Bioveiligheidsraad
Conseil de Biosécurité

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Secretariaat
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Title: Advice of the Belgian Biosafety Advisory Council on the application EFSA/GMO/NL/2010/87 from Monsanto under Regulation (EC) No 1829/2003

Context

The application EFSA/GMO/NL/2010/87 was submitted by Monsanto on 31 August 2010 within the framework of Regulation (EC) No 1829/2003[1] for authorization of the use of herbicide-tolerant genetically modified (GM) oilseed rape as or in food (including pollen and the accidental unintentional presence of viable seeds in food), completing herewith the scope of the application RX-GT73 (renewal of authorization of oilseed rape GT73 for food and feed applications) which for food covered only refined oil and food additives derived from GT73 oilseed rape.

The application EFSA/GMO/NL/2010/87 was officially acknowledged by EFSA on 22 November 2011. On the same date EFSA started the formal three-month consultation of the Member States, in accordance with Articles 6.4 and 18.4 of Regulation (EC) No. 1829/2003 (consultation of national Competent Authorities within the meaning of Directive 2001/18/EC designated by each Member State in the case of genetically modified organisms (GMOs) being part of the products).

Within the framework of this consultation, the Belgian Biosafety Advisory Council (BAC), under the supervision of a coordinator and with the assistance of its Secretariat, contacted one expert chosen from the common list of experts drawn up by the BAC and the Biosafety and Biotechnology Unit (SBB) to evaluate the new information given in the dossier in comparison with application RX-GT73 and concerning the dietary exposure of humans to the GOXv247 and CP4 EPSPS proteins in GT73. The evaluation done by the expert did not result in comments or questions to be transmitted to EFSA.

In February 2012 EFSA published a technical report on the safety of GT73 pollen (Supporting Publications 2012:EN-227). The opinion of the EFSA Scientific Panel on GMOs on application EFSA/GMO/NL/2010/87 was adopted on 23 January 2013 (The EFSA Journal, 2013, 11(2), 3079[2]), and published together with the responses of the EFSA GMO Panel to comments submitted by the Member States during the three-month consultation period.
On 19 February 2013 the opinion of EFSA was forwarded to the Belgian expert. He was invited to give comments and to react if needed to the opinion of EFSA.

The advice of the Biosafety Advisory Council given below is based on the comments formulated by the expert, the opinion of the EFSA GMO Panel, as well as the scientific advice

[1] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p.1)
[2] See: http://www.efsa.europa.eu/en/efsajournal/pub/3079.htm

Wetenschappelijk Instituut Volksgezondheid | Institut Scientifique de Santé Publique
Dienst Bioveiligheid en Biotechnologie | Service Biosécurité et Biotechnologie
Rue Juliette Wytsmanstraat 14 | B-1050 Brussels | Belgium
T + 32 2 642 52 11 | F + 32 2 642 52 92 | bac@wiv-isp.be | www.bio-council.be

given by the BAC in February 2010 on the application EFSA/GMO/RX-GT73[3] which concluded that the food and feed uses of GT73 oilseed rape present no risks for human or animal health.

Scientific evaluation

Assessment of food safety

The safety of the GOXv247 and CP4 EPSPS proteins expressed in GT73 have been previously assessed (notably in the frame of application RX-GT73) and no concerns regarding potential toxicity or allergenicity have been identified. The GOXv247 and CP4 EPSPS proteins are also expressed in pollen of oilseed rape GT73. The molecular characterization and the comparative assessment of the composition, phenotype, agronomic characteristics and nutritional value did not result in indications for unintended effects due to the genetic modification and did not raise safety concerns. Therefore no safety issues are expected from the intake of food produced from oilseed rape GT73 or its pollen.

Conclusion

Based on the scientific assessment of the dossier done by the Belgian expert, taking into account the technical report and opinion of EFSA, and considering the data presently available, the Biosafety Advisory Council is of the opinion that the previous assessment and conclusions of the BAC on safety of the GM oilseed rape GT73 reached for food/feed aspects remain valid. The Biosafety Advisory Council therefore agrees with EFSA and is of the opinion that the consumption of food produced from oilseed rape GT73 or its pollen does not constitute an additional health risk.

Other considerations

The Biosafety Advisory Council wants to point out that the environmental monitoring plan proposed by the notifier in case of accidental spillage of reproducible material is not fully satisfactory and could be improved. In particular, it should be more precise at the level of the identity, training and expertise of the people involved in the monitoring, at the level of the monitoring methods (including types of unanticipated effects to be looked at and sites to be monitored) and time-frame planning, at the level of identification methods, and at the level of risk management procedures to avoid spillage of viable oilseed rape.

p.o. Dr. M. Herman

Prof. D. Reheul
President of the Belgian Biosafety Advisory Council

Annex I: Minority declaration of Lucette Flandroy

[3] Ref. of document : BAC_2010_0158

Minority advice of L. Flandroy on the dossier EFSA-GMO-NL-2010-87 (rapeseed GT73, extended food use, including pollen)

The authorization asked in this dossier is for enlarged food uses, including of pollen, whereas the preceding authorization of GT73 rapeseed was given only for use as refined oil and food additives .

Analysis and tests made for the preceding authorization of GT73 were performed on seeds, oil and/or toasted meal (and showed raised contents, relatively to comparators, of potentially harmful glucosinolates in seeds and toasted meal) but not on the pollen of this rape. They do not preclude the possibility of unforeseen pleiotropic effects of the transgene specifically in the pollen of this strain. In the present dossier, neither compositional analysis nor toxicity or allergenicity scientific and experimental data were presented relatively to the pollen of this strain. Some people eat pure pollen. I consider it is not reasonable neither legal to allow the specific consumption of this pollen as being as safe as conventional pollen on science-sound basis without any scientific data arguing this presumption.