Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-RX-009 (soybean A2704-12) from Bayer CropScience under Regulation (EC) No. 1829/2003

Adopted on 29 January 2019
Ref. SC/1510/BAC/2019_0102

Context

Application EFSA-GMO-RX-009 was submitted by Bayer CropScience for the renewal of authorisation for the marketing of genetically modified (GM) soybean A2704-12 for food and feed uses, import and processing (excluding cultivation) within the European Union within the framework of Regulation (EC) No. 1829/2003[1].

The placing on the market of the herbicide-tolerant soybean A2704-12 for food/feed uses, except cultivation, is currently authorised following a positive opinion of EFSA (EFSA Journal 2007;5(7):524, 22)[2].

The renewal application was validated by EFSA on 9 March 2018 and a formal three-month consultation period of the Member States was started, lasting until 9 June 2018, 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 being part of the products).

Within the framework of this consultation, after analysis of the information contained in the application dossier and taking into account the advice of the Belgian Biosafety Advisory Council (BAC) on the initial application for soybean A2704-12 (application EFSA-GMO-NL-2005-18), the BAC decided to only request the collaboration of external experts for the analysis of the molecular characterisation. The Secretariat, under the supervision of a coordinator, contacted experts to evaluate the dossier, chosen from the common list of experts drawn up by the BAC and the Service Biosafety and Biotechnology (SBB). Two experts answered positively to this request, and formulated a number of comments to the dossier. See Annex I for an overview of all the comments and comments that were sent to EFSA.

The opinion of the EFSA Scientific Panel on GMOs was published on 14 January 2019 (EFSA Journal 2019;17(1):5523)[3], together with the responses from the EFSA GMO Panel to comments submitted by the Member States during the three-month consultation period.

The comments formulated by the experts on the renewal application together with the opinion of EFSA, as well as the previous advice of the BAC on soybean A2704-12 (BAC_2008_685)[4] form the basis of the advice of the Biosafety Advisory Council on application EFSA-GMO-RX-009 given below.

[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] https://doi.org/10.2903/j.efsa.2007.524
[3] https://doi.org/10.2903/j.efsa.2019.5523
[4] http://www.bio-council.be/Advices/BAC_2008_685.pdf

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Scientific evaluation

The data for application EFSA-GMO-RX-009 provided by the applicant at the time of submission included eight annual post-market environmental monitoring (PMEM) reports covering the period from September 2008 to June 2016, a systematic literature search covering the complete duration of the event's authorisation, an updated bioinformatic package with a corrected sequence for the event, including an analysis of the insert and flanking sequences, an analysis of the potential similarity to allergens and toxins of the newly expressed protein and of all possible ORFs (Open Reading Frames) within the insert and spanning the junction sites, an analysis of possible horizontal gene transfer, information on the function of the interrupted endogenous gene and a risk assessment of its interruption with respect to the agronomic–phenotypic characteristics and composition, and reports of additional studies performed by the applicant over the course of the authorisation period.

The Belgian experts and the members of the Biosafety Advisory Council did not identify any information elements in the renewal application EFSA-GMO-RX-009 that would raise a safety concern for human or animal health or the environment.

Conclusion

Based on the whole set of data on soybean A2704-12 provided by the applicant, the scientific assessment of the dossier done by the Belgian experts, the opinion of EFSA, and the original advice of the the BAC on soybean A2704-12, the Biosafety Advisory Council is of the opinion that in the context of its proposed uses, soybean A2704-12 is unlikely to pose any risk to human and animal health.

The Biosafety Advisory Council did not identify any risk that the import and processing of this GM soybean could pose to the European environment.

Dr. Corinne Vander Wauven
President of the Belgian Biosafety Advisory Council

Annex I: Compilation of comments of experts in charge of evaluating the application EFSA/GMO/RX-009 (ref. BAC_2018_0346)

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Outcome of the assessment of application EFSA/GMO/RX-009 by the Biosafety Council during the formal consultation of the Member States (3-month commenting period in accordance with Articles 6.4 and 18.4 of Regulation (EC) No 1829/2003)

04 June 2018
Ref. SC/1510/BAC/2018_0346

Mandate for the Group of Experts: Mandate of the Biosafety Advisory Council (BAC) of 3 April 2018.
Coordinator: Prof. B. Schiffers
Experts: Frank Van Breusegem (UGent), Jan Van Doorsselaere (Vives)
SBB: Didier Breyer, Fanny Coppens, Katia Pauwels.

Application for renewal: **EFSA/GMO/RX-009**
Applicant: **Bayer CropScience**
GMO: **soybean A2704-12**
Acknowledgement of receipt by EFSA: **9 March 2018**

The scope of the application is:
☒ GM plants for food use
☒ Food containing or consisting of GM plants
☒ Food produced from GM plants or containing ingredients produced from GM plants
☒ GM plants for feed use
☒ Feed produced from GM plants
☒ Import and processing (Part C of Directive 2001/18/EC)
☐ Seeds and plant propagating material for cultivation in European Union (Part C of Directive 2001/18/EC)

Given the characteristics of the GMO and its intended uses, experts were consulted to cover the following areas of expertise:
☒ Molecular characterization
☐ Environmental aspects
☐ Allergenicity
☐ Toxicology
☐ Food and Feed aspects

As this application concerns a renewal of authorization, the experts were asked in particular to evaluate the results of the monitoring and any other new information, which has become available, with regard to the evaluation of the safety of the food/feed and the risks of the food/feed to humans, animals or the environment. If information was lacking, the expert was asked to indicate which information should be provided and what the scientifically reasoning is behind this demand.

The comments are structured as in the "Guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) 1829/2003" (EFSA Journal 2015;13(6):4129).
Comments sent to EFSA are indicated in grey. It should be noted that all the comments received from the experts are considered in the evaluation of this dossier and in formulating the final advice of the Biosafety Advisory Council.

List of comments/questions received from the experts

A. GENERAL COMMENTS

Have evaluated this section and consider the information adequate: 1 expert

B. DATA REQUIREMENTS

B.1. COPY OF AUTHORISATION FOR PLACING THE FOOD/FEED ON THE MARKET

N/A

B.2. POST-MARKET MONITORING AND POST-MARKET ENVIRONMENTAL MONITORING REPORTS

Nihil

B.3. NEW INFORMATION

B.3.1. SYSTEMATIC SEARCH AND EVALUATION OF LITERATURE:

- search for new scientific information in a comprehensive and structured manner.
- search in all available databases, since the date of authorisation of the event.
- relevant for the three main areas of risk assessment (molecular characterisation, food and feed safety, and the environment).

Have evaluated this section and consider the information adequate: 2 experts

B.3.2. UPDATED BIOINFORMATICS

- similarity searches for known toxic and/or allergenic proteins, using up-to-date databases, for all ORFs between stop codons without applying a size limit.
- information on the similarities of DNA sequences inserted in the plant genome with microbial DNA sequences, with an assessment of potentially altered likelihood for horizontal gene transfer, together with an evaluation of the consequences for human and animal health and the environment.

Have evaluated this section and consider the information adequate: 1 expert

Comment 1

a) The new bioinformatics analysis indicates the interruption of the SEO e gene by the integrated transgene. It is stated that because SEO e is part of a multi-gene family it is highly likely that generedundancy is in place. I do not understand the relevance of this statement in the regulatory context.

Without experimental evidence in place, this remains anyhow a mere assumption that has no effect on likelihood of HGT or any other consequences. If to be mentioned at all, it would be more correct to state that interruption of the SEO e gene had no effect on the various phenotypes monitored.
b) For sake of completeness, a gene code of the SEO e gene/protein could be provided in the summary document as well.

B.3.3. ADDITIONAL DOCUMENTS OR STUDIES PERFORMED BY OR ON BEHALF OF THE APPLICANT

- any prohibition or restriction imposed by any third country in which the food/feed is placed on the market.
- all unpublished studies performed or sponsored by the applicant and not previously submitted to the EU, with a review and assessment of their relevance for molecular characterisation, human and animal safety and the environment.

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C. OVERALL ASSESSMENT

- potential identification of new hazards or modified exposure, or new scientific uncertainties, challenging the previous risk assessment.
- new studies in case required by the elements above.

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D. MONITORING PLAN AND PROPOSAL FOR IMPROVING THE CONDITIONS OF THE ORIGINAL AUTHORISATION

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