**EXPLANATORY MEMORANDUM TO THE**

The Genetically Modified Food (England) Regulations 2004 No.2335

**1.** This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.

**2. Description**

2.1 These Regulations provides for the administration and enforcement (including penalties and offences) of Council Regulation (EC) No. 1829/2003 dealing with authorisation procedures for and the labelling of GM food and feed.

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

3.1 None

**4. Legislative Background**

4.1 These Regulations are being made in order to provide for the administration and enforcement of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed. The Council Regulation is binding in its entirety and directly applicable in all Member States.

Article 45 of the Council Regulation requires Member States to lay down the rules on penalties applicable to infringements of the Council Regulation and to take all measures necessary to ensure that the provisions of the Council Regulation are adequately enforced.

The Council Regulation's objective is to:

(a) provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market;
(b) lay down Community procedures for the authorisation and supervision of genetically modified food and feed;
(c) lay down provisions for the labelling of genetically modified food and feed.

These Regulations are directly related to the Genetically Modified Organisms (Traceability and Labelling) (England) Regulations 2004, which implement Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms:

A transposition note is attached at Annex A.

**5. Extent**

5.1 These instruments apply to England only.

## 6. European Convention on Human Rights

The Health Minister has made the following statement regarding Human Rights:

In my view the provisions of the Genetically Modified Food (England) Regulations 2004 and The Genetically Modified Animal Feed (England) Regulations 2004 are compatible with the Convention rights.

## 7. Policy background

7.1 GM products are regulated under EC legislation for three main reasons:

- **Safety**: any possible risks to human health and the environment from GMOs must be properly assessed, managed and communicated to the public. Specific legislation has been in place in the EU since 1990 to ensure that any GM product is thoroughly assessed before being placed on the European Community market. Products that do not meet the relevant safety criteria are not allowed to be sold.
- **Consumer choice**: consumers should have reliable and appropriate information about the GM content of products.
- **Fair competition**: under EC legislation, GM products should be able to be sold and used anywhere in the EU provided they meet, and continue to meet, approval and safety criteria. Approval of a GM product under the relevant EU legislation provides access to the whole of the Community market. Member States may not restrict the sale and use of an approved product without being able to bring forward and sustain evidence of a significant adverse risk to human health or the environment.

  The EU legislative framework has, on several occasions, been revised and adapted since 1990 to keep pace with technical developments, to respond to demands for greater transparency, openness and to provide more detailed scrutiny of particular products, such as food and feed, to which GM technology may be applied.

  In 1997 the Novel Foods Regulation (EC 258/97) introduced a mandatory pre-market safety assessment before GM food products can be authorised in the Community and for products to be labelled to allow consumer choice. Labelling rules were based on the presence of GM material in the final product.

  The Commission proposed further legislation which included more specific traceability and labelling requirements, the extension of labelling to cover products derived from a GM source, GM animal feed and a centralised assessment of GM food and feed under the European Food Safety Authority, as reflected in the Council Regulations.

This instrument provides enforcement powers to ensure:

- Prohibitions (on placing on the market a food referred to in Article 3.1 or feed in Article 15.1 unless it is covered by an authorisation and satisfies relevant conditions of the authorisation) are enforced. If a product is marketed

in contravention of the prohibition, it can be removed from sale and (by a magistrate's order at a hearing where the relevant person can make representations) disposed of. The food business operator can be prosecuted for an offence.

- Requirements that products in respect of which the Commission have adopted a measure under Article 8.6 for food and Article 20.6 for feed (that the product shall be withdrawn from the market) are observed. If not the product can be removed from sale and (by a magistrate's order at a hearing where the relevant person can make representations) can be disposed of. The food business operator can be prosecuted for an offence.
- Requirements that an authorisation holder and parties concerned must comply with conditions or restrictions imposed on an authorisation for a product and with post-market monitoring requirements. If they do not comply the product can be removed from sale and (by a magistrate's order at a hearing where the relevant person can make representations) can be disposed of. The person concerned can be prosecuted for an offence.
- Requirements that an authorisation holder informs the Commission of any new scientific or technical information relating to a product, which might influence the evaluation of the safety in use of the food/feed or of any prohibition or restriction on the food/feed in a third country. Failure to notify new information potentially affecting safety is an offence. The affected product can be removed from sale and (by a magistrate's order at a hearing where the relevant person can make representations) disposed of.
- Requirements for certain labelling indications. Failure properly to label products is an offence, and the product in question can be removed from sale. A magistrate (considering the case at a hearing where the relevant person can make representations) can order the correct labelling of the goods, or their disposal, as appropriate.

A public consultation involving 1400 stakeholders was carried out between 30 March and 25 June 2004, 55 responses were received. An analysis of the consultation is detailed in the Regulatory Impact Assessment (RIA) at Annex B.

## 8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum (Annex B)

8.2 The impact on the public sector is the costs of centralising the regulatory

system through EFSA; enforcement costs for ensuring unauthorised GMOs do not enter the food and feed chain and to ensure that GM food and feed is labelled correctly.

The RIA also addresses the impacts of the related Regulation concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

## 9. Contact

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can answer any queries regarding the instrument.

**ANNEX A**

**TRANSPOSITION NOTE: Genetically Modified Food and Feed Regulation (EC) 1829/2003**

Regulation (EC) No. 1829/2003 provides a harmonised procedure for the scientific assessment and authorisation of GMOs and GM food and feed. It provides for a uniform and transparent Community procedure for all marketing applications, whether they concern the GMO itself or the food and feed derivatives. Authorisations will apply to GMOs for food or feed use, food or feed containing or consisting of GMOs; and food or feed produced from or containing ingredients produced from GMOs. The Regulation requires labelling of all GM food and feed, which contain or consist of GMOs or are produced from or contain ingredients produced from GMOs regardless of the presence or absence of GM material in the final food or feed product.

| Article | Objective | Implementation | Responsibility |
|---|---|---|---|
| Articles 4.2 and 16.2 | **Lays down a prohibition on placing on the market;**<br>• GMOs for food or feed use<br>• Food or feed containing or consisting of GMOs<br>• Food or feed produced from or containing ingredients produced from GMOs<br>unless it is covered by an authorisation and satisfies relevant conditions of the authorisation. | Food, England regulation 5 and Schedule part I<br><br>Feed, England regulation 5 and Schedule part I | Secretary of State for Health |
| Articles 8.6 and 20.6 | Allows the Commission to adopt measures requiring withdrawal of products from the market if information required for the notification of products has not been received within 6 months or is found to be incorrect, or where an application has not submitted for re-authorisation after 9 years from notification. Products derived from these products will also be withdrawn from the market. Such a measure may provide for a limited period of time within which existing stocks of the product may be used up. | Food, England regulation 5 and Schedule part II<br><br>Feed, England regulation 5 and Schedule part II | Secretary of State for Health |

| | | | |
|---|---|---|---|
| Articles 9.1 and 21.1 | This states that any condition or restriction laid down as part of an authorisation will have to be adhered to and any products which do not meet these provisions shall not be placed on the market. Where post-market monitoring has been imposed on then authorisation-holder, the authorisation-holder shall ensure that it is carried out and shall submit reports to the Commission in accordance with the terms of the authorisation.. | Food, England regulation 5 and Schedule part II<br><br>Feed England regulation 5 and Schedule part II | Secretary of State for Health |
| Articles 9.3 and 21.3 | Requires authorisation-holders to inform the Commission of any new scientific or technical information which might influence the evaluation of the safety in use of the food. The Commission must also be informed of any prohibition or restriction imposed by the competent authority of any third country in which the food is placed on the market. | Food, England regulation 5 and Schedule part II<br><br>Feed, England regulation 5 and Schedule part II | Secretary of State for Health |
| Articles 13 and 25 | Lists requirements for certain labelling provisions to indicate the GM origin of the food or feed. | Food, England regulation 5 and Schedule part II<br><br>Feed England regulation 5 and Schedule part II | Secretary of State for Health |

# PARLIAMENTARY SCRUTINY HISTORY RELEVANT TO A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON GENETICALLY MODIFIED FOOD AND FEED (EC 1829/2003)

COUNCIL REGULATION (EC) No. 1829/2003

| | |
|---|---|
| Legislation | Regulation (EC) No. 1829/2003 |
| Adopted | 22 September 2003 |
| Official Journal | L268 of 18 October 2003 (pages 1-23) |
| Explanatory Memoranda | 11576/01 of 5 December 2001<br>13132/02 of 4 November 2002<br>11804/03 of 29 August 2003 |

EXPLANATORY MEMORANDUM 11576/01

SCRUTINY COMITTEES RECOMMENDATIONS

| Commons | | Lords | |
|---|---|---|---|
| Politically important – for debate | Date: 16 January 2002<br>Report Ref: (22635)<br>HC 152 –xii (Session 2001-2002)<br>Paragraph 3 | Sifted to Sub-Committee D | Date: 11 December 2001 |
| Cleared | Date: 20 November 2002<br>Report ref. HC 63-i, paragraph 27 (Session 2002/03) | Cleared | Date: 17 June 2002<br>HoL Report (page 18) of 17.06.2002 |

SUPPLEMENTARY EXPLANATORY MEMORANDUM 13132/02 (Supplementary to EM 11576/01)

SCRUTINY COMMITTEES' RECOMMENDATIONS

| Commons | | Lords | |
|---|---|---|---|
| Not legally or politically important - cleared | Date: 20 November 2002<br>Report ref. HC 63-i, paragraph 27 (Session 2002/03) | Sifted to sub-Committee D (Sift 1120) | Date: 5 November 2002 |
| | | Cleared | Date: 4 December 2002 |

EXPLANATORY MEMORANDUM 11804/03

SCRUTINY COMMITTEES' RECOMMENDATION

| Commons | | Lords | |
|---|---|---|---|
| Not legally or politically important - cleared | Date: 10.09.2003<br>Report ref. (24781)<br>HC 63-xxxi, paragraph 17 (Session 2002-03) | Cleared without report by sub-Committee D at Sift 1152 | Date: 9 September 2003 |