European Food Safety Authority

GMO Unit

Opinion of the European Food Safety Authority in accordance with Articles 6 and 18 of Regulation (EC) No. 1829/2003 on application EFSA-GMO-UK-2005-25 for the placing on the market of glufosinate-ammonium tolerant genetically modified oilseed rape T45 for food and feed uses, import and processing and application EFSA-GMO-RX-T45 for renewal of the authorisation of oilseed rape T45 as existing products in the sense of Articles 8 and 20 of that Regulation (food additives, feed materials produced from genetically modified T45 oilseed rape) submitted by Bayer CropScience.

(Questions No. EFSA-Q-2005-278 and EFSA-Q-2007-154)

5 March 2008

Summary

This document provides an overall opinion of the European Food Safety Authority on genetically modified oilseed rape T45 in accordance with the requirements of Articles 6, 8, 18 and 20 of Regulation (EC) No. 1829/2003.

The scope of these applications includes genetically modified oilseed rape T45 for food and feed uses[1], food and feed containing, consisting of or produced from oilseed rape T45. The scope does not include cultivation.

The Scientific Panel on Genetically Modified Organisms has carried out the scientific assessment of genetically modified oilseed rape T45 (applications EFSA-GMO-UK-2005-25 and EFSA-GMO-RX-T45) in accordance with Articles 6(6) and 18(6) of Regulation (EC) No. 1829/2003 and considers that the GM oilseed rape T45 is unlikely to have any adverse effect on human and animal health or on the environment in the context of its intended uses.

The Community Reference Laboratory considers the method validated as fit for the purpose of regulatory compliance. The certified reference materials of GM oilseed rape T45 can be accessed at the American Oil Chemist's Society (AOCS – USA).

The information presented for the Cartagena Protocol, the labelling proposal and the monitoring plan are in line with Regulation (EC) No. 1829/2003.

Under the terms of the Regulation (EC) No. 1829/2003, the overall opinion fulfils the requirements of Articles 6, 8, 18 and 20 for the placing on the market of genetically modified oilseed rape T45.

[1] This does include GM oilseed rape for import and processing as designated under part C of Directive 2001/18/EC.

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Background

Application EFSA-GMO-UK-2005-25

On 4 November 2005, the European Food Safety Authority (EFSA) received from the Competent Authority of the United Kingdom an application for authorisation of GM oilseed rape T45 (unique identifier ACS-BNØØ8-2) submitted by Bayer CropScience within the framework of Regulation (EC) No. 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2005-25).

The scope of this application is genetically modified oilseed rape T45 for food and feed uses[2], food and feed containing, consisting of or produced from oilseed rape T45. The scope does not include cultivation.

In accordance with Articles 5 and 17 of Regulation (EC) No. 1829/2003, EFSA informed the Member States and the European Commission and made the summary of the application publicly available on the EFSA website[3] on 10 November 2005. EFSA initiated a completeness check of the application to check compliance with the requirements laid down in Articles 5 and 17 of Regulation (EC) No. 1829/2003. On 1st October 2004, the Community Reference Laboratory (CRL) received the detection method, samples and control samples in accordance with Articles 5 and 17 of Regulation (EC) No. 1829/2003. EFSA declared the application valid on 13 April 2007 and started the clock in accordance with Articles 6 and 18 of Regulation (EC) No. 1829/2003.

From that date, EFSA has endeavoured to respect a time limit of 6 months in giving its overall opinion (Articles 6(1) and 18(1)). EFSA made the valid application available to Member States and the European Commission. Following the procedure laid down in Articles 6(4) and 18(4) of Regulation (EC) No. 1829/2003, EFSA consulted the Member States. In this context, the Member States risk assessment bodies, as well as the national competent authorities under Directive 2001/18/EC, were given three months after the date of receipt of the valid application (*i.e.* until 13 July 2007) within which to make their opinion known.

Making use of the provisions under Articles 6(2) and 18(2), EFSA requested additional information from the applicant and the clock was stopped from 29 August 2007 to 16 January 2008 and from 25 February 2008 to 28 February 2008.

Application EFSA-GMO-RX-T45

On 29 June 2007, EFSA received from the European Commission an application for renewal of the authorisation of GM oilseed rape T45 (EFSA-GMO-RX-T45) (unique identifier ACS-BNØØ8-2), submitted by Bayer CropScience within the framework of Regulation (EC) No. 1829/2003 on genetically modified food and feed.

The scope of this application is renewal of the authorisation of oilseed rape T45 as existing products (food additives and feed materials produced from genetically modified oilseed rape T45). The scope does not include cultivation.

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[2] This does include GM oilseed rape for import and processing as designated under part C of Directive 2001/18/EC.
[3] http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html

After receiving the application EFSA-GMO-RX-T45 and in accordance with Articles 5(2)(b) and 17(2)b of Regulation (EC) No 1829/2003, EFSA informed the Member States and the European Commission and made the summary of the dossier available to the public on the EFSA website. EFSA initiated a formal review of the application to check compliance with the requirements laid down in Articles 5(3), 5(5), 17(3), 17(5) as well as 11(2) and 23(2) of Regulation (EC) No. 1829/2003. On 7 September 2007, EFSA declared the application as valid in accordance with Articles 6(1) and 18(1) of Regulation (EC) No. 1829/2003.

All data required for the risk assessment of the application EFSA-GMO-RX-T45 have also been provided in application EFSA-GMO-UK-2005-25.

The GMO Panel performed one single comprehensive risk assessment for all intended uses of genetically modified oilseed rape T45 and issued a single comprehensive scientific opinion for both applications submitted under Regulation (EC) No. 1829/2003.

The overall opinion on applications EFSA-GMO-UK-2005-25 and EFSA-GMO-RX-T45 includes the scientific opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) together with the particulars required under Articles 6(5)(a-g) and 18(5)(a-g) of Regulation (EC) No. 1829/2003: i) the name and address of the applicant, ii) the designation of the food and its specification, iii) the information required under Annex II to the Cartagena Protocol, iv) the labelling proposal, v) the method for detection, validated by the Community Reference Laboratory, including sampling, identification of the transformation event in the food-feed and/or foods-feeds produced from it, vi) an indication of where appropriate reference materials can be accessed, vii) the monitoring plan and viii) Member States' comments submitted during the three-month consultation period.

Applicant

The application was submitted by
Bayer CropScience
Industriepark Höchst, K 607
D-65926 Frankfurt am Main
Germany

Designation and specification of the product

The scope of these applications is genetically modified oilseed rape T45 for food and feed uses[4], food and feed containing, consisting of or produced from GM oilseed rape T45.

Genetically modified oilseed rape T45 expresses the phosphinothricin acetyl-transferase (PAT) enzyme to confer tolerance to glufosinate-ammonium herbicides.

[4] This does include GM oilseed rape for import and processing as designated under part C of Directive 2001/18/EC.

Scientific opinion of the GMO Panel

The GMO Panel has carried out the scientific assessment of the genetically modified oilseed rape T45 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No. 1829/2003 and adopted its scientific opinion on 30 January 2008. The GMO Panel considered all comments submitted by Member State bodies and where deemed necessary, requested additional information from the applicant before finalising its scientific assessment. The GMO Panel concludes that the information available for GM oilseed rape T45 addresses the scientific comments raised by the Member States and considers that GM oilseed rape T45 is unlikely to have any adverse effect on human and animal health or the environment in the context of its intended uses (Annex A).

Cartagena Protocol

The information presented in these applications and as required under Annex II of the Cartagena Protocol on Biosafety is in line with the scientific opinion of the GMO Panel (Annex B).

Labelling

The labelling proposal provided in these applications is in line with the requirements in Regulation (EC) No. 1829/2003. On the basis of the scientific opinion of the GMO Panel that GM oilseed rape T45 is compositionally and phenotypically equivalent to its non-genetically modified oilseed rape except for the introduced trait, EFSA is of the opinion that there is no need for a specific labelling in accordance with Articles 13(2)(a) and 25(2)(c) (Annex C).

Method for detection

The Joint Research Centre (JRC) as Community Reference Laboratory for the GM Food and Feed has carried out a collaborative study to assess the performance of a quantitative event-specific method to detect and quantify the T45 transformation event in oilseed rape DNA. The reports were published on 7 September 2006. The Community Reference Laboratory considers that the method is applicable to the control samples provided in accordance with the requirements of Annex I-2.C.2 to Commission Regulation (EC) No. 641/2004 (Annexes D1, D2, D3).

Certified reference materials

The certified reference materials of genetically modified oilseed rape T45 can be accessed at American Oil Chemist's Society (AOCS – USA). The reports were published on 27 February 2008 (Annexe E).

Post market environmental monitoring

The GMO Panel evaluated the environmental monitoring plan proposed by the applicant. The GMO Panel considered that the monitoring plan provided by the applicant is in line with the intended uses for the GMO (Annex F).

Member States' Comments

In line with the procedure[5] adopted by EFSA, the GMO Panel has addressed the comments submitted by the Member States during the three months consultation period (Annex G).

List of annexes:

Annex A: Scientific opinion of the GMO Panel (oilseed rape T45)
Annex B: Cartagena Protocol (oilseed rape T45)
Annex C: Labelling (oilseed rape T45)
Annex D1: Validation report (oilseed rape T45)
Annex D2: Validated method (oilseed rape T45)
Annex D3: Sampling and extraction (oilseed rape T45)
Annex E: Certified reference materials report (oilseed rape T45)
Annex F: Monitoring plan (oilseed rape T45)
Annex G: Member States' comments (oilseed rape T45)

[5] EFSA Strategy document
http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/109.Par.0010.File.dat/gmo_actionplan1.pdf