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/BE/2010/81 from Bayer CropScience AG under Regulation (EC) No 1829/2003

Context

The application EFSA/GMO/BE/2010/81 was submitted by Bayer on 23 June 2010 within the framework of Regulation (EC) No 1829/2003[1] for marketing of food containing or consisting of, and food produced from or containing ingredients produced from genetically modified (GM) oilseed rape Ms8, Rf3 and Ms8xRf3 which are tolerant to glufosinate containing herbicides. The scope of the application covers mainly the accidental unintentional presence of viable seeds and pollen in food of these GM oilseed rape events and excludes processed oil and cultivation.

Processed oil produced from oilseed rape events Ms8, Rf3 and Ms8xRf3 was lawfully placed on the market as a food or as a food ingredient before the date of entry into force of Regulation (EC) No 1829/2003. Idem for feed ingredients derived from oilseed rape events Ms8, Rf3 and Ms8xRf3. Renewal of authorization for these food and feed applications was requested in June 2007. In this context, the Biosafety Advisory Council (BAC) issued a positive advice on application EFSA/GMO/RX-MS8-RF3 on 11 December 2009[2]. The authorization procedure regarding this renewal is still ongoing.

Feed containing or consisting of MS8, RF3, and MS8xRF3 oilseed rape are also subject to an authorization for placing on the market under Directive 2001/18/EC (Commission Decision 2007/232/EC of 26 March 2007[3]). In the frame of this authorization procedure, the BAC issued 2 scientific advices related to notification C/BE/96/01, i.e.:
- Advice of the Biosafety Advisory Council of 26 January 2004[4];
- Advice of the Biosafety Advisory Council regarding additional information on molecular characterisation of 24 March 2009[5].

In these advices, the BAC concluded that no new risks have come to light by comparison to non-GM oilseed rape for human health and feed uses.

Detailed information on the regulatory status of oilseed rape Ms8, Rf3 and Ms8xRf3 is available from the EU register of GM food and feed[6].

[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] Ref. of document: BAC_2009_01570
[3] Commission Decision (2007/232/EC) of 26 March 2007 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of oilseed rape products (*Brassica napus* L., lines Ms8, Rf3 and Ms8xRf3) genetically modified for tolerance to the herbicide glufosinate-ammonium (OJ L 100, 17.4.2007, p.20)
[4] Ref. of document : BAC_2004_SC_084
[5] Ref. of document: BAC_2009_914
[6] See: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

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The application EFSA/GMO/BE/2010/81 was officially acknowledged by EFSA on 5 October 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). As the application did not contain new information compared with the previously assessed applications, the BAC did not take part in this consultation.

The opinion of the EFSA Scientific Panel on GMOs was adopted on 9 September 2012 (The EFSA Journal, 2012, 10 (9):2875)[7], and published together with the responses of the EFSA GMO Panel to comments submitted by the Member States during the three-month consultation period.

Conclusion

The Biosafety Advisory Council is of the opinion that application EFSA/GMO/BE/2010/81 does not contain new scientific elements that may lead to reconsider the outcome of its above-mentioned advices on GM oilseed rape MS8, Rf3 and MS8xRf3 given in 2004 and 2009. It considers therefore that the oilseed rape MS8, Rf3 and MS8xRf3 are unlikely to have an adverse effect on human and animal health or on the environment, in the context of their intended uses or in case of accidental ingestion of viable seeds and pollen from these GM plants.

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.

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[7] See: <http://www.efsa.europa.eu/en/efsajournal/pub/2875.htm>

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