1507 x 59122 x MON 810 x NK603 maize and genetically modified maize combining two or three of the single events 1507, 59122, MON 810 and NK603

Fact-sheet for operators

2021

1507 x 59122 x MON 810 x NK603 maize and genetically modified maize combining two or three of the single events 1507, 59122, MON 810 and NK603

Fact-sheet for operators

The placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 x 59122 x MON 810 x NK603 and genetically modified maize combining two or three of the single events 1507, 59122, MON 810 and NK603 was authorised, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, by the European Commission on 3 August 2018 under Commission implementing decision (EU) 2018/1110 (EC, 2018)[1].

The authorisation decision for 1507 x 59122 x MON 810 x NK603, and genetically modified maize combining two or three of the single events 1507, 59122, MON 810 and NK603 as listed in Table 1 is published at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018D1110&from=en

The following products are authorised by Commission implementing decision (EU) 2018/1110:

(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) Genetically modified maize referred to in Table 1 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.

Table 1: 1507 x 59122 x MON 810 x NK603 maize and its subcombinations covered by Commission implementing decision (EU) 2018/1110:

Maize	Unique identifier
1507 x 59122 x MON 810 x NK603	DAS-Ø15Ø7-1 x DAS-59122-7 x MON-ØØ81Ø-6 x MON-ØØ6Ø3-6
Triple stack subcombinations	
1507 x 59122 x MON 810	DAS-Ø15Ø7-1 x DAS-59122-7 x MON-ØØ81Ø-6
59122 x 1507 x NK603*	DAS-59122-7 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6
1507 x MON 810 x NK603	DAS-Ø15Ø7-1 x MON-ØØ81Ø-6 x MON-ØØ6Ø3-6
59122 x MON 810 x NK603	DAS-59122-7 x MON-ØØ81Ø-6 x MON-ØØ6Ø3-6
Double stack subcombinations	
1507 x 59122*	DAS-Ø15Ø7-1 x DAS-59122-7

[1] EC, 2018. 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 1507 x 59122 x MON 810 x NK603, and genetically modified maize combining two or three of the single events 1507, 59122, MON 810 and NK603, and repealing Decisions 2009/815/EC, 2010/428/EU and 2010/432/EU. And Corrigendum to Commission Implementing Decision (EU) 2018/1110 at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018D1109R(01)&from=EN

1507 x MON 810	DAS-Ø15Ø7-1 x MON-ØØ81Ø-6
59122 x MON 810	DAS-59122-7 x MON-ØØ81Ø-6
59122 x NK603*	DAS-59122-7 x MON-ØØ6Ø3-6

* The maize products 59122 x 1507 x NK603, 1507 x 59122 and 59122 x NK603 were previously authorised by Commission Decisions 2010/428/EU, 2010/432/EU and 2009/815/EC, respectively, which were repealed by Commission decision (EU) 2018/1110 and incorporated in the scope of that decision.

It shall be noted that 1507 x NK603 (DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6) and NK603 x MON 810 (MON-ØØ6Ø3-6 x MON-ØØ81Ø-6) which are also subcombinations of 1507 x 59122 x MON 810 x NK603 maize and are not covered under Commission implementing decision (EU) 2018/1110 are authorised by Commission decision 2019/1306 and Commission decision 2018/2045, respectively.

General Characteristics of the genetically modified maize

1507 x 59122 x MON 810 x NK603 maize has been obtained by traditional breeding between genetically modified 1507, 59122, MON 810 and NK603 maize single events. No new genetic modification has been introduced to obtain 1507 x 59122 x MON 810 x NK603 maize. Similarly, no new genetic modification has been introduced in any of the subcombinations. Therefore, 1507 x 59122 x MON 810 x NK603 maize express the transgenic proteins inherited from the single genetically modified events: Cry1F, Cry34Ab1, Cry35Ab1, Cry1Ab, PAT and CP4 EPSPS, 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- and glufosinate ammonium-based herbicides. Similarly, the different subcombinations have the characteristics conferred by the single events, as detailed below:

- 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.
- 59122 maize expresses 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.
- MON 810 maize expresses the Cry1Ab protein, which confers protection against certain lepidopteran pests, such as the European corn borer (*Ostrinia nubilalis*).
- NK603 maize expresses the CP4 EPSPS protein, which confers tolerance to glyphosate-containing herbicides.

Safety of the 1507 x 59122 x MON 810 x NK603 maize and its subcombinations

In February 2011, Pioneer submitted to the competent authority of the Netherlands an application for the placing on the market of 1507 x 59122 x MON 810 x NK603 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-2011-92). The application also covered 10 subcombinations of

the single transformation events constituting 1507 x 59122 x MON 810 x NK603 maize[2], independently of their origin.

On 14 November 2017, 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 is as safe and as nutritious as its non-GM comparator." "Since no new data on the five previously assessed subcombinations of maize 1507 x 59122 xMON810 x NK603 that would lead to a modification of the original conclusions on their safety were identified, the GMO Panel considers that its previous conclusions on these maize stacks remain valid." "The five subcombinations not previously assessed are expected to be as safe as the single maize events, the previously assessed subcombinations and the four-event stack maize"* (EFSA, 2017)[3].

The EFSA GMO panel scientific opinion is available at:
https://www.efsa.europa.eu/en/efsajournal/pub/5000

Monitoring Conditions for 1507 x 59122 x MON 810 x NK603 maize and its subcombinations

As indicated in the positive EFSA GMO Panel opinion on 1507 x 59122 x MON 810 x NK603 maize and its subcombinations, 1507 x 59122 x MON 810 x NK603 maize (and its subcombinations) is as safe and as nutritious as its non-GM comparator (EFSA, 2017).
Therefore, post-market monitoring of food/feed derived from 1507 x 59122 x MON 810 x NK603 maize and its subcombinations is not necessary, as confirmed by the EFSA GMO Panel (EFSA, 2017) and in the Commission authorisation decision for 1507 x 59122 x MON 810 x NK603 maize and its subcombinations (EC, 2018).

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 1507 x 59122 x MON 810 x NK603 maize and its subcombinations. Therefore, no case-specific monitoring of 1507 x 59122 x MON 810 x NK603 maize and its subcombinations is necessary, as confirmed by the EFSA GMO panel in its scientific opinion (EFSA, 2017).
As specified by Commission decision (EU) 2018/1110 (EC, 2018), a post-market environmental monitoring (PMEM) plan for 1507 x 59122 x MON 810 x NK603 maize and its subcombinations 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 1507 x 59122 x MON 810 x NK603 maize and its subcombinations, if any.

[2] The 10 subcombinations (8 as listed in table 1 which are covered by Commission decision (EU) 2018/1110 plus 1507xNK603 and NK603xMON810 which are authorised by Commission decisions 2007/703/EC and 2007/701/EC, respectively) were all positively assessed by the EFSA GMO panel in its scientific opinion (EFSA, 2017)

[3] EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H, Birch AN, Casacuberta J, De SchrijverA, Gralak MA, Guerche P, Jones H, Manachini B, Messean A, Nielsen EE, Nogue F, Robaglia C, Rostoks N, Sweet J Tebbe C, Visioli F, Wal J-M, Gennaro A, Lanzoni A and Olaru I, 2017. Scientific opinion on the assessment of genetically modified maize 1507 x 59122 x MON810 x NK603 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2011-92). *EFSA Journal 2017*;15(11):5000, 29 pp. https://doi.org/10.2903/j.efsa.2017.5000

As stated by the EFSA GMO Panel in its scientific opinion on 1507 x 59122 x MON 810 x NK603 maize and its subcombinations for food and feed uses, import and processing "*The EFSA GMO panel considers that the scope of the PMEM plan provided by the applicant is consistent with the intended uses of maize 1507 x 59122 xMON810 x NK603 and its subcombinations. The EFSA GMO Panel agrees with the reporting intervals proposed by the applicant in its PMEM plan.*" (EFSA, 2017).

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 Pioneer on an annual basis.
The post-market environmental monitoring plan for 1507 x 59122 x MON 810 x NK603 maize and its subcombinations has been published on the EU register for genetically modified food and feed:
http://ec.europa.eu/food/dyna/gm_register/Monitoring%20plan%20AP92.pdf

Conditions for traceability and labelling for 1507 x 59122 x MON 810 x NK603 maize and its subcombinations

Operators importing, handling and processing grain and foods and feeds derived from 1507 x 59122 x MON 810 x NK603 maize and its subcombinations 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) 2018/1110 for 1507 x 59122 x MON 810 x NK603 maize and genetically modified maize combining two or three of the single events 1507, 59122, MON 810 and NK603 (EC, 2018).

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 1507 x 59122 x MON 810 x NK603 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 1507 x 59122 x MON 810 x NK603 maize consist of the same detection, sampling and identification methods available for 1507, 59122, MON 810 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 1507 x 59122 x MON 810 x NK603 maize and its subcombinations, Pioneer provided the JRC-EURL with a PCR detection method that consists of the validated event-specific real-time PCR method for the quantification of 1507, 59122, MON 810 and NK603 maize, for verification. The detection

method has been validated by EURL in November 2013 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 1507 x 59122 x MON 810 x NK603 maize and its subcombinations consist of the CRMs for 1507, 59122, MON 810 and NK603 maize produced by the Joint Research Centre's GMO Reference Unit. The corresponding CRM sets ERM®-BF418 (for 1507), ERM®-BF424 (for 59122), ERM®-BF413 (for MON 810) and ERM®-BF415 (for NK603) can be obtained via the JRC website:
https://crm.jrc.ec.europa.eu/e/92/Catalogue-price-list-pdf

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

If required, additional comments or questions can also be addressed to:
Corteva Agriscience
Rue Montoyer 25
1000 Bruxelles
Belgium
Email address: CortevaEUBiotech@corteva.com