Part III - Summary

Request for Renewal of the Authorisation of the genetically modified herbicide tolerant soybean

A5547-127

for food and feed uses, and import and processing, in accordance with articles 11 and 23 of Regulation (EC) N° 1829/2003

EFSA-GMO-RX-XXX

Version CC1

Submitted on
10 Dec 2020

PART III – SUMMARY

EFSA-GMO-RX-XXX (A5547-127)

1. GENERAL INFORMATION

1.1. Details of application

(a) Application number

EFSA-GMO-RX-XXX

(b) Name of the product (commercial and any other names)

A5547-127, unique identifier: ACS-GMØØ6-4

(c) Date of acknowledgement of valid renewal application

Not available at the time of submission

1.2. Applicant

(a) Name of applicant

BASF Agricultural Solutions Seed US LLC

(b) Address of applicant

BASF Agricultural Solutions
Seed US LLC
100 Park Avenue
Florham Park, NJ 07932
USA

(c) Name and address of the representative of the applicant established in the Union (if the applicant is not established in the Union)

Representative of the applicant established in the Union:
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Rue Marie de Bourgogne 58,
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Belgium

1.3. Scope of the application

(a) Genetically modified food

☑ Food containing or consisting of genetically modified plants
☑ Food produced from genetically modified plants or containing ingredients produced from genetically modified plants

(b) Genetically modified feed

☑ Feed containing or consisting of genetically modified plants
☑ Feed produced from genetically modified plants

(c) Genetically modified plants for food or feed uses

☑ Products other than food and feed containing or consisting of genetically modified plants with the exception of cultivation

1.4. Has the product been subject to an application and/or authorised in a third country either previously or simultaneously to this application?

A5547-127 soybean is authorised for food and/or feed uses in Argentina, Australia/New Zealand, Brazil, Canada, China, Colombia, European Union, India, Indonesia, Japan, Korea, Malaysia, Mexico, Paraguay, Philippines, Russian Federation, Singapore, South Africa, Taiwan, Thailand, Turkey, USA, Uruguay and Vietnam.

A5547-127 has been approved for cultivation in the USA, Argentina, Brazil, Canada, Uruguay and Paraguay.

More information on the regulatory status of the product in the EU and third countries can be retrieved from the EU Register of authorised GMOs[1] and the CropLife International database[2].

1.5. General description of the product

The recipient plant is soybean, *Glycine max*. The genetically modified ACS-GMØØ6-4 soybean expresses the PAT/*pat* protein which confers tolerance to the glufosinate ammonium herbicide.

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in the Commission Implementing Decision 2012/81/EU:

(a) foods and food ingredients containing, consisting of, or produced from ACS-GMØØ6-4 soybean;
(b) feed containing, consisting of, or produced from ACS-GMØØ6-4 soybean;
(c) products other than food and feed containing or consisting of ACS-GMØØ6-4 soybean for the same uses as any other soybean with the exception of cultivation.

[1] https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm

[2] http://www.biotradestatus.com/

No mandatory conditions or restrictions on placing on the market, use of handling of A5547-127 soybean products were included as a condition of the authorisation. All standard practices applicable to soybean today remain adequate for the handling of A5547-127 soybean varieties.

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 products containing or consisting of ACS-GMØØ6-4 soybean referred to in Article 2(b) and (c) of Commission Implementing Decision 2012/81/EC.

2. Information Required Under Articles 11 and 23 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on Genetically Modified Food and Feed

2.1 A copy of the authorisation for placing the food and feed on the market

Commission Implementing Decision 2012/81/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean A5547-127 (ACS-GMØØ6-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council[3].

Commission Implementing Decision (EU) 2019/1195 amending Commission Implementing Decision 2012/81/EC as regards the authorisation holder and the representative for the placing on the market of genetically modified soybean A5547-127[4].

2.2 A report on the results of the monitoring, if so specified in the authorisation

In accordance with Article 4 of Commission Implementing Decision 2012/81/EU, the authorisation holder has ensured the implementation of the monitoring plan for environmental effects and has reported to the EC on an annual basis.

The Annual Post Market Environmental Monitoring reports for the genetically modified soybean A5547-127 covering the monitoring period from February 2012 until June 2019 are provided as part of the renewal application.

The general surveillance considering the placing on the market of A5547-127 soybean in the EU indicates that there have been no adverse health or environmental effects associated with the import or use of A5547-127 soybean.

2.3 Any other new information which has become available with regard to the evaluation of the safety in use of the food and feed and the risks of the food and feed to the consumer, animals or the environment

2.3.1 Systematic search and evaluation of literature

A scoping review was performed for A5547-127 soybean and its newly expressed protein, PAT/*pat*. There was no literature identified changing the original risk assessment conclusions.

2.3.2 Update Bioinformatics

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32012D0081&qid=1604919029366

[4] https://eur-lex.europa.eu/eli/dec_impl/2019/1195/oj

Following the requirement as laid out in the EFSA Guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003, updated bioinformatics analyses were conducted.

The results of the updated bioinformatics analyses do not change the original risk assessment conclusion on A5547-127 soybean.

2.3.3 Additional documents or studies performed by or on behalf of the applicant

None of the competent authorities has prohibited or revoked the authorisation for A5547-127 soybean for neither import nor cultivation purposes.

The detailed review of unpublished studies produced, controlled or sponsored by the applicant did not identify any studies that would constitute any new data relevant for the risk assessment of A5547-127 soybean for the scope of the application or the newly expressed protein (PAT/*pat*) or which challenge or change in any way the conclusions of the original risk assessment.

2.4 Where appropriate, a proposal for amending or complementing the conditions of the original authorisation, inter alia the conditions concerning future monitoring

This application is for renewal of the authorisation of genetically modified herbicide tolerant A5547-127 soybean for food and feed uses, import and processing. The application does not cover cultivation of A5547-127 soybean in the EU.

The initial authorisation, which was issued on 10 February 2012, Commission Implementing Decision 2012/81/EU for placing on the market of A5547-127 (ACS-GMØØ6-4) soybean pursuant to Regulation (EC) No 1829/2003 lays out conditions in Article 4 and point (h) of the Annex of the authorization decision. These lay down the need for general monitoring and do not impose specific conditions or restrictions on the placing on the market, use or handling of the products. Considering that the annual EU Post market environmental monitoring activities for the years 2012-2019 did not identify adverse effects and that there was no literature identified changing previous risk assessment conclusions, no revisions or changes to the general surveillance measures are considered necessary.

Based on the conclusions of the overall assessment of the here presented renewal application of A5547-127 soybean for food and feed uses, the conditions of the original authorisation should not be amended or complemented and should therefore remain unchanged.