

To: Interested parties

4 January 2005

Reference: NFU 475

Dear Sir/Madam

### **REGULATION (EC) NO. 1829/2003: GM FOOD AND FEED REGULATION**

I am writing to update you on the current situation with respect to products produced by a fermentation process using a genetically modified micro-organism (GMM).

On 24 September 2004, the Standing Committee on the Food Chain and Animal Health agreed that food and feed (including food and feed ingredients such as additives, flavourings and vitamins) produced by a fermentation process under contained conditions using a GMM do not fall within the scope of regulation providing there is no detectable GM material in the final product. Food and feed (including food and feed ingredients) produced by a fermentation process using a GMM which is present in the final product, totally or partially, whether viable or not, are included in the scope of Regulation (EC) No 1829/2003, in respect to both authorisation and labelling.

It was also agreed at the meeting that the scope of this Regulation in relation to products from a fermentation process using GMMs will be considered as part of the Commission's review in November 2005.

The safety evaluation of food additives and enzymes produced by GMMs will be considered in the forthcoming legislative proposals for the amendment of the framework Directive 89/107/EEC on food additives and for food enzymes. Products such as vitamins and amino acids derived from fermentations with GMMs will still be covered under the Novel Foods Regulation (Regulation (EC) No. 258/97) if they are considered to be derived from a new source (Article 1(2)(d)). For example, an organism that has not previously been used for commercial production of vitamin C might be genetically modified to be used for this purpose - the vitamin C would be classed as "novel" because it is produced from a new microbial source.

The safety evaluation and authorisation of feed produced by fermentation using a GMM will continue to be covered by the provisions of Regulation (EC) No 1831/2003 and Directive 82/471/EEC.

We have separately sought advice from the Commission on the situation regarding products arising from the use of a GM substrate used during the fermentation process. Where a GM substrate is used, the final products will not require labelling providing there is no detectable material from the GM substrate in the final product.

The guidance notes for the GM Food and Feed Regulation and the Traceability and Labelling Regulation (EC Regulation 1830/2003) are currently being finalised and will be placed on the Food Standards Agency and Department for Environment, Food and Rural Affairs websites in due course. The minutes of the 24 September 2004 Standing Committee meeting can be found at:

- [http://europa.eu.int/comm/food/committees/regulatory/scfcah/modif\\_genet/index\\_en.htm](http://europa.eu.int/comm/food/committees/regulatory/scfcah/modif_genet/index_en.htm)

Yours faithfully,



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