



Policy on scope for variation of GMO licences

Section 71 of the *Gene Technology Act 2000* (the Act) provides for the Gene Technology Regulator (the Regulator) to vary the conditions of licences authorising dealings with genetically modified organisms (GMOs), either on the Regulator's initiative or on application from the licence holder.

The tables below provide guidance to licence holders/applicants on the OGTR's policy for determining whether or not applications to extend the authority of GMO licences (for either intentional release or contained dealings) will be considered as variations or would warrant new GMO licence applications. The tables each identify three categories of proposed changes: those that are likely to be considered as variations; those likely to require a new licence application; and those that do not clearly fall into either of these categories and therefore require more specific consideration.

This policy is a guide only and is based on the OGTR's interpretation of the relevant provisions of the Act. The Regulator will not apply the policy inflexibly and will have regard to the merits of each individual application. The Regulator will apply the risk assessment process used in current risk assessment and risk management plans (RARMPs), based on the *Risk Analysis Framework*, to identify any additional risks that were not previously identified in the RARMP prepared for the licence. Licence applicants and licence holders who are concerned about the application of the policy in particular circumstances are encouraged to contact the Office for further advice and information. No conclusions can be drawn about whether a particular application for variation will be approved as this will be assessed on a case by case basis.

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

- for dealings not involving an intentional release of GMOs (DNIR) so as to authorise dealings involving intentional release (subsection 71(2));
- for dealings involving intentional release (DIR) under 'limited and controlled' conditions (s50A) unless the variation would also meet the conditions for a 'limited and controlled' release (subsection 71(2A)); or
- if satisfied that the RARMP prepared in respect of the original application for the licence did not cover the risks posed by the dealings to be authorised by the varied licence (section 71(2B)).

The Regulator must also be satisfied that any risks posed by the dealings authorised under the varied licence are able to be managed so as to protect the health and safety of people and the environment (section 71 (4)).

The Regulator may request further information from a licence holder in regard to a variation application, and may take any other appropriate action. For example the Regulator may consult the Gene Technology Technical Advisory Committee or a local council where an intentional release is proposed to occur.

Regulation 11A of the Gene Technology Regulations provides that the Regulator must vary or refuse to vary the licence within 90 days of receiving a variation application. 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 WHEN AN APPLICATION TO EXTEND THE AUTHORITY GRANTED UNDER A GMO LICENCE WILL BE CONSIDERED AS A VARIATION

Categories of proposed changes to licences authorising Dealings involving Intentional Release of a GMO into the environment (DIR licences)

Unlikely to give rise to additional risks, and therefore likely to be considered as a variation to a licence	Case specific	May give rise to additional risks, and therefore likely to require a new DIR application
<ul style="list-style-type: none"> • For limited and controlled field trials only, additional GMOs of the same species containing transformation events derived from modifications with: <ul style="list-style-type: none"> - the same constructs; or - different constructs that contain the same expression cassettes (provided that no new combination of expression cassettes is generated in any new GMO) 	<ul style="list-style-type: none"> • For limited and controlled field trials only, additional GMOs of the same species containing transformation events derived from modifications with different constructs which have: <ul style="list-style-type: none"> - the same genetic elements as in constructs previously approved under same licence - new regulatory genetic elements (<i>eg</i> promoters, terminators) with similar properties (<i>eg</i> expression profile) to those in constructs previously approved under same licence - new non-coding intron sequences in addition to previously approved genetic elements, leading to similar expression of introduced genes 	<ul style="list-style-type: none"> • For commercial release licences only, additional GM event/construct
<ul style="list-style-type: none"> • Minor changes to management protocols (<i>eg</i> change to harvest or disposal methods) 	<ul style="list-style-type: none"> • Change to a standard management condition (<i>eg</i> alteration of isolation zone to allow research, or to another management method) 	<ul style="list-style-type: none"> • Major change to management protocols (<i>eg</i> major reduction in containment measures, such as dispensing with of pollen traps or isolation zones)
<ul style="list-style-type: none"> • Minor increase of trial size 	<ul style="list-style-type: none"> • Moderate increase in trial site size or additional site 	<ul style="list-style-type: none"> • Major increase in scale (<i>ie</i> total area or number of sites)
<ul style="list-style-type: none"> • New project supervisor 	<ul style="list-style-type: none"> • Addition of sites in new local government areas 	<ul style="list-style-type: none"> • New growing region (<i>eg</i> Southern WA → Central Vic, southern Qld → North Qld)
<ul style="list-style-type: none"> • Add persons to be covered by the licence 	<ul style="list-style-type: none"> • Additional season because of exceptional circumstances (<i>eg</i> replacement season due to drought) 	<ul style="list-style-type: none"> • Transfer of GM trait to different species using conventional breeding
	<ul style="list-style-type: none"> • Stacking of 2 or more GMOs using conventional breeding, which have only been previously approved individually (see also separate paper '<i>Policy on licensing of GM plants with stacked genetic modifications</i>') 	
	<ul style="list-style-type: none"> • Add a new dealing (<i>eg</i> storage or transport) 	

Categories of proposed changes to licences authorising Dealings Not involving Intentional Release of a GMO (DNIR licences)

Unlikely to give rise to additional risks, and therefore likely to be considered as a variation to a licence	Case specific	May give rise to additional risks, and therefore likely to require a new DNIR application
<ul style="list-style-type: none"> • Addition of related gene or related parent organism 	<ul style="list-style-type: none"> • Addition of new genes unrelated to original introduced genes but within the purpose described in the original licence application 	<ul style="list-style-type: none"> • Addition of a GMO unrelated to original dealing
<ul style="list-style-type: none"> • Changes to transport of GMOs (including import) 	<ul style="list-style-type: none"> • Add a new dealing for a related purpose to that of the original dealings 	
<ul style="list-style-type: none"> • Minor changes to management protocols (<i>eg</i> change of decontamination method) 		
<ul style="list-style-type: none"> • Change facility (at same type and level or greater) 		
<ul style="list-style-type: none"> • Extension of period of the licence 		
<ul style="list-style-type: none"> • New project supervisor 		