

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 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.

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.

View outstanding changes

Changes and effects yet to be applied to :

- Art. 6(2) words substituted by [S.I. 2019/705 reg. 51](#)

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\(9\)](#)