Annex

Mandate for an EFSA opinion on genetically modified organisms engineered with gene drives (gene drive modified organisms) and their implications for risk assessment methodologies

Background

Directive 2001/18/EC[1] lays down that deliberate release of genetically modified organisms (GMOs) is subject to an environmental risk assessment. EFSA published in May 2013 a Guidance document on the environmental risk assessment of GM animals[2] to be placed on the market according to Regulation (EC) No 1829/2003[3] and Directive 2001/18/EC[4]. This guidance includes a specific section on GM insects for which some considerations are made relating to the possible presence of gene drive systems.

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) upon a request from the European Commission[5]. 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.

In the third opinion the Scientific Committees (SCs) referred to "gene drives" as an emerging technology that uses similar techniques to the ones that are commonly applied in genome editing for Synthetic Biology applications. However, the SCs decided that an analysis of the risks and implications of "gene drives" was outside the scope of their Opinion. Nevertheless, they considered that the increasing use of gene drive technology would require a similar in-depth analysis, including a detailed assessment of its implications for risk assessment methodology and its potential impact on biodiversity and the environment.

The Scientific Advice Mechanism (SAM) explanatory note of April 2017 on new techniques in agricultural biotechnology[6] also includes an outline of the agricultural application of new techniques in the fields of synthetic biology and gene drive.

Further analysis on gene drive systems has also been carried out at national level. In particular, the Scientific Committee of the French High Council for Biotechnology (Haut Conseil des Biotechnologies, HCB) published an opinion on 31 May 2017 on the use of GM mosquitos for

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[1] Directive 2001/18/EC of the European Parliament and of the Council 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), Article 4.

[2] 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.

[3] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L 268, 18.10.2003, p. 1-23.

[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. 1–39.

[5] 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

[6] https://ec.europa.eu/research/sam/index.cfm?pg=agribiotechnology

vector control[7]. The Scientific Committee concluded that criteria for risk assessment of Directive 2001/18/EC are applicable and a priori sufficient for the risk assessment of GM mosquitos for vector control in general. However, they considered that gene drive engineered systems introduce novel elements and a change of scale and objectives that require an adaptation of risk assessment.

Terms of reference

Building on the work mentioned above and taking into account the available literature, the Commission asks EFSA, in accordance with Art 29 (1) of Regulation (EC) No 178/2002, for an opinion on genetically modified organisms engineered with gene drives (gene drive modified organisms) and their implications for risk assessment methodologies. In particular, through a problem formulation exercise providing the foundation for the environmental risk assessment:

1. EFSA is requested to identify potential risks in terms of impact on human and animal health and the environment that gene drive modified organisms could pose. In this respect EFSA is also asked to identify potential novel hazards of gene drive modified organisms, considering relevant comparators, where appropriate.
2. EFSA is requested to determine whether the existing guidelines for risk assessment are adequate and sufficient for gene drive modified organisms or whether there is a need for updated guidance.
3. In the latter case EFSA is requested to identify the specific areas where such updated guidance is needed.

Under the present mandate, EFSA is not requested to develop guidelines for the risk assessment of gene drive modified organism.

EFSA is also requested to provide technical and scientific expertise on risk assessment of gene drive modified organisms to support the EU in the work under the Convention on Biological Diversity and the Cartagena Protocol on Biosafety.

[7] Haut Conseil des Biotechnologies, Comité scientifique, AVIS en réponse à la saisine du 12 octobre 2015 concernant l'utilisation de moustiques génétiquement modifiés dans le cadre de la lutte antivectorielle. 31 mai 2017. http://www.hautconseildesbiotechnologies.fr/en/avis/avis-relatif-a-lutilisation-moustiques-gm-dans-cadre-lutte-antivectorielle