EUROPEAN COMMISSION

Health and Food Safety Directorate General

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Regulatory Committee 2001/18/EC

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SUMMARY REPORT

A.01 Information and discussion on the European Court of Justice ruling (25 July 2018) on new mutagenesis techniques.

In the PAFF GMFF meeting of 11 September Member States confirmed their willingness to share with the Commission and other Member States any information relevant to the implementation of the Court ruling (potential applications, field trials, experience etc.). The Committee discussed the responses received from the Member States.

The Commission summarised the discussion as follows:

- All Member States confirmed that field trials are carried out in accordance with GMO legislation.
- On the experience on contained use, only 4 Member States provided a reply. The Commission invited the other Member States to respond at their earliest convenience.
- Several Member States confirmed that at national level no varieties produced with new mutagenesis techniques have been registered. Some Member States stressed the difficulty in identifying the technique used, especially for varieties already registered. They therefore all agreed to liaise with their respective competent authorities responsible for seeds to discuss the means (and potential challenges) to ensure that all registered varieties fulfil the legal requirements.
- Regarding official controls, the Commission invited Member States to share information on the difficulties they are confronted with (including impact on resources) for both inspections and analytical testing and to share good practices on inspections.
- Two Member States who have developed a GMO reference database agreed to present this database at a forthcoming Committee meeting.
- With a view to responding effectively to the comments raised by some Member States on the difficulties to implement the GMO legislation as interpreted by the Court, the Commission invited the Member States to provide or describe specific examples of products or specific situations where the implementation of the legislation would be challenged.

- Regarding need to update current risk assessment guidance, the Commission committed to inform the Committee on a possible mandate to EFSA to assess this need.
- The Member States agreed to continue providing available information on areas of common interest such as new techniques other than mutagenesis techniques, economic and trade impacts, ongoing research and research needs at national or EU level. The Commission confirmed its readiness to provide an overview on ongoing research under the EU programmes and possibilities for future EU research.

The Commission (JRC) gave an update on the progress of the work that the European Union Reference Laboratory on GM food and feed (EURL GMFF) and the European Network of GMO Laboratories (ENGL) are carrying out on the analytical possibilities and challenges to identify and quantify products of new mutagenesis techniques. The Commission encouraged competent authorities to discuss with their national laboratories to provide timely input to EURL GMFF/ENGL in view of finalising the draft report without undue delay.

Two Member States asked as to whether the differentiated procedures for releases of specific products produced with new mutagenesis techniques under Directive 2001/18/EC could be implemented. The Commission and the Member States agreed to reflect on this issue and to discuss it again in a future Committee meeting.

One Member State made an informal presentation on how they see the impact of the Court ruling. The Commission thanked for this and invited all Member States to inform the Commission on how they see the implementation at national level and on any forthcoming official Government position.

It was agreed to continue the discussion at the next PAFF GMFF Committee, based on further input by Member States. The Commission indicated that a joint Committee meeting of all GMO competent authorities could be organised in 2019 if all Member States considered this necessary; several Member States welcomed this possibility.

A.02 Seed sampling and testing: Discussion on how Commission Recommendation 2004/787/EC is implemented at national level in relation to seeds.

The Commission underlined that any sort of tolerance thresholds for presence of GMOs in conventional seeds is not in line with the EU legislation, which prescribes 'zero tolerance'. Member States underlined the need for a pragmatic convergence of control practices of seeds and therefore confirmed their wish that the Commission acts as a facilitator on the convergence of the practical implementation of Recommendation 2004/787/EC (on technical guidance for sampling and detection of GMOs). The Commission agreed to this while underlining that such work would not lead to a legislative measure and can only aim at aligning the control practices in agreement with all Member States. If analytical technical questions would arise, these would be transferred to the EURL – GMFF for consideration and possible follow-up through the ENGL network. The Commission will inform the Member States on the practical working arrangements.

A.03 Unauthorized genetically modified petunias – update by Member States.

The Member States updated the Commission on the controls performed and the results of these controls. Only one Member State reported the detection of GM petunias on its market. This Member State committed to further investigate the case and report to the Commission and the Member States. The Commission invited all Member States to continue reporting any relevant information.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision, repealing Decision 2002/623/EC establishing guidance notes on the environmental risk assessment of genetically modified organisms.

The Commission presented the draft for vote to Member States.

Vote taken: Favourable opinion.

Reasons for negative vote or abstention:

- No agreed national position
- Negative public opinion

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision as regards the placing on the market of a genetically modified carnation (Dianthus caryophyllus L., line FLO-40685-2).

Vote taken: No opinion.

Reasons for negative vote or abstention:

- Political reasons
- Negative public opinion
- Safety reasons

As a consequence, the Chair informed the Committee that the draft Decision will be submitted to the Appeal Committee.

M.01 Renewal of placing on the market of imported cut flowers derived from the genetically modified carnation line 123.8.12 (FLO-40689-6).

The Netherlands informed about the renewal of placing on the market of imported cut flowers derived from the genetically modified carnation (*Dianthus caryophyllus*) line 123.8.12 (FLO-40689-6). After receiving public comments on the assessment report and closing the 60-day commenting period for Member States, the Netherlands did not receive any reasoned objections. Hence, the Netherlands indicated that they would proceed with renewing the authorisation for this carnation.

M.02 Information from one Member State on a decision on *Wolbachia* bacteria.

One Member State informed that the Standing Committee on Biocidal Products had adopted a decision on *Wolbachia* bacteria, which is considered to be a biocidal product whereas the mosquitoes artificially infected with these bacteria are out of the scope of the biocides legislation. The Commission clarified that the GMO legislation would only apply in case the *Wolbachia* or the mosquitoes are genetically modified.

M.03 Information about the representative of the consent holder in the EU under Directive 2001/18/EC

Further to a question by a Member State, the Commission clarified that under Directive 2001/18/EC, the consent holder must have a representative in the EU but that there is no legal obligation for Member States to indicate the name of such EU representative in their consents.