Council of the European Union
General Secretariat

Brussels, 12 March 2019

WK 3557/2019 INIT

LIMITE

ENV

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

CONSULTATION

From: To:	General Secretariat of the Council Working Party on International Environment Issues (Biosafety)
N° prev. doc.:	WK 2777/2019 and WK 3205/2019
Subject:	Biosafety: Notification 2019-009 - Risk Assessment and Risk Management under the Cartagena Protocol on Biosafety: draft EU+MS submission of information on risk assessment of living modified organisms containing engineered gene drives and living modified fish - INFORMAL SILENCE PROCEDURE

Following the request for comments set out with WK 3205/2019 and based on comments received, delegations will find attached a draft submission by the EU and its Member States to Notification 2019-009 as regards risk assessment of living modified organisms containing engineered gene drives and living modified fish, as prepared by the Presidency.

An **informal silence procedure is hereby launched**. If no comments are received by the Presidency (Madalin.Blidaru@mmediu.ro and Adriana.Ivanus@mmediu.ro), the Commission (Ilaria.CIABATTI@ec.europa.eu, Anastasia.PAGIDA@ec.europa.eu and Frank.SWARTENBROUX@ec.europa.eu) and the General Secretariat of the Council (Pia.Sellerup@consilium.europa.eu, Ludmila.Zalik@consilium.europa.eu, aline.maretto@consilium.europa.eu and environment@consilium.europa.eu) by **Thursday 14 March 2019 at 12h00** , the attached draft submission will be deemed as agreed and sent to the CBD Secretariat.

12 March 2019

Submission by the European Union and its Member States to Notification 2019-009

Information on risk assessment of living modified organisms containing engineered gene drives and living modified fish

for an Open-ended online forum

Draft

The EU and its Member States are pleased to share their overall views and information on issues related to this notification. Additional and more specific information is provided by individual EU Member States in their national submissions.

The EU and its Member States support the establishment of an Ad Hoc Technical Expert Group (AHTEG) on risk assessment and the extension of the open-ended online forum on risk assessment and risk management to assist the work of the AHTEG on living modified organisms (LMOs) containing engineered gene drives and living modified (LM) fish; we will constructively participate in their work.

The EU and its Member States are pleased to share updated information concerning the risk assessment of LMOs containing engineered gene drives in the EU:

- The Scientific Advice Mechanism (SAM) explanatory note of April 2017 on new techniques in agricultural biotechnology[1] included an outline of the agricultural application of new techniques in the fields of synthetic biology and gene drives.
- In December 2018, the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) adopted a Position paper on emerging issues and the role of the SCHEER[2] and a Statement on emerging health and environmental issues[3].
  The Position paper describes the SCHEER's methodology for identifying emerging issues in the non-food area.
  The Statement on emerging health and environmental issues specifies 14 emerging issues in the non-food area having a potential impact on human health and/or the environment in the future.
- The European Food Safety Authority (EFSA) has been mandated for an opinion on engineered gene drives to identify potential risks and determine whether existing guidance for risk assessment is adequate or needs to be updated. Final opinion is expected by the end of 2020.
- The European Group on Ethics in Science and New Technologies (EGE) has been requested to provide an opinion on gene editing (including engineered gene drives) by summer of 2019.

[1] Scientific Advice Mechanism (SAM) High Level Group of Scientific Advisors, Explanatory Note 02 - New Techniques in Agricultural Biotechnology, Brussels, 28 April 2017, available at: https://ec.europa.eu/research/sam/index.cfm?pg=agribiotechnology

[2] SCHEER (Scientific Committee on Health, Environmental and Emerging Risks). Emerging Issues and the Role of the SCHEER. Position Paper (2018), 5-6 June 2018, available at: https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_s_001.pdf

[3] SCHEER (Scientific Committee on Health, Environmental and Emerging Risks) Statement on emerging health and environmental issues (2018), 20 December 2018, available at: https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_s_002.pdf

- Until today, no application for the authorisation of an LMO containing an engineered gene drive has been submitted in the EU.

The EU and its Member States are pleased to share updated information concerning the risk assessment of LM fish in the EU:

- The Environmental Risk Assessment (ERA) of LM fish is regulated in the EU under Directive 2001/18/EC[4]. Annex II of this Directive provides for the general principles and methodologies of ERA of LMOs, including a six-step approach of the assessment and listing relevant areas of risk.
- The European Food Safety Authority (EFSA) adopted in 2013 a *Guidance on the environmental risk assessment of genetically modified animals*[5]. The scope of this Guidance covers LM fish reared within controlled aquaculture and aquaria facilities to be placed on the market of the EU for food and feed production or other uses (i.e. ornamental fish). The Guidance considers the environmental impact both within the confined facilities and after an accidental release of LM fish into the environment.
- Additionally EFSA in 2012 adopted a *Guidance on the risk assessment of food and feed from genetically modified animals and animal health and welfare aspects*[6]. This guidance provides appropriate approaches to compare GM animals and derived food and feed with their respective comparators. Animals that are taken into consideration include all husbandry animals, and fish, as well as crustaceans and molluscs. The components included in the guidance are: the comparative analysis of the phenotypic characteristics of the LM animal, including health and physiological parameters, the molecular characterisation, the toxicological assessment, the assessment of potential allergenicity of the novel protein(s), as well as of the whole food derived from the LM animal and the nutritional assessment.
- Until today, no application for the authorisation of an LM fish has been submitted in the EU.

---

[4] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1), available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02001L0018-20180329&qid=1550847942646&from=EN

[5] EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2013. Guidance on the environmental risk assessment of genetically modified animals. EFSA Journal 2013;11(5):3200, 190 pp. doi:10.2903/j.efsa.2013.3200, available at: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2013.3200

[6] EFSA Panels on GMO and AHAW; 2012. Scientific Opinion on the Guidance on the risk assessment of food and feed from genetically modified animals and animal health and welfare aspects. EFSA Journal 2012;10(1):2501. [43 pp.] doi:10.2903/j.efsa.2012.2501, available at: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2012.2501