59122 maize
Herculex® RW Rootworm Protection
Fact-sheet for operators

2021

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Introduction

The placing on the European Union (EU) market of products containing, consisting of, or produced from 59122 maize, also referred to as maize with the Herculex® RW Rootworm Protection[1] in the commercial context, was authorised, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, by Commission decision 2007/702/EC of 24 October 2007 (EC, 2007) [2]. The authorisation was renewed pursuant to Regulation (EC) No 1829/2003 by Commission implementing decision (EU) 2018/1109 of 3 August 2018 (EC, 2018) [3].
The renewal authorisation decision for 59122 maize is published at:
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018D1109&from=EN

The following products are re-authorised:

(a) Food and food ingredients containing, consisting of, or produced from 59122 maize
(b) Feed containing, consisting of, or produced from 59122 maize
(c) 59122 maize in products containing it or consisting of it for any other use than those provided in points (a) and (b), with the exception of cultivation

It shall be noted that another application for EU authorisation for cultivation of 59122 maize seed products has been submitted and received EFSA GMO panel opinions but is pending.

General Characteristics of 59122 maize

59122 maize has been genetically modified to express the proteins Cry34Ab1 and Cry35Ab1 and phosphinothricin-N-acetyltransferase (PAT). Expression of the Cry34Ab1 and Cry35Ab1 proteins confers protection against certain coleopteran pests, such as the Western corn rootworm (*Diabrotica virgifera*) which are major insect pests of maize in agriculture. Expression of the PAT protein, used as a selectable marker during the transformation process, confers tolerance to the application of glufosinate ammonium-based herbicides.

[1] Herculex® RW Rootworm Protection technology by Dow AgroSciences and Pioneer Hi-Bred; Herculex® and the HX logo are registered trademark of Dow AgroSciences LLC.

[2] Commission Decision 2007/702/EC of 24 October 2007 concerning the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

[3] Commission Implementing Decision (EU) 2018/1109 of 1 August 2018 renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.
And Corrigendum to Commission Implementing Decision (EU) 2018/1109 at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018D1109R(01)&from=EN

Safety of the 59122 maize

In January 2005, Pioneer and Dow AgroSciences[4] submitted to the competent authority of the Netherlands an application for authorisation for the placing on the market of 59122 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-2005-12). The EFSA GMO Panel positively assessed the application and concluded in April 2007 "*that maize 59122 is unlikely to have any adverse effect on human and animal health or on the environment in the context of its intended uses."* (EFSA, 2007[5]). This resulted in October 2007, as previously indicated, in the authorisation to place on the EU market 59122 maize for food and feed uses, import and processing.

The food and feed safety of 59122 maize has also been substantiated by an EFSA GMO panel positive scientific opinion on the 59122 maize cultivation application (EFSA, 2013[6]).

In July 2016, *i.e*. at least one year before the expiry date of the authorisation, Pioneer and Dow AgroSciences submitted to the Commission an application for the renewal of the authorisation for the placing on the market of 59122 maize for food and feed uses, import and processing in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 (EFSA-GMO-RX-003). On 18 May 2017, the EFSA Panel on GMOs adopted a positive scientific opinion in which it concluded: "*Under the assumption that the DNA sequence of the event in maize 59122 considered for renewal is identical to the corrected sequence of the originally assessed event, the GMO Panel concludes that no new hazards or modified exposure and no new scientific uncertainties were identified that would change the conclusions of the original risk assessment on maize 59122"* (EFSA, 2017)[7].

The EFSA GMO panel scientific opinion for the renewal application (EFSA, 2017) is available at: https://www.efsa.europa.eu/en/efsajournal/pub/4861

Monitoring Conditions for 59122 maize

As indicated in the positive EFSA GMO Panel opinion on 59122 maize, from a nutritional point of view 59122 maize is equivalent to conventionally bred varieties (EFSA, 2007). Therefore, post-market monitoring of 59122 maize food/feed is not necessary, as reconfirmed in the Commission authorisation decision (EU) 2018/1109 for 59122 maize (EC, 2018).

[4] Member of Corteva Agriscience group of companies

[5] EFSA, 2007. Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-NL-2005-12) for the placing on the market of insect-resistant genetically modified maize 59122, for food and feed uses, import and processing under Regulation (EC) No 1829/2003, from Pioneer Hi-Bred International, Inc and Mycogen Seeds, c/o Dow AgroSciences LLC (Question No EFSA-Q-2005-045). The EFSA Journal (2007) 470, 1-25.

[6] EFSA, 2013. Scientific Opinion on an application from Pioneer Hi-Bred International and Dow AgroSciences LLC (EFSA-GMO-NL-2005-23) for placing on the market of genetically modified maize 59122 for food and feed uses, import, processing and cultivation under Regulation (EC) No 1829/2003. The EFSA Journal 2013; 11(3):3135.

[7] 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, Nogué F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal J-M, Alvarez F, Ardizzone M and Paraskevopoulos K, 2017. Scientific opinion on an application for renewal of authorisation for continued marketing of maize 59122 and derived food and feed submitted under Articles 11 and 23 of Regulation (EC) No 1829/2003 by Pioneer Overseas Corporation and Dow AgroSciences LLC. EFSA Journal 2017; 15(6):4861, 10pp. doi:10.2903/j.efsa.2017.4861

Furthermore, no potential adverse effects to human and animal health or the environment have been identified in the environmental risk assessment from the intended uses of 59122 maize (EFSA, 2007). Therefore, case-specific monitoring of 59122 maize is not necessary, as confirmed by the EFSA GMO panel in its scientific opinion (EFSA, 2007) and Commission decision 2018/1109. As specified by the Commission decision, a post-market environmental monitoring (PMEM) plan for 59122 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 59122 maize, if any.

As stated by the EFSA GMO Panel in its scientific opinion on 59122 maize for renewal of the authorisation for food and feed uses, import and processing "*The GMO Panel is of the opinion that the scope of the plan provided by the applicant is consistent with the scope of maize 59122*" (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 and Dow AgroSciences on an annual basis.

The post-market environmental monitoring plan for 59122 maize has been published on the EU register for genetically modified food and feed:
http://ec.europa.eu/food/dyna/gm_register/environmental_monitoring_plan_maize_59122.pdf

Conditions for traceability and labelling for 59122 maize

Operators importing, handling and processing 59122 maize and derived foods and feeds 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) 2018/1109 for 59122 maize.

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 the product and in the documents accompanying products containing or consisting of 59122 maize, with the exception of foods and food ingredients.

The unique identifier assigned to 59122 maize is DAS-59122-7.

Methods for detection and reference material for 59122 maize

Validated 59122 maize detection method
A validated event-specific detection method for the quantitation of 59122 maize event has been published by the Community Reference Laboratory for GM food and feed of the Joint

Research Centre (JRC). The validated detection method is publicly available from the JRC website:
http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx

59122 maize certified reference material
Certified reference material for 59122 is available at Joint Research Centre's GMO Reference Unit. The corresponding certified reference material set ERM®-BF424 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