

Making an Application to Import into Containment any New Organism that is Genetically Modified

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Associated Application Form NO2G

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Form NO2G – Import into containment any new organism that is genetically modified under section 40 of the Act

Introduction

We recommend you read this User Guide before filling out your application form.

Applications for importation into containment of genetically modified organisms must be submitted to ERMA New Zealand. Applications that involve development of genetically modified organisms must use form NO3r (for developments meeting the requirements of low risk genetic modifications as described in the HSNO (Low-Risk Genetic Modification) Regulations) or form NO3 (for genetic modifications that do not meet the low risk requirements).

Please note that the low risk regulations are currently being revised and new regulations are expected to be promulgated later in 2002. This will change some of the requirements, although most probably in the direction of making applications easier to deal with. This User Guide and the associated application form is intended to be able to be used with both the old and new low risk regulations. If you are uncertain about applying the current regulations please contact ERMA New Zealand.

Drafts of applications can be sent to ERMA New Zealand for checking before they are formally submitted. Your Institutional Biological Safety Committee (IBSC) may also be able to provide pre-application advice, but the application must be submitted to ERMA New Zealand for approval.

A new organism is defined in the HSNO Act as:

- (1)
 - (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:*
 - (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.*
- (2) *An organism ceases to be a new organism when an approval has been given in accordance with this Act for the importation for release or release from containment of an organism of the same kind as the organism.*
- (3) *Despite the provisions of this section, an organism present in New Zealand before 29 July 1998 in contravention of the Animals Act 1967 or the Plants Act 1970 is a new organism.*

You can apply for more than one new organism on a single application form if the organisms are involved in the same project and/or have similar risk profiles.

In the HSNO Act “a genetically modified organism” means an organism in which genes or other genetic material is modified by *in vitro* techniques, or contains genetic material that is inherited or otherwise derived from genetic material modified by *in vitro* techniques. Some new organisms may be developed by means other than *in vitro* genetic modification, and do not require an approval under the HSNO Act. If you are uncertain whether you are importing a genetically modified organism (GMO) please consult the *HSNO (Organisms Not Genetically Modified) Regulations 1998* to determine what is considered a GMO, or contact ERMA New Zealand staff.

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.

Level of information to be provided

The level of information and analysis you need to provide will depend upon the nature of the organism(s) and the types of genetic modifications. Organisms or modifications that present a greater potential risk will require more detailed information and assessment. It is therefore critical in your application that you clearly identify the organism(s) and modifications, and demonstrate how the organism(s) meet or do not meet the low risk criteria, and demonstrate that the organisms will be adequately contained.

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 or your IBSC 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 or your IBSC will identify information gaps but will not complete the application for you. Consequently, your application will be considered on its own merits by the ERMA New Zealand or your IBSC. Poorly prepared applications risk being declined.

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.

Section 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 well-being and for the reasonably foreseeable needs of future generations.*

Section 6. Matters relevant to the 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.*

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 register. All confidential information must be clearly identified and attached as an appendix. The application form should refer to this appendix but must be a stand-alone document as it will be available to the public. ERMA New Zealand is required to have publicly available the purpose of the application (section 2.1), a unique name for the organism(s) (section 3.5), and a summary of the application (section 7). You can discuss with ERMA New Zealand options for providing the 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, “Importation of Arabidopsis seeds containing fungal resistance genes” or “Importing knock-out rats for vascular disease studies.”

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 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.

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 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 are importing the new organism(s) and/or what the organism(s) will be used for. The statement should identify the type(s) of organisms(s) to be imported and why they are needed. Please use a maximum of 255 characters. For example:

Example A Importation of *E. coli* containing arthropod DNA for sequencing and phylogenetic studies.

Example B Importing knock-out laboratory rats for studies of vascular disease.

Example C Importation of genetically modified *Arabidopsis thaliana* and *Nicotiana tabacum* containing genes involved in fungal resistance to investigate mechanisms of pathogen resistance.

This purpose will be used in ERMA New Zealand's database and may also be made publicly available. If you have any confidential information it should not be included in this question. Please speak with ERMA New Zealand staff if you have confidential information and are unsure of how to include it in your application.

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

Section 2.2 – Background and aims of the project

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. Please attempt to keep the description to less than 1000 characters. For example:

“We are comparing the evolutionary relationships of soil invertebrates (such as centipedes, millipedes, and springtails) using DNA sequence information as well as morphology to test hypotheses of New Zealand's past geological and biological history. The species that are the source of DNA in this application are from non-native invertebrates and these will be used for comparisons with New Zealand species. This research will contribute to an improved understanding of New Zealand soil communities and New Zealand's biological diversity and history.”

“Our group has been investigating human vascular disease for 20 years and the rats to be imported will help build upon research by us and overseas groups that has identified several genes which may contribute to an increase or decrease in the potential for developing vascular diseases such as arteriosclerosis. The rats to be imported will enable us to study more precisely the roles that these genes play in vascular tissues and their effect on the development or prevention of diseases. Knock-out (disrupting a specific gene) rats by virtue of their well-defined genetic background have greatly assisted the study of a range of human diseases and the functions of genes.”

“Fungal pathogens can cause considerable damage to crops and consequent loss of production. This project builds upon previous studies that have identified genes from other plant species that help prevent the establishment of some plant fungal pathogens (e.g.,

Phytophthora and Fusarium species). The imported organisms, containing genes known to be involved in fungal resistance from a range of other plant species, will enable us to study the role of these genes more precisely, with the long-term view of modifying crop plants to be more resistant to certain fungi.”

Section 2.3 – Public interest in the application

Provide comment here on whether there is reason to believe that there is potential for public interest in any aspect of the application. This may be related to any novel or unusual genetic manipulation, use of species or subjects of cultural significance (such as native species, or for example, kumara), intended use of the GMO, level or nature of the risks involved, or the extent to which the application sets a precedent. This information is intended to help the Authority make a decision on whether to publicly notify the application, as required by section 53(2) of the HSNO Act.

If you consider that the organism(s) do not hold especial public interest you need to justify this. For example, “many other strains of this bacterium, containing similar genetic modifications, have already been approved for import. The work is only for laboratory experiments and does not involve native or valued flora or fauna.”

Section Three of Application Form — Information on the organism(s) to be imported

All new organisms that will be imported in the project need to be identified.

Generic descriptions

While a complete taxonomic description of each organism is usually required, you may be able to submit a more generic approach for vectors and sources of genetic material, within the latitude provided by the requirements of the HSNO Act. Generic applications may be used where the host organism(s) are clearly identified, but the range of modifications is broad. The bounds of a generic description need to be clearly defined so that it can easily be determined what is and is not able to be included in the description, and that the risks from the different modifications are similar. Clear bounds of the description may be able to be achieved by exclusions of certain sequences or sources of genetic material. For example, “donor genetic material is sourced from thermophilic bacteria, with the exception that genes coding for known vertebrate toxins will not be used” is acceptable since it combines a positive statement of the source of genetic material. An example of a descriptor that may *not be acceptable* is “genetic material sourced from prokaryotes” since this allows genes that are toxic to vertebrates or that may increase pathogenicity to be used – such a broad scope would require a detailed risk assessment to cover the differing levels of risk.

Generic applications that do not specifically identify the host organisms are also not acceptable. For example, “genetic modification of plant tissues with disabled *Agrobacterium* plasmid vectors” is not acceptable because the host species are not clearly identified and the type and range of foreign genetic material is not clearly specified.

Important: A generic application should reflect the scope of the work you intend to do in the near future and is not intended to provide a *carte blanche* for open-ended research.

If you are contemplating making a generic application please talk with ERMA New Zealand staff first. Describing the biological properties of the organisms will (in general) require relatively more detailed information where the potential risks are greater (such as with organisms that are pathogenic or which have greater potential to escape from containment) and relatively less detailed information where the potential risks are low (such as non-pathogenic disabled laboratory strains). Containment controls will relate to the level of potential risk associated with the organisms. For applications of a generic nature, the controls are likely to be set at a relatively high level to manage potential risks.

Section 3.1 - The unequivocal identification of the host organism(s)

In this section, you should provide information on the identification of the host organism(s) – that is, the organism(s) that you are importing. Details of how the organism(s) was modified need to be provided in subsequent questions.

You should provide sufficient information to unequivocally identify each organism. 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. This is to ensure that the organism is properly described. For example, “*Escherichia coli* (Migula 1895) Castellani & Chalmers 1919”, “*Saccharomyces cerevisiae* Meyen ex E.C. Hansen (1883)”, “*Rattus norvegicus* Linnaeus, 1758”, “*Arabidopsis thaliana* (L.) Heynh (1842)”. Note that 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, the Species 2000 Names Service (<http://www.sp2000.org/NamesService.html>), zoological record on BIOSIS (<http://www.biosis.org.uk/triton/indexfm.htm>), Landcare Research’s *New Zealand Plant Names Database* (<http://nzflora.landcareresearch.co.nz/>), or the 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].
- **Common name(s)** (where relevant). For example, brewer’s (or baker’s) yeast, laboratory rat, wall cress.
- **Type of organism** For example, bacteria, virus, fungus, plant, animal, animal cell line. This is to assist in classifying the organism(s) for the ERMA New Zealand database.
- **Taxonomic family** to which the organism belongs. This can help ERMA New Zealand, and other people, identify the relationship of the organism to other species. For example, Enterobacteriaceae, Saccharomycetaceae, Muridae, Brassicaceae. Family names can be located in books and from various internet sources (such as those listed above for taxonomic authorities).
- **Strains used** (where relevant). If your application involves specific strains or breeds these should be noted. For example, “strain DH5a”, “derivatives of strain K-12”, “non-pathogenic laboratory strains”, “strain BN”, “Landsberg and Columbia”, or “wild type”. You may also want to include information on the genotype(s) of the organism(s) if you consider that this is relevant. For example, “strain DH5a (F⁻ Φ f80d/lacZ Δ M15 Δ (lacZYAargF)U169 endA1 recA1 hsdR17(r_K m_K⁺) deoR thi-1 supE44 λ -gyrA96 relA1).” 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 the host organism has any inseparable or associated organisms.

Section 3.2 - Unique name for the new organism(s)

A short unique identifier for each new organism is required. This must describe **both** the host organism **as well as** how it has been modified. This name will be on the public register and should be in a form that is readily searchable and clearly identifies the organism and modifications. 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. We recommend you consider the format “Host organism modified by Vector(s) containing Other Genetic Material”. For example, “*Escherichia coli* DH5a modified by pBluescript vectors containing soil arthropod mitochondrial rRNA and cytochrome b genes”, “*Arabidopsis thaliana* modified by pART7 containing fungal pathogen”.

& reporter genes". Where a range of vectors are used you may omit the vector descriptor, eg "*Escherichia coli* modified by thermophilic bacterial genes".

If your application involves a broad range of vectors and/or other modifications you should discuss a suitable descriptor with ERMA New Zealand staff.

Section 3.3 - Information on how the new organism(s) was developed

Please describe how the organisms will be developed so that all potential risks can be identified (in section 5).

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 can attach diagrams of vectors if these show the main features. If some of this information is confidential it should be included as an appendix and clearly marked "confidential". Examples of ways of describing vectors are "pBluescript II vectors", "non-tumorigenic *Agrobacterium/E. coli* binary plasmid vectors", and "plasmid vectors as described in the Appendix." For generic descriptions of vectors you should discuss with ERMA New Zealand staff the best way of describing their features.

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. For example, "PCR products of mitochondrial rRNA and cytochrome b genes from Australian soil arthropods", "the nptII gene from *E. coli*", "cDNA from mice and humans associated with blood and vascular tissue development", "fungal resistance genes derived from flowering plants, excluding genetic material from native flora", "DNA from non-pathogenic lactic acid bacteria used in the food industry".

Use of special genetic material. In addition to the previous question you need to identify whether native¹ and endemic flora and fauna are involved (either as **host organisms** or as **sources of genetic material**), and if human genetic material is to be used (either taken directly from a donor or via a gene library or PCR). This information is required by ERMA New Zealand so that it can readily identify projects that Maori are likely to have a special interest in. If you have undertaken consultation with Maori or other groups on this application please indicate this by ticking the "yes" box in the table. Details of any consultation should be included in responses in section 5 of the form. Some general guidance on consultation with Maori is given in that section.

We ask you to distinguish between developments where a native organism is the organism that is modified (such as genetically modifying New Zealand flax, *Phormium tenax*) and where genetic material from native organisms are introduced into another organism (such as cloning *Phormium tenax* DNA into *E. coli*). If your application is broad in scope but you will not be using genetic material from native flora or fauna, or from humans, then you should explicitly state this in the preceding question as indicated above. Note that use of genetic material from native species will normally require consultation with the appropriate Maori

¹ **native:** Flora and fauna that have originated in New Zealand or were present at the time of first human occupation, i.e. are not exotic or introduced, but are not necessarily endemic to New Zealand. Some organisms can be native to more than one area or country, e.g., the silvereye (*Zosterops lateralis*) is considered native to both Australia and New Zealand. Organisms that are naturally found only in New Zealand are referred to as **endemic** species.

groups (as discussed below). If native material is used then you need to indicate from where it is to be obtained. For example, “material from the Kew Gardens herbarium will be used”, “animals were originally collected under a Department of Conservation permit from five sites in the southern alps”.

Where human genetic material is taken directly from a donor, appropriate informed consent and ethics committee approvals will be required, and you should provide more details about individuals or populations that the material was collected from. For example, “DNA was obtained from a blood sample given by our collaborator at Stanford University”, “individuals from the islands of Micronesia donated tissue samples with informed consent that it would be used for this work”. Where genetic material is derived from an existing gene library obtained from a reputable source (eg sourced from a human BAC library supplied by Research Genetics, Inc) then informed consent or ethics approval is not required.

Other details of the modifications. Describe what techniques were used to produce the organism(s). For example, cell fusion, transduction, transfection, transformation, particle bombardment, floral dipping, etc. Note whether the whole organism is modified or only some cells or tissues are. If you are importing plant or animal cells you should indicate whether whole organisms will subsequently be developed from them.

Note that if after importation you intend to interbreed different strains or types of new organisms then you will need to submit an application for development of a GMO (using Form NO3r or NO3, depending on the modifications involved). While you will not usually need to obtain ERMA approval to backcross the GMO with the non-modified strain from which it was derived, you should be aware that approvals are often given to **specific strains** of an organism, and that even though you may obtain approval to import two different GMOs of the same species you do not have automatic approval to interbreed these. See the *User Guides for developing genetically modified organisms* for more information.

Section 3.4 - Category of modification(s)

You need to identify which category or categories of modification(s) your organism(s) would fit within if they were developed in New Zealand. This helps to identify the level of potential risk. These categories can be found in the current *HSNO (Low-Risk Genetic Modification) Regulations*. Simply stating “category A” or “category B” is not sufficient - you need to identify how they meet the requirements of the category. Some examples of the Categorization in the revised “low risk regulations” are shown below [with their characterizations in the original 1998 low risk regulations given in the square brackets]:

- Cloning PCR fragments from non-poisonous soil arthropods using pBluescript vectors and *E. coli* strain DH5a would be a category A modification since a non-pathogenic host is used and pathogenic or toxic traits are not introduced. [In the 1998 Regulations this would be A(a)]
- Knock-out of the rat TGF- β 2 gene would be a category B modification since it involves a whole animal and does not involve production of an infectious particle or expression of a vertebrate toxin. [In the 1998 Regulations this would be B(b)(ii)(B)]
- Genetic modification of a mouse cell line that involves a viral vector able to infect humans and containing growth regulating genes would be “not low risk” – ie category C – Schedule 1(e) development. [In the 1998 Regulations this would be C(c)]

ERMA New Zealand will shortly be preparing guidance material to be included in the “Explanations of Key Concepts” Protocol on what is considered to be high-level expression and a toxin.

If you are unsure of whether the organism you wish to import involves modifications that are not Category A or B modifications please contact ERMA New Zealand staff.

Section 3.5 – Characteristics of the organism(s) to be imported

You should provide details about the essential characteristics of the organism(s). This information should be relevant to the identification of the risks of the organism (section 5.1), and you should note characteristics both of the host organism as well as any new characteristics introduced by the genetic modifications. We are especially interested in knowing if the organism is pathogenic and if it could survive and establish a population outside of containment. Where possible provide references or additional information to support your statements.

For example, “*Pichia pastoris* is non-pathogenic and the laboratory strains are dependent upon nutritional supplements for growth and survival”, “*M. smegmatis* is a fast growing mycobacterial species that is used for general studies of mycobacterial function and as a host for manipulating and expressing plasmids with mycobacterial promoters. *M. smegmatis* is classified by the Australian/New Zealand Standard AS/NZS 2243.3:2002 *Safety in Laboratories: Part 3: Microbiological aspects and containment facilities* as a Risk Group 2 micro-organism requiring special precautions.”, “*Arabidopsis thaliana* is a small self-pollinating flowering plant widely used in genetic studies. It has a generation time of approximately 6 weeks, and has been reported as growing in some areas of New Zealand (Webb *et al.* 1988).”

Section Four of Application Form — Containment system

Section 4.1 - Information on the containment system and the ability of the organism to escape

A major consideration with containment applications is that the Authority must be satisfied that the containment system is adequate, and reduces the likelihood of risk to people or the environment. It is essential that you provide good information in this section because the adequacy of containment in conjunction with the characteristics of the organism will have a major impact on whether or not your application is approved. However, it's also important that the amount of information sensibly matches the circumstances with respect to known or potential adverse effects.

You should consider two types of containment: *physical* (the facility in which the organism is maintained) and *operational* (additional containment measures). You must describe the actual containment system, as well as providing information on the control measures that are in place to maintain the security of containment and to deal with any potential risks posed by the organism. Biological features of the organism that may prevent escape from containment (such as a requirement for specific amino acids) should also be mentioned here. The containment system(s) must be appropriate for the organism(s) that are to be contained and must be registered as a Containment Facility under the Biosecurity Act (that is they must comply with the MAF/ERMA joint standards).

You will need to indicate the containment level and any other additional containment controls. For example, “PC1 microbiology laboratories: rooms 3 and 4, level 2, Microbiology Tower– MAF certificate attached”, “PC2 animal house located in the School’s Animal Breeding Unit”

Note that for genetically modified plants PC2-level plant house containment may not prevent the escape of pollen and or seed from the plant house, so that additional containment (such as bagging of maturing reproductive structures) will be necessary if plants of reproductive age are to be held.

Please provide the most recent MAF document(s) for the registration of the containment facilities to be used, or ensure that ERMA New Zealand already has copies of these. If this application is submitted to ERMA New Zealand and we do not currently hold a containment manual (as required under MAF registration) for your facility please attach one as an appendix. This manual should specify the procedures for implementing the above methods for containing the organism(s), and provide details of the qualifications of the person or persons responsible for implementing those controls, and contingency plans.

In this section you also need to identify features that may enable the organism to escape. For example, does it produce spores, pollen, or seeds? If so, how are these normally disseminated? Can it naturally infect humans, other animals or plants?

For organisms that may have abilities potentially enabling them to breach the containment system (such as viruses) then additional controls are likely to be necessary. These should be discussed here and controls to address them identified.

Section Five of Application Form — Identification and assessment of adverse effects and risks

This part of the application form requires you to identify adverse effects of the new organism(s) and assess the risks. Risk is defined in terms of both the **likelihood** of occurrence and **magnitude** of an adverse effect. You should provide information relating to the risks of the organism throughout its lifecycle, and you need to substantiate your statements and record from where the information was sourced.

It is expected that organisms that meet the low risk criteria will not normally need an assessment of risks as part of the application. Low risk will normally be accepted as *prima facie* evidence of risks that are sufficiently low to be adequately managed by the minimum controls (such as PC1 or PC2 laboratory containment). However, you should consider features of the new organism that might not be able to be managed without additional controls. In doing this, you should refer to the definition of environment and the all the matters set out in Part II of the Act, especially sections 5, 6 and 8. If the imported organisms do not meet the low risk requirements then a more detailed assessment will be required.

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

In this section you need to discuss the ability of the organism to establish a self-sustaining population if it escapes from containment. For example, is it a wild type strain or does it have mutations that make it dependent on nutritional supplements? If the organism could establish outside of containment you should discuss the feasibility of detecting it, and recovering or destroying it. Please justify your statements. For example, “the host organisms are derivatives of *E. coli* strain K-12 which have been shown to be unable to survive outside of laboratory culture because of genetic mutations (Smith 1975, Heitkamp *et al.* 1993).” “The virus is able to infect humans but since it lacks the envelope gene it is unable to produce infectious particles without the aid of a packaging cell line.” “The bacterium is a wild type strain and could probably establish a self-sustaining population if it infected a suitable host.” “If the bacterium established in the soil it is unlikely to be able to be detected easily. If it was widespread in the soil eradication would not be feasible without significant adverse effects to other soil biota.”

Section 5.2 – Identifying adverse effects

It is important that you take account of the characteristics of the organism(s) described in section 3.5 to identify adverse effects (risks and costs) associated with the new organism(s). When identifying risks, you should take into account the matters set out in Part II of the Act, specifically sections 5 and 6 (mentioned in the introduction to this User Guide) and consider whether there are any significant risks that might exist in any of these areas. You may want to consult the ERMA New Zealand Technical Guide *Identifying risks* to help you complete this section and section 5.2.

Risk identification requires identifying 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. For example, a pathogenic micro-organism is a risk source and humans may be what is adversely affected by that micro-organism. You should also identify the route (“exposure pathway”) by which the adverse effect may eventuate, such as by consumption of the

organism, or transmission by insects. The information can be presented in a variety of formats (eg text and/or tables) but should indicate that a systematic approach has been used.

You should also indicate the degree of certainty or uncertainty (knowledge) associated with the risks. For example, ‘K-12 strains of *E. coli* have been widely used in research for more than 40 years and experiments have demonstrated that they are non-pathogenic (Smith 1975)’, 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’.

You can use a variety of approaches to identify risks. For example:

- Common sense
- Analogy to known cases
- Brainstorming
- Experiments
- Decision trees

Risks should be considered in relation to:

- the sustainability of native and valued introduced flora and fauna
- the intrinsic value of ecosystems
- public health (including occupational exposure)
- the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga (sacred treasures, prized possessions, property)
- any ethical, social, or other cultural issues arising
- New Zealand’s international obligations.

To help you identify issues of significance to Maori we have prepared the following documents:

User Guide to Working with Maori under the HSNO Act 1996
Protocol 1 Series 2 Taking Account of Maori Perspectives

If you aren’t sure how to identify risks to Maori or undertake consultation, contact the ERMA New Zealand Advisor on Maori issues or an Applications Advisor who can assist you with the kinds of information required and whether or not it is likely to be necessary to consult with Maori.

Identify potential adverse effects in relation to the environment, public health, cultural, and other effects. You must consider adverse effects both when the organism(s) remain contained, as well as if the organism enters the environment unintentionally, eg if the containment system fails, or if there is an accident. It is expected that all significant costs will be addressed as risks, and you are not expected to provide details of the monetary cost of undertaking the research. If you wish to provide information about monetary costs, then along with your estimate you should discuss who bears the cost.

A. Potential adverse effects on the environment

Given the restricted use of organisms in containment applications, it is clear that the risks to the environment will not be as great as with new organisms in field trials or for release into the environment. However, you should consider what adverse effects may result if the organism does not remain contained. Of particular importance is the potential impact of the new organism(s) on the sustainability of native and valued biota and the intrinsic value of ecosystems.

For example, “the viral vector is able to infect other plants so that if it escaped it could cause disease in crop plants and/or disseminate the genetic modifications”, “the bacteria expresses anti-fungal compounds so that it may adversely affect soil microbial communities if it established outside of containment”, “the plants would be able to establish if they escaped containment and could interbreed with non-modified plants of the same species, and so pass the modifications to other individuals. The foreign genetic material is a reporter gene only and is not expected to affect the viability or reproductive potential of the plant, or to result in production of proteins toxic to the environment. The species is not known to hybridise with other species.”

If you consider that there are no adverse effects on the environment you need to justify this. For example, “no adverse effects are anticipated since the strain is not pathogenic to animals or plants and although the vertebrate toxins will be expressed the organism is not able to establish outside of laboratory culture, so that it is very unlikely that the toxin will be produced if the host escapes. There is little uncertainty on this since Boffin *et al.* (2000) demonstrated the absence of adverse effects in mesocosms.”

B. Potential adverse effects on public health

Adverse effects on human health can include occupational exposure as well as adverse effects if the organism does not remain in containment. For example, “the organism has been shown to be pathogenic to humans”, “the development will result in the production of a vertebrate toxin so that adverse effects ranging from mild discomfort up to chronic incapacitation may result if it was ingested”, “the vector is capable of self-replication and would be able to infect humans if it escaped, but it is not pathogenic”.

If you consider that there are no adverse effects on public health you need to justify this. 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”.

C. Potential adverse effects on the relationship of Maori and their culture and traditions

You need 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 especially include native and other valued flora and fauna. You should have already identified in section 3.3 whether genetic material from native flora or fauna is used. Use of such material will generally require consultation with the appropriate Maori groups – specifically those groups from where the samples were taken, and also the group(s) having *mana whenua* at the location(s) where the research will be undertaken. Work involving human genetic material may also require consultation, especially if that material is derived from Maori. If you are unsure whether you need to undertake consultation in respect to use of human genetic material please contact ERMA New Zealand.

Where taonga like native flora and fauna are involved, you will almost certainly have to consult with the local hapu or iwi in order to find out if there is a potential issue, and if so how it might be addressed. If you have undertaken consultation with any group (such as the local hapu or iwi) provide details of the consultation. Details of consultations should include whom you have consulted with or attempted to contact and what their opinions of the proposed work are. 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. 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.

Examples of responses for this question are “genetic material from kumara (*Ipomoea batatas*) is to be used and kumara is known to be of special significance to Maori. We have discussed the project with the local hapu where the material is to be collected and the research undertaken – our communications with them and their responses are in appendix 2. There were no major concerns expressed by the hapu so long as the material was not used for commercial purposes.”, “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”.

D. Other potential adverse effects

If there are additional risks not covered by the above then list them here. Such items may include risks to New Zealand’s International Obligations, or economic risks if the organism escapes. Since this is an application for containment there are unlikely to be any costs that are not addressed in the identification and assessment of risks. You are not required to identify (or assess) the financial costs of undertaking the research, but you may consider that there might be some non-monetary costs associated with, for example, needing to exclude students or staff from the area where the research is being conducted.

If you do not consider that there are any other risks you need to state this. For example, “no other risks have been identified”.

A simple table may be an appropriate way to summarise all of the adverse effects you identify (see Table 5.1), but you should ensure that adequate discussions of significant risks are included in this section. Remember that in some cases an organism may have several potential adverse effects or risks and each of these needs to be identified.

Table 5.1 Example of summary of risk identification for new organisms

Source of the risk - characteristics of the organism	Possible reasons for event triggering the risk	Adverse Effect	Exposure Pathway
1. Pathogenic organism	<ul style="list-style-type: none"> • Improper handling • Incorrect disposal • Accident during use 	Infection of researchers and adverse effect on human health	Inhalation or direct contact
2. Organism has pest potential	<ul style="list-style-type: none"> • Pollen and seeds not contained • Natural hazard, eg earthquake • Sabotage 	Escape from containment and establishment in the environment	Air or water
3. Plant viral vector pathogenic to clover	<ul style="list-style-type: none"> • Pollen, seeds or plants not contained • Transmission of virus by insects 	Escape from containment and establishment in the environment, leading to destruction of clover	Air or via insect
4. Non-pathogenic bacterium	<ul style="list-style-type: none"> • Improper handling • Incorrect disposal • Accident during use 	Escape from containment. Minimal adverse environmental and human health effects since non-pathogenic and no toxic.	Air, water, or direct contact

Section 5.3 – Assessment of adverse effects

Risk assessment consists of analysing the likelihood and magnitude of the effect, and using these estimates to evaluate the level of risk compared with other risks. An explicit risk assessment only needs to be provided for those risks that are identified as being potentially significant. Even though this is an application for contained use of a new organism you need to identify significant risks not only for when the organism remains in containment but also any that may result if the organism no longer remains contained.

Deciding whether a risk is potentially significant or not should be based on your knowledge of the organism throughout its lifecycle, and what you consider the likelihood to be of the organism escaping from containment. If you are unsure of whether a risk is significant you should include it in the assessment. If relevant, provide references to sources of data used. If there are **no** significant risks, there is no need to carry out an extensive risk assessment.

If you decide that a risk is not significant, you should explain why. It is important to provide references (and include copies of them in an appendix) or other information (such as personal experience or information from colleagues) that support your statements. Please note that it is **not** sufficient to state that a risk is not significant simply because of the existence of containment.

An example of no significant identified risks if the organism does not remain in containment is “No significant risks have been identified because the organism is unable to survive outside of laboratory culture because of genetic mutations (Smith 1975, Heitkamp *et al.* 1993). If it did survive outside of containment no adverse effects are anticipated since the organism is non-pathogenic and neither pathogenic traits nor toxin genes have been introduced.”

Information on the type and degree of risks (or adverse effects) is central to assessing any potential risks or adverse effects of the organism(s) and is also important for applying containment controls as specified in Part I of the Third Schedule to the Act.

For significant risks, assessments can be quite involved. ERMA New Zealand has produced the following Technical Guides to assist you:

- *Technical Guide - Preparing Information on Risks, Costs and Benefits*
- *Technical Guide - Assessment of Effects of Hazardous Substances and New Organisms on Human Health*

In completing this section, it is important that you take account of the proposed containment system and the control measures (physical and procedural) described in Section 4, which may significantly reduce the likelihood or the consequence of any adverse effects. We are particularly interested in knowing about those risks that remain with the containment system in place.

As the organism(s) will not be for general release, the most likely risk to humans in the first instance will be occupational exposure. You should consider the possibility of the organism escaping from containment and causing an adverse effect on the **environment, public health, and the economic, social and cultural well being** of the community.

Your analysis should include whether the organism(s) can be adequately contained by the proposed containment system and whether the (significant) risks identified in section 5.3 can be adequately managed by the containment controls detailed in section 4.

In analysing the risk you should consider the **probability** or **likelihood** of the adverse effect occurring and the **magnitude** of the adverse effect if it did occur. The evaluation should consider whether the identified risks can be adequately managed by the proposed containment system, as well as whether the organism(s) can be adequately contained.

You will need to support your statements. This can be done, for example, by referring to relevant published papers (please include copies of any that you cite, except for whole books), other documentation, or your own or colleagues experiences.

ERMA New Zealand uses **qualitative scales** for describing likelihood and magnitudes of effects. Examples of these are shown below. 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.

Table 5.2 Qualitative scales for describing effects

A. Likelihood

Descriptor	Description
Highly unlikely	Not impossible, but only occurring in exceptional circumstances
Unlikely	Could occur , but is not expected to occur under normal circumstances
Possible (50/50 chance)	Equally unlikely/likely, mean chance of occurring
Likely	Will probably occur at some time
Extremely likely	Is expected to occur (almost certain)

B. Magnitude of (adverse) effect

Descriptor	Example detail description
Minimal	Insignificant (repairable or reversible) environmental impact, no observable cultural effects, other effects slight (reversible) or very small. Dollar value low and less than \$100.
Minor	Reversible environmental impact, limited adverse cultural effects (affecting small area or localised community), other effects small and limited in scope
Moderate	Some slight effect on native species, adverse cultural effects to wider area but not considered serious, other effects medium or mid range
Major	Irreversible environmental effects but no species loss, adverse cultural effects widespread but remedial action available, other effects large
Massive	Extensive irreversible environmental effects, including species loss, adverse health effects, severe adverse cultural effects over whole country with no possible remedial action, other effects very large and widespread, Dollar value greater than \$1m

The risk analysis process integrates what the adverse effects are, the magnitude and likelihood of them occurring, how and when they are likely to occur and who or what is likely to be affected. In carrying out your risk analysis, you should consider the following:

- What is the nature and seriousness of the risks, ie 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 adverse effect occurring? Provide an assessment of whether the adverse effect will occur and substantiate this (for example, with published studies, your professional knowledge of the species, etc).
- 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 risk 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 adverse 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)

Refer to how the identified risks may be able to be managed by reference to the proposed containment system and any additional management practices. You may provide this information in whatever format you like, but the level of detail will depend on the nature of the risks and you should always justify your conclusions.

An example of a risk analysis statement is:

“Laboratory strains of *Agrobacterium tumefaciens* have been shown to survive on plants (Matzk *et al.* 1996) so that it is likely that they can survive outside of containment. However, there are no published studies on whether these strains can subsequently transform other plants so that there is uncertainty over the magnitude of the consequence of escape from containment. If the bacterium was unable to infect other plants then the magnitude of an escape would be minimal. If it was able to infect other plants then, considering that the foreign genetic material is not known to be toxic or pathogenic, the magnitude of an adverse effect could range from minimal to moderate depending upon the number and types of plants infected. Given the potential for *A. tumefaciens* to survive, transformed plants will be treated with the antibiotic timentin before being taken to the plant house, so that it is very unlikely that *A. tumefaciens* will escape from containment)”

Once you have identified and analysed significant risks and costs you need to evaluate their relative significance. This is done by considering both the likelihood of the adverse effect and its magnitude, and may use qualitative scales (see above for an example). The management regime should be taken into account in the evaluation.

Table 5.3 Example of risk evaluation for new organisms

Source of Risk and pathway	Adverse Effect	Management of risk	Likelihood of adverse effect occurring (based on containment system)	Magnitude of effect (if it occurs)	Evaluated level of risk
1. Pathogenic microbe	Infection of researchers and adverse effect on human health	Handled by trained researchers in a Class II biosafety cabinet	Very unlikely	Local and treatable so “minimal”	“Insignificant”
2. Weedy plant	Escape from containment and establishment in the environment	Monitoring of flower development, and bagging of flowers prior to maturation. Autoclaving of all plant material when no longer required.	Very unlikely	Unlikely to displace native species so “minor” to “moderate”	“Insignificant”
3. Plant viral vector	Escape from containment and establishment in the environment leading to damage to clover	Monitoring of flower development, and bagging of flowers prior to maturation. Buffer zone around plant house. Autoclaving of all plant material when no longer required.	Unlikely	Can infect clover species, so magnitude range up to “massive” depending on pathogenicity	“Insignificant” to “Medium”

4. Non-pathogenic bacterium	Escape from containment	Good microbiological practise and maintenance in PC1 lab	Very unlikely	Non-pathogenic or toxic so "minimal"	"Insignificant"
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Assessing risks to Maori

If you have identified that there may be potentially significant 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. If you have undertaken consultation, your analysis should take account of 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.

You should also take into account the principles of the Treaty of Waitangi. In assessing the significance of Treaty issues, you should consider 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. You can find more information on Treaty of Waitangi considerations in the ERMA New Zealand *“User Guide to Working with Maori under the HSNO Act 1996”* and the Protocol *“Taking Account of Maori Perspectives.”*

If you aren’t sure how to analyse or assess risks to Maori, contact an ERMA New Zealand Advisor on Maori issues or an Applications Advisor who can assist you with the kind of information required and whether or not it is likely to be necessary to consult with Maori. If you do consult with Maori, details of that consultation should be included here.

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.”

Establishment of a general relationship with the local Maori community

It cannot be too strongly emphasised that the best way to deal with Maori concerns and issues is through the establishment of a mutually acceptable, constructive and long term relationship with the local Maori community. If the first contact with the local Maori community is when consultation is required on a particular application, then it is probably too late! An adverse reaction can be expected because that is the natural reaction of any community which is suddenly confronted with a proposal which is unexpected, does not have any obvious benefits to them, and is hard to understand.

The local Maori community means the local hapu and iwi. In some localities relationships will be harder to establish than others. If you need help, do not hesitate to contact our Senior Advisor (Maori Issues) at ERMA New Zealand.

When to consult and when to inform?

It is important to recognise the circumstances where it is either necessary or desirable to consult Maori. The guidelines set out below are intended to help with this. However, these guidelines are still under development and are likely to change over time.

Although IBSCs can only deal with applications that conform with the definition of low risk, ie involve negligible physical and biological risks, there are still circumstances under which

the Maori community may have a legitimate interest in the work and under which there should be proper consultation with Maori or other interactions. Cultural and especially spiritual concerns will normally be the trigger for consultation.

Narrowing down of the circumstances in which consultation is required is important to all parties. We do not want either applicants or Maori to expend effort consulting on matters which are not important to Maori, but Maori equally need to be reassured that consultation will occur under circumstances of potential concern.

It is appropriate here to draw a distinction between *consulting* on the one hand and *informing and discussing* on the other. Consultation carries with it a (legitimate) expectation that the results of consultation will provide input to and thus may influence a decision. Informing and discussing do not carry the same level of expectation.

There are circumstances when Maori should always be consulted, even though the work involved is low risk from a biophysical point of view. Those circumstances include principally:

- Work which involves genetic material from native flora and fauna, irrespective of whether those flora and fauna are also endemic to New Zealand. The distinction between endemic and native (but not endemic) species may be particularly relevant to marine organisms.
- Work involving recognised taonga. That is, varieties or species of established special significance to Maori.
- The use of human genetic material when it is sourced directly from a person of Maori descent.

In general, consultation is not, however, required if the organisms involved are micro-organisms, because of the practical difficulties involved in fully characterising the micro-organisms that might be involved. However, there may be exceptions – for example, if the micro-organisms are well characterised and there is good reason for supposing that they are native to New Zealand.

There are other circumstances where consultation might be appropriate, but this is more of a matter of dealing with each case on its merits. Such cases include:

- Experiments involving species which may be particularly valued by Maori (s6(d) of the Act). An obvious example is kumara.
- Experiments which are intended as a precursor to field testing and possible release of the GMO, in which event there should be a strong bias toward identifying and considering any issues for Maori at the earliest possible stage.

There is, however, a very definite obligation to inform and discuss in such cases, if the Maori community which has potential interest in the work is not fully aware of the “low risk” nature of the work and what this means in practice, or does not understand the implications of and rationale for the work, more generally. This may also be appropriate if a prior dialogue with the Maori community has not already established, in general terms, what species are or are not valued.

It is recognised that a deep concern raised by many Maori is that of cultural objections to the use of human genetic material in genetic modification. This is notwithstanding the fact that

such human genetic material is, in today's science, most likely to be synthetic or copied from source material derived from an overseas DNA databank, rather than being directly obtained from a donor. There is, accordingly, an instinct to say that consultation should always occur. However, this raises the issue of what the expectations of such consultation might be. Under the HSNO framework it would be difficult to decline low risk applications simply because of a general objection to the use of human DNA.

This is an area of contention and accordingly the discussion remains open at this point.

An overriding aspect of this whole area is that the requirement to consult on individual applications might be mutually waived if there is already a strong agreement and understanding, between the institution and the local Maori community, on what type of work is or is not of concern. The need to consult may also be waived if the decision-making body has a member, or has in other ways formally involved Maori individuals who are mandated to speak on behalf of the local Maori community.

However, even in these circumstances, consultation may be required if an iwi or hapu outside of the locality is involved. A typical (and actual) case is that of research being done at a university in the North Island involving DNA from a species located in the South Island. In this case, hapu or iwi from both localities must be involved.

Who to consult and how?

More detailed information on consultation with Maori is set out in a separate *User Guide to Working with Maori under the HSNO Act 1996*, which is available from ERMA New Zealand. The material below only picks out highlights.

Consultation is a two-way process. It requires every reasonable effort on the part of the party consulting (the applicant) and a willingness to respond reasonably on the part of those consulted. The current approach is that the test of 'reasonableness' will if necessary be applied by the Authority in determining whether consultation has been appropriate or adequate. But if matters get to this point, it will be a strong indicator that consultation has not been satisfactory.

Work in containment (particularly "low risk" development work) can be expected to be of most interest to local hapu and iwi, and that is where consultation should be focussed. However, as already indicated it may sometimes be necessary to consult other hapu or iwi.

There may sometimes be difficulties in deciding on who exactly to consult with, and there have been circumstances where the Maori community itself has been divided on the issue of who has mandate to represent whom. The first recourse should always be to talk to ERMA New Zealand through our Senior Advisor (Maori Issues). But the fall-back position must always be to consult widely so that all points of view are captured.

Dealing with the results of consultation

If Maori are consulted about low risk work and either object to the work proceeding or want special conditions to be imposed, there needs to be 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.

A general approach has been evolved by the Authority for this and it is as follows:

- 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 Maori object to the work, even after applying conditions, then the IBSC should either decline the application or refer it to the Authority for a full assessment. The full assessment process will then give the Authority an opportunity to look at both the benefits and the costs of the application.

Response in the application form

If you have undertaken consultation with any group (such as the local hapu or iwi near where the samples were collected and where the work is to be conducted) please provide details of the consultation in this section, including whom you have consulted with or attempted to contact and what their opinions of the proposed work are. 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. 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 you consider that there are no adverse effects on Maori then you need to justify this. 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 you have identified that there may be potentially significant risks to Maori, you should provide an assessment of the likelihood of the adverse impact(s) on Maori and estimate how severe that impact may be. If you have undertaken consultation, your assessment should take account of 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.

Section 5.4 – Identification of beneficial effects

You should provide an indication of any non-monetary (eg, scientific) and monetary benefits to be derived from the importation of the new organism(s) and whether these are direct or indirect benefits.

Examples of non-monetary benefits are “enhancement of the reputation of New Zealand cancer research” and “acquisition of knowledge and understanding of disease processes”. An example of a monetary benefit is “enhancement of the ability of individuals and the University to attract research funds, both from New Zealand and possibly overseas”. Since this is an application for containment, the focus is likely to be on immediate benefits. You should avoid citing potential future benefits that will depend on subsequent field trial or release applications. If future benefits are discussed, you will also need to identify and analyse potential future risks.

Section 5.5 – Assessment of benefits

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, “The development of these cell lines is essential for the applicant to continue their research program, which receives support from both FRST and the US NIH. Should these organisms not be approved at least one research project would be abandoned and there would be adverse effects on a number of other investigations. This programme is expected to bring benefits to the researchers and to the organisation through increased research profile and ability to attract additional research funding”

Although all benefits are potentially admissible it is particularly important to identify and assess benefits which are of wide application, ie do not just benefit the applicant.

Section 5.6 – Overall evaluation of risks, costs, and benefits

The Authority must make a judgement on whether the positive effects (benefits) of the substance outweigh any adverse effects (risks and costs). The Authority will take into account any controls that may be imposed on the substance and the likely effects of the substance being unavailable.

If the Authority deems that the positive effects outweigh any adverse effects, it may approve the application, conditional upon controls being attached to the approval. Alternatively, if the Authority deems that any adverse effects outweigh the positive effects, it will decline the application.

In this section you can summarise why you consider the benefits outweigh the risks. For example, “since it is very unlikely, given the containment regime, that the organisms will escape from the containment system or infect workers, and there are very unlikely to be any adverse environmental or cultural effects, we consider that the benefits to New Zealand medical research outweigh any risks associated with occupational exposure to these organisms.”

Risk characteristics

In general, the Authority will be more cautious and risk-averse if any of the risks have the following characteristics:

- the exposure to the risk is involuntary
- the risk is relatively persistent
- the risk could spread uncontrollably
- the potential adverse effects are irreversible
- the risk is not understood by society
- there are risks to human health
- there are risks to the survival of native species or their habitats.

So you should ensure that these issues are addressed in the application.

Section Six of Application Form — Additional Information

Section 6.1 - Other approvals required

Please indicate here whether the new organism(s) is 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 genetic material from species listed in the appendices of the Convention on International Trade in Endangered Species (CITES) is used, then approval is required from both the importing and exporting countries. If your application involves material listed in CITES appendices then you may need to contact the Department of Conservation to help arrange the necessary approvals.

If this section is not applicable please say so.

Section 6.2 - Previous considerations

ERMA New Zealand requires information on whether any of the organisms in the application have previously been considered within New Zealand (for example, already have HSNO approvals to import or develop, or were considered by the Advisory Committee on Novel Genetic Techniques) or by other countries (Such as approved by the Australian Office of Gene Technology). This information is useful for ERMA New Zealand when considering the application. If the organism has been previously considered please provide details of the type of consideration and the result.

If this section is not applicable please say so.

Section 6.3 - Other relevant information

Please provide any other information that you consider is relevant to the application but is not already covered by any of the previous sections.

Section 6.4 - Glossary

If you use terms from the *Interpretation* section 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 6.5 - List of appendices

Please include as listed appendices any information that is commercially sensitive, or additional material included with the application (such as details of consultations, vector diagrams, referenced articles). The main application should refer to the relevant appendices but be able to be read as a stand-alone document.

Section Seven of Application Form — Application Summary

Section 20(1) of the HSNO 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 3.2), 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 (eg Ministry of Agriculture and Forestry, Ministry for the Environment, Department of Conservation, Regional Councils, etc) and for members of the public who request information. This information will also be used to prepare the public notice of the application.

You should include a summary of:

- What the purpose of the work is
- The identification of the organism(s) and how they were developed or what modifications they contain
- Information on the proposed containment
- An assessment of the potential adverse effects of the organism and how these are managed

If any consultation was undertaken with respect to the application it is helpful to note this in the summary as well.

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. Note that if the application is considered by your IBSC then no fee deposit is required, although they may want an electronic version of the application. When you submit your application to ERMA New Zealand an application deposit (including GST) and an electronic copy of the application are required.