Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

26 May 2020

Summary

Substance Name	Bayer Trial Products 2020 (1)
Application code	APP204005
Application type	To import or manufacture[1] a hazardous substance in containment under section 31 of the Hazardous Substances and New Organisms Act 1996 ("the Act")
Applicant	Bayer New Zealand Limited
Purpose of the Application	To import or manufacture Bayer Trial Products 2020 (1) in containment
Date application received	14 April 2020
Consideration date	26 May 2020
Considered by	The Acting General Manager[2] of the Environmental Protection Authority ("the EPA")
Decision	**Approved with controls**
Expiry date of approval	**26 May 2023**
Approval code	**HSC100241**

[1] Manufacturing is described as making, preparing, producing, labelling or packaging a hazardous substance, this also includes re-labelling and re-packaging. For the purpose of this application, the term "sub-sampling" of substances is considered manufacturing.
[2] The Acting General Manager of the Hazardous Substances and New Organisms group of the EPA has made the decision on this application under delegated authority in accordance with section 19 of the Act.

1. Background

1.1. Bayer New Zealand Limited ('the applicant") sought approval under section 32 of the Act to import or manufacture 14 hazardous substances ("the substances") in containment.

1.2. These substances are agricultural chemicals that include five fungicides, five herbicides and four insecticides. These substances contain active ingredients that are new to New Zealand and existing active ingredients that are present in currently approved substances in New Zealand.

1.3. The applicant intends to use the substances in small-scale field trials in order to examine the residue, efficacy and crop safety profile of each product and establish Good Agricultural Practice (GAP). Formulations successful in the initial development phase will then be tested in larger scale trials to confirm the GAP, residue, efficacy and crop safety profile when the product is applied via commercial application equipment.

1.4. Nine substances in this application are covered under existing approvals HSC100516 and HSC100618. Eight substances are covered under HSC100516 and included in this containment approval as the approval is due to expire in July. One substance covered under HSC100618 has been included in this application as the maximum amount that could be imported for the substance was reached.

2. Process

Application receipt

2.1. The application was formally received on 14 April 2020 under section 31 of the Act.

Information available for consideration

2.2. The information available for the consideration includes the:

- application form
- confidential appendices to the application, including information on the substances
- EPA staff advice memorandum.

2.3. The available information is sufficient to assess the application.

3. Hazardous properties

3.1. The applicant submitted information on the hazards of the substances for which approval is sought. It is noted that these are experimental substances, and as such there is insufficient information available for the hazard classifications of the substances to be determined.

3.2. Based on the available information, these substances may cause adverse effects to human health and the environment. The potential adverse effects are expected to be similar to other plant protection substances that are already approved under the Act for import or manufacture with controls.

4. Assessment of risks

4.1. The applicant has proposed a containment system and information on how they intend to address the risks from the following:

- To limit the likelihood of escape of any contained hazardous substances or contamination of the facility by hazardous substances
- To exclude organisms from a facility or to control organisms within a facility
- To exclude unauthorised people from a facility
- To prevent unintended release of the substance by experimenters working with a substance
- To control the effects of an accidental release of the substance
- Inspection and monitoring requirements of the containment facility

4.2. The EPA considered the applicant's assessment and determined that the substances may pose risks such as, but not limited to, those detailed below.

Risks to human health and the environment

4.3. The substances may cause adverse effects to human health and the environment if people or non-target organisms are exposed to the substances.

4.4. The substances could potentially contaminate waterways, groundwater, soil or neighbouring properties. These potential exposures could result from an incident during importation, manufacture, storage, transport, application, or disposal of the substances. The risk of an incident occurring with the proposed controls in place is considered negligible.

4.5. The likely route for human exposure is through oral or dermal contact while handling the substances. However, it is unlikely that people using the substances will be exposed in this way provided that risk mitigation measures are in place. These measures include the use of personal protective equipment (PPE), and qualification requirements for people preparing and handling the substances.

4.6. There is also a risk that members of the public may be exposed to the substances. This is mitigated by controls that limit access to the field trial sites to authorised personnel only. Field trials are limited to sites that do not include land or facilities that the public can legally access without permission

4.7. Non-target animals foraging within the field trial site may be exposed to the substances either via contact with or consumption of treated produce or vegetation. This is mitigated by a control that specifies that trial sites that are at risk of entry by grazing animals must be secured by stock-proof fencing. The approval holder is also required to ensure that non-target species are not adversely affected by the use of the substances.

4.8. With the controls in Appendix A and restrictions under other relevant legislation, the risks to human health and the environment posed by the importation or manufacture of the substances (in containment) are negligible.

4.9. There are also requirements under the Health and Safety at Work Act 2015 and associated regulations. Note: the Health and Safety at Work Requirements are not set under this approval but apply in their own right.

Risks to the relationship of Māori to the environment

4.10. The potential effects of the substances on the relationship of Māori to the environment have been assessed in accordance with sections 5(b), 6(d) and 8 of the Act. Under these sections all persons exercising functions, powers and duties under this Act shall recognise and provide for the maintenance and enhancement of people and communities to provide for their cultural well-being, and; take into account the relationship of Māori and their culture and traditions with their ancestral lands, water, taonga and the principles of the Treaty of Waitangi (Te Tiriti o Waitangi).

4.11. It is unlikely that the importation or manufacture of the substances in containment will impact on Māori culture or traditional relationships with the environment.

4.12. If the substances are managed in accordance with the controls in Appendix A, it would be likely to be consistent with the principles of the Treaty of Waitangi, particularly the principle of active protection.

Assessment of risks to society, the community and the market economy

4.13. No risks to society, communities or the market economy were identified from importing or manufacturing the substances in containment.

New Zealand's international obligations

4.14. None of New Zealand's international obligations were identified as being impacted by importing or manufacturing the substances in containment.

5. Assessment of containment

Purpose of the approval

5.1. Under section 32 of the Act, a containment approval may only be granted if the application is for one of the purposes specified in section 30 of the Act.

5.2. The applicant notes that the purpose of this application is to conduct research and development on the substances, in accordance with section 30(b) and section 30(ba) of the Act. The application is therefore eligible for consideration under section 32 of the Act. Adequacy of containment

5.3. Section 32(1) of the Act requires that the substances can be adequately contained. The potential for the substances to escape from containment was assessed by taking into account

the containment system proposed by the applicant and the potential pathways for release of the substances.

5.4. Section 32(2) of the Act specifies that a containment approval for a hazardous substance must include controls for each of the applicable matters specified in Schedule 3. The approval may also include controls that provide for any other matters in order to give effect to the purpose of the Act.

5.5. Applying the Schedule 3 requirements and using the information provided by the applicant, a set of controls was developed to ensure adequate containment of the substances.

5.6. The applicant was provided with the proposed controls and given an opportunity to comment. The applicant suggested that the wording in control 49(f and g) could be modified to account for the fact that the date of the trial and quantity of the substance may change due to the weather or other factors. These comments were acknowledged. However, the EPA staff note that it is acceptable to send more than one notification of the trial start date if there are factors affecting the start date of the trial. Therefore, control 49 was not modified as suggested by the applicant. No other concerns with the controls were raised.

5.7. Having considered all the applicable matters, the EPA has determined that the substances can be imported or manufactured in containment, provided that the controls in Appendix A are complied with.

6. Decision

6.1. Pursuant to section 32 of the Act, I have considered this application for an approval to import or manufacture Bayer Trial Products 2020 (1) in containment. I have applied the relevant sections of the Act and clauses of the Hazardous Substances and New Organisms (Methodology) Order 1998.

6.2. I am satisfied that Bayer Trial Products 2020 (1) can be adequately contained with the controls in Appendix A.

6.3. Therefore, the application to import or manufacture Bayer Trial Products 2020 (1) in containment is granted until **26 May 2023**.

Environmental Protection Authority
Te Mana Rauhi Taiao

Dr Clark Ehlers **Date: 26 May 2020**

Acting General Manager, HSNO, EPA

Appendix A: Controls applying to the importation or manufacture of Bayer Trial Products 2020 (1)

General

1. In these controls, “approval holder” refers to Bayer New Zealand Limited.

2. In these controls, “substances” refers to, and is limited only to, Bayer Trial Products 2020 (1).

3. Bayer Trial Products 2020 (1) consists of 14 formulations declared with application APP204005. These substances are summarised in confidential Appendix B.

Accountability

4. The approval holder must ensure compliance with all the controls in this approval.

Requirement for containment

5. The substances must be in containment at all stages of their life cycle in New Zealand.

Limitations

6. This approval expires on **26 May 2023**.

7. The approval holder must ensure that the nature of the field trials and manufacture of the substances are in accordance with the activities proposed in application APP204005, unless otherwise specified by the controls on this approval.

8. Over the term of this approval, the approval holder may import or manufacture up to 100 kilograms or 100 litres, of each substance covered under this approval.

General requirements

9. The substances must be correctly packaged. The substances are correctly packaged if they are packed in accordance with the Hazardous Substances (Packaging) Notice 2017 and their packaging complies with the same Notice.

10. The substances must be correctly labelled. The substances are correctly labelled if they are packed in a container that is labelled in accordance with the Hazardous Substances (Labelling) Notice 2017. The label must include the name and New Zealand contact details for Bayer New Zealand Limited, including a 24-hour emergency contact phone number.

11. A safety data sheet (SDS) must accompany the substances at all stages of their life cycles in New Zealand. The SDS must comply with the relevant requirements of the Hazardous Substances (Safety Data Sheets) Notice 2017.

Workplace site and storage requirements

12. Clauses 39 to 42 of the Hazardous Substances (Hazardous Property Controls) Notice 2017 apply to this approval, as if the substances were class 9.1A.

Containment facility

13. The approval holder must only import and subsample the substances at the facility described by the approval holder in the application. This facility is described as the “containment facility”.

14. Unauthorised persons must be excluded from the containment facility.

15. The containment facility must, as far as is reasonably practical, be managed so as to exclude unwanted organisms.

Field trial sites

16. Each field trial of a substance must be undertaken in containment within an area specifically designated as a ‘field trial site’. This site may be all or part of a property or facility.

17. The field trial sites must include:

    a. all preparation, storage and operational areas related to the study
    b. all necessary buffer zones
    c. any area used for cleaning equipment or disposing of rinse water
    d. any area on which any excess mixture of the substances are applied.

18. The field trial sites must only be land or facilities that the public cannot legally access without permission of the owner or legal occupier.

19. Unauthorised people must be excluded from the field trial sites.

20. Signs must be displayed at every vehicular and pedestrian entrance to the field trial sites for the duration of the trials. The signs must state :

    a. that the site is subject to the trial of a hazardous substance
    b. the general type of hazards of each substance that is being trialled
    c. the immediate response action to be taken in an emergency
    d. that unauthorised access to the site is not permitted
    e. a 24-hour emergency contact phone number

21. The management of the signs referred to in Control 20 must be compliant with regulation 2.5(2) of the Health and Safety at Work (Hazardous Substances) Regulations 2017, as if references to regulation 2.6 in those regulations were references to Control 20 of this approval.

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

Use

23. The substances must only be used in a workplace.

24. The substances must only be applied using ground-based methods.

25. The substances must not be applied directly to, or enter into water or a waterway.

26. The substances must not be used outdoors as bait, or part of a bait, to target vertebrate species.

27. Any crop or produce to which the substances are applied must not be used for food by people or animals, unless that use is specifically permitted by the Agricultural Compounds and Veterinary Medicines group of the Ministry for Primary Industries.

28. The use of the substances must be compliant with clause 46 of the Hazardous Substances (Hazardous Property Controls) Notice 2017, as if the substances were class 9 pesticides.

29. The use of the substances must be compliant with clause 47 of the Hazardous Substances (Hazardous Property Controls) Notice 2017, as if the substances were class 9 pesticides.

30. The field trials must not result in exposure of any of the substances to a place in which people or organisms may be significantly adversely affected by the substances.

31. All reasonable steps must be taken to ensure that non-target species are not adversely affected by the use of the substances.

32. The use of the substances as a seed treatment must be compliant with clause 54 of the Hazardous Substances (Hazardous Property Controls) Notice 2017, as if the substances were class 9.3 pesticides.

33. The use of the substances in a granular form must be compliant with clause 55 of the Hazardous Substances (Hazardous Property Controls) Notice 2017, as if the substances were class 9.3 pesticides.

34. The use of the substances must be compliant with clause 58 of the Hazardous Substances (Hazardous Property Controls) Notice 2017, as if the substances were class 9.4 pesticides.

35. Any person that handles the substances must use personal protective clothing or equipment that is designed, constructed, and operated to ensure that the person:

    a. does not come in contact with the substances

    b. is not exposed to a concentration of the substances that may cause an adverse effect to the person.

Storage

36. The substances must be held in a locked container when not in use.

Transport

37. No person may transport the substances on a passenger service vehicle[3].

Disposal

38. The disposal of the substances must be in compliance with the Hazardous Substances (Disposal) Notice 2017.

[3] As defined in section 2(1) of the Land Transport Act 1998.

39. Any equipment used to prepare or apply the substances must be cleaned after use, and the rinsate either sprayed within the field trial site or disposed of in compliance with the Hazardous Substances (Disposal) Notice 2017.

40. Any crop or produce to which the substances are applied, and is not permitted to be used as food by Control 27, must be disposed of by mulching, ploughing-in, composting or burial at the field trial site or by disposal at an approved landfill.

41. At the expiry of this approval, the substances must:

    a. have been used up, or
    b. have been disposed of, or
    c. be contained in a laboratory compliant with Part 18 of the Health and Safety at Work (Hazardous Substances) Regulations 2017, or
    d. be covered under a new approval.

Personnel qualifications

42. 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.

43. Any person entering the field trial site must have received sufficient instruction on the containment regime to enable the person to meet their responsibilities under this approval.

Record keeping and notification

44. Written records must be kept of the amount of each substance imported or manufactured under this approval.

45. Written records must be kept for each time the substances are trialled. These records must include the information specified in clause 48(3) of the Hazardous Substances (Hazardous Property Controls) Notice 2017.

46. All records kept under this approval must be held by the approval holder for not less than three (3) years after the date on which this approval expires.

47. The approval holder must provide any records kept under this approval to the EPA or WorkSafe New Zealand within five (5) working days of the approval holder receiving a written request from the EPA or WorkSafe New Zealand.

48. The approval holder must keep a record of the substance that is imported or manufactured under this approval. The record must include:

    a. the unequivocal identification of the substance;
    b. the approval number for this containment (**HSC100241**);
    c. the composition of the substance;

d. the dates of substance import or manufacture; and
e. the total quantity of the substance imported or manufactured.

49. The approval holder must notify the EPA in writing before the start of any field trial under this approval. The notification must include:

a. the application number: APP204005
b. the HSNO approval number **HSC100241**
c. the name and contact information for the person responsible for the trial
d. the physical address of the field trial location
e. the area of land or property that is designated as the field trial site
f. the date on which the trial will commence and the expected duration of the trial, and
g. the name (as given with APP204005) and total quantity of each substance that will be applied.

Emergency management

50. Any spillage of the substance must be contained, prevented from entering into any waterway, and absorbed with an appropriate material. This material must then be disposed of in compliance with the Hazardous Substances (Disposal) Notice 2017.

51. Any facility that contains the substances must be able to be readily decontaminated in the event of a spill.

Breach of containment

52. If any of the substances are applied other than in the intended application area, or are lost or spilt, the approval holder must report the nature and quantity of the substances within 24 hours of this incident to the EPA and the Regional Council or councils in whose area the incident occurred.

53. If for any reason a breach of containment occurs, other than those specified in Control 52, the approval holder must report the nature of the incident to the EPA within 24 hours of the incident occurring.

Interpretation

54. Unless defined below, terms used in the controls have the same meaning as defined in the Act or Notices made under the Act.

Term	Definition
Ground-based application methods	These methods include, but are not limited to, application by ground-boom, airblast or knapsack, and do not include aerial application methods.
Waterway	Includes every river, stream, passage, and channel on or under the ground, whether natural or not, through which water flows, whether continuously or intermittently.

Appendix B (Confidential): Substances covered under this approval (HSC100241)

The identity of the substances covered by this approval are confidential to the applicant, and are therefore removed from the publicly available documents.