

Health and Social Services Committee

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Date: 6 October 2004

Venue: Committee Room 3, National Assembly for Wales

Titles: The Genetically Modified Food (Wales) Regulations 2004; The Genetically Modified Animal Feed (Wales) Regulations 2004; The Genetically Modified Organisms (Traceability and Labelling) (Wales) Regulations 2004

Purpose

1. At the request of the Committee, Members are invited to consider the above draft Wales Regulations which cut across departmental responsibilities – the Food Standards Agency Wales leads on the GM Food and Feed regulations while the Welsh Assembly leads on the related GM traceability and labelling regulations.

Summary

2. The draft proposals implement the directly applicable EU Regulations 1829/2003 and 1830/2003 on Genetically Modified Organisms (GMOs) which are summarised below. Both regulations are now EU law. The GM Food and Feed Regulation and the Traceability and Labelling Regulation have applied in Member States since 18 April 2004 and take direct effect in the UK. Each country within the UK is required to provide for the enforcement and administration of the EU regulations. Ensuring compliance will be the responsibility of Local Authority enforcement bodies who already enforce the current GM labelling requirements.

3. Stakeholders were consulted on the Regulations on a number of occasions between 2001 and 2003 before and during negotiations on them, and a further joint FSA/ Welsh Assembly Government public consultation exercise ran from 29 April to 28 June 2004. Members of both the Assembly's Health and Social Services Committee and the Environment, Planning and Countryside Committee were included as part of that exercise. A copy of the consultees list is at Annex A and a summary table of responses is at Annex B. Both Regulations are due to come into force in Wales by early 2005.

4. The Regulations are intended to address public confidence in GM products by providing consumers with more information on the GM content of the food they are purchasing, including extending the regime to feed and by improving the approvals process. They will also contribute to relieving the trade

tensions which have developed between Europe and the U.S.

Background

5. Regulation (EC) 1829/2003 – the Food and Feed Regulations- lays down specific Community wide procedures and provisions for the assessment, authorisation, supervision and labelling of genetically modified (GM) food and feed. Its objective is to provide the basis for ensuring a high level of protection for health, animal health and welfare, environment and consumers' interests in relation to GM food and feed, whilst ensuring the effective functioning of the internal market. The Regulation also introduces a centralised assessment procedure for the approval of GM food and feed. From 18 April 2004, such assessment will be carried out through the European Food Safety Authority (EFSA) rather than by individual member states, as before that date. It will also introduce new labelling rules for GM animal feed and extend the range of GM food ingredients, which will need to be labelled. These labelling measures will impact on a wide range of businesses in relation to the agriculture, food, feed, retail and hospitality sectors. However, such businesses are already subject to a wide range of information requirements under general food law and specific product legislation.

6. Regulation (EC) 1831/2003 – the Traceability and Labelling Regulations establishes a harmonised EU framework for the traceability and identification, including labelling, of any product consisting of or containing genetically modified organisms (GMOs), -whether the DNA is detectable or not- and traceability of food and feed produced from GMOs at all stages of the production and distribution chain. Its objective is to facilitate consumer choice and risk management in relation to such products.

The need for change

7. The EU legislative framework that has existed until now 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 for more detailed scrutiny of particular products, such as food and feed, to which GM technology may be applied.

8. Following adoption of Directive 2001/18/EC in 2001, the Commission saw a need to propose further GM regulation to respond to the related pressures of public confidence (some Member States considered further measures on traceability and labelling of GMOs, going beyond Directive 2001/18) and trade tensions (the consequence of a so-called "de facto moratorium" started in 1998 under which the EU decision-making process froze creating trade tensions particularly with the US).

9. The Commission's proposals for further legislation were proposed in July 2001 with a view to unblocking the approvals impasse and raising the level of public confidence in GM regulation, principally through measures seeking to extend consumer choice over a wide range of products.

10. The main measures included in the original proposals were:

- More specific traceability and labelling provisions
- The extension of controls to cover products derived from a GM source as well as those consisting of or containing GMOs
- A 1% threshold for the adventitious presence of GM material in products , below which traceability, labelling and other requirements would not apply
- Centralisation of the assessment of GM food and feed under EFSA

11. Following amendment in negotiations, the EU Council of Ministers and the European Parliament adopted these proposals in 2003. The main change from the original proposals was to reduce the 1% threshold to 0.9% in the case of GMOs authorised in the EU and to reduce from 1% to 0.5% the separate threshold for the toleration of unapproved GMOs caught up in the decision-making impasse that have received a positive EU risk assessment.

Summary

12. As regards measures to increase public confidence in the process for ensuring any GM products placed on the market are safe for consumption the Food and Feed Regulation:

- Centralises the consideration and co-ordination of risk assessment issues under the independent European Food Safety Authority (EFSA)
- Sets up for the first time , a specific authorisation and labelling regime for GM feed
- Requires that products likely to be used for both feed and food must be assessed together

13. The change in procedure provides a ‘one door one key’ approach to the safety assessment whereby a single application for authorisation can cover environmental release and clearance for use as food and feed.

Financial implications

14. There are no additional financial implications for the Assembly arising out of the implementation of the above regulations. Finance colleagues have been consulted and are content with this information being placed before the Committee.

Cross cutting themes

15. Arrangements for a separate scrutiny of the GM Regulations by members of the Assembly’s Environment, Planning and Countryside Committee are underway.

Conclusions

16. HSS Committee members are invited to note that the Regulations are timetabled to be considered

further in plenary on 30 November.