ENVIRONMENTAL RISK MANAGEMENT AUTHORITY

DECISION

14 January 2011

Application Code
ERMA200647

Application Type
To import into containment, or manufacture in containment, a hazardous substance under Section 31 of the Hazardous Substances and New Organisms Act 1996 (“the Act”)

Applicant
AgResearch

Purpose of the Application
To manufacture in containment Yersinia entomophaga to field test for efficacy as a bio-insecticide against a range of insect pests found in productive ecosystems.

Date Application Received
8 October 2010

Consideration Date
14 January 2011

Considered by
Rob Forlong, Chief Executive of ERMA New Zealand

1 Decision

1.1 The application to manufacture in containment the hazardous substance, Yersinia entomophaga, is approved with controls as set out in Appendix 1. The approval has been made in accordance with the legislative criteria set out in Appendix 2.

1.2 The substance has been given the following unique identifier for the ERMA New Zealand Hazardous Substances Register:

Yersinia entomophaga

2 Purpose of the application

2.1 The purpose of the application is to seek approval to manufacture in containment Yersinia entomophaga to field test for efficacy as a bio-insecticide against a range of insect pests found in productive ecosystems.

3 Application process

3.1 The application was formally received on 8 October 2010.

3.2 Project Team:

Haydn Murdoch Advisor (Hazardous Substances)
Patrick Gemmell Programme Manager (Kaupapa Kura Taiao)
Matthew Allen Advisor (Hazardous Substances).
3.3 The applicant supplied the following documents:
- the application; and
- confidential appendices containing formulation details and an example trial protocol and a trial management plan.

3.4 The following government departments were advised of the receipt of the application and given the opportunity to comment:
- the Department of Labour (Workplace Group);
- the New Zealand Food Safety Authority (Agricultural Compounds and Veterinary Medicines Group (ACVM Group)).

3.5 No responses were received.

3.6 The applicant was provided with a copy of the proposed controls for *Yersinia entomophaga* and given the opportunity to comment on them (section 58). Due to delays in receiving the applicant’s comments, the consideration of the application was postponed for 20 working days. The applicant’s comments were taken into account when setting the controls.

4 Consideration

Eligibility

4.1 As the purpose (see section 2.1) amounts to “research and development on any hazardous substance”, the Project Team considers that the application qualifies for consideration under section 30(ba).

Lifecycle

4.2 The applicant is seeking approval to manufacture up to 300 L (60 L per year) of *Yersinia entomophaga* for use in the field trials. The field trials will be conducted over a period of 5 years.

4.3 *Yersinia entomophaga* for the purpose of testing in field trials will be produced by fermentation under PC2 conditions at AgResearch Lincoln Microorganism Containment Facility #480. Fermentation will be in volumes of up to 10 litres, which is within the limits for this type of work under existing ERMA approvals for the laboratory. All equipment and materials used for fermentation will be cleaned and sterilised after use, as per standard laboratory protocols for PC2 containment.

4.4 Formulations for application to the field sites will be prepared under PC2 conditions and packaged in accordance with IATA packaging instruction 650. They will be transported to field sites in suitably labelled double sealed containers, the outer being constructed of rigid plastic. The substance will be transported by carriers who will meet the requirements of the relevant NZ transport legislation. A SDS will accompany the substance in transit.

4.5 During application of *Yersinia entomophaga* to the field sites, operators will follow standard procedures for pesticide application. The application may use one of the following methods for application of the organism to the field site: liquid spray,
broadcast granules, coated seed, or formulated bait. Equipment used to apply Yersinia entomophaga formulations will be cleaned and sterilised on site or taken back to a PC2 laboratory for cleaning and sterilisation. Specific details of the type of application and formulation will be included in the experimental protocol submitted to ERMA before initiation of a field trial.

4.6 Field sites are contained in the following manner:

4.6.1 Sites where *Yersinia entomophaga* is applied will be fenced to exclude mammals and birds and appropriate signage erected to prevent access by unauthorised persons. Trial plots will be netted to prevent ingress by birds. Sites will be within fenced properties and not readily accessible by unauthorised persons, as the sites are likely to be on private land or research farms.

4.6.2 Samples will be taken from treated foliage at regular intervals (e.g. 1-3 days) to assess *Yersinia entomophaga* survival by standard plating methodology and persistence of insecticidal activity by bioassay. Containment will be maintained until bacteria and insecticidal activity are no longer detectable on the trial site.

4.6.3 In the unexpected event that *Yersinia entomophaga* is still detectable after one month from treatment, there are several options to ensure that the *Yersinia entomophaga* is removed from the site. For example, all plant material to which *Yersinia entomophaga* formulations have been applied will be removed and destroyed by autoclave or burning. In the case of application to pasture the trial area will be cultivated and foliage buried to a depth of at least 100 mm. In addition, the treated area could be sprayed with broad-spectrum insecticide to prevent movement of insects outside of the trial area.

4.7 Any un-used diluted mixture will be disposed of within the trial site by being further diluted and sprayed over a marked and designated non-crop and non-grazed area at the site. Rinsate from equipment used for application will be disposed of similarly.

**Hazardous properties**

4.8 The Project Team notes that a containment application only requires sufficient understanding of the hazardous properties of the trial substance to ensure that any risks can be managed by the containment controls. The scope of the hazard information will often be limited for containment applications, as the substance for which approval is sought is experimental.

4.9 The Project Team notes that the exact hazardous properties of formulations containing *Yersinia entomophaga* are unknown, but it is considered that the experimental substances may be classified as hazardous under the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001.
4.10 The Project Team has reviewed the summary data and other information supplied by the applicant and considers that the information is sufficient to determine that any risks posed within the defined lifecycle of the substance in New Zealand can be managed through the application of containment controls.

**Identification and evaluation of the significant risks of the substance in containment**

4.11 The applicant has identified and assessed potential risks and detailed proposals for, and impacts of, risk management. The Project Team has evaluated the applicant’s assessment of the risks to the environment, human health and Māori issues and concerns as set out below:

**Risks to the environment**

4.12 If released into the environment the substance has the potential to cause adverse effects.

4.13 On the basis of the lifecycle of the substance, adverse environmental effects could arise from:

- an accident during storage, use or transportation, resulting in release of the substance;
- failure to follow the correct operational procedures as set out in the controls and trial protocol and trial management plan as described in the application, resulting in release of the substance; or
- failure to follow correct disposal procedures.

4.14 The Project Team notes that a limited quantity of the substance will be manufactured (up to 60 L per year) in containment for use in field trials, which are to be conducted over a limited period of time (no more than 5 years).

4.15 The Project Team considers that, taking into account the limited quantity involved, the containment controls in Appendix 1 and controls in place under other legislation, there are no significant risks to the environment from these trials.

**Risks to human health**

4.16 The Project Team considers that adverse effects to human health and welfare may result from exposure(s) to the substance.

4.17 On the basis of the lifecycle of the substance, adverse effects could arise from:

- an accident during storage, use or transportation, resulting in release of the substance;
- failure to follow the correct operational procedures as set out in the controls and the trial protocol and trial management plan, resulting in personnel exposure while contained, or bystander exposure if released; or
- failure to follow correct disposal procedures.
4.18 Taking into account the quantity of substance involved in the trials, the containment regime proposed by the applicant, and the containment controls proposed in Appendix 1, the Project Team considers that there are no significant risks to human health.

**Māori issues and concerns**

4.19 The Project Team has considered this application in accordance with clauses 9(b)(i) and 9(c)(iv) of the HSNO (Methodology) Order 1998 (“the Methodology”) and sections 6(d) and 8. In addition, the Project Team used the framework contained in the ERMA New Zealand user guide “Working with Māori under the HSNO Act 1996” to assess this application.

4.20 The Project Team assessed the potential for adverse effects to the relationship of Māori to the environment taking into account the nature of the substance and the application of appropriate controls. The project team notes that this application covers the manufacture of a compound that has the potential to trigger a number of hazard classifications, giving rise to the potential for cultural risk including the deterioration of aquatic taonga flora and fauna species, the environment and the general health and well-being of individuals and the community.

4.21 Taking into account the containment measures proposed, the Project Team considers any likely impact of the substance on Māori culture or traditional relationships with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga to be negligible. In addition, because of the nature of the testing regime there is no evidence to suggest that the controlled use of this substance will breach the principles of the Treaty of Waitangi or inhibit the ability of iwi/ Māori to fulfil their role as kaitiaki. Consequently, there is no requirement for the applicant to consult with Maori regarding this application. This assessment is made on the condition that the substance is handled, stored, transported, used and disposed of, in accordance with the controls.

4.22 However, should inappropriate or accidental use, transport or disposal of the substance result in the contamination of waterways, it is suggested that the applicant notify the appropriate authorities including the relevant iwi authorities in the region. This action should include advising them of the contamination and the measures taken in response.

5 **Containment and controls**

5.1 The Project Team has evaluated the adequacy of the containment arrangements proposed by the applicant in the application and example trial design and management protocol and the controls listed in Appendix 1, and notes that these cover the matters set out in Part III of the Third Schedule of the Act, being:

- to limit the likelihood of escape of any contained hazardous substance or contamination by hazardous substance;
- to exclude organisms from a facility;
- to exclude unauthorized people from the facility;
- to prevent unintended release of the substance by experimenters working with the substance;
● to control the effects of any accidental release of the substance;
● inspection and monitoring requirements; and
● qualifications required of the person responsible for implementing the controls.

6 Conclusion

6.1 I have considered this application made under section 31 and, pursuant to section 32, I am satisfied that this application is for the purpose specified in section 30(ba), namely research and development on any hazardous substance.

6.2 Having considered the risks associated with the lifecycle of Yersinia entomophaga, I am satisfied that the controls imposed, including those in place under other legislation, will result in the substance being adequately contained.

6.3 The application to import into containment the hazardous substance Yersinia entomophaga is thus approved with controls in accordance with the relevant provisions of the Act and the Methodology as more specifically set out in Appendix 2.

Rob Forlong

Date: 14 January 2011

Chief Executive of ERMA New Zealand

ERMA New Zealand Approval Code: HSC100042
APPENDIX 1: List of Controls That Apply to *Yersinia entomophaga*

**General**

1. The trials shall be undertaken in accordance with the trial design and management protocol provided by the applicant as part of this application. Additional protocols and modifications to existing protocols may be approved in writing by ERMA New Zealand, providing that they comply with the following controls.

2. This approval remains in place for the term of any concurrent approval required under the Agricultural Compounds and Veterinary Medicines Act 1997, to a maximum of five years.

3. This approval applies only to the ground-based application of *Yersinia entomophaga*. It excludes the aerial application of the substance.

4. This approval excludes application of the substance directly into or onto water.

5. Notwithstanding the requirements of control 1 above, the trials shall also comply with the following controls:

**Import**

6. Under this approval, AgResearch may manufacture a maximum of 60 litres of *Yersinia entomophaga* per year for storage, testing and use at trial sites.

**Packaging and Information**

7. The substance shall be securely packed in suitable containers that comply with the Hazardous Substances (Packaging) Regulations 2001.

8. Packages shall be labelled with the following information:
   - the unique identifier for the substance;
   - the appropriate “*hazard pictograms*” and “*hazard statements*” for the known hazards of the substance;
   - the signal word “WARNING” followed by the statement “substance may pose hazards additional to those listed on the label”;
   - a list of mitigation measures that should be taken when handling the substance to limit exposure of people or the environment;
   - instructions that any unused substance must be returned in its original container to AgResearch;
   - instructions on the correct disposal for the empty container; and
   - enough detail to contact AgResearch either in person or by telephone.

9. The information provided on the label shall be provided in a manner compliant with regulations 32-35 and 36(1)-(7) (inclusive) of the Hazardous Substances (Identification) Regulations 2001.
10. A 16 heading layout Safety Data Sheet, consistent with the ERMA New Zealand approved
   Code of Practice for Safety Data Sheets, published by the NZ Chemical Industry Council
   (NZCIC), shall accompany the substance at all times and will provide the following:
   
   - the information required by regulation 39 (1)-(4) (inclusive) of the Hazardous
     Substances (Identification) Regulations 2001;
   
   - where known, the information required by regulations 40 – 46 (inclusive) of the
     Hazardous Substances (Identification) Regulations 2001;
   
   - statements warning that the substance may pose hazards additional to those listed;
   
   - mitigation measures that should be taken when handling the substance to limit exposure
     of people or the environment;
   
   - instructions that any remaining substance must be returned in its original container to
     AgResearch for storage; and instruction on the correct disposal of the substance and its
     packaging, in accordance with regulations 12 and 13 of the Hazardous Substances
     (Disposal) Regulations 2001.

11. The information provided on the Safety Data Sheet shall be provided in a manner
    compliant with regulations 48 – 50 (inclusive) of the Hazardous Substances (Identification)
    Regulations 2001.

Storage

12. The substance shall be securely stored in accordance with the Code of Practice for the
    Management of Agrichemicals NZS 8409: 2004 and meet the requirements of the Act and

Transport

13. The substance shall be transported in compliance with any relevant requirements of the
    Land Transport Rule: Dangerous Goods 2005, the Civil Aviation Act 1990 or the Maritime

General handling of the substance

14. Personal Protective Equipment (PPE), for example, safety glasses, gloves and protective
    clothing shall be worn when handling the substance, for example during handling, application and disposal.

Trial Sites

15. The trials shall be carried out at the sites selected for this purpose by AgResearch. The
    Trial Director¹ shall notify ERMA New Zealand in writing of the location of the trials, in
    accordance with Control 30.

16. The trial sites shall be chosen so as to prevent the substance entering any surface water or
    groundwater system.

¹ The Trial Director is the individual appointed by the applicant to be responsible for the overall conduct of the trial
in accordance with the approval controls.
17. The trial sites shall be located to prevent any residential building or workplace which is not related to the research from being exposed to the substance.

18. Access to the trial sites shall be by permission of the Trial Director or owner of the property on which it is located. The trial site boundaries shall be clearly marked and distinctly visible from outside the trial site throughout the life of the trials. The trial sites shall be signed indicating that unauthorized access is not permitted, that the site is subject to a trial and that crops should not be removed or disturbed.

19. Trial sites that are at risk of entry by grazing animals shall be secured by stock proof fencing to exclude animals for the duration of the trial.

**Trial Conditions**

20. During use the substance shall be under the control of experimental staff that are trained and experienced in the handling and administration of pesticides under test conditions using the specified equipment. Experimental staff should also be aware of the study protocol and the controls in place in order to adequately manage the substance.

21. The substance shall be mixed, diluted, prepared or otherwise handled in accordance with the relevant sections of the Code of Practice for the Management of Agrichemicals NZS 8409: 2004.

22. The amount of spray prepared shall be the minimum necessary for the trial, but if there is any surplus spray mix it shall be disposed of within the trial site by applying it over a marked and designated non-crop and non-grazed area at the site, or alternatively within the trial plot.

23. The substance shall be applied using equipment calibrated to apply accurate doses to the nominated trial plots in accordance with good practice. This would generally be achieved through compliance with the Code of Practice for the Management of Agrichemicals NZS8409:2004 or a Standard Operating Procedure retained as part of the applicant’s trial records. Special attention shall be paid to the minimisation of spray drift, and in particular to the avoidance of drift beyond boundaries agreed with the owner or occupier of the trial site and delineated in accordance with Controls 15-19.

24. A record shall be kept of all use of the substance. This record shall cover all matters referred to in Regulation 6(1) of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001 and must be kept for not less than 3 years after the date on which the substance that the record relates to is applied or discharged.

25. Any equipment used during application shall be triple rinsed after use with water and if required with an appropriate detergent or decontaminant, and the rinsate disposed of within the trial site by being applied over a marked and designated non-crop and non-grazed area at the site, or alternatively within the trial plot. Alternatively, the rinsate may be disposed of in a manner that is compliant with the disposal regulations as set out in Control 28.

**Emergency Management**

26. Any spillage of the substance (diluted or not) shall be contained, prevented from entering water bodies, and be absorbed with an appropriate absorbent material. The absorbent material shall be collected and placed in sealed containers for disposal at an appropriate
waste disposal facility (which may include a landfill), subject to the facility’s waste acceptance policy.

Disposal

27. Any surplus substance remaining at the end of the trials shall be returned to AgResearch where it shall be securely stored in an exempt laboratory, exported or degraded to a non-hazardous substance (note that one the trials are complete the substance does not have approval to be present in New Zealand except in an exempt laboratory).

28. Containers no longer used to contain the substance and residue or rinsate from equipment used to handle the substance shall be disposed of in a manner compliant with the Hazardous Substances (Disposal) Regulations 2001.

29. In the event that detectable levels of the organism or its activity persist for more than 1 month after the expected completion date of the trial, sprayed plant material shall be disposed of by ploughing in, by mulching, by burial on the trial site or by deposition at a landfill that is designed for the disposal of hazardous substances. Sprayed plant matter shall not be added into any composting operation.

Notification and Inspection

30. The Department of Labour [Attn. HSNO Project Manager (Workplace Group) or equivalent position] and ERMA New Zealand shall be informed in writing (by letter, fax or email) of the location, start, and completion of the trial. Trial protocols shall be provided prior to commencement of the trials. Notifications shall include the following details:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Yersinia entomophaga</th>
</tr>
</thead>
<tbody>
<tr>
<td>ERMA Application number</td>
<td>ERMA200647</td>
</tr>
<tr>
<td>ERMA Approval number</td>
<td>HSC100042</td>
</tr>
</tbody>
</table>

31. If for any reason a breach of containment occurs, the Trial Director shall notify the Department of Labour and ERMA New Zealand within 24 hours of the breach being detected. It is suggested that if a breach in containment results in contamination of a waterway, the relevant iwi authorities be advised.

32. The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities and trial sites at any reasonable time. Trial documentation, as described in Control 1, notwithstanding its confidential nature, shall be available for inspection by any enforcement officer, upon request.
APPENDIX 2: LEGISLATIVE CRITERIA FOR THE APPROVAL

A2.1 Unless otherwise stated, references to section numbers in this decision refer to sections of the Act and references to clauses refer to clauses in the Methodology.

A2.2 The application was lodged pursuant to section 31. The decision was made in accordance with section 32, taking into account additional matters to be considered in that section and matters specified under Part II of the Act (including the Methodology) and the provisions of Part III of the Third Schedule of the Act.

A2.3 Government departments with an interest in this type of application were advised of the receipt of the application in accordance with clause 2(2)(e).

A2.4 This application was considered by the Chief Executive of ERMA New Zealand under delegation from the Authority (section 19(2)(e)).

A2.5 In accordance with section 32, the approach adopted when considering this application was to confirm whether the application was for one of the purposes specified in section 30, to identify and assess the risks (Clauses 9, 12, 13, 14, 22, 24, 25) and to determine whether the substance could be adequately contained by controls to provide for each of the matters specified in Part III of the Third Schedule of the Act.

A2.6 In accordance with clause 36(2)(b), it is recorded that, in reaching his decision, the Chief Executive applied the criteria specified in section 32.

A2.7 The Chief Executive also applied the following criteria in the Methodology:

- clause 11 – characteristics of substance;
- clause 21 – the decision accords with the requirements of the Act and regulations;
- clause 26 – all risks negligible;
- clause 35 – the costs and benefits of the controls.