



## Who needs to apply to import or use (deal with) a GMO?



Anyone who wants to import or use a genetically modified organism (GMO) needs permission. That includes farmers, importers, schools, researchers, and members of the public. The following outlines common ways in which GMOs are used and authorised in Australia.

### In agriculture

If you plan to trial or farm a GM crop, this is defined as an 'environmental release' and is one of the most scrutinised uses of GMOs.

If you plan to import stockfeed that could contain viable GM grain then you will also need approval. If the GM seeds will be treated once they arrive in Australia so they can't germinate then a less complex process may be available.

### In research

Many uses of GMOs by researchers pose so little risk that they have been classified as **exempt** and can usually proceed without further approval, provided you take steps to ensure the GMOs are not released into the environment.

Other research which may pose a low risk (less than or equal to that of the unmodified organism) may qualify as **notifiable low risk** provided it is conducted in certified containment facilities, assessed by a biosafety committee in your organisation, and the OGTR is notified.

All other research with GMOs will require a licence from the Regulator.

Research that involves intentional release, such as a live vaccine trial is defined as 'environmental release' and is one of the most scrutinised uses of GMOs.



If you act as a supplier to a research institute you will also need approval for any activities you undertake with GMOs.

### In schools

Most school use of education kits will be **exempt** as long as they are used in accordance with the manufacturer's instructions and the GMOs are not released into the environment. Read our [GM kits in schools](#) factsheet for more information.

### Biohacking and other personal use

If you wish to conduct your own GMO research, you are bound by the same rules as all other users.

If you wish to import GM organisms, such as 'glow in the dark' fish or plants, you need permission from the quarantine authorities and from the Regulator. No one currently has permission to import 'glow in the dark' fish or plants for personal use.

### What the legislation says

All of the activities listed above are known in the gene technology legislation as 'dealings'. Dealings with a GMO that may require authorisation include experimentation, breeding, propagation, manufacture, culture, import, transport and disposal. Without authorisation these types of activities could be illegal and may attract criminal penalties.



It is illegal to carry out any dealings with GMOs, unless:

- what you are doing is classed as exempt, OR
- what you are doing is classed as notifiable, OR
- you are licensed by the Regulator, OR
- the materials are already included on the GMO Register (currently there is one entry, a blue carnation), OR
- the relevant government Minister has issued a temporary approval for a GMO (such as a vaccine) to respond to a public health or environmental emergency.

Each of these different categories is explained in this factsheet.

For most categories before you are authorised to use GMOs, you will usually need to show that the GMOs will be contained in a physical containment facility such as a laboratory, animal room or glasshouse. Your physical containment facility must be certified by the Regulator.





The different classifications of GMO dealing are:

### Exempt

Exempt dealings use basic molecular biology techniques with GM microorganisms that have a long history of safe use in schools, university teaching laboratories and research. No OGTR approval or notification is required but the GMOs must not be released into the environment. The legislation includes scientific descriptions of GMO work which is exempt.

### Notifiable low risk dealings (NLRD)

These dealings pose minimal risk to health and safety of people and the environment provided they meet specified conditions. The work must be conducted in certified containment facilities and assessed by an Institutional Biosafety Committee (IBC) before work commences. NLRDs must be reported to the OGTR annually.

### Dealings not involving intentional release (DNIR)

This typically covers the use of GMOs to study human or animal diseases and the development of treatments or cures. The GMOs used may pose a higher risk than exempt or notifiable dealings. The work must be licenced by the OGTR and is usually conducted in certified containment facilities. The work is subject to monitoring and adverse events must be reported to the OGTR. In 2015-16, 55% of this category of licence were issued to universities, 15% to hospitals and government research institutions, and 30% to private companies.



Assessment of DINR applications by the Gene Technology Regulator includes preparation of a risk assessment and risk management plan (RARMP) based on current scientific knowledge.

### Dealings involving intentional releases (DIR)

Intentional releases into the environment are the most highly scrutinised category of GMO dealings. Any intentional release must be assessed and licensed by the Regulator and will require a rigorous scientific assessment aimed at identifying potential risks to human health and the environment. This will involve consultation with the Gene Technology Technical Advisory Committee, the Minister for Environment, other Commonwealth regulatory agencies, the states and territories, local councils and the public, including by advertising in newspapers.

Risk assessments and risk management plans (RARMPs) for intentional releases are published on the [OGTR website](#). Over 85 per cent of current licences in this category are for field trials of GM plants, and the licences include conditions to limit the release of the GMO and control the spread and persistence of the GMO in the environment. The remaining licences in this category are for clinical trials of GMOs developed for prevention or treatment of human disease, or for commercial release of GM plants or live GM vaccines.

### Listed on the GMO Register

GMOs on the GMO Register can be used without a licence. To date, the only entry on the GMO Register is carnations modified to have blue/purple



flowers – first commercially released in 1995.

### Emergency dealings

During a public health or environmental emergency, the Minister may temporarily approve a GMO. This has only happened once when the Minister authorised use of a GM vaccine against equine influenza from September 2007 to September 2008. This category is only authorised once the Minister is satisfied that risks to the health and safety of people and the environment can be managed.

A separate, simpler, category of licence is available if you **inadvertently** come in to possession of something you think may be a GMO to authorise testing and safe disposal of the GMO.

#### Related factsheets

[Applying for an intentional release licence](#)

[Unintentional release of GMOs](#)

[Factsheets for further reading](#)

[Genetically modified organisms in Australia](#)

[Genetically modified \(GM\) crops in Australia](#)

[How are genetically modified organisms \(GMOs\) regulated in Australia?](#)

[The full legislation \(\*Gene Technology Act 2000\*\) is available on our website.](#)

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