Environmental Protection Authority
Te Mana Rauhī Taiao

APPLICATION FORM
CONTAINMENT

Application Form: HS3 Import or Manufacture any Hazardous Substance in Containment

under section 31 of the Hazardous Substances and New Organisms Act 1996

To submit an application, please send by post to: Environmental Protection Authority, Private Bag 63002, Wellington 6140
OR email to: HSApplications@epa.govt.nz

Payment must accompany application: see our fees and charges schedule for details. Please allow 10 working days for processing.

Applicant:

Invasive Pest Control Limited

Name of substance:

Cholecalciferol extruded pellet bait and 1080 extruded pellet bait

APPLICANT CHECKLIST

Mandatory sections filled out	☐	**Appendices enclosed**	☐
Initial fees enclosed	☐	**Signed and dated**	☐
Electronic copy of application emailed to EPA	☐		

Office use only

Application code:

Date received:

EPA contact:

Initial fees paid: $

Application version no.:

Important

1. You can talk to an applications advisor at the EPA, who can help you scope and prepare your application. We need all relevant information early on in the application process. Quality information up front will speed up the process.
2. This application form may be used to seek approvals for more than one hazardous substance where the substances are related – for example, a concentrated compound (active ingredient) and its related formulations, or a range of substances for similar purposes to be tested in a field trial.
3. Any extra material that does not fit in the application form must be clearly labelled, cross-referenced, and included in an appendix to the application form.
4. Commercially sensitive information must be collated in a separate appendix.
5. Unless otherwise indicated, all sections of this form must be completed for the application to be progressed.
6. You can get more information at any time by contacting us. One of our staff members will be able to help you.

   Environmental Protection Authority
   Private Bag 63002
   Wellington
   New Zealand
   Telephone: 64 4 916 2426
   Facsimile: 64 4 914 0433
   Email: HSApplications@epa.govt.nz
   http://www.epa.govt.nz

Section 1 – Applicant details

1.1 Name and postal address in New Zealand of the organisation making the application:

Name: [redacted]

Address: [redacted]

Phone: [redacted]

Fax:

1.2 The applicant's location address in New Zealand (if different from above):

Address: [redacted]

1.3 Name of the contact person for the application:

This person should have sufficient knowledge to respond to queries and either have the authority to make decisions that relate to processing the application on behalf of the applicant, or have the ability to go to the appropriate authority.

Name: [redacted]

Position: [redacted]

Address: [redacted]

Phone: [redacted]

Fax: -

Email: [redacted]

Section 2 – Application type and related approvals required

This form is only for an application to import a hazardous substance into containment, or manufacture a hazardous substance in containment.

2.1 Is this application to manufacture or import a hazardous substance in containment for any of the following purposes?

Containment applications can only be made for a limited range of purposes. In particular, the substance must not be intended for commercial manufacture or sale.

Small amounts of any hazardous substance for use as an analytical standard, where approval to import or manufacture that substance has been declined?	☐ Yes	☒ No
Research on any hazardous substance to acquire information for use in assessing that substance for a HSNO approval?	☒ Yes	☐ No
Research and development on any hazardous substance?	☒ Yes	☐ No
Use in an emergency?	☐ Yes	☒ No
Formulating, relabelling, repackaging, or storing any hazardous substance for export to a destination outside New Zealand?	☐ Yes	☒ No
Other purposes?	☐Yes	☒ No

2.2 If you answered 'yes' to one of the purposes listed above, please provide some supporting detail. If you answered 'yes' to 'other purpose', describe the purpose and explain why this purpose is appropriate to a containment application.

The purpose of these cage trials is to generate efficacy data for an extruded pellet bait containing 0.8% cholecalciferol and an extruded pellet bait containing 0.15% 1080. The efficacy data will be used to register both of these formulations for use on rats and possums in New Zealand. The baits will be trialed at two secure research facilities by researchers with a Controlled Substances License and extensive experience handling and trialing VTAs. The focus of these trials is to determine the efficacy of these formulations on possums and rats in captive trials.

2.3 Is the information in this application relevant to import, manufacture or both?

Import the substance(s) only?	☐ Yes	☒ No
Manufacture the substance(s) only?	☒ Yes	☒ No

Import and manufacture the substance(s)? ☐ Yes ☒ No

If import only, indicate whether or not manufacture is likely in New Zealand: ☐ Yes ☐ No

2.4 If the information in the application relates to manufacture of the substance(s) in New Zealand, provide information on the proposed manufacturing process and any alternatives.

The active ingredient cholecalciferol is currently imported to manufacture cholecalciferol paste baits registered as Feracol (ACVM V5263). The active ingredient 1080 will be imported under this approval.

The extruded cholecalciferol and 1080 pellet baits will be manufactured in 10 kg batches by Connovation Ltd at their premises. For each batch, the ingredients (*Confidential Appendix 1*) will be weighed out and mixed together. Baits will be packed in 5 kg HDPE pails with tamper resistant lids. Pails will be labelled (*Confidential Appendix 2 and Appendix 4*) and stored securely until dispatch and subsequent use. The details of the composition of the substances in the pellet baits containing cholecalciferol and the pellet baits containing 1080 are provided in *Confidential Appendix 1.* Pellet baits will be transported by dangerous goods courier to the research facilities to undertake captive trials on possums (*Trichosurus vulpecula*) and ship rats (*Rattus rattus*) (*Outlined in Confidential Appendix 1*) these trials will be undertaken between 1st February 2019 and 1st February 2020.

2.5 If this substance(s) needs an approval under any other legislation, has an application for this approval been made?

(Optional)

Name of approval	Application made
Agricultural Compounds and Veterinary Medicines Act 1997	☐ Yes ☐ No ☒NA
Food Act 1981	☐ Yes ☐ No ☒NA
Medicines Act 1981	☐ Yes ☐ No ☒NA
Chemical Weapons (Prohibition) Act 1996	☐ Yes ☐ No ☒NA
Radiation Protection Act 1965	☐ Yes ☐ No ☒NA
Biosecurity Act 1993	☐ Yes ☐ No ☒NA
Resource Management Act 1991	☐ Yes ☐ No ☒NA
Other (please specify):	
Biocidal Products Regulation (EU)	☐ Yes ☐ No
	☐ Yes ☐ No
	☐ Yes ☐ No

Section 3 – Information on the substance(s)

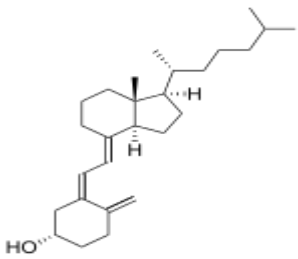
Note that all information that is commercially sensitive must be attached as an appendix. The application form should be cross-referenced to the appendix but should be able to be read as a stand-alone document (which will be publicly available).

If approval is being sought for more than one hazardous substance, this section must be completed separately for each hazardous substance.

3.1State the unequivocal identification of the substance(s).

This section should include all information necessary to unequivocally identify the substance(s) and may include:

- Chemical name (Chemical Abstracts Preferred Index name or IUPAC name): (1S)-3-[2-[(1R,7aR)-7a-methyl-1-[(2R)-6-methylheptan-2-yl]-2,3,3a,5,6,7-hexahydro-1H-inden-4-ylidene]ethylidene]-4-methylidenecyclohexan-1-ol
- Common name
  Cholecalciferol
- Synonyms
  Vitamin D_3, activated 7-dehydrocholesterol
- CAS Registry number
  67-97-0
- Molecular formula
  $C_{27}H_{44}O$
  Structural formula



- Impurities.

  Cholecalciferol impurity information is outlined in Confidential Appendix 1.

This section should include all information necessary to unequivocally identify the substance(s) and may include:
Sodium monofluoroacetate. The 1080 pellet bait contains one active ingredient, 1080 which is listed on the EPA CCLID database.

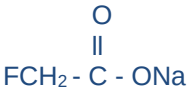
- Chemical name (Chemical Abstracts Preferred Index name or IUPAC name)

Sodium;2-fluoroacetate. Sodium monofluoroacetate

- Common name
- 1080. Sodium fluoroacetate
- CAS Registry number
- 62-74-8
- Molecular formula

  $C_2H_2FNaO_2$

  Structural formula

- Impurities.

  The 1080 active does not contain additives or impurities that would be of toxicological or environmental concern.

For mixtures, in addition to the above information being provided on the actual mixture, information is also required on the composition of the mixture – ie, the chemical name, CAS number, function (eg, active ingredient, emulsifier, surfactant, filler) and percentages of ALL components of the mixture (including non-hazardous components and impurities) should be provided. This information may be best expressed in tabular form. If the composition is variable, please ensure to state the limits.

If there are commercial reasons for not providing full information in the main part of the form, alternative approaches must be discussed with and agreed by the EPA. These must include the provision of a unique identifier of some kind.

Please refer to *Confidential Appendix 1* for product composition.

3.2 Provide information on the chemical and physical properties of the substance(s).

Provide as much information as possible on the chemical and physical properties of the substance(s) [at 20°C and 1 atmosphere unless otherwise stated] – eg:

- Appearance (colour, odour, physical state or form)
- pH
- Density
- Vapour pressure
- Boiling/melting point
- Solubility in water
- Water/octanol partitioning co-efficient.

For mixtures, information is required on the chemical and physical properties of the mixture itself. However, if this information is not available, you should provide information on the chemical and physical properties of EACH hazardous component of the mixture.

Chemical and Physical properties of the product – Cholecalciferol pellet bait

- **Appearance** (colour, odour, physical state or form):
  Green solid bait in the form of a pellet, Weight approx. 12g., containing oils and food grade ingredients attractive to rodents and possums. The grains present in the finished product give it a speckled/flecked appearance and it is dyed green.
- **pH:** This bait is solid; therefore, this property cannot be measured.
- **Density:** 0.9
- **Vapour pressure:** Not applicable, this bait is solid.
- **Boiling/melting point:** Not applicable.
- **Solubility in water:** Not applicable – insoluble, but degrades over time
- **Water/octanol partitioning co-efficient**: Not applicable

Chemical and Physical properties of the product – 1080 pellet bait

- **Appearance** (colour, odour, physical state or form):
  Green solid bait in the form of a pellet, Weight approx. 12g., containing oils and food grade ingredients attractive to rodents and possums. The grains present in the finished product give it a speckled/flecked appearance and it is dyed green.
- **pH:** This bait is solid; therefore, this property cannot be measured.
- **Density:** 0.9
- **Vapour pressure:** Not applicable, this bait is solid.
- **Boiling/melting point:** Not applicable.
- **Solubility in water:** Not applicable – insoluble, but degrades over time
- **Water/octanol partitioning co-efficient**: Not applicable

3.3 Provide information on the hazardous properties of the substance(s).

Information should be provided on the hazardous properties of the substance(s) known to the applicant. You should consider each of the six hazardous properties below and provide information on those hazardous properties. This information is needed in order to assess risks and determine whether or not, and how, the substance can be adequately contained.

Cholecalciferol pellet bait

- **Explosiveness:** This bait does not contain any components classified as explosive and all the components are stable under normal conditions. Therefore, this property does not apply to this bait.
- **Flammability:** This bait does not contain any components classified as flammable and all the components are stable under normal conditions. Therefore, this property does not apply to this bait.

- **Oxidising properties:** This bait does not contain any components classified as oxidising and all the components are stable under normal conditions. Therefore, this property does not apply to this bait.
- **Corrosiveness:** This bait does not contain any components classified as corrosive and all the components are stable under normal conditions. Therefore, this property does not apply to this bait.

1080 pellet bait

- **Explosiveness:** This bait does not contain any components classified as explosive and all the components are stable under normal conditions. Therefore, this property does not apply to this bait.
- **Flammability:** This bait does not contain any components classified as flammable and all the components are stable under normal conditions. Therefore, this property does not apply to this bait.
- **Oxidising properties:** This bait does not contain any components classified as oxidising and all the components are stable under normal conditions. Therefore, this property does not apply to this bait.
- **Corrosiveness:** This bait does not contain any components classified as corrosive and all the components are stable under normal conditions. Therefore, this property does not apply to this bait.

Cholecalciferol pellet bait

- **Toxicity:**

• **Class 6: Toxicity** • **Sub class 6.1** • **Acute toxicity (oral)** • **Acute toxicity (dermal)** • **Acute toxicity (inhalation)**	 • Not triggered • Not triggered • **Not applicable to pellet bait**
• **Sub class 6.3** • Skin irritation	 • Not triggered
• **Sub class 6.4** • Eye irritation	 • Not triggered
• **Sub class 6.5** • Sensitisation	 • Not triggered
• **Sub class 6.6** • Mutagenicity	 • Not triggered
• **Sub class 6.7** • Carcinogenicity	 • Not triggered
• **Sub class 6.8** • Reproductive/Developmental Toxicity	 • Not triggered
• **Sub class 6.9** • Target organs/systems	 • Not triggered

- **Ecotoxicity:**

• **Class 9: Ecotoxicity** • **Sub class 9.1 Aquatic**	• Not triggered
• **Sub class 9.2 Soil Environment**	• Not triggered
• **Sub class 9.3 Terrestrial Vertebrates**	• 9.3C
• **Sub class 9.4 Terrestrial Invertebrates**	• Not triggered

1080 pellet bait

- **Toxicity:**

• **Class 6: Toxicity** • **Sub class 6.1** • **Acute toxicity (oral)** • **Acute toxicity (dermal)** • **Acute toxicity (inhalation)**	• **6.1B** • **6.1C** • **Not applicable to pellet bait**
• **Sub class 6.3** • Skin irritation	• Not triggered
• **Sub class 6.4** • Eye irritation	• Not triggered
• **Sub class 6.5** • Sensitisation	• Not triggered
• **Sub class 6.6** • Mutagenicity	• Not triggered
• **Sub class 6.7** • Carcinogenicity	• Not triggered
• **Sub class 6.8** • Reproductive/Developmental Toxicity	• Not triggered
• **Sub class 6.9** • Target organs/systems	• 6.9A or 6.9B

- **Ecotoxicity:**

• **Class 9: Ecotoxicity** • **Sub class 9.1 Aquatic**	• 9.1D
• **Sub class 9.2 Soil Environment**	• Not triggered
• **Sub class 9.3 Terrestrial Vertebrates**	• 9.3A
• **Sub class 9.4 Terrestrial Invertebrates**	• Not triggered

3.4 Provide information on what will happen to the substance throughout its whole life, from its introduction into New Zealand, its uses, through to disposal.

The information provided needs to reflect the containment character of the application. It will be used in the development of exposure scenarios and the assessment of risks, and hence the specification of the containment conditions.

Cholecalciferol pellet bait

Importation
The active ingredient cholecalciferol is to be imported into New Zealand and then will be transported by road to the manufacturing site.

Manufacture
The extruded pellet bait containing 0.8% cholecalciferol will be manufactured by Connovation Limited. The pellet bait will be manufactured at Connovation Limited's premises at [redacted] under their existing ACVM approval to manufacture VTA products.

Identification
Packaging will be labelled with product information (*Confidential Appendix 4*) and a Material Safety Data Sheet (SDS) will be available (*Confidential Appendix 5*). The label and MSDS identifies the hazard statements, precaution phrases and provide advice for First Aid responses, storage, disposal and use of the product for rat control.

Transport
The active ingredient will be transported by Dangerous Goods Courier from Airport Customs to Connovation Ltd. The baits containing 0.8% cholecalciferol are not classified as a Dangerous Good Class 6.

Storage
The active ingredient and then the baits containing 0.8% cholecalciferol will be stored at a secure storage site at Connovation Limited. The storage for the active and toxic bait is within a locked room that only members of the research team have access to, this room is within a building that requires pin code access and again is limited to company employees only.

Use
An Animal Ethics Application has been approved to enable cage trials of these baits on ship rats. The bait containing 0.8% cholecalciferol is formulated as a ready-to-use bait (pellet bait) for use as a Vertebrate Toxic Agent (VTA) for possum and rat control.

The research team for cage trials will consist of Dr Lee Shapiro (CSL004729) and Grant Morriss from Landcare Research all other persons involved will be approved handlers.

Rat trials
Up to 20 individually caged ship rats will each be presented with 50 g of pellet baits containing 0.8% cholecalciferol. Rats will be left undisturbed for the first night after the baits are placed in their cages and then monitored daily for symptoms of toxicosis. Baits will be left in each cage for up to two days at which point baits will be removed. These trials will be undertaken between 01 February 2019 and 01 February 2020.

Possum trials
Up to 20 individually caged possums will each be presented with 50 g of pellet baits containing 0.8% cholecalciferol for two nights. Possums will be observed three times a day over the following week or until death for symptoms of toxicosis. Baits will be left in each cage for up to two days at which point baits will be removed. These trials will be undertaken between 01 February 2019 and 01 February 2020.

Disposal
Any uneaten or unused baits and all possum and rat carcasses will be disposed of at an approved disposal facility.

1080 pellet bait

Importation
The active ingredient cholecalciferol is to be imported into New Zealand and then will be transported by road to the manufacturing site.

Manufacture
The extruded pellet bait containing 0.15% 1080 will be manufactured by Connovation Limited. The pellet bait will be manufactured at Connovation Limited's premises at [redacted] under their existing ACVM approval to manufacture VTA products.

Identification
Packaging will be labelled with product information (*Confidential Appendix 4*) and a Material Safety Data Sheet (SDS) will be available (*Confidential Appendix 5*). The label and MSDS identifies the hazard statements, precaution phrases and provide advice for First Aid responses, storage, disposal and use of the product for rat control.

Transport
The active ingredient will be transported by Dangerous Goods Courier from Airport Customs to Connovation Ltd. The baits containing 0.15% cholecalciferol are classified as a Dangerous Good Class 6 and will require the corresponding transport.

Storage
The active ingredient and then the baits containing 0.8% cholecalciferol will be stored at a secure storage site at Connovation Limited. The storage for the active and toxic bait is within a locked room that only members of the research team have access to, this room is within a building that requires pin code access and again is limited to company employees only.

Use
An Animal Ethics Application has been approved to enable cage trials of these baits on ship rats. The bait containing 0.15% 1080 is formulated as a ready-to-use bait (pellet bait) for use as a Vertebrate Toxic Agent (VTA) for possum and rat control.

The research team for cage trials will consist of Dr Lee Shapiro (CSL004729) and Grant Morriss from Landcare Research all other persons involved will be approved handlers.

Rat trials
Up to 20 individually caged ship rats will each be presented with 50 g of pellet baits containing 0.15% 1080. Rats will be left undisturbed for the first night after the baits are placed in their cages and then checked first thing the following morning and monitored for symptoms of toxicosis four times daily for the two days after bait is presented. Baits will be left in each cage for up to two days at which point baits will be removed. These trials will be undertaken between 01 February 2019 and 01 February 2020.

Possums
Up to 20 individually caged possums will each be presented with 50 g of pellet baits containing 0.15% 1080. Possums will be observed three times a day over the following week or until death, and signs of poisoning recorded for animal welfare assessment Possums will be observed three times a day over the following week or until death for symptoms of toxicosis. Baits will be left in each cage for up to two days at which point baits will be removed. These trials will be undertaken between 01 February 2019 and 01 February 2020.

Disposal
Any uneaten or unused baits and all possum and rat carcasses will be disposed of at an approved disposal facility.

3.5 Provide information on the quantity of the substance proposed to be imported or manufactured.

This information is used in the development of exposure scenarios and the assessment of risks.

Cholecalciferol trials

Up to 3 kg of pellet baits containing 0.8% cholecalciferol will be manufactured for cage trials. A total of 2 kg of pellet baits will be used in cage trials on possums and rats (1 kg in rat trials and 1 kg in possum trials) and the remaining 1 kg will be used for analysis.

1080 trials

Up to 3 kg of pellet baits containing 0.15% 1080 will be manufactured for cage trials. A total of 2 kg of pellet baits will be used in cage trials on possums and rats (1 kg in rat trials and 1 kg in possum trials) and the remaining 1 kg will be used for analysis.

Section 4–Information on the proposed containment system

4.1 Provide information on the proposed containment system.

It is essential that good information is provided on the containment system because the adequacy of containment, in conjunction with the hazardous properties of the substance, will have a major impact on whether or not approval is given.

You will need to provide a description of the containment proposed AND information on how you intend to address the following issues (proposed controls):

Rat trials – 0.8% cholecalciferol pellets and 0.15% 1080 pellets

- Methods for preventing the escape of the contained hazardous substance and preventing the contamination of the facility

  Cholecalciferol active will be transported from Auckland Airport Customs to Connovation Ltd by Dangerous Goods courier. Pellet baits containing 0.8% cholecalciferol will be transported to the trial facility in sealed tamper resistant plastic pails. The pellet baits containing cholecalciferol will only be used under controlled conditions within this secure research facility (*See Confidential Appendix 1*), baits will be weighed and fed to individually caged rats. At the conclusion of the trials any uneaten or unused baits and all rat carcasses will be disposed of at an approved landfill.
- Methods for excluding unwanted organisms from the facility or to control organisms within the facility

  The research facility is a secure building and the only access is through locked doors which excludes unauthorised people and non-target animals from accessing the facility and baits.
- Methods for excluding unauthorised people from the facility

  The research facility is only accessible to research personnel and requires key access that excludes unauthorised people.
- Methods for preventing unintended release of the substance by experimenters

  The substances are pellet baits and will be kept in a sealed HDPE plastic tubs prior to use, bait will be weighed and placed in feed trays for rats and placed inside individual cages. Members of the research team will wear

appropriate safety gear including overalls and disposable latex gloves during the trial. At the conclusion of the trials any uneaten or unused baits and all rat carcasses will be disposed of at an approved landfill.

- Methods for controlling the effects of any accidental release of the substance

  Accidental release of this substance is highly unlikely as the research facility is a secure building and the only access is to authorised researchers through locked doors. Baits will be transported to the facility in sealed tamper resistant plastic pails. The pellet baits containing either 0.8% cholecalciferol or 0.15% 1080 will only be used under controlled conditions within this secure research facility, baits will be weighed and fed to individually caged rats. At the conclusion of the trials any uneaten or unused baits and all rat carcasses will be disposed of at an approved landfill.

- Inspection and monitoring requirements of the containment facility.

  The pellet baits containing either 0.8% cholecalciferol or 0.15% 1080 will only be used under controlled conditions within this secure research facility. Baits will be weighed and fed to individually caged rats. Rats will be left undisturbed for the first 12 hours after the baits are placed in their cages and then monitored every day for 0.8% cholecalciferol trials and four times per day for 0.15 % 1080 trials for symptoms of toxicosis. Toxic baits will only be left in cages for a maximum of two days and outside of this time paste bait will be stored inside sealed HDPE pails.

  A management plan may be attached as an appendix. This plan should specify the procedures for implementing the above methods for containing the substance(s), and provide details of the qualifications of the person responsible for implementing those controls.

Possum trials – 0.8% cholecalciferol pellets and 0.15% 1080 pellets

- Methods for preventing the escape of the contained hazardous substance and preventing the contamination of the facility

  Cholecalciferol active will be transported from Auckland Airport Customs to Connovation Ltd by Dangerous Goods courier. Pellet baits containing 0.8% cholecalciferol will be transported to the trial facility in sealed tamper resistant plastic pails. The pellet baits containing cholecalciferol will only be used under controlled conditions within this secure research facility (*Confidential Appendix 1*), baits will be weighed and fed to individually caged rats. At the conclusion of the trials any uneaten or unused baits and all possum carcasses will be disposed of at an approved facility.

- Methods for excluding unwanted organisms from the facility or to control organisms within the facility

  The research facility is a secure building and the only access is through locked doors which excludes unauthorised people and non-target animals from accessing the facility and baits.

- Methods for excluding unauthorised people from the facility

  The research facility is only accessible to research personnel and requires swipe card access that excludes unauthorised people.

- Methods for preventing unintended release of the substance by experimenters

  The substances are pellet baits and will be kept in a sealed HDPE plastic tubs prior to use, bait will be weighed and placed in feed trays for possums and placed inside individual cages. Members of the research team will

wear appropriate safety gear including overalls and disposable latex gloves during the trial. At the conclusion of the trials any uneaten or unused baits and all rat carcasses will be disposed of at an approved facility.

- Methods for controlling the effects of any accidental release of the substance

  Accidental release of this substance is highly unlikely as the research facility is a secure building and the only access is to authorised researchers through locked doors. Baits will be transported to the facility in sealed tamper resistant plastic pails. The pellet baits containing either 0.8% cholecalciferol or 0.15% 1080 will only be used under controlled conditions within this secure research facility, baits will be weighed and fed to individually caged possums. At the conclusion of the trials any uneaten or unused baits and all possum carcasses will be disposed of at an approved facility.

- Inspection and monitoring requirements of the containment facility.

  The pellet baits containing either 0.8% cholecalciferol or 0.15% 1080 will only be used under controlled conditions within this secure research facility. Baits will be weighed and fed to individually caged possums. Possums will be left undisturbed for the first 12 hours after the baits are placed in their cages and then monitored every day for 0.8% cholecalciferol trials and four times per day for 0.15 % 1080 trials for symptoms of toxicosis. Toxic baits will only be left in cages for a maximum of two days and outside of this time paste bait will be stored inside sealed HDPE pails.

  A management plan may be attached as an appendix. This plan should specify the procedures for implementing the above methods for containing the substance(s) and provide details of the qualifications of the person responsible for implementing those controls.

Section 5 – Identification and assessment of risks

In completing this section, it is important that you take account of the proposed containment system you described in Section 4. We are particularly interested in knowing about risks that may still remain with the containment system in place. You will need to consider the effects on the environment and public health, including any social effects. You should also take account of the quantity of material involved and the number of different locations that may be involved.

Complete this section as far as you can.

5.1 Identify all of the risks of the substance(s).

Include information on potentially significant, possible risks of the substance and whether or not these risks are *likely* to be significant. It is important to think about the source of the risk – ie, the way in which the risk is created (the exposure pathway) and then the consequences of exposure. Risks should be considered in relationship to:

- the sustainability of native and valued introduced flora and fauna
- the intrinsic value of ecosystems
- public health (including occupational exposure)
- the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga
- the economic and related benefits to be derived from the use of the hazardous substance
- New Zealand's international obligations.

Event	Risk pathway	Lifecycle stage
Spillage of bait	Packaging damage Traffic accident Handling bait Disposal of bait (unused or recovered bait)	T, S T U T, S, U, D
Human contact with bait	Packaging damage Traffic accident Handling bait Disposal of bait (unused or recovered bait)	T, S, U T U U, D
Non-target species (animals, birds) in contact with bait	Domestic animals, e.g. cats or dogs eating bait Birds eating bait	T T
Bait gets into water way	Packaging damage Traffic accident (spillage) Bait placement near waterway Disposal of bait Vandalism	T, S T D T, S, D
Secondary Poisoning	Non-target species, e.g. cats, dogs, birds, scavenge rodent or possum carcasses	D

T=Transport, S=Storage, U=Use, D=Disposal

5.2 Provide an assessment of the potential risks identified in Section 5.1.

An explicit risk assessment only needs to be provided for those risks which might be significant. The assessment should consider whether the identified risks can be adequately managed by the proposed containment system, and the substance(s) itself adequately contained.

The assessment should include the nature, probability of occurrence, and magnitude of each adverse effect. The uncertainty bounds of the information contained in the assessment should also be discussed.

(Optional)

Both substances (cholecalciferol and 1080) will have very limited risk of exposure to the environment and the general public. Cholecalciferol and 1080 active will be transported from Auckland Airport Customs by Dangerous Goods courier to Connovation Ltd. Pellet baits containing 0.8% cholecalciferol and pellet baits containing 0.15% 1080 will be transported to research facilities in tamper resistant HDPE pails, cage trials will be undertaken within secure facilities and at the conclusion of the trials any uneaten or unused baits and all rat and possum carcasses will be disposed of at an approved facility.

Section 6 – International considerations

6.1 The EPA is interested in whether this substance (or any of its components) has been considered by any other regulatory authority in New Zealand, or by any other country. If you are aware of this, please provide details of the results of such consideration.
(Optional)

Cholecalciferol is registered for use in NZ, Connovation Ltd has registered a paste bait containing 0.8% cholecalciferol (ACVM V5263)

1080 is registered for use in NZ in a number of forms including extruded pellet baits and gel and concentrations ranging from 0.04% to 5% (V2848, V2829)

Section 7 – Miscellaneous

7.1 Provide a glossary of scientific and technical terms used in the application.

7.2 Provide here any other information you consider relevant to this application that is not already included.

Section 8 – Summary of public information

The information provided in this section may be used in the EPA's public register of substances, required under Section 20 of the HSNO Act.

This summary information will be used to provide information for the people and agencies (eg, Ministry for the Environment, Department of Conservation, Regional Councils etc) that will be notified of the application, and for potential submitters who request information. This information will also be used to prepare the public notice of the application.

For these reasons, applicants should ensure that this summary information does not contain any commercially sensitive material.

8.1 Name of the substance(s) for the public register:
Please use a maximum of 80 characters.

Cholecalciferol active and pellet bait

1080 active and pellet bait

8.2Purpose of the application for the public register:

This should include an abstract (in a maximum of 255 characters) giving information on the intended use of the substance and why an application is needed, based on its hazardous properties.

To import the active ingredients cholecalciferol and 1080 and manufacture pellet baits containing cholecalciferol (0.8%) and pellet baits containing 1080 (0.15%) as VTAs for the control of rats and possums in cage trials

8.3Use categories of the substance(s):

The EPA has adopted the system of use categories developed by the European Union, which identify various functional uses of substances. This information is pertinent to the assessment of exposure scenarios and the determination of risk and is also useful for building up a profile of the substance. There are three sets of use categories. Within each of these, applicants should state which use categories are relevant to all intended uses of the substance(s).

Main category: There are four main categories.

3 Non-dispersive use

Industry category: There are 16 industry categories.

0 Other

Function/Use category: There are 55 function/use categories.

39. Pesticides non-agricultural

Subcategory: Pest control products

8.4 Executive summary:

In this section, the applicant should provide a summary of information contained in this application, including:

- the identification of the substance, its hazardous properties, intended uses and disposal
- an assessment of the adverse effects of the substance
- information on the proposed containment.

Pellet baits containing cholecalciferol (0.8%) are to be used in cage trials as a Vertebrate Toxic Agent (VTA) for controlling rats and possums. The cholecalciferol pellet baits have the proposed hazardous classifications of 9.3C.

Pellet baits containing 1080 (0.15%) are to be used in cage trials as a Vertebrate Toxic Agent (VTA) for controlling rats and possums. The 1080 pellet baits have the proposed hazardous classifications of 6.1B, 9.1D, 9.3A.

The cholecalciferol pellet baits and 1080 pellet baits will be used in secure research facilities under the control of an Approval Handler, personal protective equipment will be worn, appropriate equipment utilised, and documented procedures followed. Packaging will be labelled and a Material Safety Data Sheets for each bait type will be available.

An Animal Ethics approval has been obtained for cage trials for ship rats and possums. The persons carrying out the trial will be Approved Handlers and will be provided with copies of the approval documents and a Safety Data Sheet.

Any unused or uneaten bait and rat and possum carcasses will be disposed of at an approved facility.

[redacted] 21/12/2018

Signature **Date**

Appendix 1– Commercially sensitive information