

## 2 Simplifying Approval Processes for Laboratory Research

### 2.1 Summary

This section addresses two proposals recommended by the Royal Commission on Genetic Modification aimed at simplifying the approval processes for low-risk genetic modification that occurs in contained laboratories:

- group (project-based) approvals for the development of low-risk GMOs
- delegation of approval of importation of low-risk GMOs to Institutional Biological Safety Committees (IBSCs).

These proposals also aim to better align the procedures with the way scientific research actually takes place. Overall they would reduce unnecessary compliance costs without changing the scope of what would be permitted as low-risk work, or altering the level of permissible risk.

Some related work suggested by the Royal Commission is already under way or has been completed (for example, new organism application forms and the standard covering safety practices in laboratories). Also, the HSNO (Low-Risk Genetic Modification) Regulations are being amended.

While the changes to the regulations go some way towards streamlining the approval process, the system may be further improved by changes to the HSNO Act itself. The following two sections address:

- how group approvals could be provided for instead of the current case-by-case approval of individual organisms
- how flexibility to use a range of low-risk procedures under one approval could be provided
- how the identification requirements for low-risk GMOs produced during the project could be simplified
- how approval of the importation of low-risk GMOs might be delegated to IBSCs.

It is proposed that, instead of focusing on the particular organisms being genetically modified, the HSNO approval process for low-risk experiments should focus on the broader circumstances or low-risk nature of the genetic modifications proposed in a research project. It is also proposed that a means be provided to vary the approval, where those circumstances change during the course of the research. The requirement to identify the organism resulting from the approved low-risk experiments would be removed or simplified.

The HSNO Act does not distinguish between low- and higher-risk genetically modified *organisms* (GMOs) in the same way it does for processes used in low- and higher-risk genetic *modifications*. In order to enable the delegation to IBSCs of approvals for the importation of low-risk GMOs, it is proposed that criteria be developed for defining a low-risk GMO in a manner similar to that for a low-risk genetic modification, and then allow both low-risk developments and low-risk GMO importations to be rapidly assessed by IBSCs.

## 2.2 Group approvals for the development of low-risk GMOs

The circumstances in which the genetic modification of an organism is considered a low-risk genetic modification are specified in the HSNO (Low-Risk Genetic Modification) Regulations 1998. Such genetic modification developments pose low-risk to public health and the environment, and include most of the routine laboratory genetic research and teaching work carried out by universities and research institutes. The Royal Commission recommended that applications to develop low-risk GMOs in containment be assessed by IBSCs<sup>1</sup> on a project rather than an organism basis. The Government accepted the *intent* of the recommendation, which was to simplify the assessment of low-risk laboratory (i.e. fully-contained) research involving genetic modification either by using defined criteria to assess organisms, or by providing for the approval of groups of organisms of similar types and risks, rather than requiring separate approvals for each organism.

### 2.2.1 How could group approvals be allowed for?

A research project is generally considered in terms of its overall purpose and output, although it is recognised that appropriate ethical (including animal welfare) and other approvals may be required for the different procedures that may be used. It is proposed that HSNO approvals focus on the broader circumstances or low-risk nature of the intended genetic modification. The HSNO (Low-Risk Genetic Modification) Regulations already allow for a focus on the circumstances of the development (genetic modification) rather than the resulting GMO. While the proposed amendments to these regulations provide a means for defining the low-risk work that may be allowed in a particular project they do not specifically address the ‘project basis’ issue.

It is therefore proposed that the HSNO group approval cover all the low-risk genetic modifications identified as being necessary to achieve the outcome of the particular research project.

**2a What other ways are there to group (and handle/process) approvals for low-risk work?**

Please explain your answer by setting out possible illustrative examples, and by relating your suggestions to the HSNO Act's present requirements.

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<sup>1</sup> IBSCs are established by individual institutions to assess applications for low-risk genetic modifications (i.e. those developments that pose low-risk to public health and the environment). Approval to assess such applications is delegated to IBSCs by ERMA.

## 2.2.2 What happens if the research changes its course?

Often, all the likely low-risk genetic modifications are foreseen at the planning and approval stage of a project. Sometimes, however, the researcher may wish to perform different genetic modifications to meet the objective of the project. This may occur as the experimental procedures are tested and refined as the project progresses. Currently a new approval may be required.

To remove the need for a separate approval in this situation, the following process is proposed.

- The researcher either:
  - (where the changed circumstances clearly fit the criteria for a low-risk genetic modification) formally notifies the IBSC (or ERMA) of those changes and is then able to continue with the research after a certain period of time or
  - seeks a formal determination as to whether the circumstances fit the criteria for low-risk genetic modification (this option may occur in all cases, or only where there is uncertainty as to whether the changed circumstances fit the criteria for a low-risk genetic modification).
- The IBSC or ERMA would then either:
  - vary the approval as necessary or
  - advise that the alternative procedure does not fit the low-risk criteria, in which case a separate approval from ERMA would be necessary.

### **2b Is this approach workable?**

Please consider in your comments both the extent to which the approach might streamline research procedures and the extent to which it might increase risks. If you consider there are problems with this proposal, please suggest alternatives and explain these as clearly as possible, referring, where necessary, to the relevant parts of the HSNO Act.

## 2.2.3 How could the requirements for identifying organisms be simplified?

For all GMO development applications, the HSNO Act requires that the organism being developed is identified at the time of the application, along with a description of the project and the experimental procedures to be used. Experience suggests that the identification requirement is overly complex for low-risk laboratory-based research that meets the criteria for low-risk genetic modification. GMOs created during a development may include, for example, ‘libraries’ of large numbers of related GMOs, which are created as intermediate stages in the process of identifying, isolating and copying particular genes. The Act also does not recognise that, in experimental situations, the exact identification and characterisation of the final resulting GMO typically cannot be made in advance.

Two possible options for amendment have been identified.

- **Option 1:** Remove completely the prior identification requirements in the HSNO Act for low-risk developments, while retaining the requirement to describe the project and the experimental procedures that will be used. This would ensure that the criteria for low-risk genetic modification and the level of risk could be ascertained.
- **Option 2:** As for Option 1, but instead require notification to the IBSC (or ERMA) within a specified time of the identity of the GMOs resulting from the approved low-risk experiments.

**2c Which option is more appropriate?**

**2d What level of identification is required for intermediate and for resulting organisms?**

**2e When should the identification of the resulting organism occur?**

Please consider in your comments both the extent to which simplifying the identification requirements might streamline research procedures and the extent to which it might increase risks. If you consider there are problems with these options, please suggest alternatives and explain these as clearly as possible, referring, where necessary, to the relevant parts of the HSNO Act.

## 2.3 Delegating approval of importation of low-risk GMOs to IBSCs

The Royal Commission on Genetic Modification recommended that the HSNO Act be amended to allow for the efficient importation of low-risk GMOs through delegation of the approval process to IBSCs. The Government has accepted this recommendation.

Currently, approval of the low-risk development of GMOs in containment in New Zealand may be delegated to an IBSC, whereas the importation of (potentially the same) low-risk GMOs into New Zealand requires approval from ERMA.

The HSNO Act distinguishes between low- and higher-risk developments through the HSNO (Low-Risk Genetic Modification) Regulations. These regulations specify the criteria for a low-risk genetic *modification*. The Act does not distinguish between low-risk and higher-risk genetically modified *organisms* for the purpose of importation.

### 2.3.1 Proposed amendments

It is proposed that criteria be developed for defining a low-risk GMO as well as a low-risk genetic modification, and that both low-risk developments and low-risk GMO importations be allowed to be rapidly assessed under section 42. Again two main options have been identified.

- **Option 1:** Define a low-risk GMO as an organism developed according to the criteria specified in the low-risk genetic modification regulations.
- **Option 2:** Develop a separate verifiable definition or criteria for a low-risk GMO.

### 2.3.2 Discussion of options

*Option 1* raises a potential compliance issue of ensuring that the organism being imported is in fact the organism identified, and that it has been developed in the overseas laboratory in the circumstances specified as low-risk. Not all components of the low-risk modification procedure used can be determined from the organism itself (that is, the organism being imported). While the host and nucleic acid material inserted may be verified, if necessary, in many cases the use of a particular low-risk vector cannot be verified. While the vast majority of compliance under the HSNO Act is, of course, voluntary (as is the case for any statute), enforcement agencies must also be able to verify the status of an organism should verification be necessary.

This option may also not allow the importation of GMOs that are in themselves low-risk but that may have been developed using a procedure in which one or more elements is not specified in the low-risk genetic modification regulations.

With *Option 2*, for consistency it would be desirable to base the criteria for a low-risk GMO on those for a low-risk genetic modification; for example, those elements that can be independently verified (the host organism, the nucleic material being inserted, and the vector, where present).

Creation of separate criteria will require either amendment of the low-risk genetic modification regulations or promulgation of new regulations specifying the criteria for a low-risk GMO (and, in the latter case, creation of the power to make those regulations).

- 2f Is it sufficient to base the criteria for a low-risk organism on the host organism, the nucleic material being inserted, and the vector, where present?**
- 2g Will these criteria limit the importation of organisms that are demonstrably low-risk but have been developed according to other possibly higher-risk procedures?**
- 2h What other criteria might be appropriate (e.g. the phenotype of the organism)?**
- 2i Are there other general approaches to characterising low-risk organisms that may be better? If so, what are they?**

Please explain your answers by setting out possible illustrative examples and by relating your suggestions to the HSNO Act's present requirements.