

Adviesraad voor Bioveiligheid Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application GMFF-2025-34192 (genetically modified soybean DAS-44406-6 x FG72) from Syngenta under Regulation (EC) No. 1829/2003

1 October 2026
Ref. SC/1510/BAC/2026_0837

Context

Application GMFF-2025-34192 (AP197) was submitted by Syngenta for the marketing of genetically modified (GM) soybean DAS-44406-6 x FG72 (Unique Identifier DAS-44406-6 x MST-FG72-2) for food and feed uses, import and processing (excluding cultivation) within the European Union, within the framework of Regulation (EC) No. 1829/2003¹.

The two-event stack, soybean DAS-44406-6 x FG72, was obtained by conventional crossing (no new genetic modification involved) of the corresponding single events:

- DAS-44406-6, expressing the *aad-12*, *2mepsps* and the *pat* genes for tolerance to dichlorophenoxyacetic acid (2,4-D), glyphosate-based and glufosinate ammonium-containing herbicides, respectively, and
- FG72, expressing the *hppd-W336* and *2mepsps* genes conferring tolerance to hydroxyphenylpyruvate dioxygenase (HPPD)-inhibiting and glyphosate herbicides, respectively.

The application was validated by EFSA on 10 September 2025. A formal three-month consultation period of the Member States was started, lasting until 10 December 2025, 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. Two 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 29 July 2026 (EFSA Journal 2026;24: e10268)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.2026.10268>

In delivering the present advice the Biosafety Advisory Council considered in particular the following information:

- The comments formulated by the experts on application GMFF-2025-34192;
- 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
DAS-44406-6	EFSA-GMO-NL-2012-106	BAC_2017_0438 ³
FG72	EFSA-GMO-BE-2011-98	BAC_2015_0597 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 AAD-12, 2mEPSPS, HPPD-W336, 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 AAD-12, HPPD-W336, 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_2017_0438.pdf

⁴ https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2015_0597.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 DAS-44406-6 x FG72 (i.e. during transport and/or processing) into the European environment⁵ 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 DAS-44406-6 x FG72 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 DAS-44406-6 x FG72 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 DAS-44406-6 x FG72 would not raise safety concerns to the European environment.



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

Annex 1 : Minority declaration

Annex 2 : Outcome of the assessment of application GMFF-2025-34192

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 1: Minority declaration by P. Baret

Like any stacked event, this opinion depends on a positive opinion on both events. In this case, the assessment of one of the events, FG72 (EFSA-GMO-BE-2011-98, BAC_2015_0597), was approved with a negative minority opinion because the equivalence rules were not complied with. Indeed, in the case of non-equivalence, additional toxicological tests must be carried out. This was not done in 2015. It was taken into account in the new version of the dossier FG72 in 2025 but the 90-day rat study provided by the applicant for FG72 showed several statistically significant differences, including a 39% increase in creatinine-corrected urinary glucose in males.

**Annex 2 : Outcome of the assessment of application
GMFF-2025-34192 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: Wouter Vanhove

Experts: Godelieve Gheysen (UGent), Jan Van Doorselaere (Vives)

SBB: Adinda De Schrijver

Application: **GMFF-2025-34192 (AP197)**

Applicant: **Syngenta**

GMO: **Soybean DAS-44406-6 x FG72**

Validation of dossier by EFSA: **10 September 2025**

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 or 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 Biosafety Advisory Council, the Council decided to evaluate only the specific risk assessment aspects linked to the GM 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 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.

None of the comments formulated by the experts were selected to be sent to EFSA. EFSA will be informed about the data evaluated by the Council, and that the Council does not have any comments and considers that all the necessary information is present to conduct a robust risk assessment.

ANNEX – COMMENTING FORM

GENERAL COMMENTS

Comment:

DAS-44406-6 x FG72 was produced by conventional breeding of the GM soybean events DAS-44406-6 and FG72. Event DAS-44406-6 contains the transgenes *aad-12*, *2mepsps* and *pat*, while event FG72 contains the transgenes *2mepsps* and *hppdPf W336*. The stack therefore has tolerance to the herbicides 2,4-D, glyphosate, glufosinate and HPPD-inhibitors.

PART II - SCIENTIFIC INFORMATION

1. HAZARD IDENTIFICATION AND CHARACTERISATION

1.2. MOLECULAR CHARACTERISATION

1.2.1. Information relating to the genetic modification

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

1.2.2. Information relating to the genetically modified plant

(Shall include in particular the information on genetic stability, protein expression and interactions between the events)

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

Comment:

1. Sequence analysis demonstrates the presence of the single events without rearrangements in the stack obtained after several crosses during the breeding process. This proves genetic stability.
2. Expression analysis using ELISA on leaves, flowers and forage at several stages and roots and seeds generally shows the same protein levels of the 4 transgenes in the stack compared to the single event. Exceptions are seen for a) EPSPS, some samples with low expression (roots and seeds) have a protein level that is about the sum of the levels in the single events, this is not unexpected because the stack has 6 copies combining 4 and 2 copies of the transgene from the single events. b) AAD12 generally has slightly but significantly lower levels in the stack compared to the single event. c) PAT is slightly lower in the seeds of the stack compared to the single event. All these differences are within normal variation and are not considered to be of concern to risk analysis.
3. There are no scientific data that would indicate the transgenes of the single events to have synergistic or antagonistic effects when combined in the stack.

1.2.3. Conclusions of the molecular characterisation

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

Comment:

I agree with the conclusion of this analysis: 'Based on the above information, no unintended modifications or changes, nor any indications of potential interactions between the two single events in the DAS-44406-6 x FG72 soybean or between the newly expressed proteins have been identified. As overall conclusion, no safety concerns have been identified during the molecular characterisation of DAS-44406-6 x FG72 soybean.'