

EXPLANATORY MEMORANDUM TO
THE SPECIFIED PRODUCTS FROM CHINA (RESTRICTION ON FIRST
PLACING ON THE MARKET) (ENGLAND) REGULATIONS 2008

2008 No. 1079

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. **Description**

- 2.1 The Regulations implement, in England, 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 report.

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

- 3.1 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 Communities 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.

4. **Legislative Background**

- 4.1 The Regulations are made and laid under section 2(2) of the European Communities Act 1972.
- 4.2 The Regulations implement the Decision in England.

5. **Extent**

- 5.1 This instrument applies to England.
- 5.2 There will be separate, parallel, legislation in Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

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

7. Policy Background

- 7.1 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. The genetically modified rice Bt63 has not been authorised for placing on the EC market and has been found in rice products originating from China.
- 7.2 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.
- 7.3 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 additional measures in place to prevent products containing, consisting of, or produced from, Bt63 entering the EC.
- 7.4 The Decision requires the Commission to have undertaken a review of its policy by 15 October 2008 at the latest.
- 7.5 A short public consultation on the draft statutory instrument was carried out in England between 7 and 14 March. The consultation package was sent to known stakeholders, including enforcement authorities, by e-mail and was also published on the FSA's website. 7 responses were received from stakeholders, which focussed 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 has been published on the FSA's website. Responses from stakeholders to similar consultations conducted by the FSA offices in Scotland, Wales and Northern Ireland in those parts of the UK raised points along the same lines which were also taken into consideration.
- 7.6 In addition to the consultation, letters have been sent by e-mail to stakeholders, including enforcement authorities, to alert them to the 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 focussed 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.

8. Impact

- 8.1 The Decision and hence the Regulations will be relevant to only a small proportion of food and feed consignments which enter England.
- 8.2 An Impact Assessment has been prepared for this instrument and is attached.

9. Contact

Any enquiries about the contents of this memorandum should be addressed to: Dr Trudy Netherwood, GM Labelling and Food Supplements Branch, Novel Foods, Additives and Supplements Division, Food Standards Agency, e-mail: trudy.netherwood@foodstandards.gsi.gov.uk, telephone: 020 7276 8592.

Summary: Intervention & Options

Department/Agency: Food Standards Agency	Title: Impact Assessment of The Specified Products from China (Restriction on First Placing on the Market) (England) Regulations 2008	
Stage: Final	Version: 8	Date: 10 April 2008
Related Publications: 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)		

Available to view or download at:

Regulations: <http://www.opsi.gov.uk/si/si-2008-index>

Decision: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:096:0029:0034:EN:PDF>

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What is the problem under consideration? Why is government intervention necessary?

Unauthorised genetically modified rice "Bt63" in food or animal feed originating, or consigned, from China being imported into the European Community. The European 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 England, by The Specified Products from China (Restriction on First Placing on the Market) (England) Regulations 2008.

What are the policy objectives and the intended effects?

The policy objective is to prevent food or feed products containing the unauthorised genetically modified rice Bt63 from feed being placed on the market in England. Food and feed products originating, or consigned, from China may only be placed on the market in England if (a) they are accompanied by an analytical report issued by an official or accredited laboratory demonstrating they do not contain, consist of, or have not been produced from Bt63 or (b) satisfactory results of analysis are received by the food or feed authority at the point of entry into England, following sampling carried out by, or under the supervision of, that authority.

What policy options have been considered? Please justify any preferred option. [max 430 characters]

1. National legislation relating to England to implement Commission Decision 2008/289/EC.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? The Decision requires the European Commission to reassess its policy by 15 October 2008 at the latest.

Ministerial Sign-off For final stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

Dawn PrimaroloDate: **14th April 2008**

Summary: Analysis & Evidence

Policy Option: 1

Description: National Legislation to Implement Decision 2008/XXX/EC

COSTS	ANNUAL COSTS		Description and scale of key monetised costs by 'main affected groups'
	One-off (Transition)	Yrs	
	£		Food Business Operators Port Health Authorities Local Authorities
	Average Annual Cost (excluding one-off)		
	£ Not known		Total Cost (PV) £ Not known
Other key non-monetised costs by 'main affected groups'			

BENEFITS	ANNUAL BENEFITS		Description and scale of key monetised benefits by 'main affected groups'
	One-off	Yrs	
	£		Food Business Operators Consumers
	Average Annual Benefit (excluding one-off)		
	£ Not known		Total Benefit (PV) £ Not known
Other key non-monetised benefits by 'main affected groups'			

Key Assumptions/Sensitivities/Risks

Price Base Year	Time Period Years	Net Benefit Range (NPV) £ Not Known	NET BENEFIT (NPV Best estimate) £ Not known
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What is the geographic coverage of the policy/option?	England			
On what date will the policy be implemented?	15 April 2008			
Which organisation(s) will enforce the policy?	LAs & PHAs			
What is the total annual cost of enforcement for these organisations?	£			
Does enforcement comply with Hampton principles?	Yes			
Will implementation go beyond minimum EU requirements?	No			
What is the value of the proposed offsetting measure per year?	£			
What is the value of changes in greenhouse gas emissions?	£			
Will the proposal have a significant impact on competition?	Not Known			
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices)		(Increase - Decrease)	
Increase of	£ Zero	Decrease of	£ Zero
		Net Impact	£ Zero

Key: Annual costs and benefits: Constant Prices (Net) Present Value

Evidence Base (for summary sheets)

Reason for Intervention

Bt63 rice is a genetically modified (GM) organism which is not authorised in the European Community (EC) under Regulation (EC) No. 1829/2003 on Genetically Modified Food and Feed and has been found in rice products originating from China. The European Commission (the Commission) is of the view that the Chinese competent authorities have been unable to provide sufficient guarantees of the absence of Bt63 from food or feed products originating, or consigned, from China and, as such, has decided to put additional measures in place to prevent food or feed products consisting or containing or produced from Bt63 from being placed on the EC market.

Intended effect

The intended effect of the measures is to prevent food or feed products originating, or consigned, from China containing, consisting of, or produced from, Bt63 from being placed on the market in England.

Background

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.

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. As such 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.

The legislation will be relevant to only a small proportion of food and feed consignments which enter England.

Options

The only option being considered is to implement Decision 2008/289/EC. Not to do so would expose the UK to the possibility of infraction proceedings by the Commission and would also do nothing to minimise the known risk of an unauthorised genetically modified organism being placed on the market in England in food and feed products.

Costs and benefits of options

Benefits to 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 report decreases 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.

Costs to 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 England without analytical reports and of storing such consignments pending sampling and analysis.

Benefits to 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.

Costs to food / feed authorities: Costs of any addition sampling and analysis which cannot be recovered from food business operators under food or feed law.

Benefits to consumers: Decreased likelihood of an unauthorised GM organism being supplied to consumers.

Administrative Burden Costs

Costs to food / feed businesses: 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.

Costs to food / feed authorities: Costs associated with supervising any sampling and analysis undertaken by food business operators in respect of any relevant consignments arriving in England without analytical reports. These may have a higher initial cost due to consignments shipped pre Commission decision 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.

Consultation

A short public consultation on the draft statutory instrument relating to England was carried out between 7 and 14 March 2008. The consultation package was sent to known stakeholders, including enforcement authorities, by e-mail and was also published on the FSA's website. There were 7 responses to the consultation, these focussing 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. 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 has been published on the FSA's website. Responses from stakeholders to similar consultations conducted by the FSA offices in Scotland, Wales and Northern Ireland in those parts of the UK raised points along the same lines which were also taken into consideration.

Enforcement

Enforcement will be carried out by Port Health Authorities (PHAs) and Local Authorities (LAs). These food and feed 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 (England) 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.

Simplification

None.

Implementation and Review

The Decision and the national legislation will come into force at 00.01 on 15 April 2008. From then, 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 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.

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.

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.*

HMRC has established a national profile on their CHIEF system to prevent consignments consigned from China falling within the CN codes listed in the Annex to the Decision 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.

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.

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.

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 the latest.

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.

Specific Impact Tests: Checklist

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
Competition Assessment	Yes/No	Yes/No
Small Firms Impact Test	Yes/No	Yes/No
Legal Aid	Yes/No	Yes/No
Sustainable Development	Yes/No	Yes/No
Carbon Assessment	Yes/No	Yes/No
Other Environment	Yes/No	Yes/No
Health Impact Assessment	Yes/No	Yes/No
Race Equality	Yes/No	Yes/No
Disability Equality	Yes/No	Yes/No
Gender Equality	Yes/No	Yes/No
Human Rights	Yes/No	Yes/No
Rural Proofing	Yes/No	Yes/No

Annexes

Competition Assessment

N/A

Small Firms Impact Test

N/A

Sustainable development

N/A

Race equality issues

N/A

Gender equality issues

N/A

Disability equality issues

N/A