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SUMMARY REPORT OF THE
REGULATORY COMMITTEE under DIRECTIVE 2001/18/EC

16 MARCH 2015

Chair: Dorothee André

A.01 EFSA scientific opinion on the placing on the market of the genetically modified carnation IFD-25958-3 with a modified colour, for import of cut flowers for ornamental use, under Part C of Directive 2001/18/EC from Florigene – presentation by EFSA

EFSA presented the scientific opinion on the placing on the market of the genetically modified carnation IFD-25958-3 with a modified colour, for import of cut flowers for ornamental use. One Member State asked about possible risks of propagation by amateur gardeners. EFSA explained that propagation of the GM carnation, for example rooting, by individuals cannot be excluded. However, should this occur, carnation IFD-25958-3 would not show any potential for increased survival, fitness and weediness compared with its parental line.

A.02 EFSA scientific opinion on the placing on the market of the genetically modified carnation IFD-26407-2 with a modified colour, for import of cut flowers for ornamental use, under Part C of Directive 2001/18/EC from Florigene – presentation by EFSA

EFSA presented the scientific opinion on the placing on the market of the genetically modified carnation IFD-26407-2 with a modified colour, for import of cut flowers for ornamental use. One Member State asked about possible risks of propagation by amateur gardeners. EFSA explained that propagation of the GM carnation, for example rooting, by individuals cannot be excluded. However, should this occur, carnation IFD-26407-2 would not show any potential for increased survival, fitness and weediness compared with its parental line.

B.01 Draft Commission Implementing Decision concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a carnation (*Dianthus caryophyllus* L., line 25958) genetically modified for flower colour

SANTE/10174/2015

Legal Basis: Article 18(1) of Directive 2001/18/EC of the European Parliament and of the Council

Procedure: Examination procedure

Draft Decision concerning the placing on the market, in accordance with Directive 2001/18/EC, of a carnation (*Dianthus caryophyllus* L., line 25958) genetically modified for flower colour, was presented to the Committee.

The Commission explained the procedure of EFSA consultation following the reasoned objections maintained by Member States.

One Member State asked about Article 4 on the monitoring and the possibility of the consent holder to revise the environmental monitoring plan for both, the draft decision under p. B.01 and the draft decision under p. B.02. The Commission explained that in line with Article 20 of Directive 2001/18/EC, only the competent authority which received the original notification may adapt the monitoring plan.

Vote taken: no opinion

Reasons for the negative vote or abstention:

- No agreed national position
- Negative public opinion
- Political reasons
- Risk assessment deemed not sufficient
- Human-aided propagation cannot be excluded
- Potential spread of pollen and cross-pollination cannot be excluded
- Social utility of this GMO is unclear

The Chair informed that the draft Decision will be submitted to the Appeal Committee for vote.

B.02 Draft Commission Implementing Decision concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a carnation (*Dianthus caryophyllus* L., line 26407) genetically modified for flower colour

SANTE/10175/2015

Legal Basis: Article 18(1) of Directive 2001/18/EC of the European Parliament and of the Council

Procedure: Examination procedure

Draft Decision concerning the placing on the market, in accordance with Directive 2001/18/EC, of a carnation (*Dianthus caryophyllus* L., line 26407) genetically modified for flower colour, was presented to the Committee.

Vote taken: no opinion

Reasons for the negative vote or abstention:

- No agreed national position
- Negative public opinion
- Political reasons
- Risk assessment deemed not sufficient
- Human-aided propagation cannot be excluded
- Potential spread of pollen and cross-pollination cannot be excluded
- Social utility of this GMO is unclear

The Chair informed that the draft Decision will be submitted to the Appeal Committee for vote.

M.01 GM free study

The Commission informed that no decision has been taken yet regarding the publication date of the study.

M.02 Update of the annexes of Directive 2001/18/EC

The Commission explained that the update of Annex II and III of Directive 2001/18/EC is on-going in collaboration with EFSA; The discussion with Member States representatives of the Regulatory Committee for Directive 2001/18 is foreseen for July 2015.

M.03 New plant breeding techniques

One Member State asked about possible two-stage process to address the new techniques. The Commission explained that all the techniques discussed by the expert working group would be addressed at once and that the legal analysis is ongoing.

M.04 Proposal for revision procedure for authorizations for GMOs

The Commission explained that a review of the decision-making process for GMOs is currently ongoing for which the results will be communicated before the end of April, as announced by President Juncker in his political guidelines. The review will be accompanied by a proposal to be discussed in appropriate fora.

M.05 Conference in Hungary on GM-free agriculture, 16 and 17 April 2015

Hungary reported that its Ministry of Agriculture will organise an international conference focused on GM-free labelling, in Budapest on 16 and 17 April. Hungary is currently drafting a new regulation on this issue. Other related topics will be raised during the conference, such as the new Directive on cultivation or socioeconomic considerations.

M.06 Adventitious presence of GMOs in seeds

Upon a request by one Member State on adventitious presence of GMOs in seeds, the Commission recalled that a survey across all the Member States has been launched.

The Commission also informed that the Working Group on sampling and testing of seeds, which was established last year within the European Network of GMO Laboratories (ENGL), is about to finalise its report.