MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 maize and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9

Fact-sheet for operators

2021

MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 maize and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9

Fact-sheet for operators

The placing on the market of products containing, consisting of, or produced from genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and 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) 2019/2086 (EC, 2019)[1].

The authorisation decision for MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 maize and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9 as listed in Table 1 is published at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D2086&qid=1575761513438&from=EN

The following products are authorised by Commission implementing decision (EU) 2019/2086:

(a) Food and food ingredients containing, consisting of, or produced from genetically modified maize referred to in Table 1

(b) Feed containing, consisting of, or produced from genetically modified maize referred to in Table 1

(c) Products containing or consisting of genetically modified maize referred to in Table 1 for uses other than those provided for in points (a) and (b), with the exception of cultivation.

Table 1: MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 maize and its subcombinations covered by Commission implementing decision (EU) 2019/2086:

Maize	Unique identifier
MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9	MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7 × DAS-4Ø278-9
Quadruple stack subcombinations	
MON 89034 × 1507 × MON 88017 × DAS-40278-9	MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-4Ø278-9
MON 89034 × 1507 × 59122 × DAS-40278-9	MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7 × DAS-4Ø278-9
MON 89034 × MON 88017 × 59122 × DAS-40278-9	MON-89Ø34-3 × MON-88Ø17-3 × DAS-59122-7 × DAS-4Ø278-9
1507 × MON 88017 × 59122 × DAS-40278-9	DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7 × DAS-4Ø278-9

[1] EC, 2019. Commission Implementing Decision (EU) 2019/2086 of 28 November 2019 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 maize and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9 pursuant to Regulation EC) No 1829/2003 of the European Parliament and of the Council

Triple stack subcombinations	
MON 89034 × 1507 × DAS-40278-9	MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-4Ø278-9
MON 89034 × MON 88017 × DAS-40278-9	MON-89Ø34-3 × MON-88Ø17-3 × DAS-4Ø278-9
MON 89034 × 59122 × DAS-40278-9	MON-89Ø34-3 × DAS-59122-7 × DAS-4Ø278-9
1507 × MON 88017 × DAS-40278-9	DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-4Ø278-9
1507 × 59122 × DAS-40278-9	DAS-Ø15Ø7-1 × DAS-59122-7 × DAS-4Ø278-9
MON 88017 × 59122 × DAS-40278-9	MON-88Ø17-3 × DAS-59122-7 × DAS-4Ø278-9
Double stack subcombinations	
MON 89034 × DAS-40278-9	MON-89Ø34-3 × DAS-4Ø278-9
1507 × DAS-40278-9	DAS-Ø15Ø7-1 × DAS-4Ø278-9
MON 88017 × DAS-40278-9	MON-88Ø17-3 × DAS-4Ø278-9
DAS-59122-7 × DAS-4Ø278-9	59122 × DAS-40278-9

It shall be noted that 11 sub-combinations of MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 maize are not covered under Commission implementing decision (EU) 2019/2086 and are authorised by other Commission decisions as follow:

- 1507 x 59122, authorised by Commission Implementing Decision (EU) 2018/1110;
- MON 89034 × MON 88017, authorised by Commission Implementing Decision (EU) 2018/2046; and
- MON 89034 × 1507 × MON 88017 × 59122, MON 9034× 1507 × MON 88017, MON 89034 × 1507 × 59122, MON 89034 × MON 88017 × 59122, 1507 × MON 88017 x 59122, MON 89034 × 1507, MON 89034 × 59122, 1507 × MON 88017, MON 88017 × 59122, authorised by Commission Implementing Decision 2013/650/EU.

General Characteristics of the genetically modified maize

MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 maize has been obtained by traditional breeding between genetically modified MON 89034, 1507, MON 88017, 59122 and DAS-40278-9 maize single events. No new genetic modifications were introduced to obtain MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 maize. Similarly, no new genetic modifications were introduced in any of the subcombinations.

Therefore, MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 maize express the transgenic proteins inherited from the single genetically modified events: Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, Cry35Ab1, PAT, CP4-EPSPS and AAD-1, which provide protection against certain Lepidopteran and Coleopteran 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.
- MON 88017 maize expresses the Cry3Bb1 protein which confers protection against certain coleopteran pests, such as the Western corn rootworm (*Diabrotica virgifera*), and the CP4 EPSPS protein, which confers tolerance to glyphosate-based herbicides.
- 59122 maize expresses the Cry34Ab1 and Cry35Ab1 proteins which confer protection against certain coleopteran pests, such as the Western corn rootworm (*Diabrotica virgifera*), and 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 the MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 maize and its subcombinations

In February 2013, Dow AgroSciences Europe on behalf of Dow AgroSciences LLC[2] submitted to the competent authority of the Netherlands an application for the placing on the market of MON 89034 × 1507 × MON 88017 × 59122 × 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-2013-113). The application also covered 25 subcombinations of the single transformation events constituting MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 maize[3], 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:

"The GMO Panel concludes that the five-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)[4].

The EFSA GMO panel scientific opinion is available at:
https://www.efsa.europa.eu/en/efsajournal/pub/5521

[2] Dow AgroSciences Europe and Dow AgroSciences LLC are now members of Corteva Agriscience group of companies

[3] The 25 subcombinations : 14 as listed in table 1 which are covered by Commission decision (EU) 2019/2086 plus 11 already authorised: 1507 x 59122, authorised by Commission Implementing Decision (EU) 2018/1110; MON 89034 × MON 88017, authorised by Commission Implementing Decision (EU) 2018/2046; and MON 89034 × 1507 × MON 88017 × 59122, MON 89034 × 1507 × MON 88017, MON 89034 × 1507 × 59122, MON 89034 × MON 88017 × 59122, 1507 × MON 88017 × 59122, MON 89034 × 1507, MON 89034 × 59122, 1507 × MON 88017, MON 88017 × 59122, authorised by Commission Implementing Decision 2013/650/EU.

[4] 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, Nogue F, Rostoks N, Sanchez Serrano JJ, Savoini G, Veromann E, Veronesi 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 x 1507 x MON 88017 x 59122 x 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-2013-113). EFSA Journal 2019;17(1):5521, 30 pp. https://doi.org/10.2903/j.efsa.2019.5521

Monitoring Conditions for MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 maize and its subcombinations

As indicated in the positive EFSA GMO Panel opinion, MON 89034 × 1507 × MON 88017 × 59122 × 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 × MON 88017 × 59122 × DAS-40278-9 maize and its subcombinations 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 × MON 88017 × 59122 × DAS-40278-9 maize and its subcombinations 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 × MON 88017 × 59122 × DAS-40278-9 maize and its subcombinations. Therefore, no case-specific monitoring of MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 maize and its subcombinations is necessary, as confirmed by the EFSA GMO panel in its scientific opinion (EFSA, 2019).
As specified by Commission decision (EU) 2019/2086 (EC, 2019), a post-market environmental monitoring (PMEM) plan for MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 maize and its subcombinations covered by this decision 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 × MON 88017 × 59122 × DAS-40278-9 maize and its subcombinations covered by this decision, if any.
As stated by the EFSA GMO Panel in its scientific opinion on MON 89034 × 1507 × MON 88017 × 59122 × 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 five-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 five-event stack maize and its subcombinations."* (EFSA, 2019).

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 × MON 88017 × 59122 × 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_GMmaize_MON89034x1507xMON88017x59122xDAS-40278-9.pdf

Conditions for traceability and labelling for MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 maize and its subcombinations

Operators importing, handling and processing grain and foods and feeds derived from MON 89034 × 1507 × MON 88017 × 59122 × 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) 2019/2086 for MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 maize and the genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122, DAS-40278-9 (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 maize listed in Table 1 with the exception of foods and food ingredients containing, consisting of, or produced from maize listed in Table 1.

The unique identifiers assigned to MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 maize and its authorised subcombinations are listed in Table 1.

Methods for detection and reference material

Validated detection method

The detection, sampling and identification methods for MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 maize consist of the same detection, sampling and identification methods available for MON 89034, 1507, MON 88017, 59122, and DAS-40278-9 maize, which have been validated by the Joint Research Centre (JRC) of the European Union Reference Laboratory (EURL). In accordance with Regulation (EC) No 1829/2003 and in line with the above-mentioned application for authorisation of MON 89034 × 1507 × MON 88017 × 59122 × 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, MON 88017, 59122, and DAS-40278-9 maize, for verification. The detection method has been validated by EURL in November 2018 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 × MON 88017 × 59122 × DAS-40278-9 maize consist of the CRMs for MON 89034, 1507, MON 88017, 59122, and DAS-40278-9 maize. The Joint Research Centre's GMO Reference Unit has developed certified reference materials for NK603 (ERM®-BF415), 1507 (ERM®-BF418), 59122 (ERM®-BF424) 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 MON 89034 (AOCS 0906-E) and MON 88017 (AOCS 0406-D) 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 thr 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

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

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