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:

FMC New Zealand Limited

Name of substance:

Herbicide Experimental Agricultural Chemicals identified by a code number

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: FMC New Zealand Limited

Address: [redacted],
[redacted]
[redacted]

Phone: [redacted]

Fax:

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

Address:

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],
[redacted],
[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 this application is to import two (2) plant protection compounds - herbicides for experimental use in containment trials, to generate data for inclusion in a submission package to be lodged with the Environmental Protection Authority (EPA), and the Ministry for Primary Industries (MPI). For these compounds, we have provided the SDS and the composition details to acknowledge the hazards and risks involved with the proposed experimental use of the plant protection compounds.

The field trials are proposed to take place over a number of years/seasons, in various locations possibly on both the North and South Islands. The trials will be used to generate data on the efficacy, crop safety and residue profile of the compounds. The compounds will be imported into

New Zealand for use by qualified personnel in trials. The trials will be overseen by the Study Director.

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.

Not applicable

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 an application will be made if required
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):	
	☐ 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 names and composition of the mixtures are commercial-in-confidence, and are contained in Appendix 1.

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.

The chemical and physical properties the mixtures are commercial-in-confidence, and are contained in Appendix 1

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 hazardous properties of the mixtures are commercial-in-confidence, and are contained in Appendix 1.

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.

Following is the lifecycle of the experimental plant protection compounds;

1. Importation of samples
2. Transportation of samples from point of entry to Storage location
3. Storage of samples
4. Dispensing of samples into trial quantities
5. Transportation of trial samples from Storage location to trial sites
6. Preparation of spray treatment mixture
7. Application of spray mixture
8. Disposal of surplus spray mixture
9. Disposal of used containers
10. Disposal of treated produce
11. Disposal of surplus samples
12. Site close off

The substances will be packed in containers suitable for the shipment to and within New Zealand. Transport workers will only handle the fully packaged product, comprising the outer package, inner absorbent material and the inner package containing the substance. Exposure during transport, storage and handling is only possible through the breach of this packaging.

The empty containers will be triple rinsed and disposal at a licensed facility, or by burying at an approved landfill.

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.

The proposed quantity being imported for each substance are 10 kg for each formulation over the period of 3 years.

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):

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

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.

Importation of samples – samples will be imported into New Zealand port of entry in limited quantities, appropriate for the respective trial programmes. Samples will be securely packed in suitable containers that comply with the Hazardous Subtances (Packaging) Regulations 2001. Packages will be labelled according to the Hazardous Substance (Identification) Regulations 2001. Each shipment will include a Safety Data Sheet (SDS), compliant with the Hazardous Substance (Identification) Regulations 2001.

Transportation of samples from point of entry to Storage location – samples will be typically be shipped by Road transport as consigned/imported, directly to either Peracto New Zealand Limited, Pukekohe (Research facility), or alternatively directly to the Study Director. Substances shall be transported in compliance with the requirements of the Land Transport Act 1998, the Civil Aviation Act 1990 and the Maritime Transport Act 1994.

Storage of samples – samples will be placed in an appropriate sample cupboard specifically managed for such a purpose. The cupboard will be in a locked premise, that does not have public or general access. The storage of samples will be in accordance with the Code of Practice for the Management of Agrichemicals NZS 8409:2004.

Dispensing of samples into trial quantities – samples for each trial site will be decanted from the original shipping container, into smaller containers for use at each trial site. Decanting will be conducted by a person who has appropriate training, qualifications, and/or experience in handling experimental compounds. Personnel will utilise appropriate personal protective equipment (PPE) consistent with the Safety Data Sheet (SDS).

Transportation of trial samples to trial sites – typically samples will be transported to the trial site by the Study Director, preferably in the

Preparation of spray treatment mixture

Application of spray mixture – compounds will be applied by well-maintained equipment.

Exposure of non-target organisms - sites will be located clear of public areas, residential buildings, workplaces, surface water or waterways, environmental sensitive areas and grazing animals. Access to the trial sites shall be managed by the Study Director and/or the owner of the property on which the trial is located. The trial site boundaries will be clearly marked and be visible from outside the trial site. The trial site will carry signage indicating that unauthorised entry is not allowed, and that the area is an experimental site whereby produce should not be removed or disturbed.

Trial sites that are at a risk of being accessed by grazing animals are to have stock-proof fencing that will exclude animals for the duration of the trial, unless a stock withholding period has been set and/or elapsed as determined by the Ministry for Primary Industries (MPI), ACVM Group.

Disposal of surplus spray mixture – the amount of spray mixture prepared should be consistent with the amount required to treat each trial plot. Any surplus spray mixture is to be disposed of within the trial site, preferably in an area designated and marked for such disposal.

Disposal of used containers – empty containers should be returned to FMC or disposed of in accordance with the Hazardous Substances (Disposal) Regulations 2001.

Disposal of treated produce – all treated material shall not be consumed by people and/or animals, sold, offered for sale, given away, bartered or otherwise distributed unless MPI ACVM Group has approved such a process as part of provisional registration or a research permit. Treated produce maybe collected for residue analysis if required to meet ACVM guidelines.

Disposal of surplus samples – annually at the completion of each seasons trial programme all remaining samples will be returned to FMC for safe-keeping and/or disposal

Site close off

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 proposed containment system outlined in Section 5.1 is designed to provide appropriate safeguards for experimental substances commensurate with the experimental nature of these substances.

Given the high level of containment, any risks posed by the trials are likely to be improbable with minimal impact. Any risks arising will be managed as follows:

Accidental spillage

Spillage could occur at any stage of the life cycle, however as the substances will be for experimental use only, they will be in very limited quantities. An SDS detailing spill management procedures will accompany the product.

The sustainability of native and valued introduced flora and fauna.

The only threat to native and valued introduced flora and fauna would be in the event of an accidental spillage during transportation of the product. Any such spill would be cleaned up as per the procedures given in the SDS. Any adverse effects on valued native and introduced flora and fauna is expected to be minimal.

The intrinsic value of ecosystems

The high level of containment will minimise any risk to the intrinsic value of ecosystems.

Public Health (including occupational exposure)

Transport will be by trained personnel. In the unlikely event of an accident during transportation, the accompanying SDS will have directions for immediate action to minimise any risk.

General public are not expected to be at risk as the product will be stored and used at sites with no direct public access.

Assessment of effects in relation to significance to Maori

No adverse effects to Maori, their culture, traditions and ancestral lands are anticipated by the use of this product due to the limited size of the trials and control measures in place.

Accidental spillage is not expected to have any significant effect on Maori in relation to their culture and traditions as the amount of substance being transported in extremely small.

The economic and related benefits to be derived from the use of the hazardous substance.

Approval of this application will allow FMC to do trials for the new products for the agrochemical market. Successful trials will benefit New Zealand farmers and growers with new treatments for pests and diseases and the opportunity to substitute less hazardous products for current products.

New Zealand's international obligations

FMC is not aware of any international obligations, which may impact on the application.

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)

While no risks were identified as significant, accidental spillage during importation, transport and use was assessed as being the most likely risk area. The small quantities of hazardous substances imported into containment minimises this risk, and it is further reduced after decanting into trial quantities. The following controls are considered sufficient to manage the risks associated with accidental spillage:

- Product will be transported in accordance with good practice and in compliance with any relevant requirements of the Land Transport Act 1998, the Civil Aviation Act 1990 and the Maritime Transport Act 1994.
- All product will be imported and transported in secure packaging, suitable for the particular formulation.
- The appropriate storage and segregation will be observed during transport.
- All containers will be clearly labelled according to relevant legislation, and will be accompanied by a Safety Data Sheet detailing the hazards of the product, and the appropriate response in the event of an accident, including any information specific to the

particular product. The label and SDS will contain the following directions for containment of spillages: - Wear suitable protective clothing including face shield, impervious gloves and boots.

- Prevent the product or spilled material from entering water bodies.
- Absorb liquid spills with inert material such as earth or sand and place in waste containers.
- Wash area with water and absorb with further inert material. Dispose of safely.
- In a transport emergency dial 111, Police or Fire Brigade.
- For specialist advice in an emergency only, call 0800 734 607 (24 hours)

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)

Some of the compounds will be approved by other regulatory authorities, and others may be early stage experimental compounds that have not been assessed by overseas regulatory authorities. No international considerations have been identified with the compounds identified in the confidential appendix for trial in containment.

All trials will be conducted in containment to ensure that no treated produce enters the food chain and therefore does not pose risks to international trade.

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.

To import into containment experimental plant protection compounds for field trials in containment to allow assessment and development under local conditions for the control of weeds in various agricultural and horticultural crops and forestry. Where applicable, samples of crops may be collected for residue analysis at a suitable analytical laborartories.

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.

FMC experimental plant protection compounds.

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 into containment experimental plant protection compounds for field trials in containment to allow assessment and development under local conditions for the control of weeds, plant pests, diseases, or the management of various agricultural and horticultural crops or forestry.

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).

1. Main category: There are four main categories.
2. Industry category: There are 16 industry categories.
3. Function/Use category: There are 55 function/use categories.

(Optional)

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.

The purpose of this application is to import into containment experimental plant protection compounds that contain biologically active ingredient(s) for small scale field and laboratory testing. This will allow assessment and development of these compounds under local conditions for the control of insects in various agricultural or horticultural crops and forestry.

Approval is sought to import small quanties of the plant compounds sufficient to conduct relevant tests over the approval period. The trials will involve applying the compounds to defined plots within the trial areas. Applications in field trials will only involve small quantities of the compound which will occur at various locations in containment.

The trial sites will be selected based on the probability of the presence of the target weeds and appropriate crops. The trial areas will be representative of crop plants in various agricultural and horticultural crops or forestry. The compounds will be assessed for the control of insects and/or crop damaging using appropriate methodology.

The containment practices proposed with this application are designed to contain the compounds and manage any hazards and risk by covering the management of the substance throughout the life cycle particularly during storage, transport, use, and disposal.

[redacted]

6th August 2020

Signature **Date**

Appendix 1 – Commercially sensitive information

List of substances to be covered under this application, Composition details and SDSs are included in the confidential appendix.