

Explanatory Memorandum to the Specified Products from China (Restriction on First Placing on the Market) (Wales) Regulations 2008

This Explanatory Memorandum has been prepared by the Food Standards Agency Wales and is laid before the National Assembly for Wales in accordance with Standing Order 24.1.

Description

The Regulations implement, in Wales, 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.

Matters of special interest to the Subordinate Legislation Committee

These Regulations 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 2008, it was not formally notified until 3 April 2008, and not published in the Official Journal of the European Communities until 9 April 2008. These Regulations need to be brought into force on 15 April 2008 to implement the Decision that comes into force on the same day. The delay between the adoption of the Decision and its entry into force has allowed Member States time to put arrangements into place to implement the Decision in both legislative and practical terms.

Legislative Background

The powers enabling the Regulations to be made are contained in Sections 2 (2) of the European Communities Act 1972. These powers have been designated to the Welsh Ministers. The Regulations are subject to the Assembly's negative resolution procedure.

Purpose and Intended effect of the legislation

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 'Bt63' has not been authorised for placing on the EC market and has been found in rice products originating from China.

The presence of unauthorised '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.

The Commission is of the view that the Chinese competent authorities have been unable to provide sufficient guarantees of the absence of unauthorised 'Bt63' in rice and rice products originating, or consigned, from China and, as such, has decided to put measures in place to prevent food or feed originating or consigned from China containing, consisting or produced from the unauthorised genetically modified organism (GMO), 'Bt63' being imported into the European Community (EC).

The objective of these Regulations 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:

- They are accompanied by an analytical report issued by an official or accredited laboratory demonstrating that the product does not contain 'Bt63', or
- 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.

The Decision requires the Commission to have undertaken a review of its policy by 15 October 2008 at the latest.

Implementation

This Instrument is subject to the negative resolution procedure. This means that it is made (signed) and laid before the Assembly and should not normally be brought into force until at least 21 (calendar) days from the date of laying.

However as the Commission Decision becomes effective on the 15 April 2008, the Wales Regulations are required to come into force simultaneously to ensure the UK is not in breach of its Community obligations.

FSA Wales therefore recommends a breach of the 21 day rule in this instance. Failure to implement the legislation by 15 April 2008 would lead to inconsistency of procedures across the UK for dealing with the importation into the EU of non-authorised genetically modified rice products from China.

It is intended that these Regulations will come into force on 15 April 2008. Parallel legislation will also come into force simultaneously in England Scotland and Northern Ireland.

Consultation

Stakeholders in Wales including local enforcement authorities and food business operators, were contacted as part of a shortened one week consultation period (10 to 17 March 2008) which invited comments on the draft Regulations. Parallel consultation exercises were conducted in England, Scotland and Northern Ireland.

In total 16 responses UK wide were received: 7 in England, 6 in Scotland and 3 in Wales (Kwan Yick UK Ltd, GM Freeze and a private individual). No responses were received in Northern Ireland. The responses focussed mainly on the practical arrangements or issues connected with the enforcement and compliance of the Regulations rather than the necessity for, or provisions of the Regulations. The FSA has addressed the 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 placed on the FSA's website.

In addition to the consultation, letters have been sent to stakeholders, including local enforcement authorities, to alert them to the Commission 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. The FSA will inform stakeholders of the making of the Regulations and will issue further advice and guidance as necessary.

Safety of 'Bt63'/Handing

FSA Wales 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. FSA Wales has therefore issued a Food Alert requesting that local enforcement authorities take action. FSA Wales is not currently aware of any health implications for consumers who eat rice products containing, consisting of or produced from 'Bt63'. FSA Wales has communicated its views to stakeholders.

Enforcement, Sanctions and Monitoring

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 national legislation, and, in the main, existing powers which they generally use in relation to the controls of

unauthorised GM material provided by the Official Feed and Food Controls (Wales) Regulations 2007, and Regulation (EC) No. 882/2004 on official feed and food controls, the General Food (Wales) Regulations 2004 and the Food Safety Act 1990.

Post Implementation Review

The Decision requires the Commission to have undertaken a review of its policy by 15 October 2008 at the latest.

Summary

The objective of these Regulations is to prevent rice products containing unauthorised 'Bt63' being placed on the EU market and thereby entering the UK market.

Regulatory Impact Assessment

Due to the immediacy of the Regulations a Regulatory Impact Assessment has not been prepared on this occasion. The Agency does not consider the Regulations will have any impact on charities or voluntary bodies.