



Australian Government

Department of the Environment and Energy

To: The Legislative and Governance Forum on Gene Technology

Submission with respect to the third review of Australia's Gene Technology Scheme from the Department of the Environment and Energy.

The Department of the Environment and Energy (Department) welcomes the opportunity to make a submission with respect to the 2017 review of Australia's Gene Technology Scheme (the Scheme).

The Department considers that the Scheme has operated successfully since its conception, assessing and managing the risks to human health, safety and the environment. Based on the defined Terms of Reference for the 2017 Review, the Department has performed a horizon scan of issues that could be considered during the review. These issues include:

- International developments in the regulation of gene technology, and the relevance of these to the operation of the Scheme in Australia.
- Explore options to ensure that the approach to environmental risk assessments of GMO releases is efficient and commensurate with the level of identified risk. A large amount of experience has accumulated in dealing with certain kinds of GMOs and this is one aspect that could be considered when reviewing the efficiency of the risk assessment process, particularly in relation to genetic modifications of plants that have been the subject of a number of previous risk assessments.
- Consideration of the systems and processes that are in place for the reporting of adverse impacts of GMOs.
- Advances in biotechnology (such as gene drives) provide tools that could be used for germ-line manipulation of species. There are a wide range of potential applications for these technologies ranging from eradication of pests (e.g. mosquitos or rodents) to protection of threatened species (e.g. protecting Tasmanian Devils from facial tumours). The scope of the review should consider ethical questions concerning germ-line manipulation of species.
- Evaluating Australia's regulatory framework for Genetically Modified Products (as distinct from Genetically Modified Organisms) to ensure that interactions between regulatory schemes are efficient and effective.

The Department believes that the current Scheme has built and maintained public confidence in its ability to deal with the health and environmental risks of GMOs.

Additionally Australia has made a number of relevant submissions, drawing on input from a range of Australian Government agencies, to the United Nations Convention on Biological Diversity (CBD) which we have attached for reference.

Consideration of the above issues and attached submissions will help position the Scheme for the future.

James Tregurtha
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Environment Standards Division
Department of the Environment and Energy

21 September 2017

CONVENTION ON BIOLOGICAL DIVERSITY (CBD) NOTIFICATION 2015-013

Submission of Information on Synthetic Biology

Submission by Australia

NOTE: All information provided in this response has been drawn from Australian Government agency inputs only. No consultation with State and Territory governments was possible for this notification due to the deadline for the response.

Notification 2015-013: Submission on Synthetic Biology

Australia is responding to the invitation to Parties to the Convention on Biological Diversity (the Convention) other Governments, relevant organisations and indigenous peoples and local communities to submit information relevant to the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology as referenced in decision XII/24. Australia thanks the Secretariat for the opportunity to provide input on this issue.

It is Australia's view that:

- synthetic biology, and any organism that is produced by this means, would be covered by definitions in the Cartagena Protocol on Biosafety, as well as, Australia's gene technology legislation.
- current risk identification and assessment methodology as outlined in the Cartagena Protocol and Australia's Risk Analysis Framework is equally applicable and adequate to assess risks from synthetic biology.

Introductory remarks

Australia acknowledges that the term 'synthetic biology' is being used more widely in science to differentiate between the conceptual approaches used by synthetic biologists versus that of the more traditional biotechnologists. There are also arguments which suggest that synthetic biology is qualitatively different from modern biotechnology. However, given the large overlap in techniques and applications, Australia questions whether this is the case.

Australia reiterates its view, as submitted at SBSTTA 18 and COP12, that synthetic biology does not meet the criteria of a new and emerging issue, but is willing to engage in discussions anchored in sound science to explore whether there are synthetic biology applications capable of posing inherently different risks to biological diversity that fall outside of the Cartagena Protocol.

Australia also reiterates that it is important to distinguish between synthetic biology techniques undertaken in containment and environmental release of organisms derived from synthetic biology. Most applications of synthetic biology in the near future are confined to laboratory research or contained manufacturing. While it is difficult to predict how soon products of synthetic biology may be ready for wider environmental release, it is unlikely commercial applications of synthetic biology (especially organisms) would be proposed in the near future that would not be categorised and regulated as gene technology and genetically modified organisms (GMOs) in Australian and other national legislation or modern biotechnology and living modified organisms (LMOs) in the Cartagena Protocol on Biosafety¹.

a- Information that is relevant to the work of the AHTEG, including views on:

Relationship between synthetic biology and biological diversity

i- How to address the relationship between synthetic biology and biological diversity;

The majority of current synthetic biology applications in development are for contained use (research or manufacturing) and are therefore somewhat removed from a direct impact on the environment and biological diversity. From a process point of view, large scale manufacturing using a synthetic organism would be similar if not the same as other more traditional manufacturing processes using wild type (or modified) organisms (e.g. large scale fermentation), including the sourcing of input materials and treatment of process wastes. Therefore, it is important to identify causal pathways by which the use of synthetic organisms might impact on biological diversity, and whether any of those causal pathways are inherently different from those identified for wild type or LMOs and their products.

¹ For simplicity, the acronym 'LMO' used from this point forward is taken to also encompass 'GMO's, as defined under Australian national legislation.

Similarities & Differences

ii- The similarities and differences between living modified organisms (as defined in the Cartagena Protocol) and organisms, components and products of synthetic biology techniques;

In Australia's view, the term 'synthetic biology' has increasingly been used to describe a subset of biological research in which the tools of gene technology are used to apply engineering principles to the fundamental components of biology. That is, using the knowledge and tools of biotechnology to reduce biology to its most basic functional units (genes, proteins and pathways) then modify and reassemble them to produce a novel organism capable of efficiently producing the required outcome. This can be carried out *in vitro*, using modern biotechnology, or *in silico*, with the designed genome being chemically synthesised and used to create the organism (also a modern biotechnology technique). The term synthetic biology is being used to separate this, ground up, additive approach (synthesis), from the more traditional deletion or transfer approach (modification). Some synthetic biology applications may also involve the use of artificial amino acids or nucleic acids (xenobiology), though these are still at a very early stage of development and are a long way from commercialisation or release.

The broad and interdisciplinary nature of approaches described as 'synthetic biology' makes similarities and differences between synthetic biology products and living modified organisms problematic to describe categorically. As with much other contemporary scientific research there is a continuum of work being undertaken with synthetic biology representing an evolution of biotechnology towards the application of multidisciplinary engineering / systems approaches in which scientists and engineers think of DNA and proteins as parts, devices, and systems. These components can then be used and combined in new ways to achieve different outcomes.

However, in all cases the end result is a modified organism with intentional changes to its biology. The outcome of these changes can be predicted and the potential for risks or benefits from these organisms can be assessed through already established risk assessment processes used for LMOs.

The Cartagena Protocol defines 'modern biotechnology', which is part of the definition of an LMO, as follows:

"Modern biotechnology" means the application of:

- a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or*
 - b. Fusion of cells beyond the taxonomic family,*
- that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.*

The use of 'including' in part (a) of the definition indicates that the list of techniques which follows is a selection of examples of *in vitro* nucleic acid techniques, rather than a definitive list. Therefore, it is arguable that synthetic biology, in each of its various manifestations, can be described as part of modern biotechnology.

Current biotechnology applications labelled as synthetic biology, such as the production of food ingredients (e.g. vanilla flavouring) or cosmetics (e.g. rose fragrance), involve the modification of existing organisms through the addition of genes coding for entire biosynthetic pathways and/or the modification of existing genes and gene pathways to allow the production of new molecules. If such organisms are described as products of synthetic biology due to the addition of one or more biosynthetic pathways, they are very similar to some LMO plants that are considered products of modern biotechnology and, therefore, currently regulated. In these cases a parent organism and/or donor organisms can be identified and their known characteristics used in the assessment of the properties of the new 'synthetic' organism. Science-based risk assessment of these organisms is possible within the existing regulatory frameworks.

For extensively modified organisms, the scale of changes may impact on the usefulness of the parent organism as a comparator. Further information may also be required for the assessment of organisms using novel nucleic acids (xenobiology), including their ability to persist outside of laboratory conditions and their capacity to transfer genetic material to other organisms. However, the production, commercialisation and release of the potential products of xenobiology are a long way off. This expected development time and process should allow for better understanding of any scientific and regulatory gaps, including where these products might diverge from those encompassed by current regulatory instruments, including the Cartagena Protocol.

Current best practice & Adequacy of existing regulation

iii- Adequacy of existing national, regional and/or international instruments to regulate the organisms, components or products derived from synthetic biology techniques;

vi- Best practices on risk assessment and monitoring regimes currently used by Parties to the Convention and other Governments, including transboundary movement, to inform those who do not have national risk assessment or monitoring regimes, or are in the process of reviewing their current risk assessment or monitoring regimes;

Australia reiterates its previous submission to CBD Notification 2014-090, that current synthetic biology applications for research and commercial purposes involve the modification of existing organisms in ways that would be captured by regulatory schemes which cover LMOs. End products which are not themselves LMOs may be captured by other existing product regulators, such as those responsible for regulating therapeutic goods, agricultural chemicals or industrial chemicals.

In Australia, organisms created via synthetic biology would be regulated under the *Gene Technology Act 2000* (the GT Act) and applications for release into the environment would be subject to a science-based, case by case assessment. The GT Act and corresponding state legislation are administered by the Gene Technology Regulator, supported by the Office of the Gene Technology Regulator (the Office). The GT Act includes definitions of 'gene technology' and 'genetically modified organism'. Based on these definitions, known and proposed synthetic biology applications would be regulated in Australia under the GT Act. Australia maintains a watching brief on synthetic biology. The Australian gene technology regulatory scheme undergoes periodic review to ensure that it keeps pace with technology developments and scientific knowledge regarding risks. In this context, the Gene Technology Technical Advisory Committee (Technical Committee) provides scientific and technical advice to the Regulator on biosafety and gene technology.

Certain products arising from synthetic biology may also be regulated by other Australian agencies if they meet relevant definitions in the associated legislation such as, for therapeutic goods (the Therapeutic Goods Administration - TGA), veterinary and agricultural products (Australian Pesticides and Veterinary Medicines Authority - APVMA), industrial chemicals (National Industrial Chemicals Notification and Assessment Scheme - NICNAS), and foods or food packaging (Food Standards Australia New Zealand - FSANZ). The Gene Technology Regulator also has the ability to impose licence conditions relating to GM products, this could occur where end products are not regulated by other agencies, and a risk requiring management has been identified.

Other international best practice, such as good laboratory practices (GLP) and good manufacturing practices (GMP), would guide both research and commercial scale synthetic biology applications.

In Australia, research involving synthetic biology is subject to the same general requirements as all other research, including avoiding harm to human health or the environment. Access to funding under the Australian Research Council requires adherence to the *Australian Code of Conduct for Responsible Research* developed by the National Health & Medical Research Council, the Australian Research Council and Universities Australia <https://www.nhmrc.gov.au/guidelines-publications/r39>.

Import of organisms not native to Australia, and biological products would require authorisation from the Department of Agriculture under the *Quarantine Act 1908* <http://www.agriculture.gov.au/import>. Import of GMOs requires additional authorisation under the GT Act.

Definition

iv- An operational definition of synthetic biology, comprising inclusion and exclusion criteria;

Australia notes that there is no agreed definition of synthetic biology, internationally or scientifically. Synthetic biology is a very broad, umbrella term encompassing and/or applied to a wide, and varied, range of techniques and potential applications and end products. Many techniques described as synthetic biology may equally be described as techniques of modern biotechnology, gene technology or genetic engineering, in particular those applications that are closest to commercial scale application. We reiterate that, given the current debate over organisms currently classified as LMOs and those that would be described as the products of synthetic biology, existing tools and approaches for environmental risk identification and assessment are equally applicable to organisms and products derived from synthetic biology techniques. Australia recognises work being undertaken by other national and international bodies (for example, the European Commission) to develop a working definition of synthetic biology and recommends that any Convention work in this area should be in collaboration with these fora to avoid any contradictions in the definition developed.

Because of the breadth of techniques and applications which may be included in the term, agreement of a sensible definition for synthetic biology may be problematic and/or elusive. Time may be better spent in identifying/cataloguing applications referred to as synthetic biology that do not fall within the existing broad definition of "modern biotechnology" and LMOs contained within the Cartagena Protocol. These applications can then be assessed to determine whether they might pose inherently different risks to biological diversity that need to be managed.

However, should the parties to the Convention decide to move forward in developing a definition, care should be taken that the effort/time taken to develop the definition does not exceed the value of such a definition. Focus should be on developing a definition that is useful for determining which, if any, aspects of synthetic biology fall outside of current regulation and result in actual risks to biological diversity.

Risks and Benefits

v- Potential benefits and risks of organisms, components and products arising from synthetic biology techniques to the conservation and sustainable use of biodiversity and related human health and socioeconomic impacts relevant to the mandate of the Convention and its Protocols;

Given the overlap between modern biotechnology and synthetic biology, the risks and benefits arising from synthetic biology are expected to be similar to those arising from other novel organisms and their products.

Additionally, synthetic biology based work carried out entirely within containment (research, development and manufacturing) would have little or no direct contact with the environment and its biodiversity. Risk identification would need to demonstrate a clear and viable linkage between the contained work and any potential adverse environmental impact. It would also need to demonstrate that any risks identified as arising from synthetic biology are inherently different from those posed by similar uses of wild type or LMOs in order to require different management/regulation.

Australia supports a case by case, science-based risk-assessment of synthetic biology applications to identify actual risks to biodiversity and related human health. Management of identified risks (if any) should be consistent with relevant international obligations and current regulatory frameworks for LMOs.

One of the greatest potential benefits of synthetic biology would be the capacity to engineer microorganisms to be able to produce any naturally occurring molecule (e.g. flavours, scents, dyes or pharmaceuticals) and thereby eliminating the need to cultivate large monocultures of the original source plants or animals. This would also reduce the amount waste produced during extraction and purification

from the original organisms. Additionally, the ability to produce novel molecules could benefit human health by producing designer pharmaceuticals. Synthetic organisms would also be able to produce desired products all year round and would not be impacted by growing seasons, weather extremes or the need to cultivate crops in both hemispheres. This could reduce the area of land required for commercial cultivation, aiding in the conservation and sustainable use of biodiversity.

A potential benefit of xenobiology is the requirement for a substance which is not found in nature. Organisms with artificial amino acids (and which do not encode a pathway enabling them to produce the artificial amino acid) would be reliant on the supply of that amino acid and would not be able to survive in environments where the amino acid is not present. Organisms with artificial nucleic acids would not be able to exchange DNA with wild type organisms, as the recipient organism would not have the ability to replicate or translate the novel sequences. This would prevent any engineered or novel genes from 'escaping' into the natural pool of biodiversity, and again may be self-limiting, if an artificial substance is required for the production of the new nucleotides. Therefore, there would be minimal potential for harm arising from an intentional or accidental release of these organisms.

Current effectiveness?

vii -The degree to which the existing arrangements constitute a comprehensive framework in order to address impacts of organisms, components and products resulting from synthetic biology relevant to the objectives of the Convention on Biological Diversity and its Protocols, in particular threats of significant reduction or loss of biological diversity;

Currently, Australia is not aware of any synthetic organisms or novel products of synthetic biology ready for release into the environment. Nor is Australia aware of any evidence that current synthetic biology applications would result in inherently different risks to biological diversity that might be posed by wild type organisms or LMOs.

Contained work is covered by codes of responsible conduct which allow for research and developmental work to be carried out safely and sensibly. National and international biosafety and biosecurity legislation and/or codes of conduct provide for organisms to be contained in a manner which minimises exposure of people and the environment to potentially dangerous microorganisms.

b- Information on measures undertaken in accordance with paragraph 3 of the decision, including the identification of needs for guidance; and

Currently, all work with synthetic organisms in Australia would require authorisation under the GT Act. Contained work, including large-scale manufacture, must be carried out in facilities certified by the Regulator as being suitable for the work to be carried out. The certification of facilities covers both structural and behavioural aspects of containment.

Regulation of genetically modified organisms under the GT Act is underpinned by case by case, scientific risk assessment. For all proposed environmental releases of genetically modified organisms (including synthetic organisms), the Regulator must prepare a comprehensive risk assessment and risk management plan and consult with relevant State and Territory Government(s), The Australian Minister for the Environment, the Technical Committee, other regulatory agencies, Local Government and the public. Licences impose conditions to manage any risks to human health and the environment. Non-compliance with the GT Act or licence conditions carries significant penalties. Products of synthetic biology which do not meet the criteria to be GMOs are regulated by other product regulators, as identified in the answer to (iii) above.

To date, Australia has not received any applications for the intentional release of a synthetic organism into the environment. Work involving the large scale production or manufacture of synthetic organisms is also not being conducted in Australia at present.

c- Further information on the components, organisms and products resulting from synthetic biology techniques that may have impacts on the conservation and sustainable use of biological diversity and associated social, economic and cultural considerations.

Australia is not aware of any additional information to add at this stage.

CONVENTION ON BIOLOGICAL DIVERSITY (CBD) NOTIFICATION 2017-025

Submission of information on synthetic biology and nomination of experts
to participate in the Open-ended Online Forum on Synthetic Biology

Submission by Australia

NOTE: All information provided in this response has been drawn from Australian Government agency
input only.

Notification 2017-025 Submission of information on synthetic biology and nomination of experts to participate in the Open-ended Online Forum on Synthetic Biology

Australia is responding to the invitation to Parties to the Convention on Biological Diversity, other Governments, relevant organisations and Indigenous peoples and local communities to:

- (b) submit information and supporting documentation relevant to the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology as referenced in paragraph 10 of decision XIII/17, and
- (c) nominate experts to participate in the Open-ended Online Forum on Synthetic Biology.

Australia thanks the Secretariat for the opportunity to provide input on these matters.

Introductory remarks

Australia reiterates key points from its previous submission on synthetic biology (2015-013). In particular, it is Australia's view that:

- current synthetic biology applications are not qualitatively different from modern biotechnology
- synthetic biology, and any organism that is produced by this means, would be covered by definitions in the Cartagena Protocol on Biosafety, as well as Australia's gene technology legislation
- current risk identification and assessment methodology, as outlined in the Cartagena Protocol and Australia's Risk Analysis Framework 2013, is equally applicable and adequate to assess risks from synthetic biology
- it is important to distinguish between synthetic biology techniques undertaken in containment and environmental release of organisms derived from synthetic biology
- Australia supports a case-by-case, science-based risk assessment of synthetic biology applications to identify plausible risks to biodiversity and related human health. Management of identified risks (if any) should be consistent with relevant international obligations and current regulatory frameworks for LMOs
- synthetic biology does not meet the criteria of a new and emerging issue, but Australia is willing to engage in discussions anchored in sound science to explore whether there are synthetic biology applications capable of posing inherently different risks to biological diversity that fall outside of the Cartagena Protocol.

- (a) submit information and supporting documentation relevant to the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology as referenced in paragraph 10 of decision XIII/17.

In response to those elements detailed in paragraph 10 of decision XIII/17, Australia wishes to submit the following information:

(a) Research, cooperation and activities noted in paragraph 9 of decision XIII/17

For two decades, Australia's Commonwealth Scientific and Industrial Research Organisation (CSIRO), the principal agency for scientific research in Australia, has conducted benchmark research on the development of genetic based biological control technologies for invasive species management, both plant and animal. These include:

- i) insertion of gene constructs to manipulate sex expression in invasive species in the context of meiotic gene-drives based on Mendelian inheritance (so called "daughterless" or "sonless" approaches)

- ii) immuno-contraception, which involves the use of an animal's immune system to prevent it from fertilizing offspring for the control of vertebrate pests like mice and foxes, through the genetic manipulation of specific viruses as delivery mechanisms
- iii) the use of RNA interference creation and delivery to regulate gene expression to reduce fitness of pest organisms and
- iv) initial studies of the potential of CRISPR gene-drive approaches.

As the authority responsible for the regulation of work with LMOs in Australia since 2001, the Gene Technology Regulator (the Regulator) has applied Australia's Risk Analysis Framework to produce scientific risk assessments for the conduct of the above research, and all work with LMOs in Australia. The Regulator uses these risk assessments and associated risk management plans to guide decisions on whether or not to authorise work with LMOs and to identify relevant conditions which should be imposed. This has enabled the safe research and work with LMOs in Australia.

CSIRO has many peer reviewed publications that can be supplied to support the pre-deployment research, scientific risk analysis, management strategies and post-deployment analysis of the use of these approaches. Synthetic biology provides new opportunities to develop biological control systems, through gene edited living organisms or LMOs containing synthetic gene drives, which substantially change the impact of an invasive organism. CSIRO is building on its 100 year history in the development of classical biological control solutions for managing invasive species causing environmental harm to understand the best approaches and scientific risks of synthetic biology based biological control.

In addition, CSIRO has a new research initiative that has established a series of Future Science Platforms (FSP) including one for synthetic biology. The Synthetic Biology FSP acts as a collaboration hub supporting synthetic biology research both within CSIRO and across Australia through university research partners. Activities include projects focused on developing synthetic biology based solutions to protect the environment and biodiversity, as well as projects feeding into risk assessment, including modelling ecological responses to interventions. The Synthetic Biology FSP is also developing a research program in understanding social, ethical, regulatory and legal issues related to synthetic biology.

The Australian Council of Learned Academies (ACOLA) is currently developing a report entitled 'The future of Synthetic Biology in Australia'. The report has been commissioned through the Office of the Chief Scientist and will be delivered by June 2018 for consideration by the Prime Minister's Commonwealth Science Council.

(b) Evidence of benefits and adverse effects of synthetic biology vis-à-vis the three objectives of the Convention

Although there is no hard data evidence from work conducted by CSIRO to support the above aims, experience gained from work conducted by the University of Queensland and Monash University introducing new strains of the bacterium *Wolbachia* into *Aedes* mosquitoes in an effort to reduce their potential to be efficient vectors for *Dengue Fever Virus* may provide insights on the risks, benefits and management of organisms containing engineered gene drives.

(c) Experiences in conducting risk assessments of organisms, components and products of synthetic biology, including any challenges encountered, lessons learned and implications for risk assessment frameworks

CSIRO has developed a risk analysis platform for understanding the scientific risks of releasing living modified organisms and funded projects to conduct risk assessments of both gene drive containing LMOs (in the first instance, the mouse) and the use of externally applied biological agents (namely small RNA to effect transient RNA interference effects). CSIRO is involved in international discussions and collaborations to advise and inform the risk assessment frameworks to better fit the issues of concern in the release of gene drive containing LMOs.

The Regulator has not received any applications for work with organisms badged as synthetic biology organisms. However, the Regulator has produced risk assessments for genetically modified viruses containing substantial percentages of genetic material from multiple organisms, whereby comparison to a single parental organism is not practical. Australia was able to adapt current risk assessment procedures to perform an assessment based on the total risk posed by the LMO rather than assessing potential risks arising from differences between the LMO and its parent organism. It is expected that this approach will be able to be applied to risk assessments for synthetic organisms for which there is no relevant parent organism.

(d) Examples of risk management and other measures that have been put in place to avoid or minimize the potential adverse effects of organisms, components and products of synthetic biology, including experiences of safe use and best practices for the safe handling of organisms developed through synthetic biology

The Regulator has a rigorous scheme in place for the regulation of all living modified organisms, including synthetic biology organisms. This includes requirements for containment and safe handling of LMOs not authorised for release, and provisions to impose licence conditions if LMOs are being released into the environment.¹ Recently, the Regulator also issued Guidance on the Regulatory requirements for contained research with GMOs containing engineered gene drives.² This includes information on the current regulation of organisms containing gene drives as well as advice on appropriate containment levels and measures. It is also important to note that the OGTR has developed different physical certification requirements tailored to different types of organisms. For example, the containment features and work practices required for a Plant Facility will be different to those for a Invertebrate Facility (e.g. for work with insects) or an Animal Facility (e.g. for work with mice), with the differences taking account of the different biology of the subject organisms.³ The OGTR has guidelines for a range of different facility types and these are available from the OGTR website.⁴ It should also be noted that Institutional Biosafety Committees play an important role in the Australian regulation of contained GMO research, both in the correct classification of approvals required and in 'on the ground' oversight of adherence to containment and other risk management requirements. It should be further noted that OGTR undertakes monitoring of lab-based research for compliance with regulatory requirements with a focus on higher risk activities, for example higher level containment facilities.

Laboratory-based research relating to synthetic biology within CSIRO is conducted at Physical Containment level 2 (PC2) as a minimum. Minimum containment requirements for work with GMOs are set by the Gene Technology Regulations 2001 or through specific licence conditions imposed by the GT Regulator.

Through dialogue between research organisations and regulators regarding the conduct of synthetic biology, research in the field of gene-drives is to be conducted using the conditions set by the GT Regulator and, if needed, supplemented by controls suggested in peer review articles. In particular, the genetic control by the use of "split gene-drive" components, artificial genomic targets and laboratory strains of animal rather than wild strains. When a unified gene-drive is being considered in a non-laboratory strain of animal, CSIRO has proposed that this would be conducted at PC3 level containment.

¹ <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/section-working-with-gmos>

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[http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/53139D205A98A3B3CA257D4F00811F97/\\$File/OGTR%20Guidance%20on%20gene%20drives.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/53139D205A98A3B3CA257D4F00811F97/$File/OGTR%20Guidance%20on%20gene%20drives.pdf)

³ <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/FacilTypesv1-2-htm>

⁴ <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/cert-pc2-1>

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

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

CSIRO is the managing body for the Australian Animal Health Laboratory, with animal facilities that operate at this highest level of physical containment. Work of this nature is not yet underway nor are funds yet assigned for such work.

(e) Regulations, policies and guidelines in place or under development which are directly relevant to synthetic biology

As referenced above, the Regulator has legislation, regulations and guidelines in place that regulate all LMOs including synthetic biology. Please see the Australian Government submission to notification 2016-041 for further information on Australia's scheme and requirements -

<http://bch.cbd.int/database/record.shtml?documentid=110410>

CSIRO is funded by the Australian Government and has a role as trusted advisor in areas of particular scientific expertise. CSIRO and other organisations work closely with national regulators to provide impartial advice relating to the potential benefits or risks of synthetic biology-based technologies and for the development of guidelines, policies and regulations pertaining to developments in synthetic biology and their impacts on environment and health. CSIRO only provides advice in this area and has no formal responsibility.

(f) Knowledge, experience and perspectives of indigenous peoples and local communities in the context of living in harmony with nature for comparison and better understanding of the potential benefits and adverse effects of synthetic biology

Through the recently establish Synthetic Biology Future Science Platform and its re-instigated Gene Technology Working Group, CSIRO will continue to build capability in the areas of scientific risk analysis. In addition to this, CSIRO has specific liaison with Indigenous peoples groups and will continue to work closely with them where synthetic biology activities have applications or implications for the natural environment.

(b) nominate experts to participate in the Open-ended Online Forum on Synthetic Biology.

Names redacted

Names redacted

CONVENTION ON BIOLOGICAL DIVERSITY (CBD) NOTIFICATION 2017-035

Risk Assessment and Risk Management

Cartagena Protocol

Submission by Australia



Australian Government

NOTE: All information provided in this response has been drawn from Australian Government agency input only.

Australia's Submission to CBD Notification 2017-035

Notification 2017-037 - Digital Sequence Information on Genetic Resources

Australia thanks the Secretariat for the invitation to submit views and relevant information requested in decision VIII/12 on Risk Assessment and Risk Management, as communicated in notification 2017-35 Ref.:SCBD/SPS/DC/MPM/MW/86376 of 12 April 2017.

In addition to the information provided in the annex to this submission, Australia wishes to draw to the attention of the Secretariat a number of documents produced by Australia's Office of the Gene Technology Regulator (OGTR) which provide guidance relevant to the risk assessment and risk management of Living Modified Organisms (LMOs) that may be of use to Parties. Australia shares this information in line with decision VIII/12 paragraph 4.

Risk Analysis Framework

The *Risk Analysis Framework* (RAF) is a key explanatory document that provides guidance on how the Gene Technology Regulator (the Regulator) and staff under the Regulator's direction in the OGTR approach the risk analyses of LMOs. The RAF incorporates risk assessment, risk management and risk communication and provides guidance on how to characterise and deal with uncertainty. The RAF may provide guidance to other countries establishing and implementing risk assessment processes for LMOs. The current version of the RAF was published in July 2013 is available on the OGTR website at <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/risk-analysis-framework>.

Risk Assessment and Risk Management Plans (RARMPs)

The Regulator's assessment of each application to release a LMO into the environment involves the preparation of a Risk Assessment and Risk Management Plan (RARMP), which includes a critical assessment of data provided by the applicant together with a thorough review of other relevant national and international scientific literature. The risk assessment takes account of risks to human health and safety and the environment posed by the dealing and the risk management plan determines how those risks can be managed. The principles and approach set out in the RAF are put into practice in the RARMP.

Copies of RARMPs and licence conditions are publicly available through the Record of GMO dealings on the OGTR website at <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1>.

Application forms

Information relevant to guidance on risk assessment is contained in application forms for environmental release of LMOs in Australia.

The detailed application forms provide guidance to applicants and outline the type of information considered necessary to prepare a RARMP for each application to release an LMO into the Australian environment. Application forms have been developed for the experimental and commercial release of plants into the Australian environment, as well as a more general form for the release of other LMOs including animals, bacteria and therapeutics. These forms contain specific questions to elicit information necessary to address important considerations relevant to each LMO application.

Applicants must provide comprehensive information about the proposed dealings with the LMO including possible risks posed by the dealings and proposed ways each risk could be managed. All responses must be supported by appropriate data and literature citations. Additional data relevant to the application may be

Australia's Submission to CBD Notification 2017-035

sought during the risk assessment process. Application forms are available from the OGTR website at <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/forms-1>.

Biology documents

Risk assessments identify risks attributable to gene technology by considering the risks posed by a particular LMO in the context of the risks posed by the unmodified parental organism in the receiving environment. The OGTR has prepared biology documents for a number of species that provide an overview of baseline biology information to support comparative risk assessments. The biology documents may be of use to other countries conducting risk assessments on relevant GM species and are available on the OGTR website at <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/biology-documents-1>.

**FORM FOR THE SUBMISSION OF INFORMATION REQUESTED IN DECISION VIII/12 ON
RISK ASSESSMENT AND RISK MANAGEMENT**

A. Country information

Country name:	Australia
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B. Please indicate your country's needs and priorities for further guidance on specific topics of risk assessment of living modified organisms (LMOs)

	Needs and priorities for further guidance on risk assessment of LMOs	Notes
1		Australia does not support the development of separate guidance documents for the risk assessment of specific types of LMOs under the Cartagena Protocol on Biosafety. Australia supports developing a single, practical and generic guidance document based on current risk assessment practices that could be used to assess all types of LMOs.

C. Please propose possible criteria that may facilitate the selection of topics for the development of further guidance on specific topics of risk assessment of LMOs, including a technical justification for each of the criterion proposed*

	Criteria for the selection of topics	Notes and technical justification
1	Need - Is there evidence that commercially viable LMOs of that type have been/are being developed for release into the environment	The Secretariat should focus efforts on aiding in the assessment of actual commercial products rather than experimental ideas that may never make it out of the lab.
2	Scope of existing guidance - Is there scientific evidence that LMOs of that type could realistically cause harms that could not be identified and assessed under the generic guidance	Well-designed generic risk analysis guidance should allow for the identification and assessment of all plausible pathways to actual harm that could reasonably be expected to result from the intentional environmental release of LMOs.

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3	Expertise - Does the on-line forum contain enough experts in the relevant fields to be able to produce sensible and practical guidance on the topic	Practical guidance can only be produced by those with the knowledge and experience to be able to identify the areas of reasonable concern.
4	Adoption of existing guidance - Is there any relevant existing guidance that could be used to meet the need	Australia notes many countries and organisations are active in the field of the environmental risk assessment of biological organisms, both modified and wild type, and does not support unnecessary duplication of effort.
5	Adaption of existing guidance - Is there any existing environmental risk assessment guidance produced for other purposes that could be easily adapted to fit the need	Risk assessment guidance and processes used for assessing the risks involved in releasing wild type biological control or bioremediation agents, control of invasive alien species or indigenous use of threatened species may be able to be adapted to LMOs.

D. Please share your views on perceived gaps in existing guidance materials

	Perceived gaps	Views
1		Australia notes the complexity of the current guidance document and supports the development of simple, practical and generic guidance capable of enabling Parties to conduct the risk assessments required under the Cartagena Protocol.

CONVENTION ON BIOLOGICAL DIVERSITY (CBD) NOTIFICATION 2017-037

Digital Sequence Information on Genetic Resources

Submission by Australia



Australian Government

NOTE: All information provided in this response has been drawn from Australian Government agency input only.

Notification 2017-037 - Digital Sequence Information on Genetic Resources

Australia thanks the Secretariat for the invitation to submit views and relevant information on any potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention and the Nagoya Protocol, as communicated in notification 2017-37 Ref.:SCBD/SPS/DC/VN/KG/jh/86500 of 25 April 2017.

Key Points

The objectives of the Convention are:

1. the conservation of biological diversity;
2. the sustainable use of its components; and
3. the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.

"Genetic resources" as defined under the Convention and the Nagoya Protocol means genetic material of actual or potential value.

"Genetic material" as defined under the Convention and the Nagoya Protocol means any material of plant, animal, microbial or other origin containing functional units of heredity.

Digital Sequence Information on genetic resources is not defined under the Convention. For the purposes of this submission Australia defines *"digital sequence information on genetic resources"* as electronically held sequence information which represents the biological composition of *"genetic material"* as defined under the Convention.

Australia considers digital sequence information on genetic resources and the physical genetic resources and material as distinct entities. This distinction aligns with the outcome of lengthy debate in the establishment of the Nagoya Protocol. To consider digital sequence information a genetic resource under the Convention and the Nagoya Protocol would require a renegotiation of the Convention and the Nagoya Protocol to redefine 'genetic material' noting information does not contain 'functional units of heredity' or genes.

Australia does consider that digital sequence information on genetic resources has a role in supporting Parties to meet the objectives of the Convention in line with Articles 3, 15(6) and 15 (7).

3 States have, in accordance with the Charter of United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

15(6) Each Contracting party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.

15(7) Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

There is a broad range of types and quality of sequence information relating to genetic resources that may be stored and/or transmitted digitally. Different types of sequence information include DNA, RNA and protein sequences as well as information on epigenetic factors such as methylation and glycosylation sites. The quality of information can range from raw sequence data through to fully annotated, characterised and codon optimised sequences complete with information on relationships to other sequences, including from multiple source organisms.

Open access to digital sequence information deposited in the public domain is the common standard in the global scientific community. Digital sequence information is found in many publicly available databases that can be considered data hosts not data owners. For example, GenBank (including Barcode of Life database of reference sequences from vouchered specimens of species) is an open access sequence database that contains nucleotide sequences for more than 300,000 organisms with supporting biological and bibliographic annotation.

Access to, and use of, digital sequence information is fundamental to modern biotechnology. The identification of useful information from within raw sequence data relies upon vital contextual information provided through existing public databases of characterised and annotated digital sequence information.

The generation and open sharing of digital sequence information on genetic resources provides benefits through increased scientific information and discovery that enable Parties, to meet the objectives of the Convention and the Nagoya Protocol. The use of digital sequence information on genetic resources increases the value of biological diversity and enables scientific progress and innovation.

Australia finally notes a number of multilateral discussions are in progress regarding whether and how regulatory mechanisms that apply to physical resources should be extended to digital sequence information. Outside the Convention and Nagoya Protocol discussions include:

- Multilateral System of the International Treaty for Plant Genetic Resources in Food and Agriculture (genomic sequence of germplasm);
- World Health Organisation (genetic sequence data from influenza viruses with pandemic potential); and
- Biodiversity Beyond National Jurisdiction discussions under the UN Convention on Law of the Sea (digital information from marine genetic resources).

Co-ordinated and non-duplicative consideration of this crosscutting issue is required to ensure consistency across these fora. We call on the CBD Secretariat to ensure the continuation of this collaboration as we consider this to be critical to inform the work being progressed through the CBD.