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-2004-04

Application for the placing on the market of genetically modified LLRICE62 for food and feed uses from Bayer CropScience.

(Question No. EFSA-Q-2004-145)

30 November 2007

Summary

This document provides an overall opinion of the European Food Safety Authority on genetically modified LLRICE62 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No. 1829/2003.

The scope of this application is genetically modified LLRICE62 for food and feed uses[1], food and feed containing, consisting of or produced from LLRICE62. The scope does not include cultivation.

The Scientific Panel on Genetically Modified Organisms has carried out the scientific assessment of genetically modified LLRICE62 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No. 1829/2003 and considers that the genetically modified LLRICE62 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 LLRICE62 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 and 18 for the placing on the market of genetically modified LLRICE62.

[1] This does include GM LLRICE62 for import and processing as designated under part C of Directive 2001/18/EC

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Background

On 20 August 2004, the European Food Safety Authority (EFSA) received from the United Kingdom Competent Authority an application for authorisation of GM LLRICE62 (unique identifier ACS-OSØØ2-5) submitted by Bayer CropScience within the framework of Regulation (EC) No. 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2004-04).

The scope of this application is genetically modified LLRICE62 for food and feed uses[2], food and feed containing, consisting of or produced from LLRICE62. 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 26 August 2004. 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 28 July 2004, the Community Reference Laboratory (CRL) confirmed receipt of 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 14 January 2005 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 14 April 2005) 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 9 February 2005 to 25 October 2007 [4].

The overall opinion on application EFSA-GMO-UK-2004-04 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,

[2] This does include GM LLRICE62 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

[4] Request for additional information from EFSA-GMO Panel: requested (1) on 21/03/2005 - received on 10/05/2005, remain stopped (2) on 12/07/2005 - received on 02/04/2007 and 05/06/2007, requested (3) on 05/06/2007 - received on 11/06/2007, requested (4) on 18/06/2007 - received on 05/07/2007, requested (5) on 21/09/2007 - received on 12/10/2007, accepted on 25/10/2007.
Request for additional information from EFSA-JRC: requested on 09/02/2005, accepted on 31/03/2005.

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 GmbH
Industriepark Höchst, K 607
D-65926 Frankfurt am Main
Germany

Designation and specification of the product

The scope of this application is genetically modified LLRICE62 for food and feed uses[5], food and feed containing, consisting of or produced from GM LLRICE62. The scope does not include cultivation.

Genetically modified LLRICE62 expresses the phosphinothricin acetyl-transferase (PAT) enzyme to confer tolerance to glufosinate-ammonium herbicides

Scientific opinion of the GMO Panel

The GMO Panel has carried out the scientific assessment of the genetically modified LLRICE62 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No. 1829/2003 and adopted its scientific opinion on 31 October 2007. 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 LLRICE62 addresses the scientific comments raised by the Member States and considers that GM LLRICE62 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 the application 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 the application 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 LLRICE62 is compositionally and phenotypically equivalent to its non-genetically modified LLRICE62 except for the introduced traits, 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).

[5] This does include GM LLRICE62 for import and processing as designated under part C of Directive 2001/18/EC

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 LLRICE62 transformation event in rice DNA. The reports were published on 10 June 2006. The Community Reference Laboratory considers that the method as fit for enforcement purposes with respect to its intra and inter-laboratory variability, and considers the method validated as fit for the purpose of regulatory compliance (Annexes D1, D2, D3).

Certified reference materials

The certified reference materials of genetically modified LLRICE62 can be accessed at American Oil Chemist's Society (AOCS– USA). The report was published on 17 October 2006 (Annex 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[6] 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
Annex B:	Cartagena Protocol
Annex C:	Labelling
Annex D1:	Validation report (LLRICE62)
Annex D2:	Validated method (LLRICE62)
Annex D3:	Sampling and extraction (LLRICE62)
Annex E:	Certified reference materials report
Annex F:	Post market monitoring plan
Annex G:	Member States' comments

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