

Genetically modified food and feed

2001/0173(COD) - 22/09/2003 - Final act

PURPOSE: to lay down Community procedures for the authorisation, supervision and labelling of genetically modified food and feed.

LEGISLATIVE ACT: Regulation (EC) No 1829/2003/EC of the European Parliament and of the Council on genetically modified food and feed.

CONTENT: This Regulation aims to guarantee a high level of protection for human life and health, animal health, the environment and consumers' interests as regards genetically modified food and feed, while ensuring that the internal market functions properly. It also establishes transparent Community procedures to assess, authorise and monitor genetically modified food and feed and a system for the labelling of genetically modified food and feed.

The main points of the Regulation are as follows:

- the provisions of this Regulation also apply to feed intended for animals which are not destined for food production;
- the new authorisation procedures for genetically modified food and feed include the principles introduced in Directive 2001/18/EC. They also make use of the new framework for risk assessment set up by Regulation (EC) No 178/2002. Genetically modified food and feed will only be authorised for placing on the Community market after a scientific evaluation of any risks which they present for human and animal health and, as the case may be, for the environment. This scientific evaluation is followed by a risk management decision by the Community, under a regulatory procedure ensuring close cooperation between the Commission and the Member States.
- a product likely to be used both for food and feed purposes will only be authorised when fulfilling authorisation criteria for both food and feed;
- authorisation may be granted either to a GMO to be used as a source material for production of food or feed and products for food and/or feed use which contain, consist of or are produced from it, or to foods or feed produced from a GMO. Thus, where a GMO used in the production of food and/or feed has been authorised under this Regulation, foods and/or feed containing, consisting of or produced from that GMO will not need an authorisation under this Regulation, but will be subject to the requirements referred to in the authorisation granted in respect of the GMO. Furthermore, foods covered by an authorisation granted under this Regulation will be exempted from the requirements of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, except where they fall under one or more of the categories referred to in Article 1 in respect of a characteristic which has not been considered for the purpose of the authorisation granted under this Regulation.
- food additives containing, consisting of or produced from GMOs will fall also within the scope of this Regulation for the safety assessment of the genetic modification, while the final authorisation should be granted under the procedure referred to in Directive 89/107/EEC;
- flavourings which contain GMOs will also fall within the scope of this Regulation for the safety assessment of the genetic modification; -feed materials containing, consisting of or produced from GMOs will fall within the scope of this Regulation and not Council Directive 82/471/EEC;
- in addition to the authorisation procedure in Directive 70/524/EEC feed additives containing or produced from GMOs will also fall within the scope of this Regulation;
- this Regulation covers food and feed produced "from" a GMO but not food and feed "with" a GMO. The determining criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed. Processing aids which are only used during the food or feed production process are not covered by the definition of food or feed and, therefore, are not

included in the scope of this Regulation. Nor are food and feed which are manufactured with the help of a genetically modified processing aid included in the scope of this Regulation. Thus, products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products will be subject neither to the authorisation requirements nor to the labelling requirements referred to in this Regulation.

- harmonised labelling requirements are laid down for genetically modified feed to provide final users, in particular livestock farmers, with accurate information on the composition and properties of feed;
- despite the fact that some operators avoid using genetically modified food and feed, such material may be present in minute traces in conventional food and feed as a result of adventitious or technically unavoidable presence during seed production, cultivation, harvest, transport or processing. In such cases, this food or feed is not subject to the labelling requirements of this Regulation. A threshold of 0.9% is established for the adventitious or technically unavoidable presence of genetically modified material in foods or feed, both when the marketing of such material is authorised in the Community and when this presence is tolerated by virtue of this Regulation;
- when the combined level of adventitious or technically unavoidable presence of genetically modified materials in a food or feed or in one of its components is higher than 0.9%, such presence will be indicated in accordance with this Regulation;
- operators must avoid the unintended presence of GMOs in other products. The Commission will gather information and develop on this basis guidelines on the coexistence of genetically modified, conventional and organic crops. Moreover, the Commission is invited to bring forward, as soon as possible, any further necessary proposal;
- there are transitional provisions for products already on the market;
- finally, it should be noted that the traceability and labelling of GMOs at all stages of placing on the market, including the possibility of establishing thresholds, is ensured by Directive 2001/18/EC and Regulation (EC) No 1831/2003.

ENTRY INTO FORCE: 07/11/2003.