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)

Article 13 Entry into force
Signature

ANNEX I

PREPARATION AND PRESENTATION OF APPLICATIONS

The application shall contain the following information:

PART I

GENERAL INFORMATION

1. Name and address of the applicant (company or institute).

2. Name, qualification and experience of the responsible scientist(s) and contact...

3. Designation and specification of the genetically modified plant and its...

4. Scope of the application:

5. Unique identifier.

6. Where applicable, a detailed description of the method of production...

7. Where appropriate, the conditions for the placing on the market...

8. Where applicable, the status of the food or feed or...

PART II

SCIENTIFIC INFORMATION

1. HAZARD IDENTIFICATION AND CHARACTERISATION
   - 1.1. Information relating to the recipient or (where appropriate) parental plants...
     - (a) Complete name:
     - (b) Geographical distribution and cultivation of the plant within the Union;...
     - (c) Information on the recipient or parental plants relevant to their...
     - (d) Data on the past and present use of the recipient...
     - (e) Additional information relating to the recipient or parental plants required...
   - 1.2. Molecular Characterisation
     - 1.2.1. Information relating to the genetic modification
       - 1.2.1.1. Description of the methods used for the genetic modification
       - 1.2.1.2. Nature and source of vector used
       - 1.2.1.3. Source of donor nucleic acid(s) used for transformation, size and...
     - 1.2.2. Information relating to the genetically modified plant
       - 1.2.2.1. General description of the trait(s) and characteristics which have been...
       - 1.2.2.2. Information on the sequences actually inserted/deleted

PART III

CARTAGENA PROTOCOL

PART IV

LABELLING

PART V

METHODS OF DETECTION, SAMPLING AND IDENTIFICATION AND REFERENCE MATERIAL

PART VI

ADDITIONAL INFORMATION TO BE PROVIDED FOR GENETICALLY MODIFIED PLANTS AND/OR FOOD OR FEED CONTAINING OR CONSISTING OF GENETICALLY MODIFIED PLANTS

PART VII

SUMMARY OF APPLICATIONS

1. GENERAL INFORMATION
   - 1.1. Details of application
     - (a) Member State of application
     - (b) Application number
     - (c) Name of the product (commercial and any other names)
     - (d) Date of acknowledgement of valid application
   - 1.2. Applicant
     - (a) Name of applicant
     - (b) Address of applicant
     - (c) Name and address of the representative of the applicant established...
   - 1.3. Scope of the application
     - (a) Genetically modified food
     - (b) Genetically modified feed
     - (c) Genetically modified plants for food and feed use
   - 1.4. Is the product or the uses of the associated plant...
   - 1.5. Has the genetically modified plant been notified under Part B...
   - 1.6. Has the genetically modified plant or derived products been previously...
   - 1.7. Has the product been subject to an application and/or authorised...
   - 1.8. General description of the product
     - (a) Name of the recipient or parental plant and the intended...
     - (b) Types of products planned to be placed on the market...
     - (c) Intended use of the product and types of users
     - (d) Any specific instructions and recommendations for use, storage and handling,...
     - (e) If applicable, geographical areas within the Union to which the...
     - (f) Any type of environment to which the product is unsuited...
     - (g) Any proposed packaging requirements
     - (h) Any proposed labelling requirements in addition to those required by...
     - (i) Estimated potential demand
     - (j) Unique identifier in accordance with Regulation (EC) No 65/2004.
   - 1.9. Measures suggested by the applicant to take in the case...

2. INFORMATION RELATING TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS...
   - 2.1. Complete name
     - (a) Family name
     - (b) Genus
     - (c) Species
     - (d) Subspecies
     - (e) Cultivar/breeding line
     - (f) Common name
   - 2.2. Geographical distribution and cultivation of the plant, including the distribution...
   - 2.3. Information concerning reproduction (for environmental safety aspects)
     - (a) Mode(s) of reproduction
     - (b) Specific factors affecting reproduction
     - (c) Generation time
   - 2.4. Sexual compatibility with other cultivated or wild plant species (for...
   - 2.5. Survivability (for environmental safety aspects)
     - (a) Ability to form structures for survival or dormancy
     - (b) Specific factors affecting survivability
   - 2.6. Dissemination (for environmental safety aspects)
     - (a) Ways and extent of dissemination
     - (b) Specific factors affecting dissemination
   - 2.7. Geographical distribution within the Union of the sexually compatible species...
   - 2.8. In the case of plant species not normally grown in...
   - 2.9. Other potential interactions, relevant to the genetically modified plant, of...

3. MOLECULAR CHARACTERISATION
   - 3.1. Information relating to the genetic modification
     - (a) Description of the methods used for the genetic modification
     - (b) Nature and source of the vector used
     - (c) Source of donor nucleic acid(s) used for transformation, size and...
   - 3.2. Information relating to the genetically modified plant
     - 3.2.1. Description of the trait(s) and characteristics which have been introduced...
     - 3.2.2. Information on the nucleic acid(s) sequences actually inserted or deleted...
       - (a) The copy number of all detectable inserts, both complete and...
       - (b) In the case of deletion(s), size and function of the...
       - (c) Subcellular location(s) of insert(s) (nucleus, chloroplasts, mitochondria, or maintained in...
       - (d) The organisation of the inserted genetic material at the insertion...
       - (e) In the case of modifications other than insertion or deletion,...
     - 3.2.3. Information on the expression of the insert
       - (a) Information on developmental expression of the insert during the life...
       - (b) Parts of the plant where the insert is expressed
     - 3.2.4. Genetic stability of the insert and phenotypic stability of the...
     - 3.2.5. Information (for environmental safety aspects) on how the genetically modified...
       - (a) Mode(s) and/or rate of reproduction
       - (b) Dissemination

ANNEX II

SCIENTIFIC REQUIREMENTS FOR THE RISK ASSESSMENT OF GENETICALLY MODIFIED FOOD AND FEED

- 1.2.1.3. Source of nucleic acid(s) used for transformation, size and intended...
- 1.2.2. Information relating to the genetically modified plant
  - 1.2.2.1. General description of the trait(s) and characteristics which have been...
  - 1.2.2.2. Information on the sequences actually inserted/deleted
  - 1.2.2.3. Information on the expression of the insert(s)
  - 1.2.2.4. Genetic stability of the insert and phenotypic stability of the...
  - 1.2.2.5. Potential risk associated with horizontal gene transfer
- 1.2.3. Conclusions of the molecular characterisation

1.3. Comparative analysis
- 1.3.1. Choice of the conventional counterpart and additional comparators
- 1.3.2. Experimental design and statistical analysis of data from field trials...
  - 1.3.2.1. Description of the protocols for the experimental design
    - (a) Principles of experimental design
    - (b) Specific protocols for experimental design
  - 1.3.2.2. Statistical analysis
- 1.3.3. Selection of material and compounds for analysis
- 1.3.4. Comparative analysis of composition
- 1.3.5. Comparative analysis of agronomic and phenotypic characteristics
- 1.3.6. Effects of processing
- 1.3.7. Conclusion

1.4. Toxicology
- 1.4.1. Testing of newly expressed proteins
- 1.4.2. Testing of new constituents other than proteins
- 1.4.3. Information on altered levels of food and feed constituents
- 1.4.4. Testing of the whole genetically modified food and feed
  - 1.4.4.1. 90-day feeding study in rodents with whole genetically modified food/feed...
  - 1.4.4.2. Animal studies with respect to reproductive and developmental toxicity testing...
  - 1.4.4.3. Other animal studies to examine the safety and the characteristics...
  - 1.4.4.4. Interpretation of relevance of animal studies
- 1.4.5. Conclusion of the toxicological assessment

1.5. Allergenicity
- 1.5.1. Assessment of allergenicity of the newly expressed protein
- 1.5.2. Assessment of allergenicity of the genetically modified food or feed...
- 1.5.3. Adjuvanticity
- 1.5.4. Conclusion of the allergenicity assessment

1.6. Nutritional assessment
- 1.6.1. Objectives of the nutritional assessment
- 1.6.2. Points to consider for the nutritional assessment of genetically modified...
- 1.6.3. Nutritional studies of genetically modified food
- 1.6.4. Nutritional studies of genetically modified feed
- 1.6.5. Conclusion of the nutritional assessment

ANNEX III

VALIDATION OF METHODS FOR THE DETECTION, IDENTIFICATION AND QUANTIFICATION OF THE TRANSFORMATION EVENT, AND REQUIREMENTS FOR CONTROL SAMPLES AND THE CERTIFIED REFERENCE MATERIAL

(**1**) OJ L 268, 18.10.2003, p. 1.

(**2**) OJ L 31, 1.2.2002, p. 1.

(**3**) OJ L 102, 7.4.2004, p. 14.

(**4**) OJ L 106, 17.4.2001, p. 1.

(**5**) Codex Alimentarius Commission, GL 45-2003.

(**6**) EFSA Journal 2011; 9(5):2150.

(**7**) OJ L 276, 20.10.2010, p. 33.

(**8**) OJ L 50, 20.2.2004, p. 44.

(**9**) OJ L 201, 31.7.2002, p. 48.

(**10**) OJ L 287, 5.11.2003, p. 1.

(**11**) OJ L 10, 14.1.2004, p. 5.

(**12**) OJ L 368, 23.12.2006, p. 99.

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 :

- Annex 1 Pt. 7 omitted by virtue of S.I. 2019/705, reg. 54(e)(ii) (as substituted) by S.I. 2020/1504 reg. 17(10)(b)
- Annex 1 Pt. 4 words omitted by S.I. 2019/705 reg. 54(c)
- Annex 1 Pt. 5 words omitted by S.I. 2019/705 reg. 54(d)(iv)
- Annex 1 Pt. 5 words substituted by S.I. 2019/705 reg. 54(d)(i)
- Annex 1 Pt. 5 words substituted by S.I. 2019/705 reg. 54(d)(ii)
- Annex 1 Pt. 5 words substituted by S.I. 2019/705 reg. 54(d)(iii)
- Annex 1 Pt. 7 words substituted by S.I. 2019/705 reg. 54(e)(i) (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 words substituted by S.I. 2019/705 reg. 54(e)(ii) (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 words substituted by S.I. 2019/705, reg. 54(e)(i) (as substituted) by S.I. 2020/1504 reg. 17(10)(b)
- Annex 3 words substituted by S.I. 2019/705 reg. 56(b)
- Art. 3(6) substituted by S.I. 2019/705 reg. 48
- Art. 5(3) words substituted by S.I. 2019/705 reg. 50
- Art. 6(2) words substituted by S.I. 2019/705 reg. 51
- Art. 12 substituted by S.I. 2019/705 reg. 52

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)