

**EXECUTIVE NOTE TO**

**THE SPECIFIED PRODUCTS FROM CHINA (RESTRICTION ON FIRST PLACING  
ON THE MARKET) (SCOTLAND) REGULATIONS 2008**

**SSI 2008/148**

The above instrument is made under powers conferred by section 2(2) of the European Communities Act 1972(a) and of all other powers enabling them in that behalf. The instrument is subject to negative resolution procedure.

**Issue**

1. These Regulations implement, in Scotland, Commission Decision 2008/289/EC on emergency measures regarding the unauthorised genetically modified organism “Bt 63” in rice products (OJ No.L96, 9.4.2008, p.29) (the Decision). The Decision principally requires that consignments of food or feed products originating, or consigned, from China entering the European Community, which fall under the Combined Nomenclature (CN) Codes (Customs codes) listed at the Annex to the Decision, must be accompanied by an analytical report issued by an official or accredited laboratory demonstrating that they do not contain or consist of, or have not been produced from, the genetically modified rice Bt63. The Decision also sets out rules for dealing with any relevant consignments arriving in the EC without the necessary analytical reports.
2. The Regulations are to come into force on 15 April 2008 and will therefore breach the 21-day rule. The reason for the breach is that whilst the Decision was adopted by Member States on 12 February, it was not formally notified until 3 April and not published in the Official Journal of the European Community until 9 April. The Regulations need to be brought into force on 15 April 2008 to implement the Decision which comes into force on that date. The delay between the Decision’s adoption and its entry into force is to allow Member States time to put arrangements into place to implement the Decision in both legislative and practical terms.

**Legislative Background**

3. The instrument is made and laid under section 2(2) of the European Communities Act 1972.
4. These Regulations implement the Decision in Scotland.

**Extent**

- 5 The Regulations apply to Scotland. Parallel legislation is being made in England, Wales and Northern Ireland.

## **Policy Background**

6. A genetically modified organism may not be placed on the EC market unless it has been authorised under Regulation (EC) No. 1829/2003 on Genetically Modified Food and Feed. Bt63 has not been authorised for placing on the EC market and has been found in rice products originating from China.
7. The presence of Bt63 in rice products from China first became known in September 2006. The European Commission (the Commission) had worked with the Chinese authorities to ensure that products exported from China complied with EC requirements and subsequent sampling results indicated that the relevant controls were working. However, in February 2007, Bt63 was again detected in rice products and has been detected in subsequent samples.
8. The Commission is of the view that the Chinese competent authorities have been unable to provide sufficient guarantees of the absence of Bt63 in food and feed products originating, or consigned, from China and, as such, has decided to put measures in place to prevent products containing, consisting of, or produced from, Bt63 entering the EC.
9. The Decision requires the Commission to have undertaken a review of its policy by 15 October 2008 at the latest.
10. A short public consultation on the draft statutory instrument was carried out in Scotland between 7 and 14 March. The consultation package was sent to known stakeholders, including enforcement authorities, by email and was also published on the FSA's website. 6 responses were received from stakeholders, which focused mainly on practical arrangements or issues connected with the implementation of the legislation rather than the necessity for, or provisions of, the draft statutory instrument or draft Commission Decision. A summary of the responses to the consultation will be published on the FSA's website. Responses from stakeholders to similar consultations conducted by the FSA offices in England, Wales and Northern Ireland raised points along the same lines and were also taken into consideration.
11. In addition to the consultation, letters have been sent by e-mail to stakeholders, including enforcement authorities, to alert them to the draft Decision and to provide them with guidance on its likely effects and preparations for its implementation. Given the requirements set out in the Decision, the FSA's guidance has been focused on enforcement issues and practicalities. The letters to enforcement authorities have been published on the FSA website, which is the convention for all such letters. The FSA will inform stakeholders of the making of the Regulations by e-mail and via its website and will issue further advice and guidance to stakeholders as necessary.

## **Impact**

12. The Decision and hence the Regulations will be relevant to only a small proportion of food and feed consignments which enter Scotland.

13. A Regulatory Impact Assessment has been prepared for this instrument, and is attached.

**FOOD STANDARDS AGENCY SCOTLAND**

**10 April 2008**

Contact:

Karen McCallum-Smith, Food Standards Agency, St Magnus House, 25 Guild Street, Aberdeen,  
AB11 6NJ

Tel: 01224 285164

[Karen.mccallum-smith@foodstandards.gsi.gov.uk](mailto:Karen.mccallum-smith@foodstandards.gsi.gov.uk)

[www.food.gov.uk](http://www.food.gov.uk)

## **Final Regulatory Impact Assessment (RIA)**

### **1. The Specified Products from China (Restriction on First Placing on the Market) (Scotland) Regulations 2008**

1.1. Unauthorised genetically modified rice “Bt63” in food or animal feed originating, or consigned, from China may be being imported into the European Community (EC). The European Commission (the Commission) has adopted Commission Decision 2008/289/EC, to require an analytical report demonstrating that products do not contain or consist of, or have not been produced from, Bt63 to accompany relevant consignments. The Decision is being implemented in Scotland by The Specified Products from China (Restriction on First Placing on the Market) (Scotland) Regulations 2008.

### **2. Purpose & intended effect**

#### **2.1 The Objectives**

2.1.1. The policy objective is to prevent food or feed products containing the unauthorised genetically modified rice Bt63 in food or animal feed being placed on the market in Scotland. Food and feed products originating or consigned from China may only be placed on the market in Scotland if:

**a.** they are accompanied by an analytical report issued by an official or accredited laboratory demonstrating that the product does not contain Bt63, OR

**b.** satisfactory results of analysis are received by the food authority at the point of entry to the community, following sampling carried out by or under the supervision of that authority.

#### **2.2. Devolution**

2.2.1. The proposed Regulations will apply in Scotland only. England, Wales and Northern Ireland will make separate but parallel legislation.

#### **2.3. Background**

2.3.1. The presence of Bt63 in rice products from China first became known in September 2006. The Commission had worked with the Chinese authorities to ensure that products exported from China complied with EC requirements and subsequent sampling results indicated that the relevant controls were working. However, in February 2007, Bt63 was again detected in rice products. Detection of Bt63 in subsequent samples has resulted in the Commission’s decision to put measures in place.

- 2.3.2. A risk assessment has not been carried out by the European Food Safety Authority (EFSA) as insufficient data are available. The Food Standards Agency (FSA) considers that this unauthorised GM material should be considered "unsafe" within the meaning of that term in Article 14 of Regulation (EC) 178/2002 (General Food Law) which means that food business operators should inform enforcement authorities if such products have left their possession, initiate procedures under Article 19 to withdraw them and to recall them if they have reached consumers. The FSA has issued a Food Alert requesting that enforcement authorities take action. The FSA is not, at the moment, aware of any specific health implications for consumers who eat rice products containing Bt63.
- 2.3.3. The legislation will be relevant only to a small proportion of food and feed consignments which enter Scotland.

#### **2.4. Rationale for Government intervention**

- 2.4.1. Bt63 is a genetically modified organism which is not authorised in the EC under Regulation (EC) No. 1829/2003 on Genetically Modified Food and Feed and has been found in rice products originating from China. The Commission is of the view that the Chinese competent authorities have been unable to provide sufficient guarantees of the absence of Bt63 in rice and rice products originating, or consigned, from China and has decided to put additional measures in place to prevent rice products containing Bt63 being placed on the EC market.
- 2.4.2. The Specified Products from China (Restriction on First Placing on the Market) (Scotland) Regulations 2008 will implement Decision 2008/289/EC in Scotland and similar legislation will implement the Decision in England, Wales and Northern Ireland.

### **3. Consultation**

- 3.1.1. A short public consultation on the draft statutory instrument relating to Scotland was carried out between 7 and 14 March 2008. The consultation package was sent to known stakeholders, including enforcement authorities, by email and was also published on the FSA's website.
- 3.1.2. Six responses were received to the consultation, these focusing mainly on practical arrangements or issues connected with the implementation of the legislation rather than the necessity for, or provisions of, the draft statutory instrument or the draft Commission Decision. Responses to consultations conducted by the FSA offices in England, Wales and Northern Ireland raised points along the same lines which were also taken into consideration. The FSA continues to address concerns raised, through the issue of further advice and guidance to enforcement authorities and other stakeholders. A summary of the responses to the consultation will be published on the FSA's website.

## **4. Options**

### **4.1. National legislation to implement Commission Decision 2008/289/EC**

4.1.1 The only options being considered are:

- i. Option 1 - do nothing; or
- ii. Option 2 - make national legislation to implement Commission Decision 2008/289/EC.

### **4.1.2. Analysis of options**

- i. Option 1 (doing nothing) would expose the UK to the possibility of infraction proceedings by the Commission and also do nothing to minimise the known risk of an unauthorised genetically modified organism being placed on the market in Scotland in food and feed products.
- ii. Option 2 would prevent an unauthorised GM organism being placed on the market and, hence, offences under food and feed law being committed.

## **5. Costs and benefits**

### **5.1. Sector and groups affected**

5.1.1. The food and feed industry, food and feed authorities, and consumers.

5.1.2. We consider that the proposal will have no impact on racial equality, social or environmental issues.

### **5.2. Costs and Benefits**

#### **Costs**

#### Option 1

5.2.1. Doing nothing would expose the UK to the possibility of infraction proceedings by the European Commission and also do nothing to minimise the known risk of an unauthorised genetically modified organism being placed on the market in Scotland in food and feed products.

#### Option 2

5.2.2. For food/feed businesses: Any costs to ensure that analytical reports or statements accompany relevant consignments. Costs of sampling and analysis in respect of any relevant consignments reaching Scotland without analytical reports and of storing such consignments pending sampling and analysis. The FSA considers reporting any positive results of sampling and analysis to the FSA to have no incremental cost, as companies would be expected to perform this procedure as standard commercial practice.

- 5.2.3. For food/feed authorities: Costs of any additional sampling and analysis which cannot be recovered from food business operators under food or feed law. Costs associated with supervising any sampling and analysis undertaken by food business operators in respect of any relevant consignments arriving in Scotland without analytical reports. These may have a higher initial cost due to consignments shipped before the Commission decision, but which have yet to arrive in the UK. Associated administrative procedures to ensure that consignments are accompanied by relevant and valid documentation and to enable food business operators to secure release of their consignments from Her Majesty's Revenue and Customs (HMRC) will result in a slight increase in administrative costs.
- 5.2.4. For consumers: None identified.

### **Benefits**

#### Option 1

- 5.2.5. There would be no additional sampling or analysis costs, or costs to ensure reports or statements accompany consignments.

#### Option 2

- 5.2.6. Food/feed businesses: Prevention of an unauthorised GM organism being placed on the market and, hence, offences under food or feed law being committed and resulting in prosecutions. Analytical reports decrease the likelihood of delays in processing relevant consignments of food / feed at ports and also the detention, seizure and destruction of food and feed due to the presence of Bt63, and associated costs.
- 5.2.7. Food/feed authorities: Enforcement activity is facilitated by analytical reports, or statements confirming no rice products present, accompanying relevant consignments. Decreased likelihood of unauthorised GM organism being placed on the market and, hence, offences under food or feed law being committed and the need to bring prosecutions.
- 5.2.8. Consumers: Decreased likelihood of an unauthorised GM organism being supplied to consumers.

### **Small Firms Impact Test**

- 6.1. No specific impact on small firms has been identified. However, the Federation of Small Businesses was included in the consultation on these proposed draft Regulations. No concerns were raised during the consultation process.

## **7. Test Run of Business Forms**

- 7.1 No new or additional forms will be introduced.

## **8. Competition Assessment**

8.1. The proposals are not expected to distort competition. No concerns were raised during the consultation process.

## **9. Enforcement, sanctions and monitoring**

9.1. Enforcement will be carried out by the relevant food and feed authorities. These authorities will ensure compliance with the Decision and the national legislation. They will use powers granted by the national legislation and, in the main, existing powers which they generally use in relation to the control of unauthorised GM material provided by the Official Feed and Food Controls (Scotland) Regulations 2007 (the OFFC Regulations) and Regulation (EC) No. 882/2004 on official feed and food controls, the General Food Regulations 2004 and the Food Safety Act 1990.

## **10. Implementation and delivery plan**

10.1.1 The Decision and the national Regulations will come into force at 00.01 on 15 April 2008.

10.1.2 From this date, consignments of rice and rice products (including composite products) originating, or consigned, from China which fall within the Combined Nomenclature (CN) Codes (Customs Codes) set out in the Annex to the Decision must be accompanied by an analytical report demonstrating that they do not contain, consist of, or have been produced from, the unauthorised genetically modified organism “Bt63” rice. Where consignments falling within the relevant CN Codes do not contain such rice or rice products, a statement from the operator responsible for the consignment confirming that this is the case may accompany the consignment instead of the report.

10.1.3 In the event of a relevant consignment arriving without an analytical report, a food or feed business operator will be required to have the products tested before they can be placed on the market. In this eventuality, samples will be taken by, or under the supervision of, the relevant authority. If subsequently Bt63 is detected in such a consignment, it will be rejected under the provisions of Regulation (EC) 882/2004 through service of a Notice under Regulation 30 of the OFFC Regulations.

10.1.4 The Decision recommends that bulk consignments of rice should be sampled in accordance with Commission Recommendation 787/2004, resulting in a composite sample of 2.5kg that is sent for testing. The Decision defines the method to be followed by the analyst i.e. the construct-specific method developed by D Mäde *et al.*

10.1.5 HMRC has established a national profile on their CHIEF system to prevent consignments consigned from China falling within the CN codes stated in the Regulation from being cleared until necessary checks have been carried out. Consignments will be designated ‘Route 1’ which means that the analytical report, endorsed by the food or feed authority, will be required to be submitted by the importer to HMRC in order to obtain release.

10.1.6 The report, endorsed by the food or feed authority, will be provided to the importer (or their agent) who will be advised to provide a copy of this to HMRC alongside their Customs entry paperwork in the normal manner. HMRC will accept facsimile copies of endorsed analytical reports from importers, but may carry out random checks to verify the documents submitted are valid.



- 10.1.7 Any positive results from sampling activity are required to be notified to the European Commission immediately through the Rapid Alert System for Food and Feed (RASSF) system. Positive results reported to the FSA by industry will also be notified in this way.
- 10.1.8 Information on negative results obtained from official sampling activity is to be reported to the Commission on a 3-monthly basis. This information will be used to inform the Commission in its policy review, which will have taken place by 15 October 2008 at latest.
- 10.1.9 In anticipation of the coming into force of the legislation, food and feed authorities are being asked to monitor manifest information and obtain information from importers (or their agents) to identify inbound consignments due to arrive on or after 15 April 2008 to be controlled.

## **11. Post-implementation review**

The Decision requires the European Commission to reassess its policy by 15 October 2008 at the latest. In line with Scottish Government guidance we will review the continued effectiveness of this Regulation by the use of a Review Regulatory Impact Assessment that will be completed within 10 years.

## **12. Summary and Recommendation**

The proposed Regulations would ensure compliance with Community legislation and decrease the likelihood of rice products containing the unauthorised GM organism being placed on the market.

## **13. Declaration and publication**

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs.

Signed: **SHONA ROBISON**

Date: **14 April 2008**