4114 maize
(DP-ØØ4114-3 maize)
Fact-sheet for operators

2021

4114 maize

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The placing on the market of products containing, consisting of or produced from genetically modified maize 4114[1] was authorised, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, by the European Commission on 26 July 2019 under Commission implementing decision (EU) 2019/1304 (EC, 2019)[2].

The authorisation decision for 4114 maize is published at:
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.204.01.0065.01.ENG

The following products are authorised:

(a) Foods and food ingredients containing, consisting of or produced from 4114 maize
(b) Feed containing, consisting of or produced from 4114 maize
(c) products containing or consisting of 4114 maize for uses other than those provided for in points (a) and (b), with the exception of cultivation

General Characteristics of 4114 maize

4114 maize was developed to express the proteins Cry1F, Cry34Ab1 and Cry35Ab1 and phosphinothricin-N-acetyltransferase (PAT). Expression of the Cry1F protein confers protection against certain lepidopteran pests, such as the European corn borer (*Ostrinia nubilalis*); 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 confers tolerance to the application of glufosinate ammonium-based herbicides.

Safety of the 4114 maize

In November 2014, Pioneer Overseas Corporation, on behalf of Pioneer Hi-Bred International Inc. (hereafter referred to as Pioneer[3]) submitted an application for the placing on the market of 4114 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-2014-123). On 24 May 2018, the European Food Safety Authority (EFSA) Panel on Genetically Modified Organisms (GMO) first published a positive scientific opinion in which it concluded: "*The genetically modified organisms (GMO) Panel concludes that maize 4114 is as safe as the non-GM comparator(s) and non-GM maize reference varieties with respect to potential effects on human and animal health and the environment in the context of the scope of this application* (EFSA, 2018)[4].

[1] Also known as DP4114

[2] EC, 2019. Commission Implementing Decision (EU) 2019/1304 of 26 July 2019 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 4114 (DP-ØØ4114-3), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

[3] Member of Corteva Agriscience group of companies

[4] EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H,Birch AN, Casacuberta J, De Schrijver A, Gralak MA, Guerche P, Jones H, Manachini B, Messéan A,Nielsen EE, Nogué F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal J-M,Alvarez F, Ardizzone M, Paraskevopoulos K, Broll H, Devos Y, Fernandez Dumont A, Gomez Ruiz JA, Lanzoni A, Neri FM, Olaru I and Papadopoulou N, 2018. Scientific Opinion on the assessment of genetically modified maize 4114 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2014-123). EFSA Journal 2018;16(5):5280, 25 pp. doi:10.2903/j.efsa.2018.5280

The EFSA GMO panel scientific opinion is available at:
https://www.efsa.europa.eu/en/efsajournal/pub/5280

Monitoring Conditions for 4114 maize

As indicated in the positive EFSA GMO Panel opinion on 4114 maize, "*maize 4114 is as safe and nutritious as the non-GM comparator and the non-GM reference varieties tested.*" (EFSA, 2018[4]). Therefore, post-market monitoring of 4114 maize food/feed is not necessary, as confirmed by the EFSA GMO Panel (EFSA, 2018) and in the Commission authorisation decision for 4114 maize (EC, 2019)[2].

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 4114 maize. Therefore, no case-specific monitoring of 4114 maize is necessary, as confirmed by the EFSA GMO panel in its scientific opinion (EFSA, 2018).

As specified by Commission decision (EC, 2019), a post-market environmental monitoring (PMEM) plan for 4114 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 4114 maize, if any. As stated by the EFSA GMO Panel in its scientific opinion on 4114 maize for food and feed uses, import and processing "*The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of maize 4114"* (EFSA, 2018).

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 Pioneer on an annual basis.

The post-market environmental monitoring plan for 4114 maize has been published on the EU register for genetically modified food and feed:
https://webgate.ec.europa.eu/dyna/gm_register/maize4114_environmental_monitoring_plan.pdf

Conditions for traceability and labelling for 4114 maize

Operators importing, handling and processing 4114 maize grain 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) 2019/1304 for 4114 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 and in the documents accompanying the products containing or consisting of 4114 maize with the exception of foods and food ingredients containing, consisting of or produced from 4114 maize.

The unique identifier assigned to 4114 maize is DP-ØØ4114-3.

Methods for detection and reference material for 4114 maize

Validated 4114 maize detection method
In accordance with Regulation (EC) No 1829/2003 and in line with the above-mentioned application for authorisation of the 4114 maize, a validated event-specific detection method for the quantification of 4114 maize 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:
http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx

4114 maize certified reference material
In accordance with Regulation (EC) No 1829/2003 and in line with the above application for authorisation of 4114 maize, certified reference material is available at Joint Research Centre's GMO Reference Unit. The corresponding certified reference material set ERM®-BF439 can be obtained via the JRC website:
https://ec.europa.eu/jrc/en/reference-materials/catalogue/

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