

# **Submissions sought on proposed regulations for the management (through segregation and traceability schemes) of conditionally released genetically modified (GM) organisms, particularly crops.**

## **Introduction**

For the purpose of section 141(1)(a) of the Hazardous Substances and New Organisms (HSNO) Act 1996, the Environmental Risk Management Authority (ERMA) invites all interested and potentially affected parties to make submissions on a proposed Order in Council (regulations), to be made under the HSNO Act.

The proposed regulations will prescribe requirements for segregation and traceability schemes for applications to conditionally release genetically modified (GM) organisms, particularly crops. ERMA will consider those schemes, for the purpose of imposing controls, when considering such applications.

Submissions close at 5pm, Friday 15 August.

## **Background**

On Wednesday 30 July 2008 the Minister for the Environment requested ERMA to consult on proposed new regulations to be made under s140(1) of the HSNO Act and to report back by Friday 22 August 2008.

These regulations are part of a series of measures for the management of genetic modification in New Zealand, agreed to by the Government on 14 July 2008. (For more information about the changes agreed to see the Ministry for the Environment website: <http://www.mfe.govt.nz/issues/organisms/conditionally-released/index.html>).

The purpose of these changes is to provide a greater level of transparency, increased accountability and greater public openness of GM crop management, should GM crops be approved for use in New Zealand. They are aimed at ensuring that non-GM growers have a heightened level of assurance about the integrity and marketability of their product, while still allowing GM crops to be approved by ERMA subject to its standard assessment practices based on the associated risks, costs and benefits.

Below are a series of questions that may assist your response. The questions are indicative only and ERMA welcomes any submission on the matter.

### **What types of applications will the proposed regulation apply to?**

It is proposed that the regulations will apply only to applications made under s38A of the HSNO Act for approval to release a new organism with controls (conditional release applications) and in particular, to GM crops.

- Do you think that the management of types of GM organisms other than crops (for example, GM animals and vaccines) might benefit from the application of segregation and traceability schemes?
  - If yes, can you give examples of the other types of organisms and how segregation and traceability requirements would apply to these organisms?

The term “*genetically modified organism*” is defined in s2 of the HSNO Act. The term “*crop*”, however, is not defined in the HSNO Act and so would be interpreted to have its ordinary meaning, which could cover any plant species grown for food or other uses. These other uses could include trees and plants grown for fibre, oils, pharmaceuticals, energy feedstocks, ornamental purposes or for bioremediation.

- Do you think that the regulations should provide a specific definition of a GM crop?
  - If yes, can you suggest a workable definition?

### **What might the regulations require?**

The purpose of the regulations is to prescribe requirements for segregation and traceability schemes, which ERMA would then have particular regard to when imposing controls. This could be achieved by prescribing information to be provided with an application using the regulation making powers under section 140(1)(l) of the HSNO Act.

- Do you have any other suggestions for types of regulations that may be used to prescribe requirements for segregation and traceability schemes under the HSNO Act?

If regulations are made under s140(1)(l) of the HSNO Act they would prescribe that any application for approval of the conditional release of a GM crop will include information describing how the applicant proposes to comply with a relevant code of practice providing for the segregation and traceability of their GM crop. In addition s38A(2)(a) of the HSNO Act provides that an application for a conditional release approval must include all prescribed information (if any). Therefore, any such application without this information would not be able to be considered by ERMA.

In particular, these regulations could potentially require the applicant to provide the following information:

1. A completed template code of practice with information specific to the proposed crop species and location.
2. Specification of the level of segregation that would be achieved by adherence to this code of practice.
3. Proposed traceability mechanisms that would be employed over the life of the organism.
4. The details and results of any consultation conducted with potentially affected parties.

MAF will shortly begin consulting with New Zealand cropping and arable industries and research institutes about a draft template that could be used to develop GM crop-specific and variety-specific codes of practice for segregation.

- Can you suggest any other information that the applicant should be required to provide about segregation and traceability?

## What implications would the proposed regulation have?

We are interested in receiving comments on the practicality, equity, efficiency and workability of the proposed regulations. We would particularly appreciate hearing your views on the following issues:

- What do you consider are the potential advantages and disadvantages of the proposed regulations?
- What do you think the direct or short-term impacts of the proposed regulations would be (positive or negative) to you, your organisation or others?
- Can you see any other indirect or long term implications of the proposed regulations for you, your organisation or others?
- Can you identify any potential issues that would affect the workability of the proposed regulations?
- Are you aware of any factors that could effectively limit compliance with such regulations?
- Do you have any views on measures that could be taken to facilitate compliance with the proposed regulations?
- Can you see alternatives to the proposed regulations that might meet the same objectives?
- What financial cost implications (increased or decreased) do you consider you might have (as an individual or organisation) as a result of a need to comply with the regulations?

We would also appreciate receiving information on the potential financial or non-financial benefits or costs of implementing the proposal, including any specific information and examples of:

- the nature of any benefits or costs;
- an estimate of the size of the benefits or costs;
- an explanation of how you arrived at the estimate;
- the level of confidence in your estimates; and
- any suggestions as to how the costs might be reduced or minimised, and the benefits maximised.

## Submissions

Submissions will close at 5pm, Friday 15 August 2008. Unfortunately late submissions will not be able to be accepted.

Submissions can be emailed to [GMsubmissions@erманz.govt.nz](mailto:GMsubmissions@erманz.govt.nz) or posted to ERMA New Zealand, PO Box 131, Wellington. Posted submissions should be clearly marked as "Submission on Management of GM Crops".

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The Hazardous Substances and New Organisms Act 1996 is available for reference online at <http://www.legislation.govt.nz>.