31 January 2019

Call for expressions of interest
Study on Risk Assessment: application of annex I of decision CP 9/13 to living modified organisms containing engineered gene drives

In decision CP 9/13, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol decided to establish a process for the identification and prioritization of specific issues regarding risk assessment of living modified organisms with a view to developing further guidance on risk assessment on the specific issues identified, taking into account annex I which contained a list of criteria. It also decided to consider at its next meeting, whether additional guidance materials on risk assessment are needed for (a) living modified organisms containing engineered gene drives, and (b) living modified fish.

In this context, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol requested the Executive Secretary to commission a study informing the application of annex I of the decision to (i) living modified organisms containing engineered gene drives and (ii) living modified fish, to facilitate the process referred to in paragraph 6 of that decision.

The intention of the set of criteria is to offer a logical and consistent method for identification and prioritization of specific issues of risk assessment of living modified organisms that may warrant consideration under the Cartagena Protocol. The studies on the two aforementioned topics will support the testing of the criteria.

The study will be made available for discussions in an online forum and will also be reviewed by an Ad Hoc Technical Expert Group on Risk Assessment as part of its work.

The Executive Secretary invites the submission of expressions of interest from candidates interested in undertaking the study on living modified organisms containing engineered gene drives. (A separate study will be commissioned on living modified fish).

Description of duties and expected outcomes

The contractor/consultant(s) will carry out a study informing the application of annex I (here below) to living modified organisms containing engineered gene drives.

In doing so, the contractor/consultant (s) should as much as possible guide his/her work based on (i) scientifically sound information that has been published in peer-reviewed journals as well as (ii) information gathering exercises, that may involve discussions to gather information from biosafety national competent authorities, and stakeholders, and (iii) review of the application of existing risk assessment processes. This study should include, but should not be limited to: (i) information from areas where living modified organisms containing engineered gene drives are produced and/or are expected to be used for either field

testing or release, and (ii) any issues related to challenges for existing risk assessment methodologies and guidelines to assess the safety of living modified organisms containing engineered gene drives. The scope of the study should be guided by the scope of the Cartagena Protocol on Biosafety.

The study should include:
Testing of the criteria (annex below) against living modified organisms containing engineering gene drives, as well as a list of the literature consulted, the persons contacted to gather information, the risk assessment processes consulted or studied, and any other relevant information that support the application of a comprehensive, neutral and transparent work. The study should consider that the capacities to carry out risk assessment of living modified organisms containing engineered gene drives may vary from country to country.

The study delivered by the contractor/consultant(s) will be submitted to the open-ended online forum on risk assessment that will be coordinated by the Secretariat as per decision CP 9/13. The contractor/consultant (s) will be therefore requested to participate in the open-ended online forum that will be tentatively taking place during the fourth quarter of 2019 (dates to be determined). The contractor/consultant (s) participation should take place over a period of one week.

Expected outcomes:

(a) Delivery of work plan made by the contractor/consultant (s) including list of stakeholders, national competent authorities and others to be contacted. To be delivered as electronic document.

Indicators:

- Clear work plan indicating time frames, possible sources, methodology to be followed and expected results.
- The work plan reflects a neutral approach and the list of possible stakeholders and national authorities to be contacted reflects a variety of countries with different know-how and capacities in relation to organisms containing gene drives and risk assessment.

(b) First draft of the study. To be delivered as electronic document. This is an intermediate result.
Indicators:
- A complete first draft of the study, including:
  - Testing of the criteria (presented on annex I of decision CP-9/13) against living modified organisms containing engineering gene drives;
  - A list of the literature consulted;
  - A list of persons contacted to gather information;
  - The risk assessment processes consulted or studied, and any other relevant information that support the application of a comprehensive, neutral and transparent work.
- Any difficulty in testing the criteria are evidenced and clearly stated;
- The study considers that the capacities to carry out risk assessment of living modified organisms containing engineered gene drives may vary from country to country and explains how this was addressed.

(c) Final output, a study of approximately 25-30 pages with an executive summary of 2-5 pages. To be delivered as electronic document. Two documents should be presented: one showing the changes made in track changes, and a clean version.
Indicators:

- The final output incorporates the comments and suggestions provided by the Secretariat of the Convention on Biological Diversity after receiving the "first draft of the study" as per the timeline above;
- Changes made in the document should be evidenced in a tracked version.

Timeline

The tentative timeline for the study is as follows:

Date	Activity
February-March 2019	Application, selection and contractual arrangements
Week of 18 March 2019	Selected contractor/consultant(s) should provide a proposed work plan to undertake the study, including methodology, list of stakeholders, national competent authorities and others to be contacted.
17 May 2019	First draft of study submitted to Secretariat
20-31 May 2019	Secretariat's review of the study
21 June 2019	Final study submitted to Secretariat
Fourth quarter of 2019 (dates to be determined)	Participation in the open-ended online forum on risk assessment

Due to the limited time available to carry out the activities on risk assessment requested by the Parties, the selected candidate(s) will be expected to commit to providing deliverables on time.

Qualifications

It is expected that the selected candidate or team of candidates will have a combination of qualifications and experience in biological sciences or related disciplines, as well as deep knowledge and understanding of molecular biology, environmental considerations, risk assessment methodologies, familiarity and understanding of the Cartagena Protocol and biosafety regulatory systems and in particular the risk assessment process. The incumbent should also have knowledge and experience of the process to produce organisms containing engineered gene drives, their possible applications, and possible challenges that their use could bring to biosafety regulatory regimes.

How to apply

Candidates should submit their application including the following:

- CV of the candidate(s) including description of their expertise with the issues relevant to this application, as well as their familiarity with the Cartagena Protocol on Biosafety;
- Draft plan for the implementation of the study including a brief description of the methodology that the candidate(s) intends to follow in order to address the study requirements.

Expressions of interest should be submitted by e-mail to secretariat@cbd.int as soon as possible and no later than **22 February 2019**. Any questions may also be sent to the same e-mail address.

Selection process

The candidate(s) will be assessed against the criteria under "qualifications" included in this call, the availability of the candidate(s) to comply with the stipulated timeframe and the approach proposed by the candidate(s) to undertake the study.

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;

(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.