

DP4114xMON810xMIR604xNK603 maize and
and genetically modified maize
combining two or three of the single
events DP4114, MON810, MIR604 and
NK603

Fact-sheet for operators

2022

DP4114xMON810xMIR604xNK603 maize and genetically modified maize combining two or three of the single events DP4114, MON810, MIR604 and NK603

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Introduction

The placing on the market of products containing, consisting of, or produced from genetically modified maize DP4114xMON810xMIR604xNK603 (DP-ØØ4114-3 × MON-ØØ81Ø-6 × SYN-IR6Ø4-5 × MON-ØØ6Ø3-6) and genetically modified maize combining two or three of the single events DP4114, MON810, MIR604 and NK603 was authorised, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, by the European Commission on 29 June 2022 under Commission implementing decision (EU) 2022/1094 (EC, 2022)¹.

The Commission Implementing Decision (EU) 2022/1094 covered the following

- DP4114xMON810xMIR604xNK603
- MIR604 × NK603 × DP4114,
- MON 810 × NK603 × DP4114,
- MON 810 × MIR604 × DP4114,
- MON 810 × MIR604 × NK603,
- NK603 × DP4114,
- MIR604 × DP4114,
- MIR604 × NK603,
- MON 810 × DP4114 and
- MON 810 × MIR604.

The above products are authorised by Commission Implementing Decision (EU) 2022/1094 for

- (a) Food and food ingredients containing, consisting of, or produced from genetically modified maize
- (b) Feed containing, consisting of, or produced from genetically modified maize
- (c) Genetically modified maize in products containing them or consisting of them, for uses other than those provided for in points (a) and (b), with the exception of cultivation.

<https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32022D1094>

¹ EC, 2022. COMMISSION IMPLEMENTING DECISION (EU) 2022/1094 of 29 June 2022 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize DP4114 × MON 810 × MIR604 × NK603 and genetically modified maize combining two or three of the single events DP4114, MON 810, MIR604 and NK603, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2022) 4333). Official Journal of the European Union L 176/26 1.7.2022

Based on the European Food Safety Authority (EFSA) positive opinion for DP4114xMON810xMIR604xNK603 and all sub-combinations (see safety section)

Therefore, all sub-combinations of DP4114xMON810xMIR604xNK603 maize have been covered by either the current or a previous Commission Implementing Decision (see Table 1).²

Table 1: Sub-combinations of DP4114xMON810xMIR602xNK603 (DP-ØØ4114-3xMON-ØØ81Ø-6xSYN-IR6Ø4-5xMON-ØØ6Ø3-6) maize

<i>Triple stacks</i>	
DP4114xMON810xNK603	DP-ØØ4114-3-1xMON-ØØ81Ø-6xMON-ØØ6Ø3-6
DP4114xMON810xMIR604	DP-ØØ4114-3-1xMON-ØØ81Ø-6xSYN-IR6Ø4-5
DP4114xMIR604xNK603	DP-ØØ4114-3-1xSYN-IR6Ø4-5xMON-ØØ6Ø3-6
MON810xMIR604xNK603	MON-ØØ81Ø-6xSYN-IR6Ø4-5xMON-ØØ6Ø3-6
<i>Double stacks</i>	
DP4114xNK603	DP-ØØ4114-3-1xMON-ØØ6Ø3-6
NK603xMON810 *. ¹	MON-ØØ6Ø3-6xMON-ØØ81Ø-6
DP4114xMON810	DP-ØØ4114-3-1xMON-ØØ81Ø-6
DP4114xMIR604	DP-ØØ4114-3-1xSYN-IR6Ø4-5
MON810xMIR604	MON-ØØ81Ø-6xSYN-IR6Ø4-5
MIR604xNK603	SYN-IR6Ø4-5xMON-ØØ6Ø3-6

In bold sub-combinations covered by Commission Implementing Decision (EU) 2022/1094

* These products are covered by a separate authorization decision

¹ Commission Implementing Decision (EU) 2018/2045

General Characteristics of the genetically modified maize

DP4114xMON810xMIR604xNK603 maize has been obtained by traditional breeding between genetically modified DP4114, MON810, MIR604 and/or NK603 maize single events. No new genetic modifications were introduced to obtain DP4114xMON810xMIR604xNK603 maize. Similarly, no new genetic modifications were introduced in any of the subcombinations. Therefore, DP4114xMON810xMIR604xNK603 maize expresses the transgenic proteins inherited from the single genetically modified events providing i.) herbicide tolerance to glyphosate and glufosinate-ammonium herbicides due to the presence of the CP4 EPSPS and PAT proteins, respectively, ii.) protection against lepidopteran target pests based on the presence of the Cry1F and Cry1Ab proteins, conferring multiple modes of action for insect protection; and iii.) protection against coleopteran target pests based on the presence of the Cry34Ab1, Cry35Ab1 and mCry3A proteins, conferring multiple modes of action for insect protection.

² Commission Implementing Decision (EU) 2018/1110 of 3 August 2018 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize DP4114 × 59122 × MON 810 × NK603, and genetically modified maize combining two or three of the single events DP4114, 59122, MON 810 and NK603, and repealing Decisions 2009/815/EC, 2010/428/EU and 2010/432/EU (*OJ L 203, 10.8.2018, p. 13*).

Commission Implementing Decision (EU) 2018/2045 of 19 December 2018 renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize NK603 × MON 810 (MON-ØØ6Ø3-6 × MON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (*OJ L 327, 21.12.2018, p. 65*).

Genetically modified (GM) crops provide economic and environmental benefits to cultivation countries. Those GM crops containing insect resistance traits with multiple modes of action against the same target insect pest(s) are expected to slow the evolution of resistance in those pest populations relative to crops containing a single trait. They may also mitigate the impact of any target insect pest populations with resistance to an individual component. Such pyramided stacks with independent modes of action against the same target pests can substantially enhance durability and delay the development of resistance to both toxins in the insects. Similarly, the different sub-combinations have the characteristics conferred by the respective sub-combinations or single events, as detailed below:

- DP4114 maize expresses the Cry1F protein which confers protection against certain susceptible lepidopteran pests; Cry34Ab1 and Cry35Ab1 genes, which confer resistance to certain susceptible coleopteran pests; and the PAT protein, which confers tolerance to glufosinate-ammonium-based herbicides
- MON810 maize expresses the Cry1Ab protein, which confers protection against certain susceptible lepidopteran pests,
- MIR604 maize expresses the mCry3A protein, which confers protection against certain susceptible coleopteran pests, and the PMI protein, which was used as a selectable marker
- NK603 maize expresses the CP4 EPSPS protein, which confers tolerance to glyphosate-containing herbicides.

Safety of DP4114xMON810xMIR604xNK603 maize and its sub-combinations

In May 2018, an application for the placing on the market of DP4114xMON810xMIR604xNK603 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-2018-150). The application also covered 10 subcombinations of the single transformation events combining two or three of the single events DP4114, MON810, MIR604 and NK603.

On 26 January 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 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, 2022)³.

The EFSA GMO panel scientific opinion is available at:

<https://doi.org/10.2903/j.efsa.2022.7134>

Monitoring Conditions for DP4114xMON810xMIR604xNK603 maize and its sub-combinations

³ 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, Moreno, FJ, Nogué, F, Rostoks, N, Sánchez Serrano, JJ, Savoini, G, Veromann, E, Veronesi, F, Ardizzone, M, Dumont, AF, Federici, S, Gennaro, A, Gómez Ruiz, JÁ, Goumperis, T, Kagkli, DM, Lanzoni, A, Lenzi, P, Neri, FM, Papadopoulou, N, Paraskevopoulos, K, Raffaello, T, Streissl, F and De Sanctis, G, 2022. Scientific Opinion on the assessment of genetically modified maize DP4114 × MON 810 × MIR604 × NK603 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2018-150). EFSA Journal 2022; 20(3):7134, 38 pp. <https://doi.org/10.2903/j.efsa.2022.7134>.

As indicated in the positive EFSA GMO Panel opinion, DP4114xMON810xMIR604xNK603 maize and its subcombinations are as safe and as nutritious as the non-GM comparator (EFSA, 2022). Therefore, post-market monitoring of food/feed derived from DP4114xMON810xMIR604xNK603 maize and its sub-combinations is not necessary, as confirmed by the EFSA GMO Panel (EFSA, 2022) and in the Commission authorisation decision for DP4114xMON810xMIR604xNK603 and its sub-combinations (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 DP4114xMON810xMIR604xNK603 maize and its subcombinations. Therefore, no case-specific monitoring of DP4114xMON810xMIR604xNK603 and its sub-combinations is necessary, as confirmed by the EFSA GMO panel in its scientific opinion (EFSA, 2022).

As specified by Commission decision (EU) 2022/1094 (EC, 2022), a post-market environmental monitoring (PMEM) plan for DP4114xMON810xMIR604xNK603 maize and its sub-combinations 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 DP4114xMON810xMIR604xNK603 maize and its sub-combinations, if any.

As stated by the EFSA GMO Panel in its scientific opinion on DP4114xMON810xMIR604xNK603 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, 2022).

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 DP4114xMON810xMIR604xNK603 maize and its sub-combinations has been published on the EU register for genetically modified food and feed:

https://webgate.ec.europa.eu/dyna/gm_register/maize-DP4114xMON810xMIR604xNK603-environmental-monitoring-plan.pdf

Conditions for traceability and labelling for DP4114xMON810xMIR604xNK603 maize and its sub-combinations

Operators importing, handling and processing grain and foods and feeds derived from DP4114xMON810xMIR604xNK603 and its sub-combinations 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) 2022/1094 (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 maize listed in Table 1 with the exception of foods and food ingredients containing, consisting of, or produced from DP4114xMON810xMIR604xNK603 maize and its sub-combinations.

The unique identifiers assigned to DP4114xMON810xMIR604xNK603 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 DP4114xMON810xMIR604xNK603 maize consist of the same detection, sampling and identification methods available for DP4114, MON810, MIR604, and NK603 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 DP4114xMON810xMIR604xNK603 maize and its subcombinations, 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 DP4114, MON810, MIR604, and NK603 maize, for verification. The detection method has been validated by EURL in November 2020 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 DP4114xMON810xMIR604xNK603 maize consist of the CRMs for DP4114, MON810, MIR604, and NK603 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 ERM[®]-BF439 (for DP-ØØ4114-3), ERM[®]-BF413 (for MON-ØØ81Ø-6) and NK603 (ERM[®]-BF415) 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 SYN-IR6Ø4-5 (AOCS 0607) 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://croplifeurope.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