

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:

Foundation for Arable Research

Name of substance:

FAR Experimental Compounds

APPLICANT CHECKLIST			-
Mandatory sections filled out	\boxtimes	Appendices enclosed ⊠	
Initial fees enclosed	\boxtimes	Signed and dated	
Electronic copy of application emailed to EPA	\boxtimes		
		W25	

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:

Foundation for Arable Research

Address:

185 Kirk Road, Templeton, Christchurch 8042. P O Box 23133, Templeton, Christchurch 8445.

Phone:

03 345 57899

Fax:

03 341 7061

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

Address:

As above

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:

Rob Cragie

Position:

Project Manager

Address:

185 Kirk Road, Templeton, Christchurch 8042.

Phone:

03 345 5789

Fax:

03 341 7061

Email:

craigier@far.org.nz



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 a following purposes?	ny of the	
Containment applications can only be made for a limited range of purposes. In particular, the subs be intended for commercial manufacture or sale.	tance mus	st not
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	on	
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 support answered 'yes' to 'other purpose', describe the purpose and explain why this purpose is a containment application.	_	-

Approval is sought to import experimental plant protection products to evaluate them in laboratory and field trials under containment conditions. The contained trials will be small scale in nature (the overall trial size will be dependent on the number of treatments, replicates, application equipment and individual plots are likely to be no more than 10 m long and 3 m wide). A number of replicated field trials are proposed to be conducted over a period of five years. The results will determine if there will be further trials and if the products will eventually be commercialised in New Zealand. The trials may be conducted in various regions and will comply with all conditions assigned to this approval.

The compounds are likely to be hazardous but information on the actual hazard classification may be limited as they may be experimental and not commercialised. The compounds may include adjuvants, fungicides, herbicides,

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insecticides, nematicides, plant growth regulators. The application methods may include foliar application, application to the soil surface, drenching, seed treatment. No aerial application will occur.

The compound volume is not expected to exceed 20 kg/litres over the five year period. Only the amounts required for one seasons trials will be imported in any one year.

Trial protocols will be developed for each trial. The compounds will be applied by suitably qualified personnel only. All conditions assigned will from part of the trial protocols. Safety Data Sheets will be provided.

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 N		☐ Yes	⊠ No	
2.4 If the information in the application relates to manufacting information on the proposed manufacturing process as	, .	in New Ze	ealand, p	rovide
Not applicable	#O		ē	
2.5 If this substance(s) needs an approval under any other been made? (Optional)	· legislation, has an app	lication fo	r this app	proval
Name of approval	Application m	ade		
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		

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Other (please specify):	
	☐ 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.

3.1 State 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)
- Common name
- Synonyms
- Trade names
- CAS Registry number
- Molecular formula
- Structural formula
- Impurities.

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.

The composition of each substance will be provided in confidence to the EPA prior to the commencement of trials.

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)
- pН
- 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.

The known chemical and physical properties of each substance will be provided in confidence to the EPA prior to the commencement of trials.

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.

- **Explosiveness**
- Flammability
- Oxidising properties
- Corrosiveness
- Toxicity
- Ecotoxicity.

If your substance is a mixture and you cannot provide direct information on its hazardous properties, you can apply mixture rules to the hazardous components of the mixture. If you do this, then you will need to provide information on the hazardous properties of each hazardous component of the mixture, and show your workings.

The known hazardous properties of each substance will be provided in confidence to the EPA prior to the commencement of trials.

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.

a) Importation.

The substances will be imported into New Zealand in appropriate leak proof sealed containers and stored at secure premises. All care will be taken to ensure that any accidental leaks will be contained (e.g. use of absorbent material etc in the outer packaging). The volume imported will be only that required for that seasons trial work.

b) Transport.

Importation into New Zealand may be by air or sea and will be delivered to the secure storage site by experienced operators.

Transport to the trial sites will be via private vehicles driven by experienced operators.

c) Storage

The substances will be stored at the FAR site 156 Kirk Road, Templeton, Christchurch or at the NZ Arable site 60 Ryans Road, Christchurch under lock and key. Access will be limited to authorised personnel only. Laboratory trials will be conducted at Canterbury or Lincoln Universities by PHD students and their supervisors. Undergraduate students will not have access to the substances.

d) Use.

The substance will be measured out at the secure facilities. Only the amount of substance required for application that day will be transported to the field trials sites. Precision calibrated equipment will be utilised by GROSAFE accredited personnel for the field trials. This may include CO₂ pressurised spray tanks and hand held booms fitted with appropriate nozzles. Plots are usually no more than 10 x 3 m.

Hand held spray bottles or Potter tower equipment will be used by laboratory personnel.

e) Disposal of unused spray mixture.

Surplus spray mix is required to prime the application boom and nozzles. Experience has limited the volume required and the surplus mix may be applied to bare ground within the trial area.

f) Disposal of used containers.

Used containers may be recycled if appropriate or incinerated.

g) Disposal of surplus samples.

Any unused investigational substance will be either returned to the point of origin or sent for incineration.

h) Site close off.

Treated produce may be; composted (ploughed in) on site or buried on site, disposed of in a suitable landfill.

Treated produced or plant material will not enter the human or animal food chain. Stock will be excluded from the site.

i) Accidental release.

Accidental release is minimised by; restricting the quantity of substance transported to the trial site, use of appropriate packaging, use of chemical proof transport containers, availability of spill kits, applicators are GROSAFE accredited, not spraying if the wind conditions are not suitable.

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.

We envisage that up to 20 kg or litres of each product may be required over a five year period. The volume imported in any one year will be limited to the quantity required for that year.

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):

- 1. Methods for preventing the escape of the contained hazardous substance and preventing the contamination of the facility
- 2. Methods for excluding unwanted organisms from the facility or to control organisms within the facility
- 3. Methods for excluding unauthorised people from the facility
- 4. Methods for preventing unintended release of the substance by experimenters
- 5. Methods for controlling the effects of any accidental release of the substance
- 6. Inspection and monitoring requirements of the containment facilit

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.

See Appendix.

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.

The risks can be divided between Human Health Risks and Environmental Risks.

1. Human Health Risks

- a. Occupational exposure (transport, storage) could occur through spillage, leakage and fire.
- b. Worker exposure could occur during the application phase through spillage, leakage, contact with undiluted product during measuring and mixing. Exposure could occur with diluted product during application and application equipment clean up. Exposure could occur if entry into the treated area is made before the spray has dried.
- c. Public exposure could occur during the application phase, spillage during transport and fire.

The consequences of exposure to humans cannot be fully identified at this stage as there is limited information on the toxicology of the substance.

2. Environmental Risks



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- a. Air through fire/spray drift.
- b. Soil through spillage/leakage.
- c. Water through spillage/leakage/spray drift.
- Native Flora and Fauna through spillage/leakage/spray drift.

The consequences of exposure to humans cannot be fully identified at this stage as there is limited information on the eco-toxicology of the substance.

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)

	Hazard	Risk	Managed	Controls used in Management
				Minimum quantities imported/transported.
Importation and Transport	Very low	Low	Yes	Appropriate packaging and packing material.
				Trained personnel.
				SDS.
Storage	Very low	Low	Yes	Secure and appropriate storage facilities.
Measuring and Mixing	Very low	Low	Yes	Trained personnel.
Application	Very low	Low	Yes	Trained personnel.
Disposal of surplus				Trained personnel.
spray mix and unused substances	Very low	Low	Yes	Unused substances returned to point of origin or sent to incinerator.
Disposal of treated	Very low	Low	Yes	Trained personnel.
produce.				Stock excluded.

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Treated produce composted/buried.

Trained personnel.

Secure storage facilities.

Appropriate packaging.

minimum quantities transported.

The volume of the substance required will minimise most risks. Given the quantities involved, any unintended consequences from fire and spillage are minimal. The substance will be packaged in appropriate leak proof containers that will minimise/prevent spillage during transport and storage. The substance will be prepared and applied by trained staff using appropriate safety gear, thereby minimising accidental exposure to applicators, bystanders and the environment.

Low

Yes

Overall, the hazards are very low and the risks are low.

Very low

Risk to Maori:

This is very unlikely to be an issue given that:

Small quantities involved.

Accidental release

Trials will be on land that is already used for agriculture and Horticulture where approved substances/pesticides with varying degrees of hazard are currently used.

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)

If there are any international considerations attached to any substances imported under this submission, this will be provided in confidence to the EPA prior to trials commencing.

Section 7 – Miscellaneous

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

active ingredient a.i. or ai.

area around the treated part of the crop (typically one plot width Buffer zone

Formulation the form in which the substance is supplied for use

a single discreet marked unit comprising plant(s) or area of crop Plot

SDS Safety Data Sheet

Trial site a defined area comprising of contiguous plots within a crop with a clearly defined boundary

(Includes any Buffer zones)

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.

FAR Experimental substances. Each substance will have a unique FAR code.

8.2 Purpose 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 substances for the purpose of investigating under containment, in the field and laboratory, effects on pests/diseases/weeds in various plants.

8.3 Use 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.
- 2. Industry category: There are 16 industry categories.
- Function/Use category: There are 55 function/use categories.

(Optional)

Main Category:

3

Industry Category:

1

Function/Use:

38



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.

This is an application to import various substances to investigate their use in certain crops. The quantity of each substance will be no more than 20 kg or litres. The location of each trial site will be provided to the EPA and OSH.

The hazards may not fully be understood but all staff using or coming into contact with the substance are well trained in their management and use of potentially hazardous substances. The known hazards of each substance will be provided to the EPA prior to the commencement of trials.

With high level of care during handling and application, and the observance of label directions we believe the risks to users, consumers, bystanders and the environment are negligible.

In our judgement the importation and use of these substances will not adversely affect the natural resources of the flora, fauna, waterways, land and culture of the indigenous Maori.

Given the quantities of investigational material requested, the limited number of sites of use, the limited number of personnel involved and robust policies and procedures, the risks are slight but negligible.

Following importation, the substances will be handled, stored and transported by trained personnel, experienced in the safe management of hazardous substances. The overall management of the substance in respect of transport, storage, application and container disposal will be in compliance with the Code of Practice for the Management of Agrichemicals. [NZ 8409:2004]. Documentation to facilitate this will include the ready availability of the container label and Safety Data Sheet.

Signature

Date 19/8/13

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