Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-RX-022 (Soybean MON 87701 x MON 89788) from Bayer under Regulation (EC) No. 1829/2003

2 February 2023
Ref. SC/1510/BAC/2023_0109

Context

Application EFSA-GMO-RX-022 was submitted by Bayer for the renewal of authorisation for the marketing of genetically modified (GM) soybean MON 87701 x MON 89788 (Unique Identifier MON-88701-3 x MON-89788-1) for food and feed uses, import and processing (excluding cultivation) within the European Union within the framework of Regulation (EC) No. 1829/2003[1].

Soybean MON 87701 x MON 89788 expresses the *cry1Ac* gene for protection against certain lepidopteran pests and produces CP4 EPSPS for tolerance to glyphosate-based herbicides. The placing on the market of soybean MON 87701 x MON 89788 for food/feed uses, except cultivation, is currently authorised, following a positive opinion of EFSA (EFSA Journal 2012;10(2):2560)[2].

The renewal application was validated by EFSA on 7 May 2021 and a formal three-month consultation period of the Member States was started, lasting until 7 August 2021, 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, the Belgian Biosafety Advisory Council (BAC), under the supervision of a coordinator and with the assistance of its Secretariat, contacted two experts to evaluate the molecular data provided in the dossier, chosen from the common list of experts drawn up by the BAC and the Service Biosafety and Biotechnology (SBB). The experts answered positively to this request, and formulated a comment on the application (see Annex I). No comments were sent to EFSA.

The opinion of the EFSA Scientific Panel on GMOs was published on 19 December 2022 (EFSA Journal 2022;20(12):7684)[3]. The comments formulated by the experts on the renewal application, together with the opinion of EFSA, as well as the previous inconclusive advice of the BAC on soybean MON 87701 x MON 89788 (BAC_2012_0444)[4], and its latest advices on the single events MON 87701 (positive, BAC_2023_0108)[5] and MON 89788 (positive, BAC_2018_1090)[6] form the basis of the advice of the Biosafety Advisory Council on application EFSA-GMO-RX-022 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] http://www.efsa.europa.eu/en/efsajournal/pub/2560
[3] https://www.efsa.europa.eu/en/efsajournal/pub/7684
[4] https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2012_0444.pdf
[5] https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2023_0108.pdf
[6] https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2018_1090.pdf

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Scientific evaluation

The data for application EFSA-GMO-RX-022 provided by the applicant at the time of submission included the annual post-market environmental monitoring (PMEM) reports covering the years of import, systematic literature searches covering the complete duration of the event's authorisation, an updated bioinformatic package including an analysis of the insert and flanking sequences, an analysis of the potential similarity to allergens and toxins of the newly expressed proteins and of all possible open reading frames within the insert and spanning the junction sites, an analysis of possible horizontal gene transfer and a safety assessment of the newly expressed proteins Cry1Ac and CP4 EPSPS regarding their capacity to trigger celiac disease, 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-022 that would raise a safety concern for human or animal health or the environment.

The Biosafety Advisory Council notes that in 2012 it was not able to give advice on the safety for health of MON 87701 x MON 89788 soybean. This was based on the fact that the analysis of the composition of the soybean did not include a measurement of the amount of phosphatides, as was recommended by the OECD at the time of the opinion. Shortly after publishing the BAC opinion on this dossier, the OECD published an updated version of its consensus document which no longer recommends to measure the amount of phosphatides in new varieties of soybean.

Conclusion

The Biosafety Advisory Council is of the opinion that on the basis of the data on soybean MON 87701 x MON 89788 provided by the applicant, and the opinion of EFSA, taken together with the fact that the OECD no longer recommends to measure the amount of phosphatides in new varieties of soybean, in the context of its proposed uses, the continued authorisation soybean MON 87701 x MON 89788 is unlikely to pose any risk to human and animal health and the European environment.

Dr. ir. Geert Angenon
President of the Belgian Biosafety Advisory Council

Annex : Outcome of the assessment of the application

Annex : Outcome of the assessment of application EFSA/GMO/RX-022 by the Biosafety Advisory 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)

Coordinator: René Custers
Experts: Frank Van Breusegem (UGent), Jan Van Doorsselaere (Vives)
SBB: Fanny Coppens

Application for renewal: **EFSA/GMO/RX-022**
Applicant: **Bayer Agriculture**
GMO: **Soybean MON87701 x MON89788**
Validation of dossier by EFSA: **7 May 2021**

Scope of the application:
☒ 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 updated bioinformatics studies. If information was lacking, the expert was asked to indicate which information should be provided and what the scientifically reasoning is behind this demand.

List of comments/questions received from the experts

A. GENERAL COMMENTS

N/A

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

N/A

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).

N/A

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
In Gu and Silvanovich 2020 b (annex from RX-022) on page 7 (of 162) it is mentioned that "the insert site conventional sequence was used to query a maize genome assembly (Gmax-2020)"
This is not correct: it should be "soybean genome assembly… This should be corrected.
The same mistake occurs in Skottke and Silvanovich 2020b (p 7 bottom).

I can agree with the conclusions on the biosafety of the GMO soybean in the renewal dossiers. There are no additional data that would not allow a renewal.

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.

N/A

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.

N/A

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

N/A