

User Guide to Making an Application for a New Organism under the HSNO Act 1996

Form NOCR - Import for release or release from containment with controls any new organism under section 38A of the HSNO Act

Introduction

We recommend that you read this userguide before filling out your application form. If you have any queries, please contact an ERMA New Zealand Applications Advisor for assistance. We strongly encourage you to contact ERMA New Zealand before making an application for guidance. Drafts of applications can be sent to ERMA New Zealand for checking before they are formally submitted.

Other application forms

- If you are making an application to import for release or release from containment any new organism (i.e. full release **without controls** as opposed to conditional release) you should use Form NOR.
- If you are making an application for a field test in containment of any new organism you should use Form NO4.

Both of these forms are available from the ERMA web site www.ermanz.govt.nz however you should periodically check for new versions of these and other forms.

Conditional Release – some key definitions in the HSNO Act (the Act)

- A “conditionally released new organism” is defined in the Act as:

“a new organism that is subject to a conditional release approval.”

- A “conditional release approval” is defined in the Act as:

“an approval under section 38C.”

- A “new organism” is defined in the Act as:

“(a) An organism belonging to a species that was not present in New Zealand immediately before 29 July 1998:

(b) An organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed as a risk species, where that organism was not present in New Zealand at the time of promulgation of the relevant regulation:

- (c) An organism for which a containment approval has been given under this Act:*
- (ca) An organism for which a conditional release approval has been given:*
- (cb) A qualifying organism approved for release with controls:*
- (d) A genetically modified organism:*
- (e) An organism that belongs to a species, subspecies, infrasubspecies, variety, strain, or cultivar that has been eradicated from New Zealand.”*

Note: The new organism to which an approval for conditional release applies does not cease to be a new organism.

- A “genetically modified organism” (GMO) is defined in the Act as:

“unless expressly provided otherwise by regulations, any organism in which any of the genes or other genetic material:-

(a) Have been modified by in vitro techniques; or

(b) Are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by in vitro techniques:”

- Section 38D of the HSNO Act allows the Authority to impose controls on the release of the new organism. These controls **may** include but are not limited to:

(a) controlling the extent and purposes for which organisms could be used:

(b) requiring any monitoring, auditing, reporting, and record-keeping:

(c) imposing any obligation to comply with relevant codes of practice or standards (for example, to meet particular co-existence requirements):

(d) requiring contingency plans to be developed to manage potential incidents:

(e) limiting the dissemination or persistence of the organism or its genetic material in the environment:

(f) requiring the disposal of any organisms or genetic material:

(g) limiting the proximity of the organism to other organisms, including those which could be at risk from the conditionally released organism:

(h) setting requirements that must be met for any material derived from the organism:

(i) imposing obligations on the user of an approval, including levels of training or knowledge, limits on the numbers of users who may hold an approval, and the persons that they could deal with in respect of the organism:

(j) specifying the duration of the approval or of a control before requiring review by the Authority, and the nature of the review.

Note: Under section 38G(1) of the Act controls may be reviewed by the Authority (on its own initiative or on the application of various other people expressly stipulated in the Act) but only if:

“(a) the review is to amend a control so that it better meets the objective of the control; or

(b) the control included a review requirement specifying -

(i) the circumstances in which the control would be reviewed; and

(ii) the potential consequences of the review.”

Public notification and treating release applications as conditional releases

Under section 53(1)(d) of the Act applications to import for release or release from containment any new organism **with controls** are required to be publicly notified and **may** go to a hearing (section 60 of the Act). If under section 38B of the Act the Authority, with the agreement of the applicant, decides to treat an application initially made under section 34 (i.e. a full unconditional release) as if it were a conditional release application, this decision will be made prior to public notification. Because this is more directly an issue for applications for full (unconditional) release, it is dealt with in detail in the full (unconditional) release User Guide NOR.

Duration of and consequences of expiry of approvals for conditional release

Under section 38E of the Act an approval for conditional release that expressly states that it does not expire expires on the close of the date on which the last control to which the approval relates expires. There are exceptions to this provision such as an approval for conditional release may expire on the earlier of:

- “(a) the date of expiry (if any) specified in the approval; or*
- (b) if no date of expiry is specified, 5 years after the date on which the approval is granted; or*
- (c) does not expire if the Authority expressly states in the approval that the approval will not expire.*

Note: Under section 38F of the Act on the expiry of an approval for conditional release, the new organism must be disposed of unless, before the expiry of the approval, a further approval has been granted by the Authority. Therefore, the automatic expiry provisions in the Act (section 38E) and the link to the disposal of the organism at expiry (section 38F), make it important that applicants provide information about the intended duration of the approval (in section 4 of the form). The application should clearly state, with reasons, whether the approval is to have a fixed time limit or if no expiry date is required. Where appropriate the application must also provide information on the feasibility of disposing the organism once conditionally released.

How and where to complete the form

The following sections will help you to complete the application form. When filling in the form please provide your responses after the “>” icons. Examples of how to fill out questions are indicated by “underlining” in this user guide.

Note: some of these examples are fictitious and are intended to be illustrative of how particular questions in the application form should be completed.

Level of information to be provided

The level of information and analysis you need to provide for a conditional release application is considerably more than that required for a development or field test in containment application. This is because there are greater possibilities of adverse effects outside of containment. It is therefore critical in your application that you clearly identify the organism, its key characteristics and potential risks.

The onus is on the applicant to substantiate their application with referenced supporting information (such as published papers or reports, or correspondence with relevant authorities).

ERMA New Zealand can provide advice on drafts of the application to assist you in your preparation. ERMA New Zealand will, however, not engage in repeated requests for further information or clarifications to fill gaps in the application. After formally accepting your application ERMA New Zealand will identify information gaps but will not complete the application for you. Consequently, your application will be considered on its own merits by the Authority. You need to provide information about the potential adverse effects of the new organism throughout its lifecycle (such as immature, mature, reproductive or resting stages). You also need to consider the provisions set out in Part II of the Act, especially sections 5 and 6 which identify the principles and matters relevant to the purpose of the Act as follows:

“5. Principles relevant to purpose of Act--All persons exercising functions, powers, and duties under this Act shall, to achieve the purpose of this Act, recognise and provide for the following principles:

- (a) The safeguarding of the life-supporting capacity of air, water, soil, and ecosystems:*
- (b) The maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural wellbeing and for the reasonably foreseeable needs of future generations.*

6. Matters relevant to purpose of Act--All persons exercising functions, powers, and duties under this Act shall, to achieve the purpose of this Act, take into account the following matters:

- (a) The sustainability of all native and valued introduced flora and fauna:*
- (b) The intrinsic value of ecosystems:*
- (c) Public health:*
- (d) The relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga:*
- (e) The economic and related benefits to be derived from the use of a particular hazardous substance or new organism:*
- (f) New Zealand's international obligations.”*

In addition, under section 38A of the Act every application for conditional release must include:

- “(a) all prescribed information (if any); and*
- (b) information on all occasions where the organism has been considered by the government of any prescribed state or country or by any prescribed organisation and the results of the consideration; and*
- (c) the identification of the organism; and*
- (d) any likely inseparable organisms; and*
- (e) all the possible adverse effects of the organism on the environment; and*
- (f) the affinities of the organism with other organisms in New Zealand; and*
- (g) the proposed use for the organism; and*
- (h) the controls that the applicant proposes the organism would be subject to on its release.”*

These criteria form the basis for the questions that appear in the application form. You will find references to the relevant sections of the Act throughout the application form and user guide.

Confidential Information

If you think some of the information that is required to be provided should be treated as confidential you need to justify this so that ERMA New Zealand can determine whether to withhold it from the public access register. All confidential information must be clearly identified and attached as an appendix or provided under separate cover. The application should refer to this confidential appendix information but it must be a stand-alone document as parts of the application

will be available to the public. ERMA New Zealand is required to make publicly available the purpose of the application (section 2.1), the unique name for the organism(s) (section 3.3), and a summary of the application (section 8). If you have a problem with the information that needs to be made available to the public you can discuss with ERMA New Zealand options for protecting that necessary information.

Application Form – Front page

Application Title

You need to provide a short working title (as used, for example, in running headers on manuscripts) that identifies what organisms are involved and what the application is about. For example, “Conditional release from containment of genetically modified herbicide resistant soybean” or “Conditional release of genetically modified cotton with resistance to Lepidoptera pests and tolerance for glufosinate ammonium”.

Applicant Organisation

As noted in Section 1.1 below include the name of the organisation responsible for the application, or if you are a private individual put your name here.

Section One of the Application form - Applicant Details

Section 1.1

Please identify the organisation or person making the application. Note that if you belong to an institution (such as a University or Crown Research Institute) or the application is on behalf of a specific group or society (such as “the New Zealand Horticultural Society”) then this organisation is usually the official applicant. If you are making the application in a private capacity then include your contact details in this part.

Section 1.2

If the official applicant is an organisation please provide the details for a designated person in New Zealand who takes responsibility for the application. They should be available to answer queries on the application and be the official point of contact for ERMA New Zealand. This person should be available by telephone during normal business hours in New Zealand, and should have sufficient knowledge of the application to respond to queries from ERMA New Zealand staff. This person should also have the authority to make decisions on behalf of the applicant, or be able to go to the appropriate source for a decision. Note that this person should normally be available throughout the processing of the application. If that person is likely to be unavailable for some of this time than another suitable person should also be identified.

Section 1.3

If the applicant is situated overseas, then an authorised contact in New Zealand needs to be specified to handle the application. Their details need to be given in this section.

Section Two of the Application Form - Purpose of the Application

Section 2.1 – Short summary of the purpose of the application

Please provide a short easy to understand statement about why you intend to conditionally release the organism(s) and/or what the organism(s) will be used for. The statement should identify the type of organism to be conditionally released and why it is needed. Please use a maximum of **255 characters (including spaces)**. For example:

“To conditionally release, in the Hawkes Bay Region, plums genetically modified with resistance to the plum pox pathogen.”

This purpose will be used in ERMA New Zealand’s database and will also be made publicly available.

Note: Do not summarise the application here – an overall summary is required at the end of the application in section 8.

Section 2.2 – Description of the project for lay readers

This section is intended to put the organisms in perspective of the wider project(s) that they will be used in. The description should be aimed at people without a science background. You should describe the main features of the organism(s) to be conditionally released, key risks associated with their release, relevant findings from overseas regulatory agencies, general location and **duration** of the conditional release etc. Please make clear the benefits of the proposed release and attempt to keep the description to **less than one page**. This explanation is particularly important if the proposal involves DNA from human genes or native and valued flora and fauna. In addition, discuss whether expression of the foreign genetic material is anticipated, and whether any unusual procedures will be involved.

For example:

- “An approval to import 5 camels for conditional release for an initial period of 5 years is being sought. The purpose of the importation is to establish a trekking business that will be operated in a Northland location. Only castrated males will be imported to ensure that a self-sustaining population does not establish. Monitoring for any environmental deterioration will also be undertaken at the intended conditional release location where base-line data of the location is already available. Consultation with the relevant local iwi will also take place. The trekking business will provide employment and an agreement will be signed with the local iwi to ensure that a certain percentage of employees will be sourced from that local iwi.”

Section Three of Application Form - Information on the Organism(s) to be Conditionally Released

All new organisms that will be imported for conditional release or conditionally released from containment in the project need to be identified.

Section 3.1 – Taxonomic level at which the organism(s) are to be specified

Section 27A of the HSNO Act allows for the Authority to approve a new organism at any taxonomic classification that it thinks fit. The granting of approvals at different levels of taxonomic classification allows ERMA New Zealand to consider applications at the most appropriate taxonomic level for risk assessment. Given section 27A of the Act, it may be acceptable to specify the organism at a higher taxonomic level than “species”, provided this can be justified. Please state the taxonomic level at which the organism(s) to be conditionally released are to be specified and give

reasons to justify your position. It is likely that these reasons will be at least partly risk-based e.g. if a taxonomic level higher than “species” is involved, the Authority will need to be convinced that risks can be adequately identified and assessed at this higher level.

Please note that the issue of taxonomic level is different from the issue of generic specifications. The term “generic” is particularly applied to genetically modified organisms and means that the genetic constructs inserted into particular host organisms are specified in terms of types and ranges rather than on an individual basis. In general, “generic” specifications will not be acceptable for conditional releases. It is expected that by the time work reaches the conditional release stage the genetically modified organisms concerned are able to be specifically identified.

Section 32 - Unequivocal identification of the organism(s)

In this section, you should provide information on the identification of the organism(s) that you are importing for conditional release or conditionally releasing from containment.

You should provide sufficient information to unequivocally identify each organism. This includes listing the relevant taxonomic name, authorities and noting any synonyms. Listed below is an indication of the type of information required. It is not a comprehensive list, but illustrates the type of information needed:

- **Latin binomial name**, including the taxonomic authorities and year. This is to ensure that the organism has been and can be accurately identified. For example, “*Escherichia coli* (Migula, 1895) Castellani & Chalmers 1919” “*Ovis aries* Linnaeus 1758”

Note: for viruses there are generally no authority names.

Authority names for species can be found in a variety of sources, including on the internet. For example:

- Species 2000 Names Service (<http://www.sp2000.org/NamesService.html>)
- Zoological Record on BIOSIS (<http://www.biosis.org.uk/triton/indexfm.htm>)
- International Plant Names Index (<http://www.ipni.org/index.html>)
- List of Bacterial names with Standing in Nomenclature (<http://www.bacterio.cict.fr/>)

Note: these websites were current at the time this user guide was published, but access or addresses to some websites may change over time.

- **Taxonomic class, order, and family** to which the organism belongs. This can help ERMA New Zealand, and other people, to clearly identify the relationship of the organism to other species. For example, “Insecta: Diptera: Cecidomyiidae”. Family names can be located in books and from various internet sources (such as those listed above for taxonomic authorities).
- **Common name(s)** (where relevant). For example, “potato”, “sheep”, or “no common name”.
- **Type of organism**. For example, “plant”, “animal”, “virus”, “bacterium”, “fungus”. This is to assist in classifying the organism(s) for the ERMA New Zealand database.
- **Strains and genotypes used** (where relevant). If your application involves specific strains, variety, cultivar or breeds these should be noted. For example, “wild type sourced from Hawaii”, “strain DH5 α ”, “derivatives of strain K-12”, “Jersey” or “environmental isolates”. You may also want to include information on the genotype(s) of the organism(s) if you consider that this is relevant. Note that you may not need to specify strains or breeds in every

case. Please talk with ERMA New Zealand if you are unsure whether you need to include particular strains, varieties or breeds.

- **Other information** that you consider relevant to identifying the organism should also be provided. This may include information on whether it contains, or is likely to contain, inseparable organisms (such as viruses).

Section 3.3 – Provide unique name(s) for the new organism(s) to be conditionally released

These name(s) will be on the public register and should clearly identify the organism(s). In the case of genetically modified organism(s) you must describe both the host organism(s) as well as how they have been modified. Remember that you or others may want to search the ERMA New Zealand register to find out if something has already been approved so you should keep this in mind when constructing this descriptor. For example:

“Onion (*Allium cepa* L.) modified with the CP4 EPSPS gene conferring tolerance to the herbicide glyphosate.”

“Australian Green Fly (blowfly; *Lucilia cuprina*) modified with *Drosophila melanogaster* gene cassettes conferring female specific lethality.”

“Glyphosate Tolerant Soybean event GTS-40-3-2”.

Section 3.4 -Characteristics of the organism(s)

Provide information on the biology, ecology and the main features or essential characteristics of each of the organism(s) to be conditionally released. This information should be relevant to the identification and assessment of all the possible risks and adverse effects of the organism (sections 5 and 6). You should note characteristics of the host organism as well as any new characteristics introduced by any genetic modifications (where relevant). We are especially interested in knowing if the organism is pathogenic or a potential pest or weed. Information such as conditions required for growth and reproduction, reproductive ability, and other ecological information needs to be provided. In evaluating the risks associated with a genetically modified organism being conditionally released we are primarily interested in characteristics which differ from the parent organism. These characteristics should all be identified in this section. Published and non-published experimental data and information obtained from the development phase of any genetically modified organism(s) should be attached to this application to assist in risk assessment. Cross reference to the ERMA New Zealand development approval code (where applicable) would be useful. An attached appendix of information concerning the characteristics of the non-modified host organism would also be useful for risk assessment especially for applications concerning conditional releases of GM plants. Where possible provide references or additional information to support your statements. This information can be presented in any format (text, table and/or figures) and will be used to develop exposure scenarios, assess risks and specify potential controls. Note: Please refer to the appendix at the rear of this User Guide for the types of issues you should consider in completing this section 3.4 and section 5 of the application form.

Examples of information you should supply include:

- *General information on attributes and characteristics of the family and genus the proposed organism belongs to, for example:*
 - if the organism is pathogenic, what species does it infect? What is its mode of transmission? How can infection be controlled? Are infectious particles or agents produced by the organism?
 - if the organism is derived from a pathogenic species but is itself not pathogenic you need to indicate the reasons for it being benign (such as whether the pathogenic genes have been removed or lost by laboratory cultivation).

- does the organism produce spores, pollen or seeds? Discuss how these reproductive structures are spread (e.g. wind or insect borne).
- is the organism or members of the same family known to be a weed, pest or parasite? If so, provide details.
- *Information on the biology and lifecycle of the organism including:*
 - climatic and ecological preferences that result in the natural distribution of the organism;
 - habitat requirements including factors that may limit its distribution;
 - basic description of the structure of the organism;
 - life history and life cycle information;
 - affinities with New Zealand biota in terms of its potential to interact, form associations or interbreed;
 - competitors and predators in managed and natural environments;
 - potential uses.
- *In the case of genetically modified organisms:*
 - What is the phenotype of the modified organism?
 - Does it have improved biological and reproductive fitness? What conditions does the organism require to grow and reproduce, and in which environments does it normally occur?
 - Are the genetic modifications expected to result in new traits? For example, are herbicide resistant plants produced?
 - Data indicating the stability of the genetic construct over generations.
 - If a GM plant, state whether it is self-fertile or out-crossing or both.
 - Site(s) and sequence(s) of the genome where the genetic construct has integrated. Whether the modification is chromosomal or extrachromosomal (i.e. mitochondrial or chloroplast genome).
 - The level and tissue distribution of transgenic RNA and protein expression.
 - If it is derived from a pathogenic species but is itself not pathogenic you need to indicate the reasons for it being benign (such as whether the pathogenic genes have been removed or lost by laboratory cultivation).

Section 3.5 – Details on the development of any genetic modified organism(s) to be conditionally released

In the case of a conditional release for a genetically modified organism, please describe how the organism was developed so that all potential risks can be identified (in section 5). If the development was carried out under a HSNO approval, provide the ERMA New Zealand approval number and translate the information into the headings below. If development occurred elsewhere e.g. the organism was imported for conditional release from an overseas source, describe the source and its locations, and provide as much information as you can under the following headings:

Categories of HSNO (Low-Risk Genetic Modification) Regulations 2003

Identify the category of the host organism (i.e. category 1 or 2) and genetic modification (i.e. category A or B) involved in the development of the organism(s) with reference to the HSNO (Low-Risk Genetic Modification) Regulations 2003. Please explain your characterisation. For example:

“Glyphosate tolerant (expressing CP4 EPSPS transgene) soybean involves a Category B genetic modification of a Category 2 host organism.”

Vector system(s)

In addition to identifying the host organism(s) you must indicate what vectors, if any, were used and describe their essential features. You should attach diagrams of vectors/constructs to show the main features of the modification. Examples of ways of describing vectors are “non-tumourigenic Agrobacterium plasmid vectors of commercially sensitive pMON series (see confidential appendix)”, “binary plasmid vector pART27G”, and “tobacco mosaic virus with a duplicated coat protein gene promoter”. Include explanations of all regulatory elements and marker genes used

and clearly describe which elements are present in the modified organism and which were only present in the vector. For example, sequences within the T-DNA borders of vectors used in *Agrobacterium tumefaciens* are transferred to plants but not the sequences outside of the T-DNA borders, or in some cases marker genes will be removed from the organism once the desired gene is introduced. If some of this information is confidential it should be included as an appendix and clearly marked “confidential”. We encourage you to include diagrams of vectors, and you should indicate the essential features of the vectors (such as what species they can replicate in and what species nucleic acid sequences have been derived from). For example:

- “35S promoter from Cauliflower mosaic virus allows strong constitutive expression of the transgene
- GFP reporter gene allows visual selection of transgenic organisms
- 3'-untranslated region of *rbcS E9* gene of pea (*Pisum sativum*)
- Chloroplast transit peptide (CTP1) sequence from *rbcS* gene of *Arabidopsis thaliana*
- *ori-V* origin of replication from pRK2 for replication in *Agrobacterium tumefaciens*
- *ori-322* origin of replication from pBR322 for replication in *E. coli*
- Bacterial *aad* gene derived from transposon Tn7 conferring resistance to antibiotics spectinomycin and streptomycin for the selection and propagation of the plasmid in *E.coli* and *A. tumefaciens*.”

Type and source of additional genetic material

You also need to identify the types of other genetic material (including what organisms they come from) that were used to develop the organism. For example, “the *Vibrio cholerae* *ctx* toxin gene”, “CP4 EPSPS gene from *Agrobacterium tumefaciens* strain CP4 that confers tolerance to the herbicide glyphosate”, and “human alpha-1-antitrypsin gene”. Include details such as if the gene was derived from a cDNA library or if the sequence was modified and optimised for expression in another species. For example:

- “A plant preferred version of the *gox* gene from the bacterium *Ochrobactrum anthropii* was synthesised by site-directed mutagenesis. The *goxv247* allele used to modify canola plants varies from the native gene by 5 nucleotides and the expressed protein is 99% identical to the native enzyme.”

Use of special genetic material

In addition to the previous question you need to identify whether native (specify whether endemic)¹ or valued² flora and fauna were involved (either as host organisms or as sources of genetic material), and if human genetic material was used. We ask you to distinguish between experiments where a native organism was the organism that was modified (such as genetically modifying *Phormium tenax*), and where genetic material from native organisms were introduced into another organism (such as cloning *Phormium tenax* DNA into *E. coli*). You should note any particular ethical committee approvals that were obtained for this work. You should indicate if DNA was derived directly or indirectly (i.e. use of gene banks) from humans.

Other relevant details

Describe what techniques were used to produce the organism(s). For example, cell fusion, transduction, transfection, transformation, particle bombardment. Note whether the whole organism is modified or only some cells or tissues are.

¹ Native means flora and fauna that existed in New Zealand at the time of the arrival of humans e.g. kiwi.

Endemic means that it does not occur naturally outside of New Zealand e.g. therefore the kiwi is both native & endemic.

² Valued species that may be valued for symbolic, spiritual, aesthetic, economic or historic reasons.

Do not forget to include all steps in the process to creating the organism(s), such as initial manipulations in *E. coli*, then subsequent transfer of the vector to *Agrobacterium*, which is then used to modify plants.

Also describe the site of transgene integration in the host genome, transgene copy number, whether the foreign genetic material is expressed and in which tissues.

Section Four of Application Form - Proposed Conditional Release Programme and Controls

Section 4.1- Proposed Conditional Release Programme

Provide full details of your proposed conditional release programme. This would include such things as the breeding, culture (where applicable) and the life-stages of the organisms to be conditionally released. The size, number of organisms, timing and location(s) of the conditional release should also be discussed. The costs of the importation, rearing and release phases of the programme as well as handling and harvesting methods involved should all be covered.

Specifically indicate whether or not an expiry date for any approval is expected (with reasons) and where relevant, what that expiry date is. If an indefinite approval is sought i.e. no expiry date, it is particularly important to explain why that is the case.

Give an indication of any risks that may be inherent in the conditional release programme *per se* as distinct from the effects of the organism in the environment after conditional release. Please attach any confidential information as a clearly marked appendix.

For example:

“Roundup Ready canola will be planted from seed over two hectares in North Otago over a period of 20 years. Canola will only be planted in the same plot once every 4 years and will be rotated with,, and then left fallow for a year.”

Section 4.2 – Course of Action on the Expiry of a Conditional Release Approval

Under s38F of the Act, on the expiry of any conditional approval, any new organism(s) must be disposed of unless, before the expiry of the approval, another approval has been granted under the Act. Please indicate your preferred course of action if the conditional release approval is set to expire.

If your preferred option is for the organism(s) to be unconditionally released you will need to formally apply for a full (unconditional) release at or after the time of applying for a conditional release but prior to its expiry. It is legally possible to apply for a full (unconditional) release at the same time as applying for a conditional release. If this is done, the Authority will process and consider the applications together. If both are approved, it will be made clear that the full (unconditional) release approval will only take effect upon the expiry of the conditional release. However, there would have to be strong grounds to justify the simultaneous granting of such approvals.

If you prefer the organism(s) to go back into containment through an existing HSNO containment approval, please give the approval number and details of that approval. If the organism is to go back into containment through a yet to be

gained approval, you will need to formally apply for a containment approval at or after the time of applying for a conditional release but prior to its expiry.

If your preferred course of action is disposal of the organism, indicate this in the table provided and provide full details of how this would be carried out in section 4.3. In this case consideration should be given to the inherent ability to dispose of the organism and the intended programme of conditional release. For example it may not be feasible to attempt disposal of an organism that is intended for widespread conditional release into the environment. On the other hand, an organism conditionally released for research purposes is more amenable to disposal at the end of the research project.

Please note that the only circumstance under which the Authority will **not** be concerned with disposal will be if there is a containment approval for the organism already in existence. Under all other circumstances disposal may have to be retained as an option.

Section 4.3 – Disposal of the organism(s) on the expiry of the conditional release approval

Section 38F of the HSNO Act states:

*“38F Consequences of expiry of conditional release approval
On the expiry of a conditional release approval, the new organism concerned must be disposed of unless, before the expiry of the approval, another approval has been granted under this Act.”*

Section 39(3) of the Act goes on to say:

“If an application has been made to the Authority for a conditional release approval, any person may apply to the Authority for approval to put the organism into containment...”

Furthermore, section 34A(1) of the Act says:

“(1) The user of a conditional release approval, may, at or after the time of applying for the approval, apply to the Authority for approval to release the new organism at the expiry of the conditional release approval.”

Note: “Disposal” is defined in section 2 of the Act as:

*“... (i) Rendering the organism biologically inactive in such a manner as to prevent the occurrence of any future biological activity; or
(ii) Exporting the organism from New Zealand.”*

Given these sections of the Act, and assuming that your preferred course of action on the expiry of the conditional release is to dispose of your organism(s) rather than putting them back into containment or unconditionally releasing them, provide information (preferably in the form of proposed controls) to explain what steps will be taken to ensure that the organism(s) and any viable heritable material can be identified and located upon the expiry of the approval. Please also give details of the method of disposal you intend to use.

Section 4.4– Proposed controls

Outline the relevant controls that you recommend be imposed to deal with any risks that may be posed by the organism(s) to be conditionally released. Because of the interaction between proposed controls and risks it is strongly recommended that this section of the form is not completed until the assessments of risk (in section 6) are completed. Note, however, that it is the Authority that will determine what controls are deemed necessary.

Section 38D of the Act provides a list of the types of controls that the Authority may impose in the end result. However this list is not exhaustive and the Authority has full discretion to impose what ever controls it deems appropriate. Please refer to page 2 of this user guide for a citation of section 38D (controls). Because these types of controls are listed in the Act, the Authority will normally consider whether or not they are appropriate. If you do not consider any of these controls to be appropriate you should therefore explain why.

Under section 38C(3)(b) you are required to comment on how effective the controls are likely to be in meeting the objective(s) of the control(s). The effectiveness of the controls is likely to be a very important factor, especially in situations where conditional release is intended to be widespread and will involve parties other than the applicant. You will need to provide evidence relating to the ability to ensure compliance under those circumstances.

Finally it is important to note that under section 38G of the Act that the Authority may review the controls under certain circumstances. If there are particular controls which you think should be flagged for review, please identify these controls and explain why that is the case.

Hypothetical examples of proposed controls (for a limited controlled release) include:

- “An isolation zone of 200 m from any other (organism) crop, shall be maintained, to guard against the possibility of outcrossing. To ensure effective maintenance, the land comprising the isolation zone should be leased or owned by the operator of the approval until the expiry date. The isolation zone shall be monitored, with removal of any weedy (organism). The isolation zone monitoring shall be maintained during the release programme and for the subsequent 4 years, or one year beyond time when no seedlings appear. The isolation zone should not include any part of the isolation zone of any other transgenic (organism) field test or conditional release.”
- “In all growing seasons non-transgenic (organism) shall be incorporated into the conditional release design to act as a refuge for susceptible invertebrates. The non-transgenic refuge shall surround the transgenic crop on not less than 3 sides, be no more than 5 metres distance from the trial crop and be no less than 20% of the number of plants in the transgenic (organism) conditional release programme.”

Section 4.5 Monitoring of effects

Conditional releases may often provide an opportunity to collect information related to the occurrence of adverse effects, and to the operation or not of associated pathways. The Authority encourages applicants to take full advantage of the conditional release situation to conduct monitoring which will provide an assurance that risks are being effectively managed and/or provide information which will assist the consideration of any other future conditional release or full release applications. Discuss the possibility and feasibility of information collection for these purposes. For example, whether meaningful results could be generated, availability of an appropriate scientific method, availability of relevant skills to the applicant organisation and actual cost of work. Describe any monitoring you propose to put in place. For some conditional releases it may be appropriate to explicitly monitor for some specific

potential adverse effects, such as allergenicity, infection or horizontal gene transfer. Comments from you on possible monitoring controls are encouraged. For instance, whether you will be monitoring for novel viruses or gene transfer as part of the approval. You may also like to note whether existing operational procedures may address some issues, such as health of workers.

Note: Where the Authority decides that such information collection is essential for risk management purposes or to achieve other legitimate objectives, it will normally include this as a control so it becomes a mandatory condition on the approval rather than a voluntary monitoring exercise.

It may also be appropriate and useful to conduct monitoring to confirm or quantify beneficial effects (benefits). This may especially be the case if the benefits are biological rather than economic.

Section Five of Application Form - Identification of Risks, Costs and Benefits

This part of the application form requires you to, amongst other things, identify the risks, costs and benefits of the organism(s) to be conditionally released. You should provide information relating to the risks of the organism(s) throughout its lifecycle, and you need to substantiate your statements and record from where the information was sourced. Information on the type and degree of risks (or effect) is central to assessing any potential risks or adverse effects of the organism. A very broad approach should be taken to this exercise of identification, so that a wide range of possible risks, costs and benefits are canvassed. However, it is important at the end of the identification phase that a “preliminary” assessment is carried out in order to identify those risks, costs and benefits that warrant more detailed assessment (in section 6 of the form). Please refer to the ERMA New Zealand Technical Guides “*Identifying Risks for Applications*”, “*Risks, Costs and Benefits for Applications*” and “*Decision Making: techniques for identifying, assessing and evaluating risks, costs and benefits*” for further information. These are available from the ERMA New Zealand website or in hard copy on request. **Note:** Please refer to Appendix 1 of this User Guide for the types of issues you should consider in completing this section of the form.

Section 5.1 – Ability of the organism(s) to establish a self-sustaining population

As required by a number of sections in the Act, and to assist in the process of identification, you need to discuss the ability of the conditionally released organism(s) to establish a self-sustaining population and the ease with which the organism(s) could be recovered or eradicated if an undesirable self-sustaining population established. In some circumstances establishing a self-sustaining population will be the objective, e.g. in the case of the conditional release of a bio-control agent and hence the issue of recovery or eradication is not applicable. In those situations, all you would need to do in addressing this section is to state that. If this section is applicable to your application, the ability of the organism(s) to establish a self-sustaining population will be determined by a large number of factors. Important criteria to consider are:

- A) *Natural habitat of the organism(s) and how this will influence its success after conditional release into the environment:*
- Consider the natural distribution of the organism.- What niche does the organism inhabit in its home environment?
 - Describe specific habitat requirements, for example, terrestrial, aquatic, pasture, forest, scrub, mountain, arable land, wasteland etc.
- B) *Life cycle of the organism(s) and how it will affect its spread in the New Zealand environment:*

- Basic description of the structure of the organism. For example in plants you would cover, leaves, fruit, flowers, and branches of plants, and morphology, sexual dimorphism, height and spread.
- Life history and life cycle information. For example, mode of reproduction, evidence of reproductive potential in native habitat, and whether the organisms. For example:
 - Easily breeds and produces viable offspring
 - Hybridises naturally and its potential of breeding with flora and fauna already present in New Zealand to produce hybrids
 - Mode of dispersal For example with plants whether propagules are likely to be dispersed unintentionally from plants growing in heavily trafficked areas or as a produce contaminant.
 - Whether propagules are adapted to wind, water, bird dispersal, and whether propagules can survive passage through the gut.

C) *Factors limiting distribution:*

- For example information on, altitude, temperature, humidity, wind resistance, rainfall, nutrient requirements, soil type, and water quality preferences of the plant. Comment on whether the species is suited to the New Zealand climate, and how compatible is climatic data between its natural habitat and that of New Zealand.

D) *Introduction history:*

- Does the species have a history of repeated introductions outside its natural range, is it naturalised beyond its native range e.g. in areas such as garden, amenity, disturbed, agriculture, forestry, and horticulture.

E) *Competitors and browsers:*

- Information on whether the organism is likely to compete with other New Zealand flora for space and whether it is likely to be controlled by predators in managed and natural environments.

Section 5.2 - Effects of any inseparable organism(s)

State whether or not there are any inseparable organisms associated with the organism that is the subject of the application. If there are any effects of inseparable organisms that might need to be considered, identify them under the relevant headings in section 5.3. If an organism has a natural association with an inseparable organism in its natural habitat that has been removed before its conditional release into New Zealand this should be detailed.

Section 5.3 – Identify all potential risks, costs and benefits of the organism(s)

It is important that you take account of the characteristics of the organism(s) described in section 3.4 to identify the risks, costs and benefits associated with the organism(s) to be conditionally released. When identifying risks and benefits, you should take into account the matters set out in Part II of the Act (specifically sections 5 and 6) and part V of the Act (specifically sections 34 and 36) and consider whether there are any significant risks that might exist in any of these areas. You should consult the ERMA New Zealand Technical Guides “*Identifying Risks for Applications*”, “*Risks, Costs and Benefits for Applications*” and “*Decision Making: techniques for identifying, assessing and evaluation risks, costs and benefits*” to help you complete sections 5.3 and section 6 of the application form. These are available from the ERMA New Zealand website or in hard copy on request. The information can be presented in a variety of formats (e.g. text and/or tables) but should indicate that a systematic approach has been used.

Identification of risks and costs requires consideration of both the **source of the risk** and **what is at risk**. Risk sources can be thought of as hazards, and what is at risk is the ‘thing’ that might be affected (or areas of impact). For example, a pathogenic micro-organism is a risk source and, animals or humans may be adversely affected by that micro-organism. You should also identify the route (or exposure pathway) by which the adverse effect may eventuate, such as by consumption of the organism, or transmission by insects.

When dealing with benefits you should provide an indication of any non-monetary (e.g. scientific) and monetary benefits to be derived from the conditional release of the organism(s) and whether these are direct or indirect benefits. Since this is an application for conditional release, an indication of long term benefits would be appropriate with some indication of the time frames involved.

You should avoid citing potential future benefits that will depend on subsequent full (unconditional) release applications. If future benefits are identified, you will also need to identify and analyse potential future risks. You are asked to identify **all** the potential risks, costs and benefits (i.e. negligible and non-negligible) under each of the headings (areas of impact) below which reflect those matters referred to in Part II of the Act. You should then undertake a “preliminary” assessment to identify those non-negligible risks, costs and benefits that will need to be fully assessed in section 6 of the form.

A. Effects on the environment, in particular on ecosystems and their constituent parts

Among other things you will need to address the risk of displacing or reducing native or valued species. Of particular importance is the potential impact of the new organism(s) on the sustainability of native and valued introduced biota and the intrinsic value of ecosystems.

If you consider that there are no adverse effects on the environment you need to briefly justify this. For example, “no adverse effects are anticipated since the plant is not a parasite or recorded as a weed and reproduces very poorly in the wild”, or “this strain is not pathogenic to animals or plants and vertebrate toxins will not be expressed. There is little uncertainty on this since Boffin *et al.* (2000) demonstrated the absence of adverse effects in mesocosms.”

Integrity and form of the ecosystem can be influenced by a possible new organism changing dominance, nutrient flow, and energy flow. Ecosystems function within a range of energy flow parameters of its primary producers (e.g. plants), primary consumers (e.g. herbivores), decomposers (e.g. bacteria and fungi), saprophytes (e.g. earthworms and insects), and predators (e.g. predatory insects, spiders, lizards, birds, and mammals). Any marked change in these parameters resulting from new introduction is likely to be considered as affecting the ecosystem’s intrinsic value. It would be helpful to identify what place an organism will occupy within the ecosystem once it becomes established and consequently what effect it is likely to have.

Consideration must be given to the organism’s ability for hybridising with close taxonomic relatives within biota already present in New Zealand. You may also need to make comment here about the organism’s ability to totally replace an organism or organisms within the applicable ecosystem. If there is evidence that the organism will not at all have an effect on New Zealand’s inherent genetic diversity comment needs to be made. For example “It is unlikely that *P. alani* will cause any significant adverse effect to New Zealand’s inherent genetic diversity. Host specificity tests show that *P. alani* is extremely unlikely to cause the demise of any native or important introduced plant.” Or “Interbreeding with native Diptera may lead to adverse effect on New Zealand’s inherent genetic diversity”.

Benefits should also be addressed in the same manner. For instance, you should consider the potential impact of the new organism(s) on the sustainability of native and valued biota and the intrinsic value of ecosystems

B. Effects on human health and safety (including occupational exposure)

Adverse effects on human health can include occupational exposure as well as adverse effects. For example, “the organism has been shown to be pathogenic to humans”; “pollen from this species has been implicated in causing some allergic reactions in the US (Grant 1995)”. Points that should be covered include the effects the organism may have on human safety upon conditional release into the environment. The following factors need to be considered and if applicable commented on:

- Is the organism pathogenic (disease causing)?
- Is it capable of becoming a parasite?
- Is the organism a possible vector for a. disease or parasite?
- Is the organism toxic or produces toxins and if so what are its mechanisms of toxicity? Does the organism need to be in direct contact or can it influence indirectly for example inhalation of pollen?
- Is there any *in vitro*, animal or human data concerning the above? If so are they based on epidemiological studies, ecological studies and or case reports?
- Does contact always result in disease or a toxic reaction? What variability would you expect in response between individuals?
- Does exposure result in immunity and if so is this likely to be full or partial?
- How long lasting are the health effects – for the individual and within the environment?
- How severe are the effects of exposure?
- Are health effects obvious immediately or after a period of time?
- If there are indications of the above what are the chances of exposure? How often are humans likely to be exposed to the toxic effects and is it likely to affect specific communities or occupations?
- Are there antagonistic or synergistic interactions that could lead to under or over estimation of the total risk?
- Please indicate whether data is available.

If you consider that there are no adverse effects on public health you need to justify this (supported with data). For example, “since the strains are non-pathogenic and non-infective (as demonstrated by Smith 1975), and no pathogenic or toxic genes are introduced there are no identified adverse effects on humans”, “the insect has no biting mouthparts or sting, nor is known to be involved in the transmission of any human diseases so is very unlikely to pose a risk to human health.”

You also need to consider any potential **benefits** to human health. Please outline if there are any **direct** positive health effects (and what their characteristics are). For example, “the transgenic (organism) will produce (a biopharmaceutical) which is intended to be used to treat sufferers of (a disease).”

C. Effects on the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga (taking into account the principles of the Treaty of Waitangi)

Part II (sections 6(d) and 8) of the Act state that the principles of the Treaty of Waitangi and the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other

taonga shall be taken in to account when considering such things as conditional release of a new organism into the environment.

Identifying risks to Maori

ERMA New Zealand and Nga Kaihautu Tikanga Taiao (a statutory body set up to advise and assist the Authority on applications) have developed a list of criteria to help applicants identify issues (or effects) of potential significance to Maori. These criteria are described in the User Guide entitled *Working with Maori under the HSNO Act 1996* and this is available from the ERMA New Zealand website or in hard copy on request.

The criteria basically require you to consider whether the new organism will adversely affect the relationship between Maori and their culture or traditions, and taonga. Taonga are defined in the Act, but particularly include native and other valued³ flora and fauna, and human genes. Where taonga are involved, you will almost certainly have to consult with hapu or iwi in order to find out if there is a potential issue, and if so how it might be addressed.

Applicants will also need to assess the significance of Treaty issues, and whether your application will impact on the ability of Maori to control their natural resources (including indigenous flora and fauna, waterways, and land), language or culture.

Potential **benefits** specific to Maori should also be identified.

If you consider that there are no adverse effects on Maori then you need to justify this in your application. For example, “No adverse effects on Maori are anticipated since no genetic material from native or valued biota is used. No human genetic material is used, and the organisms will be kept in containment.”

If there is any doubt about whether there are issues for Maori, consultation should be carried out. Consultation is discussed in detail in section 6.3 of this User Guide. Consultation will almost certainly be required if the organism is a GMO containing DNA from native species or humans, or if there are likely to be any effects on native flora and fauna.

If you are not sure how to identify risks (and benefits) to Maori contact ERMA New Zealand’s Senior Advisor Maori for assistance.

D. Economic (and similar) effects

Relevant economic effects are those that accrue to New Zealand. The Authority is primarily concerned about external or public costs and benefits i.e. those that apply broadly in the economy. Effects of this sort include levels of production costs, consumer benefits e.g. increased nutrition or attractiveness etc. It is also appropriate to consider effects such as increased scientific or other knowledge, as these all generally lead to economic impacts and have economic value in themselves.

The Authority has developed a Technical Guide *“Assessment of economic impacts of applications for the release (with and without controls) of GM food crops”*. This guide sets out in more detail the likely information requirements for assessing economic impacts for GM crop releases. Applicants are strongly advised to read the Technical Guide before preparing any conditional release application involving GM crops. In summary the Authority will require information on the costs and benefits listed below. Some of this material is developed further in Appendix 1.

³ Valued species are those species that are deemed valuable by local iwi and will vary from area to area.

Relevant public costs might include:

A. Demand side - reduction in non-gm product demand due to :

- loss of market access
- loss of price premiums or price discounts
- costs involved in shifting to alternative markets loss of consumer choice

B. Supply side:

- New or increased production costs – on farm costs, costs of segregation/quality assurance systems etc.

Relevant public benefits might include increases or decreases in :

- Profitability
- GDP
- Employment
- Capital investment including foreign investment
- Knowledge and expertise and the innovative capacity of the economy

Applicants will need to determine on a case-by-case basis how relevant the above matters are to their proposed conditional release programme. Applications for commercial conditional releases of genetically modified food crops will need to provide extensive information while research proposals for animals for example, are unlikely to need to provide this level of information.

E. Cultural, social, ethical and spiritual effects

Section 5(b) of the Act sets out the principle that the capacity of communities and people to provide for their own social, cultural and economic wellbeing should be maintained or enhanced. This provision has been interpreted to cover social, cultural, ethical or spiritual effects or impacts. This has been further underlined by the extended provisions describing the triggers for Ministerial Call in section 68(1)(a) of the Act.

There are a number of ways in which potential issues or effects can be identified including community consultation, extrapolation from prior experience in the general area, and the review of any relevant previous decisions by the Authority. Applicants should also be conscious that submitters may well raise issues of this character, so prior discussions with likely submitters might be useful.

F. Other effects (including on New Zealand's international obligations)

Where there are additional risks, costs and benefits not covered by A to E above then list them here. Such items may include effects on New Zealand's International obligations.

Section Six of the Application Form – Assessment of Potential Non-negligible Risks, Costs and Benefits

The outcome of risk assessment is an analysis of the **likelihood** (or probability of occurrence) of the adverse effect and the **magnitude** of the adverse effect if it did occur and any related uncertainties. These estimates are then used to evaluate the level of risk compared to other risks. A detailed risk assessment only needs to be provided for those risks that you identify (from the full list in section 5.3) as being potentially non-negligible. Deciding whether a risk is

potentially non-negligible or not should be based on your knowledge of the organism throughout its lifecycle, and what you consider the residual risk to be once controls are in place. Please refer to the appendix at the back of this application form for the types of issues you should consider. If you decide that a risk is negligible and therefore will not be assessed further you should explain why. If you are unsure of whether a risk is non-negligible you should include it in the assessment. If there are **no** non-negligible risks, there is no need to carry out an extensive risk assessment but you need to have a justifiable reason for reaching that conclusion. Please note that it is not sufficient to say that a risk is negligible simply because of the existence of the controls. You need to carry out your assessment firstly in the **absence of any controls** then **with the proposed controls in place** (which may significantly reduce the likelihood or the consequence of any adverse effects. We are particularly interested in knowing about those risks that remain after controls have been imposed (residual risks).

Assessment of risks, costs and benefits can be quite involved. ERMA New Zealand has produced a technical guide “*Technical Guide to Decision Making: techniques for identifying, assessing and evaluating risks, costs and benefits*” which you should refer to for guidance. In this guide it outlines the qualitative scales that ERMA New Zealand uses for describing likelihood and magnitudes of effects. You may want to develop your own scales so that they reflect the particular risks posed by your organism(s). You can use quantitative scales in your assessment so long as you provide a rationale for the figures that you use.

In carrying out your risk analysis, you should consider the following:

- What is the nature and degree of the effect i.e. what are the potential consequences? For example, does the organism have the potential for becoming a pest or weed species, or is it pathogenic?
- What is the likelihood/probability of the effect occurring? Provide an assessment of whether the effect will occur and substantiate this (for example, with published studies, your professional knowledge of the species, etc). For example – it is calculated that increase in pasture production due to control of this weed will be result in \$5 million saving in herbicide use annually and a return of an additional \$21million in export earnings from increased stocking rates.
- What is the magnitude of the effect? In estimating the magnitude, you should consider whether the risks will be localised geographically or distributed more widely, whether particular groups in the community may be more affected than others, whether the effect will persist over time and whether any potential adverse effects are irreversible or reversible, and the ease of recovering or eradicating the organism.
- How reliable is the information (how well-known are the effects and their likelihood)?
- The distributional effects. Will effects be widely distributed or localised, both geographically and over time?
- What are the uncertainty bounds of the information used in the assessment? (For example, you might be able to estimate the maximum and minimum values for likelihood and magnitude of effect, or describe the parameters that will have the greatest effect on the estimates).

An example of a risk analysis statement is:

“There is a potential for transfer of the introduced genes to non-GM (organism) crops and the level of outcrossing could be significant depending on other (organism) species being grown in the vicinity. The propensity for outcrossing is more significant for species such as (organism) than for many other crops. Management measures (such as isolating the GM crop from other crops by buffer zones and isolation distances) can be imposed that will reduce the likelihood of gene transfer occurring. If gene transfer did occur to non-GM crops, the introduced trait is unlikely to prove more toxic or allergenic to humans or other organisms or weedy than conventional (organism)”

(reference). There is a potential for transfer of the introduced genes to weedy relatives of (organism) via outcrossing, but the likelihood is low and the inter-species hybrids are likely to have significantly reduced vigour because of the genetic incompatibility (reference). Management measures (such as removing weedy relatives from the trial site and sites adjacent to the trial) can be imposed that will further reduce the likelihood of gene transfer by outcrossing occurring.”

As with analysing the risks, you need to discuss the likelihood that the **benefits** will be realised, the magnitude of benefits associated with these new organisms (if possible), and any uncertainties associated with this assessment. You should also indicate who will receive the benefits. For example, “Reduced application of herbicide to control Mist flower will save approximately \$5 million per year in direct costs to Regional councils and will decrease damage to other species that grow in habitats s currently populated by Mist flower”. Although all benefits are potentially admissible it is particularly important to identify and assess benefits which are of wide application, i.e. do not just benefit the applicant.

You should also indicate the degree of certainty or uncertainty (knowledge) associated with the risks, costs and benefits. For example, “the host range appeared to be restricted but our work has provided further information on the species it is able to utilize”, or “the virus is known to infect members of the potato family, but as noted in the ICTV database [<http://life.anu.edu.au/viruses/canintro1.htm>] its ability to infect other plant groups has not been extensively tested”.

Finally, you will need support any statements made during your assessment of risks, costs and benefits. This can be done, for example, by referring to relevant published papers (please include copies of any that you cite, except for whole books, in an appendix), other documentation, or your own or colleagues experiences.

You are required to carry out your assessment under each of the following headings which reflect those matters referred to in Part II of the Act:

Section 6.1 - Effects on the environment (in particular on ecosystems and their constituent parts)

It is important under this section to consider both **risks and costs** and **benefits**. The effects warranting further analysis at this point should already have been identified under section 5.3A. Please refer back to the material in that part of the User Guide to give a further guide on carrying out the detailed assessments.

Section 6.2 - Effects on human health and safety (including occupational exposure)

It is important under this section to consider both **risks and costs** and **benefits**. The effects warranting further analysis at this point should already have been identified under section 5.3B. Please refer back to the material in that part of the User Guide to give a further guide on carrying out the detailed assessments.

Section 6.3 - Potential effects on the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, wahi tapu, valued flora and fauna and other taonga (taking into account the principles of the Treaty of Waitangi)

Please assess any potential adverse and beneficial effects to Maori of conditionally releasing the organism(s). If you have identified that there may be potentially non-negligible risks to Maori, you should provide an analysis of the likelihood of the adverse impact(s) on Maori and estimate how severe that impact may be. This is likely to require consultation, and where undertaken, your analysis should take account the issues raised in the consultation process. The

magnitude of risks may be influenced by whether the risk is limited to a geographical region or will affect Maori generally.

Consultation with Maori

Once you have made your initial identification of risks to Maori, and where you have determined that your application requires consultation with Maori, the User Guide *Working with Maori under the HSNO Act 1996* provides a best practice model to work from. The purpose of consultation with Maori is to obtain information that will enable the Authority to evaluate risks, costs and benefits and make informed decisions in accordance with its legal duty under the HSNO Act. Consultation is a two-way (at least) process requiring every reasonable effort on the part of the party consulting and a willingness to respond reasonably on the part of those consulted.

ERMA does not expect you to go to unreasonable lengths to consult nor to incur unreasonable costs. Realistically however, consultation is likely to incur some cost. Costs can be kept to a minimum if consultation and information gathering is conducted at the pre-application stage, i.e. well in advance of lodging your application. This is more efficient and cost effective. Deciding whether to consult locally or nationally can be a difficult question to answer and will depend on the nature of the conditional release application. If the conditional release is widespread e.g. will occur in most parts of New Zealand, then **national** consultation will be required. ERMA New Zealand's policy on this is that consultation in such instances should occur with a prescribed number and range of iwi and Maori organisations. This is deemed to at least comprise the database of 80 Runanga and Iwi Trust Boards available on request from ERMA New Zealand. This consultation will be undertaken at the pre-application stage, and should include the national distribution of letters, information, a feedback form, pre-paid return post option and offers to meet and discuss the application face to face. Requests for follow-up, either written or verbal, should be positively responded to. However, reasonable time should be allowed for responses (6 weeks is suggested) and follow-up must occur when sought.

The results of the consultation will need to be included in your application (in section 6.3). Details should cover whom you have consulted with or attempted to contact and what their opinions of the proposed work are. For example, “Initially we identified that the iwi most affected by the proposal to introduce new biological control agents for *Hieracium* were those whose lands were infested by the weed, namely Ngai Dialogue with these two iwi were initiated between November 1999 and January 2000.”, or “no adverse effects to Maori have been identified since no material from native or valued species is used and no material sourced directly from human beings is involved”.

Documents relevant to the consultation (such as dates of telephone conversations, copies of letters or e-mails, etc) can be included as an appendix to the application. For example, “Consultation with local hapu has been undertaken, and they did not have specific concerns with the use of this material so long as they are kept informed of the research (Appendix 2). A working group has been established to enable local hapu to be kept informed of the progress of this and other projects at the Institute.”

Note that the main objective of the consultation process is that you inform the relevant groups of the work that you propose to do and discuss any concerns they may have. If concerns are raised during the consultation process you should consider whether or how you are able to address those concerns. If during consultation Maori object to the work proceeding or request that special conditions be incorporated, there must be a clear understanding of what actions should be taken or are available to be taken as a result. If Maori are to be consulted, or otherwise involved, it must be with some purpose and not just as a courtesy, i.e. there must be both a commitment and a possibility of taking action as a result of the Maori response. Where Maori want special conditions to be imposed for valid cultural reasons, then as far as is practicable those requests should be complied with. In considering how far such requests should be complied

with the Authority will look at what is practicable. The question of what is practicable will of course vary from case to case, so it is important to provide good supporting information on what is or is not practicable.

If you are not sure how to undertake consultation, contact ERMA New Zealand's Senior Advisor Maori for assistance.

Section 6.4 - Economic effects

Applicants will need to provide an assessment of the size, distribution and likelihood of each of the identified risks, costs and benefits. Effects on third parties and to New Zealand of the proposed conditional release need to be specifically evaluated. A quantitative analysis should be supplied for any commercial conditional release application using standard cost benefit analysis techniques.

Section 6.5 - Cultural, social, ethical and spiritual effects

Please provide an analysis of the impact on social and cultural wellbeing (now and in the future) as a result of the proposed conditional release. Comment will need to be made on the prevailing community attitude towards the proposed conditional release from the point of view of how the proposed release will impact on community wellbeing and in particular the capacity of communities and people to provide for their own wellbeing (now and in the future). Ethical and spiritual effects should also be assessed.

Section 6.6 - Other effects (including on New Zealand's international obligations)

Assess any remaining adverse and beneficial effects not already covered in A to E above such as any effects on New Zealand's international obligations.

Section 6.7- Overall evaluation of risks, costs and benefits

The Authority must make a judgement on whether the benefits (beneficial effects) of the conditional release of the organism(s) outweigh any risks and costs (adverse effects) **after** taking into account any controls that may be imposed. If the answer to this is "yes" the Authority will approve the application, conditional upon the controls being attached to the approval. If the Authority deems that any adverse effects outweigh the beneficial effects, it will decline the application.

Although this final overall evaluation of risks, costs and benefits is the responsibility of the Authority you have the opportunity in this section 6.7 to express your view on how your application should be evaluated. If you wish to do so summarise why you consider the benefits outweigh the risks. For example,

"The key benefit of this conditional release is that the transgenic potatoes are resistant to fungal pathogens that can devastate the New Zealand potato crop. These potatoes will have a major impact on the sustainability of the potato as a crop in New Zealand which is currently threatened by an increasing resistance of fungal pathogens to the commercially available fungicides. The positive impact on ensuring the sustainability of this crop in New Zealand outweighs the negligible risks of horizontal gene transfer to soil bacteria or the effects on genetic diversity."

Section Seven of Application Form – Additional Information

Section 7.1 – Do any of the organism(s) need approvals under any other New Zealand legislation or is the application affected by New Zealand's international obligations?

Please indicate here whether the new organism(s) is/are subject to other New Zealand legislation requirements. This may include the Biosecurity Act 1993, Animal Welfare Act 1999, or another Act. Also indicate if the organism is relevant to any international obligations. For example, if species listed in the appendices of the Convention on International Trade in Endangered Species (CITES) are involved, then approval is required from both the importing and exporting countries.

With respect to new organisms in general New Zealand is a party to many international agreements and therefore obliged to comply with their requirements. In respect of new organisms New Zealand is signatory or party to the following.

- The Convention on International Trade in Endangered Species or CITES, which restricts trade in endangered species of plants and animals.

There may be other international agreements that are specific to the organism being released an example of those agreements affecting plant importation are as follows:

- The International Convention for the Protection of New Varieties of Plants. The organisation responsible for this convention is UPOV or the International Union for the Protection of New Varieties of Plants. UPOV is a sister organisation of WIPO or the World Intellectual Property Organisation.
- The International Plant Protection Convention or IPPC.
- The Plant Protection Agreement for the South East Asia and Pacific Region.
- The Convention on Conservation of Biological Diversity.
- The International Plant Protection Convention.
- European Plant Protection Organisation.
- Organisation International Epizootic or OIE.
- OECD Seed Schemes.
- OECD Fruit and Vegetable Schemes.
- International Board of Plant Genetic Resources.
- The Union for Protection of Varieties of Plants.
- The FAO, or the Food and Agricultural Organisation's, Convention on International Undertaking on Plant Genetic Resources. New Zealand did sign this FAO convention with reservation on aspects that conflict with plant breeders' rights.

If this section is not applicable please say so with reason.

Section 7.2 –Have any of the new organism(s) in this application previously been considered in New Zealand or elsewhere?

ERMA New Zealand requires information on whether any of the organisms in the application have previously been considered within New Zealand (for example, by MAF or ERMA New Zealand) or by other countries. If the organism(s) have previously been considered by ERMA New Zealand (e.g. as genetically modified development or field test) then please give brief details of the type of approval (with the appropriate approval number) and the outcome of the consideration.

If this section is not applicable please say so with reason.

Section 7.3 – Is there any additional information that you consider relevant to this application that has not already been included?

Please provide any other information that you consider is relevant to the application but is not already covered by any of the previous sections. If there are additional risks, benefits or issues not covered by the above then list them here. If you do not consider that there are any other risks you need to state this. For example, “no other risks have been identified”.

Section 7.4 – Provide a glossary of scientific and technical terms used in the application.

If you use terms from the *Interpretation* (section 2) of the HSNO Act then you don't need to define those terms. However, you need to give definitions of all other technical terms used in your application. Remember that people who are not familiar with your research area may read this application so you should endeavour to make it as easily understandable as possible.

Section 7.5 - List of appendices

List the names of any appendices included with this application. Any information that is commercially sensitive should be contained in appendices not in the body of the application (and should be clearly marked “confidential”). Additional material (such as details of consultations, vector diagrams, referenced articles) should also be included as appendices. The main application should refer to the relevant appendices but be able to be read as a stand-alone document.

Section 7.6 - References

Please include a list of the references cited in this application form.

Section Eight of Application Form — Application Summary

Section 20(1) of the Act requires the Authority to keep a public register of all applications. In addition to a purpose of the project (provided in section 2.1) and the name(s) of the new organism(s) (provided in section 3.3), an overall summary (or abstract) of the application is required. This summary should be expressed in clear, simple language that is able to be understood by the general public and should not contain commercially sensitive information. This summary information will be used to provide information for those people and agencies who will be notified of the application (e.g. Ministry of Agriculture and Forestry, Ministry for the Environment, Department of Conservation, Regional Councils, etc) and for members of the public who request information.

You should include a summary of:

- What the purpose of the application is
- The identification of the organism(s) and their main characteristics
- Proposed controls
- An assessment of the potential adverse and beneficial effects of the organism(s)
- Whether any consultation was undertaken with respect to the application

CHECKLIST

Do not forget to complete the checklist on the last page, sign and date the application and send us both a hard copy and an electronic copy in Microsoft. When you formally submit your application to ERMA New Zealand then an application deposit and an electronic copy of the application are required.

Appendix 1: Issues to be considered by applicants of conditional releases of GM crops

The purpose of this list of questions is to provide a framework for consistent information to be provided on a case-by-case basis. It is anticipated that every question will not be relevant to every application. However, it is expected that the applications will follow the format outlined below.

A. Information on the merits of using the genetically modified organism (GMO) (Suggested for sections 3 and 5)

1. What is the size and value to New Zealand of the plant into which the new gene has been introduced? In which region(s) is this industry most important?
2. What problem is the transgenic plant designed to overcome, or what benefits will be provided? Is the problem local or countrywide?
3. Is the novel trait a high priority for the farmer's current or potential future activities?
4. What is the value of the introduced gene to the farmer's activities? What is the value of the introduced gene to the whole agricultural industry?
5. Is the use of the GMO the only way to achieve the proposed change?
6. Is the use of the GMO the most agronomically appropriate use of the gene?
7. What farming systems are likely to incorporate the GMO?
8. Has the gene been introduced into other agriculturally important plants?
9. Will the introduction of the gene into the plant prejudice the use of the gene in other plants?
10. Who will be the owner of the gene? What intellectual property considerations apply? Who will own the varieties that contain the gene?

B. Plant properties (Suggested for section 3)

1. Are the genetics and population dynamics of the host plant well understood?
2. Is the host plant self fertile or out-crossing or both?
3. How readily is the pollen spread? Is it wind or insect borne? Is it fertile?
4. Does the plant produce numerous seeds? Does it have seed that persist in the soil? If so, what are the management options? Is the seed transported by wind, animals or by other natural means?

5. Is the plant a strict annual?
6. Can the plant be spread by vegetative means?
7. Does the plant naturalise in the environment, form a volunteer population in subsequent plantings, grow as a roadside weed, or persist after harvest in any other way?
8. Does the plant have any wild relatives in New Zealand? If so, does the plant cross with any of these relatives?
9. Does the plant cross with plants that are weeds (minor or major)?
10. Is genetic manipulation directed at the best cultivars or is an extensive backcrossing program needed to achieve an elite cultivar containing the transgene?

C. *Introduced nucleic acid* (Suggested for section 3)

1. What property is to be introduced? Is the nucleic acid fully characterised?
2. Does the transgene express in all parts of the plant or only in specific organs or at particular stages of the plant's growth?
3. Does the introduced gene improve the plant's fitness?
4. Will a marker gene be used in construction of the GMO? If so, will it be removed after the wanted gene(s) is introduced, or remain in the plant after general release?
5. If the marker gene remains after release, what property will be expressed and will this, or its coding DNA, in any way pose a hazard to the public, livestock, or the biota in the environment? Could it affect acceptance of the GMO or its products in the market?

D. *Farming systems* (Suggested for section 5)

1. What is the geographic distribution of the plant? Will the GMO be grown throughout New Zealand? Is its management well understood?
2. Are cultivars of the plant already in existence that carry other novel genes that could impact upon the use of this GMO?
3. Thinking across time and space (e.g. paddocks, years, rotations), are there threats to farming systems or the environment arising from development of the technology?
4. What changes do you foresee to present management practices as a result of incorporation of the GMO into farming systems?
5. Will the presence of this GMO interfere with other plants, or other GMOs?

6. What infrastructure is established in the industry to devise, implement and monitor compliance with the industry strategy for management of the transgene?
7. Is it envisaged that the technology will be packaged such that producers will receive an information package or guidelines with seed and be tied to a contract?

E. Environmental issues (*Suggested for sections 5*)

1. Can the GMO be retrieved from the environment?
2. Will the GMO pose any threat as a weed in the environment, for example to remnant vegetation or to national parks? If it does, will it be a greater threat than normally bred or current varieties?
3. Is there any threat from transfer of the GMO to other regions or farming systems?
4. Will any plant residues, including genetic material, from the GMO in soil pose any hazard to the environments?

F. Use of produce from the GMO (*Suggested for section 5*)

1. Do you foresee any difficulty in marketing the transgenic plant on the domestic or international market? If the latter, which countries and why?
2. Under what conditions will the produce from the plant be disposed of?
3. Will the modified plant cause any problems with chemical residues in produce for domestic or export markets (for example, as a result of increased or altered use of a herbicide or pesticide on the plant)?
4. Will the modified plant cause any problems with chemical residues in (i) grain, (ii) stubble, (iii) fodder fed to animals on farms?

G. Herbicide resistance genes (*Suggested for sections 3 and 5*)

1. Describe the magnitude of the weed problem in the crop.
2. Are the weeds difficult to control by other means?
3. Have the weeds developed resistance to herbicides?
4. Is the herbicide to which the plant has been made resistant currently used to control volunteers of the crop?
5. Does the transgenic crop build on existing tolerance found in the crop or does it create a new use for the herbicide?

6. How does introduction of herbicide resistance fit in the context of integrated weed management? Will the modification lead to sequential use in the crop rotation of like-herbicides, or of herbicides known to give rise to cross-resistance problems?
7. Are the weeds, given their history and biology, likely to develop resistance to the herbicide used in the crop, or cross-resistance to other herbicides?
8. Is a resistance management strategy essential to sustain use of the modified crop (i.e. to delay or prevent the emergence of resistance)? If so, describe the elements of a resistance management strategy that might be used in this case.
9. Will the modification lead to greater use of herbicides (i) per hectare, or (ii) in the country?
10. Will the modification lead to use of more or less benign herbicides?
11. Will the modification change the range of herbicides that can be used?

H. Insect resistant genes

1. What is the target pest?
2. Describe the magnitude of the pest problem in the target crop, including current management tactics, frequency of spraying, quantities of pesticide used, financial costs of control and of losses due to the pest.
3. Is the insect pest native or introduced?
4. Has the target pest evolved resistance to pesticides (in the target crop or any other crops)?
5. What resistance management strategies have been implemented applicable to this crop?
6. Host specificity of the pest:
 - i How many host plants have been recorded?
 - ii How many of these are commercial crops? How many are native plants?
 - iii Indicate the major crop hosts of the insect.
 - iv How commonly is the pest found on crops?
 - v What proportion of the pest population is associated with the target crop?
7. Pest distribution and ecology:
 - i Describe the geographic distribution of the pest.
 - ii How many generations does the pest have per year?
 - iii What is known of the mobility of the target pest (inter-crop, inter-regional)?
 - iv Is there a diapause phase?
8. Is the mode of action of the introduced gene understood?

9. Has the gene already been introduced into other crops? If so, are any of these uses commercially available?
10. Does the target pest occur on other crops in which this gene is also deployed?
11. What is the spatial proximity of the target crop to other crops in which the gene is deployed?
12. What is the temporal association of the target crop and others in which the gene is deployed?
13. What changes in pest management practice could occur with deployment of the modified plant?
14. How does incorporation of the resistance gene fit in the context of integrated pest management?
15. Are there likely to be any secondary pest issues associated with deployment of the resistance gene?
16. Is a resistance management strategy essential to sustain use of the resistance gene? If not, explain.
17. Describe the elements of a resistance management strategy which might be used for the GMO.
18. How might such a strategy be integrated with existing uses of the same, or related, resistance genes in other crops?
19. Have any discussions occurred with representatives of these other breeders?

I. Virus resistance genes (Suggested for sections 3 and 5)

1. What is the target virus?
2. Describe the magnitude of the virus problem in the target crop.
3. What virus management strategies have been implemented (e.g. genetic resistance, chemical control of insect vectors, clean seed, and cultural methods)?
4. Has the virus or insect vector overcome any of these management strategies?
5. Is the virus native or introduced?
6. Host specificity:
 - i How many host plants have been recorded?
 - ii What are the major crop hosts of the virus?
 - iii How many hosts are native plants or weeds?
 - iv Do any hosts usually occur as weeds in the target crops.
7. Transmission of the virus:

- i Is the virus transmitted by seed or by an insect vector?
 - ii What is the distribution and ecology of the insect vector? Include a consideration of geographic distribution, mobility (inter-regional and inter-crop), alternative hosts, and rate of build-up in the crop or other hosts.
8. Is the viral resistance gene likely to increase the fitness of weeds if it were transferred to them?
 9. Is virus resistance mediated by expression of a protein or is it nucleic acid mediated? Does the resistance gene include complete viral genes, or sequence of the viral genome?
 10. Is the resistance gene a whole coat protein gene from the virus?
 11. If a viral coat protein gene has been introduced into the plant, what is the risk of transcapsidation of heterologous viruses (that is, encapsidation of the genome of a heterologous virus by the virus coat protein expressed in the transgenic plant)? Include a consideration of other viruses likely to infect the transgenic crop, and the vector(s) of the virus from which the gene was derived.
 12. What is the risk of recombination between the genes and viruses to create more virulent chimeric viruses?
 13. What changes in either virus or insect vector management practice could occur with deployment of the transgenic plant?
 14. Are changes needed in seed production, deployment or cultivation of the transgenic crop?

J. *Fungus resistance genes* (Suggested for sections 3 and 5)

1. What is the target fungus?
2. Describe the magnitude of the fungus problem in the target crop.
3. What fungus management strategies have been implemented (e.g. genetic resistance, chemical control of fungus, vectors, clean seed, and cultural methods)?
4. Has the fungus or its vector overcome any of these management strategies?
5. Is the fungus native or introduced?
6. Host specificity:
 - i How many plants have been recorded as host?
 - ii What are the major crop hosts of the fungus?
 - iii How many hosts are native plants or weeds?
 - iv Do any hosts usually occur as weeds in the target crop?
7. What natural variability (e.g. races) occurs in the fungus?

- 8 Dispersal of the fungus:
 - i Is the fungus spread aurally, in soil, in water, on seed or on plant residues?
 - ii Is the fungus restricted in its geographic distribution?
 - iii What environmental factors influence growth and spread of the fungus?
9. Is the mode of action of the resistance gene understood?
10. Is the fungal-resistance gene likely to increase the fitness of weeds if it were transferred to them?
11. Will deployment of the fungal-resistance gene affect the effectiveness or use of existing resistance genes for the fungus?
12. What changes in disease management practices could occur with deployment of the transgenic crop?

K. Gene altering quality (*Suggested for sections 3 and 5*)

Generally, genes that alter properties such as the type of starch, the composition of oil in seeds, or the type of protein in the plant, are not likely to have much effect on management systems, unless they cause an agronomic side-effect such as a change in fitness, time of flowering or seed set.

1. What property is changed?
2. What effect on the growth of the plant will this change have?
3. Will the changed property cause the plant to become toxic, allergenic or carcinogenic?
4. Will the changed property have any unwanted effect on the sale of the plant product?
5. If the GMO is fed to stock, will the altered property affect the sale of livestock?