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 I

GENERAL PROVISIONS

Article 1

Scope

This Regulation shall apply to applications submitted under Articles 5, 11, 17 and 23 of Regulation (EC) No 1829/2003 for the authorisation of:

(a) genetically modified plants for food or feed uses;

(b) food or feed containing or consisting of genetically modified plants;

(c) food produced from or containing ingredients produced from genetically modified plants or feed produced from such plants.

Article 2

Definitions

For the purposes of this Regulation, the definitions in Regulation (EC) No 1829/2003 apply.

The definitions of ‘risk’, ‘risk assessment’ and ‘hazard’ applicable for the purposes of this Regulation are those provided in Article 3 of Regulation (EC) No 178/2002.

CHAPTER II

GENERAL REQUIREMENTS

Article 3

Preparation and presentation of applications submitted under Articles 5(1) and 17(1)

1 The application submitted under Articles 5(1) and 17(1) of Regulation (EC) No 1829/2003 shall:

a be submitted in accordance with the requirements for the preparation and presentation of applications set out in Annex I;

b contain all the information required by Annex I, in accordance with the specific requirements of Articles 4, 5 and 6.

2 The application shall include, for each of the specific requirements laid down in Articles 4, 5 and 6:

a the summaries and results of the studies referred to in the application;

b annexes where detailed information on those studies is provided.

3 The application shall contain a checklist demonstrating that the information required under Articles 4, 5 and 6 is complete.

4 Where an application is limited to either food or feed use, it shall contain a verifiable justification explaining why the authorisation shall not cover both uses in accordance with Article 27 of Regulation (EC) No 1829/2003.

5 The application shall, at the time of submission, clearly state which parts of the application are claimed to be confidential and provide verifiable justification in accordance with Article 30 of Regulation (EC) No 1829/2003.

Additional information submitted during the authorisation procedure shall, at the time of submission, clearly state which parts of this additional information is claimed to be confidential and provide verifiable justification in accordance with Article 30 of Regulation (EC) No 1829/2003.

6 When studies have been already submitted to the European Food Safety Authority (EFSA) for the purposes of an application and, where relevant, to the extent that they may be used by the applicant in accordance with Article 31 of Regulation (EC) No 1829/2003, a reference to such studies and the results of the EFSA's assessment may, with the agreement of EFSA, be made in the framework of another application.

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).

CHAPTER IV

TRANSITIONAL AND FINAL PROVISIONS

Article 9

Transitional provisions

1 Until 8 December 2013, applicants may choose to submit applications falling under the scope of this Regulation under Regulation (EC) No 641/2004 in the version of that Regulation in force on 8 June 2013.

2 By way of derogation from Article 4(2), in the case of studies launched prior to the date of entry into force of this Regulation and conducted under quality assurance systems other than GLP and ISO, the applicant shall provide:

a a thorough description of the quality assurance system under which such studies were performed; and

b comprehensive information on the protocols and the results obtained from the studies including the raw data.

Article 10

Amendments to Regulation (EC) No 641/2004

Regulation (EC) No 641/2004 is amended as follows:

(1) Article 1 is replaced by the following:

Article 1

This chapter provides detailed rules concerning applications for authorisation submitted in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 except for those applications covered by Commission Implementing Regulation (EU) No 503/2013[(1)].;

(2) Articles 5 to 19 are deleted.

Article 11

Amendments to Regulation (EC) No 1981/2006

Regulation (EC) No 1981/2006 is amended as follows:

(1) in Article 2, point (a) is replaced by the following:

(a) "full validation procedure" means:

(i) the assessment through a ring trial involving national reference laboratories of the method performance criteria set by the applicant as compliant with the document entitled "Definition of minimum performance requirements for analytical methods of GMO testing" referred to:

— in the case of genetically modified plants for food or feed uses, food or feed containing or consisting of genetically

modified plants and food produced from or containing ingredients produced from genetically modified plants or feed produced from genetically modified plants, in point 3.1.C.4 of Annex III to Commission Implementing Regulation (EU) No 503/2013[(2)],

— in all other cases, in point 1(B) of Annex I to Regulation (EC) No 641/2004;

and

(ii) the assessment of the precision and trueness of the method provided by the applicant.;

(2) in Article 3(2), the first and second subparagraphs are replaced by the following:

2. The CRL shall request the applicant to pay an additional contribution of EUR 60 000 where a full validation procedure of a method of detection and identification for a single GMO event according to the requirements laid down in the following provisions is required:

a Annex III to Implementing Regulation (EU) No 503/2013, when the application is related to:

(i) genetically modified plants for food or feed uses;

(ii) food or feed containing or consisting of genetically modified plants;

(iii) food produced from or containing ingredients produced from genetically modified plants or feed produced from such plants; or

b point 1(B) of Annex I to Regulation (EC) No 641/2004, in all other cases.

That amount shall be multiplied by the number of GMO events to be fully validated..

Article 12

Review

1 The Commission shall monitor the application of this Regulation, the developments in scientific knowledge on replacement, reduction and refinement of animal use in scientific procedures and the publication of new guidance from EFSA. The Commission shall in particular monitor the outcome of the research project called GRACE (GMO Risk Assessment and Communication of Evidence) under the 2012 work programme of the seventh Framework Programme for Research (FP7).

2 The Commission shall review the requirement to perform 90-day feeding studies in rodents with whole genetically modified food/feed (point 1.4.4.1 of Annex II) on the basis of new scientific information. The results of this review shall be published by 30 June 2016 at the latest.

Article 13

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 April 2013.

For the Commission

The President

José Manuel BARROSO

(**1**) OJ L 157, 8.6.2013, p. 1.';

(**2**) OJ L 157, 8.6.2013, p. 1.';

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 503/2013. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.