Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application GMFF-2024-21774 (genetically modified soybean GMB151 x DAS44406-6) from BASF under Regulation (EC) No. 1829/2003

24 March 2026
Ref. SC/1510/BAC/2026_0319

Context

Application GMFF-2024-21774 (AP190) was submitted by BASF Agricultural Solutions for the marketing of genetically modified (GM) soybean GMB151 x DAS-44406-6 (Unique Identifier BCS-GM151-6 x DAS-444Ø6-6) 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 two-event stack, soybean GMB151 x DAS-44406-6, was obtained by conventional crossing (no new genetic modification involved) of the corresponding single events:
- GMB151, expressing the *cry14Ab-1* and *hppd-4* genes conferring resistance to soybean cyst nematode and tolerance to HPPD inhibitor herbicides, respectively; and
- DAS-44406-6, expressing the *aad-12, 2mepsps* and the *pat* genes for tolerance to 2,4-D, glyphosate-based and glufosinate ammonium-containing herbicides, respectively.

The application was validated by EFSA on 13 September 2024. A formal three-month consultation period of the Member States was started, lasting until 17 December 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).

As this application concerns a stacked event, and the single events have previously received a positive advice from the Biosafety Advisory Council, the Council decided to evaluate only the specific risk assessment aspects linked to the stacked event as mentioned in the Commission Implementing Regulation (EU) No. 503/2013, i.e. stability of the traits, expression of the new proteins, and interactions between the newly expressed traits.

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, invited experts from the common list of experts established jointly by the BAC and the Service Biosafety and Biotechnology (SBB) to evaluate the specific risk assessment aspects mentioned above. Three experts answered positively to this request (see Annex).

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 27 January 2026 (EFSA Journal 2026;24: e9844)[2].

[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.2026.9844

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In delivering the present advice the Biosafety Advisory Council considered in particular the following information:
- The comments formulated by the experts on application GMFF-2024-21774;
- The opinion of EFSA; and
- The advices already adopted by the BAC on the single events. The conclusions of the BAC for the most recent applications for the single events were positive:

Event	Dossier	BAC advice
GMB151	EFSA-GMO-NL-2018-153	BAC_2021_0523 [3]
DAS-44406-6	EFSA-GMO-NL-2012-106	BAC_2017_0438 [4]

Scientific evaluation

1. Molecular characterisation

With regard to the molecular characterisation, the Biosafety Advisory Council is of the opinion that the information provided on the stability of the traits, expression of the new proteins, and interactions between the newly expressed traits is sufficient and does not raise safety concerns.

2. Assessment of food/feed safety and nutritional value

2.1. Assessment of compositional analysis

Taking into account the previous assessments of the single events, the Biosafety Advisory Council did not evaluate the data provided for the stacked event.

2.2. Assessment of toxicity

The Biosafety Advisory Council has evaluated the safety of the newly produced Cry14Ab-1, HPPD-4, AAD-12, 2mEPSPS and PAT proteins in the context of the single applications, and no food and feed safety concerns regarding toxicity were identified. Since no new information on the toxicity of these proteins has become available, the Council is of the opinion that its previous conclusions remain valid.

The Biosafety Advisory Council is also of the opinion that the combined presence of the newly expressed proteins in the stacked event 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 Cry14Ab-1, HPPD-4, AAD-12, 2mEPSPS and PAT proteins in the context of the single applications, and no concerns regarding allergenicity were identified. Since no new information on the allergenicity of these proteins has become available, the Council is of the opinion that its previous conclusions remain valid.

The Biosafety Advisory Council is also of the opinion that the combined presence of the newly expressed proteins in the stacked event does not raise concerns regarding allergenicity.

2.4. Nutritional value

Taking into account the previous assessments of the single events, the Biosafety Advisory Council did not evaluate the nutritional data provided for the stacked event.

[3] https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2021_0523.pdf
[4] https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2017_0438.pdf

3. Environmental risk assessment

Based on the assessment of the single events, the Biosafety Advisory Council is of the opinion that it is unlikely that the accidental release of soybean GMB151 x DAS-44406-6 (i.e. during transport and/or processing) into the European environment[5] will lead to environmental harm.

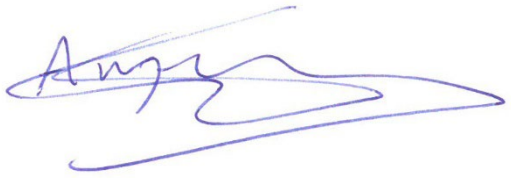
4. Monitoring

Taking into account the previous assessments of the single events, the Biosafety Advisory Council did not evaluate the monitoring data provided for the stacked event.

Conclusion

Based on the molecular data on soybean GMB151 x DAS-44406-6 provided by the applicant, the scientific assessment of the dossier done by the Belgian experts, the positive opinion of EFSA on the two-event soybean stack, and the advices already adopted by the Council on the single soybean events, the Biosafety Advisory Council:

1) Agrees with the GMO panel of EFSA that in the context of its proposed uses, soybean GMB151 x DAS-44406-6 is as safe as the non-GM comparator and the tested non-GM soybean varieties with respect to risks to human and animal health;
2) Agrees with the GMO panel of EFSA that there is no reason to expect interactions between the newly expressed proteins that would give rise to food and feed safety and nutritional concerns;
3) Agrees with the GMO panel of EFSA that accidental environmental release of soybean GMB151 x DAS-44406-6 would not raise safety concerns to the European environment.



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

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

[5] As the scope of the application does not include the cultivation of the GM crop within the EU, a comprehensive environmental assessment, such as that required for a cultivation dossier, is not necessary.

Annex : Outcome of the assessment of application GMFF-2024-21774 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)

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Experts: Dimitri Gilis (ULB), Frank van Breusegem (VIB-Ugent), Jan Van Doorsselaere (VIVES)
SBB: Adinda De Schrijver

Application: **GMFF-2024-21774**
Applicant: **BASF**
GMO: **soybean GMB151 x DAS-44406-6**
Validated by EFSA: **13 September 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

As this application concerns a stacked event, and the single events have previously received a positive advice from the Council, the Biosafety Council decided to evaluate only the specific risk assessment aspects linked to the stacked event as mentioned in the Commission Implementing Regulation (EU) No 503/2013, i.e. stability of the traits, expression of the new proteins, and interactions between the newly expressed traits.

The experts didn't make any comment on the application. The following comment was sent to EFSA: “We do not have any comments and we consider all the necessary information is present to conduct a robust risk assessment.”