Ref.: SCBD/SPS/DC/MPM/MW/86376 12 April 2017

**N O T I F I C A T I O N**

**Submission of information requested in decision VIII/12   
on Risk Assessment and Risk Management**

Dear Madam/Sir,

In its decision VIII/12, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) invited interested Parties, other Governments and relevant organizations to take the Guidance on Risk Assessment of Living Modified Organisms into account as a voluntary tool to assist in conducting risk assessment in accordance with the Cartagena Protocol while acknowledging that other guidance documents and national approaches can also assist in conducting risk assessment in accordance with the Protocol.

In the same decision, COP-MOP invited Parties to submit to the Executive Secretary:

(a) Information on their needs and priorities for further guidance on specific topics of risk assessment of living modified organisms;

(b) Proposals on criteria, including the technical justification, that may facilitate the selection of topics for the development of further guidance; and

(c) Views on perceived gaps in existing guidance materials.

COP-MOP requested the Executive Secretary to compile and submit the views submitted by Parties for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA).

Furthermore, COP-MOP requested SBSTTA to review the information provided and to recommend a way forward to address the needs, priorities and gaps identified by Parties for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its ninth meeting, including the possible establishment of a new ad hoc technical expert group, with the understanding that new guidance proposals should only be presented upon approval by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol.

Accordingly, I would kindly invite you to submit to the Secretariat the information referred to above as soon as possible but no later than **25 August 2017**. Late submissions will not be considered. Furthermore, Parties are kindly requested to make their submissions using the template annexed herewith. Submissions made in any other format will not be considered.

Parties may send submissions online through the Biosafety Clearing-House at <http://bch.cbd.int/managementcentre/edit/submission.shtml> or via e-mail to [secretariat@cbd.int](mailto:secretariat@cbd.int).

I appreciate your continued support towards the implementation of the Cartagena Protocol on Biosafety.

Please accept, Madam/Sir, the assurances of my highest consideration.

Cristiana Paşca Palmer, PhD

Executive Secretary

***Annex***

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

***A. Country information***

|  |  |
| --- | --- |
| **Country name:** | **New Zealand** |

***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 | None | New Zealand’s definition of a GMO in its *Hazardous Substances and New Organisms Act 1996* (the HSNO Act) is consistent with the Cartagena Protocol’s (CP) LMO definition[[1]](#footnote-1). It is New Zealand’s view that all applications of Modern Biotechnology – as it is defined in the CP, and including synthetic biology – are covered under the HSNO Act GMO definition and the CP LMO definition.  New Zealand specifies its own risk/benefit/uncertainty assessment procedures, conducted by the Environmental Protection Authority (the Authority), in Regulation under the HSNO Act, using the *Hazardous Substances and New Organisms (Methodology) Order 1998* (the Methodology). Briefly, the Methodology requires that the Authority assesses risks, costs, benefits and any other impacts which relate to a number of specific environmental criteria, taking into account their magnitude and probability of occurrence. The Methodology also allows for the engagement of expert bodies to provide additional pertinent information, or to review and verify submitted information, so that the Authority may be expertly informed in its assessment and decision-making processes. The Methodology further specifies where and when public consultation is required, and how it must be taken into account. Finally, the Methodology has very specific procedures in place for taking uncertainty into account in any assessment of a GMO.  Regarding international needs and priorities for further guidance, New Zealand notes that there are many published risk assessment guidelines (refer to our response to item ***D.***for further detail) available for use by any Party, that demonstrate how to evaluate risks, benefits and uncertainty in regulatory decision-making processes. New Zealand considers that these publicly available resources are more than adequate for interested Parties, and that there are many governmental and non-governmental bodies that are prepared to offer assistance to Parties that request it. |

***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 |  | New Zealand’s view is that all current biotechnological approaches and techniques – including synthetic biology and gene drive – are readily covered under the CP LMO definition, and thus in New Zealand by the HSNO Act and its Methodology, as well as other available risk assessment guidelines. New Zealand therefore considers that there are no valid criteria for the selection of topics for risk assessment of LMOs.  We note that there are suggestions in the synthetic biology online forum that there is a need for additional guidance on risk assessment of synthetic biology where there is no existing comparator organism. For clarity, New Zealand considers that the lack of a comparator organism for risk assessment is insufficient as a technical criterion/justification for the selection of topics, since such organisms fall within the CP’s LMO definition, and numerous freely available risk assessment guidelines provide ample direction on the evaluation of scientific uncertainty in risk assessment and subsequent decision-making processes. |

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

|  |  |  |
| --- | --- | --- |
|  | **Perceived gaps** | **Views** |
| 1 | None | As has been noted in our responses to items ***B.*** and ***C.***, New Zealand is of the view that living organisms derived from the use of modern biotechnology meet the definition of a LMO in the CP. Therefore, New Zealand is also of the view that the existing published guidance material (e.g., Australia’s Risk Analysis Framework[[2]](#footnote-2), or the Environmental Risk Assessment Guide[[3]](#footnote-3), both written by groups of risk assessors well-versed in the nuances of the CP) is adequate for the assessment of risks, benefits and uncertainties of all LMOs. Finally, New Zealand wishes to stress that it is important to consider the potential benefits of a LMO, as well as its risks. It is New Zealand’s view that there are a number of guidance documents that have identifiable gaps in both the assessment of benefits and the assessment of scientific uncertainty, which may therefore lead to overly precautionary decision-making in environmental risk assessments of LMOs. |

1. With the exception of fusion of cells beyond the taxonomic family, which is instead regulated under the Imports and Exports (Living Modified Organisms) Prohibition Order 2005. [↑](#footnote-ref-1)
2. <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/risk-analysis-framework> [↑](#footnote-ref-2)
3. <https://goo.gl/T4uXnl> [↑](#footnote-ref-3)