

**Note to the applicants on the type and nature of control samples provided in the context of applications for authorisation for the placing on the market of genetically modified food and feed according to Reg. (EC) No 1829/2003**

With the present note, the Community Reference Laboratory for Genetically Modified Food and Feed (CRL-GMFF) recalls the applicant for authorisation for placing on the market of genetically modified food and feed according to Reg. (EC) No 1829/2003 on the definition and requirements of the control samples submitted to the CRL-GMFF in the context of the validation of the methods for detection of the GMOs in food and feed products.

- 1) Reg. (EC) No 1829/2003, Art. 2 (11) provides the definition of control samples: *'control sample' means the GMO or its genetic material (positive sample) and the parental organism or its genetic material that has been used for the purpose of the genetic modification (negative sample)'*;
- 2) Annex I.4 to Reg.(EC) No 641/2004 states that the type and amount of the control samples have to be indicated by the CRL-GMFF : *"In view of implementing Articles 5(3)(j) and 17(3)(j) of Regulation (EC) No 1829/2003, the applicant shall, together with the information specified under sections 1, 2 and 3 of this Annex, also provide samples of the food and feed and their control samples of a type and amount to be specified by the CRL for the specific application for authorisation."*;
- 3) Reg. (EC) No 1829/2003 states that *"the definitions of 'organism', 'deliberate release' and 'environmental risk assessment' referred to in Directive 2001/18/EC shall apply"*;
- 4) Reg. (EC) No 1829/2003, further specifies that *"genetically modified organism' or 'GMO' means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC"*;
- 5) Article 2 of Directive 2001/18/EC states that *"organism means any biological entity capable of replication or of transferring genetic material"*; and *"genetically modified organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination"*;

6) The guidance document entitled "Explanatory Notes to Applicant" (available at <http://gmo-crl.jrc.it/guidancedocs.htm>) further details the characteristics that samples of food and feed and their control samples need to be endowed with. This document is periodically revised and reflects the current scientific understanding of the matter.

Having regard to the above quoted legal texts and to the guidance document, the CRL-GMFF underlines that only the genetically modified organism (GMO) and its non-modified counterpart or their respective genetic material (DNA) can be considered as control samples. In case the submission concerns genetically modified plant species, the GMO shall be adequately represented by intact seeds or grains that should not be treated in such a way to prevent their abilities to generate a GMO; therefore, flour or semi-ground seeds or grains cannot be considered as appropriate control samples.

Ispra, 28/1/2008