ANNEX I

PREPARATION AND PRESENTATION OF APPLICATIONS

PART II

SCIENTIFIC INFORMATION

All the requirements of Part II shall be provided in the application except where such requirements are not justified by the scope of the application (for example, where the application is limited to food or feed produced from GMOs).

1. HAZARD IDENTIFICATION AND CHARACTERISATION

1.1. **Information relating to the recipient or (where appropriate) parental plants**

(a) Complete name:

(i) family name;

(ii) genus;

(iii) species;

(iv) subspecies;

(v) cultivar, breeding line;

(vi) common name;

(b) Geographical distribution and cultivation of the plant within the Union;

(c) Information on the recipient or parental plants relevant to their safety, including any known toxicity or allergenicity;

(d) Data on the past and present use of the recipient plant, such as history of safe use for consumption as food or feed, including information on how the plant is typically cultivated, transported and stored, whether special processing is required to make the plant safe to eat, and the plant normal role in the diet (for example, which part of the plant is used as a food source, whether its consumption is important in particular subgroups of the population, what important macro- or micro-nutrients it contributes to the diet);

(e) Additional information relating to the recipient or parental plants required for the environmental safety aspects:

(i) information concerning reproduction:
- — mode(s) of reproduction;
- — specific factors affecting reproduction (if any);
- — generation time;

(ii) sexual compatibility with other cultivated or wild plant species;

(iii) survivability:
- — ability to form structures for survival or dormancy;
- — specific factors, if any, affecting survivability;

(iv) dissemination:

— ways and extent of dissemination (to include, for example, an estimation of how viable pollen and/or seed declines with distance);

— special factors affecting dissemination, if any;

(v) geographical distribution within the Union of the sexually compatible species;

(vi) where a plant species is not grown in the Union, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts;

(vii) other potential interactions of the genetically modified plant with organisms in the ecosystem where it is usually grown, or used elsewhere, including information on toxic effects on humans, animals and other organisms.

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 intended function of each constituent fragment of the region intended for insertion

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 introduced or modified

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 genetically modified plant

1.2.2.5. Potential risk associated with horizontal gene transfer

1.2.3. *Additional information relating to the genetically modified plant required for the environmental safety aspects*

1.2.3.1. Information on how the genetically modified plant differs from the recipient plant in reproduction, dissemination, survivability or other properties.

1.2.3.2. Any change to the ability of the genetically modified plant to transfer genetic material to other organisms, namely:

(a) Plant to bacteria gene transfer;

(b) Plant to plant gene transfer.

1.2.4. *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 for comparative analysis*

1.3.2.1. Description of the protocols for the 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 natural food and feed constituents*

1.4.4. *Testing of the whole genetically modified food or feed*

1.4.4.1. 90-day feeding study in rodents

1.4.4.2. Animal studies with respect to reproductive, developmental or chronic toxicity

1.4.4.3. Other animal studies to examine the safety and the characteristics of genetically modified food and feed

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 whole genetically modified plant*

1.5.3. *Conclusion of the allergenicity assessment*

1.6. **Nutritional assessment**

1.6.1. *Nutritional assessment of the genetically modified food*

1.6.2. *Nutritional assessment of the genetically modified feed*

1.6.3. *Conclusion of the nutritional assessment*

2. EXPOSURE ASSESSMENT — ANTICIPATED INTAKE OR EXTENT OF USE

3. RISK CHARACTERISATION

4. POST-MARKET MONITORING ON THE GENETICALLY MODIFIED FOOD OR FEED

5. ENVIRONMENTAL ASSESSMENT

6. ENVIRONMENTAL MONITORING PLAN

7. ADDITIONAL INFORMATION RELATED TO THE SAFETY OF THE GENETICALLY MODIFIED FOOD OR FEED

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 shall be included in the application. This systematic review shall be carried out by taking into account the guidance of EFSA on application of systematic review methodology to food and feed safety assessments to support decision making[(1)].

Where the information obtained from those studies is not coherent with the information obtained from the studies performed in accordance with the requirements set out in Annex II, the applicant shall provide a thorough analysis of the respective studies and provide plausible explanations for the observed discrepancies.

Additional information which might influence the evaluation of the safety of the genetically modified food or feed generated following the submission of the application, as well as any information regarding any prohibition or restriction imposed by a competent authority of any third country on the basis of a safety assessment shall be provided by the applicant.

(**1**) EFSA Journal 2010; 8(6):1637.

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 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)