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:

Dow AgroSciences (NZ) Ltd

(a member of the Corteva Agriscience group of companies)

Name of substance:

Experimental pesticides

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.:

[1]Working days to exclude public holidays as listed by Employment New Zealand

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: Dow AgroSciences (NZ) Ltd (a member of the Corteva Agriscience group of companies)

Address: [redacted]

Phone: [redacted]

Fax: [redacted]

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: N/A

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.

Approval is sought to import experimental pesticides (as listed in the confidential appendix) for the use in field, glasshouse and laboratory research trials in containment. Further information on how these substances will be applied is provided in the relevant Project Plan. The purpose of this research is to generate data to support both local and overseas registration activity related to product characterisation (discovery) and development. Substances related to this application are considered as hazardous however, due to the experimental nature of these substances, the information available is often limited as the substance may not yet be commercialised. An SDS/RSSDS will be provided for each substance listed.

This application is submitted to replace, in part, the current EPA Containment Approval HSC100131 which expires December 17th 2020. The information and controls in the following sections are based on HSC100131 and are appropriate given the level of containment management achieved through business practices, the confidential appendix A and relevant SOPs.

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
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.

Please refer to the confidential appendix.

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.

Please refer to the SDS/RSSDS for each substance.

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.

Please refer to the SDS/RSSDS for each substance.

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 typical life cycle for the listed substances includes the following:

1. *Import substance.*
2. *Transport substance according to international or HSNO requirements between point of entry and place of storage. Substances may also be sub-sampled between the storage site and trial site.*
3. *Application of the required quantity of the substance to the designated trial area. Depending on the situation this may be to a trial plot in an agricultural setting (e.g. horticultural crops, arable, pasture and forestry), glasshouse (small plots or pots) or laboratory (e.g. resistance testing, insect or disease bioassays and spray drift investigation). The remainder of the substance will be returned to storage. Equipment will be cleaned and rinsate disposed of by industry best practice and the proposed controls.*
4. *At the completion of a project or expiry of the containment approval (unless covered by a new approval), unused substance will be returned to an exempt laboratory for storage, destruction or export.*

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 quantity of each substance imported is proposed to be up to 100 L or kg over the entire life of the approval.

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.

The containment system and proposed controls are based on the risks associated with import and life cycle management of the substances. The means of implementing these controls are described in the Confidential Appendix A.

Proposed controls:

General

1. *Substances will not be applied as a seed treatment or by aerial application methods.*

2. *Substances will not be applied into or onto water. Water means water in all its physical forms whether flowing or not, and whether above or under ground, includes fresh water, coastal water, and geothermal water, but does not include water in any form while in any pipe, tank, cistern or water used in the dilution of the substances prior to application.*

3. *The import of each substance will not exceed the following quanity limits over the term of this approval:*

    - *100 L or 100 kg of substances used for field, glasshouse or laboratory trials.*

Personnel

4. *The qualification for a person that mixes, loads or otherwise handles the substances in preparation for application must be compliant with the relevant qualification requirements in clauses 60, 63 and 64 of the Hazardous Substances (Hazardous Property Controls) Notice 2017 as if the substances were class 9.1A, 9.2A, 9.3A or 9.4A pesticides or plant growth regulators.*

5. *All persons entering a notified trial site or using a listed substance must have received sufficient instruction on the containment regime appropriate to the level of risk of exposure to the substance to enable the person to meet their responsibilities under this approval.*
6. *Any person that handles the substance will use appropriate personal protective clothing or equipment that is designed, constructed, and operated to protect against potential hazards to the person's safety or health.*

Packaging

7. *Each substance will be packaged in accordance with the Hazardous Substances (Packaging) Notice 2017.*

Labelling

8. *The following information will be provided in English or a commonly accepted scientific notation:*

    - *Signal words*
    - *Identity of the substance*
    - *Net contents*
    - *Batch number*
    - *Date of manufacture and/or expiry*
    - *Emergency contact*

    Containers for use in trials may be identified by a code that cross-references to provide information on the substance identity and hazardous properties.

Safety Data Sheet

9. *A SDS or RSSDS will be available at all stages of the substance life cycle in New Zealand and contain relevant information that is currently available.*

Transport and storage

10. *The substance will not be transported on a passenger service vehicle.*
11. *Transport of the substance will comply with current NZ Standard for Transport of Dangerous Goods on Land and Land Transport Rules.*
12. *When not in use the substance will be held in secured storage.*

Notification

13. *EPA will be notified, in writing, prior to the commencement of the project and associated trials. This excludes activities related to planning and preparation. The Project Plan will be provided to notifications@epa.govt.nz and will include:*

    - *Date of notification*
    - *Containment application and approval number*
    - *MPI Operating Plan number*
    - *Substance identity*

- *Project title and objectives*
- *Situation (e.g. crop or pest) that the substance will be applied to*
- *Application method*
- *Application timing and frequency*
- *Estimated total treated area and plot size*
- *Estimated substance quantity to be used in the trials*
- *The name and contact information for the person responsible for the trials*
- *Expected completion date*
- *Information on how residues on the treated crop will be managed with regards to risk pertaining to the HSNO Act (this excludes risk areas pertaining to the ACVM Act). This includes the risk to birds for seed treatments and risks to bees for substances toxic to terrestrial invertebrates (see points 25 – 30 below).*

Trial sites

14. *Each trial of a substance in containment will be undertaken within an area specifically designated as a 'trial site'. This site may be all or part of a property or facility.*

15. *The trial site will include:*

    - *All test plots and buffer zones (for field sites)*
    - *Any area used for cleaning equipment or disposing of rinse water*
    - *Any area on which any excess mixture of the substance is applied*

16. *The trial site will not include land or facilities that the public can legally access without permission of the owner or legal occupier.*

Signage

17. *Signs will be clearly displayed at the trial site or entrance to the containment facility for the duration of the trial. The signs will state:*

    - *That the site is subject to the trial of a hazardous substance*
    - *Unauthorised access to the site is not permitted*
    - *A 24 hour contact number*

Records

18. *Written records of the trials in containment will be maintained and available for verification. The records will be kept for at least three years after the trials are completed and will include the following information:*

    - *Containment approval number*
    - *Identity of the substance*

- *Date of substance import*
- *Total quantity of the substance imported*
- *Date and location (property address, GPS coordinates and field number (if available)) of each substance application*
- *Applicators contact details*
- *Measures taken to ensure that adverse effects do not occur beyond the boundary of the application area.*

19. *Records kept under this approval will be made available to EPA or MPI within five working days following receipt of a written request.*

Use

20. *No crop or produce, to which a substance is applied, will be used for food by people or animals unless that use meets the requirements of a valid Operating Plan issued by MPI and as specified by the Project Plan.*

21. *All reasonable steps will be taken to ensure there are no significant adverse effects to the environment beyond the application area.*

22. *All reasonable steps will be taken to ensure that people are not adversely affected by the use of the substance.*

23. *Trial sites that are at risk of entry by unwanted grazing animals must be secured by stock-proof fencing to exclude grazing animals for the duration of the trial.*

24. *If the substance meets threshold of a 9.4 substance or where bee toxicity is unknown, the substance will not be applied to plants likely to be visited by foraging bees:*

    - *At the time of applications, or*
    - *Until after the spray has dried.*

Disposal

25. *The substances covered by this approval will comply with the relevant provisions of the Hazardous Substances (Disposal) Notice 2017.*

26. *At the completion of the project, or at such a time that a substance is no longer covered by a valid approval, the substance will have:*

    - *Been used up, or*
    - *Been disposed of, or*
    - *Be contained in a facility compliant with Part 18 of the Health and Safety at Work (Hazardous Substances) Regulations 2017, or*
    - *Been approved for use.*
    - *Been exported.*

27. *Any equipment used to prepare or apply the substances will be cleaned after use and rinsate either sprayed within the site or disposed of in compliance with the Hazardous Substance (Disposal) Notice 2017.*

28. *Any crop or produce, to which a substance is applied, not allowed to enter the food chain in accordance with the ACVM Act, will be disposed of. Disposal methods may include mulching, ploughing in, dropping onto the ground under the tree or vine, composting or burial at the trial site, or by disposal of at an approved landfill.*

Emergency management

29. *Any spill of the substances will be contained, prevented from entering into any waterway or ground water and absorbed with an appropriate material.*

30. *Heavily contaminated soil will be removed and disposed of appropriately.*

31. *Any spilled substance, material used to clean up the spill and contaminated soil may be disposed of in a landfill, sewage facility or by incineration if the facility will treat the substance so that it is no longer hazardous.*

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

Breach of containment

33. *If any of the substance is applied other than in the intended application area, or are lost or spilt (where the spill cannot be immediately contained) outside of the defined trial site and related facilities, the nature and quantity of the spill will be reported to EPA within 24 hours of becoming aware of this incident.*

34. *If for any reason a breach of containment occurs, other than those specified above, the nature of the incident will be reported to the EPA within 24 hours of becoming aware of the incident occurring.*

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.

As these substances are undergoing characterisation, there may be limited information available about the relavent hazards hence the proportionate controls proposed. The risk of accidental release is low due to the management practices in place to implement the controls.

There is a low risk of accidental spills of a substance, this may occur during transport, in storage, during spray preparation or application. However, the quantity of each substance in any one place in New Zealand at any one time and the management procedures in place to implement the related controls mean that exposure to the environment as a result of an accidental spill is negligible.

Given the proposed controls and resulting level of containment, the risk to native and valued introduced flora and fuana, intrinsic value of ecosystems and public health is very low. The risk to Māori and their culture and traditions is also considered to be low as their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga are unlikely to be affected by the substances due to the management of containment and selection of trial site locations.

There is also a low risk of breach in containment as a result of unintended release of treated produce entering the foodchain. Again, given the management procedures in place to implement the proposed controls, the risk is not considered to be significant.

The most likely, although still low risk, is to personnel involved in the application of the substances. This risk is managed through training, best practice operating procedures and by use of application equipment and personal protective equipment appropriate to and conservative of the known hazardous properties of each substance. Hence it's concluded that the risk to public health (including occupational exposure) and the environment is very low.

In terms of the economic and related benefits likely to be derived by the use of the substance, the trials to be conducted in containment under this approval are to generate data to support both local and overseas registration activities related to product characterisation (discovery) and development. The result of this research activity is to bring innovative agricultural crop protection products to New Zealand and overseas growers in order to facilitate production of "best in class" produce required for export and domestic consumption. The agricultural industry is a leading contributor to the New Zealand economy with pest and disease being a significant cause for loss in production.

Corteva Agriscience, of which Dow AgroSciences is a member, is a global, agricultural research and development agrichemical company present in over 140 countries around the world and employing more than 2000 discovery and field research scientists. We are one of a very few companies that work on discovering innovative agricultural molecules globally and the only major agriscience company completely dedicated to agriculture. Our presence in New Zealand goes as far back as mid-40s. We have decades of experience conducting R&D trials with plant protection products in New Zealand with a focus on novel product with improved environmental and toxicological profiles, drift reduction technology and targeted efficacy for use in sector wide and national Integrated Pest Management (IPM) systems such as "A Lighter Touch".

In writing this containment application we have relied on this experience, the current industry best practices and most importantly, drawn from our experience operating under the current HSC100131 approval (since December 2015) and its predecessor HSC100040 (December 2010 – December 2015).

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)

Not provided as none of the risks identified in section 5.1 are considered to be significant.

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)

Substances imported for trials in containment under this approval will also need to comply with conditions outlined in the associated MPI Operating Plan pertaining to the ACVM Act. ACVM will be notified of the same Project Plan, including the identification of each substance. In some instances, overseas regulators may also be aware of these substances depending on the development stage of the substance. Many substances are trialled in multiple locations globally allowing for a full data profile (e.g. efficacy and residues) to be generated.

Section 7 – Miscellaneous

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

SDS *– Safety Data Sheet*

RSSDS *– Research Sample Safety Data Sheet*

Project *– A set of trials designed to meet one or more study objectives. A Project may include multiple substances, crops or situations, and locations. A Project may be active over several seasons or years.*

Trial – *A single study in one location and one crop (possibly including multiple varieties) or situation that may include multiple substances. A trial may be conducted in the field (e.g. on land, or in a greenhouses) or in a laboratory (e.g. a bioassay or spray tunnel). A trial may continue over multiple seasons or years.*

Trial site *– A single area of separate but adjoining plots (either treated or untreated) with a define boundary. A trial site may contain plots treated by several different substances at varying rates at different times (including more than once) and may be applied to different cultivars or varieties of the same crop group (e.g. kale, swede and turnip forage brassicas).*

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.

Experimental pesticides.

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 use in field, glasshouse and laboratory research trials in containment. The purpose of this research is to generate data to support both local and overseas registration activities related to product characterisation and development.

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)

Main category: 3 – Non-dispersive use

Industry category: 1 – Agricultural industry

Function/Use category: 38 - Pesticides

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 experimental pesticides for the purpose of conducting trials in containment to generate data for characterisation and development. Registration of these substances may later be sought for use in New Zealand as agricultural crop protection products.

Approval is sought to import 100 L or kg of each substance over the life of the approval.

[redacted] 3rd September 2020

Signature **Date**

Appendix 1 – Commercially sensitive information

Please see appendix attached separately to this application.