

1507 maize
Herculex[®] I Insect Protection
Fact-sheet for operators

2021



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The placing on the market of products containing, consisting of or produced from genetically modified maize 1507¹ maize received full European Union (EU) approval for import and use as or in food, feed and processing in March 2006 in accordance with Commission Decision 2005/772/EC² and the final consent of the Dutch Competent Authority (the Rapporteur Competent Authority under Directive 2001/18/EC) issued on 16 March 2006³, as well as Commission Decision 2006/197/EC⁴. Furthermore, renewal of the authorisation to place on the market existing feed produced from 1507 maize was granted in accordance with Commission Decision 2011/365/EU⁵ amending Decision 2006/197/EC.

The authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507, was renewed by Commission implementing decision (EU) 2017/2452 of 21 December 2017, pursuant to Regulation (EC) No 1829/2003 (EC, 2017).⁶

The renewal authorisation decision for 1507 maize is published at: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017D2452&from=EN>

The following products are re-authorised:

- (a) Food and food ingredients containing, consisting of, or produced from 1507 maize
- (b) Feed containing, consisting of, or produced from 1507 maize
- (c) 1507 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 a dossier for EU approval of 1507 maize seed products for cultivation has been submitted and received numerous positive EFSA opinions but is still awaiting authorisation from the European Commission.

General Characteristics of 1507 maize

1507 maize has been genetically modified to express the proteins Cry1F and phosphinothricin-N-acetyltransferase (PAT). Expression of the Cry1F protein confers protection against certain lepidopteran pests, such as the European corn borer (*Ostrinia nubilalis*) which are major insect

¹ Herculex® I Insect Protection technology by Dow AgroSciences and Pioneer Hi-Bred; Herculex® is a registered trademark of Dow AgroSciences LLC

² Commission Decision 2005/772/EC concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., line 1507) genetically modified for resistance to certain lepidopteran pests and for tolerance to the herbicide glufosinate-ammonium published on 3 November 2005, and the final consent of the Dutch Competent Authority, the Rapporteur Competent Authority under Directive 2001/18/EC, issued on 16 March 2006

³ Decision DGM/SAS C/NL/00/10 of 16 March 2006 of the Dutch Directorate General for Environment Management

⁴ Commission Decision 2006/197/EC authorising the placing on the market of food containing, consisting of, or produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, issued on 3 March 2006

⁵ Commission Decision 2011/365/EU amending Decision 2006/197/EC as regards the renewal of the authorisation to place on the market existing feed produced from genetically modified maize line 1507 (DAS-01507-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, issued on 17 June 2011

⁶ Commission Implementing Decision (EU) 2017/12452 of 21 December 2017 renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 (DAS-Ø15Ø7-1), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

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.

Safety of the 1507 maize

The EFSA GMO Panel positively assessed the dossiers submitted by Pioneer and Dow AgroSciences for 1507 (the notification for 1507 maize import, processing and animal feed (C/NL/00/10), the application submitted for food uses of 1507 maize (EFSA-GMO-NL-2004-02) and the notification submitted for import, feed, industrial processing and cultivation (C/ES/01/01)) and concluded in each case *“that 1507 maize will not have an adverse effect on human and animal health in the context of its proposed use”* (EFSA, 2004⁷, 2005a⁸, 2005b⁹). This resulted in March 2016, as previously indicated, in the authorisation to place on the EU market 1507 maize for food and feed uses, import and processing.

On 28 May 2009, the EFSA GMO Panel adopted a positive opinion on the application submitted for renewal of the authorisation for continued marketing of existing feed produced from maize line 1507 and *“reiterate[d] the previous conclusions that genetically modified maize 1507 is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed uses. This includes the use of feed materials and feed additives produced from maize 1507.”* (EFSA, 2009)¹⁰

The food and feed safety of 1507 maize has also been substantiated by EFSA scientific opinions on the 1507 maize cultivation notification (EFSA, 2008¹¹, 2012¹²).

In February 2015, i.e. 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 1507 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-001).

On 30 November 2016, 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 1507 considered for renewal is identical to the corrected sequence of the originally assessed event, the GMO Panel*

⁷ EFSA, 2004. Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the notification (Reference C/NL/00/10) for the placing on the market of insect-tolerant genetically modified maize 1507, for import and processing, under Part C of Directive 2001/18/EC from Pioneer Hi-Bred International/Mycogen Seeds. The EFSA Journal 124, 1-18

⁸ EFSA, 2005a. Opinion of the GMO Panel on an application (reference EFSA-GMO-NL-2004-02) for the placing on the market of insect-tolerant genetically modified maize 1507, for food use, under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred International/Mycogen Seeds (Question No EFSA-Q-2004-087). EFSA Journal 182, [pp. 22]

⁹ EFSA, 2005b. Opinion of the GMO Panel related to the notification (Reference C/ES/01/01) for the placing on the market of insect-tolerant genetically modified maize 1507 for import, feed and industrial processing and cultivation, under Part C of Directive 2001/18/EC from Pioneer Hi-Bred International/Mycogen Seeds (Question No EFSA-Q-2004-072). The EFSA Journal 181, [pp. 33].

¹⁰ EFSA, 2009. Scientific Opinion of the Panel on Genetically Modified Organisms on Application (EFSA-GMO-RX-1507) for renewal of authorisation for the continued marketing of existing products produced from maize 1507 for feed use, under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred International, Inc./Mycogen Seeds. EFSA Journal 1138, 1-11

¹¹ EFSA, 2008. Request from the European Commission to review scientific studies related to the impact on the environment of the cultivation of maize Bt11 and 1507 - Scientific opinion of the Panel on Genetically Modified Organisms (Question No EFSA-Q-2008-679). EFSA Journal 851, 1-27

¹² EFSA, 2012. Scientific Opinion supplementing the conclusions of the environmental risk assessment and risk management recommendations on the genetically modified insect resistant maize 1507 for cultivation. EFSA Journal 10, 2934.

concludes that no new hazards or modified exposure and no new scientific uncertainties were identified for the application for renewal that would change the conclusions of the original risk assessment on maize 1507 (EFSA, 2005b, 2009)” (EFSA, 2017)¹³.

The EFSA GMO panel scientific opinion for the renewal application (EFSA, 2017) is available at: <https://www.efsa.europa.eu/en/efsajournal/pub/4659>

More detailed information on the food and feed safety analysis of 1507 maize and environmental risk assessment of 1507 maize is also available in Baktavachalam et al. (2015)¹⁴.

Monitoring Conditions for 1507 maize

As indicated in the positive EFSA GMO Panel opinions on 1507 maize, 1507 maize is nutritionally equivalent to non-genetically modified control maize (EFSA, 2004, 2005a, 2005b). Therefore, post-market monitoring of 1507 maize food/feed is not necessary, as reconfirmed in the Commission authorisation decision (Eu) 2017/2452 for 1507 maize (EC, 2017).

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 maize (EFSA 2004, 2005a, 2005b). Therefore, case-specific monitoring of 1507 maize is not necessary, as confirmed by the EFSA GMO panel in its scientific opinions (EFSA 2004, 2005a, 2005b) and Commission decision 2017/2452. As specified by the Commission decision, a post-market environmental monitoring (PMEM) plan for 1507 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 1507 maize, if any.

As stated by the EFSA GMO Panel in its scientific opinion on 1507 maize for renewal of the authorisation for food and feed uses, import and processing *“The GMO Panel is of the opinion that the PMEM plan and the general surveillance system implemented by the applicant is in line with the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2008/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC”* (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 1507 maize has been published on the EU register for genetically modified food and feed:

https://webgate.ec.europa.eu/dyna/gm_register/Monitoring%20plan%20maize%201507.pdf

¹³ EFSA, 2017. Scientific opinion on an application for renewal of authorisation for continued marketing of maize 1507 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(1):4659, 11pp. doi:10.2903/j.efsa.2017.4659

¹⁴ Baktavachalam G., Delaney B., Fisher T., Ladics G., Layton R., Locke M., Schmidt J., Anderson J., Weber N., Herman R. and Evans S. (2015) Transgenic maize event TC1507: Global status of food, feed, and environmental safety. *GM Crops & Food: Biotechnology in Agriculture and the Food Chain*, 6:2, 80-102, DOI: 10.1080/21645698.2015.1054093

Conditions for traceability and labelling for 1507 maize

Operators importing, handling and processing 1507 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) 2017/2452 for 1507 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 1507 maize, with the exception of foods and food ingredients.

The unique identifier assigned to 1507 maize is DAS-Ø15Ø7-1.

Methods for detection and reference material for 1507 maize

Validated 1507 maize detection method

A validated event-specific detection method for the quantitation of 1507 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>

1507 maize certified reference material

Certified reference material for 1507 is available at the Joint Research Centre's GMO Reference Unit. The corresponding certified reference material set ERM[®]-BF418 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:

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