

## II

(Acts whose publication is not obligatory)

## COMMISSION

## COMMISSION DECISION

of 6 November 2006

**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(2006) 5266)

(Text with EEA relevance)

(2006/754/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 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) 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.

(4) In view of the presumption of risk on products not authorised according to Regulation (EC) No 1829/2003, 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<sup>(3)</sup> provisionally banned the placing on the market of the contaminated products. Those emergency measures were confirmed by Commission Decision 2006/601/EC<sup>(4)</sup> which repealed and replaced Decision 2006/578/EC and 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'.

<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.

<sup>(3)</sup> OJ L 230, 24.8.2006, p. 8.

<sup>(4)</sup> OJ L 244, 7.9.2006, p. 27.

- (5) The European Food Safety Authority, requested for scientific support on the issue, issued a statement on 14 September 2006 concluding that although it can be considered that the consumption of imported long grain rice containing trace levels of 'LL RICE 601' is not likely to pose an imminent safety concern to humans or animals the available data are insufficient to enable a full safety assessment of the genetically modified rice 'LL RICE 601' in accordance with the EFSA guidance for risk assessment.
- (6) Checks carried out in the Member States have shown that in addition to the rice products currently referred to in Decision 2006/601/EC other rice products may be contaminated with the genetically modified rice 'LL RICE 601'. Such products should therefore be included in the scope of Decision 2006/601/EC.
- (7) Checks carried out by Member States have also revealed the presence of genetically modified rice 'LL RICE 601' in some consignments despite being accompanied by an original analytical report as requested by Decision 2006/601/EC. Contacts initiated thereafter with the US authorities in order to eliminate the risk of presence of unauthorised GM rice have not been successful. In those circumstances, in order to ensure that no contaminated product is placed on the market and in order to guarantee the high level of health protection required in the Community, without imposing restrictions to trade which go beyond what it is necessary, it appears necessary, while maintaining the obligation to issue an analytical report as requested by Decision 2006/601/EC, to provisionally carry out systematic official sampling and analysis of each consignment of specific products originating from the United States before their placing on the market.
- (8) Sampling methodologies play a crucial role in obtaining representative and comparable results; it is therefore appropriate to define a common protocol for sampling and analysis for the control of the absence of the genetically modified rice 'LL RICE 601'.
- (9) Since the measures provided for in this Decision have an impact on the control resources of the Member States it is appropriate to require that all costs resulting from sampling, analysis and storage and all costs resulting from official measures taken as regards non-compliant consignments are to be borne by the importers or food business operators concerned.
- (10) Those measures should be reviewed within two 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.
- (11) Decision 2006/601/EC should therefore be amended accordingly.
- (12) 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 1 is replaced by the following:

*'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'

2. 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 original of an analytical report confirming that the products do not contain the genetically modified rice "LL RICE 601". That report shall be issued by an accredited laboratory and based on a suitable and validated method for detection of genetically modified rice "LL RICE 601".

2. Member States shall ensure that, at the point of entry into the Community, official sampling and analysis of each consignment of products referred to in Article 1 is carried out before they are placed on the Community market to demonstrate that it does not contain genetically modified rice "LL RICE 601". For that purpose official sampling and analysis shall be carried out in accordance with the methods described in the Annex and within a maximum period of 15 working days.

3. The competent authorities of the Member States referred to in paragraph 2 shall issue an official accompanying document indicating that the consignment has been subject to official sampling and analysis and setting out the result of the analysis.

4. If a consignment is split, copies of the original analytical report as referred to in paragraph 1 and of the official accompanying document as referred to in paragraph 3 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.

5. Any presence of genetically modified rice "LL RICE 601" detected by the controls provided for in paragraph 2 shall be reported to the Commission and the Member States through the Rapid Alert System for food and feed established by Article 50 of Regulation (EC) No 178/2002.

6. Member States shall by 31 December 2006 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. Article 3 is replaced by the following:

*'Article 3*

### **Other control measures**

Member States shall take appropriate measures, including random sampling and analysis carried out in accordance with the Annex, concerning the products referred to in Article 1 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.'

4. Article 5 is replaced by the following:

*'Article 5*

### **Recovery of costs**

1. All costs resulting from sampling, analysis, storage and issuing of official accompanying documents and of copies of analytical reports and accompanying documents pursuant to Article 2(1) to (4) shall be borne by the food business operator responsible for the consignment or its representative.

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.'

5. Article 6 is replaced by the following:

*'Article 6*

### **Review of the measures**

The measures provided for in this Decision shall be reviewed by 15 January 2007 at the latest.'

*Article 2*

This Decision is addressed to the Member States.

Done at Brussels, 6 November 2006

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

## ANNEX

**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 <sup>(1)</sup>. 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 <sup>(2)</sup>, 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.

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<sup>(1)</sup> OJ L 348, 24.11.2004, p. 18.

<sup>(2)</sup> OJ L 191, 28.5.2004, p. 1.