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 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.

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. 5(3) words substituted by S.I. 2019/705 reg. 50

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)

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– 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)