Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

15 May 2020

Summary

Substance Name	Toxin-laced rodent carcasses
Application code	APP204000
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	Zero Invasive Predators Ltd (ZIP)
Purpose of the Application	To import or manufacture Toxin-laced rodent carcasses in containment
Date application formally received	12 March 2020
Consideration date	17 April 2020 – 15 May 2020
Considered by	The Acting General Manager[1] of the Environmental Protection Authority ("the EPA")
Decision	**Approved with controls**
Expiry date of approval	**31 July 2021**
Approval code	**HSC100238**

[1] The Acting 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. Zero Invasive Predators Ltd (ZIP) ("the applicant") sought approval under section 32 of the Act to manufacture and conduct field trials in containment with "Toxin-laced rodent carcasses" ("the substance"). This substance consists rat carcasses laced with sodium fluoracetate ("1080").

1.2. 1080 is a Vertebrate Toxic Agent (VTA) that is approved in New Zealand (HSR002771). However, "Toxin-laced rodent carcasses" is considered a formulated susbstance, which is not approved in New Zealand.

1.3. 1080 is already present in various approved formulations for the control of rabbits, possums, deer, wallabies, feral cats and other pests. It is also effective for controlling stoats scavenging on poisoned animals.

1.4. The purpose of this application is to manufacture the substance in order to test a novel technique to control stoats. The applicant proposes to feed captive rats with cereal pellets containing 1080 in a laboratory, and use the 1080-laced rat carcasses in a field trial (located in South Westland) in order to target stoats through secondary poisoning.

2. Process

Application receipt

2.1. The application was formally received on 12 March 2020 under section 31 of the Act.

Information available for consideration

2.2. The information available for the consideration includes the:

- application form
- 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 an 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 VTA formulations (containing 1080 as the active ingredient) 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 provided information on how they intend to address potential risks. 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

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

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

4.4. 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.

4.5. There is also a risk that members of the public may be exposed to the substance. This is mitigated by a control that requires warning signs to be erected at access points of the field trial sites and by controls that limit access to the manufacturing site to authorised personnel only.

4.6. It is very unlikely that native, non-target, species would be exposed to the substance. The field site for which this application pertains has recently had an aerial 1080 operation (2019), which aimed at eradicating rats, stoats and possums. It is not anticipated that this trial will create undue risks to native species as it uses a more targeted approach to secondary poisoning of stoats. The applicant's purpose with this containment application is to develop a tool to control pests and reduce pressure on native species. The applicant proposes to produce up to 150 rat carcasses in total, which will be used in up to 20 monitored sites within the field trial site. The applicant proposes to carry out several trial events, each of them lasting for a maximum of 10 days. Any carcasses remaining after 10 days will be removed.

4.7. Overall, it is considered that the risks from this field trial will be less than those associated with the use of already approved substances containing 1080. It is also noted that current use of 1080-based baits generates 1080-laced rat carcasses in a wider, more dispersive way than the activities proposed under this application, which involves a more controlled approach to secondary poisoning of stoats.

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

4.12. The application site has a history of 1080 control operations (including aerial drops) that occurred in 2019. Since the applicant recently carried out 1080 operations in this area, it is assumed that the applicant already holds the necessary authorisations (the applicant stated that the trial site currently has permission from the Ministry of Health to use 1080) and that consultation with local iwi was undertaken for those previous operations. Overall, it is considered that the risks from this containment application will be less than the risks from 1080 operations that already occurred in the same area.

4.13. 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

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

New Zealand's international obligations

4.15. 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 substance, in accordance with 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 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 an opportunity to comment on the controls as set out in this decision and made some comments which were subsequently integrated into the final documents.

5.7. Having considered all the applicable matters, the EPA has determined that the substance 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 Toxin-laced rodent carcasses 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 Toxin-laced rodent carcasses can be adequately contained with the controls in Appendix A.

6.3. Therefore, the application to manufacture Toxin-laced rodent carcasses in containment is granted until **31 July 2021**.

Doug Jones	**Date: 15 May 2020**
Acting General Manager, HSNO, EPA	

Appendix A: Controls applying to Toxin-laced rodent carcasses in containment

General

1. In these controls, “approval holder” refers to Zero Invasive Predators Ltd (ZIP).
2. In these controls, “substance” refers to, and is limited only to, Toxin-laced rodent carcasses.
3. Toxin-laced rodent carcasses consists of one bait substance declared with application APP204000.

Accountability

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

Requirement for containment

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

Limitations

6. This approval expires on **31 July 2021**.
7. The 1080-based vertebrate toxic agent used in this approval to prepare the substance must be approved under the HSNO Act.
8. The approval holder must ensure that the nature of the field trials and manufacture of the substance are in accordance with the activities proposed in application APP204000, unless otherwise specified by the controls on this approval.
9. Over the term of this approval, the approval holder may manufacture and undertake field trials with up to 150 dead rats laced with the vertebrate toxic agent sodium fluoroacetate.

General requirements

10. 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 its packaging complies with the same Notice.
11. 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 New Zealand contact details for Zero Invasive Predators Ltd (ZIP), including a 24-hour emergency contact phone number.
12. 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. The SDS used for this approval can be the SDS of the 1080-based VTA used to feed the captive rodents.

Workplace site and storage requirements

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

Manufacturing facility

14. The approval holder must only manufacture the substance at the manufacturing facility described by the approval holder in the application. This facility is described as the "manufacturing facility".

15. Unauthorised persons must be excluded from the manufacturing facility.

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

17. The manufacturing facility must be a laboratory compliant with Part 18 of the Health and Safety at Work (Hazardous Substances) Regulations 2017.

18. The manufacture of the substance must occur in a facility that is approved to manufacture vertebrate toxic agents under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

Field trial site

19. 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.

20. The field trial site must include all preparation, storage and operational areas related to the study.

21. The approval holder must obtain permission from the owner or legal occupier of the land before the area is designated as a field trial site for the purpose of this approval.

22. At least three days before the substance is laid, signs must be erected at every normal point of entry. The signs must:

    a. state the unequivocal nature of trials

    b. state precautions that should be taken by members of the public

    c. advise the action to be taken in an emergency

    d. provide sufficient information to enable a member of the public to contact the approval holder

23. The signs must remain in place either for a minimum of six months after the trial end date, or until any stoat carcass is no longer toxic.

24. 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.

25. The approval holder must ensure that the trials do not result in exposure of the substance to any property, whether residential or commercial, that is not related to 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 placed in the vicinity of any pathway accessible to the public and must not visible to any member of the public taking the pathway.

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 a class 9 pesticide.

31. The use of the substance must be compliant with clause 47 of the Hazardous Substances (Hazardous Property Controls) Notice 2017, as if the substance was a class 9 pesticide.

32. 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.

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

34. At the end of the trial, the approval holder must ensure that any uneaten substance used in the trial is recovered and disposed of in accordance with Control 40.

35. For the duration of the trial, the approval holder must ensure that baits are continuously monitored by cameras and checked every 10 days. Any evidence of bait consumption by non-target native species must be reported to the EPA in accordance with Control 55.

36. For the duration of this approval, each trial event is restricted to a maximum of 10 days.

37. 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

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

Transport

39. No person may transport the substance on a passenger service vehicle[2].

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

Disposal

40. The approval holder must ensure that the substance is disposed of in accordance with the Hazardous Substances (Disposal) Notice 2017.

41. The approval holder must ensure that any deceased stoats that are found are collected and disposed of in accordance with the waste management rules for dead animals set by the relevant regional, district or city council or territorial authority. In addition, disposal of stoat carcasses must not result in secondary poisoning of non-target organisms or contamination of waterways or groundwater.

42. Any equipment used to prepare or apply the substance must be cleaned after use or disposed of in compliance with the Hazardous Substances (Disposal) Notice 2017.

43. 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

44. The qualification for a person that mixes, loads, or otherwise handles the substance in preparation for application must be compliant with the relevant qualification requirements in clause 61 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 vertebrate toxic agent. Where relevant, clause 66 of the Hazardous Substances (Hazardous Property Controls) Notice also applies.

45. Any person present during the manufacture or trial of the substance must have received sufficient instruction on the containment regime to enable the person to meet their responsibilities under this approval.

Record keeping and notification

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

47. 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.

48. 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.

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

50. The approval holder must keep a record of the substance that is manufactured under this approval. The record must include:

    a. the unequivocal identification of the substance;
    b. the approval number for this containment (**HSC100238**);
    c. the composition of the substance;
    d. the dates of substance manufacture; and
    e. the total quantity of the substance manufactured.

51. 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: APP204000
    b. the HSNO approval number **HSC100238**
    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 APP204000) of the substance that will be applied.

Emergency management

52. Any spilled substance must be contained and prevented from entering any waterway.

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

Breach of containment

54. If any of the substance is applied other than in the intended application area, or is 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.

55. If for any reason a breach of containment occurs, other than those specified in Control 54, the approval holder must report the nature of the incident to the EPA within 24 hours of the incident occurring.

Interpretation

56. 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.