Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMFF-2023-21116 (soybean MON 94637) from Bayer under Regulation (EC) No. 1829/2003

3 December 2025
Ref. SC/1510/BAC/2025_1358

Context

Application EFSA-GMFF-2023-21116 (AP188) was submitted by Bayer CropScience for the authorisation for the marketing of genetically modified (GM) soybean MON 94637 (Unique Identifier MON-94637-8) 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 94637 produces the Cry1A.2 and Cry1B.2 proteins conferring protection against certain lepidopteran pests.

The application was validated by EFSA on 3 May 2024 and a formal three-month consultation period of the Member States was started, lasting until 3 August 2024, 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 experts to evaluate the dossier, chosen from the common list of experts drawn up by the BAC and the Service Biosafety and Biotechnology (SBB). Four experts answered positively to this request, and formulated a number of comments to the dossier. See Annex for an overview of all the comments and the comments sent to EFSA on 30 July 2024.

The scientific opinion of EFSA's GMO Panel, including the responses from the Panel to comments submitted by the Member States during the three-month consultation period, was published on 23 October 2025 (EFSA Journal 2025;23:e9581[2]). On 23 October 2025 these two documents were forwarded to the Belgian experts. They were invited to give comments and to react if needed.

In delivering the present advice, the BAC considered in particular the comments formulated by the experts on application GMFF-2023-21116 and the opinion of EFSA.

[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 https://doi.org/10.2903/j.efsa.2025.9581

Biosafety Advisory Council - Secretariat • Service Biosafety and Biotechnology (SBB)
Sciensano • Rue Juliette Wytsmanstraat 14 • B-1050 Brussels • Belgium
T + 32 2 642 52 93 • bac@sciensano.be • www.bio-council.be

Scientific evaluation

1. Molecular characterisation

With regard to the molecular characterisation, the Biosafety Advisory Council is of the opinion that the information provided is sufficient and does not raise safety concerns.

2. Assessment of food/feed safety and nutritional value

2.1. Assessment of compositional analysis

The Biosafety Advisory Council agrees with the GMO panel of EFSA that the compositional data of GM soybean MON 94637, in comparison with its conventional counterpart, do not raise safety concerns.

2.2. Assessment of toxicity

The Biosafety Advisory Council evaluated the safety of the newly produced Cry1A.2 and Cry1B.2 proteins and no food and feed safety concerns with respect to toxicity were identified.

The Biosafety Advisory Council is also of the opinion that the combined presence of the newly produced proteins in soybean MON 94637 does not raise food and feed safety concerns regarding toxicity.

The Biosafety Advisory Council agrees with the GMO panel of EFSA that the available data on the toxicity of GM soybean MON 94637, in comparison with its conventional counterpart, does not raise food and feed safety concerns regarding toxicity.

2.3. Assessment of allergenicity

The Biosafety Advisory Council has evaluated the safety of the newly produced Cry1A.2 and Cry1B.2 proteins, including their combined presence, and no concerns regarding allergenicity were identified.

2.4. Nutritional value

The Biosafety Advisory Council is of the opinion that the information provided is sufficient to conclude that the nutritional characteristics of soybean MON 94637-derived food and feed are not expected to differ from those of conventional soybean varieties.

3. Environmental risk assessment

The Biosafety Advisory Council is of the opinion that it is unlikely that the accidental release of soybean MON 94637 (i.e. during transport and/or processing) into the European environment[3] will lead to environmental harm.

4. Monitoring

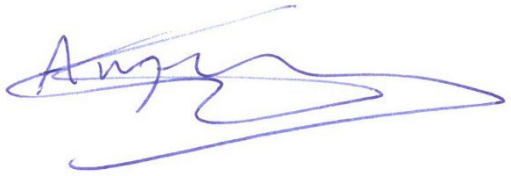
With regard to monitoring, the Biosafety Advisory Council is of the opinion that the information provided is sufficient.

[3] As the application doesn't imply cultivation of the GM crop in the EU, a full environmental assessment, as in the case of a cultivation dossier, is not warranted.

Conclusion

Based on the whole set of data on soybean MON 94637 provided by the applicant, the scientific assessment of the dossier done by the Belgian experts, the opinion of EFSA, and the answers of the EFSA GMO panel to the questions raised by the Belgian experts, the Biosafety Advisory Council:

1) Agrees with the GMO panel of EFSA that soybean MON 94637 is as safe as its conventional counterpart and the tested non-GM soybean varieties with respect to potential effects to human and animal health;
2) Agrees with the GMO panel of EFSA that accidental environmental release of soybean MON 94637 seeds would not raise environmental safety concerns.



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

Annex : Outcome of the assessment of the application and comments sent to EFSA

Annex : Outcome of the assessment of application GMFF-2023-21116 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) and feedback from the EFSA GMO Panel

Coordinator: René Custers
Experts: Dimitri Gilis (ULB), André Huyghebaert (UGent), Frank van Breusegem (VIB-UGent), Erik Van Miert (DSM-Firmenich)
SBB: Adinda De Schrijver

Application: **GMFF-2023-2116**
Applicant: **Bayer CropScience**
GMO: **soybean MON 94637**
Validated by EFSA: **3 May 2024**

The scope of the application is:
(a) GM food
☒ Food containing or consisting of GM plants
☒ Food produced from GM plants or containing ingredients produced from GM plants
(b) GM feed
☒ Feed containing or consisting of GM plants
☒ Feed produced from GM plants
(c) GM plants for food or feed use
☒ Products other than food and feed containing of consisting of GM plants with the exception of cultivation
☐ Seeds and plant propagating material for cultivation in the EU

The experts were asked to evaluate whether the information provided in the application is sufficient in order to state that the marketing of the genetically modified plant for its intended uses will not raise any problems for the environment or human or animal health. If information is lacking, the expert was asked to indicate which information should be provided and what the scientifically reasoning is behind this demand.

The comments indicated in grey in the annex were sent to EFSA. It should be noted that all the comments mentioned in the annex were 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

PART II - SCIENTIFIC INFORMATION

1. HAZARD IDENTIFICATION AND CHARACTERISATION

1.1. INFORMATION RELATING TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS

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

Comment:
It is questionable whether a few % of cross pollination at a certain distance is satisfactory; this is not negligible. In the study of Yook et al. (2021), they report a distance of 37.7m for minimising the gene flow between GM and wild soybean.

Note SBB & coordinator: We consider isolation distances to minimise gene flow rather an issue for when an authorisation for cultivation is requested. Soybean MON 94637 is meant for import and processing of food/feed. Moreover, although wild relatives exist elsewhere, wild soybean does not naturally occur in Europe.

1.2. MOLECULAR CHARACTERISATION

1.2.1. Information relating to the genetic modification

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

Comment:
Remarks are provided in sections 1.4 and 1.5.

1.2.2. Information relating to the genetically modified plant

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

Comment:
Remarks are provided in sections 1.4 and 1.5.

1.2.3. Additional information relating to the genetically modified plant required for the environmental safety aspects

Have evaluated this section and consider the information adequate: 3 experts

1.2.4. Conclusions of the molecular characterisation

Have evaluated this section and consider the information adequate: 3 experts

1.3. COMPARATIVE ANALYSIS

1.3.1. Choice of the conventional counterpart and additional comparators

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

Comment:
A traditional approach is followed as it is the case in previous similar dossiers: A comparison is performed between the GMO plant, a soya with similar genetic background and a range of commercial varieties. No further remarks.

1.3.2. Experimental design and statistical analysis of data from field trials for comparative analysis

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

Comment:
The methods used are well accepted. They have been used in previous dossiers. No further remarks.

1.3.3. Selection of material and compounds for analysis

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

Comment:
No specific remarks as this section is also in line with previous applications.

1.3.4. Comparative analysis of composition

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

Comment:
The applicant concludes that MON 94637 is not a significant contributor to natural variability of soybeans. I agree with this conclusion.

1.3.5. Comparative analysis of agronomic and phenotypic characteristics

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

Comment:
Same conclusion as in 4.4

1.3.6. Effects of processing

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

1.3.7. Conclusion

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

Comment:
As already mentioned before I agree with the conclusions of the applicant.

1.4. TOXICOLOGY

1.4.1. Testing of newly expressed proteins

Comment 1:

- In section 1.4.1.4. it is stated that *"The susceptibility of the Cry1A.2 and Cry1B.2 proteins to pepsin and pancreatin was evaluated as described in M-827971-01 (2023) and M-827969-01 (2023), respectively.*" However, the references to the studies do not appear to be correct it should read: "*The susceptibility of the Cry1A.2 and Cry1B.2 proteins to pepsin and pancreatin was evaluated as described in M-827971-02 (2023) and M-827969-02 (2023), respectively*".
- M-847831-01: There is an inconsistency in table 29: Selected Motor Activity Values (Males): The historical control data are significantly above the data obtained in the study. As such, the statement in the report "*Additionally, the mean value was within the Charles River Ashland historical control range*" seems incorrect.
- Overall, I agree with the general conclusions made in this section.

Feedback from the EFSA GMO Panel: The GMO Panel thanks Belgium for the comments provided. The M-827971-02 and M-827969-02 are full original reports that also include amendments of M-827971-

01 and M-827969-01 reports, duly documented. Please also note that the GMO Panel requested the applicant for additional clarifications (Additional information_ADR4). The applicant addressed the discrepancy identified on the selected motor activity values which had no impact on the interpretation of the data and the conclusions provided. Furthermore, additional inconsistencies of the study reports on protein reporting of the Cry1A.2 protein, incubation time, molecular weight of fragments and plasmid numbers were amended by the applicant.

Comment 2:
It seems to me that the protein's pH stability report is missing. The reports (M-827969-02, 2023; M-827971-02, 2023) deal with protein digestibility and not pH stability. Some information about the stability of the protein in the absence of pepsin or pancreatin can be found in these reports, but this is not a true analysis of stability under acidic or basic conditions.

The digestibility reports are M-827969-02_2023 and M-827971-02_2023 and not M-827969-01_2023 and M-827971-01_2023.

Feedback from the EFSA GMO Panel: The evaluation of studies on stability of the newly expressed proteins can be found in Section 3.5.1.2.3 of the Scientific Opinion. In relation to pH stability, the applicant referred to information on molecular mass and immunoreactivity of the proteins at pH 1.2 and 7. The applicant provided studies on effect of temperature and protein degradation studies. This information relevant to the safety of the newly expressed proteins and that also included in vivo studies was evaluated following a weight of evidence approach. The GMO Panel concluded that the newly expressed Cry1A.2 and Cry1B.2 proteins in soybean MON 94637 do not raise safety concerns for human and animal health (see Section 3.5 of the Scientific Opinion).

1.4.2. Testing of new constituents other than proteins

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

1.4.3. Information on natural food and feed constituents

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

1.4.4. Testing of the whole genetically modified food or feed

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

Comment:
Overall, I agree with the points and conclusions made in this section.

1.4.5. Conclusion of the toxicological assessment

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

Comment:
Conclusion: Low levels of exposure to the Cry1A.2 and Cry1B.2 proteins from consumption of foods, pollen supplements and protein supplements made from MON 94637 soybean will not adversely affect human health in the EU. Therefore, there is reasonable certainty that consumption of MON 94637 will not adversely affect the health of adults or children in the EU. Overall, I agree with the points and conclusions made in this section.

1.5. ALLERGENICITY

1.5.1. Assessment of allergenicity of the newly expressed protein

Comment:
Bioinformatic techniques show that the Cry protein under consideration has no similarities to existing allergens or toxins listed as such. The bioinformatic analysis of potential ORFs was carried out correctly.

I draw attention to the fact that the literature on the potential allergenicity or toxicity of Cry proteins presents divergent results. The review article by Rubio-Infante & Moreno-Fierros (2016) is a critical and independent review of the literature on allergenicity and toxicity of Cry proteins. In the opinion of these authors "the term 'toxic' is not appropriate for defining the effects these toxins have on mammals", but they also argue for additional mammalian testing as knowledge is still limited. Moreover, Oliveira-Filho & Grisolia (2022) write that "Complementary studies should be carried out to assess possible effects on human health." (speaking about Cry proteins).

1.5.2. Assessment of allergenicity of the whole genetically modified plant

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

1.5.3. Adjuvanticity

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

1.5.4. Conclusion of the allergenicity assessment

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

1.6. NUTRITIONAL ASSESSMENT

No comments received

2. EXPOSURE ASSESSMENT — ANTICIPATED INTAKE OR EXTENT OF USE

No comments received

3. RISK CHARACTERISATION

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

4. POST-MARKET MONITORING ON THE GENETICALLY MODIFIED FOOD OR FEED

No comments received

5. ENVIRONMENTAL RISK ASSESSMENT (ERA)

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

6. POST-MARKET ENVIRONMENTAL MONITORING PLAN (PMEM)

No comments received

7. ADDITIONAL INFORMATION RELATED TO THE SAFETY OF THE GENETICALLY MODIFIED FOOD OR FEED

No comments received

8. REFERENCES

Oliveira-Filho EC, Grisolia CK. The ecotoxicology of microbial insecticides and their toxins in genetically modified crops: An overview. Int J Environ Res Public Health. 2022,19:16495.

Rubio-Infante N, Moreno-Fierros L. An overview of the safety and biological effects of Bacillus thuringiensis Cry toxins in mammals. J Appl Toxicol. 2016,36:630-48.

Yook et al. Environmental risk assessment of glufosinate-resistant soybean by pollen-mediated gene flow under field conditions in the region of the genetic origin. Sci Total Environ. 2021,762:143073.