Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-BE-2018-155 (genetically modified cotton T304-40 x GHB119 x COT102) from BASF under Regulation (EC) No. 1829/2003

3 February 2026
Ref. SC/1510/BAC/2026_0126

Context

Application EFSA-GMO-BE-2018-155 was submitted by BASF for the marketing of genetically modified (GM) cotton T304-40 x GHB119 x COT102 (Unique Identifier BCS-GHØØ4-7 x BCS-GHØØ5-8 x SYN-IR1Ø2-7), 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 three-event stack, cotton T304-40 x GHB119 x COT102, was obtained by conventional crossing (no new genetic modification involved) of the corresponding single events:
- T304-40, expressing the *cry1Ab* gene for resistance to certain lepidopteran pests, and the *pat* gene for tolerance to herbicide products containing glufosinate ammonium;
- GHB119, expressing the *cry2Ae* gene for resistance to certain lepidopteran pests, and the *pat* gene for tolerance to herbicide products containing glufosinate ammonium;
- COT102, expressing the *vip3Aa19* gene for resistance against lepidopteran pest, and the *aph4* gene as a marker.

The application was validated by EFSA on 8 July 2020. A formal three-month consultation period of the Member States was started, lasting until 15 August 2023, 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 all 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.

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 dossier. Two experts accepted the invitation. 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 4 December 2025 (EFSA Journal 2025;23(12): e9753)[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.2025.9753

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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 EFSA-GMO-BE-2018-155;
- The opinion of EFSA;
- 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 all positive:

Event	Application number	BAC advice
T304-40	GMFF-2024-23010 (RX044)	BAC/2025/1206[3]
GHB119	EFSA-GMO-UK-2010-96	BAC/2016/0789[4]
COT102	EFSA-GMO-DE-2017-141	BAC/2023/0891[5]

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 three-stack event.

2.2. Assessment of toxicity

The Biosafety Advisory Council has evaluated the safety of the newly produced PAT, Cry1Ab, Cry2Ae, Vip3Aa19 and APH4 proteins in the context of previous 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 PAT, Cry1Ab, Cry2Ae, Vip3Aa19 and APH4 proteins in the context of previous 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.

[3] https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2025_1206.pdf
[4] https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2016_0789.pdf
[5] https://www.bio-council.be/sites/biocouncil.be/files/advices/bac_2023_0891.pdf

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 three-stack event.

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 cotton T304-40 x GHB119 x COT102 (i.e. during transport and/or processing) into the European environment[6] will lead to environmental harm.

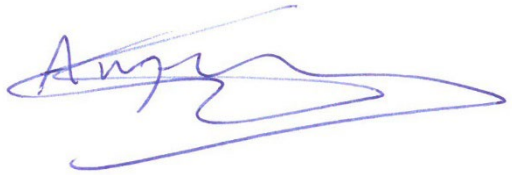
4. Monitoring

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

Conclusion

Based on the molecular data on T304-40 x GHB119 x COT102 provided by the applicant, the scientific assessment of the dossier done by the Belgian experts, the opinion of EFSA, and the advices already adopted by the Council on the three single events, the Biosafety Advisory Council:

1) Agrees with the GMO panel of EFSA that in the context of its proposed uses, cotton T304-40 xGHB119 x COT102 is as safe as the non-GM comparator and the tested non-GM 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 the potential environmental release of cotton T304-40 x GHB119 x COT102 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

[6] 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 EFSA/GMO/BE/2018/155 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: Henri Batoko (UCL), Frank Van Breusegem (UGent)
SBB: Adinda De Schrijver

Application: **EFSA/GMO/BE/2018/155**
Applicant: **BASF**
GMO: **Cotton T304-40 x GHB119 x COT102**
Validation of dossier by EFSA: **8 July 2020**

Scope of the application:
☒ Food containing or consisting of GM plants
☒ Food produced from GM plants or containing ingredients produced from GM plants
☒ Feed containing or consisting of GM plants
☒ Feed produced from GM plants
☒ 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 European Union (Part C of Directive 2001/18/EC)

As this application concerns a stacked event, and all the single events and lower order stacks 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 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 experts didn't make any comment on the application, and no questions were sent to EFSA. 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.”