Genetically modified food and feed

2001/0173(COD) - 22/12/2006 - Implementing legislative act

LEGISLATIVE ACT : Commission Regulation 1981/2006/EC on detailed rules for the implementation of Article 32 of Regulation 1829/2003/EC of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms.

CONTENT : Regulation 1829/2003/EC provides for a Community reference laboratory (CRL) to carry out certain duties and tasks set out in that Regulation. It also provides that the CRL is to be assisted by national reference laboratories.

This Regulation lays down detailed rules for the implementation of Article 32 of Regulation 1829/2003 /EC as regards:

-the contribution to the costs of the tasks of the Community reference laboratory (CRL) and of the national reference laboratories, as referred to in the Annex to the Regulation; and

-the establishment of national reference laboratories.

Contributions: for each application, a flat-rate contribution of EUR 30 000 must be paid by the applicant to the CRL. Where a full validation procedure of a method of detection and identification for a single GMO event according to the requirements laid down in Annex I of Regulation 641/2004/EC is required, the CRL will request the applicant to pay an additional contribution of EUR 60 000. This amount will be multiplied by the number of GMO events to be fully validated. Where the costs of the validation of the detection method proposed by the applicant substantially exceed these amounts, an additional amount will be requested.

However, the CRL will reduce the amount of the additional contribution, in proportion of the costs saved: where the material needed to perform the full validation procedure is supplied by the applicant; and/or where the applicant provides data that refer to modules, such as DNA extraction protocols, already validated and published by the CRL.

The Regulation sets out circumstances where the contribution will be reduced or exempted, for example, where the applicant is a SME or has its head office established in a developing country.

National reference laboratories: laboratories which assist the CRL in testing and validating the method of detection and identification must fulfil the minimum requirements laid down in Annex I to the Regulation. The laboratories listed in Annex II, are meeting those requirements, and are appointed as national reference laboratories under Regulation 1829/2003/EC to assist the CRL for testing and validating the method of detection. The CRL and the national reference laboratories listed in Annex II must enter into a written agreement to define the relations between them, notably in financial matters.

ENTRY INTO FORCE : 12/01/2007.