



DECISION

21 May 2013

1. Summary

Substance	ETEC Crop Solutions Limited Experimental Plant Protection Compounds
Application code	APP201721
Application type	To import or manufacture a hazardous substance in containment under Section 31 of the Hazardous Substances and New Organisms Act 1996 ("the Act")
Applicant	ETEC Crop Solutions Limited
Purpose of the Application	To import or manufacture in containment experimental plant protection compounds for the purpose of testing for the control of weeds, insects, fungi or bacteria or other plant damaging organisms or the management of crop plants.
Unique identifier of substance	ETEC Crop Solutions Limited Experimental Plant Protection Compounds
Date application received	16 April 2013
Parties Notified	On 23 April 2013 the following were advised of this application and invited to comment on it: <ul style="list-style-type: none">• The Ministry of Business, Innovation and Employment (MBIE) (Labour Group); and• The Ministry for Primary Industries (MPI) (ACVM Group). No responses were received.
Consideration date	21 May 2013
Considered by	The Chief Executive ¹ of the Environmental Protection Authority ("the EPA")
Decision	Approved with controls
Approval code	HSC100096

¹ The Chief Executive of the EPA has made the decision on this application under delegated authority in accordance with section 19 of the Act.

2. Background

- 2.1. A containment approval is required for experimental substances that require efficacy and residue studies to be completed before they can be registered. A generic containment approval allows a company to carry out the testing of unapproved substances without having to apply for an approval each time. This approval is time limited and assigns controls that must be complied with.
- 2.2. ETEC Crop Solutions Limited Experimental Plant Protection Compounds include insecticides, herbicides, fungicides, plant growth regulators, wetting agents and other plant protection compounds. The substances will be imported into New Zealand.
- 2.3. The purpose of this application is to import limited quantities of experimental hazardous substances in containment for research and development. The substances will be trialled in New Zealand with the intention of gaining full EPA approval and registration under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

3. Eligibility

- 3.1. As the purpose of the application amounts to 'research and development on any hazardous substance to acquire information for use in assessing the substance in accordance with the Act' the staff consider that the application qualifies for consideration under section 30(b) of the Act.

4. Hazardous properties

- 4.1. The application includes sufficient information to be able to identify the purpose of the application and controls to ensure that the substances can be adequately contained.
- 4.2. The staff note that the hazard information available on the substances is limited, as the substances are experimental and not yet commercialised. However, it is assumed that ETEC Crop Solutions Limited Experimental Plant Protection Compounds have the potential to cause adverse effects to human health and the environment. Controls have been assigned to the substances to mitigate these potential risks and ensure ETEC Crop Solutions Limited Experimental Plant Protection Compounds are contained.

5. Potential risks

- 5.1. The applicant has identified and assessed the potential risks and given detailed proposals for, and identified impacts of, risk management. The staff have considered the risks to the environment, human health and Māori as set out below.

- 5.2. The staff consider that, based on the considerations below and the controls imposed, ETEC Crop Solutions Limited Experimental Plant Protection Compounds can be adequately contained.

Risks to the environment

- 5.3. The staff consider that adverse effects on the environment could arise from:
- an accident during storage, use or transportation of ETEC Crop Solutions Limited Experimental Plant Protection Compounds, resulting in their release. For example, a spillage could contaminate waterways.
 - failure to follow procedures in Sections 3.4 and 4 of the application (see Appendix C of this decision) resulting in release of the substances beyond containment, which may result in the destruction of beneficial plants and insects.
- 5.4. The controls in Appendix A are set to reduce the risk of these adverse effects occurring. These controls relate to the packaging of, use of, emergency management and disposal of ETEC Crop Solutions Limited Experimental Plant Protection Compounds. They also set requirements for field trials to ensure ETEC Crop Solutions Limited Experimental Plant Protection Compounds are kept contained.
- 5.5. The staff consider that, taking into account the containment regime proposed by the applicant including packaging, storage, transport, use, disposal and minimisation of the potential for accidental release, plus the containment controls in Appendix A and controls in place under other legislation, the risks to the environment are negligible.

Risks to human health

- 5.6. The staff consider that adverse effects on human health could arise from:
- an accident during storage, use or transportation of ETEC Crop Solutions Limited Experimental Plant Protection Compounds, resulting in their spill or release beyond containment. For example, a spillage could result in a worker being exposed.
 - failure to follow procedures in Sections 3.4 and 4 of the application (see Appendix C) resulting in release of the substances from containment and exposure to people. To mitigate the risk, people handling ETEC Crop Solutions Limited Experimental Plant Protection Compounds should have specialist training and use personal protective equipment.
- 5.7. The controls in Appendix A are set to reduce the risk of adverse effects occurring. These controls relate to the packaging of, use of, emergency management and disposal of ETEC Crop Solutions Limited Experimental Plant Protection Compounds. They also set requirements for field trials to ensure ETEC Crop Solutions Limited Experimental Plant Protection Compounds are kept contained.

- 5.8. The staff consider that, taking into account the containment regime proposed by the applicant, the containment controls in Appendix A and controls in place under other legislation, the risks to human health and welfare are negligible.

Risks to the relationship of Māori to the Environment

- 5.9. The staff note that ETEC Crop Solutions Limited Experimental Plant Protection Compounds have the potential to pose an ecotoxicity hazards to the environment. These hazards give rise to the potential for cultural risk. Cultural risk may result in the deterioration of the mauri of taonga flora and fauna species, the environment and the general health and well-being of individuals and the community.
- 5.10. In general, the introduction and use of hazardous substances has the potential to inhibit the ability of iwi/Māori to fulfil their role as kaitiaki. This is particularly in relation to the guardianship of waterways, given the ecotoxic nature of some substances to aquatic species, and potential risks to the mauri ora of human health under prolonged exposure to some substances.
- 5.11. Based on the information provided by the applicant, including the proposed use pattern and the containment controls for ETEC Crop Solutions Limited Experimental Plant Protection Compounds, the staff consider that the risks to Māori culture or their traditional relationships with ancestral lands, water, sites, wāhi tapu, valued flora and fauna or other taonga are likely to be negligible.
- 5.12. In addition, should the use, transport or disposal of the substances result in the contamination of waterways, the approval holder must notify iwi authorities. This should include advising them of the contamination, its location, and the measures taken in response.

6. Controls

- 6.1. Under section 32 of the Act, a containment approval must include controls for each of the applicable matters specified in Schedule 3 of the Act and may include controls that provide for any other matters on order to give effect to the purpose of the Act.
- 6.2. The purpose of the controls is to ensure that the substances can be adequately contained.
- 6.3. Schedule 3 requires that the following matters be addressed:
- preventing the escape of the contained hazardous substance and preventing the contamination of the facility
 - excluding unwanted organisms from the facility or controlling organisms within the facility
 - excluding unauthorised people from the facility
 - preventing unintended release of the substance by experimenters
 - controlling the effects of any accidental release of the substance

- inspection and monitoring requirements of the containment facility.
- 6.4. In Sections 3.4 and 4 of the application form, the applicant has indicated how the Schedule 3 matters will be addressed. This includes the careful selection of the trial sites, management plans and the use of qualified staff to carry out the trials.
- 6.5. Taking the Schedule 3 requirements and the applicant's proposed controls into account, the staff have prepared a set of controls that they consider should be applied to ETEC Crop Solutions Limited Experimental Plant Protection Compounds. The controls to be imposed on this approval are listed in Appendix A and the staff consider that they will ensure that the substances are contained.
- 6.6. The applicant was given an opportunity to comment on the proposed controls as set out in this decision. The applicant had no issues with the proposed controls.

7. Decision

- 7.1. Pursuant to the section 32 of the Act, I have considered this application to import or manufacture hazardous substances in containment made under section 31 of the Act and have applied the relevant sections of the Act and clauses of the Hazardous Substances and New Organisms (Methodology) Order 1998 ("the Methodology") as detailed in the decision path and explanatory notes available from the EPA website².
- 7.2. Having considered the risks associated with ETEC Crop Solutions Limited Experimental Plant Protection Compounds, I am satisfied that the controls imposed will result in the substances being adequately contained.
- 7.3. The application to import or manufacture in containment ETEC Crop Solutions Limited Experimental Plant Protection Compounds for the purpose of research and development is approved with controls as set out in Appendix A and in accordance with the relevant provisions of the Act and the Methodology.
- 7.4. This approval is valid until 31 May 2018.

Rob Forlong

Date:

Chief Executive, EPA

²<http://www.epa.govt.nz/publications/er-pr-02-decision-paths.pdf>

APPENDIX A: Controls applying to ETEC Crop Solutions Limited Experimental Plant Protection Compounds

General

1. This approval expires on 31 May 2018.
2. This approval applies exclusively to substances being studied by or on behalf of ETEC Crop Solutions Limited who are referred to in the controls as the “approval user”.
3. This approval does not apply to substances with any hazardous property in classes 1, 2, 3.2, 4 or 5.
4. The approval user may import a maximum of 100 kg or 100 litres of each ETEC Crop Solutions Limited Experimental Plant Protection Compound over the term of this approval.

Packaging and Information

5. The approval user must ensure that each ETEC Crop Solutions Limited Experimental Plant Protection Compound is securely packed in containers on entry to New Zealand that comply with the Hazardous Substances (Packaging) Regulations 2001.
6. The approval user must ensure that information on safety precautions necessary to provide safeguards against any of the substance’s physical, toxic and ecotoxic properties accompanies each substance at all stages of its lifecycle in New Zealand. This must include, but not be limited to, information on the protective clothing that is to be used when handling the substance and first aid measures for immediate action pending medical attention.
7. The approval user must ensure that packages containing a ETEC Crop Solutions Limited Experimental Plant Protection Compound are:
 - a. labelled in accordance with the Hazardous Substances (Identification) Regulations 2001; and
 - b. labelled with instructions requiring that any of the substance remaining after its trial must be returned in the original container to the approval user.

Notification

8. The approval user must ensure that notification of each substance imported or manufactured under this approval is made in writing to the EPA at least 10 working days before the start of any trial using a substance covered by this approval. Notification must include:
 - (i) a unique identifier for the substance;
 - (ii) it’s composition details;
 - (iii) a project plan for the trial, containing information as specified in Appendix B;
 - (iv) a safety data sheet and/or any known hazard information; and
 - (v) the following information:

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Field trial sites

9. The approval user must take measures to ensure that no person enters a trial site without the express permission of the approval user's representative on site. Signs must be displayed at all entrances to the trial site that state that an ETEC Crop Solutions Limited Experimental Plant Protection Compound is at the site and that:
 - a. the site is subject to a field trial of a hazardous substance; and
 - b. unauthorised access to the site is not permitted, and;
 - c. the telephone number of the approval holder's representative on site.
10. Where animals are in the vicinity, the approval user must ensure that trial sites are secured by stock proof fencing to exclude animals not taking part in a trial.

Field trials

11. The approval user must ensure that the trials are undertaken in accordance with Sections 3.4 and 4 of the application form (see Appendix C) and the Project Plan (see Appendix B) which accompanies the notification of each substance.
12. The approval user must ensure that the trials do not result in exposure of ETEC Crop Solutions Limited Experimental Plant Protection Compounds to any residential building or workplace, which is not related to the trial.
13. The approval user must ensure that a record is kept of each application of an ETEC Crop Solutions Limited Experimental Plant Protection Compound. This record must include, but not be limited to, details representing all matters referred to in Regulation 6(1) of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001. Each record of application must be kept for three years after the date on which the final trial is completed under this approval.
14. The approval user must ensure that the personnel applying the substances to the crops comply with Section 3.4 of the application form (see Appendix C) and the requirements of these controls in order to adequately manage the substances.

Emergency Management

15. Any person handling ETEC Crop Solutions Limited Experimental Plant Protection Compounds must comply with the emergency management provisions as prescribed by the Hazardous Substances (Emergency Management) Regulations 2001.

16. The approval user must ensure that any spillage of an ETEC Crop Solutions Limited Experimental Plant Protection Compounds, including contaminated material, is collected, placed in a sealed container and disposed of at an appropriate facility.

Disposal

17. The approval user must ensure that disposal of ETEC Crop Solutions Limited Experimental Plant Protection Compounds is carried out in a manner compliant with the Hazardous Substances (Disposal) Regulations 2001.
18. The approval user must use or dispose of all of the substances before the expiry of this approval.

Breach of containment

19. If for any reason a breach of containment occurs, the approval user must notify the EPA within 24 hours of the breach being detected. If a breach in containment results in contamination of a waterway, the relevant regional council and the local iwi authorities must be advised. This should include advising them of the contamination, its location and measures taken in response. Contact details for iwi authorities are available from the relevant regional council.

Appendix B: Contents of Project Plan

The Project Plan to be supplied for each substance must contain information on the following points:

1. Identification and contact details of the person with overall responsibility for the trial
2. Unequivocal identification and quantity of substance
3. Project title
4. Purpose
5. Address of each trial location
6. Plot size and total treated area
7. Application method, application period and application rate
8. Protection of bees
9. Protection of birds (if substance is used as a seed treatment)
10. The security systems and containment provisions specific to the location
11. A copy of the trial protocol (or study plan)
12. Trial dates (start and completion)
13. Disposal of treated produce and any unused substance.

Application for approval to import or manufacture in containment ETEC Crop Solutions Limited Experimental Plant Protection Compounds
(APP201721)

Appendix C: Application Form