

## Adviesraad voor Bioveiligheid Conseil consultatif de Biosécurité

### Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-NL-2019-164 (genetically modified maize NK603 x T25 x DAS-40278-9 and subcombinations) from Pioneer under Regulation (EC) No. 1829/2003

2 February 2022  
Ref. SC/1510/BAC/2022\_0153

#### Context

Application EFSA-GMO-NL-2019-164 was submitted by Pioneer for the marketing of genetically modified (GM) maize NK603 x T25 x DAS-40278-9 (Unique Identifier MON-ØØ6Ø3-6 x ACS-ZMØØ3-2 x DAS-4Ø278-9) and its subcombinations, for food and feed uses, import and processing (excluding cultivation) within the European Union, within the framework of Regulation (EC) No. 1829/2003<sup>1</sup>.

The three-event stack maize NK603 x T25 x DAS-40278-9 was obtained by conventional crossing (no new genetic modification involved) of the corresponding single events:

- NK603, expressing the CP4 EPSPS protein and its variant CP4 EPSPS L214P, for tolerance to glyphosate;
- T25, expressing the PAT protein that confers tolerance to herbicide products containing glufosinate ammonium;
- DAS-40278-9, expressing the AAD-1 protein for tolerance to 2,4-D and AOPP herbicides.

The application was validated by EFSA on 26 March 2020. A formal three-month consultation period of the Member States was started, lasting until 29 June 2020, 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 molecular data of the dossier, chosen from the common list of experts drawn up by the BAC and the Service Biosafety and Biotechnology (SBB). Two experts answered positively to this request, and did not formulate any comments. 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 stack 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 opinion of the EFSA Scientific Panel on GMOs was published on 13 December 2021 (EFSA Journal 2021;19(12):6942<sup>2</sup>).

In delivering the present advice the BAC considered in particular the following information:

- 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 and two subcombinations were as follows:

<sup>1</sup> 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).

<sup>2</sup> See <https://www.efsa.europa.eu/en/efsajournal/pub/6942>

Event	Application number	BAC advice	Conclusions
NK603	EFSA-GMO-RX-NK603	BAC_2009_1367 (02/10/2009)	No major risks for human and animal health or concerning the environment were identified.
T25	EFSA-GMO-RX-T25	BAC_2014_0329 (21/05/2014)	Unlikely to pose any risk to human and animal health. No risk identified for the European environment.
DAS-40278-9	EFSA-GMO-NL-2010-89	BAC_2017_0066 (31/01/2017)	No conclusion about the food and feed safety of maize DAS-40278-9 in the context of its proposed uses. [in dossier EFSA-GMO-NL-2018-151 a 90-day feeding study was added, leading to the conclusion that from a toxicology point of view the event is safe]
NK603 x T25	EFSA-GMO-NL-2010-80	BAC_2015_0596 (08/09/2015)	Unlikely to pose any risk to human and animal health. No risk identified for the European environment.
NK603 x DAS-40278-9	EFSA-GMO-NL-2013-112	BAC_2019_0248 (19/03/2019)	Unlikely to pose any risk to human and animal health. No risk identified for the European environment.

All GM maize events mentioned in the table above are authorised in the EU for food and feed uses<sup>3</sup>.

## 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

Taking into account the previous assessment of the single events and two subcombinations, the Biosafety Advisory Council agrees with the GMO panel of EFSA that the compositional data of GM maize NK603 x T25 x DAS-40278-9, in comparison with its conventional counterpart, do not raise safety concerns.

#### 2.2. Assessment of toxicity

The Biosafety Advisory Council has evaluated the safety of the newly expressed CP4 EPSPS, CP4 EPSPS L214P, PAT and AAD-1 proteins in the context of previous applications, and no safety concerns were identified. Taking into account the updated information considered in the current application, the Council is of the opinion that its previous conclusions remain valid.

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

#### 2.3. Assessment of allergenicity

The Biosafety Advisory Council has evaluated the safety of the newly expressed CP4 EPSPS, CP4 EPSPS L214P, PAT and AAD-1 proteins in the context of previous applications, and no concerns were identified. Since no new information on 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 expression of the newly expressed proteins in the stacked event does not raise concerns regarding the allergenicity.

<sup>3</sup> See EU register of GM food and feed: [http://ec.europa.eu/food/dyna/gm\\_register/index\\_en.cfm](http://ec.europa.eu/food/dyna/gm_register/index_en.cfm)

## 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 maize NK603 x T25 x DAS-40278-9-derived food and feed are not expected to differ from those of conventional maize varieties.

## 3. Environmental risk assessment

The Biosafety Advisory Council is of the opinion that it is unlikely that the accidental release of maize NK603 x T25 x DAS-40278-9 (i.e. during transport and/or processing) into the European environment<sup>4</sup> 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 whole set of data on maize NK603 x T25 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 BAC on the three single events and two subcombinations, the Biosafety Advisory Council:

- 1) Agrees with the GMO panel of EFSA that the potential environmental release of maize NK603 x T25 x DAS-40278-9 is unlikely to pose any threat to the European environment;
- 2) Agrees with the GMO panel of EFSA that there is no reason to expect interactions between the newly expressed proteins that could impact on the food or feed safety;
- 3) Agrees with the GMO panel of EFSA that in the context of its proposed uses, maize NK603 x T25 x DAS-40278-9 is unlikely to pose any risk to human and animal health;



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<sup>4</sup> 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.