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 details of the responsible person for all dealings with the European Food Safety Authority (EFSA).

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

4. Scope of the application:

(a) Genetically modified food

- # Food containing or consisting of genetically modified plants
- # Food produced from genetically modified plants or containing ingredients produced from genetically modified plants

(b) Genetically modified feed

- # Feed containing or consisting of genetically modified plants
- # Feed produced from genetically modified plants

(c) Genetically modified plants for food or feed uses

- # Products other than food and feed containing or consisting of genetically modified plants with the exception of cultivation
- # Seeds and other plant propagating material for cultivation in the Union.

5. Unique identifier.

A proposal for a unique identifier for the genetically modified plant developed in accordance with Regulation (EC) No 65/2004.

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

This description would include, for example, a detailed description of specific methods of production of food or feed which would be due to the nature of the genetic modification or which would lead to food or feed with specific characteristics.

7. Where appropriate, the conditions for the placing on the market of the genetically modified food(s) or feed(s), including specific conditions for use and handling.

8. Where applicable, the status of the food or feed or of related substances under other provisions of Union law.

Additional authorisation requirements provided for in Union law, related to the placing on the market of the food or feed or applicable 'maximum residue level' (MRL) where the food or feed is likely to contain residues of plant protection products.

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.

PART III

CARTAGENA PROTOCOL

The application shall provide the information required under Articles 5(3)(c) and 17(3)(c) of Regulation (EC) No 1829/2003 for the purpose of complying with Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

The provided information shall contain as a minimum the information specified in Annex II to Regulation (EC) No 1946/2003 of the European Parliament and of the Council[(2)]:

(a) The name and contact details of the applicant for a decision for domestic use;

(b) The name and contact details of the authority responsible for the decision;

(c) Name and identity of the GMO;

(d) Description of the gene modification, the technique used, and the resulting characteristics of the GMO;

(e) Any unique identification of the GMO;

(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety;

(g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate;

(h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety;

(i) Approved uses of the GMO;

(j) A risk assessment report consistent with Annex II to Directive 2001/18/EC;

(k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

PART IV

LABELLING

The application shall include:

(a) a proposal for labelling in all official languages of the Union, where a proposal for specific labelling is required in accordance with Articles 5(3)(f) and 17(3)(f) of Regulation (EC) No 1829/2003;

(b) either a reasoned statement that the food or feed does not give rise to ethical or religious concerns or a proposal for labelling in all official languages of the Union as required by Articles 5(3)(g) and 17(3)(g) of Regulation (EC) No 1829/2003;

(c) when appropriate a proposal for labelling complying with the requirements of point A(8) of Annex IV to Directive 2001/18/EC.

PART V

METHODS OF DETECTION, SAMPLING AND IDENTIFICATION AND REFERENCE MATERIAL

The applicant shall provide methods for detection, sampling and identification, as well as samples of the food or feed and their controls samples to the European Union Reference Laboratory (EURL) as referred to in Article 32 of Regulation (EC) No 1829/2003.

The application shall include a copy of the completed form for the submission of those samples to the EURL and proof of sending to the EURL.

The application shall include information as to the place where the reference material can be accessed.

The applicant shall follow the instructions for the preparation and the sending of the samples provided by the EU Reference laboratory (EURL) as referred to in Article 32 of Regulation (EC) No 1829/2003. These instructions are published on the following webpage: http://gmo-crl.jrc.ec.europa.eu/guidancedocs.htm

PART VI

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

The information required in the notification as set out in Annex III to Directive 2001/18/EC shall be provided where it is not covered by the requirements of other parts of the application.

PART VII

SUMMARY OF APPLICATIONS

This Part specifies the standardised form, which the summary of the application dossier must follow.

Depending on the scope of the application, some of the requested information may not be applicable.

The summary shall not contain parts considered to be confidential in accordance with Article 30 of Regulation (EC) No 1829/2003.

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 in the Union (if the applicant is not established in the Union)

1.3. **Scope of the application**

(a) Genetically modified food

Food containing or consisting of genetically modified plants
Food produced from genetically modified plants or containing ingredients produced from genetically modified plants

(b) Genetically modified feed

Feed containing or consisting of genetically modified plants
Feed produced from genetically modified plants

(c) Genetically modified plants for food and feed use

Products other than food and feed containing or consisting of genetically modified plants with the exception of cultivation
Seeds and plant propagating material for cultivation in the Union

1.4. **Is the product or the uses of the associated plant protection product(s) already authorised or subject to another authorisation procedure within the Union?**

No	#	
Yes	#	(in that case, specify)

1.5. **Has the genetically modified plant been notified under Part B of Directive 2001/18/EC?**

Yes	#	
No	#	(in that case, provide risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC)

1.6. **Has the genetically modified plant or derived products been previously notified for marketing in the Union under Part C of Directive 2001/18/EC?**

No	#	
Yes	#	(in that case, specify)

1.7. **Has the product been subject to an application and/or authorised in a third country either previously or simultaneously to this application?**

No	#	
Yes	#	In that case, specify the third country, the date of application and, where available, a copy of the risk assessment conclusions, the date of the authorisation and the scope of the application

1.8. **General description of the product**

(a) Name of the recipient or parental plant and the intended function of the genetic modification

(b) Types of products planned to be placed on the market according to the authorisation applied for and any specific form in which the product must not be placed on the market (such as seeds, cut-flowers, vegetative parts) as a proposed condition of the authorisation applied for

(c) Intended use of the product and types of users

(d) Any specific instructions and recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for

(e) If applicable, geographical areas within the Union to which the product is intended to be confined under the terms of the authorisation applied for

(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 other applicable EU legislation than Regulation (EC) No 1829/2003 and when necessary a proposal for specific labelling in accordance with Article 13(2) and (3), Article 25(2)(c) and (d) and Article 25(3) of Regulation (EC) No 1829/2003

In the case of products other than food and feed containing or consisting of genetically modified plants, a proposal for labelling which complies with the requirements of point A(8) of Annex IV to Directive 2001/18/EC must be included.

(i) Estimated potential demand

(i) In the EU

(ii) In EU export markets

(j) Unique identifier in accordance with Regulation (EC) No 65/2004.

1.9. **Measures suggested by the applicant to take in the case of unintended release or misuse of the product as well as measures for its disposal and treatment**

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 within the Union**

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 environmental safety aspects)**

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 (for environmental safety aspects)**

2.8. **In the case of plant species not normally grown in the Union description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts (for environmental safety aspects)**

2.9. **Other potential interactions, relevant to the genetically modified plant, of the 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 (for environmental safety aspects)**

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

3.2. **Information relating to the genetically modified plant**

3.2.1. *Description of the trait(s) and characteristics which have been introduced or modified*

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 partial

(b) In the case of deletion(s), size and function of the deleted region(s)

(c) Subcellular location(s) of insert(s) (nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form) and methods for its/their determination

(d) The organisation of the inserted genetic material at the insertion site

(e) In the case of modifications other than insertion or deletion, describe function of the modified genetic material before and after the modification, as well as direct changes in expression of genes as a result of the modification

3.2.3. *Information on the expression of the insert*

(a) Information on developmental expression of the insert during the life cycle of the plant

(b) Parts of the plant where the insert is expressed

3.2.4. *Genetic stability of the insert and phenotypic stability of the genetically modified plant*

3.2.5. *Information (for environmental safety aspects) on how the genetically modified plant differs from the recipient plant in:*

(a) Mode(s) and/or rate of reproduction

(b) Dissemination

(c) Survivability

(d) Other differences

3.2.6. *Any change to the ability of the genetically modified plant to transfer genetic material to other organisms (for environmental safety aspects)*

(a) Plant to bacteria gene transfer

(b) Plant to plant gene transfer

4. COMPARATIVE ANALYSIS

4.1. **Choice of the conventional counterpart and additional comparators**

4.2. **Experimental design and statistical analysis of data from field trials for comparative analysis**

Description of the experimental design (number of locations, growing seasons, geographical spread, replicates and number of commercial varieties in each location) and of the statistical analysis.

4.3. **Selection of material and compounds for analysis**

4.4. **Comparative analysis of agronomic and phenotypic characteristics**

4.5. **Effect of processing**

5. TOXICOLOGY

(a) Toxicological testing of newly expressed proteins

(b) Testing of new constituents other than proteins

(c) Information on natural food or feed constituents

(d) Testing of the whole genetically modified food and feed

6. ALLERGENICITY

(a) Assessment of allergenicity of the newly expressed protein

(b) Assessment of allergenicity of the whole genetically modified plant

7. NUTRITIONAL ASSESSMENT

(a) Nutritional assessment of the genetically modified food

(b) Nutritional assessment of the genetically modified feed

8. EXPOSURE ASSESSMENT — ANTICIPATED INTAKE/EXTENT OF USE

9. RISK CHARACTERISATION

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

11. ENVIRONMENTAL ASSESSMENT

11.1. **Mechanism of interaction between the genetically modified plant and target organisms**

11.2. **Potential changes in the interactions of the genetically modified plant with the biotic environment resulting from the genetic modification**

(a) Persistence and invasiveness

(b) Selective advantage or disadvantage

(c) Potential for gene transfer

(d) Interactions between the genetically modified plant and target organisms

(e) Interactions of the genetically modified plant with non-target organisms

(f) Effects on human health

(g) Effects on animal health

(h) Effects on biogeochemical processes

(i) Impacts of the specific cultivation, management and harvesting techniques

11.3. **Potential interactions with the abiotic environment**

11.4. **Risk characterisation**

12. ENVIRONMENTAL MONITORING PLAN

(a) General (risk assessment, background information)

(b) Interplay between environmental risk assessment and monitoring

(c) Case-specific genetically modified plant monitoring (approach, strategy, method and analysis)

(d) General surveillance of the impact of the genetically modified plant (approach, strategy, method and analysis)

(e) Reporting the results of monitoring

13. DETECTION AND IDENTIFICATION TECHNIQUES FOR THE GENETICALLY MODIFIED PLANT

14. INFORMATION RELATING TO PREVIOUS RELEASES OF THE GENETICALLY MODIFIED PLANT (FOR ENVIRONMENTAL RISK ASSESSMENT ASPECTS)

14.1. **History of previous releases of the genetically modified plant notified under Part B of Directive 2001/18/EC or under Part B of Council Directive 90/220/EEC[3] by the same notifier**

(a) Notification number

(b) Conclusions of post-release monitoring

(c) Results of the release with respect to any risk to human health and the environment, submitted to the competent authority in accordance with Article 10 of Directive 2001/18/EC

14.2. **History of previous releases of the genetically modified plant carried out outside the Union by the same notifier**

(a) Release country

(b) Authority overseeing the release

(c) Release site

(d) Aim of the release

(e) Duration of the release

(f) Aim of post-releases monitoring

(g) Duration of post-releases monitoring

(h) Conclusions of post-release monitoring

(i) Results of the release with respect to any risk to human health and the environment

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

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

(**3**) OJ L 117, 8.5.1990, p. 15.

Status:
Point in time view as at 31/12/2020.

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.