Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

Date	26 June 2012
Application code	ERMA200907
Application type	To release any new organism under section 34 of the Hazardous Substances and New Organisms Act 1996
Applicant	Stefan Pollard
Date application received	20 February 2012
Hearing and Consideration date	24 May 2012
Considered by	A decision-making committee of the Environmental Protection Authority (the Committee)[1] Dr Valerie Orchard (Chair) Dr Shaun Ogilvie Dr Deborah Read
Purpose of the application	To import three nitrogen-fixing bacteria for release
The new organisms approved for release	*Azoarcus indigens* *Azorhizobium caulinodans* *Azospirillum brasilense*

1. Summary of decision

1.1 The application to import for release *Azorhizobium caulinodans*, *Azoarcus indigens* and *Azospirillum brasilense* (the Microorganisms), was lodged under section 34 of the Hazardous Substances and New Organisms Act 1996 (the Act). The Committee has **approved** the application without controls in accordance with section 38(1)(a) of the Act.

2. Application process

Application Receipt

2.1. The application was formally received for processing on 20 February 2012.

[1] The Committee referred to in this decision is the subcommittee that has made the decision on this application under delegated authority in accordance with section 18A of the Act.

Public notification

2.2. Section 53(1)(b) of the Act provides that an application under section 34 of the Act must be publicly notified by the EPA.

2.3. The application was notified by placing a notice on the EPA website on 2 March 2012.

2.4. In accordance with section 53(4) of the Act, letters or emails notifying the Minister for the Environment, the Ministry for Primary Industries (MPI), the Department of Conservation (DOC), and other government departments, crown entities, and local authorities who have expressed an interest in being notified about applications for non-genetically modified new organisms were sent. Māori organisations, non-government organisations and stakeholders who have expressed an interest in being notified about applications for non-genetically modified new organisms were directly notified. Those parties had an opportunity to comment on the application as per section 58(1)(c) of the Act and clause 5 of the Hazardous Substances and New Organisms (Methodology) Order 1998 (Methodology).

2.5. Section 59(1)(c) of the Act requires an application to be open for the receipt of submissions for 30 working days from the date of public notification. The application was open for submissions for a period of 30 working days from 2 March 2012 until17 April 2012.

2.6. Three submissions were received – from Greg Sneath on behalf of the New Zealand Fertiliser Manufacturers' Research Association (NZFMRA), Dr Cliff Mason, and Edward Ellison on behalf of Te Rūnanga o Ngāi Tahu. Greg Sneath and Dr Mason requested to be heard.

Comments from MPI and DOC

2.7. MPI expressed some concerns over the risk assessment of the Microorganisms and these are discussed in more detail in Section 6 of this document; Assessment of adverse effects.

2.8. DOC was involved in the selection of the 24 native species chosen for the AgResearch trial (Dowsett et al 2010)[2] to test for negative effects on native flora. As a result of the trial, DOC had no concerns about the effects of the Microorganisms on native flora and had no other comments on this application.

Reports sought

2.9. Internal EPA staff advice was provided under section 58(1)(a) of the Act.

2.10. Ngā Kaihautū Tikanga Taiao (NKTT) also provided advice under section 19 of the Environmental Protection Authority Act 2011.

[2] AgResearch was commissioned to undertake a trial of the microorganisms on behalf of the applicant, and provided a report of the results to the applicant. This report was included as part of the application.

2.11. On 10 May 2012, the EPA staff advice and the NKTT report were published on the EPA website and the applicant and submitters were informed of their availability.

Hearing and consideration

2.12. Section 59(1)(d) of the Act requires a date for the commencement of the hearing of this application that is not more than 30 working days after the closing date for submissions.

2.13. The hearing took place in Wellington on 24 May 2012.

2.14. The applicant, Stefan Pollard presented his application and introduced his one expert witness, Rob Bower. Two submitters, Greg Sneath and Cliff Mason presented their submissions. These submissions are discussed in more detail below. The Committee found the information supplied to be valuable and informative in assisting them to make a decision, and were very grateful for these contributions and for submitters' participation in the process.

Information available for the consideration

2.15. The information available for the consideration comprised:

- The application;
- Internal EPA staff advice;
- Comments received from MAF and DOC;
- The Ngā Kaihautū Tikanga Taiao (NKTT) report;
- Public submissions; and
- Information obtained during the hearing.

2.16. In addition to the material above, Dr Mason made reference to several scientific papers in an email to the Committee the day before the hearing. These papers were not available for review until after the hearing, however they did not provide any new information that would have altered the Committees decision.

Legislative criteria for application

2.17. The application was determined in accordance with section 38 of the Act, taking into account the matters specified in sections 36 and 37, relevant matters in Part 2 of the Act, and the Methodology.

3. Minimum Standards

3.1. The Committee considered whether the Microorganisms meet the five minimum standards as specified in section 36 of the Act:

- Cause any significant displacement of any native species within its natural habitat; or
- Cause any significant deterioration of natural habitats; or
- Cause any significant adverse effects on human health and safety; or

- Cause any significant adverse effects to New Zealand's inherent genetic diversity; or
- Cause disease, be parasitic, or become a vector for human, animal, or plant disease, unless the purpose to import or release an organism to cause disease, be a parasite, or a vector for disease.

Consideration of section 36(a) of the Act

3.2. The Committee considered whether the Microorganisms are likely to cause any significant displacement of any native species within its natural habitat.

3.3. Cliff Mason felt that this application had not met section 36(a) of the Act and proposed that the application should not be approved because "*the organisms should not displace any native species*". As there is no literature about native organisms in the rhizoplane, rhizosphere, or endorhizosphere of New Zealand plants, he considered "*we haven't identified the organisms which could stand to be displaced by these organisms that are proposed for introduction*". He continued "*The [*AgResearch*] report doesn't examine these at all. It only examines the bacterial components in the bulk soil. It doesn't investigate soil or the plant material itself which is, I contend, the area of interest. It is where the native species could be displaced*". He concluded that "*in the presence of a complete lack of information that the application fails to reach that minimum criteria* [sic]".

3.4. The Committee notes that the methodology used by Dowsett et al. (2010) described how three soil cores (10mm diameter x 80mm depth) were collected from each pot, pooled and thoroughly mixed. Thus the Committee considered that roots and soil were both sampled, capturing those organisms in the rhizoplane and rhizosphere, and to some extent, the endorhizosphere. The Committee considered that any displacement of native species in the rhizoplane, rhizosphere and endorhizosphere would only occur in the short term.

3.5. MPI considered that there is a "*real difficulty in conducting* in vitro *assessments on microbial functional diversity within soil ecosystems*". They considered that the assessments that have been undertaken appear to have used all three organisms together within a very "closed" and stressed environment, atypical of an *in vivo* situation. They questioned how realistically the results can be extrapolated to the field.

3.6. Rob Bower presented evidence from trials by the University of La Frontera, Chile (2010-2011). He explained that trial plots were directly adjacent to each other, and the centre strip of each plot was sampled. Control plots were adjacent to treated plots, with no movement of Microorganisms from adjacent treated plots observed in the control plots. This demonstrates that the Microorganisms do not move across the few metres between trial plots.

3.7. After assessing all the information, the Committee is satisfied that the Microorganisms will not cause any significant displacement of any native species within its natural habitat.

Consideration of section 36(b) of the Act

3.8. The Committee considered whether the Microorganisms are likely to cause any significant deterioration of natural habitats.

3.9. The Committee considers that Dowsett et al. (2010) provided a robust report on the potential detriment to native plants, despite some plant deaths during the experiments. Statistically significant results on plant health were obtained, and the Committee considers the report valid.

3.10. After assessing all the information, the Committee is satisfied that the Microorganisms will not cause any significant deterioration of natural habitats.

Consideration of section 36(c) of the Act

3.11. The Committee considered whether the Microorganisms are likely to cause any significant adverse effects on human health and safety.

3.12. After assessing all the information, the Committee is satisfied that the Microorganisms will not cause any significant adverse effects on human health and safety.

Consideration of section 36(d) of the Act

3.13. The Committee considered whether the Microorganisms are likely to cause any significant adverse effect to New Zealand's inherent genetic diversity.

3.14. The Committee has not found evidence of horizontal gene transfer or other interactions between nitrogen fixing bacteria and other microorganisms in natural or agricultural environments.

3.15. After assessing all the information, the Committee is satisfied that the Microorganisms will not cause any significant adverse effect on New Zealand's inherent genetic diversity.

Consideration of section 36(e) of the Act

3.16. The Committee considered whether the Microorganisms are likely to cause disease, be parasitic, or become a vector for human, animal, or plant disease.

3.17. After assessing all the information, the Committee is satisfied that the Microorganisms will not cause disease, be parasitic, or become a vector for human, plant or animal diseases.

4. The ability to establish an undesirable self-sustaining population and the ease of eradication

4.1. Section 37 of the Act requires the Committee to have regard to the ability of the organism to establish an undesirable self-sustaining population and the ease with which the organism could be eradicated if it established such a population.

4.2. The Committee noted that the Microorganisms could establish self-sustaining populations and that the eradication of such a population would be very difficult. However, all three organisms diminish in the soil unless regularly re-applied; so, while they may be able to establish a self-sustaining population and still be present, they would only occur at very low levels. The Committee considered that eradication would not be necessary as a self-sustaining population would not be considered undesirable due to these very low levels.

5. Effects of any inseparable organism

5.1. No inseparable organisms associated with the Microorganisms were identified.

6. Assessment of adverse effects

6.1. The Committee considered the potential adverse effects of the organism, including any risks and costs associated with the release of the organism, on human health and safety, the environment, society and communities, Māori culture and traditions, and the principles of the Treaty of Waitangi (Te Tiriti o Waitangi), and the market economy.

Effects on human health and safety

6.2. After assessing all the information, the Committee did not identify any adverse effects on human health and safety from the release of these Microorganisms.

Effects on the environment

6.3. MPI questioned the level of New Zealand specific information in the application at a species level. Greg Sneath raised MPI's comments at the hearing and asked for assurance that there is a high level of confidence regarding the importation of new soil species.

6.4. Rob Bower explained on behalf of the applicant that "the AgResearch trial tested those exact species from a viable product and they looked at the effects of those microbes on the various species that make up the soil micro fauna at a species level, so if there had been a change in species composition due to addition of these microbes, this test was specifically designed to detect this."

6.5. MPI expressed the view that there is no such thing as “no risk” and, in the context of soil microorganisms and the potential effects on soil ecosystems; there is insufficient information to fully assess the risks. While Greg Sneath commented that “*New Zealand based science should be sufficient to reasonably inform the decision process*”, he does not feel that this is the case with regards to these Microorganisms.

6.6. The Committee considers that to the extent that it is possible, all the risks and benefits associated with this release application have been identified. The Committee has taken advice from one of New Zealand’s leading soil microbiologists, Professor Clive Ronson, and is satisfied that New Zealand based science is sufficient to inform the decision making process. The Committee is confident that there is sufficient species specific information to have conducted a risk assessment.

6.7. Cliff Mason highlighted a perceived lack of knowledge of microbial ecology as a “*consequence of irreducible complexity of soil microorganism systems*”. He considered that it is “*difficult to scale-up the variations we know are occuring at the micro scale*” and that “*reductionist analysis really fails because of the overwhelming number of variables*”.

6.8. The Committee noted and recognised the difficulty in a reductionist approach to soil microbial biodiversity and species interaction. However, considering the experience of use of these species and other similar species as soil innoculants overseas, and the lack of any suggestion or evidence that they have any detrimental effect, the Committee considers the inability to take a reductionist approach was immaterial to the risk assessment. It did not affect the Committee’s ability to assess the risk of the Microorganisms to the environment.

6.9. Cliff Mason suggested that “*gains made through increased yields by increased nitrogen are to the detriment of the quality of food in terms of vitamin and nutrient contents because we haven’t addressed the micronutrients adequately*”.

6.10. The Committee noted that the suggested use of the product containing the Microorganisms is in conjunction with mainstream nitrogen fertiliser, albeit at reduced rates, and that the manufacturer recommends that growers continue to apply traditional amounts of other macro- and micro-nutrients. The Committee does not consider that the use of the Microorganisms in agriculture will affect the nutritional value of our food products.

6.11. Cliff Mason suggested that if the Microorganisms have a beneficial effect on plant growth, they could promote weed growth and increase their “*weediness*”. The Committee considers that as these bacteria would need to be re-applied regularly, any advantage given to weeds would be short lived.

6.12. Greg Sneath expressed concern at the risk posed to New Zealand’s pastoral industry. His submission discussed the effects of nitrogen fixation on pastoral grasses. Dowsett et al. (2010)

examined the pasture species white clover and perennial rye grass in their BioLog Assays. They concluded that none of the Microorganisms had an adverse effect on the pasture species tested. Evidence provided by the applicant shows trials of the Microorganisms on pasture in Ireland had no ill effects on pastures. Additional evidence supplied by the applicant after a request at the hearing from the Chair, demonstrates that the bacteria have been used on pastures and in trials in Australia since 2008 (Lee 2009; GreenPastures 2009) without destroying beneficial microbes, and pasture and herd health appears to have improved.

6.13. After assessing all the information, the Committee is confident that there is sufficient information to assess whether or not there are likely to be adverse effects on the environment. The Committee did not identify any adverse effects on the environment from the release of the Microorganisms.

Effects on society and communities

6.14. Neither the applicant nor submitters identified any potential adverse effects on society and community.

6.15. The Committee considers that there may be a negative effect on individual consumers as they must bear the cost should the product containing the Microorganisms prove ineffective. However, buyers are able to exercise choice, and this increased choice is viewed by the Committee as a social benefit.

6.16. After assessing all the information, the Committee did not identify any adverse effects on society and communities from the release of the Microorganisms.

Effects on Māori and their culture and traditions and the principles of the Treaty of Waitangi (Te Tiriti o Waitangi)

6.17. The Committee took into account the effects on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga, and the principles of the Treaty of Waitangi (Te Tiriti o Waitangi).

6.18. The applicant undertook extensive consultation to determine which native, valued and endemic plant species should be tested for adverse effects and consequently commissioned a report (Dowsett et al. 2010) to look at effects on native and pasture species.

6.19. After assessing all the information, particularly the NKTT report and the submission from Ngai Tahu, the Committee considers it unlikely that the application would have any adverse effects on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga.

6.20. Given that the Committee did not identify any effects of significance to iwi/Māori (as outlined in the protocol 'Incorporating Māori perspectives in HSNO Act decision making') the Committee considers the application to be broadly consistent with the principles of the Treaty of Waitangi (Te Tiriti o Waitangi).

Effects on the market economy

6.21. The applicant did not identify any potential adverse effects on the market economy. However, Greg Sneath outlined concerns that the Microorganisms may impact nitrogen fixation currently taking place in pastures. He highlighted the importance of pastoral systems to New Zealand and asked for assurance that the agricultural economy would not be negatively impacted.

6.22. As Dowsett et al. (2010) included pasture grasses in their trials, and found no negative effects on pastoral plants (white clover and perennial rye), the Committee did not identify any adverse effects on the market economy from the release of the Microorganisms.

Conclusion

6.23. After considering the information provided, the Committee did not identify any adverse effects, risks or costs from the release of the Microorganisms.

7. Assessment of positive effects

7.1. The Committee considers that there are potential positive effects (including benefits) of the organism on human health and safety, the environment, society and community, Māori culture and traditions, and the market economy.

Potential long term positive effects

7.2. The applicant and Te Rūnanga o Ngāi Tahu identified that there may be potential long term positive effects for the environment, human health and safety, Māori culture and traditions, and the market economy.

7.3. Potential long term benefits may include cleaner waterways as a result of the reduced input of nitrogen in agriculture, and a reduction in New Zealand's carbon footprint by reducing the amount of synthetic fertilisers being used in agriculture.

7.4. The Committee noted that such long term positive effects would require large scale uptake of the use of the Microorganisms across the agricultural sector. The Committee considered that there is insufficient information to assess any potential long term positive effects.

Potential medium and short term positive effects

7.5. The applicant and the EPA staff identified a range of shorter term positive effects and the Committee considers that some sectors of New Zealand are likely to benefit more than others. These benefits are likely to be negligible at a national scale but could be non-negligible at an individual farm level if well managed. The Committee assessed these positive effects as likely to happen if the product containing the Microorganisms is used as recommended.

7.6. The Committee considers that plant growth is likely to improve as a result of soil inoculation by the Microorganisms (Fibach-Paldi et al. 2012; Kennedy et al. 2004).

7.7. The Committee considers that increasing choices in nitrogen fixation tools available to farmers, especially organic farmers, provides a social benefit to New Zealand and may lead to a localised reduction in the use of synthetic fertilisers in agriculture.

7.8. The Committee considers that use of the Microorganisms could be considered innovative, particularly for future use in bioremediation (e.g. Huang et al. 2004; Eckford et al. 2002).

Conclusion

7.9. After considering all the information, the Committee considered that the benefits associated with release of the Microorganisms are non-negligible.

8. Achieving the purpose of the Act

8.1. The purpose of the Act is to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms (section 4 of the Act).

8.2. In order to achieve the purpose of the Act, when considering the application theCommittee recognised and provided for the following principles:

- the safeguarding of the life-supporting capacity of air, water, soil and ecosystems; and
- the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social and cultural well-being and for the reasonably foreseeable needs of future generations.

8.3. The Committee took into account the following matters when considering the application in order to achieve the purpose of the Act:

- The sustainability of all native and valued introduced flora and fauna;
- The intrinsic value of ecosystems;
- Public health;

- 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 and costs of using a particular hazardous substance or new organism;
- New Zealand's international obligations;
- The need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects; and
- The principles of the Treaty of Waitangi (Te Tiriti o Waitangi).

8.4. The Committee is satisfied that this decision is consistent with the purpose of the Act and the above principles and matters. Any substantive issues arising from the legislative criteria and issues raised by submitters have been discussed in the preceding sections of this decision.

9. Evaluation and weighing of positive and adverse effects

9.1. The Committee took into account all the effects of the Microorganisms, and all the measures available for risk management, and concluded that the Microorganisms pose negligible risks, and that it is evident that the positive effects of releasing the Microorganisms outweigh the adverse effects.

10. Decision

10.1. After reviewing all of the information contained in the application, the Committee was satisfied that the application met the requirements of section 34 of the Act. In any event, in accordance with section 59(3)(a)(ii), the Committee waives any information requirement that has not been met as requested by the applicant in its application.

10.2. The Committee considered that the threshold for approval under section 38 of the Act had been met. The Committee concluded that the organisms meet the minimum standards set out in section 36 of the Act and that the positive effects of the organisms outweigh the adverse effects of the organisms, taking into account all of the following:

- All the effects of the Microorganisms;
- The matters in section 37 of the Act;
- The relevant matters in Part 2 of the Act; and
- The Methodology.

10.3. The Committee decided to exercise its discretion and **approve** the release of the Microorganisms under section 38(1)(a) of the Act. The Committee noted that in accordance with section 38(2) of the Act, the approval has been granted without controls.

10.4. The Committee noted that under section 38(3) of the Act, if the Microorganisms have not been released within five years of the date of this decision the approval for release will lapse. However, any person may apply before the expiry of the time limit for an extension of that time limit for a further period of up to five years.

10.5. The Committee has waived the requirement under section 38(4) of the Act, to notify the EPA of the release of the Microorganisms.

10.6. The Committee would like to thank all people who provided information that has been used in making this decision.

Signed **Dr Val Orchard** **Chair, Decision Making Committee** **Environmental Protection Authority**	**27 June 2012**

Approval codes: NOR100065-67

Approval numbers for organisms in application ERMA200907

Organism	Approval number
Azoarcus indigens	**NOR100065**
Azorhizobium caulinodans	**NOR100067**
Azospirillum brasilense	**NOR100066**