

## COMMISSION DECISION

of 26 February 2008

**amending Decision 2006/601/EC on emergency measures regarding the non-authorised genetically modified organism 'LL RICE 601' in rice products***(notified under document number C(2008) 743)***(Text with EEA relevance)**

(2008/162/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>(1)</sup>, and in particular Article 53(1) thereof,

Whereas:

(1) Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed<sup>(2)</sup> provide that no genetically modified food or feed is to be placed on the Community market unless it is covered by an authorisation granted in accordance with that Regulation. Article 4(3) and Article 16(3) of the same Regulation lay down that no genetically modified food and feed may be authorised unless it has been adequately and sufficiently demonstrated that it does not have adverse effects on human health, animal health or the environment, that it does not mislead the consumer or the user, and that it does not differ from the food or feed it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for humans or animals.

(2) Article 53(1) of Regulation (EC) No 178/2002 provides for the possibility to adopt appropriate Community emergency measures for food and feed imported from a third country in order to protect human health, animal health or the environment, where the risk cannot be contained satisfactorily by means of measures taken by the Member States concerned.

(3) In view of the presumption of risk on products not authorised according to Regulation (EC) No

1829/2003, Commission Decision 2006/601/EC of 5 September 2006 on emergency measures regarding the non-authorised genetically modified organism 'LL RICE 601' in rice products<sup>(3)</sup> required Member States not to allow the placing on the market of certain rice products originating from the United States unless the consignment is accompanied by an original analytical report issued by an accredited laboratory attesting that the product does not contain genetically modified rice 'LL RICE 601' and to carry out systematic official sampling and analysis of each consignment of specific products originating from the United States before their placing on the market.

(4) On 5 October 2007, the United States Department of Agriculture (USDA) published the results of its investigation on, in particular, the presence of 'LL RICE 601' in US commercial rice. While the exact mechanisms of the contamination could not be established, the findings indicate that the source of the contamination by 'LL RICE 601' was limited.

(5) The US Rice federation has adopted a plan aiming to remove 'LL RICE 601' from the US export channels. This plan includes testing of the seeds before planting, as well as documentary and analytical controls at the delivery points of the 2007 harvest. Only some aspects of this plan are subject to regulatory requirements in some US States. It is therefore necessary to ensure that all the consignments of rice originating from the United States of America imported in the European Union were subject to this plan.

(6) On 9 November 2007, USDA submitted a proposal of protocol to the Commission that would ensure that the products falling under the scope of Decision 2006/601/EC are subject to official sampling by the Grain Inspection, Packers and Stockyards Administration (GIPSA) and analysed using the 'P35S:BAR' method referred to in Decision 2006/601/EC in a laboratory participating successfully in the dedicated proficiency program administered by GIPSA. In accordance with that protocol, the consignments of those products would be accompanied by the original of an analytical report and by a letterhead issued by GIPSA indicating that 'LL RICE 601' was not detected.

<sup>(1)</sup> OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).

<sup>(2)</sup> OJ L 268, 18.10.2003, p. 1. Regulation as amended by Commission Regulation (EC) No 1981/2006 (OJ L 368, 23.12.2006, p. 99).

<sup>(3)</sup> OJ L 244, 7.9.2006, p. 27. Decision as amended by Commission Decision 2006/754/EC (OJ L 306, 7.11.2006, p. 17).

- (7) The official involvement of the GIPSA, as described in the proposal of protocol, provides appropriate reassurances as to the quality of the controls made. As a consequence, mandatory official sampling and analysis by Member States at the point of entry into the Community is no more considered necessary.
- (8) Those measures should be reviewed within six months in order to assess whether they are still necessary, in the light of their impact and of the practical experience gained on the existing testing requirements.
- (9) Decision 2006/601/EC should therefore be amended accordingly.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

*Article 1*

Decision 2006/601/EC is amended as follows:

1. Article 2 is replaced by the following:

*'Article 2*

**Conditions for first placing on the market**

1. Member States shall allow the first placing on the market of the products referred to in Article 1 only if the consignment of those products is accompanied by the following documents:

- (a) a statement from the food business operator responsible for the consignment that the products do only contain rice, from the 2007 or a subsequent harvest, that was subject to the plan of the USA Rice federation aiming to remove "LL RICE 601" from the US export channels; and
- (b) the original of an analytical report issued by a laboratory referred to in Annex II confirming that the products do not contain the genetically modified rice "LL RICE 601". The analytical report shall be accompanied by an official document issued by the Grain Inspection, Packers and Stockyards Administration (GIPSA) of the United States Department of Agriculture (USDA) in accordance with the protocol described in Annex II.

2. If a consignment is split, copies of the documents referred to in paragraph 1 shall accompany each part of the split consignment up to and including the wholesale stage. Those copies shall be certified by the competent

authority of the Member State on whose territory the splitting has taken place.'

2. Article 3 is replaced by the following:

*'Article 3*

**Other control measures**

1. Member States shall take appropriate measures, including random sampling and analysis carried out in accordance with Annex I concerning the products referred to in Article 1 presented for importation or already on the market in order to verify the absence of genetically modified rice "LL RICE 601". They shall inform the Commission of positive (unfavourable) results through the Rapid Alert System for food and feed.

2. Member States shall by 26 July 2008 at the latest submit to the Commission a report of all analytical results of official controls on consignments of products referred to in Article 1.'

3. Paragraph 1 of Article 5 is replaced by the following:

'1. All costs resulting from issuing the accompanying documents pursuant to Article 2(2) shall be borne by the food business operator responsible for the consignment or its representative.'

4. Article 6 is replaced by the following:

*'Article 6*

**Review of the measures**

The measures provided for in this Decision shall be reviewed by 26 August 2008 at the latest.'

5. In the heading of the Annex the word 'Annex' is replaced by 'Annex I'.
6. The text in the Annex to this Decision is added as Annex II.

*Article 2*

This Decision is addressed to the Member States.

Done at Brussels, 26 February 2008.

*For the Commission*  
Markos KYPRIANOU  
*Member of the Commission*

## ANNEX

## ‘ANNEX II

**Protocol for sampling and testing U.S. long grain rice shipments before export from the United States of America to the European Community**

**Sampling.** Each consignment (lot) of U.S. long grain rice to be shipped to Europe shall be officially sampled by USDA's Grain Inspection, Packers and Stockyards Administration (GIPSA) personnel in accordance with established sampling procedures. These procedures appear in GIPSA's *Rice Inspection Handbook, Chapter 2, Sampling*.

The size of the original bulk sample shall be in accordance with Commission Recommendation 2004/787/EC. GIPSA personnel shall prepare a representative 2,5 kg lot composite sample for the testing laboratory and will retain an identical 2,5 kg file sample. GIPSA will apply a seal to the laboratory sample and record the seal number for future reference.

**Testing.** The applicant for service shall forward the sealed sample to one of the commercial testing laboratories participating successfully in the LibertyLink rice proficiency program administered by GIPSA and listed at this location: <http://archive.gipsa.usda.gov/rdd/l/riceprof.pdf> Each laboratory tests pools of samples within its verified detection level to achieve a 0,01 per cent level of detection.

The laboratory shall record the seal number, break the seal, and test four 240 gram samples taken from the single laboratory sample. One extraction will be made from each sample. Two PCR analyses shall be made for each extraction using the 35S:BAR method developed by Bayer CropScience and verified by both GIPSA and the JRC. The lot shall be considered negative only when all sample results are negative.

**Reporting.** The laboratory shall report results, and the GIPSA seal number, on the lab report, and provide it to the applicant for service. The applicant shall provide the lab report to the GIPSA office that sampled the lot. GIPSA will issue an official document as follows, and provide it to the applicant:

“GIPSA officially sampled the lot of rice identified as (*specify lot identification*) and applied seal number (*enter seal number*). (*Enter lab name*), who participates in the LibertyLink rice proficiency program administered by GIPSA, tested a sample identified with this seal number and did not detect LibertyLink rice based on the verified 35S:BAR method. The lab report is attached.”

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