



DECISION

5 November 2014

1. Summary

Substance	JCL-Jatranz Experimental Plant Protection Compounds
Application code	APP202317
Application type	To import hazardous substance in containment under Section 31 of the Hazardous Substances and New Organisms Act 1996 ("the Act")
Applicant	EX JCL Limited (trading as Jatranz)
Purpose of the Application	To import under containment experimental plant protection compounds for the purpose of testing adjuvants, fungicides, herbicides, insecticides, nematicides and plant growth regulators on a variety of plants in various agricultural, horticultural and forestry crops and in amenity horticulture
Unique identifier of substance	JCL-Jatranz Experimental Plant Protection Compounds
Date application received	24 October 2014
Consideration date	5 November 2014
Considered by	The Chief Executive ¹ of the Environmental Protection Authority ("the EPA")
Decision	Approved with controls
Approval code	HSC100122

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 to conduct studies with experimental hazardous substances that are not currently approved for use in New Zealand. A generic containment approval allows a company to test unapproved substances without having to apply for an approval each time. Such approvals are time-limited and are subject to controls that must be complied with.
- 2.2. The purpose of this application is to import limited quantities of experimental hazardous substances in containment for research and development. These substances will be known as 'JCL-Jatranz Experimental Plant Protection Compounds'.
- 2.3. The substances will be trialled in New Zealand with the intention of gaining full approval under the Act and registration under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.
- 2.4. The applicant has indicated they intend to conduct trials that are reliant on a level of infestation of a target pest/disease/weed/crop growth stage.
- 2.5. In this application, JCL-Jatranz Experimental Plant Protection Compounds refers to a number of experimental substances including adjuvants, fungicides, herbicides, insecticides, nematocides, plant growth regulators and seed treatments for controlling weeds and plant damaging organisms, or the management of crop plants in agricultural, horticultural or forestry crops or in amenity horticulture.

3. Eligibility and consultation

- 3.1. The purpose of the application (see Appendix D) is to conduct 'research and development on any hazardous substance'; therefore I consider that the application qualifies for consideration as a containment approval under section 30(ba) of the Act.
- 3.2. The staff of the EPA ("the staff") have reviewed the application and the proposed containment system. The staff have advised me that the information provided is sufficient to understand what is proposed and to assess the risks involved.
- 3.3. The Ministry for Primary Industries (ACVM Group) were advised of the application and invited to comment. No comments were received.

4. Hazardous properties

- 4.1. The staff have advised me that the hazard information available on the substances is limited because the substances are experimental. However, it is assumed that JCL-Jatranz Experimental Plant Protection Compounds have the potential to cause adverse effects to human health and the environment. Therefore, controls have been assigned to reduce the risk of those effects occurring and to ensure that JCL-Jatranz Experimental Plant Protection Compounds are adequately contained.

5. Potential risks

- 5.1. The applicant has identified and assessed the potential risks posed by JCL-Jatranz Experimental Plant Protection Compounds and has provided detailed proposals to manage those risks (Appendices C and D). The staff have assessed the risks to the environment, human health and Māori cultural considerations as set out below.

Risks to the environment

- 5.2. The staff have advised me that adverse effects on the environment could arise from:
- An accident during manufacture, storage, transport, application or disposal of JCL-Jatranz Experimental Plant Protection Compounds, resulting in their release. For example, a spill could contaminate waterways.
 - Spraydrift during application, or inappropriate disposal, which could result in the contamination of waterways, groundwater or soil.
 - Application of the substances in areas where honey bees are actively foraging, or near beehives, which could result in adverse effects on honey bee populations.
 - Natural hazards, such as earthquakes, damaging storage or manufacturing facilities resulting in contamination of waterways, groundwater or soil.
 - Failure to follow procedures in Section 4 of the application (refer to the confidential appendix) and the trial management plan (see Appendix C) resulting in release of the substances beyond containment, which may result in the destruction of beneficial plants and insects, and/or general degradation of the environment.
- 5.3. The controls in Appendix A are set to reduce the risk of these adverse effects occurring. These controls relate to the manufacture, packaging, storage, transport, use, emergency management and disposal of JCL-Jatranz Experimental Plant Protection Compounds. They also set requirements for field trials to ensure JCL-Jatranz Experimental Plant Protection Compounds remain contained within the trial site(s).
- 5.4. Assuming compliance with the containment regime proposed by the applicant, the containment controls in Appendix A and restrictions in place under other legislation, I consider that the risks to the environment are negligible.

Risks to human health

- 5.5. The staff have advised me that adverse effects on human health could arise from:
- An accident during manufacture, storage, transport, application or disposal of JCL-Jatranz Experimental Plant Protection Compounds, resulting in people being exposed. For example, a worker could be splashed in the face with water containing a substance while preparing the tank mix to be sprayed.

- Removal of the substance, or sprayed produce, from the trial site; for example by livestock entering the treated area or removal of chemicals or treated produce by unauthorised visitors entering the site.
 - Failure to follow procedures in Section 4 of the application (see Appendix D) and the trial protocol for each trial (see Appendix C) resulting in the release of the substances from containment and exposure to people.
- 5.6. The controls in Appendix A are set to reduce the risk of adverse effects occurring. These controls relate to the manufacture, packaging, storage, use, transport, emergency management and disposal of JCL-Jatranz Experimental Plant Protection Compounds. They also set requirements for field trials to ensure that JCL-Jatranz Experimental Plant Protection Compounds are kept contained.
- 5.7. Assuming compliance with the containment regime proposed by the applicant, the containment controls in Appendix A and controls in place under other legislation, I consider that the risks to human health and welfare are negligible.

Risks to the relationship of Māori to the Environment

- 5.8. The staff have considered the potential Māori cultural impacts of this application in accordance with sections 6(d) and 8 of the Act.
- 5.9. From the information provided, and considering that the application is for containment, the staff have advised me that JCL-Jatranz Experimental Plant Protection Compounds are unlikely to have an impact on the relationship between Māori culture and their traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga. This is on the condition that the substances are used in accordance with the controls for this application.
- 5.10. The trial of these substances does not involve significant community exposure or significant exposure to the environment. Therefore, the staff have advised me that the EPA's obligations under section 6d and 8 of the Act can be met without the need for consultation with Māori.
- 5.11. There is no evidence to suggest that the controlled use of JCL-Jatranz Experimental Plant Protection Compounds will breach the duties of the EPA to protect taonga and improve Māori participation in Hazardous Substances decision making in alignment with the principles of the Treaty of Waitangi as expressed in the Act.
- 5.12. However, should the manufacture, packaging, storage, use, transport, emergency management or disposal of the substances result in the contamination of waterways, the applicant must contact local Iwi authorities within 24 hours. This notification should include advising the Iwi of the nature of the contamination and the measures taken in response.

Overall Evaluation

- 5.13. Based on the considerations above and the controls imposed, I consider that JCL-Jatranz Experimental Plant Protection Compounds can be adequately contained.

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 in 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. The applicant has indicated how the Schedule 3 matters will be addressed in the application and the confidential information provided with the application. They have also supplied a trial management plan (see Appendix C) which sets out management standards for the field trials.
- 6.5. The applicant intends to conduct trials that are reliant on a level of infestation of a target pest/disease/weed/crop growth stage and therefore the trial location, start date etc. may not be confirmed until immediately before the trial commences. Therefore the notification controls allows these aspects to be notified after the trial has started.
- 6.6. Taking the Schedule 3 requirements and the applicant's containment and trial management plans into account, the staff have prepared a set of controls that they consider should be applied to JCL-Jatranz Experimental Plant Protection Compounds to ensure containment of the substances. The controls to be imposed on this approval are listed in Appendix A.
- 6.7. The applicant was given an opportunity to comment on the proposed controls as set out in this decision.

7. Decision

- 7.1. Pursuant to 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

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(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 JCL-Jatranz 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 in containment JCL-Jatranz Experimental Plant Protection Compounds for the purpose of research and development is approved with controls as set out in Appendix A.
- 7.4. This approval expires on the 5 November 2019.

Rob Forlong

Chief Executive, EPA

Date:

5/11/14

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

Appendix A: Controls applying to JCL-Jatranz Experimental Plant Protection Compounds

General

1. This approval expires on 5 November 2019.
2. This approval applies exclusively, and is limited, to substances being studied by or on behalf of EX JCL Limited (with Jatranz Trading Name), who are referred to in the controls as the "approval user".
3. The term JCL-Jatranz Experimental Plant Protection Compound includes adjuvants, pesticides, plant growth regulators and seeds treated with another JCL-Jatranz Experimental Plant Protection Compound.
4. This approval applies only to the ground-based application of JCL-Jatranz Experimental Plant Protection Compounds.
5. This approval excludes any aerial application of the substances, and excludes the application of the substances directly to water.
6. This approval excludes any substance which is a biopesticide or which is or contains a microbial active ingredient.
7. This approval does not cover substances which trigger any hazardous property thresholds in classes 1, 2, 3.2, 4 or 5.2.
8. The approval user may import or manufacture a maximum of 20 L or 20 kg of each JCL-Jatranz Experimental Plant Protection Compound over the term of this approval.

Packaging and information

9. The approval user must ensure that each JCL-Jatranz Experimental Plant Protection Compound is securely packed in containers that comply with the Hazardous Substances (Packaging) Regulations 2001.
10. The approval user must ensure that packages containing JCL-Jatranz Experimental Plant Protection Compounds are labelled in accordance with the Hazardous Substances (Identification) Regulations 2001; and the label must include:
 - a. an instruction that any of the substance remaining after the trial must be returned to JCL-Jatranz Experimental Plant Protection Compounds in the original container for disposal; and
 - b. the name and contact details of the person with overall responsibility for the trial.
11. The approval user must ensure that information on the 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 is not

limited to, information on the protective clothing that must be used when handling the substance, first aid measures, and how to safely clean up the substance in the event of a spill.

Notification

12. The approval user must notify the EPA in writing of each trial. The notification requirements are detailed below.
13. The information specified in the Project Plan (Appendix B) must be notified to the EPA in writing at least 10 working days before the start of the trial.
14. The trial location and the date that the substance is applied must be notified to the EPA in writing no later than 48 hours after the substance is applied. This notification must include:
 - a. Application number: APP202317
 - b. HSNO approval number HSC100122
 - c. Unique identifier of the substance (product name or code)
 - d. Address of the trial location
 - e. Identification of the trial location within the trial sites (e.g. field number, description)
 - f. Date (day/month/year) substance was applied

Field trial sites

15. The approval user must designate an area (or areas) as the trial site (or sites) for each trial, which may be all or part of a property or facility.
16. The trial site must include the following:
 - 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; and
 - d. any area on which any excess mixture of the substance (tank mix) will be sprayed.
17. The trial site must not include land that the public can legally access without permission of the land owner or occupier.
18. The approval user must take measures to ensure that no person enters a trial site without the express permission of the approval holder or the approval holder's representative on site. Signs must be displayed at the entrances to the trial site that state:
 - a. that a JCL-Jatranz Experimental Plant Protection Compound is at the site;
 - b. that the site is subject to a field trial of a hazardous substance;
 - c. that unauthorised access to the site is not permitted; and
 - d. the telephone number of the approval user's representative on site.

19. The approval user must take measures to ensure that livestock do not enter the trial site.

Field trials

20. The approval user must ensure that the trials are undertaken in accordance with the application form (Appendix D), the trial management plan (Appendix C) and the project plan (see Appendix B) that accompanies the notification of each substance.
21. The approval user must ensure that the trials do not result in any residential building or workplace which is not related to the research being exposed to a JCL-Jatranz Experimental Plant Protection Compound.
22. The approval user must keep a record of each application of a JCL-Jatranz Experimental Plant Protection Compound. This record must include, but is not limited to, 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 from the date on which the final trial is completed under this approval and must be produced for any enforcement officer or the EPA on request.
23. The approval user must ensure that each person using a JCL-Jatranz Experimental Plant Protection Compound has read, understands, and complies with:
- a. the controls in this approval;
 - b. the trial management plan attached to and forming part of this approval (see Appendix C); and
 - c. the project plan (Appendix B) which accompanies the notification of the substance, or substances, which that person will be handling.
24. The approval user must ensure that any crop to which a JCL-Jatranz Experimental Plant Protection Compound is applied is not used for food by people or animals, unless that use is specifically permitted by the ACVM Group of the Ministry for Primary Industries.
25. The approval user must ensure that no JCL-Jatranz Experimental Plant Protection Compound or any seed treated with a JCL-Jatranz Experimental Plant Protection Compound is applied or disposed of within 20m of a water body³.

Seed treatments and treated seeds

26. The approval user must ensure that JCL-Jatranz Experimental Plant Protection Compound are only applied to seeds in either a purpose-built seed coating machine in a treatment plant or in a secure laboratory.
27. The approval user must ensure that seeds treated with a JCL-Jatranz Experimental Plant Protection Compound are:
- a. Dyed to differentiate them from untreated seeds;

³ Water body means any fresh water or geothermal water in a river, lake, stream, pond, wetland, or aquifer, or any part thereof.

- b. Completely covered with soil when sown;
- c. Not used for human or animal consumption; and
- d. Stored so that the seeds are not accessible to birds.

Storage

28. The approval user must ensure that JCL-Jatranz Plant Protection Compounds are held in locked storage when not in use. Locked storage includes, but is not limited to, a secure laboratory.

Transport

29. No person may transport a JCL-Jatranz Experimental Plant Protection Compound on a passenger service vehicle⁴.

Handling and personal protective equipment

30. Any person handling or applying a JCL-Jatranz Experimental Plant Protection Compound must either be an approved handler or be working under the direct supervision of an approved handler.
31. No person may eat, drink or smoke while handling a JCL-Jatranz Experimental Plant Protection Compound.

Emergency management

32. The approval user must ensure that the manufacturing, trial sites, storage, use, transport and disposal of all JCL-Jatranz Experimental Plant Protection Compounds complies with the emergency management provisions as prescribed by the Hazardous Substances (Emergency Management) Regulations 2001.
33. Any person handling a JCL-Jatranz Experimental Plant Protection Compound must ensure that any spill, or material contaminated by a spill, is collected and placed in a sealed container, and then returned to the approval user for disposal.

Disposal

34. The approval user must ensure that JCL-Jatranz Experimental Plant Protection Compounds are disposed of in a manner compliant with the Hazardous Substances (Disposal) Regulations 2001.
35. The approval user must ensure that any produce to which a JCL-Jatranz Experimental Plant Protection Compound has been applied, and which is not permitted to be used as food as defined in control 24, is disposed of by mulching, ploughing in, composting or burial at the trial site or by disposal at a landfill.

⁴ As defined in section 2(1) of the Land Transport Act 1998.

36. The approval user must ensure that at the expiry of this approval all EX JCL Limited (with Jatranz Trading Name) Experimental Plant Protection Compounds have been:
- a. used;
 - b. disposed of;
 - c. contained in a laboratory with HSNO exempt status; or
 - d. covered under a new HSNO approval.

Breach of containment

37. If for any reason a breach of containment occurs, the approval user must notify the EPA within 24 hours of the breach being detected.
38. If a breach in containment results in contamination of a waterway, the approval user must notify the relevant regional council and local iwi authorities within 24 hours. 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 the following information:

1. Project title
2. Name, position and contact details of the person responsible for the trial
3. Trial dates (earliest start date and latest completion date) (day/month/year)
4. Unequivocal identification of the substance (product name or code)
5. The full composition of the trial substance
6. A safety data sheet for the substance
7. Total quantity/volume of the substance manufactured or imported
8. Size of the total area to be treated
9. Application method
10. Application rate
11. Steps taken to ensure that bees are not adversely affected
12. Steps taken to ensure that birds are not exposed to treated seeds (only for treated seeds)
13. How treated produce will be disposed of.

Confidential Appendix C: Trial Management Plan

This section contains the confidential information submitted as part of the application.

Appendix D: Application Form

This section contains the application form including the confidential appendix submitted as part of the application.