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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 draft Notice and EFSA presented the relevant parts of its practical arrangements, which will be adopted pursuant to Article 32c(3), 32b(8), 38(3) and 39d(5) of Regulation (EU) 2019/1381.

The draft Notice aims to facilitate an aligned implementation of the relevant provisions of Regulation (EU) 2019/1381 and to provide guidance both to business operators that intend to submit notifications under Part C of the Directive and to the competent authorities of the Member States that receive such notifications.

The Commission provided clarifications and took note of the Member States' comments, in view of further improving the text of the draft Notice. Member States were asked to provide their comments in writing, by the 4 December, so that an updated version of the draft Notice can be discussed at the next meeting of the Regulatory Committee.

A.02 *ENGL evaluation of a detection method for a genome-edited oil seed rape. Presentation by EURL/ENGL and discussion.*

The European Union Reference Laboratory for GM food and feed (EURL) informed the Committee about the discussion that took place in October in the 30th European Network of GMO Laboratories (ENGL) Plenary meeting and the subsequent joint EURL/ENGL evaluation on the recent publication of a detection method for a gene edited oilseed rape. The EURL explained the design of the detection method and the result of the ENGL evaluation. The main conclusion is that, although this method complies in many aspects with the performance requirements in the ENGL's Minimum Performance Requirements (MPR) guidelines, this method cannot be applied for unequivocal detection, identification and quantification in the frame of enforcing EU legislation on GMOs, and that enforcement of GM legislation for gene-edited crops is not further advanced. In addition, the ENGL also concluded that the statements and conclusions published in the *ENGL Report on the detection of food*

and feed plant products obtained by new mutagenesis techniques remain valid. Two Member States fully supported the findings of the ENGL and no Member State disagreed or challenged the evaluation.

One Member State informed the Committee of the analysis of 18 mixed samples containing oil seed rape. These samples were taken during a control by an organisation responsible for controls and labelling of non-GMO products in the frame of GM-free supply chain. The samples were analysed by an official control laboratory. None of the samples tested positive for the genome-edited oil seed rape.

Two Member States asked clarification of the legal status of the concerned oil seed rape. In this respect, the Commission reiterated its request expressed during the meeting of the joint working group on new genomic techniques held on 18 September 2020 asking Member States to share all available information with the Commission in view of a future discussion.

A.03 EFSA scientific opinion on plants developed using type 1 and type 2 Site Directed Nuclease and Oligonucleotide Directed Mutagenesis. Presentation by EFSA.

A.04 EFSA scientific opinions on Synthetic Biology developments in plants and microorganisms. Presentation by EFSA.

A.05 EFSA scientific opinion on gene drive modified organisms and their implications for risk assessment methodologies. Presentation by EFSA.

EFSA presented the four opinins recently adopted, which respond to specific mandates by the Commission in 2018 and 2019, on

- Plants developed using the mutagenesis techniques SDN-1, SDN-2, ODM
- Plants and microorganisms developed through synthetic biology (two opinions)
- Gene Drive modified insects

EFSA informed that the synthetic biology microorganisms and gene drive modified insects opinions had been published, while the SDN1/SDN2/ODM and synthetic biology plants opinions would be published in the coming weeks.

One Member State asked about the definition of synthetic biology. EFSA explained that there is no internationally agreed definition of synthetic biology, but EFSA based its work on the definition provided by the EC non-food Scientific Committees in 2014[1]. EFSA also added that a more precise definition (based on thresholds) might be difficult, but is not the work of EFSA and is not needed for risk assessment of the product per se.

Two Member States commented that as regards risk assessment methodologies, other sectors (e.g. the pharmaceutical sector) could also be informative.

One Member States asked for clarification on the conclusion by EFSA that no new hazards have been identified for current and near future synthetic biology plant applications. EFSA referred to the Commission mandate, which requested the identification of new hazards compared to established techniques of genetic modification, and confirmed that with the case studies addressed in the opinion no new risks/hazards have been identified for the microbial and molecular characterisation and ERA. EFSA also added that further work on food and feed

[1] https://ec.europa.eu/health/sites/health/files/scientific_committees/emerging/docs/scenihr_o_044.pdf

aspects will complement this analysis. The current methodologies are considered adequate to identify potential hazards, but problem formulation and case-by-case risk assessment might require more considerations in the future.

One Member State enquired on whether EFSA considered the gene drive modified insects alone or in a real life scenario which may involve pesticides to reduce the number of insects before release. EFSA confirmed the need to expand the concept of comparators, including the possibility to make a comparison with other vector control approaches.

The Commission informed that EFSA scientific opinion on plants developed using SDN1, SDN2 and ODM will contribute to the ongoing Commission study on new genomic techniques. The three opinions on synthetic biology and gene drive modified insects will increase the knowledge and understanding of these technological developments and will also support the EU in the international negotiations under the Convention on Biological Diversity and the Cartagena Protocol on Biosafety.

The Commission enquired the Member States on possible follow-up work by EFSA to these scientific opinions. One Member State proposed a broad discussion, taking into account that research in Europe in key areas started lagging behind. Another Member State raised the need to develop guidance on genome edited organisms and synthetic biology plants.

The Commission proposed the MS to send their views in writing before the end of the year break for further discussion at the next Regulatory Committee meeting and announced that the Commission will continue discussion with EFSA on possible next steps on EFSA's future work.

A.06 Brexit preparedness.

The Commission recalled that the transition period provided in the EU-UK Withdrawal Agreement will come to an end on 31 December 2020, and reiterated its availability to address any questions from Member States related to actions needed to implement the Agreement.

One Member State asked about the possibility to market maize MON810 seeds in the UK as from 1 January 2021, in view of the existence of cultivation bans in some parts of the country (NI, Scotland and Wales). The Commission clarified that as from 1 January maize MON810 seeds as well as all other EU-authorised GM products will continue to have access to the market of NI, but for the time being there is no information on whether and under which conditions EU-authorised GM products will have access to the rest of the UK (England, Scotland and Wales).

M.01 Imports of products

A Member State asked how Member States should handle imports of products, which are not considered as GMOs in third countries (including the UK) but are considered GMOs in the EU. The Commission clarified that this question is not linked to Brexit and confirmed that it is addressed in the study on the status novel genomic techniques, requested by the Council. The study will also include the views of the Member States and relevant stakeholders on these aspects.

M.02 TBT notification

Two Member States asked the Commission about the TBT notification G/TBT/N/IND/168 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.