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:

Bayer New Zealand Limited

Name of substance:

Bayer Trial Products 2021 (1)

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.

Bayer is seeking approval to import formulated crop protection products for the purpose of conducting field trials in containment. We are seeking approval under section 30(b) of the HSNO Act 1996. Our intention is to conduct small plot trials in the first three to four years in order to examine the residue, efficacy and crop safety profile of each product and establish Good Agricultural Practice (GAP). Formulations that are successful in this initial development phase will then need to be tested in larger scale trials for a further one to two years in order to confirm the GAP, residue, efficacy and crop safety profile when the product is applied via commercial application equipment. Large scale trials are necessary because of the difference in application characteristics between handheld experimental sprayers and commercial application equipment such as tractor-drawn boom and air blast sprayers.

The specific products to be trialled are listed in the Confidential Appendix. In terms of function, the products are insecticides, herbicides and fungicides. Given that the products are designed to have a biological effect, they are expected to trigger classification under the HSNO Act.

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.

N/A

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.

Details are provided in 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 Safety Data Sheet (SDS) for each product for the known properties of 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.

The expected hazardous properties of the products are detailed in the Safety Data Sheets provided to the EPA. None of the products are explosive, flammable, oxidising or corrosive. As a matter of practice, Bayer screens compounds early in the research phase to eliminate any that have undesirable characteristics. For example, where the weight of evidence from early screening suggests that a molecule has high intrinsic toxicity then Bayer would discontinue development of such molecules. The compounds that do make it into field trials would have passed

the early safety screening tests, though of course the more advanced toxicity and ecotoxicity studies will still be ongoing. Internally, Bayer always requires researchers to handle experimental products as though they were classified with the highest toxicity, regardless of the findings from the early screening.

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.

The lifecycle of trial products is as follows.

Sample acquisition

Bayer New Zealand orders products for experimental use from Bayer AG via a dedicated system. The system tracks the products ordered, the quantity, purpose, expiry date and other relevant parameters. Only one individual within Bayer is authorised to place these orders. The products are brought into the country by air freight. Clearance by Customs is contingent upon Bayer New Zealand providing proof that the products are allowed to be imported into New Zealand. Once cleared, the products delivered to Bayer and stored in a dedicated storage facility under our control.

Sample distribution

Our trial products are applied by qualified Bayer personnel who have experience handling agrochemicals. We also use reputable contract research organisations to conduct some of our trials. In all cases persons handling our products are required to treat them as though they were highly hazardous. All substances will be packed and transported in high density polyethylene (HDPE) containers which are intended to handle dangerous goods.

Bayer New Zealand orders small containers of trial products to make sample distribution to various researchers easier. For example, trials are going to be conducted in 3 different regions of the country and a total of 1.5 litres is required, Bayer New Zealand may order 6 x 250 ml containers rather than 1 litre containers which will then need to be divided up. In this case we would then 2 x 250 ml containers to each region. This has the effect of eliminating the need for local relabelling of sub-samples, and limiting decanting to only those occasions when researchers are actually loading the product into their sprayers.

All samples are accompanied by safety data sheets. A register is maintained detailing the amount of product sent to each researcher. Any product left over (e.g. if there was a crop failure and it was no longer necessary to spray) is returned to Bayer, unless the trials are to be repeated the following season and appropriate long term storage is available.

Product application

Trial sites will be negotiated with land owners and agreements signed before trials can begin. These agreements will stipulate the owner's obligations, including the need for them to not collect plants from the trial area, and to

not allow unauthorised persons to enter the site. Trial locations will be marked out and labelled in accordance with controls set under the EPA containment approval and Bayer's MPI-approved Operating Plan. Signs will be put up indicating that an experimental product is in use and warning unauthorised people to not enter the site.
All trials will be conducted in accordance with written protocols that specify the personal and environmental safety precautions, trial objectives, the crop type, the plot size, the application rate, number of applications, application timing, interval between applications and other relevant parameters. All staff and contractors will be required to handle the products as though they were highly hazardous. The application will be made using calibrated equipment.
Exact quantities of the test substance and the spray mixture are measured out in order to minimise the chances of left-over spray mixture. Any leftover materials are disposed of in accordance with instructions on the SDS. In general, only very limited quantities would be left over.

Assessment and Site Close-off

Trial personnel will enter the site periodically to carry out assessments or collect samples for analysis as needed. Once the trial has been completed, the treated material will either be disposed of at a land fill or harvested if permitted under the MPI-approved Operating Plan.
The signs and demarcations are then removed and the site is returned to the owner's control.

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.

Approval is sought to import up to 100 litres or kilograms of each trial product over a five year period. The exact amount eventually imported will depend on the application rate as well as the number of trials that will need to be run to fully establish efficacy, crop safety and residue behaviour. The quantity requirements will be outlined in the Project Plans developed for each series of trials on a year-by-year basis.

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.

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

1. Investigational products are manufactured and packaged overseas in containers meeting Dangerous Goods requirements. These containers are usually high density polyethylene (HDPE);
2. The amount of product imported is limited to that necessary to meet the requirements of the trial. This is carefully controlled to minimise the chance of product going obsolete and having to be disposed of;
3. Products are imported into our Christchurch office, where they are stored in an alarmed room under lock and key;
4. The products are imported in small containers to minimise the need for decanting and the chance of opened containers needing to be carried forward to the next season;
5. Investigational products are under the control of a qualified and experienced scientist who is responsible for issuing out required quantities based on the ISPs for each set of trials;
6. When needed, specific quantities of product are withdrawn from the store and issued to research staff. An entry is made on the product inventory, indicating how much product was issued and to whom. Quantities issued are based on the study requirements as detailed in the ISP for that set of trials;
7. The investigational products are not volatile nor gaseous: they will either be liquids, granules or powders. Therefore, there is minimal risk of product escaping from containers and contaminating the storage facilities;
8. In terms of field application, small quantities of product are used to prepare a spray mix for application via backpack spray or other small-scale treatment methods;

9. Products will be applied onto plots specifically designated and marked for each treatment. The application techniques aim to to minimise of-target application of the spray. The equipment used is hand held/operator worn and uses hydraulic pressure or compressed CO_2;
10. The trial areas will be is isolated from commercial crops by buffer zones and demarcated by labelled pegs;
11. Spraying will be in accordance with Section 5 of the NZS8409: 2004 Code of Practice for the Management of Agrichemicals. In the case of foliar applications, the spray is normally applied to ensure good coverage but without run-off;
12. Discharge to surface or ground water is very unlikely at the treatment stage;
13. Field trial sites will not be contiguous with any water source;
14. Field sites will be fenced to prevent access by stock;
15. Solid waste (treated produce) will be disposed of either by ploughing in, mulching, or at an approved landfill unless authorised to enter the food chain under the MPI permit;
16. The trial facility will be a very small part of a larger commercial entity that is self contained;
17. The substance will be securely packed in the original labelled container, with an SDS. Transportation will be by approved carriers;
18. All surplus samples will be held in original containers and stored in the company's laboratory until after the product is registered for use, or, if the product is not registered, it will be suitably destroyed via an appropriate company;

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

19. The facilities where investigational products are stored is inaccessible to livestock, birds, rats and other organisms;
20. Where investigational product is applied as a spray, it is normally applied to the point of run-off with very limited amounts settling off-target. Soil-applied products such as pre-emergence herbicides work by sticking to soil particles on and just below the surface, which allows them to come into contact with germinating weeds and control them before they emerge. Seed-treatment products are designed to stick to the seed surface and if systemic, to be absorbed by the young seedling. In all cases small quantities of the active ingredient may be washed off by rain, but these are expected to have minimal effects given the limited quantities applied;
21. Trials will be clearly marked and there will be stock-proof fencing where needed;

Methods for excluding unauthorised people from the facility

22. The investivational products will be stored under lock and key in an alarmed facility. Only authorised personnel will be able to access them;
23. Before trials can be conducted, Bayer establishes agreements with the landowners which stipulate among other things that unauthorised personnel are not allowed at trial sites.
24. Trial sites will be clearly marked out as having been treated with experimental products and prohibiting unauthorised access as well as harvesting;

Methods for preventing unintended release of the substance by experimenters

25. All researchers will be issued with product based on an agreed study plan, and they will account for the product that they are issued with;
26. All staff are well trained in agronomic practices and competent to apply investigational products as required;
27. The trial sites shall be chosen so as to prevent the substance entering water bodies;
28. The trial sites shall be located to prevent any building where people live or work being exposed to the substance;

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

29. The products will be imported in multiple small containers. Therefore, any accidental release will likely involve no more than a few hundred millilitres of product at the most;
30. Only the quantity of products required to fulfill the study requirements for each season is issued out to research scientists;

Inspection and monitoring requirements of the containment facility.

31. Trial sites will be visited for assessment and monitoring as per the requirements of the individual study plan;
32. Storage facilities for samples and investigational products will be inspected in keeping with the requirements of the Health and Safety at Work Act.

The standard operating procedures (SOP) relating to the containment system are also attached to this application.

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.

Activity	Associated risks
Sample origin	Inadequate quality standards in country of origin may introduce highly hazardous substance with unacceptable human and environmental impacts.
Sample transport and storage	Failure to follow relevant safety precautions and correct procedures may result in the release of the substance with the following adverse effects • Health impacts upon persons through direct contact • Unintended environmental effects
Sample dispensing	Accidental spillage of the substance resulting in human and environmental impacts
Preparation of spray mixture	Failure to follow relevant safety precautions and procedures during mixing and loading may result in the release of the substance with the following adverse effects • Health impacts upon persons through direct contact • Unintended environmental effects
Application of spray mixture	Failure to follow relevant safety precautions and correct procedures may result in human exposure and / or off-target release of the substance, leading to human health impacts and unintended environmental effects.

Disposal of surplus spray mixture	Improper disposal of the substance resulting in human and environmental exposure
Access control	Inadequate access control resulting in animal or human exposure to spray or treated produce and associated health impacts.
Disposal of treated produce	Failure to follow relevant safety precautions and correct procedures may result in human and animal exposure to residues of the substance, thus affecting their health.
Disposal of used containers	Failure to follow relevant disposal procedures may result in the release of the substance with the following adverse effects • Health impacts upon persons through direct contact • Environmental effects, particularly in respect of non-target species
Disposal of surplus samples	Failure to follow relevant disposal procedures may result in the release of the substance with the following adverse effects • Health impacts upon persons through direct contact • Environmental effects, particularly in respect of non-target species
Site close off	Failure to follow relevant site close-off procedures may result in human and animal exposure to residues of the substance, thus affecting their health.

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)

Table 2: Risk Assessment and Management

Activity and risks	Classification of Risk (Note 1)	Significance of Risk (Note 2)	Spatial Distribution (Note 3)	Options and Proposals for Risk Management	Impacts of Risk Management
Sample origin – highly hazardous substance erroneously manufactured and imported	Direct; Remote possibility of occurrence; Small consequence.	Negligible to low	Regional	Manufacturing process and quality control. Technical assessment and review of data.	Reduced likelihood of out-of-spec product being manufactured and imported into New Zealand
Sample transportation – accident resulting in spillage of product	Direct; Unlikely to occur and low, localised consequence.	Negligible to low	Site specific / localised	Transport of samples to be in accordance with SDS for substances, NZS8409: 2004 and the Management Plan	Reduced likelihood of spillage.
Sample dispensing – spillage of the trial product	Direct; Unlikely to occur; Small consequence.	Low	Site specific / localised	Dispensing of samples to be in accordance with SDS for substances, NZS8409: 2004 and the Management Plan	Reduced likelihood of spillage.
Preparation of spray mixture – spillage or overdosing	Direct; Unlikely to occur; Small consequence.	Low	Site specific / localised effects	Preparation of spray mixture to be in accordance with SDS for substances, NZS8409: 2004 and the Management Plan	Reduced likelihood of release.
Application of spray mixture – overdosing	Direct; Unlikely to occur ; Small consequence	Negligible to low	Localised effects	Application of spray mixture to be in accordance with SDS for substances, NZS8409: 2004 and the Management Plan (3.5)	Reduced likelihood of overdosing.
Inappropriate disposal of surplus spray mixture resultiing in human and environmental impacts	Direct; Unlikely to occur ; Small consequence	Negligible to low	Localised effects	Disposal of surplus spray mixture to be in accordance with SDS for substances, NZS8409: 2004 and the Management Plan Only amount of spray mix required is prepraed	Reduced likelihood of excess spray mix being generated; reduced requirements for disposal.
Disposal of treated produce – unintended animal exposure	Indirect; Unlikely to occur ; Small consequence	Negligible to low	Localised effects	Disposal of treated produce to be in accordance with SDS for substances, NZS8409: 2004 and the Operating Plan approved by the ACVM.	Reduced likelihood of contamination; appropriate time for returning trial site to normal production.
Disposal of used containers – spillage of left-over product	Indirect; Unlikely to occur ; Small consequence	Negligible to low	Localised effects	Disposal of used containers to be in accordance with SDS for substances, NZS8409: 2004 and the Management Plan	Reduced likelihood of contamination.
Disposal of surplus samples – environmental and human exposure	Indirect; Unlikely to occur ; Small consequence	Negligible to low	Localised effects	Disposal of surplus sample to be in accordance with SDS for substances, NZS8409: 2004 and the Management Plan (3.7)	Reduced likelihood of contamination.

Notes:

1. Grouped as direct or indirect; Probability/likelihood of occurrence is given on the following scale:
   Highly probable, probable, likely, unlikely, remote possibility

Consequence is rated on the following scale; Small, medium, large

2. The significance of the risk (estimated from the potential severity of the event and the probability of occurrence) is given on the following scale: Negligible, low, moderate, high, extreme.
3. Spatial distribution is identified in terms of the following criteria: Nationwide, Regional (more than one District), District (generally a local authority area), Local (within an existing street/road network or city block) and Site Specific

TABLE 3: Assessment of Effects in Relation to Significance to Maori

Activity	Identification and Description of any Effects on Environmental Values	Outcomes of Consultation in Relation to Identified Effects	Identification and Description of any Effects on Cultural Values	Outcomes of Consultation in Relation to Identified Effects
Sample origin, importation, storage, transportation, dispensing, preparation of treatment mixture, application, disposal of surplus spray mixture, handling of treated produce, used containers, surplus samples and site close off.	Minor or no impact on: • Traditional food sources • Indigenous or valued flora and fauna • Natural habitats • Life sustaining capacity of air, land or water	As identified, impacts are minor or nil. No consultation was required	Minor or nil impact on: • Maori cultural health and well being • Maori cultural, spiritual, ethical or socio-economic values • Maori traditional knowledge • The mauri of Maori culture, language and knowledge • The mauri of land, air and other taonga • The maintenance, expression and control of traditional practices	As identified, impacts are minor or nil. No consultation was required

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)

The first eight substances in the list are currently covered in existing containment approvals i.e. HSC100186, HSC100209 and HSC100217 that are expiring soon.Therefore they have been assessed already by EPA.

For the remaining substances they are not currently covered in any of the existing containment approvals and some contain new active ingredients.

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.

Bayer Trial Products 2021 (1)

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 Bayer plant protection products into containment for field trials in New Zealand. The trials are intended to investigate the residue behaviour, efficacy and crop safety of the products under New Zealand conditions. The products are for the control of insect pests, plant diseases or weeds.

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.

Approval is sought, pursuant to section 30(b) of the HSNO Act 1996 to import into containment experimental plant protection products for small scale field and laboratory testing. This will allow assessment and development of this compound under local conditions for the control of pests, dieases and weeds in relevant crops. This information is required to enable the registation of the product under the Agricultural Compunds and Veterinary Medinces Act. Information about the composition of the products is confidentialy provided to the EPA.

Small quanties of the compounds will be imported sufficient to conduct relevant tests over the approval period. Applications in field trials will only involve small quantities of the compounds to small areas which will occur at various locations in containment.The containment practices proposed with this application are designed to contain the compound and manage any hazards and risk by covering the management of the substance throughout the life cycle particularly during storage, transport, use, and disposal. Due to the small volumes of products to be used and the proposed use of the products adverse effects upon the environment, human health and the relationship of Māori and their culture with their environment are not anticipated.

[redacted] 27/03/2021

Signature **Date**

Appendix 1 – Commercially sensitive information

See attached.