NK603 x T25 x DAS-40278-9 maize and its sub-combination T25 × DAS-40278-9

Fact-sheet for operators

2022

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Introduction

The placing on the market of products containing, consisting of, or produced from genetically modified maize NK603 x T25 x DAS-40278-9 and its sub-combination T25 x DAS-40278-9 was authorised, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, by the European Commission on 19 May 2022 under Commission implementing decision (EU) 2022/797 (EC, 2022)[1].

The authorisation decision for NK603 x T25 x DAS-40278-9 and its sub-combination T25 x DAS-40278-9 granted to Corteva Agriscience LLC, represented in the Union by Corteva Agriscience Belgium B.V, is published at:
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022D0797

The following products are authorised by Commission implementing decision (EU) 2022/797:

(a) Food and food ingredients containing, consisting of or produced from NK603 x T25 x DAS-40278-9 and its sub-combination T25 x DAS-40278-9
(b) Feed containing, consisting of or produced from NK603 x T25 x DAS-40278-9 and its sub-combination T25 x DAS-40278-9
(c) Products containing or consisting of NK603 x T25 x DAS-40278-9 and its sub-combination T25 x DAS-40278-9 for uses other than those provided for in points (a) and (b), with the exception of cultivation.

It shall be noted that among the three sub-combinations[2] of the transformation events constituting NK603 x T25 x DAS-40278-9 maize, two of those sub-combinations, NK603 x T25 and NK603 x DAS-40278-9, have already been authorised by Commission Implementing Decision (EU) 2015/2279[3] and Commission Implementing Decision (EU) 2019/2085[4], respectively.

1 EC, 2022. Commission Implementing Decision (EU) 2022/797 of 19 May 2022 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603 x T25 x DAS-40278-9 maize and its sub-combinationT25 x DAS-40278-9, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

[2] The European Food Safety Authority (EFSA) positively assessed the three sub-combinations in the frame of the NK603xT25xDAS-40278-9 application (please refer to the section Safety of NK603 x T25 x DAS-40278-9 maize and its sub-combinations hereafter)

[3] Commission Implementing Decision (EU) 2015/2279 of 4 December 2015 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603 × T25 (MON-ØØ6Ø3-6 × ACS-ZMØØ3-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 322, 8.12.2015, p. 58).

[4] Commission Implementing Decision (EU) 2019/2085 of 28 November 2019 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1 507 × NK603 × DAS-40278-9 and sub-combinations MON 89034 × NK603 × DAS-40278-9, 1 507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 316, 6.12.2019, p. 80).

General Characteristics of the genetically modified maize

NK603 x T25 x DAS-40278-9 maize has been obtained by traditional breeding between genetically modified NK603, T25 and DAS-40278-9 maize single events. No new genetic modifications were introduced to obtain NK603 x T25 x DAS-40278-9 maize. Similarly, no new genetic modifications were introduced in any of the subcombinations.
Therefore, NK603 x T25 x DAS-40278-9 maize express the transgenic proteins inherited from the single genetically modified events: CP4-EPSPS, PAT and AAD-1, which provide tolerance to the application of glyphosate, glufosinate, 2,4-dichlorophenoxyacetic acid (2,4-D) and aryloxyphenoxypropionate (AOPP) herbicides. Similarly, the different subcombinations have the characteristics conferred by the single events, as detailed below:

- NK603 maize expresses the CP4 EPSPS protein, which confers tolerance to glyphosate herbicides.
- T25 maize expresses the PAT protein, which confers tolerance to glufosinate-ammonium-based herbicides.
- DAS-40278-9 maize expresses the AAD-1 protein, which confers tolerance to 2,4-D and AOPP herbicides.

Safety of NK603 x T25 x DAS-40278-9 maize and its sub-combination

In December 2019, an application for the placing on the market of NK603 x T25 x DAS-40278-9 maize for food and feed uses, import and processing was submitted to the competent authority of The Netherlands in accordance with articles 5 and 17 of Regulation (EC) No 1829/2003 (EFSA-GMO-NL-2019-164). The application also covered three subcombinations of the single transformation events constituting NK603 x T25 x DAS-40278-9 maize[5], independently of their origin.

On 29 October 2021, the European Food Safety Authority (EFSA) Panel on Genetically Modified Organisms (GMO) adopted a positive scientific opinion in which it concluded:
"The GMO Panel concludes that the three-event stack maize and its subcombinations are as safe as the non-GM comparator and the selected non-GM reference varieties with respect to potential effects on human and animal health and the environment." (EFSA, 2021)[6].

The EFSA GMO panel scientific opinion is available at:
https://www.efsa.europa.eu/en/efsajournal/pub/6942

[5] Among the 3 subcombinations, one is authorised by Commission Implementing decision (EU) 2022/797 and two had already been authorised by other Commission Implementing decisions (see the Introduction section above).

[6] EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins E,Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Naegeli H, MorenoFJ, Nogué F, Rostoks N, Sanchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Ardizzone M, DeSanctis G, Fernandez Dumont A, Federici S, Gennaro A, Gomez Ruiz AJ, Kagkli DM, Lanzoni A, Neri FM, Papadopoulou N, Paraskevopoulos K and Raffaello T, 2021. Scientific Opinion on the Assessment of genetically modified maize NK603xT25xDAS-40278-9 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2019-164). EFSA Journal 2021;19(12):6942, 35 pp. https://doi.org/10.2903/j.efsa.2021.6942ISSN:1831-4732.

Monitoring Conditions for NK603 x T25 x DAS-40278-9 maize and its sub-combination T25 x DAS-40278-9

As indicated in the positive EFSA GMO Panel opinion, NK603 x T25 x DAS-40278-9 maize and its subcombinations are as safe and as nutritious as the non-GM comparator (EFSA, 2021). Therefore, post-market monitoring of food/feed derived from NK603 x T25 x DAS-40278-9 maize and its sub-combination T25 x DAS-40278-9 is not necessary, as confirmed by the EFSA GMO Panel (EFSA, 2021) and in the Commission authorisation decision for NK603 x T25 x DAS-40278-9 and its sub-combination T25 x DAS-40278-9 (EC, 2022).

Furthermore, no potential adverse effects to human and animal health or the environment have been identified in the environmental risk assessment from the uses of NK603 x T25 x DAS-40278-9 maize and its subcombinations. Therefore, no case-specific monitoring of NK603 x T25 x DAS-40278-9 and its sub-combination T25 x DAS-40278-9 is necessary, as confirmed by the EFSA GMO panel in its scientific opinion (EFSA, 2021).
As specified by Commission decision (EU) 2022/797 (EC, 2022), a post-market environmental monitoring (PMEM) plan for NK603 x T25 x DAS-40278-9 maize and its sub-combination T25 x DAS-40278-9 is in place and consists of a general surveillance plan, not based on a particular hypothesis, to report observed unanticipated adverse effects on human and animal health or the environment arising from handling or use of viable NK603 x T25 x DAS-40278-9 maize and its sub-combination T25 x DAS-40278-9, if any.

As stated by the EFSA GMO Panel in its scientific opinion on NK603 x T25 x DAS-40278-9 maize and its subcombinations for food and feed uses, import and processing: *"The GMO Panel considers that the scope of the PMEM plan provided by the applicant is consistent with the intended uses of the three-event stack maize. The GMO Panel agrees with the reporting intervals proposed by the applicant in its PMEM plan. The PMEM plan and reporting intervals are in line with the intended uses of the three-event stack maize and its subcombinations."* (EFSA, 2021).

The monitoring takes place in cooperation with monitoring networks of trade associations representing operators importing, handling and processing viable maize commodity, which report back to the CropLife Europe. The result of the monitoring activities is reported back to the European Commission by Corteva Agriscience on an annual basis.
The post-market environmental monitoring plan for NK603 x T25 x DAS-40278-9 maize and its sub-combination T25 x DAS-40278-9 has been published on the EU register for genetically modified food and feed:
https://webgate.ec.europa.eu/dyna/gm_register/maize-NK603xT25xDAS-40278-9_%20sub-combination_environmental-monitoring-plan.pdf

Conditions for traceability and labelling for NK603 x T25 x DAS-40278-9 maize and its sub-combination T25 x DAS-40278-9

Operators importing, handling and processing grain and foods and feeds derived from NK603 x T25 x DAS-40278-9 and its sub-combination T25 x DAS-40278-9 in the EU shall comply with the conditions for traceability and labelling outlined in Regulations (EC) No 1829/2003 and 1830/2003 and in Commission Implementing Decision (EU) 2022/797 (EC, 2022).

For the purposes of the specific labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the name of the organism shall be maize.

The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of NK603 x T25 x DAS-40278-9 maize and its sub-combination T25 x DAS-40278-9 with the exception of foods and food ingredients containing, consisting of, or produced from NK603 x T25 x DAS-40278-9 maize and its sub-combination T25 x DAS-40278-9.

The unique identifiers assigned to NK603 x T25 x DAS-40278-9 and its sub-combination T25 x DAS-40278-9 are indicated below:

- NK603 x T25 x DAS-40278-9: MON-ØØ6Ø3-6 x ACS-ZMØØ3-2 x DAS-4Ø278-9
- T25 x DAS-40278-9 : ACS-ZMØØ3-2 x DAS-4Ø278-9

Methods for detection and reference material

Validated detection method

The detection, sampling and identification methods for NK603 x T25 x DAS-40278-9 maize consist of the same detection, sampling and identification methods available for NK603, T25 and DAS-40278-9 maize, which have been validated by the Joint Research Centre (JRC) of the European Union Reference Laboratory (EU-RL). In accordance with Regulation (EC) No 1829/2003 and in line with the above-mentioned application for authorisation of NK603 x T25 x DAS-40278-9 maize and its subcombination T25 x DAS-40278-9, the applicant provided the JRC-EURL with a PCR detection method that consists of the validated event-specific real-time PCR method for the quantification of NK603, T25 and DAS-40278-9 maize, for verification. The detection method has been validated by EURL in September 2021 and is publicly available from the JRC-EURL website:
https://gmo-crl.jrc.ec.europa.eu/method-validations

Maize certified reference material

The Certified Reference Materials (CRM) for the individual traits comprising NK603 x T25 x DAS-40278-9 maize consist of the CRMs for NK603, T25 and DAS-40278-9 maize. The Institute for Reference Materials and Measurements (IRMM) of the Joint Research Centre (JRC) of the European Commission has developed certified reference materials for NK603 (ERM®-BF415) and DAS-40278-9 (ERM®-BF433) maize, accessible via the Joint Research Centre (JRC) of the European Commission at https://crm.jrc.ec.europa.eu/. The American Oil Chemists Society has developed certified reference materials for T25 (AOCS 0306-H9) accessible via the American Oil Chemists Society at https://www.aocs.org/crm.

Contact points for Operators

As there are other technology providers for GM maize and shipments entering the European harbours may be commingled, an industry wide approach has been developed. Therefore, CropLife Europe is the central communication point for the GM plant technology providers. CropLife Europe is the primary address for reporting general surveillance activities or any unanticipated adverse effects and is skilled to provide adequate response. In addition, CropLife Europe will transfer the messages to the relevant industry partner if further action is required.

Operators are requested to report, if possible via their branch representative, any unanticipated adverse effect to CropLife Europe at: https://croplifeeurope.eu/product-information/

If required, additional comments or questions can also be addressed to:
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1000 Brussels
Belgium
Email address: CortevaEUBiotech@corteva.com