



Convention on Biological Diversity

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CONFERENCE OF THE PARTIES TO THE CONVENTION
ON BIOLOGICAL DIVERSITY SERVING AS THE
MEETING OF THE PARTIES TO THE CARTAGENA
PROTOCOL ON BIOSAFETY

Ninth meeting
Sharm El-Sheikh, Egypt, 17-29 November 2018
Agenda item 15

DECISION ADOPTED BY THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY

9/13. Risk assessment and risk management (Articles 15 and 16)

The Conference of the Parties serving as the meeting to the Parties to the Cartagena Protocol on Biosafety,

Recalling decisions [BS-VII/12](#) and [XII/24](#) recommending a coordinated approach on the issue of synthetic biology,

Reaffirming decision XII/24 of the Conference of the Parties urging Parties and inviting other Governments to take a precautionary approach, in accordance with the preamble of the Convention and with Article 14, when addressing threats of significant reduction or loss of biological diversity posed by organisms, components and products resulting from synthetic biology, in accordance with domestic legislation and other relevant international obligations,

1. *Notes* the availability of numerous guidance documents and other resources to support the process of risk assessment, but *recognizes* the gaps and needs identified by some Parties;
2. *Recognizes* the divergence of views among Parties on whether or not additional guidance on specific topics of risk assessment is needed;
3. *Also recognizes* that, as there could be potential adverse effects arising from organisms containing engineered gene drives, before these organisms are considered for release into the environment, research and analysis are needed, and specific guidance may be useful, to support case-by-case risk assessment;
4. *Notes* the conclusions of the Ad Hoc Technical Expert Group on Synthetic Biology that, given the current uncertainties regarding engineered gene drives, the free, prior and informed consent of indigenous peoples and local communities might be warranted when considering the possible release of organisms containing engineered gene drives that may impact their traditional knowledge, innovation, practices, livelihood and use of land and water;
5. *Calls for* broad international cooperation, knowledge sharing and capacity-building to support, inter alia, Parties in assessing the potential adverse effects on the conservation and sustainable use of biodiversity from living modified fish and other living modified organisms produced through new developments in modern biotechnology, including living modified organisms developed through genome editing and living modified organisms containing engineered gene drives, taking into account risks to human health, the value of biodiversity to indigenous peoples and local communities, and relevant experiences of individual countries in performing risk assessment of such organisms in accordance with annex III of the Cartagena Protocol;

6. *Decides* to establish a process for the identification and prioritization of specific issues regarding risk assessment of living modified organisms for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol with a view to developing further guidance on risk assessment on the specific issues identified, taking into account annex I;

7. *Also decides* to consider, at its tenth meeting, whether additional guidance materials on risk assessment are needed for (a) living modified organisms containing engineered gene drives, and (b) living modified fish;

8. *Further decides* to establish an Ad Hoc Technical Expert Group on Risk Assessment, composed of experts selected in accordance with the consolidated modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice,¹ in accordance with the terms of reference contained in annex II;

9. *Decides* to extend the online forum on risk assessment and risk management in order to assist the Ad Hoc Technical Expert Group on Risk Assessment;

10. *Invites* Parties, other Governments, indigenous peoples and local communities, and relevant organizations to submit to the Executive Secretary information relevant to the work of the online forum and the Ad Hoc Technical Expert Group;

11. *Requests* the Executive Secretary, subject to the availability of resources:

(a) To commission a study informing the application of annex I to (i) living modified organisms containing engineered gene drives and (ii) living modified fish, to facilitate the process referred to in paragraph 6 above, and present it to the open-ended online forum and Ad Hoc Technical Expert Group on Risk Assessment and Risk Management;

(b) To collect and synthesize relevant information to facilitate the work of the online forum and the ad hoc technical expert group;

(c) To assist the lead moderator of the online forum in convening discussions and reporting on the results of the discussions;

(d) To convene a face-to-face meeting of the Ad Hoc Technical Expert Group on Risk Assessment;

12. *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice to make a recommendation as to whether additional guidance materials on risk assessment are needed for (a) living modified organisms containing engineered gene drives, and (b) living modified fish for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its tenth meeting.

Annex I

Identification and prioritization of specific issues of risk assessment of living modified organisms that may warrant consideration

The process for recommending specific issues of risk assessment for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety should include a structured analysis to evaluate whether the specific issues fulfil the following criteria:

(a) They are identified by Parties as priorities, taking into account the challenges to risk assessment, particularly for developing country Parties and countries with economies in transition;

(b) They fall within the scope and objective of the Cartagena Protocol;

¹ [Decision VIII/10](#), annex III.

(c) They pose challenges to existing risk assessment frameworks, guidance and methodologies, for example, if the issue at hand has been assessed with existing risk assessment frameworks but poses specific technical or methodological challenges that require further attention;

(d) The challenges in addressing the specific issue are clearly described;

and considering, inter alia:

(e) The specific issues concerning living modified organisms that:

- (i) Have the potential to cause adverse effects on biodiversity, in particular those that are serious or irreversible, taking into account the urgent need to protect specific aspects of biodiversity, such as an endemic/rare species or a unique habitat or ecosystem, taking into account risks to human health and the value of biological diversity to indigenous peoples and local communities;
- (ii) May be introduced into the environment either deliberately or accidentally;
- (iii) Have the potential to disseminate across national borders;
- (iv) Are already, or are likely to be, commercialized or in use somewhere in the world;

and consider a stock-taking exercise to determine if resources on similar issues have been developed by national, regional and international bodies and, if so, whether such resources may be revised or adapted to the objective of the Cartagena Protocol, as appropriate.

Annex II

Terms of reference for the Ad Hoc Technical Expert Group on Risk Assessment

The Ad Hoc Technical Expert Group on Risk Assessment, taking into account the work undertaken by the Ad Hoc Technical Expert Group on Synthetic Biology, shall:

(a) Review the study referred to in paragraph 11(a) of decision CP-9/13, and perform an analysis on (i) living modified organisms containing engineered gene drives and (ii) living modified fish, according to annex I, and supported by the data in the study;

(b) Consider the needs and priorities for further guidance and gaps in existing guidance identified by Parties in response to decision CP-VIII/12 with regard to specific topics of risk assessment and prepare an analysis;

(c) Make recommendations on (i) the need for guidance to be developed on risk assessment of living modified organisms containing engineered gene drives and living modified fish, and (ii) any adjustments to annex I of decision CP-9/13;

(d) Prepare a report for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice with a view to enabling the Subsidiary Body to prepare a recommendation for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety at its tenth meeting.
