

Appendix VIII

Regulation concerning genetically modified organisms

Apart from Act XXVII of 1998 on gene technology activities and Regulation 1830/2003/EC concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, the labelling requirements related to genetically modified organisms are provided for in the joint decree 142/2004 (IX. 30.) of the Ministry of Agriculture and Rural Development and the Ministry of Economy and Transport concerning certain rules of gene technology activities in agriculture and industry, Government Decree 132/2004 (IV. 29.) on the authorisation procedures of gene technology activities and the exchange of information with the European Commission during procedures, and Regulation 1829/2003/EC on genetically modified food and feed. These provisions ensure that the fact of genetic modification must be clearly indicated on products consisting of genetically modified organisms and products whose content exceeds the limit for such organisms, and on documents certifying the quality of such products. On the label, the manufacturer or the distributor must provide the information required for the use of the product and warn the product user of the risks of use contrary to this information.

The regulations concerning registration are provided for in Act XXVII of 1998 on gene technology activities and in the Ministry of Agriculture and Rural Development Decree 82/2003 (VII. 16.) on the rules of registration and the provision of information concerning gene technology activities and on the documentation to be attached to applications for the licence required for gene technology activities. According to these regulations, authorised genetically modified organisms are registered by the Agricultural Biotechnology Research Centre (www.biosafety.hu). Other gene technology-related information is also available at the web site. The institute keeps a record of the following data: the description and OECD code of the genetically modified organisms, the name and address of the applicant, and the purpose and geographic location of the gene technology activity. The registration body provides the required data in the form of a print-out generated from the records for a set fee. Data transmitted through an IT/telecommunication system are provided free of charge.

In the framework of compliance with the obligations of the Cartagena Protocol, a web site is currently being developed to operate as an information system (Biosafety Clearing House, BCH). The web site will be completed and available to everyone by April 2005. It will be continuously updated in the light of new information and linked to the central web site of the Cartagena Protocol (<http://bch.biodiv.org>). The web site will ensure public access to information related to the Cartagena Protocol and genetically modified organisms (the texts of Hungarian, European Union and other international legislation, reports, risk analyses, permits issued, directives, programmes, publications, news and up-to-date information, etc.) as well as enable the public to submit comments.

The licences concerning the production and distribution of genetically modified organisms and the products produced of such organisms are published by the competent authority in its official journal. The data published includes the names of the producer and the distributor, the number of the licence, the subject of the production and distribution, and the genes employed for the genetic modification. The communication must also include a description of the proportion of genetically modified organisms in the product.

The competent ministries involve civil society organisations and interest representations in the legislative processes related to gene technology activities.

The Gene Technology Committee, the scientific advisory body for the decision-making authorities, is also involved in the licensing process concerning gene technology activities.

The gene technology authority assesses licence applications taking into consideration the opinion of the Committee. Civil society organisations registered for environmental protection, health protection, biotechnology and consumer protection purposes each have an elected representative on the Committee.

Pursuant to the provisions of Act XXVII of 1998 on gene technology activities, the Government must ensure that it makes users and consumers of genetically modified organisms aware of the essence and the fields of application of gene technology, and the environmental, health, economic and social effects and risks of the use of such organisms through school and non-school education, training and other means of providing information. This provision is partly effected by making available a considerable amount of gene technology-related information to the public at the two web sites referred to above. In 2004 the Prime Minister's Office proposed that coordinated government communication be conducted concerning the licensing of genetically modified organisms. Preparatory work in the field was started in July 2004. Government communication is coordinated by the Hungarian Food Safety Office.

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