

Request for Renewal of the Authorization for placing on the market of products containing or produced from genetically modified oilseed rape T45 (ACS-BNØØ8-2) resulting from the commercialization of this oilseed rape in third countries until 2005, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003

EFSA-GMO-RX-XXX

Submitted on:

09 January 2018

The submitted information contains scientific data and other information which is protected under Article 31 of Regulation (EC) No 1829/2003 and copyright laws. This submitted information may only be used for the evaluation by the regulatory authority to which it has been submitted as requested in the application of Bayer. Any other use of this information, in whole or in part, without prior written consent of Bayer, is strictly prohibited. By submitting this information, Bayer does not grant any person or entity any right to use or license the information, data or intellectual property contained in this submitted information.

SUMMARY

1. GENERAL INFORMATION

1.1. Details of application

(a) Member State of application

NA

(b) Application number

NA at the moment of submission

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

Oilseed rape T45 (OECD ID: ACS-BNØØ8-2)

(d) Date of acknowledgement of valid application

Not applicable at the time of submission

1.2. Applicant

Name of applicant

Bayer CropScience LP

(a) 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. Mommaertsiaan 14
1831 Diegem
Belgium

(b) 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 for placing on the market of products containing or produced from genetically modified oilseed rape T45 resulting from the

commercialisation of this oilseed rape in third countries until 2005, 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)

Oilseed rape T45 has been authorised in the EU as described in section 1.6.

Maximum residue level (MRL) is established for glufosinate-ammonium in oilseed rape seed 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 for placing on the market of products containing or produced from genetically modified oilseed rape T45 resulting from the commercialisation of this oilseed rape in third countries until 2005, 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 10 March 2009, the European Commission issued Commission Decision 2009/184/EC¹ authorising the placing on the market of products containing or produced from genetically

modified oilseed rape T45 resulting from the commercialisation of this oilseed rape in third countries until 2005 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

See Section 2.3.3.

1.8. General description of the product

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

Oilseed rape T45 was produced by means of *Agrobacterium*-mediated transformation using vector pHOE4/Ac(II). Oilseed rape T45 contains the *pat* gene (origin *Streptomyces viridochromogenes*), coding for the phosphinothricin acetyltransferase (PAT/*pat*) protein which confers tolerance to glufosinate-ammonium. The *pat* gene is driven by the 35S promoter that allows a high level of constitutive expression. The OECD identifier of oilseed rape T45 is ACS-BNØØ8-2.

(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 for placing on the market of products containing or produced from genetically modified oilseed rape T45 resulting from the commercialisation of this oilseed rape in third countries until 2005. The T45 line grown historically in Canada/US on a very limited surface will only enter the European Union (EU) by import at low level in commodity rapeseed.

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

De-registration of the T45 derived varieties was initiated in 2003 and completed in 2004 with the exception of a single line that was still sold in limited quantities until 2005.

(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 T45 oilseed rape has shown that no specific instructions and/or recommendations for use, storage and handling of products containing low levels of T45 oilseed rape are necessary. Therefore, no specific instructions and/or recommendations are warranted or required 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.

De-registration of the T45 derived varieties was initiated in 2003 and completed in 2004 with the exception of a single line that was still sold in limited quantities until 2005. However, it cannot be overemphasized that regardless of the efficacy of a product discontinuation strategy no system can assure the complete absence of an allele after it has been introduced

into the commodity due to several factors like farm saved seed, volunteers, adventitious presence in certified seed and holding grains in storage at farmer level. Therefore, the T45 line grown historically in Canada/US on a very limited surface will only enter the European Union (EU) by import at low level in commodity rapeseed.

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

The scope of the current application is for renewal of the authorisation for placing on the market of products containing or produced from genetically modified oilseed rape T45 resulting from the commercialisation of this oilseed rape in third countries until 2005. The T45 line grown historically in Canada/US on a very limited surface will only enter the European Union (EU) by import at low level in commodity rapeseed.

(g) Any proposed packaging requirements.

The scope of the current application is for renewal of the authorisation for placing on the market of products containing or produced from genetically modified oilseed rape T45 resulting from the commercialisation of this oilseed rape in third countries until 2005. The T45 line grown historically in Canada/US on a very limited surface will only enter the European Union (EU) by import at low level in commodity rapeseed.

(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 Commission Decision 2009/184/EC.

(i) Estimated potential demand

The scope of the current application is for renewal of the authorisation for placing on the market of products containing or produced from genetically modified oilseed rape T45 resulting from the commercialisation of this oilseed rape in third countries until 2005. The T45 line grown historically in Canada/US on a very limited surface will only enter the European Union (EU) by import at low level in commodity rapeseed.

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

The OECD unique identifier for T45 oilseed rape is ACS-BNØØ8-2.

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

The scope of the current application is for renewal of the authorisation for placing on the market of products containing or produced from genetically modified oilseed rape T45 resulting from the commercialisation of this oilseed rape in third countries until 2005. The T45 line grown historically in Canada/US on a very limited surface will only enter the European Union (EU) by import at low level in commodity rapeseed. Therefore, the likelihood of the spread and establishment of T45 oilseed rape feral population is very low (if not negligible) and the unintended environmental effects due to this oilseed rape will be no different from that of conventional oilseed rape varieties. Therefore, no special measures are considered to be required in case of misuse or unintended release.

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

A copy of Commission Decision 2009/184/EC authorizing the placing on the market of products containing or produced from genetically modified oilseed rape T45 (ACS-BNØØ8-2) resulting from the commercialization of this oilseed rape in third countries until 2005 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document number C(2009) 1541) is provided with the application.

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

Annual reports on the implementation and the results of the general surveillance activities (from 2009 till 2017) together with results of the monitoring activities for the presence of T45 oilseed rape in shipments of oilseed rape imported in the European Union from a third country in which T45 oilseed rape seeds were commercialized until 2005 are provided with this request. The results of post market environmental monitoring reports indicate that there is no need to challenge or change in any way the conclusions of the original risk assessment. No modifications to the implemented management and monitoring measures for the T45 oilseed rape are required.

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 T45 oilseed rape and the newly expressed PAT/*pat* protein, in order to identify any specific questions regarding food and feed safety, environmental safety, and molecular characterization that might require in-depth examination and to support decisions about the value of conducting more focused systematic literature reviews. This literature search and review of the retrieved articles identified relevant references that supports the existing safety assessment of T45 oilseed rape.

2.3.2 Updated bioinformatics

The results of the updated bioinformatics analyses do not change the original risk assessment conclusion on oilseed rape T45.

2.3.3 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 oilseed rape T45 or the newly expressed protein PAT/*pat* 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

The scope of the current application is for renewal of the authorisation for placing on the market of products containing or produced from genetically modified oilseed rape T45 resulting from the commercialisation of this oilseed rape in third countries until 2005. The T45 line grown historically in Canada/US on a very limited surface will only enter the European Union (EU) by import at low level in commodity rapeseed. Conditions of the original consent have been defined in Articles 3 and 4 of Commission Decision 2009/184/EC. They include, among other, conditions concerning monitoring. Considering that the annual Post market environmental monitoring reports of T45 oilseed rape in the EU for the whole authorization period (from 2009 till 2017) and the comprehensive literature review indicated that there have been no adverse health or environmental effects associated T45 oilseed rape. Therefore, no revisions to the general surveillance plan or changes to the existing restrictions and conditions of release/use as laid down in the initial authorisation are considered necessary for T45 oilseed rape renewal application.