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Y Cwnsler Cyffredinol ac Arweinydd y Tŷ
Counsel General and Leader of the House



Llywodraeth Cynulliad Cymru
Welsh Assembly Government

Lord Dafydd Elis-Thomas AM
Presiding Officer
National Assembly for Wales

14 April 2008

Dear Dafydd

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

I am writing to inform you that in order to bring The Specified Products from China (Restriction on First Placing on the Market) (Wales) Regulations 2008 into force in Wales in line with the rest of the UK, it has become necessary to breach the 21 day rule. These Regulations were made and laid in Table Office on 14 April 2008 and will come into force on 15 April 2008.

These Regulations are required to implement European Commission Decision 2008/289/EC on emergency measures regarding the unauthorised genetically modified rice 'Bt63'. The Decision was adopted 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).

Regulation (EC) No. 1829/2003 on Genetically Modified Food and Feed stipulates that food and feed containing genetically modified material cannot be placed on the EC market unless the associated GMO has been authorised under the Regulation, following a rigorous safety assessment. Material from unauthorised GMOs in food or feed is not permitted at any level.

Commission Decision 2008/289/EC requires that food and feed products originating, or consigned from China, may only be placed on the market in Wales if they are either accompanied by an analytical report issued by an official or accredited laboratory demonstrating they do not contain, consist of, or have been produced from the unauthorised GMO, '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 that authority.

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Wedi'i argraffu ar bapur wedi'i ailgylchu (100%)

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The presence of unauthorised '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 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 rice products containing 'Bt63' being placed on the EC market.

A risk assessment in respect of 'Bt63' 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 local enforcement authorities take action. The FSA is not currently aware of any health implications for consumers who eat rice products containing 'Bt63'.

Commission Decision 2008/289/EC was adopted on 12 February and Member States were formally notified on 3 April 2008. Following a period to allow Member States to put relevant measures and arrangements into place the Decision comes into force on 15 April 2008. Domestic Regulations are required to be put into place as a matter of urgency simultaneously across the UK. Parallel Regulations in England, Scotland and Northern Ireland will also come into force on that date. Therefore, if the Regulations did not come into force in Wales on the same date it would lead to inconsistencies of procedures across the UK for dealing with the importation into the EU of non-authorised genetically modified rice products from China. Furthermore, the UK would be in breach of its Community obligations were this requirement in Wales not brought into effect.

Due to the immediacy of the Instrument, these Regulations have not been subject to a full 12 week public consultation or a Regulatory Impact Assessment. However, stakeholders in Wales including local enforcement authorities and food business operators were contacted as part of a shortened one-week consultation (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 at: <http://www.food.gov.uk/consultations/>

An Explanatory Memorandum has been prepared and this has been laid, together with the Regulations, in Table Office.

A copy of this letter goes to Dr Dai Lloyd, Chair of the Subordinate Legislation Committee and to Anna Daniel, Clerk to the Subordinate Legislation Committee.

Yours sincerely

A handwritten signature in cursive script, appearing to read 'C. J. Jones', is written in black ink on the page.