

This document is meant purely as a documentation tool and the institutions do not assume any liability for its contents

► **B**

COMMISSION DECISION

of 5 September 2006

on emergency measures regarding the non-authorised genetically modified organism ‘LL RICE 601’ in rice products

(notified under document number C(2006) 3932)

(Text with EEA relevance)

(2006/601/EC)

(OJ L 244, 7.9.2006, p. 27)

Amended by:

		Official Journal		
		No	page	date
► <u>M1</u>	Commission Decision 2006/754/EC of 6 November 2006	L 306	17	7.11.2006
► <u>M2</u>	Commission Decision 2008/162/EC of 26 February 2008	L 52	25	27.2.2008

**COMMISSION DECISION****of 5 September 2006****on emergency measures regarding the non-authorised genetically modified organism 'LL RICE 601' in rice products***(notified under document number C(2006) 3932)***(Text with EEA relevance)**

(2006/601/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 ⁽¹⁾, and in particular Article 53(2), second subparagraph, 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 provide that no genetically modified food or feed ⁽²⁾ 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) On 18 August 2006, the authorities of the United States of America informed the Commission that rice products contaminated with the genetically modified rice 'LL RICE 601' ('the contaminated products'), which have not been authorised for placing on the market in the Community, had been found in rice samples taken on the US market from commercial long-grain rice from the 2005 crop. The contamination of products was reported to the US authorities on 31 July 2006 by Bayer Crop Science, which is the company that developed the genetically modified rice 'LL RICE 601'. The US authorities later informed the Commission that it is still not known to what extent the supply chain has been contaminated and that information on possible contamination of exports to the Community cannot be given at present. In addition, they informed the Commission that those products had not been authorised for placing on the market in the United States either.
- (3) Without prejudice to the control obligations of the Member States, the measures to be adopted further to the likely imports of contaminated products should form a comprehensive and common approach allowing rapid and effective action to be taken and avoiding disparities between the treatment of the situation by the various Member States.

⁽¹⁾ 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).

⁽²⁾ OJ L 268, 18.10.2003, p. 1.

▼B

- (4) Article 53 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.
- (5) Since genetically modified rice 'LL RICE 601' is not authorised under Community legislation and in view of the presumption of risk on products not authorised according to Regulation (EC) No 1829/2003, which takes into account the precautionary principle laid down in Article 7 of Regulation (EC) No 178/2002, it is appropriate to take emergency measures to prevent the placing on the market in the Community of the contaminated products.
- (6) According to the general requirements laid down in Regulation (EC) No 178/2002, food and feed business operators have primary legal responsibility for ensuring that foods or feeds within the businesses under their control satisfy the requirements of food law and for verifying that such requirements are met. It is, therefore, the operators responsible for first placing food and feed on the market who should be under the duty to prove that they do not contain the contaminated products. To this end, the measures provided for in this Decision should require that consignments of specific products originating from the United States may be placed on the market only if an analytical report demonstrating that the products are not contaminated with 'LL RICE 601' is provided. The analytical report should be issued by an accredited laboratory conforming to internationally recognised standards.
- (7) In order to facilitate controls, all genetically modified food and feed placed on the market should be subject to a validated method of detection. Bayer Crop Science has been requested to provide methods for detection of 'LL RICE 601' as well as control samples. It has made available two methods which have been validated by the Grain Inspection, Packers and Stockyards Administration (GIPSA) of the US Department of Agriculture, in collaboration with the Community reference laboratory referred to in Article 32 of Regulation (EC) No 1829/2003.
- (8) The measures provided for in this Decision must be proportionate and no more restrictive of trade than is required and should therefore cover only products considered likely to be contaminated with 'LL RICE 601', which according to the information received, are imported from the United States into the Community.
- (9) Despite requests made by the Commission, the US authorities have been unable to provide any guarantee that rice products imported from the United States will not contain 'LL RICE 601'.
- (10) With regard to feed products or other food products not covered by the measures provided for in this Decision, Member States should monitor whether such products have been contaminated by 'LL RICE 601'. On the basis of the information provided by Member States, the Commission will consider the need for any additional appropriate measures.
- (11) Commission Decision 2006/578/EC of 23 August 2006 on emergency measures regarding the non-authorised genetically modified organism LL RICE 601 in rice products ⁽¹⁾ was adopted to ban provisionally the placing on the market of contaminated products.
- (12) Those provisional measures should be confirmed.

⁽¹⁾ OJ L 230, 24.8.2006, p. 8.

▼B

- (13) It is therefore appropriate to repeal and replace Decision 2006/578/EC.
- (14) The measures provided for in this Decision should be reviewed within six months in order to assess whether they are still necessary,
- (15) 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:

▼M1*Article 1***Scope**

This Decision applies to the following products originating from the United States of America:

Product	CN Code
rice in the husk, parboiled Long A	1006 10 25
rice in the husk parboiled Long B	1006 10 27
rice in the husk other than parboiled Long A	1006 10 96
rice in the husk other than parboiled Long B	1006 10 98
husked (brown) rice Parboiled Long A	1006 20 15
husked (brown) rice Parboiled Long B	1006 20 17
husked (brown) rice Long A	1006 20 96
husked (brown) rice Long B	1006 20 98
semi-milled Parboiled rice Long A	1006 30 25
semi-milled Parboiled rice Long B	1006 30 27
semi-milled rice Long A	1006 30 46
semi-milled rice Long B	1006 30 48
wholly milled Parboiled rice Long A	1006 30 65
wholly milled Parboiled rice Long B	1006 30 67
wholly milled rice Long A	1006 30 96
wholly milled rice Long B	1006 30 98
broken rice (unless it is certified as not obtained from Long-grain)	1006 40 00

▼M2*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

▼ M2

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.

*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.

▼ B*Article 4***Contaminated consignments**

Member States shall take the necessary measures to ensure that the products referred to in Article 1 that are found to contain genetically modified rice 'LL RICE 601' are not placed on the market.

▼ M1*Article 5***Recovery of costs****▼ M2**

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.

▼ M1

2. All costs related to official measures taken by the competent authorities as regards non-compliant consignments shall be borne by the food business operator responsible for the consignment or its representative.

▼ M2*Article 6***Review of the measures**

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

▼ B

Article 7

Repeal

Decision 2006/578/EC is repealed.

Article 8

Addressees

This Decision is addressed to the Member States.

▼M2*ANNEX I***▼B****Methods of sampling and analysis for official control regarding the non-authorised genetically modified organism LL RICE 601 in rice products**

1. Purpose and scope

The present annex is based on Recommendation 2004/787/EC ⁽¹⁾. It takes in particular into account that the currently available methods are qualitative and that it addresses the detection of a non-authorised GMO for which there is no tolerance threshold. Samples intended for the official control for the absence of LL RICE 601 in rice products shall be taken according to the methods described below. The bulk samples thus obtained shall be considered as representative of the lots from which they are taken.

2. Definitions

For the purpose of the current annex, definitions of Recommendation 2004/787/EC apply.

3. Sampling lots of bulk commodities and preparation of the analytical samples

The number of incremental samples for the constitution of the bulk sample and the preparation of the analytical samples shall be made in accordance with Recommendation 2004/787/EC. The size of the laboratory sample shall be 2,5 kg. For the purpose of Article 11(5) of Regulation (EC) 882/2004 ⁽²⁾, a second laboratory sample shall be constituted.

4. Analysis of the laboratory sample

The control laboratory shall take from the homogenised laboratory sample four analytical samples of 240 grams. The four analytical samples have to be ground and further analysed separately.

The PCR method to be used is the construct-specific method 'P35S:BAR' that has been developed by Bayer CropScience and verified by the USDA and the JRC in its quality of Community reference laboratory for GM Food and Feed. In case of positive results, the presence of LL RICE 601 shall be confirmed by the event-specific method.

The lot shall be considered to be positive when one of the four analytical samples is positive.

⁽¹⁾ OJ L 348, 24.11.2004, p. 18.

⁽²⁾ OJ L 191, 28.5.2004, p. 1.

▼ M2

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/lriceprof.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.'