Environmental Protection Authority
Te Mana Rauhī Taiao

EPA advice on application APP201151 – the proposed release of *Mastrus ridens* for the biological control of codling moth (*Cydia pomonella*)

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 March 2012, Pipfruit New Zealand Inc. (PNZI) made an application to the Environmental Protection Authority (EPA) seeking to release an ecto-parasitoid wasp, *Mastrus ridens*(*M. ridens*), as a biological control agent for codling moth, *Cydia pomonella* (*C. pomonella*).

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

Submission process

1.3. Application ERMA201151 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 13 March 2012 and closed on 26 April 2012.

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

- Methodology of the host-range testing;
- 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 the codling moth to be a threat to valuable export markets. They consider the codling moth to be one of the most serious pests for apple growers for both the domestic and international markets. The codling moth also attacks pears, nashi, quinces, plums, apricots and walnuts.

1.6. PNZI has been supporting research into the potential for a parasitoid wasp (*M. ridens*) to act as a biocontrol agent for codling moth. They have provided information to suggest that it acts effectively and is virtually host specific (i.e. parasitises only the codling moth). They are confident that introduction of the wasp poses little risk to the New Zealand environment.

[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.

2. The organisms proposed for release

Background on *M.ridens*

2.1. All parasitoids are insects. The immature stages kill their host - usually another insect - in order to complete their own development. Ecto-parasitoids do this by laying their eggs onto the outside of the body of their prey.

2.2. Female *M. ridens* attack codling moth larvae or pre-pupae within their cocoons. They search for a codling moth cocoon using specific chemical receptors, then paralyse it and lay several (usually 1-7) eggs on the outside of the larva.

2.3. Emerging wasp larvae feed on the codling moth larva until they develop into adults (in about 3 weeks, depending on temperature). They then disperse in search of new codling moth larvae on which to lay their eggs.

2.4. There are no inseparable organisms associated with *M. ridens*.

3. Risk and benefit assessment

3.1. We conducted a risk benefit assessment for the release of *M ridens*. This includes risk and benefits to human health, environment, economy, society and culture.

3.2. Biological control agents can take many years to establish widely and have an impact on the target species. There is uncertainty about whether *M ridens* will establish and disperse successfully, and how long this will take. If it does not establish, it can be assumed that there will be no effect (adverse or beneficial) from the release. Conversely, if it does successfully establish, effects will occur at the highest level. Therefore, in conducting this risk assessment we have assumed that *M ridens* will become widely established.

Host-range testing

3.3. We have examined the host-range testing information provided by PNZI (see section 6 of the application; Charles and Dugdale 2011; Charles et al. *in prep* a; and Charles et al. *in prep* b). The references cited by the applicant detailing the results of the host-range testing have been peer reviewed and we are satisfied that the authors represent the appropriate scientific expertise to make this information sufficiently robust.

3.4. Five New Zealand non-target species in the Torticidae family were selected based on their phylogenetic relatedness to codling moth, their ecological similarity and their socioeconomic value to New Zealand (Charles and Dugdale 2011).

3.5. During host-range tests *M. ridens* was confined with codling moth and related native and introduced leaf-roller cocooned larvae. The *M. ridens* females quickly recognised the codling moth as a host. Most non-target species were ignored as hosts, but some larvae from two species of common native leaf-roller larvae (*Argyroploce chlorosaris* Fig 1a and *Ctenopseustis obliquana:* Fig 1b) were accepted for oviposition[3].

Figure 1 a) *Argyroploce chlorosaris* and b) *Ctenopseustis obliquana*

3.6. When deceived into laying their eggs on non-target hosts (see Charles et al. *in prep a* for a description of the method used to achieve this), the proportion of *M. ridens* larvae that survived to adulthood on codling moth pupae was significantly higher than those that survived on non-target hosts (Charles et al. *in prep* a). *Mastrus ridens* reared from non-target larvae survived through the first generation but were smaller and weaker than larvae raised on codling moth, and failed to successfully develop through to the end of the second generation.

3.7. We are satisfied with the rigour of the host-range testing presented by the applicant and accept that no native New Zealand species will be significantly adversely affected by the release of *M. ridens*.

Impacts to the relationship of Māori to the environment

3.8. Prior to lodging this application the applicant distributed information on the proposal nationally to iwi/Māori for feedback. Thirteen responses were received with queries and replies subsequently addressed by the applicant where appropriate.

3.9. The responses broadly sought assurance that native species and ecosystems would not be adversely affected by the release of *M.ridens* and that the role of Māori as kaitiaki would not be impacted. In their submission to the application Te Rūnanga o Ngāi Tahu outlined three

[3] Oviposition: to lay eggs

core values referenced in their consideration of the application, those being whakapapa, kaitiakitanga and rangatiratanga.

3.10. Of relevance to whakapapa, a number of respondents were concerned that the integrity of native species would be compromised. Ngāi Tahu noted in their submission concern that the consultation with Māori should have included a discussion on the range of native species included in the host-range testing. In terms of kaitiakitanga, from a Māori cultural perspective it is the responsibility of kaitiaki to ensure the protection of cultural and spiritual health and well-being for the resources for which it is their duty to protect[4]. Of particular relevance to 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.

3.11. When considering rangatiratanga, Te Rūnanga o Ngāi Tahu requested that they be provided with the results of monitoring and expressed an expectation that if successful, the use of chemical sprays would be reduced. We strongly encourage the applicant to provide such information so that future decision making by iwi/Māori groups can be better informed.

3.12. The applicant responded individually to consultation queries, and in the application, providing assurance by outlining the results of host-range testing and providing some context to the testing regime. Given this and the other areas of assessment outlined in this report, we are satisfied that the relationship of Māori to the environment will not be significantly impacted by the release of *M.ridens*.

Minimum standards

3.13. Prior to approving any new organism the EPA is required to ensure that if the organism were to be released that it would meet the minimum standards set out in the in the HSNO Act.

The EPA considered whether *M. ridens* is likely to cause any significant displacement of any native species within its natural habitat.

3.14. Dr Mason considers in his submission (#102565) that the "*introduction of a biological control agent with a demonstrated capacity to parasitise native organisms is a special situation that should disqualify it from use in New Zealand*". Clinton Care (# 102535) also voiced the

[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)

concern that *M. ridens* might attack native moth and butterfly pupae once codling moth is eradicated as their food source.

3.15. The applicant has provided evidence that *M. ridens* can only locate hosts through encountering specific contact chemical cues and acoustic sounding (Charles et al. *in prep* b). *Mastrus ridens* females are attracted to volatile kairomones6 associated with the silk of the cocoon, rather than the codling moth larva itself. However, four of the 13 individual *A. chlorosaris* and three of the 31 individual *C. obliquana* offered during tests were accepted as hosts and eggs laid on each (see Charles et al. *in press* b: tables 1 and 2). Other than the two species discussed in the application, the applicant demonstrates that no native moths or butterflies will be parasitised.

3.16. We understand that host recognition and acceptance among biocontrol agents in the artificial conditions prevailing in containment can lead to an overestimation of host-range (van Lenteren et al. 2006). We also consider that the population of *M. ridens* will be directly proportional to the population of codling moth.

3.17. The applicant has demonstrated that *M. ridens* operates in a habitat that contains codling moth prey and is unlikely to be attracted to native environments due to its semiochemical attraction to codling moths. While we accept that non-target prey may be attacked under exceptional circumstances, we consider that the codling moth is the only genuine host of *M. ridens* in the wild and that New Zealand's insects will not be threatened.

3.18. *Mastrus ridens* cannot form a self-sustaining population on any species other than codling moth. Even when non-target species are parasitised, the offspring are smaller and fail to thrive by the second generation. According to Vison (1985), who defined the steps of parasitoid success, parasitoid development and survival are paramount to the concept of parasitoid success. If the attacked host does not support sustainable development of the parasitoid, then it cannot be considered as a host from an ecological perspective (Charles et al. *in prep* b).

3.19. We consider that despite the potential for *M. ridens* to parasitise non-target species, it could not form a self-sustaining population on the non-target hosts and that there is not likely to be any significant displacement of any native species within its natural habitat.

[6] A **kairomone** is a semiochemical, emitted by an organism, which mediates interspecific interactions in a way that benefits an individual of another species which receives it, without benefiting the emitter (Grasswitz & Jones 2002).

The EPA considered whether *M. ridens* is likely to cause any significant deterioration of natural habitats.

3.20. Mark Fort of Gold'n Pear Orchards (#102560) expressed concern over the risk that *M. ridens* could evolve in such a way that it leads to a loss of native insects. The applicant has provided a response to this in section 8 of the application. The applicant states that *"It is erroneous to extend the concept of host-switching or evolution of a wider host-range, to a host specific parasitoid such as* M. ridens*, and to expect that they will attack other species if numbers of their primary host are low."* They explain that *"female* M. ridens *only recognise host cocoons that have the chemical identification signals specific to codling moth."*

3.21. We consider that there is no evidence that *M. ridens* could cause any significant deterioration of natural habitats.

The EPA considered whether *M. ridens* is likely to cause any significant adverse effects on human health and safety.

3.22. There are already many species of native and introduced parasitoid wasps in New Zealand and none are known to adversely affect human health. We consider that there is no evidence that *M. ridens* could cause any significant effects on human health and safety.

The EPA considered whether *M. ridens* is likely to cause any significant adverse effect to New Zealand's inherent genetic diversity.

3.23. We recognise that the introduction of any new organism to New Zealand has the potential to cause harm to New Zealand's genetic diversity. However, *M. ridens* is unlikely to mate with any native ecto-parasitoid wasp species and evolve into a new species.

3.24. We consider that the evolutionary changes required for this to occur happen over hundreds and thousands of generations and cannot be considered as part of the HSNO risk assessment. We therefore consider that *M. ridens* is unlikely to cause any significant adverse effects to New Zealand's inherent genetic diversity.

The EPA considered whether *M. ridens* is likely to cause disease, be parasitic, or become a vector for human, animal, or plant disease.

3.25. We consider that there is no evidence that *M. ridens* could cause disease, be parasitic, or become a vector for human, animal, or plant disease, except where it is intended to parasitise its host.

Conclusion on the minimum standards

3.26. We consider *M. ridens* is unlikely to cause significant displacement of other organism's, cause significant deterioration of natural habitats, cause significant deterioration of natural

habitats, any significant adverse effects on human health and safety, or have a significant adverse effect on New Zealand's inherent genetic diversity.

3.27. We therefore consider that *M. ridens* meets the minimum standards as stated in the HSNO Act.

Adverse effects

3.28. The applicant has identified potential adverse effects associated with the release of *M. ridens* (see pages 10-14 of the application). In particular, the application identifies the possible impact of *M. ridens* on non-target species as a potential risk.

3.29. Federated Farmers (#102566) expressed concern over the potential for *M. ridens* to attack, damage, out-compete or otherwise damage non-target insect species, with specific reference to the honeybee and the bumblebee.

3.30. There is no evidence that *M. ridens* is aggressive and no records of it attacking species other than those it parasitises. The applicant states that "*like all wasps,* M. ridens *adults eat sugars to maximise their lifespan and fitness. These sugars are usually in the form of nectar from flowers or sometimes honey-dew produced by sap feeding insects.* Mastrus ridens *will feed predominantly on nectar from flowers present in orchards and the modified environments in which they search for hosts. Adults are not much bigger than a flying ant, and the quantity consumed will be negligible compared with honey bees or bumble bees. We consider it very unlikely that these wasps will ever come into contact with native insects that produce honeydew (especially those in beech forests)"* (see page 7 of the application).

3.31. We consider this sufficient evidence to demonstrate that no honey bees or bumblebees will be attacked or outcompeted by *M. ridens*.

3.32. We consider that there is sufficient evidence in the references provided by the applicant to conclude that there is no risk to non-target species. The adverse effects on non-target species will be localised, whereby some faunal communities may be temporarily damaged but this will not result in damage to the species or extinctions. These adverse effects will not occur through the normal prey searching behaviour of *M. ridens*.

3.33. Therefore we consider that the adverse effects associated with the release of *M. ridens* are **negligible.**

Positive effects

3.34. We considered all the possible positive effects associated with the release of *M. ridens*.

3.35. The applicant has identified potential positive effects associated with the release of *M. ridens* (see pages 8-10 of the application) including; increased stability and returns from export markets, improved market access for both conventional and organic apples, substantial reduction in production costs associated with controlling immigrant moths, reduced use (or absence) of synthetic pesticides (the use of which is increasingly restricted for export markets), and improved biocontrol of codling moth in home garden trees accompanied by reduced use of broad spectrum insecticides in these (often urban) environments.

3.36. Mark Fort stated in his submission that he supported the release of *M. ridens* on the grounds that it may reduce the amount of pesticides used in orchards, and could improve the quality of fruit that can currently be infested with codling moth.

3.37. Dr Mason stated in his submission that while he considers that the benefits of releasing *M. ridens* may be significant, it is unlikely codling moth will be eliminated and therefore the benefits outlined by the applicant are unlikely to be attained.

3.38. We consider that inhibiting the migration of codling moth from fruit trees outside commercial orchards will reduce the quantity of synthetic pesticides currently being used. Many orchards in New Zealand operate an integrated pest management system of pesticide and beneficial organism use. Growers are mindful of the phenology[7] of pests and beneficial organisms, and manage their spray programs accordingly.

3.39. As reducing pesticides in commercial and urban environments may lead to improved health for orchard workers and home gardeners, we consider this to be a benefit, albeit an unquantifiable one

3.40. We consider that improved local and international market access resulting from reduced pesticide use will benefit New Zealand at a national level. This benefit will accrue gradually and may not be evident until codling moth population's drop.

3.41. We consider both these benefits are **likely** to occur and that the beneficial effects that can be accredited to the release of *M. ridens* are **non-negligible**.

[7] Phenology: the study of periodic plant and animal life cycle events and how these are influenced by seasonal and interannual variations in climate.

Conclusion on adverse and positive effects

3.42. After reviewing the relevent information, we consider that the positive effects of releasing *M. ridens* are **non-negligible** and the adverse effects are **negligible**. Therefore the positive effects outweigh the adverse.

4. Recommendation

4.1. After weighing the negative and positive effects, we recommend that the release of *M. ridens* be approved.

5. Submissions

5.1. Four submissions were received in response to the application. One urged caution, one supported the application, one neither supported nor opposed, and one was in opposition to the application.

Submissions in support of the application

5.2. Te Rūnanga o Ngāi Tahu do not oppose the application but noted that if successful, this release should result in a reduction in the use of chemical sprays to control codling moth. They have asked that results of post release monitoring be made available to them. The applicant has declared a commitment to measure the post release establishment and impact of *M. ridens* and the EPA encourages them to make this post release monitoring publically available.

5.3. Mark Fort supported the application on the grounds that it may be able to reduce the amount of sprays and may also lead to better access to local and export markets. He also hoped it may improve fruit quality.

Submissions in opposition to the application and response to some additional key points

5.4. Mark Fort, in addition to his submission in support of the application, expressed his concern that evolutionary development or hybridisation could lead to a loss of native insects and asked for assurances that these tests had been carried out.

5.5. The EPA directed him to the applicant for an explanation of host-range testing carried out by the applicant, and after consultation between the two parties, Mr Fort withdrew his request to speak at a hearing.

5.6. Dr Cliff Mason has suggested that *M. ridens* is attracted to Tortricids (Tortricidae) that are not phylogenetically close to codling moth and that this implies the possibility that other species of insect larvae may produce similar chemical and be potential targets for *M. ridens.*

5.7. We are satisfied that the applicant did in fact choose phylogenetically close subjects for their host-range testing (see Charles and Dugdale 2011 and Charles et al. *in prep* b) and have demonstrated the low risk to native insects associated with the release of *M. ridens*.

6. Comments from MPI and DOC

Comments received from DoC

6.1. On the evidence the applicant's provided, DOC concur that this application is likely to pose a low risk to conservation values.

6.2. DOC asked that it be noted that they consider the risk low rather than negligible, given the reliance on theory in some areas. They commented that "*although there is no evidence to support a hypothesis that 'interbreeding' between* M. ridens *reared from codling moth and* A. chlorosaris *will result in improved vigour of the parasitoid on the latter, there is no evidence to dispute this either. However, we acknowledge the difficulty of doing such tests with limited material."*

6.3. Accordingly, the Department does not oppose this application.

Comments received from MPI

6.4. MPI were given the opportunity to comment, and provided no opinion on the application.

7. References

Charles JG and Dugdale JS 2011. Non-target species selection for host-range testing of *Mastrus ridens. New Zealand Entomologist* 34: 45-51

Charles JG, Sandanayaka MWR, Chhagan A, Page-Weir NEM *in prep* a. Survival of the gregarious ectoparasitoid *Mastrus ridens* on codling moth, *Cydia pomonella,* and non-target species.

Charles JG, Sandanayaka MWR, Chhagan A, Page-Weir NEM *in prep* b. Host selection behaviour in *Mastrus ridens*, a gregarious ectoparasitoid of codling moth, *Cydia pomonella*.

Grasswitz TR, Jones GR 2001. Chemical ecology. *Encyclopaedia of Life Sciences*. John Wiley and Sons.doi.org/10.1038/npg.els.0003265

Van Lenteren JC, Cock MJW, Hoffmeister TS, Sands DPA 2006. Host specificity in arthropod biological control, methods for testing and interpretation of the data. In: Bigler F, Babendreir D, Kuhlmann E eds. Environmental impact of invertebrates for biological control of arthropods. Methods and risk assessment. CABI Publishing.

Vinson SB 1985. The behaviour of parasitoids. In: Kergut GA, Gilbert LI. Comprehensive insect physiology, biochemistry and pharmacology. 9th edition. New York, Pergamon Press.

Appendix 1

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[8] 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.

[8] 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.

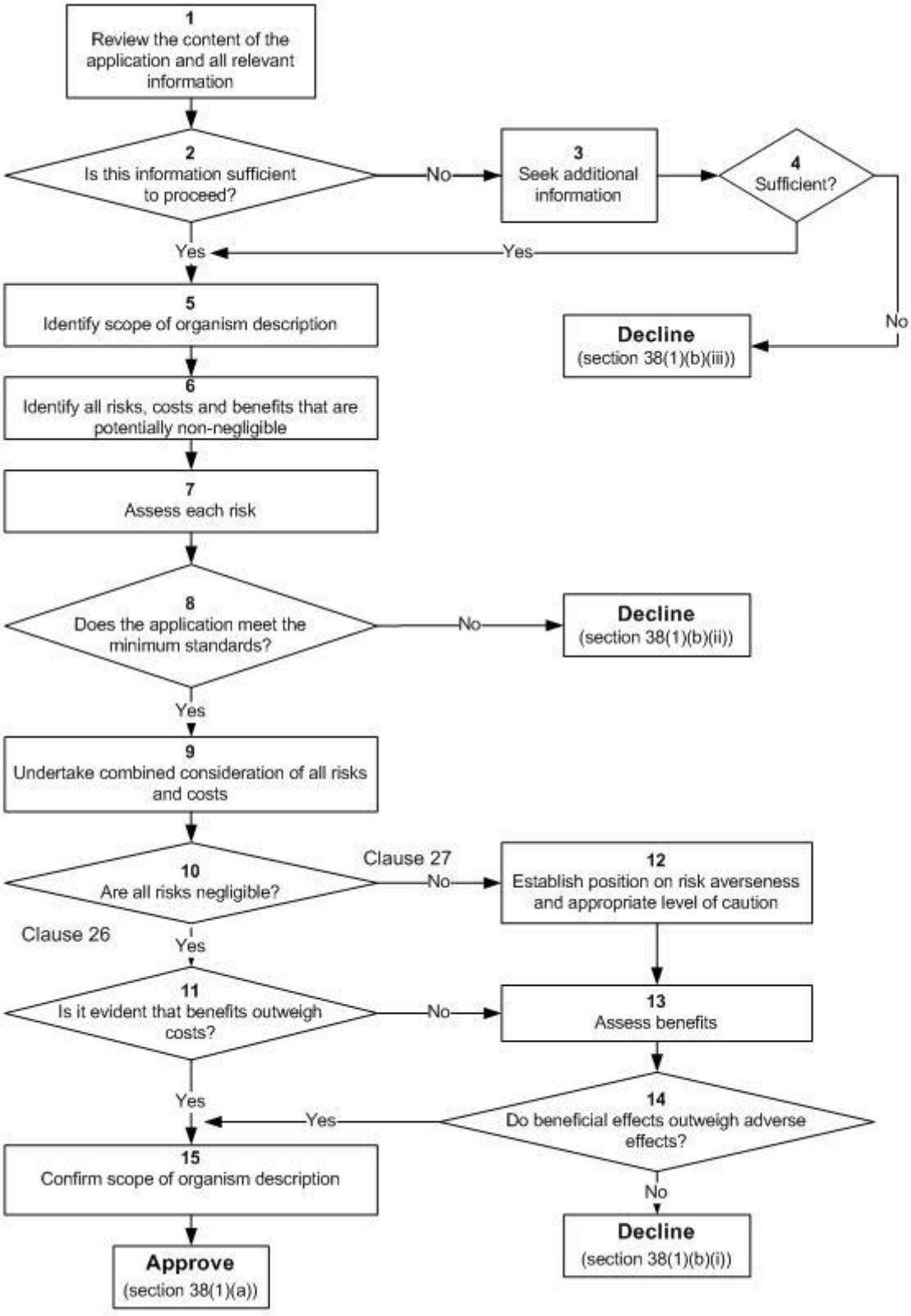


Figure 6 Explanatory Notes

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[9]). 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 organism description where a range or variety of new organisms is being

[9] 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

	considered.	
Item 6:	**Identify all risks, costs and benefits that are potentially non-negligible[10]** 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[11]. 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[12], 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**	

[10] 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.

[11] 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.

[12] 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".

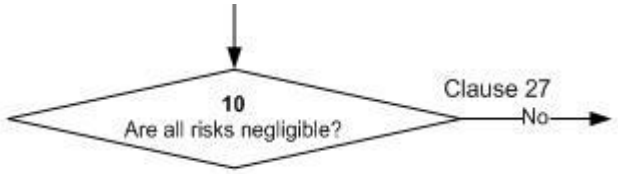
	The assessment of potentially non-negligible risks and costs should be carried out in accordance with clauses 12, 13, 15, 22, 24, 25, and 29 to 32 of the Methodology. Most of these risks and costs will relate to matters in sections 5 and 6 of the Act. In undertaking this assessment the HSNO decision 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[13].
	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

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

	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.
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[14]. 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).

[14] 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 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).
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[15]. 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

[15] Clause 13 of the Methodology

	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.