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STATUTORY INSTRUMENTS

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**2008 No.**

**AGRICULTURE, ENGLAND**

**FOOD, ENGLAND**

**The Rice Products from China (Restriction on First Placing on the Market) (England) Regulations 2008**

<i>Made</i> - - - -	2008
<i>Laid before Parliament</i>	2008
<i>Coming into force</i> - -	15th April 2008

The Secretary of State makes the following Regulations in exercise of the powers conferred on him by section 2(2) of the European Communities Act 1972 (a).

The Secretary of State has been designated for the purpose of that section in relation to measures relating to food (including drink) including the primary production of food and measures relating to feed produced for or fed to food-producing animals(b).

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council 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(c) there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

**Title, application and commencement**

1. These Regulations may be cited as the Rice Products from China (Restriction on First Placing on the Market) (England) Regulations 2008, apply in relation to England only and come into force on 15th April 2008.

**Interpretation**

2.—(1) In these Regulations—  
“the Agency” means the Food Standards Agency;  
“authorised officer”, in relation to a feed authority or a food authority, means any person (whether or not an officer of the authority) who is authorised by it in writing, either generally or specially, to act in matters arising under these Regulations;

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(a) 1972 c. 68.  
(b) SI 2003/2901.  
(c) OJ No. L31, 1.2.2002, p.1, as last amended by Commission Regulation (EC) No. 575/2006 amending Regulation (EC) No. 178/2002 of the European Parliament and of the Council as regards the number and names of the permanent Scientific Panels of the European Food Safety Authority (OJ No. L100, 8.4.2006, p.3).

“the Commission Decision” means Commission Decision [ ] on emergency measures regarding the unauthorised genetically modified organism “Bt 63” in rice products(a) ;

“feed” has the meaning given to it in Article 3.4 of Regulation 178/2002;

“feed authority” means the authority required by section 67(1) of the Agriculture Act 1970(b) to enforce that Act within its area or as the case may be district;

“food” has the meaning given to it in Article 2 of Regulation 178/2002;

“first placing on the market” has the meaning that it bears in the Commission Decision;

“food authority” has the meaning that it bears by virtue of section 5(1) of the Food Safety Act 1990(c) except that it does not include the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner and Middle Temple);

“rice product” means any rice product listed in the Annex to the Commission Decision that originates from or has been consigned from China; and

“Regulation 178/2002” means Regulation (EC) No. 178/2002 of the European Parliament and of the Council 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.

(2) Where any functions under the Food Safety Act 1990 are assigned—

- (a) by an order under section 2 or 7 of the Public Health (Control of Disease) Act 1984(d), to a port health authority;
- (b) by an order under section 6 of the Public Health Act 1936(e), to a joint board for a united district; or
- (c) by an order under paragraph 15(6) of Schedule 8 to the Local Government Act 1985(f), to a single authority for a metropolitan county,

any reference in these Regulations to a food authority shall be construed, so far as relating to those functions, as a reference to the authority to whom they are so assigned.

### **Restriction on first placing on the market of rice products**

3.—(1) The first placing on the market of any rice product is prohibited unless—

- (a) the conditions specified in paragraphs (1), (2) and (4) and the second and third sentences of paragraph (3) of Article 2 of the Commission Decision are complied with in relation to that product; and
- (b) arrangements have been made to ensure compliance with the condition specified in the first sentence of paragraph (3) of Article 2 of that Decision in relation to that product.

(2) Any person who knowingly contravenes the prohibition in paragraph (1) is guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale, to imprisonment for a term not exceeding three months or to both.

### **Notification of positive results**

4.—(1) An operator who becomes aware of a positive result of a test for the presence of the genetically modified rice “Bt 63” in a rice product that is under his control shall inform the Agency of that result immediately.

(2) Any person who without reasonable excuse fails to comply with the obligation in paragraph (1) is guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale, to imprisonment for a term not exceeding three months or to both.

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(a) OJ No. [ ] .

(b) 1970 c. 40.

(c) 1990 c.16.

(d) 1984 c.22; section 7(3)(d) was substituted by paragraph 27 of Schedule 3 to the Food Safety Act 1990.

(e) 1936 c.49; section 6 is to be read with paragraph 1 of Schedule 3 to the Food Safety Act 1990.

(f) 1985 c.51; paragraph 15(6) was amended by paragraph 31(b) of Schedule 3 to the Food Safety Act 1990.

## Enforcement

5.—(1) It shall be the duty of each feed authority to execute and enforce these Regulations within its area or as the case may be district in relation to feed.

(2) It shall be the duty of each food authority to execute and enforce these Regulations within its area in relation to food.

(3) For the purposes of enabling the feed authority to exercise its duty under paragraph (1) and the food authority to exercise its duty under paragraph (2), an authorised officer of the authority concerned shall ensure that the requirements referred to in paragraph (4) are adhered to.

(4) The requirements are those specified in –

- (a) Article 2 of the Commission Decision (which is concerned with the conditions under which consignments of rice products may first be placed on the market);
- (b) the first sentence of Article 3 of that Decision (which is concerned with control measures relating to rice products already on the market); and
- (c) Article 4 of that Decision (which is concerned with contaminated consignments).

(5) Each feed authority and each food authority shall give such assistance and information to the Secretary of State and the Agency as they may reasonably request in connection with the execution and enforcement of these Regulations.

## Application of various provisions of the Food Safety Act 1990

6. The following provisions of the Food Safety Act 1990 shall apply for the purposes of these Regulations with the modification that any reference in those provisions to that Act or Part thereof shall be construed as a reference to these Regulations —

- (a) section 20 (offences due to fault of another person);
- (b) section 21 (defence of due diligence)(**a**), with the modification that subsections (2) to (4) shall apply in relation to an offence under regulation 3(2) as they apply in relation to an offence under section 14 or 15, that in subsections (2)(a) and (3)(b) the references to “food” shall be deemed to be references to feed or food and that in subsection (4)(b) the references to “sale or intended sale” shall be deemed to be references to “first placing on the market”;
- (c) section 32 (powers of entry), with the modification that in subsection (1) the reference to “an enforcement authority” shall be deemed to be a reference to a feed authority or a food authority, the references to “the authority’s area” shall be deemed to be references to the authority’s area or as the case may be district and the reference to “a food authority” shall be deemed to be a reference to a feed authority or a food authority;
- (d) section 33(1) (obstruction etc. of officers);
- (e) section 33(2), with the modification that the reference to “any such requirement as is mentioned in subsection (1)(b) above” shall be deemed to be a reference to any such requirement as is mentioned in section 33(1)(b) as applied by sub-paragraph (d);
- (f) section 35(1) (punishment of offences)(**b**), in so far as it relates to offences under section 33(1) as applied by sub-paragraph (d);
- (g) section 35(2) and (3)(**c**), in so far as it relates to offences under section 33(2) as applied by sub-paragraph (e);
- (h) section 36 (offences by bodies corporate);
- (i) section 36A (offences by Scottish partnerships)(**d**); and

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(a) Section 21 was amended by S.I. 2004/3279.

(b) Section 35(1) is amended by the Criminal Justice Act 2003 (2003 c. 44), Schedule 26, paragraph 42, from a date to be appointed.

(c) Section 35(3) was amended by S.I. 2004/3279.

(d) Section 36A was inserted by the Food Standards Act 1999 (1999 c. 28), Schedule 5, paragraph 16.

- (j) section 44 (protection of officers acting in good faith), with the modification that the references to “food authority” shall be deemed to be references to feed authority or food authority.

Signed by authority of the Secretary of State for Health

Date

*Name*  
Minister of State,  
Department of Health



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,  
C(2008)

final

Draft

**COMMISSION DECISION**

of

**on emergency measures regarding the unauthorised genetically modified  
organism "Bt 63" in rice products**

**(Text with EEA relevance)**

(Memorandum from Mr M. KYPRIANOU)

tabled at  
SCSFEAH  
12/2/08 pm.

Draft

## COMMISSION DECISION

of

**on emergency measures regarding the unauthorised genetically modified organism "Bt 63" in rice products**

**(Text with EEA relevance)**

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) 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<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. 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 from China contaminated with the unauthorised genetically modified rice "Bt 63" were discovered in the United Kingdom, France and Germany and notified to the Rapid Alert System for Food and Feed (RASFF).
- (3) The Chinese competent authorities were immediately requested to provide detailed information concerning the genetic constructs of the unauthorised genetically modified rice "Bt 63". Explanations were also requested as regards the origin of the presence on

<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. Regulation as amended by Commission Regulation (EC) No 1981/2006 (OJ L 368, 23.12.2006, p. 99)

the Chinese market of genetically modified rice and the way the Chinese competent authorities intended to ensure that exported products complied with Community requirements. In response, the Chinese authorities conducted checks on the cases notified in the RASFF and suspended exports by the enterprises concerned. They also decided to carry out testing on exported rice and rice products and required exporting enterprises to strengthen controls over raw material purchasing. Furthermore, information was provided to the Commission concerning the overall situation of GM rice in the Chinese market and the Bt genetic construct concerned, confirming that the genetically modified rice "Bt 63" is not authorised on the Chinese market.

- (4) The Member States were immediately informed of the situation during the meetings of the Standing Committee on the Food Chain and Animal Health held on 11 September and 23 October 2006. Member States and operators were also reminded in writing of their obligations to ensure that no unauthorised GMO is placed on the EU market.
- (5) After several findings of the unauthorised genetically modified rice "Bt 63" were notified through the RASFF in the period between September and October 2006, the flow of rapid alerts stopped, supporting the presumption that the measures taken by the Chinese authorities were effective.
- (6) In February 2007, a new finding of the unauthorised genetically modified rice "Bt 63" was once again notified through the RASFF. This new alert concerned a shipment of rice protein concentrate for feed use which reached Greece via the Netherlands. The shipment in question left China on 20 December 2006, thus after the implementation of the control measures by the Chinese authorities. Informed by the Commission of this new alert and requested by it to provide additional guarantees, the Chinese authorities decided to strengthen the sampling and testing of rice products and required rice products to be accompanied by an official Chinese Inspection and Quarantine Certificate. The Standing Committee on the Food Chain and Animal Health was informed on 2 March 2007.
- (7) Notwithstanding the measures announced by the Chinese authorities, several other alerts concerning the presence of the unauthorised genetically modified rice "Bt 63" were subsequently reported until late November 2007.
- (8) Despite reiterated requests by the Commission, the Chinese authorities were unable to provide the Commission's Joint Research Centre (JRC) with control samples and a protocol of a detection method that were qualitatively and quantitatively appropriate for the JRC to validate the detection method used by the Chinese control authorities.
- (9) Considering the failure of the Chinese competent authorities to provide sufficient guarantees of the absence of the unauthorised genetically modified rice "Bt 63" in rice products originating from China and without prejudice to the control obligations of the Member States, measures should be adopted to ensure a comprehensive and common approach allowing rapid and effective action to be taken and avoiding disparities between the treatment of the situation by the various Member States.
- (10) 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.

- (11) Since the genetically modified rice "Bt 63" is not authorised under Community legislation and in view of the presumption of risk attached to products not authorised according to Regulation (EC) No 1829/2003, which takes into account the precautionary principle laid down in Article 7 of Regulation (EC) No 178/2002, emergency measures should be taken to prevent the contaminated products being placed on the Community market.
- (12) According to the general requirements laid down in Regulation (EC) No 178/2002, food and feed business operators have primary legal responsibility for ensuring that foods or feeds within the businesses under their control satisfy the requirements of food law and for verifying that such requirements are met. It is, therefore, the operator responsible for first placing food and feed on the market who should be under the duty to prove that they do not contain the contaminated products. To that end, the measures provided for in this Decision should require that consignments of specific products originating from China may be placed on the market only if an analytical report is provided demonstrating that the products are not contaminated with the unauthorised genetically modified rice "Bt 63". The analytical report should be issued by an accredited or official laboratory conforming to internationally recognised standards. In the case of an analytical report issued by an accredited laboratory it seems appropriate to foresee that this report is endorsed by the relevant competent authority.
- (13) Due to the lack of a validated detection method and control samples of adequate quality and quantity - and in order to facilitate controls - the analytical report should be issued using the construct-specific method developed by D. Mäde et al. (2006)<sup>3</sup>. The Community Reference Laboratory for Genetically Food and Feed (CRL-GMFF) within the Joint Research Centre (JRC) judged this method to be currently the most appropriate one.
- (14) For the purpose of the sampling and detecting activities required in order to prevent that products contaminated with the unauthorised genetically modified rice "Bt 63" are placed on the market, account should be taken of the 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<sup>4</sup>. *Modified*
- (15) The measures provided for in this Decision must be proportionate and no more restrictive of trade than is required and should therefore cover only products originating in or consigned ~~imported~~ from China into the Community and considered likely to be contaminated with the unauthorised genetically modified rice "Bt 63". Given the huge variety of products that could be contaminated with the unauthorised genetically modified rice "Bt 63", it seems appropriate to target a long list of products which could contain, consist or be produced from rice. Some of the identified products, however, may or may not be containing, consisting or produced from rice. It seems therefore proportionate to allow the operators to issue a simple declaration

<sup>3</sup> Eur. Food Res. Technol, 224:271-278 (2006).

<sup>4</sup> OJL 348, 24.11.2004, p.18

when the product is not containing, consisting or produced from rice, thus avoiding the compulsory analysis and certification.

- (16) The situation concerning the possible contamination of rice product with the unauthorised GM rice Bt63 should be reviewed within six months in order to assess whether the measures provided for in this Decision are still necessary.
- (17) It is appropriate to foresee a reasonable period of time between the entry into force and the date of applicability of this Decision, in order to allow the Member States take the practical arrangements for its implementation.
- (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 applies to the food and feed products listed in the Annex, originating in or consigned from China.

*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 where an original analytical report<sup>(2)</sup> based on the construct-specific method developed by D. Mäde et al., for detection of the genetically modified rice "Bt 63", issued by an official or accredited laboratory and accompanying the consignment demonstrates that the product does not contain the genetically modified rice "Bt 63".
2. ~~2.~~ In the case of an analytical report issued by <sup>a Chinese</sup> ~~an~~ accredited laboratory, the analytical report shall be endorsed by the relevant competent authority.
3. ~~2.~~ If a consignment of products referred to in Article 1 is split, a certified copy of the analytical report shall accompany each part of the split consignment. In the absence of an analytical report as referred to in paragraph 1, the operator established in the Community who is responsible for the first placing on the market of the product shall have the products referred to in Article 1 tested to demonstrate that they do not contain the genetically modified rice "Bt 63". Pending availability of the analytical report, the consignment shall not be placed on the Community market.

<sup>5</sup> The analytical report shall be drawn up in a language understood by the certifying officer, enabling the certifying officer to be fully aware of the significance of the contents of each analytical report he signs and in a language understood by the control official of the country of import

[ie The person signing the report.]

3.4. Where a product referred to in the Annex is not containing, consisting or produced from rice, the original analytical report may be replaced by a statement<sup>6</sup> from the operator responsible for the consignment indicating that the food is not containing, consisting or produced from rice.

### *Article 3* *Control measures*

Member States shall take appropriate measures, including random sampling and analysis carried out using the method referred to in Article 2, concerning the products referred to in Article 1 presented for importation or already on the market in order to ensure compliance with the requirements of this Decision ~~verify the absence of the genetically modified rice "Bt 63"~~. They shall inform the Commission of positive (unfavourable) results through the Rapid Alert System for Food and Feed. Negative (favourable) results shall be reported to the Commission on a three-monthly basis.

### *Article 4* *Contaminated consignments*

Member States shall take the necessary measures to ensure that products referred to in Article 1 that are found to contain, to consist or to be produced from the genetically modified rice "Bt 63" are not placed on the market.

### *Article 5* *Recovery of costs*

Member States shall ensure that the costs incurred in the implementation of Articles 2 and 4 are borne by the operators responsible for the first placing on the market.

### *Article 6* *Re-assessment of the measures*

The situation shall be reassessed by the 15<sup>th</sup> of October 2008 at the latest.

### *Article 7* *Applicability*

This Decision is applicable from the 15<sup>th</sup> of April 2008

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<sup>6</sup> The statement shall be drawn up in a language understood by the operator, enabling the operator to be fully aware of the significance of the contents of the statement he signs and in a language understood by the control official of the country of import

*Article 8  
Addressees*

This Decision is addressed to the Member States.

Done at Brussels,

*For the Commission  
Markos KYPRIANOU  
Member of the Commission*

ANNEX

Product	CN Code
Rice in the husk ("paddy" or rough)	100610
Husked (brown) rice	100620
Semi-milled or wholly milled rice, whether or not polished or glazed	100630
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 Müsli type based on unroasted cereal flakes	1904 20 10
Prepared foods obtained from unroasted cereal flakes or from mixtures of unroasted cereal flakes or swelled cereals, obtained from rice (excluding preparations of the Müsli type on the basis of unroasted cereal flakes)	1904 20 95

Rice, pre-cooked or otherwise prepared, not elsewhere specified or included (excluding 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)	1904 90 10
Rice paper	ex 1905 90 20
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

## Summary: Intervention & Options

<b>Department/Agency:</b> <b>Food Standards Agency</b>	<b>Title:</b> <b>Impact Assessment of The [Draft] Chinese Rice Products (Restriction on First Placing on the Market) (England) Regulations 2008</b>	
<b>Stage:</b> Draft	<b>Version:</b> 3	<b>Date:</b> 7 March 2008
<b>Related Publications:</b> Draft Commission Decision 2008/XXX/EC		

Available to view or download at:

<http://www>. [not yet available]

Contact for enquiries: Dr Trudy Netherwood

Telephone: 020 7276 8592

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

Unauthorised genetically modified rice "Bt63" in food or feed rice products originating, or consigned, from China being imported into the EU. The Commission has adopted and notified the UK of, draft Commission Decision 2008/xxxx/EC, to require an analytical report demonstrating the absence of Bt63 to accompany consignments of such products. The Decision is being implemented, in England, by The Chinese Rice Products (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 rice products containing Bt63 being placed on the EU market and thereby entering the UK market. Rice and rice products originating in or consigned from China may only be placed on the EU market 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.

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

1. National legislation to implement Commission Decision 2008/XXX/EC

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

**Ministerial/CEO Sign-off** For consultation 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/Chief Executive\*:

.....Date:

\* for Impact Assessments undertaken by non-ministerial departments/agencies and NOT being considered by Parliament

## Summary: Analysis & Evidence

<b>Policy Option:</b>	<b>Description: Implementing Decision 2008/XXX/EC</b>
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<b>COSTS</b>	<b>ANNUAL COSTS</b>	Description and scale of <b>key monetised costs</b> by 'main affected groups' Food Business Operators Port Health Authorities Local Authorities		
	<b>One-off</b> (Transition) <span style="float: right;"><b>Yrs</b></span>			
	<b>Average Annual Cost</b> (excluding one-off)			
	<b>£</b>		<b>Total Cost (PV)</b>	<b>£</b>
Other <b>key non-monetised costs</b> by 'main affected groups'				

<b>BENEFITS</b>	<b>ANNUAL BENEFITS</b>	Description and scale of <b>key monetised benefits</b> by 'main affected groups' Food Business Operators Consumers		
	<b>One-off</b> <span style="float: right;"><b>Yrs</b></span>			
	<b>Average Annual Benefit</b> (excluding one-off)			
	<b>£</b>		<b>Total Benefit (PV)</b>	<b>£</b>
Other <b>key non-monetised benefits</b> by 'main affected groups'				

Key Assumptions/Sensitivities/Risks
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Price Base Year	Time Period Years	<b>Net Benefit Range (NPV)</b> £	<b>NET BENEFIT (NPV Best estimate)</b> £
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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?	Yes/No
Annual cost (£-£) per organisation (excluding one-off)	Micro      Small      Medium      Large
Are any of these organisations exempt?	No      No      N/A      N/A

<b>Impact on Admin Burdens Baseline</b> (2005 Prices)		(Increase - Decrease)
Increase of £	Decrease of £	<b>Net Impact</b> £

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

## Evidence Base (for summary sheets)

### Reason for Intervention

Bt63 is a genetically modified organism, which is not authorised in the European Community and has been found in rice products 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. Bt63 has not been authorised under Regulation (EC) No 1829/2003 on Genetically Modified Food and Feed, a risk assessment has not been carried out by the European Food Safety Authority, as insufficient data is available. The FSA is not aware of any health implications for consumers that eat rice products containing Bt63.

The Chinese Rice Products (Restriction on First Placing on the Market) (England) Regulations 2008 will implement Decision 2008/XXX/EC in England and similar legislation will implement the Decision in Scotland, Wales and Northern Ireland.

### Intended effect

The intended effect is to prevent any rice and rice products originating, or consigned, from China which contain Bt63 from being placed on the UK market. It is anticipated that implementation of the Decision in the EC will, in due course, have the effect of deterring the export of such products containing Bt63 to the EU.

### Background

The presence of Bt63 in rice products from China first became known in September 2006. The European 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 controls were working. However, in February 2007, Bt63 was again detected in rice products. Subsequent detection of Bt63 in further samples has resulted in the Commission's move to put emergency measures in place.

### Options

The only option being considered is to implement Decision 2008/XXX/EC because not to do so would expose the UK to the possibility of infraction proceedings by the European Commission and also do nothing to minimise the known potential presence of an unauthorised genetically modified organism being imported into the EU/UK in food and feed.

### Costs and benefits of options

**Benefits to food / feed businesses:** Decreased likelihood of unauthorised GM organism being placed on the market, hence decreased likelihood of offences under food law and prosecution.

**Costs to food / feed businesses:** Any costs to ensure reports or statements accompany consignments. Any costs of sampling and analysis of consignments reaching UK without reports.

**Benefits to food / feed authorities:** Enforcement activity facilitated by analytical reports accompanying consignments and statements confirming no rice products present in consignments. Decreased likelihood of unauthorised GM organism being placed on the market, hence decreased likelihood of the need to prosecute.

**Costs to food / feed authorities:** Any extra sampling costs that cannot be passed on.

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

### **Administrative Burden Costs**

**Costs to food / feed businesses:** Any costs of ensuring that consignments are accompanied by the relevant report / statement. Minimal costs associated with reporting any positive results to the Food Standards Agency.

**Costs to food / feed authorities:** The legislation is relevant only to a small proportion of food consignments. Administrative procedures to ensure that consignments are accompanied by relevant and valid documentation and enable food business operators to secure release of their consignments from HMRC will result in a slight increase in administrative costs.

### **Consultation**

This impact assessment forms part of a short, weeklong, consultation on the draft national legislation designed to implement the Decision on its coming into force date of 15 April 2008, as the European legislative timescale does not allow a consultation over the longer 12-week period to be carried out.

[Results of Consultation will be inserted here]

### **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.

### **Simplification**

None

### **Implementation and Review**

The Decision and the national Regulations will come into force at 00.01 on 15 April 2008 and must be acted on from then.

From this date, consignments of rice and rice products (including composite products) originating, or consigned, from China which fall within the CN Codes set out in the Annex to the Decision must be accompanied by an analytical report demonstrating they are free from the unauthorised genetically modified organism "Bt63". 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 consignment arriving without an analytical report, a food or feed business operator will be required to have the products tested before placing 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 Official Feed and Food Controls Regulations 2007.

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.*

Her Majesty's Revenue and Customs (HMRC) has established a national profile on their CHIEF system to prevent consignments consigned from China which 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 and feed authority, will be required to be submitted by the importer to HMRC in order to obtain release.

The report, endorsed by the food and 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 Food Standards Agency by industry will also be notified in this way.

Information on negative results obtained from official sampling activity is to be reported to the European Commission on a 3-monthly basis. This information will be used to inform the European 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

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

**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

**Competition Assessment**

**Small Firms Impact Test**

**Sustainable development**

**Race equality issues**

**Gender equality issues**

**Disability equality issues**

**List of Interested Parties**

Heads of Environmental Health Services (England)  
Directors of Trading Standards (England)  
Association of Port Health Authorities (APHA)  
Association of Port Authorities (APA)  
LACORS  
Chartered Institute of Environmental Health (CIEH)  
Trading Standards Institute (TSI)  
HM Revenue and Customs (HMRC)  
Department for Environment, Food and Rural Affairs (Defra)  
HM Treasury (HMT)  
Health Protection Agency (HPA)  
Office of Government Commerce (OGC)

Abbott Nutrition  
AgraFood Biotech  
Agricultural Industries Confederation  
ASDA  
Association of Convenience Stores  
ATC Limited  
Berry Ottaway & Associates Ltd  
Brand Partnerships  
British Airways  
British Chilled Food Association  
British Frozen Food Federation  
British Goat Society  
British Hospitality Association  
British Potato Council  
British Retail Consortium  
BSI Group Headquarters  
Buckinghamshire County Council  
Campden and Chorleywood Food Research Association  
Chaucer Foods Ltd  
Cheltenham Friends of the Earth  
Cheshire Trading Standards  
City of York Council  
CMI  
Commerical Farmers Group  
Co-operative Group, Quality and Consumer Care  
Coors Brewers Limited  
CPB Twyford Ltd  
Custom Pharmaceuticals Ltd  
Davies Arnold Cooper  
DCSF Educational Procurement Centre  
EH Booth & Co Ltd  
EH Thorne (Beehives) Ltd  
European Commission - DG Joint Research Centre  
Federation of Synagogues  
Food and Drink Federation

Friends of the Earth  
Genus Plc.  
GM Freeze  
Gordon Jopling (Food Ingredients) Ltd  
Grain and Feed Trade Association  
Greenpeace  
Harvest (Essential Trading Ltd)  
Hemel Hempstead GM Action Group  
Hermitage Leisure Centre  
HM Prison Service  
Holland & Barrett UK  
Hoo Hing  
House of Commons Purchasing  
Hyperama PLC  
Institute for Optimum Nutrition  
Institute of Biology  
Interlink Direct  
John Innes Centre  
John West Foods Ltd  
Keele University  
Kellogg Europe Trading Limited  
Loon Fung  
Maltsters Association of Great Britain  
MH Foods  
Monsanto UK Ltd  
National Cattle Association (Dairy)  
National Health Service Supply Chain  
National Institute for Biological Standards & Controls (NIBSC)  
Northern Foods Plc  
NUS Services Ltd  
Organic Farmers and Growers Ltd  
Pioneer Overseas Corporation  
Provision Trade Federation  
Reading Borough Council  
Scottish Beekeepers' Association  
Small Farms Association (Yorkshire)  
Soil Association  
Sommerfield  
SOP International Ltd  
SPL Ltd.  
Stayton Road Residents Assn.  
Sunrise Poultry Farms Ltd  
SW Trading Ltd (SeeWoo)  
Syngenta Crop Protection AG  
Taziki Foods Ltd  
The Design and Technology Association  
The House of Commons  
The Whitehouse Consultancy Ltd  
UKDPC (United Kingdom's Disabled People's Council)  
Unilever Foods R & D

Waitrose Ltd  
Weetabix Ltd  
West Mill Foods  
Which?  
Wing Yip  
WT Foods Group  
Yorkshire Beekeepers' Association