SYHT0H2 Soybean

EU Authorisation for food, feed, import and processing

Information for Operators

February 2021

Introduction

This document summarizes the main characteristics of SYHT0H2 soybean and the requirements for post-market environmental monitoring of all operators handling viable beans from this product. It also includes references to the relevant detection method and contact points for operators to report on general surveillance activities and on any unanticipated adverse effects.

Characteristics and benefits of SYHT0H2 soybean

Genetically modified event SYHT0H2 soybean has been developed by Syngenta to facilitate growers with a means to control weeds by conferring tolerance to p-hydroxyphenylpyruvate dioxygenase (HPPD)-inhibiting herbicides, such as mesotrione, and glufosinate-ammonium herbicides.

Herbicide tolerance is provided through the expression of the enzymes AvHPPD-03 and PAT (phosphinothricin acetyltransferase) in SYHT0H2 soybean plants.

- The AvHPPD-03 protein, derived from *Avena sativa*, confers tolerance to HPPD-inhibiting herbicides, such as mesotrione herbicide products.
- The PAT protein, derived from the soil bacterium *Streptomyces viridochromogenes*, acetylates glufosinate-ammonium, thus inactivating it and conferring tolerance to glufosinate-ammonium herbicides.
    - PAT was also used as a selectable marker in the development of SYHT0H2 soybean.

Safety of SYHT0H2 soybean

The safety of Syngenta's products for humans, animals and the environment is of paramount importance. SYHT0H2 soybean 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 soybean on the environment.

EFSA evaluation of SYHT0H2 soybean for food, feed, import and processing in the EU

On 8 August 2012, the European Food Safety Authority (EFSA) received from the German competent authority an application for authorisation of SYHT0H2 soybean submitted by Syngenta Crop Protection AG within the framework of Regulation (EC) No 1829/2003 on GM food and feed. On 20 January 2020, the EFSA Panel on Genetically Modified Organisms (GMO Panel) published its scientific opinion[1] and concluded that SYHT0H2 soybean (EFSA-GMO-DE-2012-111) is as safe as its conventional counterpart and the tested non-

[1] EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Mullins E, Nogué F, Rostoks N, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Àlvarez F, Ardizzone M, Dumont AF, Devos Y, Gennaro A, Gómez Ruiz JÀ, Lanzoni A, Neri FM and Paraskevopoulos K, 2020. Scientific Opinion on the assessment of genetically modified soybean SYHT0H2 for food and feed uses, import and processing, under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2012-111). EFSA Journal 2020;18(1):5946, 29 pp. https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2020.5946

GM soybean reference varieties with respect to potential effects on human and animal health and the environment.

Authorisation in the EU of SYHT0H2 soybean for food, feed, import and processing

The Commission Implementing Decision of 22 January 2021 authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean SYHT0H2 (SYN-ØØØH2-5), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed is published at:
Commission Implementing Decision (EU) 2021/64 of 22 January 2021

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-ØØØH2-5 soybean;
(b) feed containing, consisting of or produced from SYN-ØØØH2-5 soybean;
(c) products containing or consisting of SYN-ØØØH2-5 soybean 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 SYHT0H2 soybean 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=121

Conditions for traceability and labelling of SYHT0H2 soybean 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 ‘soybean’.

The words ‘not for cultivation’ shall appear on the label of and in documents accompanying the products containing or consisting of SYN-ØØØH2-5 soybean, 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-ØØØH2-5 soybean).

The unique identifier assigned to SYHT0H2 soybean is: SYN-ØØØH2-5.

Post market monitoring of SYHT0H2 soybean 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 SYHT0H2 soybean 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 at the EU Register of authorised GMOs: Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC

Methods for detection and reference material

An event-specific real-time quantitative PCR-based method for SYHT0H2 soybean 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.

Certified Reference Materials for SYHT0H2 soybean are accessible via the American Oil Chemists Society at https://www.aocs.org/crm#soybean.

Contact point for Operators

As there are other technology providers for genetically modified soybean it is essential to develop an industry wide approach because the shipments entering the European ports may be comingled. CropLife Europe, plays an important role in this area and is the central communication point for all 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 GMO 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: https://croplifeeurope.eu/product-information/.

If required, additional comments or questions related to SYHT0H2 soybean can also be addressed at:

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