Request for Renewal of the Authorisation of the genetically modified herbicide tolerant soybean A2704-12 for food and feed uses, import and processing, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003

EFSA-GMO-RX-009

SUMMARY

EFSA-GMO-RX-009 (A2704-14 SOYBEAN)

1. GENERAL INFORMATION

1.1. Details of application

(a) Member State of application

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(b) Application number

EFSA-GMO-RX-009

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

Soybean A2704-14

(OECD ID: ACS-GMØØ5-3)

(d) Date of acknowledgement of valid application

Not applicable at the time of submission

1.2. Applicant

(a) Name of applicant

Bayer CropScience LP

(b) Address of applicant

Bayer CropScience LP
2 T.W. Alexander Drive
P.O. Box 12014
Research Triangle Park
RTP, North Carolina 27709
USA

Represented by:
Bayer CropScience SA-NV
J.E. Mommaertslaan 14
1831 Diegem
Belgium

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

Bayer CropScience SA-NV is the contact for this submission and all correspondence should be directed to:

CropScience Division
Bayer CropScience SA-NV
Regulatory Affairs
Square de Meeûs 40
1000 Brussel,
Belgium

1.3. Scope of the application

This application is for renewal of the authorisation of genetically modified herbicide tolerant soybean A2704-12 for food and feed uses, import and processing, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003.

(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
☐ Seeds and plant propagating material for cultivation in the Union

1.4. Is the product or the uses of the associated plant protection product(s) already authorised or subject to another authorisation within the Union?

No ☐

Yes ☑ (in that case, specify)

Soybean A2704-14 has been authorised in the EU as described in section 1.6.

Maximum residue level (MRL) is established for glufosinate-ammonium in soybean according to Commission Regulation (EU) No 2015/845 of 27 May 2015.

1.5. Has the genetically modified plant been notified under Part B of Directive 2001/18/EC?

Yes ☐

No ☑ (in that case, provide risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC)

This application is for renewal of the authorisation of genetically modified herbicide tolerant soybean A2704-12 for food and feed uses, import and processing, and does not include cultivation in the EU. Risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC is provided in the application.

1.6. Has the genetically modified plant or derived products been previously notified for marketing in the Community under Part C of Directive 2001/18/EC?

No ☐

Yes ☑ (in that case, specify)

On 8 September 2008, Commission Decision 2008/730/EC authorised the placing on the market of soybean A2704-12 (ACS-GMØØ5-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

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

No ☐

Yes ☑

Cultivation approvals are present in Canada, USA, Argentina and Brazil. Approvals for import and uses for food and/or feed are in place in Australia, New Zealand, USA, Canada, Mexico, EU, Russia, Turkey, Argentina, Brazil, Colombia, Uruguay, Japan, Korea, China, Taiwan, Philippines, Singapore, Malaysia, India, Vietnam and South Africa.

1.8. General description of the product

(a) Name of the recipient or parental plant and the intended function of the genetic modification.

Bayer has developed the soybean A2704-12 (OECD unique identifier ACS-GMØØ5-3) through direct gene transfer using vector pB2/35SacK containing the *pat* expression cassette. Soybean A2704-12 produces the phosphinothricin acetyltransferase (PAT) protein, which confers tolerance to glufosinate ammonium herbicides.

(b) Types of products planned to be placed on the market according to the authorisation applied for and any specific form in which the product must not be placed on the market (such as seeds, cut-flowers, vegetative parts) as a proposed condition of the authorisation applied for.

The scope of the current application is for renewal of the authorisation of soybean A2704-12 for import, processing and all uses as any other soybean in the EU, according to Articles 11 and 23 of Regulation (EC) No 1829/2003, with the exception of cultivation. The range of uses of this soybean is identical to the full range of equivalent uses of conventional soybean.

(c) Intended use of the product and types of users.

Soybean A2704-12 will continue to be traded and used in the EU in the same manner as current conventional commercial soybean and by the same operators currently involved in the trade and use of soybean.

(d) Any specific instructions and recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for.

Safety evaluation of soybean A2704-12 has shown that no specific instructions and/or recommendations for use, storage and handling of soybean A2704-12 are necessary. Therefore, soybean A2704-12 and its derived products will be stored, packaged, transported, handled and used in the same manner as current commercial soybean products. No specific instructions and/or recommendations are warranted or required for the placing on the market of soybean A2704-12 for import, processing and all uses, excluding cultivation, in the EU.

(e) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for.

Soybean A2704-12 is suitable for use throughout the EU as any other soybean. The scope of this application covers the import, processing and all uses of soybean A2704-12, excluding cultivation.

(f) Any type of environment to which the product is unsuited.

Soybean A2704-12 is suitable for use throughout the EU as any other soybean. The scope of this application covers the import, processing and all uses of soybean A2704-12, excluding cultivation.

(g) Any proposed packaging requirements.

With the exception of the tolerance to glufosinate ammonium herbicides, which only have agronomic relevance, the characteristics of soybean A2704-12 are not different from those of conventional commercial soybean. Therefore, soybean A2704-12 and derived products will be used in the same manner as other soybean and no specific packaging is required.

(h) Any proposed labelling requirements in addition to those required by other applicable EU legislation then (EC) No 1829/2003 and when necessary a proposal for specific labelling in accordance with Article 13(2) and (3), Article 25(2)(c) and (d) and Article 25(3) of Regulation (EC) No 1829/2003. In the case of products other than food and feed containing or consisting of genetically modified plants, a proposal for labelling which complies with the requirements of point A(8) of Annex IV to Directive 2001/18/EC must be included.

The labelling requirements remain as currently described by section (c) of the Annex to the Commission Decision 2008/730/EC

(i) Estimated potential demand

In the EU

This application is for renewal of the authorisation of genetically modified herbicide tolerant soybean A2704-12 for food and feed uses, import and processing. There are no anticipated changes to the demand as a result of the renewal of soybean A2704-12.

In EU export markets

This application is for renewal of the authorisation of genetically modified herbicide tolerant soybean A2704-12 for food and feed uses, import and processing. The application does not cover cultivation of soybean A2704-12 in the EU.

(j) Unique identifier in accordance with Regulation (EC) No 65/2004

The OECD unique identifier for soybean A2704-12 is ACS-GMØØ5-3.

1.9. Measures suggested by the applicant to take in case of unintended release or misuse as well as measures for its disposal and treatment

This application is for renewal of the authorisation of genetically modified herbicide tolerant soybean A2704-12 for food and feed uses, import and processing. The application does not cover cultivation of soybean A2704-12 in the EU. Based on the conclusions from the environmental risk assessment of soybean A2704-12, the likelihood of the spread and establishment of soybean A2704-12 feral population is very low and

the unintended environmental effects due to this soybean will be no different from that of conventional soybean varieties. Furthermore, in case of unintended release, soybean volunteers can be easily controlled using currently available selective herbicides (other than glufosinate) or by mechanical means. Therefore, no special measures are considered to be required in case of misuse or unintended release.

2. INFORMATION RELATING TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS

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

A copy of the Commission Decision 2008/730/EC authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean A2704-12 (ACS-GMØØ5-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council is provided with the application.

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

The Annual Post Market Monitoring reports for the genetically modified soybean A2704-12 covering the authorisation period from September 2008 until June 2016 are provided with this application. The general surveillance considering the placing on the market of soybean A2704-12 in the EU indicates that there have been no adverse health or environmental effects associated with the import or use of soybean A2704-12.

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

(a) Systematic search and evaluation of literature

A systematic literature search was performed for soybean A2704-12 and the newly expressed protein PAT/*pat*. This systematic literature search identified no relevant references that negatively impacted the safety assessment of soybean A2704-12 or the PAT/*pat* protein.

(b) Updated bioinformatics

The results of the updated bioinformatic analyses do not change the original risk assessment conclusion on soybean A2704-12.

(c) Additional documents or studies performed by or on behalf of the applicant

A detailed review of studies performed by or on behalf of the applicant did not identify any study that would constitute any new data relevant to the risk assessment of soybean A2704-12 or the newly expressed protein within the scope of the application.

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 soybean A2704-12 for food and feed uses, import and processing. The application does not cover cultivation of soybean A2704-12 in the EU.

The initial authorisation which was issued on 8 September 2008, Commission Decision 2008/730/EC for placing on the market of soybean A2704-12 (ACS-GMØØ5-3) pursuant to Regulation (EC) No 1829/2003 lays out conditions in Article 4 and point (h) of the Annex of the authorisation 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 2009-2016 did not identify adverse effects and that there was no literature identified changing previous risk assessment conclusions, we do not consider revisions or changes necessary to the general surveillance measures.

Based on the conclusions of the overall assessment of the renewal application of soybean A2704-12 for food and feed uses we do not consider the need to update the monitoring plan or propose changes to the existing restrictions and conditions of release/use as laid down in the initial authorisation.