

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 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<sup>(1)</sup>;

- (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:

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- (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<sup>(2)</sup>,
    - 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

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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*.

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- (1) [OJ L 157, 8.6.2013, p. 1.](#);
- (2) [OJ L 157, 8.6.2013, p. 1.](#);

### Changes to legislation:

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### Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by [S.I. 2019/705 reg. 53](#)
- Annex 1 Pt. 7 para. 1.1(a) omitted by [S.I. 2019/705 reg. 54\(e\)\(iii\)](#) (This amendment not applied to legislation.gov.uk. Reg. 54(e) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 17(10)(b))
- Annex 1 Pt. 7 para. 1 substituted by S.I. 2019/705, reg. 54(e)(iv) (as substituted) by [S.I. 2020/1504 reg. 17\(10\)\(b\)](#)
- Annex 1 Pt. 1 para. 2 words substituted by [S.I. 2019/705 reg. 54\(a\)\(i\)](#) (This amendment not applied to legislation.gov.uk. Reg. 54(a)(b) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 17(10)(a))
- Annex 1 Pt. 1 para. 4(c) words substituted by [S.I. 2019/705 reg. 54\(a\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. Reg. 54(a)(b) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 17(10)(a))
- Annex 1 Pt. 1 para. 8 words substituted by [S.I. 2019/705 reg. 54\(a\)\(iii\)](#) (This amendment not applied to legislation.gov.uk. Reg. 54(a)(b) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 17(10)(a))
- Annex 1 Pt. 2 para. 1.1(b) words substituted by [S.I. 2019/705 reg. 54\(b\)\(i\)](#) (This amendment not applied to legislation.gov.uk. Reg. 54(a)(b) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 17(10)(a))
- Annex 1 Pt. 2 para. 1.1(e)(v) words substituted by [S.I. 2019/705 reg. 54\(b\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. Reg. 54(a)(b) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 17(10)(a))
- Annex 1 Pt. 2 para. 1.1(e)(vi) words substituted by [S.I. 2019/705 reg. 54\(b\)\(iii\)](#) (This amendment not applied to legislation.gov.uk. Reg. 54(a)(b) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 17(10)(a))
- Annex 1 Pt. 2 para. 7 words substituted by [S.I. 2019/705 reg. 54\(b\)\(iv\)](#) (This amendment not applied to legislation.gov.uk. Reg. 54(a)(b) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 17(10)(a))
- Annex 1 Pt. 7 para. 1.8(h) words substituted by [S.I. 2019/705 reg. 54\(e\)\(iv\)](#) (This amendment not applied to legislation.gov.uk. Reg. 54(e) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 17(10)(b))
- Annex 1 Pt. 1 para. 2 words substituted by S.I. 2019/705, reg. 54(a)(i) (as substituted) by [S.I. 2020/1504 reg. 17\(10\)\(a\)](#)
- Annex 1 Pt. 1 para. 4 words substituted by S.I. 2019/705, reg. 54(a)(ii) (as substituted) by [S.I. 2020/1504 reg. 17\(10\)\(a\)](#)
- Annex 1 Pt. 1 para. 8 words substituted by S.I. 2019/705, reg. 54(a)(iii) (as substituted) by [S.I. 2020/1504 reg. 17\(10\)\(a\)](#)
- Annex 1 Pt. 2 para. 1 words substituted by S.I. 2019/705, reg. 54(b)(i) (as substituted) by [S.I. 2020/1504 reg. 17\(10\)\(a\)](#)
- Annex 1 Pt. 2 para. 1 words substituted by S.I. 2019/705, reg. 54(b)(ii) (as substituted) by [S.I. 2020/1504 reg. 17\(10\)\(a\)](#)
- Annex 1 Pt. 2 para. 1 words substituted by S.I. 2019/705, reg. 54(b)(iii) (as substituted) by [S.I. 2020/1504 reg. 17\(10\)\(a\)](#)
- Annex 1 Pt. 2 para. 7 words substituted by S.I. 2019/705, reg. 54(b)(iii) (as substituted) by [S.I. 2020/1504 reg. 17\(10\)\(a\)](#)
- Annex 1 Pt. 7 para. 1 words substituted by S.I. 2019/705, reg. 54(e)(iii) (as substituted) by [S.I. 2020/1504 reg. 17\(10\)\(b\)](#)
- Annex 3 para. 1 words omitted by [S.I. 2019/705 reg. 56\(a\)\(ii\)](#)
- Annex 3 point C para. 3.1(4) words omitted by [S.I. 2019/705 reg. 56\(c\)](#)
- Annex 3 para. 1(3) words substituted by [S.I. 2019/705 reg. 56\(a\)\(i\)](#)

- Annex 2 s. 2para. 1.3.1 words omitted by [S.I. 2019/705 reg. 55\(a\)\(ii\)](#)
- Annex 2 s. 2para. 2 words omitted by [S.I. 2019/705 reg. 55\(a\)\(ix\)\(aa\)](#)
- Annex 2 s. 2para. 1.1.2(b) words substituted by [S.I. 2019/705 reg. 55\(a\)\(i\)](#)
- Annex 2 s. 2para. 1.3.2.1 words substituted by [S.I. 2019/705 reg. 55\(a\)\(iii\)](#)
- Annex 2 s. 2para. 1.3.2.2 words substituted by [S.I. 2019/705 reg. 55\(a\)\(iv\)](#)
- Annex 2 s. 2para. 2 words substituted by [S.I. 2019/705 reg. 55\(a\)\(ix\)\(bb\)](#)
- Annex 2 s. 2para. 1.4.2 words substituted by [S.I. 2019/705 reg. 55\(a\)\(v\)](#)
- Annex 2 s. 2para. 1.4.4.1 words substituted by [S.I. 2019/705 reg. 55\(a\)\(vi\)](#)
- Annex 2 s. 2para. 1.5 words substituted by [S.I. 2019/705 reg. 55\(a\)\(vii\)](#)
- Annex 2 s. 2para. 1.6.4 words substituted by [S.I. 2019/705 reg. 55\(a\)\(viii\)](#)
- Art. 4(1)(b) words substituted by [S.I. 2019/705 reg. 49](#) (This amendment not applied to legislation.gov.uk. Reg. 49 substituted immediately before IP completion day by [S.I. 2020/1504, regs. 1\(2\), 17\(9\)](#))
- Art. 4(1)(b) words substituted by [S.I. 2019/705, reg. 49](#) (as substituted) by [S.I. 2020/1504 reg. 17\(9\)](#)