Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMFF-2022-6232 (AP183) (genetically modified maize DP202216 x NK603 x DAS-40278-9) from Corteva Agriscience under Regulation (EC) No. 1829/2003

3 February 2026
Ref. SC/1510/BAC/2026_0128

Context

Application EFSA-GMFF-2022-6232 (AP183) was submitted by Corteva Agriscience for the marketing of genetically modified (GM) maize DP202216 x NK603 x DAS-40278-9 (Unique Identifier DP-2Ø2216-6xMON-ØØ6Ø3-6xDAS-4Ø278-9) and all subcombinations, 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, maize DP202216 x NK603 x DAS-40278-9, was obtained by conventional crossing (no new genetic modification involved) of the corresponding single events:
- DP202216, expressing the ZMM28 protein for enhanced yield and the PAT protein for tolerance to herbicide products containing glufosinate ammonium;
- NK603, expressing the CP4 EPSPS and the CP4 EPSPS L214P proteins for tolerance to glyphosate herbicides;
- DAS-40278-9, expressing the AAD-1 protein for tolerance to 2,4-D and AOPP herbicides.

The application was validated by EFSA on 9 February 2024. A formal three-month consultation period of the Member States was started, lasting until 9 May 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 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 specific risk assessment aspects mentioned above. Three experts answered positively to this request.

The scientific opinion of EFSA's GMO Panel was published on 5 December 2025 (EFSA Journal. 2025;23:e9746)[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.2025.9746

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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-GMFF-2022-6232 (AP183);
- 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 as follows:

Event	Dossier	BAC advice	Conclusion
DP202216	EFSA-GMO-NL-2019-159	BAC_2024_0636 [3]	Positive advice
NK603	GMFF-2023-21250 (RX-040)	BAC_2025_1202 [4]	Positive advice
DAS-40278-9	EFSA-GMO-NL-2010-89	BAC_2017_0066 [5]	Inconclusive due to shortcomings in the 28-day toxicity study (*)

(*) Subsequent applications of stacked events containing DAS-40278-9 received a positive advice from the Council:
- EFSA-GMO-NL-2013-112 (Maize MON89034 x 1507 x NK603 x DAS-40278-9): https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2019_0248.pdf
- EFSA-GMO-NL-2013-113 (Maize MON89034 x 1507 x MON88017 x 59122 x DAS-40278-9) : https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2019_0101.pdf
- EFSA-GMO-NL-2018-151 (Maize MON89034 x 1507 x MIR162 x NK603 x DAS-40278-9, with added 90-day feeding study): https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2022_1053.pdf
- EFSA-GMO-NL-2019-164 (Maize NK603 x T25 x DAS-40278-9): https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2022_0153.pdf
- EFSA-GMO-NL-2020-171 (Maize DP4114 x MON89034 x MON87411 x DAS-40278-9): https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2023_0102.pdf

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 for event maize DP202216 x NK603 x DAS-40278-9.

2.2. Assessment of toxicity

The Biosafety Advisory Council has evaluated the safety of the newly produced ZMM28, CP4 EPSPS, CP4 EPSPS L214P, PAT and AAD-1 proteins in the context of other applications (see above), and no food and feed safety concerns regarding toxicity remain. 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.

[3] https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2024_0636.pdf
[4] https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2025_1202.pdf
[5] https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2017_0066.pdf

2.3. Assessment of allergenicity

The Biosafety Advisory Council has evaluated the safety of the newly produced ZMM28, CP4 EPSPS, CP4 EPSPS L214P, PAT and AAD-1 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 for event maize DP202216 x NK603 x DAS-40278-9.

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 maize DP202216 x NK603 x DAS-40278-9 (i.e. during transport and/or processing) into the European environment will lead to environmental harm.

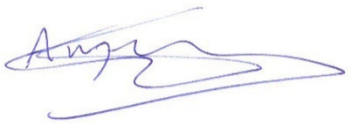
4. Monitoring

Taking into account the previous assessment of the single events, the Biosafety Advisory Council did not evaluate the monitoring data for event maize DP202216 x NK603 x DAS-40278-9.

Conclusion

Based on the molecular data on maize DP202216 x NK603 x DAS-40278-9 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 single events, the Biosafety Advisory Council:

1) Agrees with the GMO panel of EFSA that maize DP202216 x NK603 x DAS-40278-9 does not raise any nutritional concern and is as safe as its non-GM comparator and the selected non-GM reference varieties;
2) Agrees with the GMO panel of EFSA that the possible interactions between the events DP202216, NK603 and DAS-40278-9 in the three-stack event and sub-combinations would not raise safety concerns;
3) Agrees with the GMO panel of EFSA that additional environmental effects, as compared to conventional maize resulting from the release of maize DP202216 x NK603 x DAS-40278-9 into the environment, are unlikely.



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-NL-2022-183 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: Lieve Gheysen
Experts: Jacques Dommes (ULg), Frank Van Breusegem (UGent), Jan Van Doorsselaere (Vives)
SBB: Fanny Coppens

Application: **EFSA-GMO-NL-2022-183**
Applicant: **Corteva Agriscience**
GMO: **Maize DP202216 x NK603 x DAS-40278-9 and all subcombinations**
Validation of dossier by EFSA: **9 February 2024**

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)

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 stacked event, and all the single events and lower order stacks have previously received a positive advice from the Council (except for DP202216, for which the Council's advice is currently in preparation and during the evaluation of which no questions were sent to EFSA), 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 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.”