*19 February 2019*

**Submission by the European Union and its Member States to Notification 2018-103:**

**Information on synthetic biology and nomination of experts for an Open-ended online forum**

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 submissions.

The EU and its Member States support the extension of the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology and the open-ended online forum to support the work of the AHTEG; we will constructively participate in their work.

The EU and its Member States also support a coordinated approach on synthetic biology between the Convention and its Protocols, taking into account that synthetic biology is a cross-cutting issue and may have potential impacts vis-à-vis the three objectives of the Convention and those of the Cartagena Protocol and Nagoya Protocol. In particular, the EU and its Member states recommend coordination and sharing of expertise between the AHTEG on Synthetic Biology and the AHTEG on Risk Assessment under the Cartagena Protocol.

With regard to the completion of the analysis requested in decision XIV/19, paragraph 18 a) and b), the EU and its Member States support the decision to build on and fully recognise the analysis prepared by the Executive Secretary in document SBSTTA/22/INF/17. We will contribute constructively to this process in order to make a final decision at the fifteenth meeting of the Conference of the Parties.

The EU and its Member States are pleased to share updated information concerning past and ongoing initiatives on synthetic biology and engineered gene drives in the EU:

* The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Consumer Safety (SCCS) delivered in 2014 and 2015 three opinions on synthetic biology (SynBio) [[1]](#footnote-1). The opinions addressed definition of synthetic biology, risk assessment methodologies and safety aspects, risks to the environment and biodiversity and research priorities in the field of synthetic biology.
* The Scientific Advice Mechanism (SAM) explanatory note of April 2017 on new techniques in agricultural biotechnology [[2]](#footnote-2) 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 [[3]](#footnote-3) and a Statement on emerging health and environmental issues [[4]](#footnote-4).

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. Among these issues, the Committee has identified new RNA pesticides and gene editing to reduce/eradicate pest populations and Do-it-Yourself Synthetic Biology.

* The European Food Safety Authority (EFSA) has been mandated for two opinions on plants and microorganisms respectively, obtained through synthetic biology. The objective is to identify new developments, potential risks and determine whether existing guidance for risk assessment is adequate or needs to be updated. Final outcome is expected by the end of 2020.
* EFSA has also been requested 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.

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1. SCENIHR, SCCS, SCHER (2014) Synthetic Biology I Definition, Opinion, September 2014. Available from: http://ec.europa.eu/health/scientific\_committees/emerging/docs/scenihr\_o\_044.pdf SCENIHR, SCCS, SCHER (2015) Synthetic Biology II - Risk assessment methodologies and safety aspects, Opinion, May 2015. Available from: http://ec.europa.eu/health/scientific\_committees/emerging/docs/scenihr\_o\_048.pdf SCENIHR, SCCS, SCHER (2015) Synthetic Biology III – Research priorities, Opinion, December 2015. Available from: http://ec.europa.eu/health/scientific\_committees/emerging/docs/scenihr\_o\_050.pdf [↑](#footnote-ref-1)
2. Scientific Advice Mechanism (SAM) High Level Group of Scientific Advisors, Explanatory Note 02 - New Techniques in Agricultural Biotechnology, Brussels, 28 April 2017. https://ec.europa.eu/research/sam/index.cfm?pg=agribiotechnology [↑](#footnote-ref-2)
3. SCHEER (Scientific Committee on Health, Environmental and Emerging Risks). Emerging Issues and the Role of the SCHEER. Position Paper (2018), 5-6 June 2018. https://ec.europa.eu/health/sites/health/files/scientific\_committees/scheer/docs/scheer\_s\_001.pdf [↑](#footnote-ref-3)
4. SCHEER (Scientific Committee on Health, Environmental and Emerging Risks) Statement on emerging health and environmental issues (2018), 20 December 2018. https://ec.europa.eu/health/sites/health/files/scientific\_committees/scheer/docs/scheer\_s\_002.pdf [↑](#footnote-ref-4)