



**5307 Maize  
Syngenta Agrisure Duracade®**

**EU authorisation for food, feed, import and  
processing**

**Information for Operators**

**(August 2019)  
(Updated December 2020)**

Disclaimer

From Jan 1, 2021, all activities performed by EuropaBio mentioned  
in this document will be conducted by CropLife Europe

## **Introduction**

This document summarizes the main characteristics of 5307 maize (trade mark Agrisure Duracade) and the requirements for post-market environmental monitoring of all operators handling viable grain from this product. It also includes references to the relevant detection methods and contact points for operators to report on general surveillance activities and on any unanticipated adverse effects.

## **Characteristics and benefits of 5307 maize**

Maize is susceptible to attack by a variety of insects from the time it is planted until it is consumed as food or feed. Genetically modified event 5307 maize has been developed by Syngenta to provide growers with maize hybrids that are resistant to feeding damage caused by certain coleopteran insect pests such as *Diabrotica virgifera virgifera* (Western corn rootworm) and related *Diabrotica* species.

Protection against coleopteran insect pests is provided through the expression of an engineered eCry3.1Ab protein derived from the native Cry3A protein from *Bacillus thuringiensis* subsp. *tenebrionis*, and from the Cry1Ab protein from *B. thuringiensis* subsp. *kurstaki* HD-1.

5307 maize also expresses phosphomannose isomerase (PMI), an enzyme derived from *Escherichia coli*, which serves as a selectable marker during the transformation process. PMI allows transformed maize cells to utilize mannose as the sole carbon source, whereas maize cells lacking PMI fail to grow with mannose as single carbon source.

Corn rootworms are highly devastating pests of maize which are estimated to decrease global production and cause an estimated loss to growers of over \$1 billion annually. Event 5307 maize represents an environmentally sustainable and highly effective way to control certain coleopteran insect pests of maize, such as corn rootworms. This helps farmers improve productivity, secure and increase yields, and improves the environmental footprint of modern agriculture.

## **Safety of 5307 maize**

The safety of Syngenta's products for humans, animals and the environment is of paramount importance. 5307 maize has been assessed and endorsed by numerous independent scientific committees around the world. These conclusions have been based on a full range of scientific studies, including tests which examined the potential for human and animal health effects of the product, nutritional equivalency, the effects of the introduced genes and proteins, and the potential impacts of the maize on the environment.

## **EFSA evaluation of 5307 maize for food, feed, import and processing in the EU**

On 7 April 2011, the European Food Safety Authority (EFSA) received from the German competent authority an application for authorisation of 5307 maize submitted by Syngenta Crop Protection AG within the framework of Regulation (EC) No 1829/2003 on GM food

and feed. On 11 April 2018, the EFSA Panel on Genetically Modified Organisms (GMO Panel) published a statement<sup>1</sup> complementing its scientific opinion<sup>2</sup> and concluded that 5307 maize is as safe and nutritious as its conventional counterpart in the scope of the application.

### **Authorisation in the EU of 5307 maize for food, feed, import and processing**

The Commission Implementing Decision of 26 July 2019 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize 5307 (SYN-Ø53Ø7-1), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed is published at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D1303&from=EN>

The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of or produced from SYN-Ø53Ø7-1 maize;
- (b) feed containing, consisting of or produced from SYN-Ø53Ø7-1 maize;
- (c) products containing or consisting of SYN-Ø53Ø7-1 maize for uses other than those provided for in points (a) and (b), with the exception of cultivation.

The Decision does not include the need of specific conditions or restrictions for the placing on the market, for the use and handling, including post-market monitoring requirements regarding the consumption of the food and feed, or for the protection of particular ecosystems/environment or geographical areas, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.

However, the Commission Decision mandates the monitoring for environmental effects in accordance with the environmental monitoring plan for 5307 maize conforming with Annex VII of Directive 2001/18/EC. For more information, please visit the EU Register of authorised GMOs:

[https://webgate.ec.europa.eu/dyna/gm\\_register/gm\\_register\\_auth.cfm?pr\\_id=89](https://webgate.ec.europa.eu/dyna/gm_register/gm_register_auth.cfm?pr_id=89)

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<sup>1</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, Messean A, Nielsen EE, Nogue F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal J-M, Paraskevopoulos K and Lanzoni A, 2018. Statement complementing the EFSA Scientific Opinion on application (EFSAGMO-DE-2011-95) for the placing on the market of genetically modified maize 5307 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Crop Protection AG taking into consideration an additional toxicological study. EFSA Journal 2018;16(4):5233, 9 pp. <https://doi.org/10.2903/j.efsa.2018.5233>

<sup>2</sup> EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015. Scientific Opinion on application (EFSA-GMO-DE-2011-95) for the placing on the market of genetically modified maize 5307 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Crop Protection AG. EFSA Journal 2015;13(5):4083, 29 pp. doi:10.2903/j.efsa.2015.4083

## **Conditions for traceability and labelling of 5307 maize for food, feed, import and processing in the EU**

The legal obligations relating to traceability and labelling are 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.

For the purposes of the labelling requirements laid down in Article 13(1) and Article 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 documents accompanying the products containing or consisting of SYN-Ø53Ø7-1 maize, with the exception of products referred to in point (a) of Article 2 of the Commission Implementing Decision (foods and food ingredients containing, consisting of or produced from SYN-Ø53Ø7-1 maize).

The unique identifier assigned to 5307 maize is: SYN-Ø53Ø7-1.

## **Post market monitoring of 5307 maize for food, feed, import and processing in the EU**

The Decision does not require post market monitoring for the use of the food for human consumption.

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No 1829/2003 a Post Market Environmental Monitoring Plan for 5307 maize has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC.

The monitoring plan for environmental effects is accessible on the internet at the EU Register of authorised GMOs: [https://webgate.ec.europa.eu/dyna/gm\\_register/Maize5307-environmental\\_monitoring\\_plan.pdf](https://webgate.ec.europa.eu/dyna/gm_register/Maize5307-environmental_monitoring_plan.pdf)

## **Methods for detection and reference material**

An event-specific real-time quantitative PCR-based method for 5307 maize is validated by the European Union Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>.

Reference material AOCs 0411-C and 0411-D are accessible via the American Oil Chemists Society at <https://www.aocs.org/store/shop-aocs/shop-aocs?productId=2976496>.

## **Contact point for Operators**

As there are other technology providers for genetically modified maize it is essential to develop an industry wide approach because the shipments entering the European ports may

be comingled. EuropaBio, the European Association for Bioindustries, plays an important role in this area and is the central communication point for all GM plant technology providers.

EuropaBio is the primary address for reporting general surveillance activities or any unanticipated adverse effects, and is skilled to provide adequate response. In addition, EuropaBio will transfer the messages to the relevant GMO industry partner if further action is required. Operators are requested to report, if possible via their branch representative, any unanticipated adverse effect to EuropaBio at: <https://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information/introduction>.

If required, additional comments or questions relative to 5307 maize can also be addressed at:

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