise specified by the controls on this approval.
9. Over the term of this approval, the approval holder may manufacture up to 5 kilograms of each substance covered under this approval.
10. The substances under this approval must be manufactured, stored and used in a secure facility.

Manufacture

11. The manufacture of Cholecalciferol extruded pellet bait and 1080 extruded pellet bait must occur in a laboratory that is compliant with Part 18 of the Health and Safety at Work (Hazardous Substances) Regulations 2017.
12. The manufacture of Cholecalciferol extruded pellet bait and 1080 extruded pellet bait must occur in a facility that is approved to manufacture vertebrate toxic agents (VTAs) under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

General requirements

13. The substances must be correctly packaged. The substances are correctly packaged if they are packed in accordance with the Hazardous Substances (Packaging) Notice 2017 and their packaging complies with the same Notice.

14. The substances must be correctly labelled. The substances 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 the name and contact details for Invasive Pest Control Limited.

15. A safety data sheet (SDS) must accompany the substances at all stages of their 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 requirement.

Workplace site and storage requirements

16. The Hazardous Substances (Hazardous Property Controls) Notice 2017 applies to this approval, as if the substances were class 9 pesticides.

17. The substances must be stored in a locked container when not in use.

Equipment and facility requirements

18. The manufacture, storage and use of the substances must be undertaken in containment within an area specifically designated for the manufacture, storage or use of the substances. This site may be all or part of a facility.

19. The area of a facility used for the manufacture, storage or use of the substances must be able to be readily decontaminated in the event of a spill.

20. All entrances to any facility that manufactures, stores or uses the substances must be secured at all times to prevent access of unauthorised people.

21. Unauthorised people must be excluded from any facility that manufactures, stores or uses the substances.

22. Signs must be displayed at all entrances to any facility that manufactures, stores and uses the substances. The signs must state (or words to the effect):

    a. that the site is subject to the manufacture, storage or trial of hazardous substances
    b. the general type of hazards of each substance that is being manufactured, stored or 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.

23. The management of the signs referred to in Control 22 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 22 of this approval.

Use

24. The substances must only be used in a workplace.

25. The substances must not be applied directly to, or enter into water or a waterway.

26. The use of the substances must be compliant with clause 46 of the Hazardous Substances (Hazardous Property Controls) Notice 2017, as if the substances were class 9 pesticides.

27. The use of the substances must be compliant with clause 47 of the Hazardous Substances (Hazardous Property Controls) Notice 2017, as if the substances were class 9 pesticides.

28. The manufacture, storage and use of the substances must not result in exposure of any of the substances to a place in which people or non-target organisms may be significantly adversely affected by the substances.

29. For the duration of the trial, the approval holder must ensure that secure cages which contain the substances are identified with signs that clearly communicate the presence of a hazardous substance.

30. The approval holder must ensure that trials undertaken with the substances occur in secure cages within the secure facility and that the cages are designed and maintained so as to prevent the access of other organisms into the secure cages.

31. For the duration of the trial, the approval holder must ensure that baits are checked daily and that any uneaten bait present in the cage of a deceased rat or possum is recovered and disposed of in accordance with Control 36.

32. Any evidence of the presence of other organisms must be checked for, and if found, reported to the EPA in accordance with Control 49.

33. At the end of the trial, the approval holder must ensure that the substances used in the trial are recovered and disposed of in accordance with Control 36.

34. Any person that handles the substances must use PPE that is designed, constructed, and operated to ensure that the person:

    a. does not come in contact with the substances
    b. is not exposed to a concentration of the substances that may cause an adverse effect to the person.

Transport

35. No person may transport the substances on a passenger service vehicle[2].

Disposal

36. The disposal of the substances must be in compliance with the Hazardous Substances (Disposal) Notice 2017, with the exception of subclauses 9(1)(b) and 10(1)(b).

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

37. Any equipment used to prepare or apply the substances must be cleaned after use, and the rinsate disposed of in compliance with the Hazardous Substances (Disposal) Notice 2017 as if it were a class 9 hazardous substance.

38. The approval holder must ensure that any deceased rats and possums are collected and disposed of in accordance with the Hazardous Substances (Disposal) Notice 2017 as if they were a class 9 hazardous substance.

39. At the expiry of this approval, the substances 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

40. The qualification for a person that mixes, loads, or otherwise handles the substances in preparation for application must be compliant with the relevant qualification requirements in clauses 61 and 66 of the Hazardous Substances (Hazardous Property Controls) Notice 2017 as if the substances were class 9.1A, 9.2A, 9.3A, or 9.4A pesticides.

41. Any person entering the manufacturing, storage or 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

42. Written records must be kept of the amount of each substance manufactured under this approval.

43. Written records must be kept for each time the substances are 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 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 notify the EPA in writing prior to the start of any trial under this approval. The notification must include:

    a. the application number: **APP203788**
    b. the HSNO approval number **HSC100195**
    c. the name and contact information for the person responsible for the trial

d. the physical address of the trial location
e. the date on which the trial will commence and the expected duration of the trial
f. the name (as given with APP203788) and quantity of each substance that will be applied
g. details on how the uneaten and unused substances and rat and possum carcasses will be disposed of.

Emergency management

47. 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.

48. The approval holder must ensure that the trial sites, storage, use, transport and disposal of the substances comply with the emergency management provisions prescribed by the Hazardous Substances (Hazardous Property Controls) Notice 2017 in addition to the Health and Safety at Work (Hazardous Substances) Regulations.

Breach of containment

49. If for any reason a breach of containment occurs, the approval holder must report the nature of the incident to the EPA within 24 hours of the incident occurring.

Interpretation

50. 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
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 (HSC100195)

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