



Part I. Endorsement of submission

Name of Country: **MALAYSIA**

Name of Cartagena Protocol Focal point endorsing: **MS. ROSLINDA BINTI ULANG**

Signature of the Cartagena Protocol Focal Point:

Date: **10 JANUARI 2023**

Roslinda binti Ulang
SUB (BPAS)

Part II. Submission of information

The Conference of the Parties serving as the meeting to the Parties to the Cartagena Protocol on Biosafety, on decision CP-9/13, paragraph 6, decided 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 to that decision.

Based on the above, please submit information on the following areas:

(a) Name of Party identifying the issue/priority area taking into account the challenges to risk assessment, particularly for developing country Parties and countries with economies in transition;

MALAYSIA

(SUBMISSION OF 2 PROPOSALS FOR DEVELOPING GUIDANCE DOCUMENT)

(b) Indicate how the issue/priority area falls within the scope and objective of the Cartagena Protocol;

SUGGESTION 1 – RISK ASSESSMENT FOR RELEASE OF GM AQUATIC ORGANISMS / FISH

Genetically modified aquatic organisms/ fish fall under the definition of Living Modified Organism. Ensuring that a proper risk assessment and adequate risk management is conducted would meet the objectives of the Cartagena Protocol.

(c) Indicate how the issue/priority area 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;

SUGGESTION 1 – RISK ASSESSMENT FOR RELEASE OF GM AQUATIC ORGANISMS/ FISH

GM aquatic organisms, particularly GM fish (such as zebra fish for example) is used widely in research work. In addition, the non-research and development segment of aquatic organisms (commercial farming) is now active and expanding as well. There is a high possibility that the option of using GM aquatic organisms/ fish may be considered for commercial farming at a larger scale (compared to a manageable number for research and development phase).

Possible consequence with the release of GM fish/ aquatic organisms may affect the biodiversity and have irreversible consequences if it is not managed well.

(d) The challenges in addressing the specific issue are clearly described; and considering, inter alia:

SUGGESTION 1 – CHALLENGES IN RISK ASSESSMENT FOR RELEASE OF GM AQUATIC ORGANISMS/ FISH

Aquatic organisms/ fish are extremely mobile and have the potential to disseminate across national borders and different types of waterways. Introduction of GM fish/ aquatic organism into the waterways may have an irreversible impact on delicate ecosystems. Guidance for management of GM fish/ aquatic organism in a research and development setting and commercial farming is needed.

(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.

(a) Name of Party identifying the issue/priority area taking into account the challenges to risk assessment, particularly for developing country Parties and countries with economies in transition;

MALAYSIA

(SUBMISSION OF 2 PROPOSALS FOR DEVELOPING GUIDANCE DOCUMENT)

(b) Indicate how the issue/priority area falls within the scope and objective of the Cartagena Protocol;

SUGGESTION 2 – RISK ASSESSMENT OF GENOME EDITED PLANTS AND ANIMALS

Genome editing may be considered as an *in vitro acid nucleic technique* and is included under the national regulatory scope of some countries. Therefore plants and animals genetically manipulated using genome editing may fall under the scope of the Cartagena Protocol, which is modern biotechnology. Ensuring a proper risk assessment and sufficient risk management is conducted would meet the objectives of the Cartagena Protocol.

(c) Indicate how the issue/priority area 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;

SUGGESTION 2 – RISK ASSESSMENT OF GENOME EDITED PLANTS AND ANIMALS

Conducting a risk assessment for genome edited plants/ animals with no history of safe use may be challenging taking into consideration that this method is relatively new and an established risk assessment mechanism for these organisms have yet to be established locally.

(d) The challenges in addressing the specific issue are clearly described; and considering, inter alia:

SUGGESTION 2 – CHALLENGES IN RISK ASSESSMENT OF GENOME EDITED PLANTS/ ANIMALS

Advancement in genome editing is progressing swiftly and many new plants/ animals are manipulated genetically using this method. However, experience in conducting a risk assessment for the release of

genome edited plants/ animals is lacking. A guidance document on points to consider that can be applied would be very useful.

(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.