

Federal Institute for Risk Assessment (BfR)

Questions and answers on genetically modified food and feed

The "Bill for the Implementation of the Regulations of the European Community in the Field of Genetic Engineering and for the Amendment to the Novel Food and Food Ingredients Regulation" adopted by the Federal Cabinet on 14 January 2004 aims to restructure national responsibilities and lay down sanctions in the event of violations of the provisions in the regulations.

What has changed?

The EC Regulations on genetically modified food and feed, whose enactment is regulated in Germany through the Implementing Act, replace the provisions which had applied up to now for these foods in the Regulation concerning Novel Foods (Novel Foods Regulation) which came into force on 15 May 1997.

The new EC Regulations aim to render the marketing authorisation procedures simpler and more transparent, to harmonise safety assessments and to extend the labelling obligation. The goal is to create the preconditions which set aside the 'de facto' moratorium which has been in place since 1998 in the EU because of a blocking minority.

The new labelling provisions are of special interest for consumers. Up to now only those products had to be labelled which had been proven to contain ingredients from genetically modified organisms (GMOs). In future, irrespective of analytical detectability, the consumer must be informed about all foods manufactured from GMOs by means of the wording "genetically modified" or "made from genetically modified" (e.g. maize). Only those products containing traces of GMOs of up to 0.9% will not require labelling.

There is a new labelling obligation for genetically modified feed. However, foods obtained from animals fed genetically modified feed (meat, eggs, milk, etc.) are still exempt from the labelling obligation.

Already now food and feed derived from genetically modified soya and maize as well as cooking oil derived from various types of genetically modified rapeseed and cotton may be legally placed on the market in the European Union. This will continue to be the case even after the entry into force of the new regulations as long as the responsible parties ensure that they are labelled in accordance with the new provisions.

Is consumer safety guaranteed?

As in the past, marketing authorisation for a food or feed may only be granted in future, too, if it has no negative impact on the health of humans, animals or the environment and does not mislead the consumer or user.

Furthermore, the products may not differ from comparable products which they are to replace to such an extent that their normal consumption could lead to nutritional deficiencies in humans or animals. Feed may not impair the specific traits of products obtained from the animals fed on it to such an extent that it could harm or mislead the consumer.

By way of deviation from the previous procedure laid down in the *Novel Foods Regulation* whereby safety assessment was the overall responsibility of one of the national authorities, in future there is to be a centralised procedure with overall responsibility being assumed by the new European Food Safety Authority (EFSA). EFSA can, however, delegate the safety

assessment of food and feed and the environmental impact assessment of genetically modified organisms (GMOs) to one of the competent authorities in the Member States. In Germany these assessments would be undertaken by BVL in agreement with the competent scientific authorities specified in the future implementing law.

The safety assessment of food and feed continues to be the responsibility of the Federal Institute for Risk Assessment (BfR). It is based on the comparison of the genetically modified product with the conventional starting product. This includes the characterisation of the genetic modification and the resulting new proteins as well as a comparative analysis of the nutritive, anti-nutritive, toxic and allergenic ingredients of relevance for the respective organism. This is done in order to determine whether any unintended changes have been triggered by the genetic modification. If differences are found, depending on the type and scale, a decision will be taken as to what more extensive studies are required in order to prove the safety of the product.

If new findings are available indicating that a genetically modified food or feed, which has been legally placed on the market, probably constitutes a serious threat to the health of humans, animals or the environment, trade with this product may be suspended or subjected to specific requirements.

How and by whom are labelling and traceability controlled?

Besides a labelling proposal, detection methods for the product and the reference material required for its testing and evaluation must be submitted together with the application for marketing authorisation.

The testing and evaluation of the detection methods is the responsibility of the Joint Research Centre of the European Commission which already established, for this purpose, a European Network of GMO Laboratories in December 2002. BfR, whose staff started developing detection methods for genetically modified foods back in 1995, is one of the founding members of this network.

Working groups of the German and European Standardisation Institutes DIN and CEN under the aegis of staff members of the Federal Institute for Risk Assessment (BfR), are involved in the standardisation of methods, including those evaluated by the Joint Research Centre, for the detection and quantification of genetic modifications in foods

Furthermore, in future authorised food and feed will be entered in a Community register along with the date of marketing authorisation and, where appropriate, a specific detection market for the respective GMO. The persons involved in placing a product of this kind on the market must establish systems and standardised procedures by means of which the data on the GMO can be stored for a period of five years.

This creates the preconditions in the European Union for the control of labelling provisions and for the stipulated future monitoring of the environmental impact of GMOs and, if necessary, for the withdrawal of food and feed produced from GMOs from the market.