

MON 89034 × 1507 × NK603 × DAS-40278-9 maize and sub-combinations  
MON 89034 × NK603 × DAS-40278-9,  
1507 × NK603 × DAS-40278-9 and  
NK603 × DAS-40278-9  
Fact-sheet for operators

2021

**MON 89034 × 1507 × NK603 × DAS-40278-9 maize and sub-combinations**  
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## **Introduction**

The placing on the market of products containing, consisting of, or produced from genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 and sub-combinations MON 89034 × NK603 × DAS-40278-9, 1507 × NK603 × DAS-40278-9 and NK603 × 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 28 November 2019 under Commission implementing decision (EU) 2019/2085 (EC, 2019)<sup>1</sup>.

The authorisation decision for MON 89034 × 1507 × NK603 × DAS-40278-9 maize and sub-combinations MON 89034 × NK603 × DAS-40278-9, 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9 (hereafter referred to as ‘MON 89034 × 1507 × NK603 × DAS-40278-9 maize and sub-combinations covered by this authorisation’) is published at:

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D2085&qid=1575761513438&from=EN>

The following products are authorised by Commission implementing decision (EU) 2019/2085:

- (a) Food and food ingredients containing, consisting of, or produced from MON 89034 × 1507 × NK603 × DAS-40278-9 maize and sub-combinations covered by this authorisation
- (b) Feed containing, consisting of, or produced from MON 89034 × 1507 × NK603 × DAS-40278-9 maize and sub-combinations covered by this authorisation
- (c) Products containing or consisting of MON 89034 × 1507 × NK603 × DAS-40278-9 maize and sub-combinations covered by this authorisation for uses other than those provided for in points (a) and (b), with the exception of cultivation.

It shall be noted that among the ten sub-combinations of the transformation events constituting MON 89034 × 1507 × NK603 × DAS-40278-9 maize, seven of those sub-combinations are already authorised as follows: MON 89034 × 1507, authorised by Commission Implementing Decision 2013/650/EU; MON 89034 × NK603, authorised by Commission Implementing Decision (EU) 2018/1111; 1507 × NK603, authorised by Commission Implementing Decision (EU) 2019/1306; MON 89034 × 1507 × NK603, authorised by Commission Implementing Decision 2013/648/ EU; and MON 89034 × 1507 × DAS-40278-9, MON 89034 × DAS-40278-9, 1507 × DAS-40278-9, authorised by Commission Implementing Decision (EU) 2019/2086.

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<sup>1</sup> EC, 2019. 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 × 1507 × NK603 × DAS-40278-9 maize and sub-combinations MON 89034 × NK603 × DAS-40278-9, 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

## General Characteristics of the genetically modified maize

MON 89034 × 1507 × NK603 × DAS-40278-9 maize has been obtained by traditional breeding between genetically modified MON 89034, 1507, NK603 and DAS-40278-9 maize single events. No new genetic modifications were introduced to obtain MON 89034 × 1507 × NK603 × DAS-40278-9 maize. Similarly, no new genetic modifications were introduced in any of the subcombinations.

Therefore, MON 89034 × 1507 × NK603 × DAS-40278-9 maize express the transgenic proteins inherited from the single genetically modified events: Cry1A.105, Cry2Ab2, Cry1F, PAT, CP4-EPSPS and AAD-1, which provide protection against certain Lepidopteran insect pests which are major insect pests of maize in agriculture and 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:

- MON 89034 expresses the Cry1A.105 and Cry2Ab2 proteins which confer protection against certain lepidopteran pests, such as the European corn borer (*Ostrinia nubilalis*).
- 1507 maize expresses the Cry1F protein which confers protection against certain lepidopteran pests, such as the European corn borer (*Ostrinia nubilalis*), and the PAT protein, which confers tolerance to glufosinate-ammonium-based herbicides.
- NK603 maize expresses the CP4 EPSPS protein, which confers tolerance to glyphosate herbicides.
- DAS-40278-9 maize expresses the AAD-1 protein, which confers tolerance to 2,4-D and AOPP herbicides.

## Safety of MON 89034 × 1507 × NK603 × DAS-40278-9 maize and sub-combinations MON 89034 × NK603 × DAS-40278-9, 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9

In January 2013, Dow AgroSciences Europe, on behalf of Dow AgroSciences LLC<sup>2</sup>, submitted to the competent authority of the Netherlands an application for the placing on the market of MON 89034 × 1507 × NK603 × DAS-40278-9 maize for food and feed uses, import and processing in accordance with articles 5 and 17 of Regulation (EC) No 1829/2003 (EFSA-GMO-NL-2013-112). The application also covered 10 subcombinations of the single transformation events constituting MON 89034 × 1507 × NK603 × DAS-40278-9 maize<sup>3</sup>, independently of their origin.

On 28 November 2018, the European Food Safety Authority (EFSA) Panel on Genetically Modified Organisms (GMO) adopted a positive scientific opinion in which it concluded:

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<sup>2</sup> Dow AgroSciences Europe and Dow AgroSciences LLC are now members of Corteva Agriscience group of companies

<sup>3</sup> Among the 10 subcombinations, 3 are authorized by Commission Implementing decision (EU) 2019/2085, and 7 are already authorised by other Commission Implementing decisions (see the Introduction section above).

*“The GMO Panel concludes that the four-event stack maize and its subcombinations are as safe as its non-GM comparator and the tested non-GM reference varieties with respect to potential effects on human and animal health and the environment.” (EFSA, 2019)<sup>4</sup>.*

The EFSA GMO panel scientific opinion is available at:

<https://www.efsa.europa.eu/en/efsajournal/pub/5522>

### **Monitoring Conditions for MON 89034 × 1507 × NK603 × DAS-40278-9 maize and sub-combinations MON 89034 × NK603 × DAS-40278-9, 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9**

As indicated in the positive EFSA GMO Panel opinion, MON 89034 × 1507 × NK603 × DAS-40278-9 maize and its subcombinations are as safe and as nutritious as its non-GM comparator (EFSA, 2019). Therefore, post-market monitoring of food/feed derived from MON 89034 × 1507 × NK603 × DAS-40278-9 maize and sub-combinations covered by this authorisation is not necessary, as confirmed by the EFSA GMO Panel (EFSA, 2019) and in the Commission authorisation decision for MON 89034 × 1507 × NK603 × DAS-40278-9 maize and sub-combinations covered by this authorisation (EC, 2019).

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 MON 89034 × 1507 × NK603 × DAS-40278-9 maize and its subcombinations. Therefore, no case-specific monitoring of MON 89034 × 1507 × NK603 × DAS-40278-9 maize and sub-combinations covered by this authorisation is necessary, as confirmed by the EFSA GMO panel in its scientific opinion (EFSA, 2019).

As specified by Commission decision (EU) 2019/2085 (EC, 2019), a post-market environmental monitoring (PMEM) plan for MON 89034 × 1507 × NK603 × DAS-40278-9 maize and sub-combinations covered by this authorisation 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 MON 89034 × 1507 × NK603 × DAS-40278-9 maize and sub-combinations covered by this authorisation, if any.

As stated by the EFSA GMO Panel in its scientific opinion on MON 89034 × 1507 × NK603 × 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 four-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 four-event stack maize and its subcombinations.”* (EFSA, 2019).

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<sup>4</sup> EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Mullins E, Nogué F, Rostoks N, Sanchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Alvarez F, Ardizzone M, Fernandez Dumont A, Gennaro A, Gomez Ruiz JA, Lanzoni A, Neri FM, Papadopoulou N and Ramon M, 2019. Scientific Opinion on the assessment of genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 and subcombinations independently of their origin for food and feed uses, import and processing, under Regulation (EC) No 1829-2003 (application EFSA-GMO-NL-2013-112). EFSA Journal 2019;17(1):5522, 30 pp. <https://doi.org/10.2903/j.efsa.2019.5522>

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 CropLife Europe. The result of the monitoring activities is reported back to the European Commission by Dow AgroSciences on an annual basis.

The post-market environmental monitoring plan for MON 89034 × 1507 × NK603 × DAS-40278-9 maize and its subcombinations covered by this authorisation has been published on the EU register for genetically modified food and feed: [https://webgate.ec.europa.eu/dyna/gm\\_register/environmentalmonitoringplan\\_maize\\_MON%2089034x1507xNK603xDAS-40278-9.pdf](https://webgate.ec.europa.eu/dyna/gm_register/environmentalmonitoringplan_maize_MON%2089034x1507xNK603xDAS-40278-9.pdf)

### **Conditions for traceability and labelling for MON 89034 × 1507 × NK603 × DAS-40278-9 maize and sub-combinations MON 89034 × NK603 × DAS-40278-9, 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9**

Operators importing, handling and processing grain and foods and feeds derived from MON 89034 × 1507 × NK603 × DAS-40278-9 maize and its subcombinations covered by this authorisation 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) 2019/2085 (EC, 2019).

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 MON 89034 × 1507 × NK603 × DAS-40278-9 maize and its subcombinations covered by this authorisation with the exception of foods and food ingredients containing, consisting of, or produced from MON 89034 × 1507 × NK603 × DAS-40278-9 maize and its subcombinations covered by this authorisation.

**Table 1:** MON 89034 × 1507 × NK603 × DAS-40278-9 maize and its subcombinations covered by Commission implementing decision (EU) 2019/2085:

Maize	Unique identifier
MON 89034 × 1507 × NK603 × DAS-40278-9	MON-89034-3 × DAS-01507-1 × MON-00603-6 × DAS-40278-9
MON 89034 × NK603 × DAS-40278-9	MON-89034-3 × MON-00603-6 × DAS-40278-9
1507 × NK603 × DAS-40278-9	DAS-01507-1 × MON-00603-6 × DAS-40278-9
NK603 × DAS-40278-9	MON-00603-6 × DAS-40278-9

### **Methods for detection and reference material**

#### *Validated detection method*

The detection, sampling and identification methods for MON 89034 × 1507 × NK603 × DAS-40278-9 maize consist of the same detection, sampling and identification methods available

for MON 89034, 1507, NK603 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 MON 89034 × 1507 × NK603 × DAS-40278-9 maize and its subcombinations, Dow AgroSciences provided the JRC-EURL with a PCR detection method that consists of the validated event-specific real-time PCR method for the quantification of MON 89034, 1507, NK603 and DAS-40278-9 maize, for verification. The detection method has been validated by EURL in June 2016 and is publicly available from the JRC-EURL website: <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>

#### *Maize certified reference material*

The Certified Reference Materials (CRM) for the individual traits comprising MON 89034 × 1507 × NK603 × DAS-40278-9 maize consist of the CRMs for MON 89034, 1507, NK603 and DAS-40278-9 maize. The Joint Research Centre's GMO Reference Unit of the European Commission has developed certified reference materials for 1507 (ERM<sup>®</sup>-BF418), NK603 (ERM<sup>®</sup>-BF415) and DAS-40278-9 (ERM<sup>®</sup>-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 MON 89034 (AOCS 0906-E) 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: [www.ecpa.eu/product-info](http://www.ecpa.eu/product-info)

If required, additional comments or questions can also be addressed to:

Corteva Agriscience  
Rue Montoyer 25  
1000 Bruxelles  
Belgium  
Email address: [CortevaEUBiotech@corteva.com](mailto:CortevaEUBiotech@corteva.com)