# CARTAGENA PROTOCOL ON BIOSAFETY

# NOTIFICATION 2016-009

# SUBMISSION OF INFORMATION REQUESTED IN DECISION ON CONTAINED USE (ARTICLE 6)

# AUSTRALIAN COMMENTS, APRIL 2016

Australia is responding to the invitation to Parties to the Cartagena Protocol (the Protocol) and other Governments to submit information, tools, practical experience and guidance related to existing mechanisms and requirements regarding the contained use of Living Modified Organisms (LMOs or GMOs), including any specific requirement relating to the type and level of containment. Australia thanks the Secretariat for the opportunity to provide input on this issue.

The Australian Government supports science-based decision making and recognises that innovations in agricultural biotechnology can help support global efforts to meet challenges such as food security. Australia has a rigorous framework for managing and regulating genetically modified (GM) crops and GM food for the protection of human health and the environment. This framework is supported by legislation and includes the *Gene Technology Act 2000[[1]](#footnote-1)*, the Australia New Zealand Food Standards Code[[2]](#footnote-2), the *Biosecurity Act 2015*[[3]](#footnote-3), the *Imported Food Control Act 1992*[[4]](#footnote-4) and the *Environment Protection and Biodiversity Conservation Act 1999*[[5]](#footnote-5)(the EPBC Act).

As well as managing and regulating food and crop GMOs, Australia also regulates all GMOs involved in research (such as health, medical, veterinary and agricultural) as well as the commercialisation of any resulting GMO products. These end products may also be regulated under the *Industrial Chemicals (Notification and Assessment) Act 1989*[[6]](#footnote-6), *Agricultural and Veterinary Chemicals Code Act 1994*[[7]](#footnote-7) and the *Therapeutic Goods Act 1989*[[8]](#footnote-8) depending on their intended end use.

The biosafety contained use field is a well-established discipline in existence for more than 30 years. Australia is of the view that the principles of containment that apply to non-transgenic human, animal and plant pathogens pose similar or greater risks (e.g. biosecurity) to LMOs and are transferable to different types of organisms, including LMOs. Therefore, Australia considers separate guidance for LMOs under the Cartagena Protocol for Biosafety as unnecessary, and may create conflicting requirements for those countries with national regulations already in place. Additionally, there is extensive international, regional and national/regional guidance and regulations for the handling, transport, packaging and identification of biological organisms under contained use, including LMOs. Submissions to this call for information will be a useful mechanism for countries to share their existing guidance and regulatory materials.

## Gene Technology Regulation

In Australia, all dealings with genetically modified organisms (GMOs) (equivalent to living modified organisms (LMOs)) including the containment requirements for the transport, storage and disposal of commercial GM crops and vaccines, field trials and other research, are prohibited unless authorised by the Gene Technology Regulator (the Regulator) under the *Gene Technology Act 2000* (the GT Act). The object of the GT Act is ‘*to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs*’. Australia’s GMO regulatory system is administered by the Gene Technology Regulator (the Regulator), supported by the Office of the Gene Technology Regulator (OGTR).

Sound science and rigorous risk analysis underpin the Regulator’s decisions under the GT Act, and are central to the regulatory activities undertaken by the Regulator. The staff of the OGTR support the Regulator by providing scientific and technical advice and conducting risk analyses. Each licence application is subject to a comprehensive, science-based, case-by-case analysis process which includes public consultation. Risk analysis is undertaken in accordance with the Regulator’s *Risk Analysis Framework*[[9]](#footnote-9).

The GT Act requires that dealings with GMOs need authorisation as:

* a licensed dealing;
* a Notifiable Low Risk Dealing;
* an Exempt dealing;
* included on the GMO Register; or
* specified in an Emergency Dealing Determination.

The type of authorisation required for each type of dealing is based on the level of risk that the dealings may pose to people and the environment. All work with GMOs which involves an intentional release into the environment requires a licence from the Regulator. Contained dealings may be conducted under licence; as a Notifiable Low Risk Dealing (NLRD); or as an exempt dealing. Schedules 2 and 3 of the Gene Technology Regulations 2001[[10]](#footnote-10) (the GT Regulations) set out the kinds of contained dealings which are suitable to be carried out as exempt or NLRDs, and those which require a licence[[11]](#footnote-11). These classifications have been determined through a combination of science based risk assessment and experience gained from a history of use within the science research community. They have also been informed by other risk based standards for the classification and containment of organisms such as the Australia New Zealand Standard AS/NZS 2242.3:2010 *Safety in laboratories - Microbiological safety and containment*[[12]](#footnote-12) and related international documents such as the World Health Organisation’s *Laboratory biosafety manual*[[13]](#footnote-13) and the Centers for Disease Control and Prevention’s *Biosafety in Microbiological and Biomedical Laboratories* (BMBL)[[14]](#footnote-14). Classification and containment of other organisms have also been informed by experience and practice for their non-modified counterparts.

For the most part, GMOs that are microorganisms are required to be kept at the same containment level as the parent organism (as specified in AS/NZS 2242.3:201012). However, the Regulator can increase or decrease the containment level depending on the effect of the modifications on the properties of the organism. This would only occur if a science based risk assessment in accordance with the Regulator’s *Risk Analysis Framework* determined that a change in containment level was warranted. This can be done through a licence or through inclusion in the GT Regulations.

Most genetically modified animals (including invertebrates) and plants are required to be kept in physical containment (PC) level 2 facilities unless infected with microorganisms requiring higher levels of containment. However, the GT Regulations allow that some GM laboratory mice, rats, rabbits and guinea pigs can be held at the lower classification PC1, depending on the nature of the genetic modification.

Authorisations under the GT Act are typically issued to an organisation rather than an individual. Accredited organisations[[15]](#footnote-15) are required to have access to an Institutional Biosafety Committee (IBC) which includes members with a breadth of relevant expertise both to understand and analyse risks associated with the particular dealings and to provide expert commentary on those risks including, where relevant, any containment measures for GMOs involved in the dealings and the classification of the dealings with the GMO in accordance with the GT Regulations.

Operation of Australia’s regulatory framework for GMOs is supported by local IBC’s. Under the GT Act IBC’s are responsible for assessing whether proposed work with GMOs meet the requirements of an exempt dealing, an NLRD or require a licence, and for screening licence applications prior to submission to the Regulator. As well as providing training in general laboratory safety IBC’s may also provide GMO specific biosafety training. IBC’s may also provide institutional level oversight of work with GMOs. This takes account of the lower risk level of much research work.

## Facility Certification by the Gene Technology Regulator

Contained work in Australia is underpinned by certification of facilities and practices. In Australia, certain work with GMOs must only be undertaken in contained facilities that are certified by the Regulator. The GT Act allows the Regulator to certify PC facilities to ensure that appropriate standards are met for containment of GMOs and that trained and competent staff are carrying out procedures and practices. Under the GT Act, the Regulator has issued guidelines specifying the requirements for certification of each type of facility (laboratory, plant and animal, etc) to PC levels 1, 2, 3 or 4, which must be met before a facility can be certified.

PC facilities are classified according to the level of stringency of measures for containing GMOs. The classifications relate to the structural integrity of buildings and equipment used as well as to the handling practices employed by those working in the facility. PC level 1 (PC1) facilities are used to contain organisms posing the lowest risk to human health and the environment. PC level 4 (PC4) facilities provide the most secure and stringent containment conditions12.

The facility holder must ensure all certified facilities are inspected against the Regulator’s certification guidelines by a suitably qualified person before certification and annually thereafter (except those certified as a PC1 facility). Additionally, facilities certified to PC3 or PC4 are inspected by OGTR staff prior to certification and at least once every three years thereafter. The OGTR’s Monitoring and Compliance section also routinely undertakes inspections of facilities to assess compliance with certification conditions.

The Regulator’s guidelines for the certification of facilities and supporting explanatory information can be found on the Regulator’s website[[16]](#footnote-16).

These guidelines are outcome focused in nature in that they specify particular characteristics of facilities and the required containment outcomes, then allow the facility holder to decide how to meet those requirements. This allows for flexibility; with facility holders choosing building materials, equipment, chemicals and procedures which best fit their needs, while still meeting the Regulator’s requirements. However, facility holders must be able to explain how the facility meets each of the requirements and provide evidence of efficacy as required.

## Movement of GMOs

The facility guidelines are supported by the Regulator’s *Guidelines for the Transport, Storage and Disposal of GMOs*[[17]](#footnote-17) (the TSDs) which specify how GMOs are to be transported, stored or disposed of while within Australia. This includes packaging and labelling requirements for GMOs which apply from the moment they are imported into Australia; for all movement in Australia; and, for GMOs being exported, up to the point of departure from Australia. These guidelines are consistent with the International Air Transport Association (IATA) Dangerous Goods Regulations[[18]](#footnote-18) packaging and labelling requirements for GMOs which are infectious substances.

Australia notes that the Cartagena Protocol does not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import. Australia’s regulations include conditions which must be met to import biological, plant or animal materials (including GMOs). Many goods also require an import permit for which applications are submitted to the Australian Government Department of Agriculture and Water Resources (DAWR) for assessment.

Import is a dealing regulated under the GT Act and importing organisations are required to have the appropriate approvals in place prior to importing the GMO. Unless alternative approvals have been given, all GMOs entering Australia are required to be packaged and labelled in accordance with the TSD’s. Live plant or animal specimens, or reproductive material, may only be imported if they appear on the live import list[[19]](#footnote-19) under the EPBC Act and may require a live import permit under the EPBC Act. Import of viable GMOs must also comply with the requirements of the *Biosecurity Act 2015*. The Regulator works closely with existing customs arrangements to ensure the import of GMOs is managed appropriately.

Export is not a regulated dealing under the GT Act. However, GMOs transported to the border must be transported in accordance with the TSDs, this includes the outermost packaging being labelled as containing GMOs. Packaging for export would also be expected to comply with the IATA Dangerous Goods Regulations. Export of viable GMOs must also comply with the requirements of the *Biosecurity Act* 2015. Statements on the GM status of shipments of plant products can be provided if required by the receiving country.

## Monitoring for compliance

The Monitoring and Compliance Section supports the Regulator by undertaking monitoring, audits, inspections and investigations under the auspices of the GT Act. Monitoring and compliance activities also comprise risk assessment and management, reviews of an organisation's activities, and reporting.

The aim of the OGTR monitoring and compliance activities is to ensure that dealings with GMOs comply with regulatory requirements. These requirements are designed to meet the object of the GT Act.

The GT Act allows OGTR inspectors to enter a release site or certified facility at any time. Typically this would be an announced visit, in that the responsible person/organisation would be informed of the inspector’s intention to visit and a time agreed upon. However the GT Act also allows for unannounced visits.

Information on Monitoring and Compliance under the GT Act, including the Regulator’s *Compliance and Enforcement Policy*, *Monitoring and Compliance Framework* and a variety of related protocols, are also available on the Regulator’s website[[20]](#footnote-20).

## Quarantine Approved Premises

DAWR also has a role in the containment of LMOs where the department has identified an organism as being a harmful pest or disease of quarantine concern. These LMOs would require an import permit, and the permit would prescribe the type (and location) of facility where the organism can be held. DAWR approves Quarantine Approved Premises (QAPs) as places where post-entry quarantine requirements may be carried out on a wide range of microorganisms, plants, animals and plant and animal products.

QAP’s are assessed against specific criteria which can be found on the DAWR website[[21]](#footnote-21) and include the same four containment levels as for OGTR facilities (known as QC1-QC4), but cover a wider range of facility types. As part of the approval process facilities are initially assessed by approved engineer assessors[[22]](#footnote-22) against specified design and construction aspects of the Australian and New Zealand Standards, prior to auditing by DAWR audit staff. DAWRs Biosecurity Officers routinely audit all QAPs, with audit frequency dependent on the compliance history of the facility holder[[23]](#footnote-23).

## Australian Standards

All new facilities for conducting research with microorganisms are expected to be designed and constructed in accordance with the relevant Australian Standards including AS/NZS 2982:2010 *Laboratory design and construction*[[24]](#footnote-24) and AS/NZS 2242.3:2010 *Safety in laboratories - Microbiological safety and containment*[[25]](#footnote-25). The later standard contains detailed requirements for work with microorganisms including a discussion on containment levels and the risk grouping of microorganisms. AS/NZS 2242.3:2010 is currently being amended and it is expected that a revised version will be published this year.

Both the Regulator and DAWR have representatives on the committee responsible for creating and maintaining the standard AS/NZS 2242.3:2010.

1. <https://www.legislation.gov.au/Details/C2016C00189> [↑](#footnote-ref-1)
2. <http://www.foodstandards.gov.au/code/Pages/default.aspx> [↑](#footnote-ref-2)
3. <https://www.legislation.gov.au/Details/C2015A00061> [↑](#footnote-ref-3)
4. <https://www.legislation.gov.au/Details/C2016C00291> [↑](#footnote-ref-4)
5. <https://www.legislation.gov.au/Details/C2016C00322> [↑](#footnote-ref-5)
6. <https://www.legislation.gov.au/Details/C2016C00273> [↑](#footnote-ref-6)
7. <https://www.legislation.gov.au/Details/C2016C00255> [↑](#footnote-ref-7)
8. <https://www.legislation.gov.au/Details/C2016C00269> [↑](#footnote-ref-8)
9. <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/risk-analysis-framework> [↑](#footnote-ref-9)
10. <https://www.legislation.gov.au/Details/F2011C00732> [↑](#footnote-ref-10)
11. <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/apps-for-gmo> [↑](#footnote-ref-11)
12. Information on facility classification levels and the risk grouping of microorganisms can be found in the Australia New Zealand Standard AS/NZS 2242.3:2010 *Safety in laboratories - Microbiological safety and containment* (which can be purchased from <http://infostore.saiglobal.com/store/Details.aspx?ProductID=1430097>). [↑](#footnote-ref-12)
13. <http://www.who.int/ihr/publications/WHO_CDS_CSR_LYO_2004_11/en/> [↑](#footnote-ref-13)
14. <http://www.cdc.gov/biosafety/publications/bmbl5/> [↑](#footnote-ref-14)
15. <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/accreditation-process> [↑](#footnote-ref-15)
16. PC1 - <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/cert-pc1-1>

PC2 – <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/cert-pc2-1>

PC3 – <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/cert-pc3-1>

PC4 - <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/cert-pc4-1>

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/FacilTypesv1-2-htm> [↑](#footnote-ref-16)
17. <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/transport-guide-1> [↑](#footnote-ref-17)
18. <http://www.iata.org/publications/dgr/pages/index.aspx> [↑](#footnote-ref-18)
19. <http://www.environment.gov.au/biodiversity/wildlife-trade/live/import-list> [↑](#footnote-ref-19)
20. <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/mc-protocols-1> [↑](#footnote-ref-20)
21. <http://www.agriculture.gov.au/import/arrival/arrangements/qap/qapcriteria>

<http://www.agriculture.gov.au/import/arrival/arrangements/qap/qap-general-policies> [↑](#footnote-ref-21)
22. <http://www.agriculture.gov.au/import/arrival/arrangements/qap/third-party-assessors>

<http://www.agriculture.gov.au/import/arrival/arrangements/qap/engineer-assessors> [↑](#footnote-ref-22)
23. <http://www.agriculture.gov.au/import/arrival/arrangements/qap/qap-general-policies#monitoring-and-assessing-compliance> [↑](#footnote-ref-23)
24. which can be purchased from <http://infostore.saiglobal.com/store/Details.aspx?productID=1391032> [↑](#footnote-ref-24)
25. which can be purchased from <http://infostore.saiglobal.com/store/Details.aspx?ProductID=1430097> [↑](#footnote-ref-25)