



Australian Government

Department of Health and Ageing

Office of the Gene Technology Regulator

POLICY ON LICENSING OF PLANT GMOs IN WHICH DIFFERENT GENETIC MODIFICATIONS HAVE BEEN COMBINED (OR ‘STACKED’) BY CONVENTIONAL BREEDING

This document provides guidance to licence holders/applicants on the OGTR’s policy in relation to licensing for commercial release¹ of genetically modified (GM) plants produced by conventional breeding (‘stacking’) between different, separately licensed, plant genetically modified organisms (GMOs). The following questions are addressed:

- Is specific approval required for a stacked GMO?
- Can stacked GMOs be licensed by variation of existing licences or only through new licence applications?
- What level and type of data are required in support a licence application, or variation request, relating to a stacked GMO?

OGTR policy on these three questions, respectively, is that:

- Dealings involving intentional release for any GMO, including one derived by conventional breeding between different GMOs, must be licensed.

For a commercial release, this requirement may be met through:

- (i) explicit listing of a particular stacked GMO in a GMO licence (through the licence application process or licence variation); or
- (ii) inclusion of specific conditions in the licences for the parent GMOs to encompass stacking between genetic modifications listed in separate GMO licences. In this case, dealings with particular stacked GM plants would not require separate licensing but would be subject to, and need to comply with, the conditions of licences for both parent GMOs. To date such conditions have not been included in GMO licences.

The Regulators’ decisions on authorising a particular stacked GMO, through a specific licence or inclusion of licence conditions to encompass stacking, will be made based on the relevant case-by-case Risk Assessment and Risk Management Plans (RARMPs);

- variation requests to allow stacking between genetic modifications listed in separate GMO licences will be assessed by the Regulator on a case-by-case basis.

As described in the current [policy document on variation of GMO licences](#), all variation requests will be assessed using the hazard identification process used in current RARMPs, based on the [Risk Analysis Framework](#).

If additional risks are identified a new application is likely to be required; and

¹ The term commercial release has no status under the *Gene Technology Act 2000* but is conventionally used to describe a licence for which a risk assessment and risk management plan has determined that no containment conditions are required. As a consequence commercial licences contain limited or no restrictions on where the GMO may be grown or by whom.

- Sufficient data must be available to enable the Regulator to assess if a particular stacked GMO poses risks which require specific treatment in licence conditions. This information may be in a new application or in previous applications or RARMPs (and not restricted by third party Confidential Commercial Information (CCI)). Information on the potential for interaction of the GM traits combined by stacking will be required for the Regulators' assessment of a stacked GMO. The specific data required will depend on this potential.

Applicants who are considering the release of GM plants with stacked genetic modifications should consult the OGTR about what information should be included in their application or variation request.

Applicants are strongly encouraged to consider potential stacking, and the need for any associated data, when preparing an application for commercial release of any GM plant.

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