Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 (Text with EEA relevance)

CHAPTER III

SPECIFIC REQUIREMENTS

Article 4

Requirements for the performance of studies for applications submitted under Articles 5(3) and 17(3)

1 Toxicological studies shall be conducted in facilities which comply with the:

a requirements of Directive 2004/10/EC; or

b 'OECD Principles on Good Laboratory Practice' (GLP), if carried out outside the Union.

The applicant shall provide evidence to demonstrate such compliance.

2 Studies, other than toxicological studies, shall:

a comply with the principles of Good Laboratory Practice (GLP) laid down in Directive 2004/10/EC; or

b be conducted by organisations accredited under the relevant ISO standard.

3 Information on the study protocols and the results obtained from the studies referred to in paragraphs 1 and 2 shall be comprehensive and include the raw data in an electronic format, suitable for carrying out statistical or other analysis.

Article 5

Scientific requirements for the risk assessment of genetically modified food and feed for applications submitted under Articles 5(3) and 17(3)

1 Information, including studies, required to accompany the application as referred to in Article 5(3)(a) to (f) and (h) and in Article 17(3)(a) to (f) and (h) of Regulation (EC) No 1829/2003 shall be provided in accordance with the scientific requirements for the risk assessment of genetically modified food and feed set out in Annex II to this Regulation.

2 By way of derogation from paragraph 1, an application may be submitted that does not satisfy all the requirements of that paragraph provided that:

a particular information is not necessary owing to the nature of the genetic modification or of the product; or

b it is not scientifically necessary, or technically possible to supply such information.

The applicant shall submit reasoned justification for the derogation.

3 Paragraphs 1 and 2 shall not prevent the EFSA to request, where appropriate, the applicant to supplement the particulars accompanying the application as provided for in Articles 6(2) and 18(2) of Regulation (EC) No 1829/2003.

Article 6

Additional information related to the risk assessment of genetically modified food or feed for applications submitted under Articles 5(3) and 17(3)

1 In addition to the information required in accordance with Article 5 and Annex II, the application shall include a systematic review of studies published in the scientific literature and studies performed by the applicant within the period of 10 years prior to the date of submission of the dossier on the potential effects on human and animal health of the genetically modified food and feed covered by the application.

2 During the authorisation procedure, the applicant shall submit, without delay, to the EFSA additional information which might influence the risk assessment of the genetically modified food or feed generated following the submission of the application. In particular, the applicant shall submit to the EFSA information regarding any prohibition or restriction imposed by a competent authority of any third country on the basis of a risk assessment of the genetically modified food and feed.

Article 7

Requirements applicable for post-market monitoring of genetically modified food or feed for applications submitted under Articles 5(3) and 17(3)

1 The applicant shall submit a proposal for post-market monitoring regarding the use of the food and feed as referred to in Articles 5(3)(k) and 17(3)(k) of Regulation (EC) No 1829/2003 when the information provided in accordance with Articles 4, 5 and 6 demonstrates that the genetically modified food and feed comply with Articles 4(1) and 16(1) of Regulation (EC) No 1829/2003 and when, in accordance with the outcome of the risk assessment, it is appropriate to confirm:

a that specific recommendations of uses are followed by the consumer/animal owner;

b the predicted consumption of the genetically modified food or feed; or

c the relevance and intensity of effects and unintended effects detected during the pre-market risk assessment which can only be further characterised by post-market monitoring.

2 The applicant shall ensure that the post-market monitoring is:

a developed to collect reliable information with respect to one or several of the aspects set out in paragraph 1. This information shall allow the detection of indications on whether any (adverse) effect on health may be related to genetically modified food or feed consumption;

b based on strategies aiming at collecting relevant information from specific stakeholders including consumers and on a reliable and validated flow of information between the different stakeholders. More specific strategies shall be included when data on individual intakes of a specific food item or intakes of particular age groups have to be collected;

c accompanied by adequate justification and a thorough description of the selected methodologies for the proposed post-market monitoring including aspects related to the analysis of the collected information.

Article 8

Requirements concerning the methods of detection, identification and quantification and for control samples and reference material of genetically modified food or feed for applications submitted under Articles 5(3), 11(2), 17(3) and 23(2)

1 Applications submitted under Articles 5(1) and 17(1) of Regulation (EC) No 1829/2003 shall comply with the following requirements, as referred to in Article 5(3)(i) and (j) and Article 17(3)(i) and (j) of that Regulation, and set out in Annex III to this Regulation, for:

a the methods for detection and identification of the transformation event;

b samples of food or feed and their control samples, and information as to the place where the reference material can be accessed.

2 For applications submitted under Articles 11(1) and 23(1) of Regulation (EC) No 1829/2003, the requirements set out in Annex III to this Regulation for:

a the methods for detection and identification of the transformation event;

b samples of food or feed and their control samples, and information as to the place where the reference material can be accessed,

shall apply only for the purposes of application of Articles 11(2)(d) and 23(2)(d).