

# DP915635 maize

Fact-sheet for operators

2024

## **DP915635 maize**

Commission Implementing Decision (EU) 2024/1822<sup>1</sup> of 2 July 2024 authorised the placing on the market of products containing, consisting of or produced from genetically modified maize DP915635 pursuant to Regulation (EC) No 1829/2003<sup>2</sup> of the European Parliament and of the Council.

The following products are authorised by Commission Implementing Decision (EU) 2024/1822<sup>1</sup>:

- (a) foods and food ingredients containing, consisting of or produced from genetically modified maize DP915635;
- (b) feed containing, consisting of or produced from genetically modified maize DP915635;
- (c) products containing or consisting of genetically modified maize DP915635 for uses other than those provided for in points (a) and (b), with the exception of cultivation

### **General Characteristics**

Genetically modified maize DP915635 was developed to confer tolerance to glufosinate herbicide and resistance to corn rootworm pests. These properties were achieved by expression of IPD079Ea protein for control of corn rootworm pests, phosphinothricin acetyltransferase (PAT) protein that confers tolerance to the glufosinate ammonium-containing herbicides, and the phosphomannose isomerase (PMI) protein that was used as a selectable marker during transformation.

### **Safety**

In December 2020, Corteva Agriscience Belgium B.V. submitted to the competent authority of the Netherlands an application for authorisation of maize DP915635, according to Regulation (EC) No 1829/2003<sup>2</sup> (FSA-GMO-NL-2020-172).

On 30 November 2023, 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 maize DP915635 is as safe as its conventional counterpart and the tested non-GM maize varieties with respect to potential effects on human and animal health and the environment”*<sup>3</sup>.

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<sup>1</sup> Commission Implementing Decision (EU) 2024/1822 of 2 July 2024 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize DP915635 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32024D1822&qid=1720078762695>

<sup>2</sup> Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. Official Journal L 268 , 18/10/2003 P. 0001 – 0023. <http://data.europa.eu/eli/reg/2003/1829/oj>

<sup>3</sup> Assessment of genetically modified maize DP915635 for food and feed uses, under regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2020-172). *EFSA Journal*, 22(1), e8490. <https://doi.org/10.2903/j.efsa.2024.8490>

## Monitoring Conditions

As indicated in the positive EFSA GMO Panel opinion, maize DP915635 does not raise any nutritional concern and is as safe as its conventional counterpart and the non-GM reference varieties tested<sup>3</sup>. Therefore, the GMO Panel concludes that based on the information considered in its safety assessment, a post-market monitoring plan for food and feed is not necessary.

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 DP915635. Therefore, the GMO Panel concludes that no case-specific monitoring is required.

As specified by Commission Implementing Decision 2024/1822<sup>1</sup>, a post-market environmental monitoring (PMEM) plan for DP915635 maize 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 DP915635 maize, if any.

As stated by the EFSA GMO Panel in its scientific opinion on DP915635 maize 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 DP915635. The GMO Panel agrees with the reporting intervals proposed by the applicant in its PMEM plan”*<sup>3</sup>. The post-market environmental monitoring plan for DP915635 maize has been published on the EU register for genetically modified food and feed<sup>4</sup>.

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<sup>5</sup>.

## Conditions for traceability and labelling

Operators importing, handling and processing grain and foods and feeds derived from DP915635 maize in the EU shall comply with the conditions for traceability and labelling outlined in Regulations (EC) No 1829/2003<sup>2</sup> and 1830/2003<sup>6</sup> and in Commission Implementing Decision (EU) 2024/1826<sup>1</sup>.

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<sup>4</sup> <https://webgate.ec.europa.eu/dyna2/gm-register/>

<sup>5</sup> [https://food.ec.europa.eu/plants/genetically-modified-organisms/post-authorisation/monitoring-plans-and-reports\\_en](https://food.ec.europa.eu/plants/genetically-modified-organisms/post-authorisation/monitoring-plans-and-reports_en)

<sup>6</sup> Regulation (EC) No 1830/2003 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. Official Journal L 268 , 18/10/2003 P. 0024 – 0028. <http://data.europa.eu/eli/reg/2003/1830/oj>

For the purposes of the specific labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003<sup>2</sup>, and in Article 4(6) of Regulation (EC) No 1830/2003<sup>6</sup>, 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 DP915635 maize with the exception of foods and food ingredients containing, consisting of, or produced from DP915635 maize.

The unique identifiers assigned to DP915635 maize is DP-915635-4.

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

### *Validated detection method*

In accordance with Regulation (EC) No 1829/2003<sup>2</sup> and in line with the above-mentioned application for authorisation of DP915635 maize, a validated event-specific detection method for the quantification of DP915635 maize event has been published by the European Union Reference Laboratory (EURL) of the Joint Research Centre (JRC). The validated detection method is publicly available from the JRC-EURL website<sup>7</sup>.

### *Certified reference material*

In accordance with Regulation (EC) No 1829/2003<sup>2</sup> and in line with the above application for authorisation of DP915635 maize, certified reference material is available at the Institute for Reference Materials and Measurements (IRMM). Reference Material: ERM<sup>®</sup>- BF447a-e is accessible via the Joint Research Centre (JRC) of the European Commission<sup>8</sup>.

## **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/>

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<sup>7</sup> European Union Reference Laboratory for Genetically Modified Food and Feed (EURL GMFF). Method validations. <https://gmo-crl.jrc.ec.europa.eu/method-validations>

<sup>8</sup> <https://crm.jrc.ec.europa.eu/>

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

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1000 Brussels

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