1. **Information on their needs and priorities for further guidance on specific topics of risk assessment of living modified organisms.**

The EU and its Member States are of the opinion that the updating of the current Guidance on Risk Assessment (the Roadmap) should take priority over the development of further guidance. When selecting topics for possible further guidance, we consider it important to assess their practical relevance to the objective of Cartagena Protocol. In this context, we note the recommendation of the AHTEG on risk assessment and risk management to develop outlines for further Guidance.

1. **(b) Existing guidance on specific topics of risk assessment of living modified organisms.**

The European Food Safety Authority (EFSA) has produced the following guidance documents:

*- Guidance on the environmental risk assessment of genetically modified animals.*

This document provides guidance for the environmental risk assessment (ERA) of living genetically modified (GM) animals, namely fish, insects and mammals and birds, to be placed on the European Union (EU) market in accordance with Regulation (EC) No 1829/2003 or Directive 2001/18/EC. It provides guidance for assessing potential effects of GM animals on animal and human health and the environment and the rationales for data requirements for a comprehensive ERA. The ERA should be carried out on a case-by-case basis, following a step-by-step assessment approach. This document describes the six sequential steps for the ERA of GM animals, as indicated in Directive 2001/18/EC: (1) problem formulation including hazard and exposure identification; (2) hazard characterisation; (3) exposure characterisation; (4) risk characterisation; (5) risk management strategies; and (6) an overall risk evaluation. The Scientific Panel on Genetically Modified Organisms of the European Food Safety Authority follows Annex II of Directive 2001/18/EC, considering specific areas of risk to be addressed by applicants and risk assessors during the ERA of GM fish, GM insects and GM mammals and birds. Each specific area of risk is considered in a structured and systematic way following the aforementioned six steps. In addition, this Guidance Document describes several generic cross-cutting considerations (e.g. choice of comparators, use of non-GM surrogates, experimental design and statistics, long-term effects, uncertainty analysis) that need to be accounted for throughout the whole ERA.

<http://www.efsa.europa.eu/en/efsajournal/pub/3200>

*- Guidance on the environmental risk assessment of genetically modified plants.*

This document provides guidance for the environmental risk assessment (ERA) of genetically modified (GM) plants submitted within the framework of Regulation (EC) No. 1829/2003 on GM food and feed or under Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (GMOs). This document provides guidance for assessing potential effects of GM plants on the environment and the rationales for the data requirements for a comprehensive ERA of GM plants. The ERA should be carried out on a case-by-case basis, following a step-by-step assessment approach. This document describes the six steps for the ERA of GM plants, as indicated in Directive 2001/18/EC, starting with (1) problem formulation including hazard identification; (2) hazard characterisation; (3) exposure characterisation; (4) risk characterisation; (5) risk management strategies; and (6) an overall risk evaluation. The scientific Panel on Genetically Modified Organisms (of the European Food Safety Authority (EFSA GMO Panel) considers seven specific areas of concern to be addressed by applicants and risk assessors during the ERA (1) persistence and invasiveness of the GM plant , or its compatible relatives, including plant-to-plant gene transfer ; (2) plant-to-micro-organism gene transfer; (3) interaction of the GM plant with target organisms and (4) interaction of the GM plant with non-target organisms, including criteria for selection of appropriate species and relevant functional groups for risk assessment; (5) impact of the specific cultivation, management and harvesting techniques; including consideration of the production systems and the receiving environment(s); (6) effects on biogeochemical processes; and (7) effects on human and animal health. Each specific area of concern is considered in a structured and systematic way following the above-mentioned steps (1 to 6). In addition, the guidance document is supplemented with several general cross-cutting considerations (e.g. choice of comparator, receiving environment(s), general statistical principles, long-term effects) that need to be considered in the ERA.

<http://www.efsa.europa.eu/en/efsajournal/pub/1879>

*- Guidance on the agronomic and phenotypic characterisation of genetically modified plants.*

This document provides guidance for the agronomic and phenotypic characterisation of genetically modified (GM) plants and clarifies the EFSA GMO Panel’s view on how agronomic and phenotypic data support the risk assessment of GM plants. Specific recommendations are given on (1) the selection of sites and test materials; (2) the quality and design of field trials; (3) the selection of relevant agronomic and phenotypic endpoints; and (4) data analysis. The guidance proposes a comprehensive and harmonised approach for the agronomic and phenotypic characterisation of GM plants, which should ensure the best use of agronomic and phenotypic data for the comparative analysis of GM plants and derived food and feed products, and for their food and feed and environmental risk assessment.

<http://www.efsa.europa.eu/en/efsajournal/pub/4128>

*- Guidance Document for the risk assessment of genetically modified plants containing stacked transformation events by the Scientific Panel on Genetically Modified Organisms (GMO).*

The objective of this document is to set the scene with respect to the risk assessment, under Regulation (EC) No 1829/2003 and Directive 2001/18/EC, of Genetically Modified (GM) plants containing stacked transformation events. For the purpose of this document “stacked” events are defined as those combined by conventional breeding . This document will be used by the EFSA Scientific Panel on Genetically Modified Organisms (GMO Panel) when reviewing and updating its current Guidance Document for risk assessment of genetically modified plants and derived food and feed.

<http://www.efsa.europa.eu/en/efsajournal/pub/512>

*- Guidance on selection of comparators for the risk assessment of genetically modified plants and derived food and feed.*

This opinion provides guidance in the area of comparators taking into account the requirements for the molecular characterisation, the food and feed and the environmental risk assessments. A key step in the risk assessment of genetically modified (GM) plants and derived food and feed is the identification of intended and unintended differences and equivalences between the GM plant and its comparator(s), taking into account the range of natural variation. In line with Regulation (EC) No 1829/2003 and Directive 2001/18/EC, the EFSA GMO Panel has, to date, required the use of non-GM lines with comparable genetic background as comparators. In the case of vegetatively propagated crops, these are the isogenic lines. In the case of sexually propagated crops these are non-GM lines as close as possible genetically to the GM plant under assessment. The identification and production of such comparators is becoming increasingly challenging due to the increasing complexity of GM plants, e.g. those developed by combining (stacking) events through conventional crosses, or those in which extensive compositional changes are targeted. Consequently, the EFSA GMO Panel has developed this guidance on the selection of comparators for the risk assessment of GM plants and derived food and feed. Whilst considering the requirements of Directive 2001/18/EC and Regulation (EC) No 1829/2003, the EFSA GMO Panel provides options which introduce flexibility in the selection of comparators based on sound scientific principles. This document addresses the selection of comparators for GM plants containing single or multiple events stacked by either conventional breeding, or by other approaches such as re-transformation, co-transformation and the use of multiple gene cassettes. The EFSA GMO Panel also considers situations where additional comparators may be required on a case-by-case basis and scenarios where appropriate comparators are not available (e.g. where extensive compositional changes are targeted). The EFSA GMO Panel recognises the different requirements for comparators for the molecular characterisation, food and feed and environmental components of the risk assessment.

<http://www.efsa.europa.eu/en/efsajournal/pub/2149>

Further to the abovementioned guidance documents, EFSA has also produced other guidance documents that may be of relevance:

*- Guidance on the risk assessment of food and feed from genetically modified animals and on animal health and welfare aspects.*

This document provides guidance for the risk assessment of food and feed containing, consisting of or produced from genetically modified (GM) animals, as well as for the health and welfare assessment of these animals, within the framework of Regulation (EC) No 1829/2003 on GM food and feed. The assessment strategy seeks to deploy appropriate approaches to compare GM animals and derived food and feed with their respective comparators. The health status of a food/feed producing animal has traditionally been considered as an important indicator of the safety of derived foods/feed and therefore comparative analysis of the phenotypic characteristics of the GM animal with the traditionally-bred animal, including health and physiological parameters, is considered an important component in the risk assessment. The document addresses the molecular characterisation, which provides information on the structure and expression of the insert(s) and on the stability of the intended trait(s); the toxicological assessment, which addresses the possible impact of biologically relevant change(s) in the GM animal and/or derived food and feed, the allergenicity assessment of the novel protein(s), as well as of the whole food derived from the GM animal; and the nutritional assessment to evaluate whether food and feed derived from a GM animal is as nutritious to humans and/or animals as food and feed derived from traditionally-bred animals. This guidance document also addresses the scientific requirements for the assessment of health and welfare of GM animals bred for food and feed use. The assessment is made in terms of the effective functioning of their body systems in a given environment. The document does not cover the environmental risk assessment of GM animals, which will be addressed in stand-alone guidance under development by the EFSA GMO Panel.

<http://www.efsa.europa.eu/en/efsajournal/pub/2501>

*- Guidance on the risk assessment of genetically modified microorganisms and their products intended for food and feed use.*

Genetically modified microorganisms (GMMs) are involved in the production of a variety of food and feed. The marketing of these products within the European Union falls under different legislative instruments, which establish the requirement for a risk assessment for the authorisation of the product. The present guidance describes the principles to be followed when conducting such a risk assessment, as well as the scientific information required in applications for authorisation to be evaluated by the Scientific Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel). Products form four categories, depending on their nature and the level of scientific information required for their evaluation by the EFSA GMO Panel. The guidance details the data to be provided for the assessment of products of each category, providing reference to other guidance that is also applicable. This document draws on the experience gained by the EFSA GMO Panel in assessing applications for marketing food and feed involving GMMs and takes into account the input received from different stakeholders, and updates the “Guidance Document for the risk assessment of genetically modified microorganisms and their derived products intended for food and feed”, adopted by the EFSA GMO Panel in 2006.

<http://www.efsa.europa.eu/en/efsajournal/pub/2193>

*- Guidance for risk assessment of food and feed from genetically modified plants.*

This document provides updated guidance for the risk assessment of food and feed containing, consisting or produced from genetically modified (GM) plants, submitted within the framework of Regulation (EC) No 1829/2003 on GM food and feed. The risk assessment strategy for GM plants and derived food and feed proposed seeks to deploy appropriate approaches to compare GM plants and derived food and feed with their respective comparators. The underlying assumption of this comparative approach is that traditionally cultivated crops have gained a history of safe use for consumers and/or domesticated animals. The document provides guidance on how to perform the comparative analysis of the relevant characteristics of the GM plant. The document addresses the details of the different components of the risk assessment: the molecular characterisation, which provides information on the structure and expression of the insert(s) and on the stability of the intended trait(s); the toxicological assessment, which addresses the impact of biologically relevant change(s) in the GM plant and/or derived food and feed resulting from the genetic modification; the assessment of potential allergenicity, of the novel protein(s) as well as of the whole food derived from the GM plant; the nutritional assessment to evaluate whether food and feed derived from a GM plant is not nutritionally disadvantageous to humans and/or animals. In addition every section of the document addresses specifically the requirements for GM plants containing a combination of transformation events, providing guidance on how to establish that the combination is stable and that no interactions occurs between the events that may raise safety concerns. The document does not cover the environmental risk assessment of GM plants which is addressed in a stand-alone environmental risk assessment (ERA) guidance document developed by the EFSA GMO Panel.

<http://www.efsa.europa.eu/en/efsajournal/pub/2150>