

EXPLANATORY MEMORANDUM TO

THE SPECIFIED PRODUCTS FROM CHINA (RESTRICTION ON FIRST PLACING ON THE MARKET) (ENGLAND) (AMENDMENT) REGULATIONS 2012

2012 No. 47

- 1.** This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

- 2. Purpose of the instrument**

- 2.1** This instrument provides for the implementation in England of the provisions of Commission Implementing Decision 2011/884/EU¹ on emergency measures regarding unauthorised genetically modified (GM) rice in rice products originating from China and repealing Commission Decision 2008/289/EC (“the emergency Decision”). It achieves this by amending the Specified Products from China (First Placing on the Market) (England) Regulations 2008 (“the 2008 Regulations”).

- 3. Matters of special interest to the Joint Committee on Statutory Instruments**

- 3.1** This instrument comes into force on 12 January 2012 to meet the date on which the emergency Decision specifies it must be implemented in Member States. It therefore breaches the Parliamentary 21-day rule. The emergency Decision was published in the Official Journal of the European Union (EU) on 23 December 2011 and did not appear on the EU website until 28 December 2011, greatly restricting the time available to bring the instrument into force.
- 3.2** It is necessary for this instrument to come into force on 12 January 2012 otherwise there would be a gap in import controls between the repeal of Commission Decision 2008/289/EC and the implementation of the emergency Decision. This would mean that Enforcement Authorities would lack the powers necessary to carry out the additional controls required by the emergency Decision presenting the risk of food and animal feed containing unauthorised GM rice entering the UK and being released for free circulation within the EU.

- 4. Legislative Context**

- 4.1** Regulation (EC) No. 1829/2003² stipulates that food and feed containing GM material cannot be placed on the market in the EU unless the associated genetically modified organism has been authorised under the Regulation, following a rigorous safety assessment.

¹ OJ No. L343, 23.12.2012, p.140

² Regulation (EC) No. 1829/2003 on Genetically Modified Food and Feed

- 4.2 The emergency Decision is made under Article 53 of Regulation (EC) No. 178/2002³ (emergency measures for food and feed). It lays down additional controls for the import into the EU of rice and rice products originating in, or consigned from, China for use as food or animal feed with the aim of avoiding the import of such products containing unauthorised GM rice.
- 4.3 This instrument is made under Section 2(2) of the European Communities Act 1972 and implements the emergency Decision by means of amendments to the 2008 Regulations. It provides for an offence of contravening the import restrictions and specifies the penalties that the Courts may impose upon conviction for that offence. It also provides powers for enforcement authorities to recover costs from food and feed business operators, provides for a transitional arrangement and revokes a provision that is now redundant along with the associated offence.

5. Territorial Extent and Application

- 5.1 This instrument applies to England only.
- 5.2 Separate but parallel legislation is being made for Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

- 6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- What is being done and why
- 7.1 In 2006, EU Member States began detecting the presence of the unauthorised GM rice variety ‘Bt63’ in consignments of rice and rice products imported from China. The Commission took matters up with the Chinese authorities and after initial improvement, the situation worsened again in 2007. The Commission therefore brought forward emergency Commission Decision 2008/289/EC requiring additional import controls for consignments of rice and rice products imported from China (“the Bt63 Decision”).
- 7.2 In 2010, Germany identified, and notified via the EU Rapid Alert System for Food and Feed (RASFF), the presence of two new GM rice varieties in imported food (referred to as Kefeng 6 and KMD1) which are not authorised in the EU or China and the Commission wrote to the Chinese authorities raising its concerns. Inspection missions to China by the Commission’s Food and Veterinary Office (FVO) in Autumn 2008 and Spring 2011 indicated uncertainty as to the level, number and type of GM rice varieties which may be circulating in China and consequently that there was a high risk of unauthorised GM rice being present in rice and rice products imported from China.

³ Regulation (EC) No. 178/2002 laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

- 7.3 In the light of the outcomes of the FVO missions, the European Commission brought forward a proposal for emergency import restrictions to replace those set out in the Bt63 Decision. The proposal was agreed by Member States by unanimity at a meeting of the EU Standing Committee on the Food Chain and Animal Health (SCOFCAH) on 14 November 2011 and was published formally in the Official Journal of 23 December 2011 as Commission Implementing Decision 2011/884/EU. It comes into force on 12 January 2012.
- 7.4 The requirements of the emergency Decision are summarised below:
- i. Food and feed business operators must give adequate prior notice of the arrival of consignments falling within the Combined Nomenclature (CN) customs codes listed at Annex I (“relevant consignments”).
 - ii. Relevant consignments must be accompanied by either:
 - An analytical report confirming the absence of GM rice, based on the analytical methods stipulated in Annex II and a health certificate signed and verified by an authorised representative of the Chinese import/export authority; or
 - A statement indicating that the products in the consignment do not contain or consist of rice and have not been produced from rice.
 - iii. Relevant consignments that are not accompanied by the required documentation must be re-dispatched to the country of origin or destroyed.
 - iv. All relevant consignments accompanied by analytical reports and health certificates must be sampled by Enforcement Authorities and analysed in accordance with the methods stipulated in Annex II to ensure the absence of unauthorised GM rice.
 - v. All costs arising from the official controls undertaken must be borne by food and feed business operators.
 - vi. Quarterly reports of the results of analytical tests carried out and the number of consignments rejected due to the absence of the necessary documentation must be submitted to the European Commission to allow it to monitor the effectiveness of the emergency Decision.

8. Consultation outcome

Informal Consultation

- 8.1 The Food Standards Agency (FSA), which has policy responsibility for GM food and animal feed, has consulted informally with interested parties. It has written twice to enforcement and industry partners and their representatives drawing their attention to the emergency Decision and its requirements. The FSA also held a meeting with industry, enforcement and consumer partners on 15 December 2011 to discuss the new legislation, its implementation and its impact.

Formal Public Consultation

8.2 Due to short timeframe within which the emergency Decision is to come into force following its formal publication in the Official Journal of the EU, it has not been possible for the FSA to carry out a formal public consultation. The FSA will carry out a formal public consultation on this instrument and an associated impact assessment as soon as possible and will publish a full summary of comments received in response to the consultation on its website.

9. Guidance

9.1 The FSA has no current plans to issue detailed guidance, but has written to interested parties to alert them to the legislative changes and will produce a Q&A document that includes questions raised at the meeting with interested parties held on 15 December 2011. The FSA will also work with interested parties if any further problems or issues arise.

9.2 The European Union Reference Laboratory for GM Food and Feed (EURL-GMFF) has produced a report on the application of analytical methods for the detection of genetically modified rice originating from China⁴. The emergency Decision requires that regard is given to this document, which is available on the EURL-GMFF website at <http://gmo-crl.jrc.ec.europa.eu/BT63update.htm>.

10. Impact

10.1 Food and feed business operators that import rice or rice products originating in, or consigned from, China will be affected by the emergency Decision and this instrument, as will wholesalers and retailers (including SMEs).

10.2 Operators will need to be aware of the differences between the requirements of the Bt63 Decision and those of the emergency Decision. As such, there will be one-off costs to operators associated with reading and familiarising themselves with the emergency Decision and the amendments this instrument makes to the 2008 Regulations.

10.3 The actual costs incurred by Enforcement Authorities in undertaking the official controls required by the emergency Decision must be borne by food and feed business operators. As such, operators will bear the additional impact arising from the import restrictions set down by the emergency Decision.

10.4 There is no particular impact on charities or voluntary bodies or rural areas. The products which are subject to the emergency Decision may be used extensively by particular ethnic or racial groups. Consequential impact on these groups may therefore arise with regard to product availability.

10.5 Impact on the public sector will fall chiefly on Enforcement Authorities with regard to the submission of the results of the analytical tests they carry out on relevant consignments to the FSA for onward transmission to the Commission on a quarterly basis. A small additional impact on the FSA will also arise in this regard.

⁴ Report on the application of P-35S, T-nos, CryIAb/Ac and rice PLD methods for the detection of genetically modified rice originating from China using real-time PCR

10.6 Due to the short timeframe within which the emergency Decision is to come into force following its publication in the Official Journal of the EU, the FSA has been unable to finalise an Impact Assessment. Following formal public consultation the Impact Assessment will undergo scrutiny by the Regulatory Policy Committee and Reducing Regulation Committee. It will then be submitted for Ministerial signature and published alongside this Explanatory Memorandum on www.legislation.gov.uk.

11. Regulating small business

11.1 The instrument will apply to all businesses small and large.

12. Monitoring & review

Monitoring

12.1 The emergency Decision requires Member States to submit to the Commission a quarterly report of all results of analytical tests carried out during the period to enable them to monitor its effectiveness.

12.2 The Agency will work with Enforcement Authorities where problems or suspected infringements of the legislation arise. The effectiveness of the instrument will be also be monitored via general feedback from industry and Enforcement Authorities on the number of consignments that fail to comply with the Decision.

Statutory Review

12.3 The FSA is required, by virtue of Regulation 3 of this instrument, to carry out a review of the 2008 Regulations, as amended by this instrument, within five years of it coming into force.

12.4 In carrying out the review, the FSA is required to produce a report that sets out the objectives of this instrument, the extent to which they have been achieved and whether they could be achieved by means that impose less regulation. Information gathered via the activities described in paragraphs 12.1 and 12.2 above will inform the review.

13. Contact

13.1 Nasreen Shah at the Food Standards Agency, Tel: 020 7276 8553, E-mail: nasreen.shah@foodstandards.gsi.gov.uk can answer any queries regarding the instrument.