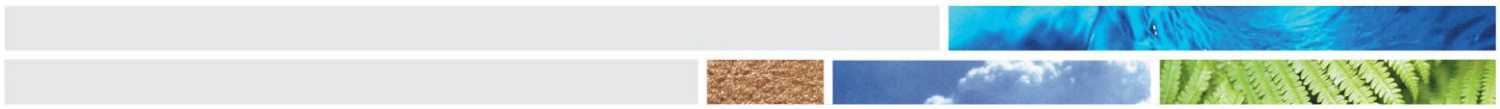
Environmental Protection Authority
Te Mana Rauhī Taiao

EPA advice on application ERMA200907- the proposed release of three nitrogen fixing bacteria

MAY 2012



Under section 34 of the Hazardous Substances and New Organisms Act 1996

ADVICE TO THE DECISION MAKING COMMITTEE

New Zealand Government

1. The application process

Purpose of this document

1.1. In February 2012, an application was made to the Environmental Protection Authority (EPA) seeking to release three endophytic nitrogen-fixing bacteria that take nitrogen from the air and convert it to a form that plants can use. Endophytic bacteria have been found in almost all plant species. They colonise the internal tissues of their host plant and form a range of different symbiotic relationships. Endophytic, nitrogen-fixing-bacteria can promote plant growth and yield and can also be beneficial to their host by producing a range of natural substances that facilitate the uptake of nutrients from the soil (Verma et al. 2010).

1.2. This document is produced by the EPA to facilitate the decision making process. The document discusses information provided in the application and other readily available sources.

Submission Process

1.3. Application ERMA200907 was publicly notified as required by section 53(1) (b) of the Hazardous Substances and New Organisms (HSNO) Act. The 30 working day notification period began on 2 March 2012 and closed on 17 April 2012.

1.4. The EPA asked submitters to provide information, make comments and raise issues, particularly with regard to the following matters:

- Methodology;
- Adverse effects, especially adverse effects not identified in the application[1]; and
- Positive effects, especially positive effects not identified in the application[2].

Application Summary

1.5. The applicant considers that the New Zealand agricultural and horticultural sectors are largely reliant on synthetic fertilisers to supply nitrogen to crops. The applicant states that the use of synthetic fertilisers is at great expense to these industries and is unsustainable; leading to the degradation of groundwater, rivers and drinking supplies.

1.6. The applicant states that the three microorganisms named in the application; *Azorhizobium caulinodans, Azoarcus indigens* and *Azospirillum brasilense,* are used successfully in both

[1] Adverse effects can include any risks and costs associated with approving the release of these organisms.

[2] Positive effects can include any benefits associated with approving the release of these organisms.

conventional and registered organic systems around the world to reduce the levels of synthetic fertilisers used in cropping systems. The applicant asserts that research has demonstrated that these microorganisms pose no risk to the environment.

2. The organisms proposed for release

Background on *Azorhizobium caulinodans*

2.1. *Azorhizobium caulinodans* is a free-living stem and root nodulating, nitrogen fixing bacterium capable of colonising non-legumes such as wheat. It stimulates lateral root development. It can undertake nitrogen fixation both through the formation of nodules and in its free living state (Saikia and Jain 2007).

Background on *Azoarcus indigenes* and *Azospirillum brasilense*

2.2. *Azoarcus indigenes* is a diazotrophic bacterium capable of invading the root-tissue of host plants, and expressing nitrogenise genes in the aerenchyma[3] of the roots (Saikia and Jain 2007). *Azospirillum brasilense* is an associative nitrogen-fixing bacterium that is closely associated with plant roots (Saikia and Jain 2007).

3. Risk and Benefit assessment

3.1. The EPA has conducted a risk benefit assessment for the release of *Azorhizobium caulinodans, Azoarcus indigens* and *Azospirillum brasilense.* This includes risk and benefits to human health, environment, economy, society and culture.

3.2. In conducting this assessment we have conducted our own research in addition to what was provided in the application and the submissions. We have also consulted independent experts: Dr Joanne Kelly, consultant scientist on the Te Ohu Mo Papatuanuku- Bio Remediation Project as well as honorary research associate at the University of Waikato; and Professor Clive Ronson from the University of Otago, who is a microbial geneticist specialising in the way microbes and plants recognise each other and develop a nitrogen-fixing symbiosis, and in microbial evolution.

[3] spaces or air channels in the leaves, stems and roots of some plants, which allows exchange of gases between the shoot and the root

Impacts to the relationship of Māori to the Environment

3.3. The applicant undertook a two stage consultation with iwi/Māori nationwide. The first was to seek advice on which native plants should be tested to assess impacts, and then the second stage was to consult over the proposal to release the micro-organisms before the application was lodged with the EPA. Queries and replies received from consulted parties were subsequently addressed by the applicant where appropriate.

3.4. Of the consultation respondents and Māori submitters only one opposed the proposal expressing concern at the absence of sufficient information about the potential for adverse effect to native plants and soil microbes. From a Māori cultural perspective it is the responsibility of kaitiaki to ensure the protection of cultural and spiritual health and well-being for themselves and the resources for which it is their duty to protect[4]. Of particular relevance for this application is the role of kaitiaki in protecting the mauri[5] of species or their surrounding environment for this generation and for those to come.

3.5. Te Rūnanga o Ngāi Tahu noted in their submission that the testing undertaken on native species provided a level of comfort to their kaitiaki interests. Other respondents also noted comfort with the proposal given the testing undertaken and the potential for beneficial effects to the environment and to their role as kaitiaki.

Minimum standards

3.6. Prior to approving any new organism the EPA is required to ensure that if the organism were to be released that it would not exceed the maximum acceptable risk set out by the minimum standards in the HSNO Act

The EPA considered whether the microorganisms are likely to cause any significant displacement of any native species within its natural habitat.

3.7. The distribution of bacteria in the environment is the subject of on-going research. It has been proposed that a bacterial species will either exhibit biogeography (it is only found at specific locations and therefore limited in distribution) or will not (it is ubiquitous i.e. unlimited in distribution) (Finlay 2002; Fenchel 2003).

3.8. Examples of organisms that show biogeography are plant pathogenic bacteria which are highly evolved to a host species and exhibit the same biogeography as the host, or bacteria

[4] 'Incorporating Māori Perspectives in Part V Decision Making' (ER-PR-01-02 11/04)

[5] The active life-giving principle that provides conditions within the environment that harmonise and balance the systems of nature (taken from ER-PR-01-02 11/04).

of ‘rare biospheres’, such as those that live in very specific but limited habitats e.g. thermal vents (Patterson 2009).

3.9. Soil bacteria are likely to be ubiquitous as they are easily dispersed and readily find suitable habitats in which to grow (Geddes 2009).

3.10. The composition of microbial populations can be influenced by a number of factors. For example, in soil the composition of microbial populations fluctuates depending upon the temperature, soil texture and structure, pH, salinity, moisture levels, which plants are grown in the soil, and the presence or absence of suitable resources (Turbé et al, 2010). So although ubiquitous microorganisms may be detected everywhere (Griffin, 2007), they will only be metabolically “active” if the appropriate environmental conditions prevail.

3.11. In many cases, it is the presence of a suitable substrate which is quickly utilised so that the microbe might only be metabolically active while an ephemeral island of opportunity (the substrate) exists. As Garrett (1951) noted, with reference to soil fungi, within a particular environment there is an assemblage of species observed that can quickly utilise an ephemeral substrate rather than an ecosystem.

3.12. We consider that *Azorhizobium caulinodans, Azoarcus indigens* and *Azospirillum brasilense* would only be metabolically active immediately after inoculation and would quickly diminish in the soil substrate. Dowsett et al. (2010) measured functional soil diversity in a range of soil samples. They noted that “there is no statistically significant difference between treatments”, indicating that application of *Azorhizobium caulinodans*, *Azoarcus indigens* and *Azospirillum brasilense* does not influence soil microbial diversity.

3.13. Professor Ronson also states that “they would be unlikely to persist in significant numbers”.

The EPA considered whether the microorganisms are likely to cause any significant deterioration of natural habitats.

3.14. The EPA finds that the Dowsett et al. (2010) report in to the potentially detrimental effects on native flora is sufficiently robust, despite some plant deaths during the experiments. As the deaths occurred in both the controls and the test subjects, the EPA agrees that growing conditions were unsuitable for native flora. However, sufficient significant results were obtained for these to be considered valid.

The EPA considered whether the microorganisms are likely to cause any significant adverse effects on human health and safety, and whether the microorganisms are likely to cause disease, be parasitic, or become a vector for human, animal, or plant disease.

3.15. Although some human pathogens have been identified as bacterial endophytes (Rosenblueth and Martinez-Romero 2006), there is no evidence to suggest that the three species named in this application have that potential. The advice from Professor Ronson supports the EPA's view that these bacteria are not disease causing.

3.16. After reviewing the known biological characteristics, there is no evidence that *Azorhizobium caulinodans, Azoarcus indigens* and *Azospirillum brasilense* will cause disease in humans, plants and/or animals or will become a vector for human, plant or animal diseases.

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

3.17. We recognise that the introduction of any new organism to New Zealand has the potential to cause harm to New Zealand's biological or genetic diversity. Although we recognise the limitations of the testing presented by the applicant, having sought independent advice, reviewing the testing done by AgResearch (Dowsett et al. 2010), and the biology of these organisms, we are satisfied that they are not harmful to New Zealand's genetic or biological integrity.

3.18. The EPA has found no evidence of gene transfer or other interactions between nitrogen fixing bacteria in natural or agricultural environments.

3.19. We consider that *Azorhizobium caulinodans*, *Azoarcus indigens* and *Azospirillum brasilense* are unlikely to displace other organism's present, cause significant deterioration of natural habitats or have a significant adverse effect on New Zealand's inherent genetic diversity.

3.20. Therefore we consider that *Azorhizobium caulinodans, Azoarcus indigens* and *Azospirillum brasilense* all meet the minimum standards as stated in the HSNO Act.

Risks

3.21. The applicant has identified potential adverse effects associated with the release of these three bacteria (see pages 7-9 of the application). In particular, the application identifies the displacement of native soil microbes as a possible effect, although testing provided by the applicant (see Dowsett et al. 2010) shows that native soil microbes out-compete all three of the proposed new organisms.

3.22. The applicant notes that in the absence of regular "top-ups", *Azorhizobium caulinodans, Azoarcus indigens* and *Azospirillum brasilense* are unlikely to be the predominant microorganisms present within the soil/plant microcosm, unless specific conditions occur where the microorganisms have a selective advantage.

3.23. Professor Ronson states that “they have not been associated with adverse plant growth effects” and does not consider that “their importation would lead to any risk”.

3.24. The EPA has not found any “specific conditions” under which these bacteria may have a competitive advantage or any resulting adverse effects. Given the low prevalence of these bacteria in the soil microbial community, and the fact that they diminish through time unless applied repeatedly, we do not consider that any adverse effects will occur from the release of *Azorhizobium caulinodans*, *Azoarcus indigens* and *Azospirillum brasilense* (Appendix 1).

Benefits

3.25. The EPA considered all the possible positive effects associated with the release of *Azorhizobium caulinodans*, *Azoarcus indigenes* and *Azospirillum brasilense*.

3.26. The applicant claims that long term benefits will flow from the release of these microbes (see pages 7-9 and appendix 1 of the application), including improvement in the health of New Zealand waterways, and reduced carbon emissions. The EPA considers that these long term benefits would require large scale uptake of the use of these bacteria by the agricultural sector.

3.27. The New Zealand Fertiliser Manufacturers’ Research Association stated in their submission that the applicant has “overstated and misrepresented the potential benefits” of the release of *Azorhizobium caulinodans*, *Azoarcus indigenes* and *Azospirillum brasilense*. The EPA considers that these bacteria are unlikely to be used extensively in New Zealand and agrees that the proposed benefits to New Zealand waterways and reduced carbon emissions are unlikely to eventuate to any significant degree. However, there are likely to be smaller scale benefits associated with providing farmers, particularly in the organics sector, with an increased range of choice in the methods they use to promote plant growth.

3.28. We consider that there are benefits to individuals at a local level for people who believe this product enhances their production system and the suppliers that will profit from selling of products containing these organisms. The EPA understands that while there is controversy about the nitrogen fixing potential of these bacteria in the scientific literature, there is little doubt that application of these bacteria does in fact promote plant growth (see Gapalaswamy et al. 1999, Fibach-Paldi et al. 2012, and Kennedy et al. 2004). We therefore consider that although the application understated this effect, it is a genuine benefit for New Zealand at a local level.

3.29. The applicant has provided additional information on the efficacy of the product that contains *Azorhizobium caulinodans*, *Azoarcus indigenes* and *Azospirillum brasilense.* Mapeleton

International's reports into TwinN efficacy in soybean, pasture and potatoes, all indicate an increased yield of product, or better pasture production and quality.

3.30. The EPA considers that there is a non–negligible beneficial effect that can be accredited to these organisms.

3.31. The EPA identified the potential use of these bacteria in phytoremediation. We sought independent expert advice from Dr Kelly (see submission 102570), who provided evidence that *Azospirillum brasilense* has been used in successful phytoremediation (Huang et al. 2004). In addition, *A. brasilense* has been found to contribute to fuel spill bioremediation in Antarctic soils (Eckford et al. 2002).

3.32. The EPA considers that this is an additional benefit to those named by the applicant.

Weighing of risk and benefit

3.33. The EPA does not consider that the release of *Azorhizobium caulinodans*, *Azoarcus indigenes* and *Azospirillum brasilense* would impact on the relationship of Māori to the environment.

3.34. After reviewing the relevent information, the EPA considers that the benefits of releasing *Azorhizobium caulinodans*, *Azoarcus indigenes* and *Azospirillum brasilense* outweigh the risks.

4. Submissions

4.1. Three submissions were received in response to the application. One was in support and two opposed the application. Comments from MAF and DoC are included in this summary.

Submissions in support of the application

4.2. Te Rūnanga o Ngāi Tahu support the application on the grounds that their kaitiaki interests are protected, the microbes pose few risks to native organisms, and the introduction of these bacteria could improve the health of the waterways and reduce carbon emissions.

Submissions in opposition to the application

4.3. Two submitters opposed approval of the application and their concerns are discussed below:

EPA response to the some of the key points raised in submissions

The level of scientific understanding of microorganism communities

4.4. Nitrogen-fixing bacteria are well studied both in New Zealand and overseas. There is a wealth of literature available on these bacteria and their effects. We have also sought independent advice on the effects of these bacteria. We consider that there is sufficient knowledge to undertake a risk assessment on these three species.

The wider effects of nitrogen-fixing bacteria on fresh water environments

4.5. The reference cited by Dr Mason in his submission (Magesan et al. 2012) strongly recommends research into the contribution of leached nitrogen from soils and the impact it has on eutrophication of water bodies, but this paper specifically reviews the possible effects of leguminous plants, rather than diazotrophic bacteria. The EPA considers that the addition of nitrogen fixing bacteria into the pastoral system will not add any new nitrogen into the system, that is not already being added via cuurent fertilisation methods, and therefore will have no effect on eutrophication of fresh water systems in New Zealand.

The alternative use of native bacteria to boost nitrogen fixation

4.6. The EPA is not aware of any commercially available nitrogen fixing bacteria native to New Zealand.

Concerns about the lack of understanding about nitrogen inputs/outputs in farming

4.7. The EPA agrees that the applicant has provided limited insight into the nitrogen inputs and outputs in farming practices. However, as we cannot identify any risks to New Zealand from the release of these bacteria, we consider that this is outside the scope of the HSNO Act.

The current use of nitrogen fixing in the pastoral industry

4.8. After water, nitrogen is the most limiting factor in plant growth. Crops like wheat and rice need 20 - 40 kg soil N ha^{-1} over 3 - 5 months to satisfy the nitrogen requirements per tonne of grain produced. To meet such high demand, farmers either apply inorganic synthetic nitrogen fertilisers or rely on biological nitrogen fixation (BNF) and recycled organic wastes, such as manure (Orr et al. 2012 and references therein).

4.9. Nitrogen cycling in natural ecosystems and traditional agricultural production relies on biological nitrogen fixation primarily by diazotrophic[6] bacteria. Diazotrophs are highly diverse and widely distributed across bacterial taxa. Most of biological nitrogen fixation (BNF) is carried out by diazotrophs in symbiosis with legumes (Orr et al. 2012).

[6] A diazotroph is an organism that grows without external sources of fixed nitrogen

4.10. The EPA considers that producers should have the option to employ diazotrophs that are symbiotic with legumes, or free living endophytic bacteria such as those named in the application. Although the applicant has not covered current farming practices in the application, the EPA has not identified any potential adverse effects on current farming practices.

The degree of certainty required about the genuine risks and benefits prior to release and the lack of such evidence provided by the applicant

4.11. The EPA is satisfied that our risk assessment has provided a degree of certainty about the risks and benefits of this application. We have not identified any risks associated with the release of these organisms. While we agree that the benefits may not be as profound as the applicant has asserted, we feel that the benefits are genuine.

Comments received from DOC

4.12. DOC commented that "the AgResearch Containment Trial Report illustrates that a wide range of native species have been tested and concludes that there are not likely to be significant detrimental effects on the growth and development of native plant species. On this basis, the Department does not oppose this application. We are unable to provide comment on whether the three microbes could displace native bacteria or adversely affect the native microbial functional diversity in New Zealand's soils."

4.13. The EPA understands that the three microbes named in the application will not displace native bacteria or adversely affect the native microbial diversity of New Zealand soils, not least because they will be applied in heavily disturbed agronomic environments.

Comments received from MAF

4.14. MAF noted that the applicant is seeking to import the organisms rather than source them from other containment facilities in New Zealand.

4.15. The EPA understands that the applicant intends to use the three species in conjunction with a product designed for soil conditioning. The species will therefore be imported together in a single organically certified product (see OMRI and NASAA certificates of registration).

4.16. MAF is presuming that the AgResearch trials have been conducted using organisms imported by Landcare under NOC99014. While the risk assessment that was conducted for that application was generic, MAF questions whether the application should include a more detailed assessment on risk at a species level. Furthermore, the information that has been provided

in the application itself appears to be largely based on data that is not specific to the species proposed to be imported and more focused on the risks at a genus level.

4.17. The EPA conducted our risk assessment at a species level and is confident that each individual species does not pose a threat to New Zealand.

4.18. MAF is of 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 risks.

4.19. The EPA feels that to the extent that it is possible, we have identified all the risks and benefits associated with this release application.

4.20. MAF asserted that the impacts assessment appears to have been conducted using a combination of the three microorganisms together, rather than as separate species. Was there a reason for this and how can a comprehensive assessment on each species be conducted if this was the case?

4.21. See section 6.22. The EPA is confident that a comprehensive assessment has been made for each individual species.

4.22. MAF reiterated that there is a real difficulty in conducting in vitro assessments on microbial functional diversity within soil ecosystems. 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. How realistic, therefore, can the results be extrapolated to the field?

4.23. The EPA considers modern farming practice to be a very closed and stressed environment. We understand that these bacteria will dissipate in the soil strata unless repeatedly re-applied, thus we are confident in the results presented in the report from AgResearch.

5. Recommendation

5.1. The EPA recommends that the release of *Azorhizobium caulinodans*, *Azoarcus indigenes* and *Azospirillum brasilense* be approved.

6. References

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Appendix 1

Assessment of potentially significant adverse and beneficial effects from the release of *Azorhizobium caulinodans, Azoarcus indigens* and *Azospirillum brasilense*

Potentially significant effect	Significance	Discussion
Potentially significant adverse effect on the environment. • Potential for native flora to be damaged	• **Negligible**	• The EPA is satisfied that the report by AgResearch, (Appendix 2) of the application, has adequately tested sufficient native species to determine that addition of the microbes will not harm native flora.
• Potential for native microbial to be displaced	• **Negligible**	• The EPA is satisfied that the report by AgResearch, (Appendix 2) of the application, demonstrates that the functional diversity of the soil was not adversely affected by inoculation of the 3 bacteria named in the application.
• Potential for gene transfer between the new organisms and native microbia	• **Negligible**	• The EPA has found no evidence of gene transfer or other interactions between nitrogen fixing bacteria in natural or agricultural environments.
Potentially significant adverse effect on human health and safety	None identified	
Potentially significant adverse effect on Māori culture and traditions:	None identified	
Potentially significant adverse effect on the market economy:	None identified	
Potentially significant adverse effect on society and the community:	None identified	
Potentially significant beneficial effects on the environment: • Possibility of use in phtyoremediation	**Non-negligible**	We have assessed the likelihood of this occurring as **likely** The magnitude of this benefit has been assessed as **minimal.**
Potentially significant beneficial effects on human health and safety:	None identified	
Potentially significant beneficial effects on Māori culture and traditions:	None identified	
Potentially significant beneficial effects on market economy: • Organic methods of promoting plant growth without adding NKP fertilisers	**Medium**	We have assessed the likelihood of this occurring as **likely**. The magnitude of this benefit has been assessed as of **moderate** significance to New Zealand and New Zealanders.

Potentially significant effect	Significance	Discussion
Potentially significant beneficial effects on society and the community: • Provide growth and support opportunities for associated companies	**Non-negligible**	We acknowledge that once approved, these bacteria could be used by any company to promote plant growth. We therefore consider that this application has the potential to provide growth opportunities for the organic fertiliser sector. We have assessed this as **likely**. The magnitude of the benefits has been assessed as **minor** based on their significance to New Zealanders and New Zealand.

Appendix 2

Figure 6: Decision path for applications to import for release or release a new organism from containment (NO and GMO)

Context

This decision path describes the decision-making process for applications to import for release or release a new organism from containment. These applications are made under section 34 of the HSNO Act, and determined under section 38 of the Act. Section 38 requires consideration of the criteria specified in section 36 (whether the organism meets the minimum standards) and section 37 (ability of the organism to form an undesirable self-sustaining population and ease of eradication).

Introduction

The purpose of the decision path is to provide the HSNO decision maker[7] with guidance so that all relevant matters in the HSNO Act and the Methodology have been addressed. It does not attempt to direct the weighting that the HSNO decision maker may decide to make on individual aspects of an application.

In this document 'section' refers to sections of the HSNO Act, and 'clause' refers to clauses of the Methodology.

The decision path has two parts –

- Flowchart (a logic diagram showing the process prescribed in the Methodology and the HSNO Act to be followed in making a decision), and
- Explanatory notes (discussion of each step of the process).

Of necessity the words in the boxes in the flowchart are brief, and key words are used to summarise the activity required. The explanatory notes provide a comprehensive description of each of the numbered items in the flowchart, and describe the processes that should be followed to achieve the described outcome.

For proper interpretation of the decision path it is important to work through the flowchart in conjunction with the explanatory notes.

[7] The HSNO decision maker refers to either the EPA Board or any committee or persons with delegated authority from the Board.

Figure 6 Flowchart: Decision path for applications to import for release or release a new organism (NO and GMO) from containment (application made under section 34 of the Act and determined under section 38 of the Act)

For proper interpretation of the decision path it is important to work through the flowchart in conjunction with the explanatory notes.

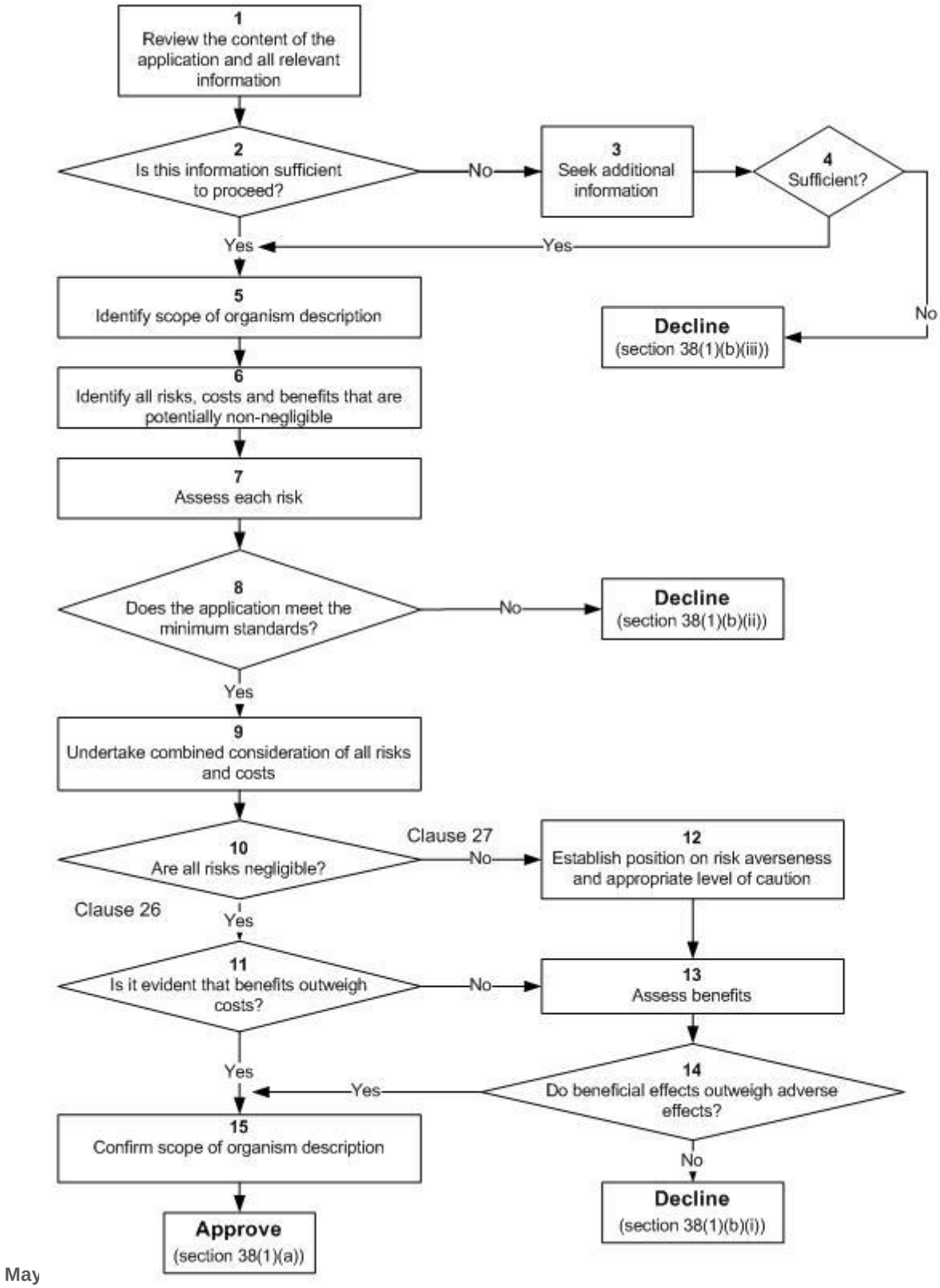


Figure 6 Explanatory Notes

An application may be for a single new organism, or for a variety or range of new organisms where the boundaries of the extent of modifications envisaged are well defined (see EPA Protocol: Interpretations and Explanations of Key Concepts interpretation 'Identification of New Organisms'). In both of these cases organisms having similar risk profiles should be grouped into categories. Each category should be considered separately via the path below.

Section 38B of the Act allows the HSNO decision maker, with the agreement of the applicant, to treat an application for release under section 34 as if it were an application for conditional release (made under section 38A). This will in most circumstances be determined prior to public notification of the application (see Policy[8]). Accordingly a switch to conditional release is not included in this decision path.

Item 1:	**Review the content of the application and all relevant information** Review the application, the E&R Report (or draft decision and EPA staff advice), information received from experts and that provided in submissions (where relevant) in terms of section 38A(2) of the Act and clauses 8, 15, 16, 20 and 23 of the Methodology.
Item 2:	**Is this information sufficient to proceed?** Review the information and determine whether or not there is sufficient information available to make a decision. The Methodology (clause 8) states that the information used by the HSNO decision maker in evaluating applications shall be that which is appropriate and relevant to the application. While the HSNO decision maker will consider all relevant information, its principal interest is in information which is significant to the proper consideration of the application; ie information which is "necessary and sufficient" for decision-making.
Item 3:	**(if no) Seek additional information** If there is not sufficient information then additional information may need to be sought from the applicant, the EPA staff or other parties/experts under section 58 of the Act (clause 23 of the Methodology).
Item 4:	**Sufficient?** When additional information has been sought, has this been provided, and is there now sufficient information available to make a decision? If the HSNO decision maker is not satisfied that it has sufficient information for consideration, then the application may be declined under section 38(1)(b)(iii).
Item 5:	**Identify scope of organism description** Clearly identify the scope of the organism description. Particular attention should be paid to whether the application is for a single new organism or a variety of new organisms as referenced in the Introduction to these notes. Exclusions may be used to sets bounds on the scope of the

[8] Protocol Interpretations and Explanations of Key Concepts: Conditional release of New Organisms http://www.epa.govt.nz/Publications/ER-PR-03-22-Key-Concepts-Master-File.pdf

	organism description where a range or variety of new organisms is being considered.	
Item 6:	**Identify all risks, costs and benefits that are potentially non-negligible[9]** Costs and benefits are defined in the Methodology as the value of particular effects (clause 2). However, in most cases these 'values' are not certain and have a likelihood attached to them. Thus costs and risks are generally linked and may be addressed together. If not, they will be addressed separately. Examples of costs that might not be obviously linked to risks are direct financial costs that cannot be considered as 'sunk' costs (see footnote 2). Where such costs arise and they have a market economic effect they will be assessed in the same way as risks, but their likelihood of occurrence will be more certain (see also item 12). Identification is a two step process that scopes the range of possible effects (risks, costs and benefits).	
	Step 1:	Identify all risks and costs (adverse effects) and benefits (beneficial effects) associated with the approval of the organism(s), and based on the range of areas of impact described in clauses 9 and 10 of the Methodology and sections 5 and 6 of the Act[10]. Relevant costs and benefits are those that relate to New Zealand and those that would arise as a consequence of approving the application (clause 14). Consider short term and long term effects. Identify situations where risks and costs occur in one area of impact or affect one sector and benefits accrue to another area or sector; that is, situations where risks and costs do not have corresponding benefits.
	Step 2:	Document those risks, costs and benefits that can be readily concluded to be negligible[11], having regard to the characteristics of the organism and the circumstances of the application, and eliminate them from further consideration. Note that where there are costs that are not associated with risks some of them may be eliminated at this scoping stage on the basis that the financial cost represented is very small and there is no overall effect on the market economy.
Item 7:	**Assess each risk** The assessment of potentially non-negligible risks and costs should be carried out in accordance	

[9] Relevant effects are marginal effects, or the changes that will occur as a result of the organism(s) being available. Financial costs associated with preparing and submitting an application are not marginal effects and are not effects of the organism(s) and are therefore not taken into account in weighing up adverse and positive effects. These latter types of costs are sometimes called 'sunk' costs since they are incurred whether or not the application is successful.

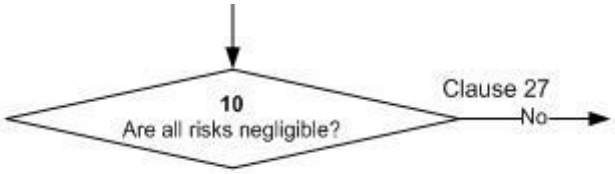
[10] Effects on the natural environment, effects on human health and safety, effects on Maori culture and traditions, effects on society and community, effects on the market economy.

[11] Negligible effects are defined in the Annotated Methodology as "Risks which are of such little significance in terms of their likelihood and effect that they do not require active management and/or after the application of risk management can be justified by very small levels of benefits".

	with clauses 12, 13, 15, 22, 24, 25, and 29 to 32 of the Methodology. Most of these risks and costs will relate to matters in sections 5 and 6 of the Act. In undertaking this assessment the HSNO decision maker must take into account the principles of the Treaty of Waitangi (section 8, and clause 9(c)(iv)). Assess each potentially non-negligible risk and cost estimating the magnitude of the effect if it should occur and the likelihood of it occurring. In estimating the magnitude of the adverse effect take into account the extent to which the risk might be mitigated by how or whether it might be possible to eradicate the organism if a significant adverse effect eventuated. When estimating the likelihood of the effect occurring, consider the full pathway, that is, all the possible steps that must occur before the final identified effect is realised. Estimating the likelihood requires combining (multiplying) all of the individual likelihoods for each link in the chain of events. Where there are non-negligible financial costs that are not associated with risks then the probability of occurrence (likelihood) may be close to 1. Relevant information provided in submissions should be taken into account. The distribution of risks and costs should be considered, including geographical distribution and distribution over groups in the community, as well as distribution over time. This information should be retained with the assessed level of risk/cost. The assessment should consider the following matters:
	Self sustaining population Section 38C(3)(c) requires the HSNO decision maker to consider the ease with which the organism could be recovered or eradicated if it formed a self-sustaining population considering whether the organism meets the minimum standards (item 7) In assessing the adverse effects, Section 38(1) of the Act requires the HSNO decision maker to regard to the ability of the organism to establish a self sustaining population and the ease of recovery or eradication should it establish an undesirable self-sustaining population (section 37). Thus whether the organism(s) can form a self sustaining population is addressed in two parts of the decision process. “Undesirable” is interpreted as being (in effect) able to create significant risks because of the reference to significant effects in section 36 (minimum standards).
	Approach to risk and approach to uncertainty Consider the HSNO decision maker’s approach to risk (clause 33 of the Methodology) or how risk averse the HSNO decision maker should be in giving weight to the risk. The risk characteristics set out in clause 33 are: a. Exposure to the risk is involuntary; b. The risk will persist over time; c. The risk is subject to uncontrollable spread and is likely to extend its effects beyond the immediate location of incidence; d. The potential adverse effects are irreversible; and e. The risk is not known or understood by the general public and there is little experience or understanding of possible measures for managing the potential adverse effects. Consider each non-negligible risk in terms of the factors listed and decide whether to be risk averse by giving additional weight to that risk. This may be done as part of estimating the magnitude of the effect or where this is not relevant, it may be done separately. Where the HSNO decision maker chooses to be risk averse, and there is uncertainty as well, the

	approach to risk may be consolidated with the approach to uncertainty by adopting a conservative approach such as the worst feasible case scenario. See the EPA report 'Approach to Risk' for further guidance[12].
	The assessment includes consideration of how cautious the HSNO decision maker will be in the face of uncertainty (section 7 and clauses 29-32). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the adverse effect as a means of identifying the range of uncertainty (clause 32). It is also important to bear in mind the materiality of the uncertainty and how significant the uncertainty is for the decision (clause 29(a)). For each component (magnitude and likelihood) consider the degree of uncertainty associated with the estimation of each component. In some cases it may be clear that the uncertainty could be reduced by gathering further information (undertaking more scientific tests, or extending the literature search). Before requesting or seeking further information it is important to consider how important the uncertainty is in terms of the decision (clause 29(a) – materiality), and to essentially consider the cost-effectiveness of gathering further information. Another approach to addressing uncertainty is to look at a range of scenarios and consider a best feasible-worst feasible scenario range. However, where there is a large degree of uncertainty, this may not be particularly meaningful for calculating the level of risk. In other cases, calculating the level of risk for each end of the range may result in a fairly similar level of risk. Where this does not occur, rather than presenting a wide range in the level of risk it may be better to concentrate on analysing why the uncertainty occurs and whether or not there is any obvious way of resolving it.
Item 8:	**Does the application meet the minimum standards?** If an organism does not meet the minimum standards set out in Section 36 the HSNO decision maker must decline the application. To meet the minimum standards an organism must not be likely to cause any of the following: a. any significant displacement of any native species within its natural habitat; b. any significant deterioration of natural habitats; c. any significant adverse effects on human health and safety; d. any significant adverse effect to New Zealand's inherent genetic diversity; or e. any disease, be parasitic, or become a vector for human, animal, or plant disease, unless the purpose of that importation or release is to import or release an organism to cause disease, be a parasite, or a vector for disease. The organism is tested against the minimum standards after the assessment of adverse effects because the information from the assessment and in particular the analysis of pathways is an input to this evaluation.
Item 9:	**Undertake combined consideration of all risks and costs** Once the risks and costs have been assessed individually, if appropriate consider all risks and costs together as a 'basket' of risks/costs. This may involve combining groups of risks and costs as indicated in clause 34(a) of the Methodology where this is feasible and appropriate, or using other techniques as indicated in clause 34(b). The purpose of this step is to consider the interactions between different effects and determine whether these may change the level of individual risks.

[12] http://www.epa.govt.nz/Publications/Approach-to-Risk.pdf

Item 10:	**Are all risks negligible?** At this point the decision path branches. Looking at individual risks in the context of the 'basket' of risks, consider whether all of the residual risks are negligible. Consider also the cumulative effect of the assessed risks. Where all risks are negligible, and the cumulative effect of the risks is considered to be negligible then take the clause 26 option and move to item 10. If one or more of the risks is considered to be non-negligible, or the cumulative sum of the risks is non-negligible, then take the clause 27 option and move to item 11.
Item 11:	 **(from item 9 - if 'yes') Is it evident that benefits outweigh costs?** Risks have already been determined to be negligible (item 9), therefore the decision must be made under clause 26 of the Methodology. In the unusual circumstance where there are non-negligible costs that are not associated with risks they have been assessed in item 6. Costs are made up of two components: internal costs or those that accrue to the applicant, and external costs or those that accrue to the wider community. Consider whether there are any non-negligible external costs that are not associated with risks. If there are no external non-negligible costs then external benefits outweigh external costs. The fact that the application has been submitted is deemed to demonstrate existence of internal or private net benefit, and therefore total benefits outweigh total costs[13]. As indicated above, where risks are deemed to be negligible, and the only identifiable costs resulting from approving an application are shown to accrue to the applicant, then a cost-benefit analysis will not be required. The act of an application being lodged will be deemed by the HSNO decision maker to indicate that the applicant believes the benefits to be greater than the costs. However, if this is not the case and there are external non-negligible costs then all benefits need to be assessed (via item 12).
Item 12:	 **(from item 9 - if 'no') Establish position on risk averseness and appropriate level of caution** Although 'risk averseness' (approach to risk, clause 33) is considered as a part of the assessment of individual risks, it is good practice to consolidate the view on this if several risks are non-negligible. This consolidation also applies to the consideration of the approach to uncertainty (section 7).

[13] Technical Guide 'Decision making' section 4.9.3. Where risks are negligible and the costs accrue only to the applicant, no explicit cost benefit analysis is required. In effect, the HSNO decision maker takes the act of making an application as evidence that the benefits outweigh the costs. See also Protocol Series 1 'General requirements for the Identification and Assessment of Risks, Costs, and Benefits'.

Item 13:	**(from item 11, or from item 10 if 'no') Assess benefits** Assess benefits or positive effects in terms of clause 13 of the Methodology. Since benefits are not certain, they are assessed in the same way as risks. Thus the assessment involves estimating the magnitude of the effect if it should occur and the likelihood of it occurring. This assessment also includes consideration of the HSNO decision maker's approach to uncertainty or how cautious the HSNO decision maker will be in the face of uncertainty (section 7). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the positive effect. An understanding of the distributional implications of a proposal is an important part of any consideration of costs and benefits, and the distribution of benefits should be considered in the same way as for the distribution of risks and costs. The HSNO decision maker will in particular look to identify those situations where the beneficiaries of an application are different from those who bear the costs[14]. This is important not only for reasons related to fairness but also in forming a view of just how robust any claim of an overall net benefit might be. It is much more difficult to sustain a claim of an overall net benefit if those who enjoy the benefits are different to those who will bear the costs. Thus where benefits accrue to one area or sector and risks and costs are borne by another area or sector then the HSNO decision maker may choose to be more risk averse and to place a higher weight on the risks and costs.
Item 14:	**Do beneficial effects outweigh adverse effects?** In weighing up positive and adverse effects, consider clause 34 of the Methodology. Where possible combine groups of risks, costs and benefits or use other techniques such as dominant risks and ranking of risks. Where this item is taken in sequence from items 11 and 12 (i.e. risks are not negligible) it constitutes a decision made under clause 27 of the Methodology. Where this item is taken in sequence from items 10 and 12 (i.e. risks are negligible, and there are external non-negligible costs) it constitutes a decision made under clause 26 of the Methodology.
Item 15:	**Confirm scope of organism description** At this step the scope of the organism description for generic applications should be reviewed. If changes are made to the organism description, items 4-13 above should be repeated for the revised organism description. Then the weighing up process in this item for the revised organism description should also be repeated. The scope of the organism description has been identified in item 4. This step in the decision-making process confirms the scope of the organism description in such a way that the risk boundaries are defined.

[14] Clause 13 of the Methodology