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

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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

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.

ANNEX 1

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

A. Country information

Country name:	Australia

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.

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.