

1507xNK603 maize  
(DAS-Ø15Ø7-6xMON-ØØ6Ø3-6)  
Herculex<sup>®</sup> I x Roundup Ready<sup>®</sup> Corn 2  
Fact-sheet for operators

2021

## 1507xNK603 maize Fact-sheet for operators

### Introduction

The placing on the European Union (EU) market of products containing, consisting of, or produced from 1507xNK603 maize (also referred to as Herculex® I Insect Protection trait<sup>1</sup> stacked with the Roundup Ready® Corn 2 trait<sup>2</sup> in the commercial context), was authorised, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, by Commission decision 2007/703/EC of 24 October 2007 (EC, 2007)<sup>3</sup>. The authorisation was renewed pursuant to Regulation (EC) No 1829/2003 by Commission implementing decision (EU) 2019/1306 of 26 July 2019 (EC, 2019)<sup>4</sup>.

The renewal authorisation decision for 1507xNK603 maize is published at:

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D1306&from=EN>

The following products are re-authorised:

- (a) foods and food ingredients containing, consisting of, or produced from 1507xNK603 maize
- (b) feed containing, consisting of, or produced from 1507xNK603 maize
- (c) products containing or consisting of 1507xNK603 maize for uses other than those provided for in points (a) and (b), with the exception of cultivation

### General Characteristics of 1507xNK603 maize

1507xNK603 maize has been developed by conventional breeding cross between genetically modified maize 1507 and NK603, to express the Cry1F protein, the phosphinothricin acetyltransferase (PAT) protein and the CP4 5-enolpyruvyl-shikimate-3-phosphate synthase (CP4 EPSPS) protein. Expression of the Cry1F protein provides protection against certain lepidopteran insect pests, such as the European corn borer (*Ostrinia nubilalis*) which are major insect pests of maize in agriculture. Expression of the PAT and CP4 EPSPS proteins confer tolerance to the applications of glufosinate ammonium-based herbicides and glyphosate-based herbicides, respectively.

### Safety of the 1507xNK603 maize

In September 2004, Pioneer and Dow AgroSciences<sup>5</sup> submitted to the competent authority of the United Kingdom an application for authorisation for the placing on the market of 1507xNK603 maize for food and feed uses, import and processing in accordance with articles

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<sup>1</sup> Herculex® I Insect Protection technology by Dow AgroSciences and Pioneer Hi-Bred; Herculex® is a registered trademark of Dow AgroSciences LLC; Herculex® I Insect Protection is identified by the OECD unique identifier DAS-Ø15Ø7-1.

<sup>2</sup> Roundup Ready® is a registered trademark of Monsanto Technology LLC. Roundup Ready® Corn 2 is identified by the OECD unique identifier MON-ØØ6Ø3-6. Note that maize is referred to as corn in the United States.

<sup>3</sup> Commission Decision 2007/703/EC of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507xNK603 (DAS-Ø15Ø7-1xMON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

<sup>4</sup> Commission Implementing Decision (EU) 2019/1306 of 26 July 2019 renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 x NK603 (DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

<sup>5</sup> Member of Corteva Agriscience group of companies

5 and 17 of Regulation (EC) No 1829/2003 (EFSA-GMO-UK-2004-05). The EFSA GMO Panel positively assessed the application and concluded in the opinion adopted in March 2006 *“that the GM maize 1507 x NK603 is as safe as its conventional counterparts with respect to effects on human and animal health and the environment. Therefore the Panel concludes that this maize is unlikely to have any adverse effect on human and animal health and the environment in the context of its intended uses.”* (EFSA, 2006<sup>6</sup>). This resulted in October 2007, as previously indicated, in the authorisation to place on the EU market 1507xNK603 maize for food and feed uses, import and processing.

In October 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 1507xNK603 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-008). On 20 June 2018, the EFSA Panel on GMOs adopted a positive scientific opinion in which it concluded that: *“there is no evidence in the renewal application EFSA-GMO-RX-008 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize 1507 x NK603 (EFSA, 2006)”* (EFSA, 2018)<sup>7</sup>.

The EFSA GMO panel scientific opinion for the renewal application (EFSA, 2018) is available at: <https://www.efsa.europa.eu/en/efsajournal/pub/5347>

## **Monitoring Conditions for 1507xNK603 maize**

As indicated in the positive EFSA GMO Panel opinion on 1507xNK603 maize, from a nutritional point of view 1507xNK603 maize is equivalent to conventionally bred varieties (EFSA, 2006). Therefore, post-market monitoring of 1507xNK603 maize food/feed is not necessary, as reconfirmed in the Commission authorisation decision (EU) 2019/1306 for 1507xNK603 maize (EC, 2019<sup>5</sup>).

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 1507xNK603 maize (EFSA, 2006). Therefore, case-specific monitoring of 1507xNK603 maize is not necessary, as confirmed by the EFSA GMO panel in its scientific opinions (EFSA, 2006, 2018) and Commission decision 2019/1306.

As specified by the Commission decision, a post-market environmental monitoring (PMEM) plan for 1507xNK603 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

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<sup>6</sup> EFSA, 2006. Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-UK-2004-05) for the placing on the market of insect-protected and glufosinate and glyphosate-tolerant genetically modified maize 1507 x NK603, for food and feed uses, and import and processing under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred and Mycogen Seeds. The EFSA Journal (2006) 355, 1-23.

<sup>7</sup> 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, De Sanctis G, Fernandez Dumont A, Ruiz Gomez JA, Lanzoni A, Papadopoulou N and Paraskevopoulos K, 2018. Scientific Opinion on the assessment of genetically modified maize 1507 x NK603 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-008). EFSA Journal 2018;16 (7):5347, 11 pp. <https://doi.org/10.2903/j.efsa.2018.5347>

animal health or the environment arising from handling or use of viable 1507xNK603 maize, if any. As stated by the EFSA GMO Panel in its scientific opinion on 1507xNK603 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 1507xNK603*” (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 and Dow AgroSciences on an annual basis.

The post-market environmental monitoring plan for 1507xNK603 maize has been published on the EU register for genetically modified food and feed:

[http://ec.europa.eu/food/dyna/gm\\_register/maize\\_1507xNK603\\_environmental\\_monitoring\\_plan.pdf](http://ec.europa.eu/food/dyna/gm_register/maize_1507xNK603_environmental_monitoring_plan.pdf)

### **Conditions for traceability and labelling for 1507xNK603 maize**

Operators importing, handling and processing 1507xNK603 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) 2019/1306 for 1507xNK603 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 1507xNK603 maize, with the exception of foods and food ingredients.

The unique identifier assigned to 1507xNK603 maize is DAS-Ø15Ø7-1xMON-ØØ6Ø3-6.

### **Methods for detection and reference material for 1507xNK603 maize**

#### *Validated 1507xNK603 maize detection method*

The detection and quantification methods for 1507xNK603 maize consist of the same detection and quantification methods available for 1507 and NK603 maize, which have been validated by the Joint Research Centre (JRC) of the Community Reference Laboratory<sup>8</sup>. The event-specific 1507 and NK603 PCR-based detection methods have been validated by the EURL to detect and quantify both events on 1507 x NK603 material. The validated detection method for 1507xNK603 maize is publicly available from the JRC-EURL website:

<http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>

#### *1507xNK603 maize certified reference material*

The Certified Reference Materials (CRM) for 1507xNK603 maize consist of the CRMs for 1507 and NK603 maize produced by the Joint Research Centre’s GMO Reference Unit. The corresponding CRM set ERM<sup>®</sup>-BF418 (for 1507) and ERM<sup>®</sup>-BF415 (for NK603) can be obtained via JRC website:

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<sup>8</sup> Now referred to as European Union Reference Laboratory for GM Food and Feed (EURL)

<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](http://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](mailto:CortevaEUBiotech@corteva.com)