

DP4114xMON89034xMON87411xDAS-40278-9

maize and its sub-combinations

DP4114xMON89034xMON87411,

DP4114xMON89034xDAS-40278-9,

DP4114xMON87411xDAS-40278-9,

MON89034xMON87411xDAS-40278-9,

DP4114xMON89034, DP4114xMON87411,

DP4114xDAS-40278-9,

MON89034xMON87411, MON89034xDAS-

40278-9, MON87411xDAS-40278-9

Fact-sheet for operators

2023



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DP4114 x MON89034 x MON87411 x DAS-40278-9 maize
and its subcombinations DP4114xMON89034xMON87411,
DP4114xMON89034xDAS-40278-9, DP4114xMON87411xDAS-40278-9,
MON89034xMON87411 xDAS-40278-9, DP4114xMON89034,
DP4114xMON87411, DP4114xDAS-40278-9, MON89034xMON87411,
MON89034xDAS-40278-9, MON87411xDAS-40278-9

Commission implementing decision (EU) 2023/1209¹ of 21 June 2023 authorised the placing on the market of products containing, consisting of, or produced from genetically modified maize DP4114xMON89034xMON87411xDAS-40278-9² and its sub-combinations DAS-40278-9xDP4114xMON87411, MON89034xDP4114xMON87411, MON89034xDAS-40278-9xMON87411, MON89034xDAS-40278-9xDP4114, DP4114xMON87411, DAS-40278-9xMON 87411, DAS-40278-9xDP4114, MON89034xDP4114³, pursuant to Regulation (EC) No 1829/2003⁴ of the European Parliament and of the Council.

The following products are authorised by Commission implementing decision (EU) 2023/1209:

- (a) Food and food ingredients containing, consisting of, or produced from DP4114xMON89034xMON87411xDAS-40278-9 maize and its sub-combinations covered by this authorisation
- (b) Feed containing, consisting of, or produced from DP4114xMON89034xMON87411xDAS-40278-9 maize and its sub-combinations covered by this authorisation
- (c) Products containing or consisting of DP4114xMON89034xMON87411xDAS-40278-9 maize and its 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 single events constituting DP4114xMON89034xMON87411xDAS-40278-9 maize, two of those sub-combinations, MON89034xMON87411 and MON89034xDAS-40278-9, have already been authorised by Commission implementing decisions (EU) 2021/65⁵ and (EU) 2019/2086⁶, respectively.

¹ EC, 2023. Commission Implementing Decision (EU) 2023/1209 of 21 June 2023 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize DP4114xMON89034xMON87411xDAS-40278-9 maize and sub-combinations DAS-40278-9xDP4114xMON87411, MON89034xDP4114xMON87411, MON89034xDAS-40278-9xMON87411, MON89034xDAS-40278-9xDP4114, DP4114xMON87411, DAS-40278-9xMON87411, DAS-40278-9xDP4114, MON 89034xDP4114 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023D1209>

² Also known as Vorceed™ Enlist® in the commercial context. ™, ® Trademarks of Corteva Agriscience and its affiliated companies.

³ Hereafter referred to as DP4114xMON89034xMON87411xDAS-40278-9 maize and its sub-combinations covered by this authorisation

⁴ EC, 2003. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. <https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32003R1829>

⁵ EC, 2021. Commission Implementing Decisions (EU) 2021/65 of 22 January 2021 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × MIR162 × MON 87411 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162 and MON 87411 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021D0065&qid=1688114154028>

⁶ 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 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. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D2086&qid=1688114309174>

Therefore, the placing on the market of all sub-combinations of DP4114xMON89034xMON87411xDAS-40278-9 maize is authorised in the European Union.

General Characteristics

DP4114xMON89034xMON87411xDAS-40278-9 maize has been obtained by traditional breeding between genetically modified DP4114, MON89034, MON87411 and DAS-40278-9 maize single events. No new genetic modifications were introduced to obtain DP4114xMON89034xMON87411xDAS-40278-9 maize nor any of its sub-combinations.

Therefore, DP4114xMON89034xMON87411xDAS-40278-9 maize expresses the newly expressed proteins and dsRNA inherited from the single events:

- DP4114 maize expresses the Cry1F, Cry34Ab1 and Cry35Ab1 proteins, which confer protection against certain lepidopteran and coleopteran pests and the phosphinothricin acetyltransferase (PAT) protein, which confers tolerance to glufosinate-ammonium-based herbicides.
- MON89034 maize expresses the Cry1A.105 and Cry2Ab2 proteins, which confer protection against certain lepidopteran pests.
- MON87411 maize expresses the DvSnf7 dsRNA, which confers protection against western corn rootworm, the Cry3Bb1 protein, which confers protection against certain coleopteran pests, and 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.

DP4114xMON89034xMON87411xDAS-40278-9 maize therefore confers i.) herbicide tolerance to glufosinate, glyphosate, 2,4-D and AOPP herbicides, due to the presence of the PAT, CP4 EPSPS and AAD-1 proteins, respectively; ii.) control of certain lepidopteran pests based on the presence of the Cry1F, Cry1A.105 and Cry2Ab2 proteins, conferring multiple modes of action for insect protection; and iii.) control of certain coleopteran pests based on the presence of the Cry34Ab1, Cry35Ab1 and Cry3Bb1 proteins and DvSnf7 dsRNA, conferring multiple modes of action for insect protection. Trait pyramids such as DP4114xMON89034xMON87411xDAS-40278-9 maize provide greater potential durability compared to products expressing a single mode of action, because each mode of action controls insects that are partially or completely resistant to the other mode of action.

Similarly, the different sub-combinations of DP4114xMON89034xMON87411xDAS-40278-9 maize have the characteristics conferred by the respective sub-combinations of single events.

Safety

In December 2020, Pioneer Overseas Corporation⁷ submitted to the competent authority of the Netherlands an application for the placing on the market of DP4114xMON89034xMON87411xDAS-40278-9 maize and all its sub-combinations for food and feed uses, import and processing in accordance with articles 5 and 17 of Regulation (EC) No 1829/2003 (EFSA-GMO-NL-2020-171).

⁷ member of Corteva Agriscience group of companies.

On 29 September 2022, 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 four-event stack maize and its subcombinations are as safe as its non-GM comparator and the tested non-GM maize varieties with respect to potential effects on human and animal health and the environment.”⁸

Monitoring Conditions

As indicated in the positive EFSA GMO Panel opinion, DP4114xMON89034xMON87411xDAS-40278-9 maize and its sub-combinations are as safe and as nutritious as its non-GM comparator⁶. Therefore, post-market monitoring of food/feed derived from DP4114xMON89034xMON87411xDAS-40278-9 maize and its sub-combinations is not necessary, as confirmed by the EFSA GMO Panel opinion⁶ and the Commission authorisation decision¹.

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 DP4114xMON89034xMON87411xDAS-40278-9 maize and its sub-combinations. Therefore, no case-specific monitoring of DP4114xMON89034xMON87411xDAS-40278-9 maize and its sub-combinations is necessary, as confirmed by the EFSA GMO panel in its scientific opinion⁶.

As specified by Commission decision (EU) 2023/1209¹, a post-market environmental monitoring (PMEM) plan for DP4114xMON89034xMON87411xDAS-40278-9 maize and its 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 DP4114xMON89034xMON87411xDAS-40278-9 maize and its sub-combinations covered by this authorisation, if any.

As stated by the EFSA GMO Panel in its scientific opinion on DP4114xMON89034xMON87411xDAS-40278-9 maize and its sub-combinations 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 maize DP4114 × MON 89034 × MON 87411 × DAS-40278-9. 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.”⁶*

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 Corteva Agriscience on an annual basis.

The post-market environmental monitoring plan for DP4114xMON89034xMON87411xDAS-40278-9 maize and its subcombinations covered by

⁸ EFSA GMO Panel, 2022. Scientific opinion on the assessment of genetically modified maize DP4114x MON 89034x MON 87411x DAS-40278-9 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA GMO-NL-2020-171). EFSA Journal, 20(11), p.e07619. <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7619>

this authorisation has been published on the EU register for genetically modified food and feed⁹.

Conditions for traceability and labelling

Operators importing, handling and processing grain and foods and feeds derived from DP4114xMON89034xMON87411xDAS-40278-9 maize and its sub-combinations covered by this authorisation in the EU shall comply with the conditions for traceability and labelling outlined in Regulations (EC) No 1829/2003⁴ and 1830/2003¹⁰ and in Commission decision (EU) 2023/1209¹.

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 DP4114xMON89034xMON87411xDAS-40278-9 maize and its sub-combinations covered by this authorisation with the exception of foods and food ingredients containing, consisting of, or produced from DP4114xMON89034xMON87411xDAS-40278-9 maize and its sub-combinations covered by this authorisation.

The unique identifiers assigned to DP4114xMON89034xMON87411xDAS-40278-9 maize and its sub-combinations covered by this authorisation are listed in Table 1.

Table 1: DP4114xMON89034xMON87411xDAS-40278-9 maize and its sub-combinations covered by Commission decision (EU) 2023/1209¹:

Maize	Unique identifier
DP4114xMON89034xMON87411xDAS-40278-9	DP-ØØ4114-3xMON-89Ø34-3xMON-87411-9xDAS-4Ø278-9
DAS-40278-9xDP4114xMON87411	DAS-4Ø278-9xDP-ØØ4114-3xMON-87411-9
MON89034xDP4114xMON87411	MON-89Ø34-3xDP-ØØ4114-3xMON-87411-9
MON89034xDAS-40278-9xMON87411	MON-89Ø34-3xDAS-4Ø278-9xMON-87411-9
MON89034xDAS-40278-9xDP4114	MON-89Ø34-3xDAS-4Ø278-9x DP-ØØ4114-3
DP4114xMON87411	DP-ØØ4114-3xMON-87411-9
DAS-40278-9xMON 87411	DAS-4Ø278-9xMON-87411-9
DAS-40278-9xDP4114	DAS-4Ø278-9x DP-ØØ4114-3
MON89034xDP4114	MON-89Ø34-3xDP-ØØ4114-3

Methods for detection and reference material

Validated detection method

The detection, sampling and identification methods for DP4114xMON89034xMON87411xDAS-40278-9 maize consist of the same detection, sampling and identification methods available for DP4114, MON89304, MON87411 and DAS-

⁹ https://webgate.ec.europa.eu/dyna2/gm-register/details/environmental_monitoring_plan_maize_DP4114xMON89034xMON87411xDAS-40278-9_and_subcombinations.pdf

¹⁰ EC, 2003. Regulation (EC) No1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC

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 DP4114xMON89034xMON87411xDAS-40278-9 maize and its sub-combinations, the applicant provided the JRC-EURL with a detection method that consists of the validated event-specific PCR method for the quantification of DP4114, MON89034, MON87411 and DAS-40278-9 maize, for verification. The detection method has been validated by EURL in July 2022 and is publicly available from the JRC-EURL website¹¹.

Certified reference material

The Certified Reference Materials (CRM) for the individual events comprising DP4114xMON89034xMON87411xDAS-40278-9 maize consist of the CRMs for DP4114, MON89034, MON87411 and DAS-40278-9 maize. The certified reference materials for DP4114 (ERM[®]-BF439) and DAS-40278-9 (ERM[®]-BF433) maize are accessible via the JRC of the European Commission¹². The certified reference materials for MON 89034 (AOCS 0906-E) and MON87411 (AOCS 0215-B) are accessible via the American Oil Chemists' Society¹³.

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:

Corteva Agriscience
Rue Montoyer, 25
1000 Brussels
Belgium
Email address: CortevaEUBiotech@corteva.com

¹¹ European Union Reference Laboratory for Genetically Modified Food and Feed (EURL GMFF). Method validations. <https://gmo-crl.jrc.ec.europa.eu/method-validations>

¹² <https://crm.jrc.ec.europa.eu/>

¹³ <https://www.aocs.org/crm>