National Gene Technology Scheme
An Australian, State and Territory Governments Collaboration

AUTHORISATION PATHWAYS

When the National Gene Technology Scheme commenced in 2000, the main applications of gene technology were in laboratory research and crop plants. Technology use and understanding of risk has since changed, and the Scheme needs to change to keep up.

New Authorisation Pathways

Nearly 25 years of regulatory experience can be harnessed to make the Scheme more efficient. New authorisation pathways are proposed to ensure dealings with genetically modified organisms (GMOs) are regulated based on the level of risk they pose.

GMO Permits

GMO permits will be added as an alternative to licences for authorisation of some activities that have been licenced before, e.g. some GM plant field trials. The risk management conditions for permits will be standardised, allowing a short assessment timeframe of only 30 business days.

Notifiable Dealings

Currently, only contained activities with GMOs can be done as notifiable low risk dealings (NLRDs). The NLRD pathway will be replaced with notifiable dealings, which will be expanded to include other low risk dealings where risks can be managed by standard conditions.

These dealings might include lower risk dealings done in containment in a certified facility or approved by the Gene Technology Regulator (the Regulator), or dealings that are already regulated by another authority. Notification to the Regulator will maintain awareness of these activities and, for some activities, notification will need to occur before they commence.

Streamlining licences

GMO licence application assessments will be streamlined where regulatory experience shows that's appropriate. All licence applications will continue to receive case-by-case assessment and licences will only be issued if risks can be managed.

Consultations required and timeframes for decisions currently depend on whether the proposed activities involve intentional release of GMOs into the environment. However, this does not apply well to therapeutic GMOs and can result in misplaced regulatory effort. To improve clarity for therapeutic applications, this separation will be removed.

Public consultations for licence applications will focus attention on GMOs that are novel, unless they involve therapeutic GMOs or activities in containment facilities. Consultation will be used more efficiently but will still gather information to support the Regulator's decisions on licence applications. Currently, similar consultations lengthen assessment timeframes without obtaining new information.

Improved responsiveness

To support the assessment of dealings with GMOs based on their level of risk and enable the legislation to keep up with gene technology developments, the structure of the legislation will be changed.

The Gene Technology Regulations will continue to describe the groups of dealings in lower authorisation pathways, but these will be described more generally.

The Regulator will be empowered to make rules to specify the dealings in each authorisation pathway within the limits set by regulations. The Regulator will also make rules setting conditions for notifiable dealings and permits. This will make the Scheme more responsive because rules can be changed more readily than regulations.

What stays the same?

The current authorisation pathways for contained activities, such as laboratory research, already work well to match the level of regulation to the level of risk. With some renaming, these pathways will be maintained. Non-notifiable dealings will replace the current 'exempt dealings' category.

Emergency Dealing Determinations and the GMO Register will continue.

Want more detail?

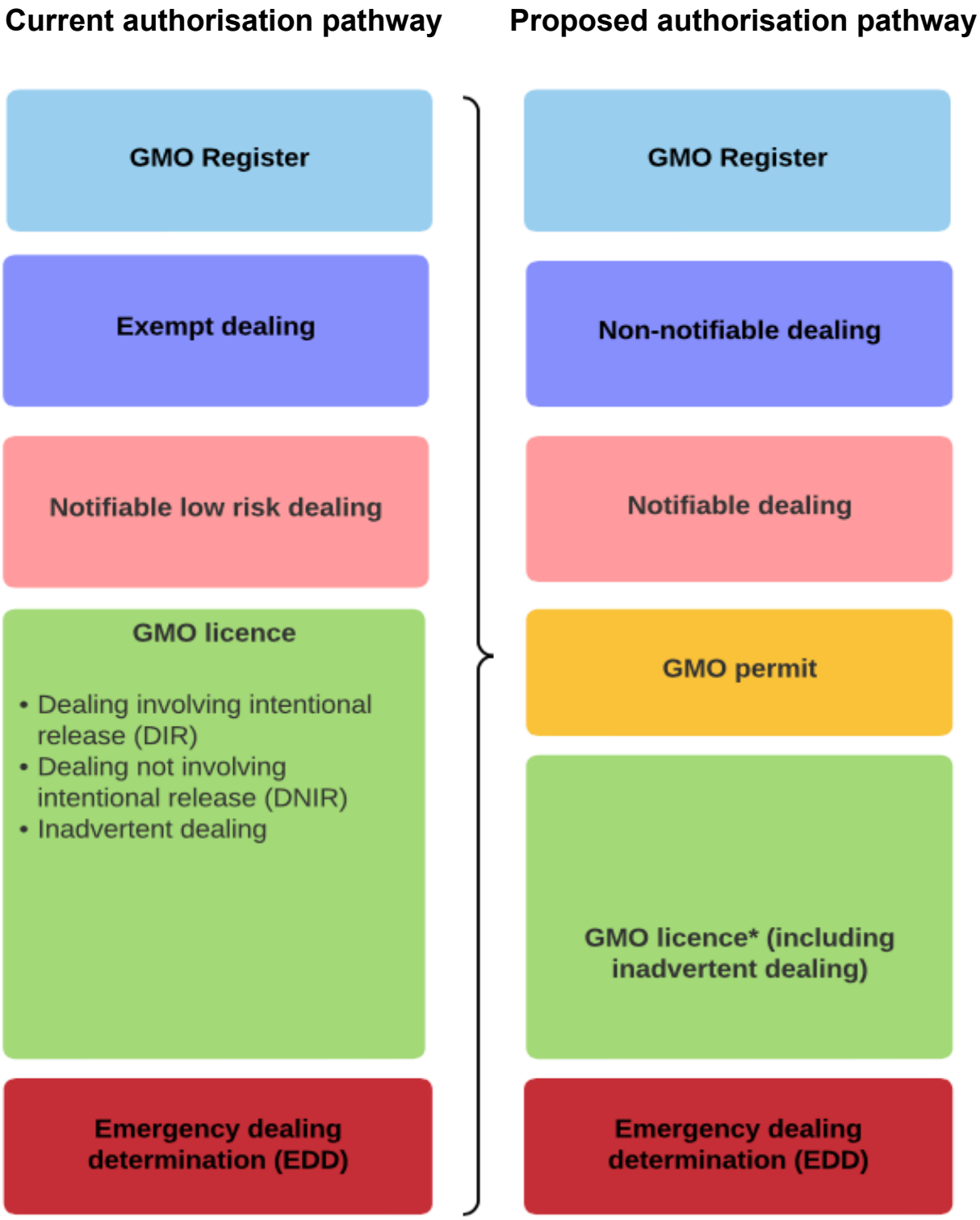
You can review the proposed changes to the authorisation pathways and resulting structural changes in the draft Gene Technology Amendment Bill.

The policy rationale for all the changes has been outlined in the Consultation Paper: Draft Gene Technology Amendment Bill.

Contact us for more information on this consultation:

gene.technology.implementation@health.gov.au

Proposed New Authorisation Pathways



*Note that some dealings covered by a GMO licence currently may fall into lower authorisation pathways under the new regulatory approach (e.g. GMO permit or notifiable dealing).