EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2021)1325880

Standing Committee on Plants, Animals, Food and Feed
Section *Regulatory Committee 2001/18/EC*
03 February 2021

CIRCABC Link: *https://circabc.europa.eu/w/browse/c7be6790-ac84-4a2f-a3c3-e91aeafa44c6*

SUMMARY REPORT

A.01 Draft Commission Notice on the submission of notifications under Articles 13 and 17 of 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 and under the relevant provisions of Regulation (EC) 178/2002, as amended by Regulation (EU) 2019/1381 - Presentation by the Commission and discussion.

The Commission presented the revised draft Notice and explained how the Member States' comments have been taken into account in this revised draft. The Commission also provided answers to the questions of the Member States. Discussions focused on clarifying the roles of EFSA and the Member States in the new steps, introduced by Regulation (EU) 2019/1381 (Transparency Regulation) when applicable during the procedure under the Directive 2001/18/EC.

Two Member States expressed their concern on the legal basis for the implementation of the new Transparency Regulation provisions.

The Commission clarified that the Transparency Regulation is a targeted amendment of the General Food Law as well as eight other sectoral acts, including the Directive to ensure the necessary consistency (recital 39 of the Transparency Regulation).

The General Food Law is the founding regulation of EFSA regulating all aspects pertinent to the risk assessment activities entrusted to the latter, which includes scientific opinions on products other than food and feed relating to genetically modified organisms under the Directive 2001/18/EC (Article 22 (5)(c) of the General Food Law).

Given the nature of the instrument (EU Regulation), all General Food Law provisions are directly applicable in the national legal order without the need to amend the GMO Directive. As a consequence, all relevant amendments brought about in the General Food Law by the Transparency Regulation, which concern the EU risk assessment performed by EFSA, are directly applicable also in the area of the GMO Directive, including:

- Pre-submission advice given by EFSA upon request by a potential notifier;
- Notification of commissioned studies and relevant procedural consequences;
- Public consultations pertaining to renewals and for new approvals;

- Standard data formats

The Commission clarified that, in line with Article 39(2)(b) of Regulation (EC) 178/2002, the Committee would be involved in any future implementing act concerning standard data formats for the purposes of the notifications under Part C of the Directive.

A.02 Electronic submission system provided by the Commission: submission of notifications under Part C of the Directive 2001/18/EC - Presentation by the Commission and discussion.

The Commission gave a demonstration of the new IT tool for the e-submission and process of notifications under Part C of the Directive. One Member State asked about the process of public dissemination of the notification to which the Commission replied that this would be handled by EFSA once the notification arrives at EFSA. Another Member State asked if there is a direct link between this e-submission system and the Biosafety Clearing House (BCH) website. This is not the case for the moment, but could be implemented in the future, if needed. The Commission invited the Member States to provide comments on the e-submission system based on the presentations given.

A.03 Information submitted by the Member States to the Commission on the development and application of *in vitro* mutagenesis techniques on certain varieties of agricultural species – Presentation by the Commission and discussion.

The Commission presented an overview of the replies submitted by Member States on the development and application of *in vitro* mutagenesis techniques to varieties of agricultural species. The data submitted provided no evidence that there would be a difference between *in vivo* and *in vitro* random mutagenesis. Member States had no further comments to report.

A.04 EFSA scientific opinions on synthetic biology and genetically modified insects containing engineered gene drives: follow-up EFSA work – Discussion.

Following EFSA's presentation of the scientific opinions on synthetic biology and gene drives at the Directive 2001/18 Regulatory Committee of 12 November 2020, the Commission summarised the feedback received from Member States on the appropriate follow-up work by EFSA in these areas. EFSA informed that the scientific opinion on Synthetic Biology developments in plants will be published on 5 February and addressed some comments received from the Member States. Questions were raised about next steps and the Commission replied that dialogue with EFSA was ongoing to define future mandates and that Member States considerations would be taken into account. As regards synthetic biology in plants and microorganisms, the Commission also informed that EFSA had already started follow-up work on food and feed aspects, which were not covered in the recent scientific opinions.

M.01 Third Countries' requests for non-GMO certificates for exports.

A Member State raised the issue of non-GMO certificates for exports that some third countries are requesting. Many Member States expressed their concerns and asked for an EU approach in this matter. The Commission explained the role of different actors in third country requests and updated the Member States on recent developments.

Two Member States asked the Commission about a TBT notification of India, relating to the requirement of GM free certificate for imported food consignments. The Commission informed the Committee about its reaction to this notification.

M.02 Follow up of a notification about unauthorised seeds

A Member State informed the Committee about their investigations on unsolicited seed packages from China, which had been found positive for unauthorised genetic modifications. The seeds in question lacked germination capacity and therefore it was concluded that they posed no risks for the environment.