Appendix J Preliminary Draft Provisions (CMA)

Genetically Modified Organisms (GMOs) – Draft Amendments to Provisions

B Definitions

Genetically Modified Organism (GMO)	Unless expressly provided otherwise by regulations, any organism in which any of the genes or other genetic material: (a) have been modified by in vitro techniques; or (b) are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by in vitro techniques. This does not apply to genetically modified products that are not viable and are no longer genetically modified organisms, or products that are dominantly non-genetically modified but contain non-viable genetically modified ingredients, such as processed foods.
Genetically Modified Organism Field Trials	The carrying on of outdoor trials, on the effects of the organism under conditions similar to those of the environment into which the organism is likely to be released, but from which the organism, or any heritable material arising from it, could be retrieved or destroyed at the end of the trials.
Genetically modified organism release	To allow the organism to move within New Zealand free of any restrictions other than those imposed in accordance with the Biosecurity Act 1993 or the Conservation Act 1987. A Release may be without conditions (s34, HSNO Act) or subject to conditions set out s38A of the HSNO Act.
Genetically Modified Veterinary Vaccine	A veterinary vaccine that is a genetically modified organism as defined in this Plan.
Genetically modified medical applications	The manufacture, trialling or use of viable and/or non-viable genetically modified organisms for medical purposes recognised as medicines under the Medicines Act 1981 and approved as safe to use by the Ministry of Health, including EPA approved releases, except for the outdoor cultivation of pharmaceutical producing organisms.
Viable Genetically Modified Veterinary Vaccine	A genetically modified veterinary vaccine that could survive or replicate in the environment or be transmitted from the inoculated recipient.

C Rules

C.1.8 Genetically Modified Organisms

C.1.8.1

GMOs in the Coastal Marine Area – permitted activities

The following activities involving genetically modified organisms are permitted activities:

1. research and trials within contained laboratories, and
2. medical applications (including vaccines), and
3. veterinary applications of genetically modified organisms (including vaccines) provided that any veterinary application of viable genetically modified organism vaccines is to be supervised by a veterinarian.
4. any other genetically modified organism release or use not specifically provided for or prohibited

The RMA activities this rule covers:

- Use of genetically modified organisms in the coastal marine area (s12(3))

C.1.8.2

GMO Field Trials - discretionary activity

A genetically modified organism field trial in the coastal marine area is a discretionary activity provided:

1 The GMO activity has the relevant approval from the Environmental Protection Authority; and is undertaken in accordance with Environmental Protection Authority approval conditions for the activity.

2 A Risk Management Plan is provided with the application, including details of:

- the species, its characteristics and lifecycle, to which the genetically modified organism activities will relate
- the research undertaken that characterises and tests the GMO, and the certainty associated with the accuracy of that information.
- the areas in which the activity, including discharges, is to be confined.
- proposed containment measures for the commencement, duration and completion of the proposed activity.

- the potential adverse effects to the environment, cultural values and economy associated with the activity, including in the event that GMOs escape from the prescribed activity area,
- the proposed measures, including contingency measures, that will be taken to avoid, remedy or mitigate potential adverse effects.
- how and by whom monitoring will be undertaken
- reporting requirements
- recommended conditions of resource consent covering the matters listed above.

2. Details of a performance bond, with an approved trading bank guarantee, are provided, to ensure the performance of any one or more of the conditions of the consent.

   The bond is to be available for payment to redress any adverse environmental effects and any other adverse effects to third parties (including economic effects) that become apparent during or after the expiry or surrender of the consent.

Notification:

Any application for resource consent under rule C.1.8.4 must be publicly notified:

The RMA activities this rule covers:

- Use of genetically modified organisms in the coastal marine area (s12(3))

C.1.8.3

Viable GMO Veterinary Vaccines - discretionary activity

The use of any viable genetically modified veterinary vaccine that is not a permitted activity under rule C.1.9.1 GMOs in the Coastal Marine Area – permitted activities, is a discretionary activity, provided:

1 The GMO activity has the relevant approval from the Environmental Protection Authority; and is undertaken in accordance with Environmental Protection Authority approval conditions for the activity.

The RMA activities this rule covers:

- Use of genetically modified organisms in the coastal marine area (s12(3))

C.1.8.4

GMO releases – prohibited activity

The following activity is a prohibited activity:

1 Genetically modified organism releases – both food-related and non-food related within the coastal marine area.

The RMA activities this rule covers:

- Use of genetically modified organisms in the coastal marine area (s12(3))

D Policies

D.2 General

D.2.3

Application of policies in the Regional Policy Statement for Northland to non-complying activities

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11. Policy 6.1.2 – Precautionary approach

D.5 Coastal

D.5.28

Managing the effects of the use of genetic engineering or the release of genetically modified organisms

1. Adopt a precautionary approach to assessing the risks, significance, scale and nature of potential adverse effects associated with the use of genetic engineering or the release of genetically modified organisms.
2. Adopt an adaptive approach to the management of the outdoor use, storage, cultivation, harvesting, processing or transportation of a genetically modified organism through periodic reviews of the genetically modified organism provisions, particularly if new information on the benefits and/or adverse effects of a genetically modified organism activity becomes available.
3. Ensure that a resource consent granted for genetically modified organism field trials is subject to conditions that serve to avoid, as far as can reasonably be achieved, risk to the environment, adverse effects on indigenous flora and fauna, and the relationship of

tangata whenua with flora and fauna from the use, storage, cultivation, harvesting, processing or transportation of a genetically modified organism.

4. Require, where appropriate, more stringent measures than those required under the provisions of the Hazardous Substances and New Organisms Act 1996 to manage potential risks.
5. Require consent holders for a genetically modified organism activity to be liable (to the extent possible) for any adverse effects caused beyond the site for which consent has been granted for the activity.
6. Ensure that a resource consent granted for the genetically modified organism field trials of a genetically modified organism is subject to conditions that ensure that the consent holder is financially accountable (to the extent possible) for any adverse effects associated with the activity, including clean-up costs and remediation.
7. Require performance bonds as a means to redress any adverse environmental effects and any other adverse effects to third parties (including economic effects) that become apparent during or after the expiry or surrender of a consent, including consideration of:
   (a) the significance, scale, nature and timescale of potential adverse effects,
   (b) the degree to which the consent holder for the activity has sought to avoid potential adverse effects, and the certainty associated with whether the measures taken will avoid those effects:
   (c) the extent of monitoring that may be required in order to establish whether an adverse effect has occurred or whether any adverse effect has been appropriately remedied.
   (d) the likely scale of costs associated with remediating any adverse effects that may occur.

F Objectives

FO:15 The coastal marine area is protected from potential adverse effects associated with the use of genetic engineering and the release of genetically modified organisms to the environment through the adoption of a precautionary approach, including adaptive responses, to manage uncertainty and lack of information.