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Health and Food Safety Directorate General

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SUMMARY REPORT OF THE REGULATORY COMMITTEE ON DIRECTIVE 2001/18/EC HELD IN BRUSSELS ON 13 OCTOBER 2017

CIRCABC Link: *https://circabc.europa.eu/w/browse/2f3e0a8b-1415-46fe-b85c-e6548c8ff5d6*

A.01 Unauthorized genetically modified petunias – update by Member States and the Commission.

The Commission presented a summary of the reports submitted by the Member States, including controls, findings, measures taken and risk assessment. In 12 Member States the environmental risk of this unauthorized release was assessed and in all cases no risk has been identified. Considering that any remaining plants will not overwinter, it was concluded that the unauthorised release has been terminated.

The Member States' proposals for the way forward were also discussed. The following actions were agreed:

These Member States in which petunia breeders are established will communicate to the Commission by mid-December the measures in place to ensure that no GM petunias are placed again on the market; Member States will raise awareness of operators; Member States will in the controls focus on key points of the distribution chains and, when the marketing season starts, perform random controls of retailers; Member States will assess (on the basis of scientific literature, ongoing and past field trials or any other relevant information) whether and which other species of GM ornamental plants could potentially enter the EU market.

The Commission will continue to facilitate the effective information sharing with Member States.

The issue will be discussed again in a Regulatory Committee meeting in early 2018.

A.02 Update by Spain on measures taken and their results to eliminate teosinte from maize fields.

Spain presented an update of the state of play and measures taken to eliminate the presence of teosinte from Spanish maize fields. According to Spain, teosinte was found in Catalonia and Aragon. The measures taken, such as destruction of the weeds and training of the farmers, have had a good impact as the infection rate has decreased to very low levels. Research is also being carried out to study the characteristics of teosinte and its effects on maize cultivation. The abovementioned actions are relevant also for GM maize fields.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Directive, amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms.

The Commission presented the draft that was submitted to the Committee on 15 September 2017. The comments submitted by Member States were discussed, and the majority of those comments aimed at improving the clarity of the document. Regarding specific points raised by certain Member States, the Commission also clarified the following:

- The technical relevance of the notion of "limit of concern";
- The risk assessment approach for stacked transformation events must be totally coherent to that of Regulation (EU) 503/2013;
- Resistance of a target organism to the protein expressed by GM plants has always been considered as an "environmental" issue under the GMO framework;.
- The need to take account of potential receiving environments is strengthened in the draft proposal;
- The process to assess stacked events includes the requirement to assess additive and synergistic and antagonistic effects;
- The Council conclusions have all been taken into account in so far as the legal basis of the draft allows only for adaptation to technical progress and does not allow for amending essential elements of Directive 2001/18/EC.

The text was further elaborated based on the technical comments made by Member States with a view to reach an agreement.

Vote taken: Favourable opinion

Reasons for negative vote or abstention:

- The obligation for stacked transformation events, to submit an ERA of each single transformation event contained in the stack, is not justified from a scientific point of view;
- The evolution of resistance of the target organism to the expressed protein and any adverse environmental effects thereof, should not be regarded as an environmental effect;
- Long-standing opposition to GMOs as well as to the negative perception of national public opinion regarding GMOs;
- The conclusions of the Environment Council of 4 December 2008 of GMOs regarding long-term effects and receiving environments have not all been taken into account;
- Risk assessment of stacked events should be more detailed in order to address synergistic and cumulative effects;
- Reservations regarding the completeness of the risk assessment framework.
- No national position could be agreed;
- The draft was still assessed at national level, on the date of the vote.

Written statement from the Netherlands regarding the vote on the draft Commission Directive, aiming to amend the Annexes to Directive 2001/18/EC, regarding the Environmental Risk Assessment (13 October 2017).

The Netherlands can only consent to requirements that are necessary to assess the risk to humans and the environment. The Netherlands votes against the draft amendment because of two reasons.

The first reason is the requirement in the proposed Annex II, C.4 (a) that in case of an application for a GMO containing stacked transformation events," the notifier shall provide an ERA for each single transformation event in the GMO or refer to already submitted notifications for those single transformation events". However, this information is not always necessary to perform an ERA of a GMO with stacked events. To make this mandatory as a general rule would impose unnecessary requirements on applicants.

The second reason is the requirement in the proposed Annex IIIB, II.B.4 (c) (ii), to provide an assessment "of the potential for evolution of resistance of the target organism to the expressed protein (based on the history of evolution of resistance to conventional pesticides or transgenic plants expressing similar traits) and any adverse environmental effect(s) thereof". Considering that a resistance to a certain chemical substance in the target organism develops regardless of the source of the substance, it should not be relevant that the source is a GMO. The Netherlands considers the development of resistance in target organisms to chemical substances applied in agriculture as an agronomical or economic effect, but not as an environmental effect. This view is in line with the assessment under the Pesticide Regulation. To make this a requirement for environmental risk assessment of a GMO would therefore both be unnecessary and inconsistent with the Pesticide Regulation.

In conclusion, the Netherlands considers the current draft amendment to the Directive as a step forward from the previous versions, but, for the two reasons stated above, votes against the amendment.

M.01 Regulatory status of mosquito control methods (question submitted by a Member State).

The Member State explained their question on the regulatory status of mosquitoes, artificially infected with Wolbachia bacteria, for the control of mosquito pests, causing human diseases. The Commission asked Member States for their views on the matter. One Member State considered that this would not result in a GM organism but would rather be a biological control agent.

The Commission explained that the GMO legislation or the biocides legislation would be applicable depending on the particular case.

The applicability of the GMO legislation must be analysed in light of the GMO status of both the bacteria and the artificially infected mosquito and the definition laid down in Article 2(2) and the techniques referred to in Annex I of Directive 2001/18/EC.

The applicability of Regulation (EU) No 528/2012 on biocidal products must be analysed on the basis of Article 3(1) of that Regulation, considering whether such use or the used organisms would fall under the definitions of 'biocidal product', 'micro-organism', 'active substance' and 'treated article'. These aspects need to be discussed with the Competent Authorities in the biocides area.

It was agreed that Member States send their views on the issue. Based on this, the Commission will report back to the Member States through the relevant Committee meetings in the GMO and Biocides areas.

M.02 Unauthorized oilseed rape seeds – notification by a Member State.

A Member State notified the Commission that a small consignment of conventional oilseed rape seeds was found positive for a genetic modification at a level below 0.1% and the consignment was rejected. The lot was produced in one Member State and that Member State explained that it was sold to two Member States only. In the production Member State the product was found negative, while in the other two Member States the same product was found positive just above the detection limit. In one Member State the seeds had been planted before the notification. The Commission asked the Member States involved to follow-up and share the developments in their countries. The Commission also offered possible technical assistance via the EURL, should the Member States involved consider it necessary.

M.03 Update by Commission on NBT conference.

The Commission reported shortly on the recent conference on Modern Biotechnologies in Agriculture, which took place on 28 September 2017 in Brussels. Overall more than 380 participants from a range of different sectors, including from the most of the Member States, attended the conference. Moreover, several hundred people followed the conference via web-streaming. A report summarising the discussions will be published on the conference website. The video recording of the conference can also be found on this website.

M.04 Experimental (Part B) releases: reminder for reporting period of 2016.

The Commission informed the Member States that they will be invited by email to provide information on experimental releases for 2016.

M.05 Coexistent measures at national level to avoid cross-border contamination in accordance with Article 26a.1a of Directive 2001/18/EC.

The Commission informed the Member States that the coexistence measures (taken at national level by the Member States concerned) to avoid cross-border contamination in accordance with Article 26a.1a of Directive 2001/18/EC have been uploaded on the website of DG SANTE,
(link: https://ec.europa.eu/food/sites/food/files/plant/docs/plant_gmo_auth_nat-measures_summary-cross-border-national-measures.pdf).