Commission Implementing Decision of 22 December 2011 on emergency measures regarding unauthorised genetically modified rice in rice products originating from China and repealing Decision 2008/289/EC (Text with EEA relevance) (2011/884/EU)

COMMISSION IMPLEMENTING DECISION

of 22 December 2011

on emergency measures regarding unauthorised genetically modified rice in rice products originating from China and repealing Decision 2008/289/EC

(Text with EEA relevance)

(2011/884/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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(1) thereof,

Whereas:

(1) Articles 4(2) and 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[(2)] provide that no genetically modified food or feed is to be placed on the Union market unless it is covered by an authorisation granted in accordance with that Regulation. Articles 4(3) and 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) In September 2006, rice products originating in or consigned from China, contaminated with the unauthorised genetically modified rice Bt 63, were discovered in the United Kingdom, France and Germany and were notified to the Rapid Alert System for Food and Feed (RASFF). Notwithstanding the measures announced by the Chinese authorities to control the presence of that unauthorised Genetically Modified Organism (GMO), several other alerts concerning the presence of the unauthorised genetically modified rice Bt 63 were subsequently reported.

(3) Considering the continuing alerts and the lack of sufficient guarantees from the Chinese competent authorities concerning the absence of the unauthorised genetically modified rice Bt 63 in products originating in or consigned from China, Commission Decision

2008/289/EC[3] was adopted which introduced emergency measures regarding the unauthorised GMO Bt 63 in rice products. That Decision required that prior to placing on the market, operators should submit an analytical report to the relevant Member State competent authorities demonstrating that the consignment of rice products was not contaminated with genetically modified rice Bt 63. Additionally, that Decision provided for Member States to take appropriate measures, including random sampling and analysis carried out using a specific method described therein, concerning products presented for importation or already on the market.

(4) In March 2010, Germany notified the RASFF with regard to the presence of new rice varieties carrying unauthorised genetic elements encoding insect resistance which had characteristics similar to the GMO Kefeng 6. Subsequently, several additional similar alerts were notified, which in addition to Kefeng 6, also included the presence of another insect resistant rice line which contained genetic elements similar to the GMO Kemingdao 1 (KMD1). Kefeng 6 and KMD1 are not authorised either in the Union or China.

(5) All RASFF notifications were notified to the relevant Chinese authorities and additionally the Commission wrote to the authorities both in June 2010 and February 2011 requesting action to address the increasing number of alerts.

(6) The Food and Veterinary Office conducted an inspection in China in October 2008 with the objective of evaluating the implementation of Decision 2008/289/EC, which was subsequently followed up with another mission in March 2011. The conclusions of the 2008 mission and the initial findings of the 2011 mission indicated uncertainty as to the level, type and number of genetically modified rice varieties which may have contaminated rice products originating in or consigned from China, and that therefore there was a high risk of further introductions of unauthorised GMOs in such rice products.

(7) In light of the findings of the 2008 and 2011 missions of the Food and Veterinary Office, and the numerous RASFF notifications concerning unauthorised genetically modified rice events, the measures provided by Decision 2008/289/EC should be enhanced accordingly so as to prevent any contaminated product being placed on the Union market. Therefore it is necessary to replace Decision 2008/289/EC by means of this Decision.

(8) Taking into account the fact that no genetically modified rice products are authorised in the Union, it is appropriate to extend the scope of measures provided for by Decision 2008/289/EC, which is limited to genetically modified rice Bt 63, and to broaden it to all genetically modified organisms found in rice products originating in or consigned from China. The obligation to provide an analytical report on sampling and analysis demonstrating the absence of genetically modified rice events, established by Decision 2008/289/EC, should be maintained. However, it is appropriate to reinforce Member State controls through enhanced frequency of sampling and analysis which should be set at 100 % of all consignments of rice products originating from China, and to introduce the obligation for food and feed operators to give prior notification of the estimated date, time and place of the physical arrival of the consignment.

(9) 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 genetically modified rice in imports originating from China. The principles for reliable sampling procedures for bulk agricultural commodities are laid down in Commission Recommendation 2004/787/EC of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003[(4)] and for prepacked food in CEN/TS 15568 or equivalent. With regard to feed, such principles laid down in Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed[(5)] shall apply.

(10) Due to the number of potential genetically modified rice events, the lack of validated detection methods and control samples of adequate quality and quantity, and in order to facilitate controls, it is appropriate to replace the method for sampling and analysis provided for in the Decision 2008/289/EC with the analytical screening methods provided in Annex II.

(11) The new proposed screening methods for analysis should be based on Recommendation 2004/787/EC. It particularly takes into account that currently available methods are qualitative and should address the detection of a unauthorised GMO for which there is no tolerance threshold for sampling and analysis.

(12) The European Reference Laboratory for Genetically Modified Food and Feed (EU-RL GMFF) within the Joint Research Centre (JRC) verified and confirmed the suitability of the proposed screening methods for the detection of genetically modified rice.

(13) For the purpose of the sampling and detecting activities required in order to prevent that products containing unauthorised rice events are placed on the market, it is necessary that both operators and official services follow such methods of sampling and analysis provided for in Annex II. In particular it is necessary that account is taken of the guidance provided by the EU-RL GMFF concerning the application of these methods.

(14) Rice products, as listed in Annex I, originating in or consigned from China, should be released for free circulation only if they are accompanied by an analytical report and health certificate issued by the Entry Exit Inspection and Quarantine Bureau of the People's Republic of China (AQSIQ) in accordance with the models laid down in Annex III and IV to this Decision.

(15) In order to be able to have a continuous assessment of the control measures, it is appropriate to introduce an obligation for Member States to report regularly to the Commission concerning official controls on consignments of rice products originating or consigned from China.

(16) The measures provided for in this Decision should be proportionate and no more restrictive of trade than is required and should therefore cover only products originating in or consigned from China and considered likely to be contaminated with unauthorised genetically modified rice events. Given the range of products that could be contaminated with such unauthorised genetically modified rice events, it seems

appropriate to target all food and feed products which have rice listed as an ingredient. Some products, however, may or may not be containing, consisting or produced from rice. It seems therefore proportionate to allow operators to issue a simple declaration when the product is not containing, consisting or produced from rice, thus avoiding the compulsory analysis and certification.

(17) The situation concerning the possible contamination of rice product with unauthorised genetically modified rice lines should be reviewed within 6 months in order to assess whether the measures provided for in this Decision are still necessary.

(18) 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

Scope

This Decision shall apply to rice products listed in Annex I, originating in or consigned from China.

Article 2

Definitions

1 For the purposes of this Decision, the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002, Article 2 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[(6)] and Article 3(b) and (c) of Commission Regulation (EC) No 669/2009[(7)] on increased controls on imports of certain feed and food of non-animal origin shall apply.

2 The following definitions shall also apply:

(a) Lot	:	a distinct and specified quantity of material.
(b) Increment sample	:	small equal quantity of product taken from each individual sampling point in the lot through the full depth of the lot (static sampling), or taken from the product stream during a stated portion of time (flowing commodities sampling).
(c) Bulk sample	:	quantity of product obtained by combining and mixing the increments taken from a specific lot.
(d) Laboratory sample	:	quantity of product taken from the bulk sample intended for laboratory inspection and testing.
(e) Analytical sample	:	homogenised laboratory sample, consisting either of the whole laboratory sample or a representative portion thereof.

Article 3

Prior notification

Feed and food business operators or their representatives shall give adequate prior notification of the estimated date and time at the designated point of entry of the physical arrival of the consignment and of the nature of the consignment. Operators must also indicate the designation of the product as to whether it is food or feed.

Article 4

Import conditions

1 Each consignment of products referred to in Article 1 shall be accompanied by an analytical report for each lot, and by a health certificate in accordance with the models set out in Annexes III and IV, completed, signed and verified by an authorised representative of the 'Entry Exit Inspection and Quarantine Bureau of the People's Republic of China' (AQSIQ).

2 Where a product referred to in Annex I is not containing, consisting of or produced from rice, the analytical report and the health certificate may be replaced by a statement from the operator responsible for the consignment indicating that the food or feed is not containing, consisting or produced from rice.

3 Sampling and analysis for the purposes of the analytical report referred to in paragraph 1 shall be performed in accordance with Annex II.

4 Each consignment shall be identified with the code appearing on the health certificate. Each individual bag, or other packaging form, of the consignment shall be identified with that code.

Article 5

Official controls

1 The competent authority of a Member State shall ensure that all the products referred to in Article 1 are subject to documentary checks to ensure that the import conditions provided for in Article 4 are complied with.

2 Where a consignment of products other than those described in Article 4(2) is not accompanied by a health certificate and the analytical report provided for in Article 4, the consignment shall be re-dispatched to the country of origin or destroyed.

3 Where a consignment is accompanied by the health certificate and the analytical report provided for in Article 4 the competent authority shall take a sample for analysis in accordance with Annex II for the presence of unauthorised GMOs with a frequency of 100 %. If the consignment consists of several lots, each lot shall be submitted to sampling and analysis.

4 The competent authority may authorise onward transportation of the consignment pending the results of the physical checks. In such a case the consignment shall remain under the continuous control of the competent authorities pending the results of the physical checks.

5 The release for free circulation of consignments shall only be allowed when, following sampling and analyses performed in accordance with Annex II, all lots of that consignment are considered compliant with Union Law.

Article 6

Reporting to the Commission

1 Member States shall prepare a report every 3 months, giving an account of all the results of all analytical tests carried out in the previous 3 months on consignments of the products referred to in Article 1.

Those reports shall be submitted to the Commission during the month following each three-month period, in April, July, October, and January.

2 The report shall include the following information:

a the number of consignments subjected to sampling for analysis;

b the results of the checks as provided for in Article 5;

c the number of consignments which have been rejected due to the absence of a health certificate or an analytical report.

Article 7

Splitting of a consignment

Consignments shall not be split until all official controls have been completed by the competent authorities.

In the case of subsequent splitting following official control, an authenticated copy of the health certificate and the analytical report shall accompany each part of the split consignment.

Article 8

Costs

All costs resulting from the official controls including sampling, analysis, storage and any measures taken following non-compliance, shall be borne by the food and feed business operators.

Article 9

Transitional provisions

By way of derogation from Article 4(1), Member States shall authorise the imports of consignments of products referred to in Article 1 which left China prior to 1st of February 2012 provided that sampling and analysis has been conducted in accordance with the Article 4.

Article 10

Review of the measure

The measures provided for in this Decision shall be reviewed by the 6 months following adoption at the latest.

Article 11

Repeal

Decision 2008/289/EC is hereby repealed.

References to the repealed Decision shall be construed as references to this Decision.

Article 12

Entry into force

This Decision shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Done at Brussels, 22 December 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX I

LIST OF PRODUCTS

Product	**CN code**
Rice in the husk (‘paddy’ or rough)	1006 10
Husked (brown) rice	1006 20
Semi-milled or wholly milled rice, whether or not polished or glazed	1006 30
Broken rice	1006 40 00
Rice flour	1102 90 50
Rice groats and meal	1103 19 50
Rice pellets	1103 20 50
Flaked rice grains	1104 19 91
Rolled or flaked cereal grains (excluding grains of oats, wheat, rye, maize and barley, and flaked rice)	1104 19 99
Rice starch	1108 19 10
Preparations for infant use, put up for retail sale	1901 10 00
Uncooked pasta, not stuffed or otherwise prepared, containing eggs	1902 11 00
Uncooked pasta, not stuffed or otherwise prepared, not containing eggs	1902 19
Stuffed pasta, whether or not cooked or otherwise prepared	1902 20
Other pasta (other than uncooked pasta, not stuffed or otherwise prepared, and other than stuffed pasta, whether or not cooked or otherwise prepared)	1902 30
Prepared foods obtained by swelling or roasting cereals or cereal products, obtained from rice	1904 10 30
Preparations of the muesli-type based on unroasted cereal flakes	1904 20 10
Prepared foods obtained from unroasted cereal flakes or from mixtures of unroasted cereal flakes and roasted cereal flakes or swelled cereals, obtained from rice (excluding preparations of the muesli-type on the basis of unroasted cereal flakes)	1904 20 95
Rice, pre-cooked or otherwise prepared, not elsewhere specified or included (excluding	1904 90 10

flour, groats and meal, food preparations obtained by swelling or roasting or from unroasted cereal flakes or from mixtures of unroasted cereal flakes and roasted cereal flakes or swelled cereals)	
Ricepaper	ex 1905 90 20
Biscuits	1905 90 45
Extruded or expanded products, savoury or salted	1905 90 55
Bran, sharps and other residues, whether or not in the form of pellets, derived from the sifting, milling or other working of rice with a starch content not exceeding 35 % by weight	2302 40 02
Bran, sharps and other residues, whether or not in the form of pellets, derived from the sifting, milling or other working of rice other than with a starch content not exceeding 35 % by weight	2302 40 08
Peptones and their derivatives; other protein substances and their derivatives, not elsewhere specified or included; hide powder, whether or not chromed	3504 00 00

ANNEX II

Methods of sampling and analysis for official control regarding unauthorised genetically modified organism in rice products originating from China

1. General provisions

Samples intended for the official control for the absence of GM rice in rice products shall be taken according to the methods described in this Annex. The bulk samples thus obtained shall be considered as representative of the lots from which they are taken.

2. Sampling

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

The number of incremental samples which make up the bulk sample and the preparation of the analytical samples shall be made in accordance with Recommendation 2004/787/EC and Regulation (EC) No 152/2009 for feed. The size of the laboratory sample shall be 2,5 kg but may be reduced to 500 grams for processed food or feed. For the purpose of Article 11(5) of Regulation (EC) No 882/2004, a second laboratory sample shall be constituted from the bulk sample.

2.2. Sampling of prepacked food and feed

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 CEN/ISO 15568 or equivalent. The

size of the laboratory sample shall be 2,5 kg but may be reduced to 500 grams for processed food or feed. For the purpose of Article 11(5) of Regulation (EC) No 882/2004, a second laboratory sample shall be constituted from the bulk sample.

3. Analysis of the laboratory sample

The laboratory analysis at the point of origin shall be carried out in a designated AQSIQ laboratory, and prior to release for free circulation in the Union in a Member State designated official control laboratory. Screening tests shall be performed by real-time PCR according to the method published by the EU-RL GMFF[8], for at least the following genetic elements: the CAMV (Cauliflower Mosaic Virus) 35S promoter, the NOS (nopaline synthase) terminator from *Agrobacterium tumefaciens* and the engineered CryIAb, CryIAc and/or CryIAb/CryIAc from *Bacillus thuringiensis*.

In the case of grain samples the designated control laboratory shall take from the homogenised laboratory sample four analytical samples of 240 grams (equivalent 10 000 rice grains). For processed products such as flour, pasta or starch the analytical samples this may be reduced to 125 grams. The four analytical samples shall be ground and further analysed separately. Two extractions shall be made from each analytical sample. One PCR test for each GM genetic element shall be made for each extraction in accordance with the screening methods detailed under point 4 below. The consignment shall be considered non-compliant if at least one GM genetic element is considered detectable in at least one analytical sample of the consignment according to the guidelines provided in the EU-RL report.

4. The following analytical methods shall be used:

(a) For screening for the CAMV (Cauliflower Mosaic Virus) 35S promoter and the NOS (nopaline synthase) terminator from *Agrobacterium tumefaciens*.

ISO 21570: 2005 Methods of analysis for the detection of genetically modified organisms and derived products—quantitative nucleic acid based methods. Annex B1.

H.-U. Waiblinger *et al*., (2008) 'Validation and collaborative study of a P35S and T-nos duplex real-time screening method to detect genetically modified organisms in food products' Eur. Food Res. and Technol., Volume 226, 1221-1228.

E. Barbau-Piednoir *et al*., (2010) 'SYBR®Green qPCR screening methods for the presence of "35S promoter" and "NOS terminator" elements in food and feed products' Eur. Food Res. and Technol Volume 230, 383-393.

Reiting R, Broll H, Waiblinger HU, Grohmann L (2007) Collaborative study of a T-nos real-time PCR method for screening of genetically modified organisms in food products. J Verbr Lebensm 2:116–121.

(b) For screening for the engineered CryIAb, CryIAc and/or CryIAb/CryIAc from *Bacillus thuringiensis*.

E. Barbau-Piednoir *et al.*, (in press) 'Four new SYBR®Green qPCR screening methods for the detection of Roundup Ready®, LibertyLink® and CryIAb traits in genetically modified products' Eur. Food Res. and Technol DOI 10.1007/s00217-011-1605-7.

Following verification of the specificity of the methods by the EU-RL GMFF on a wide variety of Chinese rice samples such method shall be considered as appropriate for these screening purposes.

5. The application of the above screening methods shall take into consideration the guidance document published by the EU RL GMFF.

ANNEX III

MODEL OF HEALTH CERTIFICATE

Header of the authority

Health Certificate for the importation into the European Union of

.....

Consignment Code: ..... **Certificate Number:** .....

According to the provisions of Commission Implementing Decision 2011/884/EU on emergency measures regarding unauthorised genetically modified rice in rice products originating from China and repealing Decision 2008/289/EC

.....
(competent authority referred to in Article 4(1) of Implementing Decision 2011/884/EU)

CERTIFIES that the .....
(insert foodstuffs/feed referred to in Article 1 of Implementing Decision 2011/884/EU)

of this consignment composed of: .....
(description of consignment, product, number and type of packages, gross or net weight)

embarked at .....
(embarkation place)

by .....
(identification of transporter)

going to .....
(place and country of destination)

which comes from the establishment .....
(name and address of establishment)

have been produced, sorted, handled, processed, packaged and transported in line with good hygiene practices.

From this consignment, samples were taken in accordance with Annex II of Implementing Decision 2011/884/EU on ..... (date), subjected to laboratory analysis on ..... (date) in the ..... (name of laboratory), to determine the absence of any unauthorised GM Rice.

The details of sampling, methods of analysis used and all results are attached.

This certificate is valid until .....

Done at: ..... on .....

Stamp and signature of authorised representative of competent authority referred to in Article 4(1) of Implementing Decision 2011/884/EU

ANNEX IV

MODEL OF ANALYTICAL REPORT

Note: please compile an annex form for each sample tested

Parameter to be reported	**Information provided**
Name and address of the test laboratory[a]	
Test report identification code[a]	<<000>>
Laboratory sample identification code[a]	<<000>>
Size of laboratory sample[a]	X kg
In case of sample division: Number and size of analytical samples	X analytical samples of Y g
Number and size of test portions analysed[a]	X test portions of Y mg
Total DNA amount analysed[a]	X ng/PCR
DNA sequence(s) tested for[a]:	For each of the following provide reference to the method used and the average Ct number obtained Rice marker: 35S promoter: NOS terminator: CryIAb/CryIAc:
Other sequence(s) tested for:	Validation status: (e.g. inter-laboratory validated, in-house validated [please indicate according to which standard, guideline]) Description of DNA sequences detected (reference + target genes): Specificity of the method (screening, construct-specific or event-specific): Absolute Limit of Detection (copy number): Practical Limit of Detection (LOD related to the sample analysed), if determined:
Description of positive controls for target DNA, and reference materials[a]	Source and nature of the positive control and reference materials (e.g. plasmid, genomic DNA, CRM …)
Information on the positive control[a]	Please indicate the amount (in ng DNA) of positive control analysed and the average Ct number obtained
Comments	

a Obligatory fields

(**1**) OJ L 31, 1.2.2002, p. 1.

(**2**) OJ L 268, 18.10.2003, p. 1.

(**3**) OJ L 96, 9.4.2008, p. 29.

(**4**) OJ L 348, 24.11.2004, p. 18.

(**5**) OJ L 54, 26.2.2009, p. 1.

(**6**) OJ L 165, 30.4.2004, p. 1.

(**7**) OJ L 194, 25.7.2009, p. 11.

(**8**) http://gmo-crl.jrc.ec.europa.eu