CARTAGENA PROTOCOL ON BIOSAFETY

CBD NOTIFICATION 2017-087

SUBMISSION OF INFORMATION REQUESTED IN DECISION VIII/17 ON CONTAINED USE (ARTICLE 6)

AUSTRALIAN COMMENTS, JANUARY 2018

Australia is responding to the invitation to Parties to the Cartagena Protocol (the Protocol) and other Governments to submit practical guidance on specific measures for contained use of living modified organisms (LMOs) that effectively limit their contact with, and impact on, the external environment.

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 in place 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 including:
the *Gene Technology Act 2000*[1](GT Act), Australia New Zealand Food Standards Code[2], *Biosecurity Act 2015*[3], *National Health Security Act 2007* (NHS Act)[4], *Imported Food Control Act 1992*[5] and *Environment Protection and Biodiversity Conservation Act 1999*[6] (EPBC Act).

As well as managing and regulating food and crop LMOs, Australia also regulates all LMOs involved in research (such as health, medical, veterinary and agricultural) as well as the commercialisation of any resulting LMO products. These end products may also be regulated under the *Industrial Chemicals (Notification and Assessment) Act 1989*[7], *Agricultural and Veterinary Chemicals Code Act 1994*[8] and *Therapeutic Goods Act 1989*[9] depending on their intended end use.

The biosafety field is a well-established discipline which has been in existence for more than 30 years and has considerable experience in the containment of organisms. Australia is of the view that as a general principle, unmodified human, animal and plant pathogens pose a similar or greater risk to that of LMOs and that the principles of containment that apply to pathogens are transferable to different types of organisms, including LMOs. However, Australia has in place mechanisms through its gene technology regulation to identify where LMOs may pose and greater risk and subsequently impose more stringent containment requirements. Therefore, Australia considers separate guidance for LMOs under the

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[1] https://www.legislation.gov.au/Latest/C2016C00189

[2] http://www.foodstandards.gov.au/code/Pages/default.aspx

[3] https://www.legislation.gov.au/Latest/C2015A00061

[4] https://www.legislation.gov.au/Latest/C2016C00847

[5] https://www.legislation.gov.au/Latest/C2016C00291

[6] https://www.legislation.gov.au/Latest/C2016C00322

[7] https://www.legislation.gov.au/Latest/C2016C00273

[8] https://www.legislation.gov.au/Latest/C2016C00255

[9] https://www.legislation.gov.au/Latest/C2016C00269

Cartagena Protocol for Biosafety as unnecessary; and indeed considers its introduction may create conflicting requirements for those countries, such as Australia, with appropriate national regulations already in place.

Additionally, we note the extensive international, regional and national guidance on and regulation of the handling, transport, packaging and identification of organisms which is already in place. Much of this guidance could/would also apply to LMOs destined for contained use.

Submissions to this call for practical guidance on specific measures for contained use of LMOs that effectively limit their contact with, and impact on, the external environment will, however, serve as a useful mechanism for countries to share their existing guidance and regulatory materials to stimulate international convergence and to avoid duplication of effort.

Gene Technology Regulation in Australia

In Australia, all dealings[10] with genetically modified organisms (GMOs[11]) including commercial GM crops and vaccines, field trials and other research, are prohibited unless authorised by the Gene Technology Regulator (the Regulator) under the GT Act. Australia's GMO regulatory system is administered by the Regulator, supported by the Office of the Gene Technology Regulator (OGTR).

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*'.

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 officers of the OGTR support the Regulator by providing scientific and technical advice and undertaking risk analyses of GMOs. Each application for a licence to work with a GMO 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*[12]. Sustaining

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

- a Licensed dealing;
- a Notifiable Low Risk Dealing (NLRD);
- 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 the dealing 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 an NLRD; or as an Exempt dealing. Schedules 2

[10] 'Dealing' in relation to a GMO is defined in the GT Act and includes making and sustaining a GMO, conducting experiments with a GMO, using the GMO to make other things, as well as importing, transporting and disposing of the GMO.

[11] equivalent to LMOs

[12] http://www.ogtr.gov.au/internet/ogtr/publishing nsf/Content/risk-analysis-framework

and 3 of the Gene Technology Regulations 2001[13] (the GT Regulations) set out the kinds of contained dealings which are suitable to be carried out as Exempt dealings or NLRDs, and those which require a licence[14]. These classifications have been determined through a combination of science-based risk assessment and experience gained from a history of use within the scientific research community. They have also been informed by other risk based standards for the classification and containment of organisms including: the Australia New Zealand Standard AS/NZS 2242.3:2010 *Safety in laboratories - Microbiological safety and containment*[15] and related international documents such as the World Health Organisation's *Laboratory biosafety manual*[16], the Centers for Disease Control and Prevention's *Biosafety in Microbiological and Biomedical Laboratories* (BMBL)[17], the *Canadian Biosafety Handbook*[18] and *Canadian Biosafety Standard*[19]. Classification and containment of other organisms have also been informed by experience and practice for their non-modified counterparts.

Authorisations under the GT Act are typically issued to an organisation rather than an individual. Operation of Australia's regulatory framework for GMOs is supported by local Institutional Biosafety Committees (IBCs). Accredited organisations[20] are required to have access to an 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. IBCs ay advise on additional containment measures for GMOs involved in the dealings.

Under the GT Act IBC's are responsible for assessing whether proposed work with GMOs meets the requirements of an Exempt dealing, an NLRD or require a licence in accordance with the GT Regulations. IBCs also screen licence applications prior to submission to the Regulator, provide training in general laboratory safety and may also provide GMO specific biosafety training. IBCs may also provide institutional level oversight of work with GMOs. This takes account of the lower risk level of much research work.

Importation of a GMO is a dealing regulated under the GT Act. Importing organisations are required to have the appropriate approvals in place prior to importing the GMO and the Regulator works closely with existing customs arrangements to ensure the import of GMOs is managed appropriately. Unless alternative approvals have been given, all GMOs entering Australia are required to be packaged and labelled in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*[21] (the TSDs). Live

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[13] https://www.legislation.gov.au/Latest/F2011C00732

[14] http://www.ogtr.gov.au/internet/ogtr/publishing nsf/Content/apps-for-gmo

[15] 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).

[16] http://www.who.int/ihr/publications/WHO_CDS_CSR_LYO_2004_11/en/

[17] http://www.cdc.gov/biosafety/publications/bmbl5/

[18] https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/handbook-second-edition html

[19] https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/second-edition.html

[20] http://www.ogtr.gov.au/internet/ogtr/publishing nsf/Content/accreditation-process

[21] http://www.ogtr.gov.au/internet/ogtr/publishing nsf/Content/transport-guide-1

plant or animal specimens, or reproductive material, may only be imported if they appear on the live import list[22] under the EPBC Act; they may also require a live import permit under this Act. In addition, import of viable GMOs must comply with the requirements of the *Biosecurity Act 2015*.

Export, however, is not a regulated dealing under the GT Act although it is a requirement that all GMOs transported to the border are transported in accordance with the TSDs. This includes that the outermost packaging is labelled to indicate the package contains GMOs. Packaging for export is also expected to comply with the International Air Transport Association (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.

Containment of GMOs within certified facilities

Contained work with GMOs in Australia is underpinned by certification of facilities, with requirements addressing both the physical and behavioural aspects of containment. In Australia, certain work with GMOs must only be undertaken in facilities that are certified by the Regulator. The GT Act allows the Regulator to certify Physical Containment (PC) facilities to ensure that appropriate standards are met for containment of GMOs, and that only trained and competent staff work with GMOs in these facilities. The Regulator has issued guidelines under the GT Act specifying requirements for various facility types (for example, laboratory, plant and animal etc.) which must be met prior to certification.

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 the equipment used, as well as the handling practices employed by those working in the facility. PC level 1 (PC1) facilities are certified to contain GMOs posing the lowest risk to human health and the environment, while PC level 4 (PC4) facilities provide the most secure and stringent containment conditions and are certified to contain GMOs posing the greatest risk[12].

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 as 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 all levels of PC 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[23]. These guidelines are outcome focused in nature. This means they specify particular characteristics of facilities and the required containment outcomes only, thus allowing the facility holder to decide how best to meet those requirements. The advantage of this outcomes-focussed method is it allows for flexibility; with facility holders choosing building materials, equipment, chemicals and

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[22] http://www.environment.gov.au/biodiversity/wildlife-trade/live/import-list

[23] 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

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.

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 2242.3:2010[12]). However, the Regulator can make a decision to change the required containment level for a particular GMO where a science-based risk assessment has concluded that the effect of the genetic modification(s) on the organism would significantly increase or decrease its risk to the health of humans and the environment. These containment levels are mandated through specific licence conditions for undertaking the dealing or through inclusion in the GT Regulations.

Most genetically modified plants and animals, including invertebrates, are required to be kept in PC level 2 (PC2) facilities unless they have been infected with microorganisms requiring a higher level 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.

Containment of GMOs outside certified facilities

For GMO dealings not involving intentional release into the environment, transport, storage and disposal outside of certified facilities must be in accordance with the TSDs. These guidelines are consistent with the IATA Dangerous Goods Regulations[24] packaging and labelling requirements for GMOs which are infectious substances.

Australia notes that the Cartagena Protocol does not apply to the transboundary movement of GMOs 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 entering Australia also require an import permit[25]. The Australian Government Department of Agriculture and Water Resources (DAWR) assesses applications for import permits.

Monitoring for compliance

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 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 GT Act empowers 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.

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[24] http://www.iata.org/publications/dgr/pages/index.aspx

[25] http://www.agriculture.gov.au/import/online-services/bicon

http://www.agriculture.gov.au/import/online-services/bicon/bicon-permit

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[26].

Containment of GMOs which are also a pest or disease of quarantine concern

DAWR also has a role in the containment of GMOs where the department has identified an organism as being a harmful pest or disease of quarantine concern. These GMOs would require an import permit, and the permit would prescribe the type (and location) of facility where the organism can be held.

Approved arrangement (AA) sites are premises where post-entry quarantine activities and treatments may be performed on goods, animals and plants that are approved by DAWR. These AA sites are grouped by the type of commercial operation and the biosecurity activities that are authorised to take place at these facilities.

AA sites are assessed against specific requirements which can be found on the DAWR website[27] and include the same four containment levels as for OGTR facilities but are known as Biosecurity Containment (BC) levels, BC1-BC4 and cover a wider range of facility types. As part of the approval process facilities are initially assessed by approved engineer assessors[28] against specified design and construction aspects of the Australian and New Zealand Standards, prior to auditing by DAWR audit staff. DAWR's Biosecurity Officers routinely audit AA sites, with audit frequency dependent on the compliance history of the facility holder[29].

Security Sensitive Biological Agent Regulatory Scheme

Additional biosecurity controls may be appropriate where a LMO is derived from a pathogen identified as a potential harmful biological agent, or could be used to manufacture a harmful biological agent.

Through the Australian Government Department of Health, Australia also administers the Security Sensitive Biological Agent (SSBA) Regulatory Scheme[30] to limit opportunities for acts of bioterrorism or biocrime to occur using harmful biological agents. The scheme is built around a two tiered List of SSBAs[31] considered to be of security concern to Australia and requires all entities and facilities handling SSBAs to comply with the *National Health Security (NHS) Act 2007*, the *National Health Security Regulations 2008*[32] (the NHS Regulations) and the SSBA Standards[33].

The NHS Act establishes the regulatory scheme and the NHS Regulations provide further operational detail, including reporting requirements. The SSBA Standards include specific requirements which cover risk and incident management, personnel security, physical

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[26] http://www.ogtr.gov.au/internet/ogtr/publishing nsf/Content/mc-protocols-1

[27] http://www.agriculture.gov.au/import/arrival/arrangements/requirements

[28] http://www.agriculture.gov.au/import/arrival/arrangements/assessors

[29] http://www.agriculture.gov.au/import/arrival/arrangements/general-policies

[30] http://www.health.gov.au/ssba

[31] http://www.health.gov.au/ssba#list

[32] https://www.legislation.gov.au/Latest/F2016C00626

[33] http://www.health.gov.au/ssba#standards

security, information security, transport, inactivation and decontamination and the requirement for establishment of an SSBA management system.

The SSBA Regulatory Scheme was developed using risk management principles to achieve a balance between counter-terrorism concerns and the interests of the regulated community and aims to maintain full access to SSBAs for those with a legitimate need. Compliance with the SSBA Regulatory Scheme is monitored through an inspection program which is supported through the provision of inspectors from the OGTR.

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*[34] and AS/NZS 2242.3:2010 *Safety in laboratories - Microbiological safety and containment*[35]. The latter 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.

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

[34] which can be purchased from http://infostore.saiglobal.com/store/Details.aspx?productID=1391032

[35] which can be purchased from http://infostore.saiglobal.com/store/Details.aspx?ProductID=1430097