Australian Government
Department of Health
Office of the Gene Technology Regulator

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Policy on scope for variation of GMO licences

This document provides information on the scope of changes which may be made to a genetically modified organism (GMO) licence after the licence has been issued, and outlines the Gene Technology Regulator's (the Regulator's) approach to considering applications to vary conditions of a GMO licence.

The tables below provide guidance on the types of changes that are likely to be authorised as a variation, as well as on those that are likely to require a new GMO licence application.

Note that this document is a guide only and is based on the OGTR's interpretation of the relevant provisions of the *Gene Technology Act 2000* (the Act). No conclusions should be drawn about whether or not a particular application for variation will be approved, as each application will be assessed on its individual merits.

Legislative basis and OGTR assessment

Section 71 of the Act provides for the Regulator to vary the conditions of licences authorising dealings with GMOs, either on the Regulator's initiative or on application from the licence holder.

The Act specifies that the Regulator must not vary a licence:

- unless satisfied that any risks posed by the GMO dealings are able to be managed to protect people and the environment
- unless the risks posed by the varied licence are covered by the risk assessment and risk management plan (RARMP) prepared for the original licence application or by the RARMP of another application for a licence that has been issued
- if the original licence is for dealings not involving intentional release (DNIR, e.g. work in a laboratory or other contained facility) – to authorise environmental release of a GMO
- if the original licence is for dealings involving intentional release (DIR) under 'limited and controlled' conditions – unless the varied licence would also qualify as a 'limited and controlled' release.

In assessing variation applications, the Regulator will apply the risk assessment process used in current RARMPs, based on the OGTR's *Risk Analysis Framework*. If new risks associated with the variation are identified that were not identified in a relevant RARMP(i.e. the original RARMP or a RARMP for related GMOs/dealings), or if the level of a risk is increased, it is likely that a new licence application will be required.

Variation application

There is currently no application form for licence variations. However an application to vary a GMO licence must be made in writing (by email or letter). This should include the reason for the requested variation, details of the requested variation and a statement that the person making the request is authorised to do so on behalf of the licence holder (i.e. the organisation to which the licence was issued). If the proposed variation has been considered by the organisation's Institutional Biosafety Committee (IBC), IBC comments should also be included.

The timeframe for decision on a variation application is 90 working days. Any period when the Regulator is waiting for additional information from the applicant, and cannot proceed with the decision making process, does not count as part of this timeframe (i.e. 'the clock stops').

The Regulator will notify the licence holder of the decision in writing.

For more information or to discuss a proposed variation application please contact the OGTR.

Guidance on scope for variation of DIR licences (environmental releases – limited and controlled or commercial)

<table>
<tr><th>Changes likely to be accepted as a variation
The following types of changes are likely to be authorised by variation of an existing DIR licence, as they are unlikely to give rise to risks that are not covered in a relevant RARMP.</th><th>Changes unlikely to be accepted as a variation
The following types of changes are unlikely to be authorised by variation of an existing DIR licence as they may give rise to additional risks not covered in a relevant RARMP. A new DIR licence application may be needed.</th></tr>
<tr><td>Minor administrative changes such as updating organisation details, amending reporting conditions, adding or removing persons covered by the licence</td><td>Addition of the same GM trait to an unrelated species</td></tr>
<tr><td rowspan="2">Minor changes to management protocols such as:
- a short delay to harvest or cleaning of a trial site or destruction of GMOs
- change to standard management conditions which achieve the same outcomes as those required by the licence and described in a relevant RARMP (e.g. method of harvest or destruction)</td><td>Addition of GMOs containing a novel trait which was not assessed in the original RARMP</td></tr>
<tr><td rowspan="2">Major changes to management protocols relative to those required by the licence and described in a relevant RARMP (e.g. major reduction in containment measures, such as dispensing with pollen traps or isolation zones)</td></tr>
<tr><td>Addition of a new GMO dealing which presents similar risks to dealings proposed in the original application and which have been assessed in a relevant RARMP (e.g. adding import or storage)</td><td rowspan="2">Addition of a new dealing which presents different risks to dealings assessed in the original RARMP and which significantly changes the scope of the licence (e.g. adding growing to an import and distribution licence; adding vaccine manufacture to a clinical trial licence)</td></tr>
<tr><td>Minor to moderate increase in scale or duration relative to that assessed in the original RARMP, such as:
- increase in total area or number of sites in an already included local government area (LGA)
- addition of release sites in new LGA(s) in same geographic region as LGA(s) originally proposed
- one or two additional growing seasons/years, taking the total duration into consideration</td></tr>
<tr><td>For limited and controlled release licences only, additional GMOs of the same species containing transformation events derived from modifications with:
- the same gene(s) but with new promoters or other regulatory elements
- genes homologous to those assessed in the original RARMP (e.g. gene with identical function derived from a different source organism)
- genes of similar functionality (i.e. affecting the same pathway and producing same desired trait) as those assessed in the original RARMP
- genes producing the same trait as those assessed in the original RARMP and which have been assessed in a relevant RARMP</td><td rowspan="2">Major increase in scale or duration relative to that assessed in the original RARMP, such as:
- large increase in total area, number of sites or number of LGA(s)
- addition of release sites in a region not originally proposed or considered in a relevant RARMP (e.g. Southern WA→ Central Vic; Southern Qld → North Qld)
- large increase in duration, or long total duration</td></tr>
<tr><td>Combining traits from two or more plant GMOs which have been approved under separate licences by conventional breeding (commonly referred to as ‘stacking’) if one of the risk assessments for the parental GMOs considered the potential for stacking. See also separate paper Policy on licensing of GM plants with stacked genetic modifications)</td></tr>
</table>

Guidance on scope for variation of DNIR licences (work with GMOs in contained facilities)

Changes likely to be accepted as a variation The following types of changes are likely to be authorised by variation of an existing DNIR licence, as they are unlikely to give rise to risks that were not assessed in a relevant RARMP.	Changes unlikely to be accepted as a variation The following types of changes are unlikely to be authorised by variation of an existing DNIR licence as they may give rise to additional risks not assessed in a relevant RARMP. A new DNIR licence application may be needed.
Administrative changes such as updating organisation details	Addition of a GMO unrelated to GMOs assessed in the original RARMP
Extension of period of the licence	
Minor changes to management protocols (*e.g.* a new decontamination method or type of personal protective equipment [PPE] that is demonstrated to be equally or more effective than those originally specified)	Major changes to management protocols (*e.g.* use of a different type of equipment or decontamination method which presents a new exposure pathway with potential for harm) not considered in a RARMP in relation to similar GMO dealings
Changes to transport or storage conditions (*e.g.* add import or supply to another organisation; allow storage outside a certified facility)	
Removal of particular GMOs or dealings from the licence (e.g. if a GMO is no longer being dealt with by the licence holder; or if a dealings is now covered by an NLRD)	
Addition of a gene, host/vector system or parent organism that is related to a gene, host/vector system or parent organism in the original licence, and which does not change the category of dealings as defined in Schedule 3, Part 3 of the Gene Technology Regulations 2001	Addition of a new category of dealings as defined in Schedule 3, Part 3 of the current Gene Technology Regulations 2001 that has not been considered in a RARMP in relation to similar GMOs
Addition of a new category of dealings, as defined in Schedule 3,Part 3 of the Gene Technology Regulations 2001, which is within the broad scope of the project assessed in the original RARMP (e.g. addition of *in vivo* dealings with GMOs [3.1(d)] to a licence which only authorises *in vitro* dealings with those GMOs) and where any risks associated with *in vivo* dealings have been considered in a RARMP in relation to similar GMOs	
Addition of a certified facility of the same type and the same or higher physical containment (PC) level, or remove a certified facility	Addition of a certified facility of a different type (e.g. laboratory rather than animal house) or lower physical containment (PC) level not considered for similar GMO dealings in a relevant RARMP
For a clinical trial, addition of new trial sites, or a small to moderate increase in the number of trial participants	For a clinical trial, a significant change in scope (e.g. moving from a small phase 1 trial to a large phase 3 trial)