European Food Safety Authority

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GUIDANCE OF EFSA

EFSA guidance on the submission of applications for authorisation of genetically modified plants under Regulation (EC) No 1829/2003[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

This guidance, published on 17 February 2014, replaces the earlier version published on 6 December 2013[4]

ABSTRACT

This document provides guidance to applicants for submitting an application for authorisation of genetically modified (GM) plants for food and feed uses, import and processing, and/or cultivation in the European Union under Regulation (EC) No 1829/2003. The EFSA submission guidance describes the community procedures in the European Union for handling GM plant applications, and provides instructions to applicants on how to prepare and present data in an application. It is supplemented with seven appendices providing templates of data presentation to be followed by applicants, including a completeness checklist. The earlier versions are now updated to account for requirements outlined in Implementing Regulation (EU) No 503/2013. Instructions for submission described in this EFSA guidance are applicable to all GM plant applications submitted under Articles 5, 11, 17 and 23 of Regulation (EC) No 1829/2003.

KEY WORDS

Application, submission, genetically modified plants, GMO, Regulation (EC) No 1829/2003, Implementing Regulation (EU) No 503/2013

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[4] On 12 February 2014 three editorial changes were made to the version published on 6 December 2013: the total number of pages in the suggested citation, approval date in footnote 1, a publication year was added to the reference list. On 6 December 2013 the version 3 of this guidance was published. Modifications in version 3 include: main text – updated according to the Implementing Regulation (EU) No 503/2013; Appendices A, I and J – removed; Appendix B – renamed as Appendix A, sections on molecular characterisation, food and feed risk assessment are aligned to the Implementing Regulation; Appendices C and H – renamed respectively as Appendices B and G, both are modified slightly; Appendices D, E and G – renamed respectively as Appendices C, D and F, content unchanged; Appendix F – renamed as Appendix E, modified.

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SUMMARY

The EFSA submission guidance provides guidelines for handling applications for authorisation of genetically modified (GM) plants for food and feed uses, import and processing, and/or cultivation (referred to hereafter as "GM plant applications") in the European Union (EU), submitted under Regulation (EC) No 1829/2003. It consists of the following five chapters:

- Chapter 1 describes the EU procedure for handling GM plant applications;
- Chapter 2 provides detailed instructions on the structure of an application and the presentation of data in the desired format;
- Chapter 3 explains specific requirements for different parts of an application, in particular, Parts I, II and VIII;
- Chapter 4 explains requirements specific to applications concerning GM plants containing stacked events.
- Chapter 5 explains requirements specific for GM plants application for renewal of authorisation.

Instructions described in the EFSA submission guidance are applicable to all GM plant applications submitted under Articles 5, 11, 17 and 23 of Regulation (EC) No 1829/2003.

The EFSA submission guidance is supplemented by seven appendices:

- Appendix A is a completeness checklist to be filled by applicants;
- Appendix B provides templates to summarise scientific information as well as exemplar figures for data presentation;
- Appendix C specifies data to be provided for the comparative analysis of the GM plant agronomic/phenotypic characteristics;
- Appendices D-F specify data to be provided for the environmental risk assessment (ERA);
- Appendix G is the proof of reception issued by the EU Reference Laboratory for GM Food and Feed;

The abovementioned appendices should be filled out and submitted by applicants. These are then checked by EFSA to ensure that: (i) all necessary information and documentation specified by this submission guidance, is present in the data package; and (ii) an application data package conforms with the recommended structure and format.

The EFSA submission guidance is now updated to account for requirements outlined in Implementing Regulation (EU) No 503/2013. This Regulation only covers GM plant applications for food and feed uses, and excludes GM plant applications for cultivation in the EU. Therefore, the update of the EFSA submission guidance focuses on the relevant parts related to molecular characterisation and food and feed safety assessment as outlined in Appendix A (the completeness checklist). Parts pertaining to the ERA were not changed, except for Appendix E that was updated.

The EFSA submission guidance and appendices are available in electronic format on EFSA website.

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BACKGROUND

Genetically modified organisms (GMOs) and derived food and feed products are subject to a risk analysis and regulatory approval before entering the European market. Regulation (EC) No 1829/2003[5] lays down the community procedures in the European Union (EU) for the authorisation and supervision of genetically modified (GM) food and feed, as well as for the labelling of such food and feed. In this process, the role of the European Food Safety Authority (EFSA) is to independently assess, providing scientific advice to risk managers, any possible risks that the consumption or cultivation of a GMO may pose to human and animal health and the environment.

In accordance with Articles 5(8), 11(6), 17(8) and 23(6) of Regulation (EC) No 1829/2003, EFSA and its GMO Panel are responsible for developing detailed guidance to assist applicants in the preparation and presentation of GMO market registration applications. As a first result of this task, the EFSA GMO Panel published the Guidance document for the risk assessment of GM plants and derived food and feed, together with four Annexes (I to IV) providing instructions for the presentation of applications (EFSA, 2006).

EFSA developed a Guidance to applicants on the preparation and presentation of GM plant applications (referred to hereafter as "submission guidance") in 2011, following the update of the EFSA GMO Panel Guidance Documents for risk assessment of GM food and feed (EFSA, 2011a) and for the ERA of GM plants (EFSA, 2010a). In the following year, EFSA gained significant experience in checking the completeness of GM plant applications. This, together with feedback received from applicants, other stakeholders and EU Member States, motivated a first revision of this EFSA submission guidance in 2012.

The recent publication of Implementing Regulation (EU) No 503/2013[6] necessitates an additional revision of this EFSA submission guidance, in order to reflect the data requirements outlined in this Regulation. Therefore, EFSA decided to align its submission guidance to the requirements of the Implementing Regulation (EU) No 503/2013.

TERMS OF REFERENCE AS PROVIDED BY EFSA

The EFSA submission guidance assists applicants for the preparation and presentation of an application for authorisation of GM plants and derived products for food and feed uses, import and processing, and/or seeds and plant propagating material for cultivation in the EU, submitted under Articles 5 and 17 of Regulation (EC) No 1829/2003. This submission guidance applies also to applications for the renewal authorisation of existing products produced from GM plants submitted under Articles 11 and 23 of Regulation (EC) No 1829/2003.

The submission guidance provides information on the structure of applications, the naming of documents, the presentation of reports, data and confidential information. It includes a completeness checklist, reflecting the requirements for GM plant applications as outlined in the Implementing Regulation (EU) No 503/2013 and the EFSA GMO Panel Guidance document for the environmental risk assessment of GM plants. The completeness checklist should be filled by applicants, then checked by EFSA to ensure that (i) GM plant applications follow the required structure; and (ii) all required information and documents are provided.

SCOPE OF THE EFSA SUBMISSION GUIDANCE

EFSA requested its GMO Unit to align the EFSA submission guidance to the requirements outlined in the Implementing Regulation (EU) No 503/2013.

[5] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18.10.2003, p. 1–23.

[6] 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. OJ L 157, 8.6.2013, p. 1-48

GUIDANCE

1. Procedure for handling GM plant applications in the EU

One objective of Regulation (EC) No 1829/2003 is to lay down community procedures for the authorisation and supervision of GM food and feed in the EU. The different steps of handling GM plant applications submitted under Regulation (EC) No 1829/2003 are illustrated in Figure 1 and explained in Sections 1.1 to 1.10.

1.1. Submission of an application

In accordance with Articles 5(2) and 17(2) of Regulation (EC) No 1829/2003, applicants shall submit their GM plant applications. The MS CA shall acknowledge receipt of the application to the applicant in writing within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application. The MS CA shall, without delay**,** inform EFSA and forward the application and any supplementary information supplied by the applicant to EFSA.

In accordance with Articles 11(1) and 23(1) of Regulation (EC) No 1829/2003, GM plant applications for the renewal authorisation shall be sent to the European Commission (EC) at least one year before the expiry date of the authorisation. The EC then mandates EFSA to assess the renewal application.

1.2. Submission to an institute developing certified reference materials

In accordance to Articles 5(3)(j) and 17(3)(j) of Regulation (EC) No 1829/2003, reference materials must be developed. Applicants shall submit samples of the food and feed and their controls to the institute that is responsible for the production of certified reference materials (CRM). A statement that the certified reference materials are produced, in accordance to Annex II of Regulation (EC) No 641/2004, should be included in the GM plant application under Part V (see Section 3.5).

1.3. Submission to the European Union Reference Laboratory for GM Food and Feed

In accordance with Article 32 and the Annex of Regulation (EC) No 1829/2003, the European Union Reference Laboratory for GM Food and Feed (EURL-GMFF), formerly named Community Reference Laboratory, is the Commission's Joint Research Centre. EURL-GMFF is responsible for the validation of methods for sampling, detection and identification of the GM food and feed. After evaluation, the EURLGMFF submits its full evaluation report to EFSA.

The EURL-GMFF examines the completeness of the information related to the presence of samples and detection methods. More information on the requirements can be consulted at its website.

During the completeness check of GM plant applications (see Section 1.5) EFSA verifies that a proof of submission of the samples, reagents and methods issued by the EURL-GMFF is provided in the application. Therefore, EFSA recommends the applicant to submit documents and samples to EURL-GMFF before submitting GM plant applications to the MS CA, so that the proof of reception by the EURL-GMFF can be readily included in the application (see Appendix G).

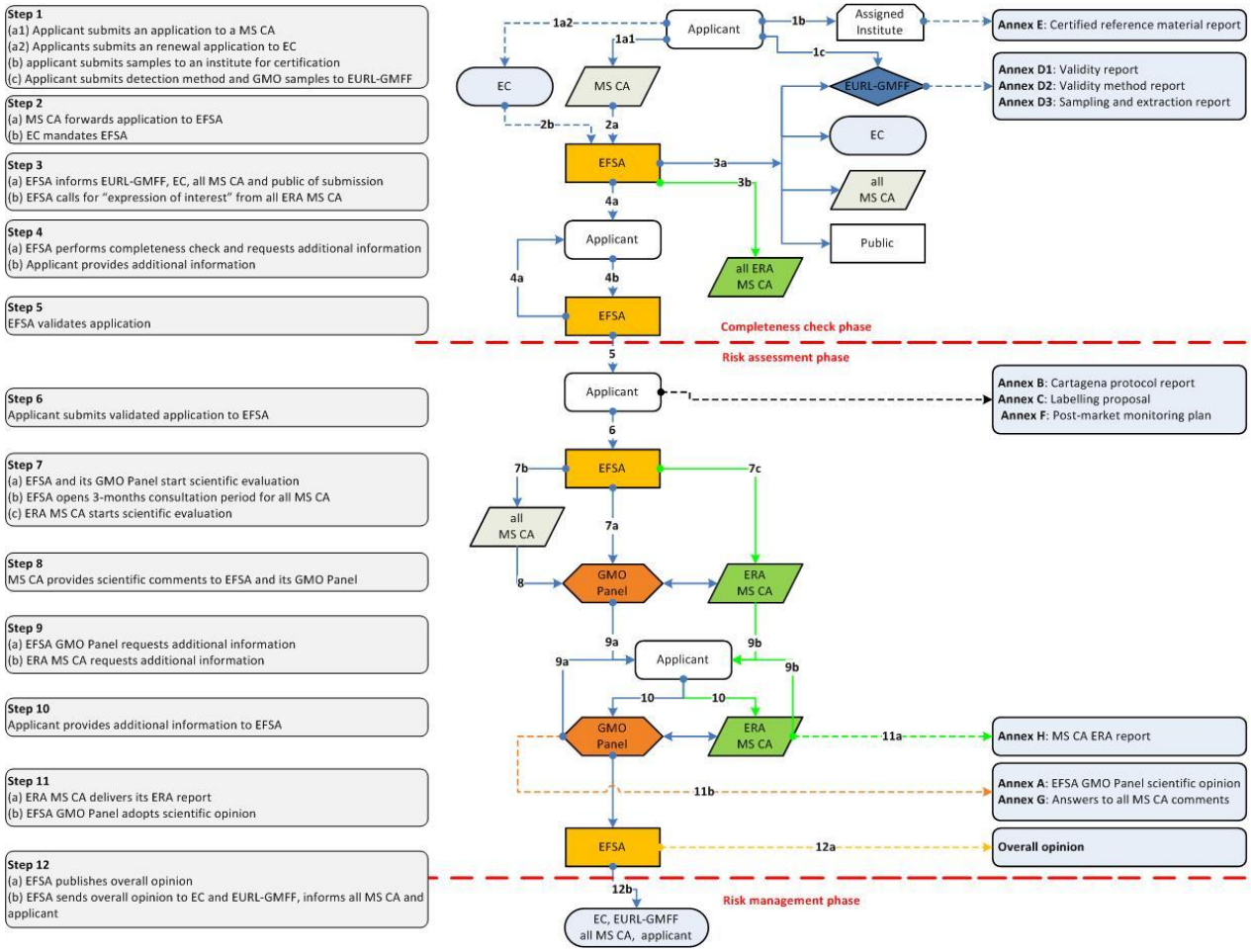


Figure 1: Steps for handling GM plant applications submitted under Regulation (EC) No 1829/2003. Figure 1 is organised in three parts: The left part consists of grey boxes representing the successive steps for handling GM plant applications. The central part of the figure depicts the process as flowchart with arrows indicating the information flow between the different actors involved; blue arrows represent steps specific for GM plant applications for food and feed uses, import and processing, while green arrows indicate the additional steps for GM plant applications for cultivation. The right part of the figure consists of blue boxes describing the type of deliverables. The dashed lines specify who is responsible for producing the respective deliverables. Note that not all steps are applicable to each GM plant application. Abbreviations: EC: European Commission; ERA: environmental risk assessment; EURL-GMFF: European Union's Reference Laboratory for GM Food and Feed; MS CA: national Competent Authority of a Member State.

1.4. Receipt of the application by EFSA

Correspondence to EFSA concerning GM plant applications should be addressed to:

European Food Safety Authority
Head of Applications Desk Unit
Via Carlo Magno 1A
43126 Parma
Italy
E-mail: APDESK.applications@EFSA.europa.eu

The Applications Desk Unit is responsible for the registration of market applications for regulated products in EFSA, and is the contact point for applicants until the GM plant application is validated. In accordance with Articles 5(2) and 17(2) of Regulation (EC) No 1829/2003, once the MS CA forwards a GM plant application to EFSA, EFSA acknowledges the receipt of the application to the MS CA. EFSA, without delay, informs the other MS CA and EC. EFSA endeavours to make the summary of GM plant applications available to the public through the Register of Questions within two weeks following reception. Via its electronic system, known as the EFSA GMO Extranet, EFSA makes the summary of GM plant applications available to: EFSA GMO Panel and its standing Working Groups (WGs); EC; and all MS CA.

1.5. Completeness check by EFSA

At reception, a GM plant application is given an identification code. This code should be included in all further correspondence with EFSA, the EURL-GMFF and EC. After reception Applications Desk Unit, with the technical support of GMO Unit, checks the completeness of the application (Figure 1) and validates it when it fulfils the legal requirements outlined in Implementing Regulation (EU) No 503/2013. EFSA endeavours to have the first outcome of the completeness check available within 30 working days after the reception date.

The completeness check process might require further exchange of information between the applicant and EFSA. In such case, EFSA informs the applicant, in writing, if certain parts of the GM plant application need modification or completion, in order to proceed to validation. After receiving a request for additional information, the applicant should submit the response within 30 days. When this is not possible, the applicant should indicate to EFSA the date by which the response is expected. EFSA will notify the acceptance of the new submission date via e-mail.

When responding to EFSA questions, the applicant should submit an updated version of the entire GM plant application (Parts I to VIII) on CD-ROM(s). EFSA advises to accompany the submission of an updated GM plant application with a cover letter wherein the applicant precisely describes how each EFSA question was addressed. Missing information should be incorporated in all relevant parts of the GM plant application. EFSA endeavours to inform the applicant within 15 working days if the updated GM plant application is complete or if further revision is required.

1.6. Validation of application by EFSA

Once the GM plant application fulfils all requirements, EFSA issues a validity statement. The valid GM plant application is then made available to all MS CAs and the EURL-GMFF via EFSA GMO Extranet. Upon validity, EFSA updates the summary (Part VII) of the GM plant application on the publicly accessible EFSA Register of Questions.

With the validity statement, the applicant is requested to submit one paper copy of the valid GM plant application and one electronic copy of the public access version (see Section 2.2) to EFSA. The applicant shall confirm by letter that this paper copy is identical to the validated electronic version of the GM plant application. At this stage, EFSA does not accept any further modification of the GM plant application other than editorial ones. EFSA may request additional electronic and paper copies of

the valid version. As stated in the validity statement, after validation, EFSA GMO Unit becomes the point of contact for applicants.

All information provided by the applicant is available on the EFSA GMO Extranet. EFSA informs registered GMO Extranet members about the updates of GM plant applications via e-mail on a weekly basis. This includes correspondence such as declarations of validity, questions sent to applicants, responses from applicants, spontaneously submitted information from applicants, as well as calls for 'expression of interest' to all MS CA designated, in accordance with Article 4 of Directive 2001/18/EC[7], to perform the initial ERA of GM plant applications for cultivation.

1.7. Risk assessment, MS comments and request for additional information

From the date of validity, GM plant applications enter the risk assessment phase in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. The EFSA GMO Panel is supported by three WGs, each focusing on specific areas of the risk assessment: the WG on Molecular Characterisation (MC) considers all relevant scientific data on the molecular characterisation of the GM plant, such as detailed information on the source and function of the donor DNA, the transformation method, the organisation of the inserted DNA at the insertion site(s), and the expression and stability of the insert. The WG on Food/Feed Risk Assessment (FF) focuses on the agronomic and phenotypic characteristics, composition, toxicity, allergenicity and nutritional value of the GM plant and its derived food and feed. The WG on Environmental Risk Assessment (ENV) considers elements such as changes in interactions with biotic and abiotic factors, changes in the persistence (weediness) and invasiveness ability of the GM plant, potential for gene transfer and its environmental consequences, interactions between the GM plant and target and non-target organisms, effects on biogeochemical processes, as well as impacts of specific cultivation, management and harvesting techniques associated with the cultivation of the GM plant.

GM plant applications are discussed in the three WGs mentioned above and the outcomes of such discussions are summarised in the respective WG meeting minutes. EFSA endeavours to send the first questions identified within two and half months after the date of validity.

In accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003, EFSA shall endeavour to respect a time limit of six months, from the validity date of a GM plant application to the publication of the EFSA overall opinion in the EFSA Register of Questions (see Section 1.9).

1.7.1. Member States comments

Within three months following the date of validity, all MS CA can submit to EFSA, via the EFSA GMO Extranet, comments or questions on valid GM plant applications under assessment. The three WGs consider all MS comments submitted during this consultation period and provide a response to each comment. These are published as Annex G of the EFSA overall opinion (see Section 1.9).

1.7.2. Request for additional information

EFSA may request additional information in order to clarify specific risk assessment issues. The rationale for asking a question is provided to applicants. A question raised will not be reiterated. As outlined in Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003, the request for additional information extends the six-month time limit (known as the "stop-the-clock" mechanism).

After receiving a request for additional information, the applicant should submit the response within 30 working days. When this is not possible, the applicant should indicate to EFSA the date by which the response is expected. EFSA will notify the acceptance of the new submission date via e-mail. If, in exceptional cases, the agreed timeline cannot be met, the applicant should immediately inform EFSA.

[7] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC – Commission declaration. OJ L 106, 17.4.2001, p. 1–39.

A request for additional information may address several parts of a GM plant application. The applicant is asked to provide one complete answer addressing all issues raised. If the additional information raises new questions, EFSA will send a letter to the applicant with the new questions and the clock remains stopped. If the additional information does not raise new questions, EFSA will restart the clock and inform the applicant in writing.

The additional information should be provided in electronic form. If confidential information is included (see Section 2.1.2) a public access version should also be provided. In addition, the overview table on studies and relevant figures should be updated (see Appendix B).

Additional information may also be requested by the EURL-GMFF. EFSA will stop the clock for the clarification on or provision of any elements required under Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003.

Requests for additional information may also come from the MS CA carrying out the initial evaluation of the ERA for GM plant applications for cultivation. In this case, the lead MS CA asks EFSA to stop the clock with additional questions to the applicant. EFSA then proceeds with the request by informing the applicant in writing, including the letter of this MS CA in an annex.

1.7.3. Adoption of a scientific opinion by the EFSA GMO Panel

During the risk assessment phase the WGs prepare a scientific opinion for a GM plant application, which is discussed, amended and adopted by the EFSA GMO Panel at plenary meetings. EFSA endeavours to publish the scientific opinion in the EFSA Journal within three weeks from the date of adoption.

1.8. Networking with Member States on GM plant applications for cultivation

If a GM plant application involves the cultivation of the GM plant (as seeds or other plant-propagating material) in the EU, EFSA shall ask a MS CA to perform the initial ERA, in accordance to Articles 6(3) and 18(3) of Regulation (EC) No 1829/2003..In such cases, EFSA will call for 'expressions of interest' from all MS CA, designated in accordance with Article 4 of Directive 2001/18/EC. EFSA will select a MS CA on the basis of the following criteria:

(i) experience in performing ERA;
(ii) experience in writing national risk assessment reports;
(iii) interest in the crop/trait;
(iv) availability.

If no MS CA expresses an interest, a formal request will be addressed to the MS CA to which the GM plant application was submitted.

The selected MS CA will carry out the initial ERA by following the EFSA GMO Panel Guidance on the ERA of GM plants (EFSA, 2010a) and will work in close contact with EFSA. After finalising its evaluation, the MS CA submits its ERA report to EFSA. This report will be considered by the EFSA GMO Panel before adopting its scientific opinion, and will be included as Annex H of the EFSA overall opinion (see Section 1.9).

1.9. EFSA overall opinion

The EFSA overall opinion is prepared when all parts are finalised, as mentioned in Article 6(5) and 18(5) of Regulation (EC) No 1829/2003. In accordance with Articles 6(7) and 18(7) of Regulation (EC) No 1829/2003, EFSA makes the overall opinion available to the public through its Register of Questions.

The overall opinion includes the following annexes as applicable:

Annex A	Scientific opinion of the EFSA GMO Panel
Annex B	Compliance report for the Cartagena Protocol (from the applicant)
Annex C	Labelling proposal (from the applicant)
Annex D1	Validation report (from EURL-GMFF)
Annex D2	Validated method report (from EURL-GMFF)
Annex D3	Sampling and extraction report (from EURL-GMFF)
Annex E	Certified Reference Materials report (from the assigned institute)
Annex F	Monitoring plan (from the applicant)
Annex G	Comments from MS CAs and replies from the EFSA GMO Panel
Annex H	MS CA ERA report for GM plant applications (only for cultivation)

In accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003, EFSA sends the overall opinion to the EC and EURL-GMFF, and informs all MS CA and the applicant. The EFSA scientific opinion on GM plant applications is then passed to the EC and EU Member States. The application now enters the risk management phase including the adoption of a decision. The authorisation procedure can be found at the DG SANCO website. The status of the decision on authorisation can be found in the EU register of genetically modified food and feed.

1.10. Withdrawal of GM plant applications

If an applicant wishes to withdraw its GM plant application during the completeness check or risk assessment phase, the applicant should request EFSA in writing for withdrawal, putting in copy EC and the MS CA to which the GM plant application was submitted. This letter will be made available on the EFSA Register of Questions.

2. Preparation of GM plant applications

2.1. Structure of GM plant applications

To submit an application, the applicant should send a paper and an electronic (CD-ROM) copy to the national Competent Authority of a Member State (MS CA). Such application should consist of eight parts: Part I through Part VII are defined by Implementing Regulation (EU) No 503/2013; Part VIII is required by EFSA. Documents should be named and organised in folders as illustrated in Table 1. EFSA does not accept parts of GM plant applications submitted by different applicants, nor does EFSA compile information submitted by different applicants to obtain one complete application for a GM plant.

Table 1: Overview of the required structure and folder/file names

Folder name	File name and sub-folder name
Part_I_General_info →	General_info.pdf
Part_II_Scientific_info →	Main_text_[Application_identification code].pdf PMEM_Plan.pdf References[1] Appendices[2,3] ERA Appendices D to F
Part_III_Cartagena_Protocol →	Cartagena.pdf
Part_IV_Labelling_Proposal →	Labelling.pdf
Part_V_Sampling and Detection →	Sampling and Detection.pdf EURL_proof_submission.pdf (Appendix G)
Part_VI_Additional_info	Additional_info.pdf
Part_VII_Summary of applications →	Summary_[Application_number].pdf
Part_VIII_Administrative_doc	See Section 3.8

[1]All published documents cited in the main text of the application shall be present in subfolder References and formatted as indicated in Section 3.2.3.

[2]All unpublished documents provided by the applicant and cited in the main text of the application shall be present in the subfolder Appendices and formatted as indicated in Section 3.2.3.

[3]In case unpublished studies of the applicant are classified as CI and non-CI, two sub-folders should be provided: "Appendices (CI)" and "Appendices (non-CI)". If the Appendices folder is not labelled with CI or non-CI, all documents within that folder will be considered being non-CI.

2.1.1. Submission version

The electronic copy of an application should contain all information and should be structured as indicated in Table 1. The applicant can choose to either divide *confidential* (CI) and *non-confidential* (non-CI) *information* into separate CD-ROMs, or to include them on the same CD-ROM. Each CD-ROM containing CI should be labelled as described in Section 2.4. In case a CD-ROM is password protected, the password should be provided.

The paper copy of an application should contain the same information as the electronic version, except for: legal references (e.g. Directive 2001/18/EC, Regulation (EC) No 1829/2003, etc.), consensus documents (e.g. Organisation for Economic Co-operation and Development (OECD), *Codex alimentarius*, etc.), EFSA outputs (e.g. scientific opinions and statements published previously by the EFSA GMO Panel), and scientific articles published in peer-reviewed journals.

Confidential information: The applicant should indicate which parts of the application are claimed to be confidential in accordance with Article 2(3) of Regulation (EC) No 641/2004, together with a verifiable justification in accordance with Article 30 of Regulation (EC) No 1829/2003. EC will determine which information can be kept confidential and will inform the applicant and EFSA about its decision.

The main text of the application cannot contain confidential information. Sections or studies considered confidential by the applicant should be identified by including CI in brackets in the file name, e.g. "Appendix x (CI).pdf" and indicating "CONFIDENTIAL" on the corresponding pages. If the name of an author is claimed as confidential, it should not be included in the file name and citation (see Section 3.2.3). A list, containing all the names to be treated as confidential, should be included in Part VIII (see Table 2).

When submitting additional information, the accompanying cover letter should always indicate whether such additional information contains confidential information.

2.1.2. Public access version

In accordance with Regulation (EC) No 1049/2001[8] EFSA will grant public access, on request, to the non-confidential parts of an application after validity without prior consultation of the applicant. Therefore, upon validation, the applicant should provide EFSA with a CD-ROM containing the public access version of the application.

The recommended name for the CD-ROM is "Public_Access_[Application identification code]". The public access version of the application must follow the same structure as the original application (see Table 1). The public access version should not contain confidential information and it should be otherwise identical to the validated electronic version.

During the risk assessment phase, when the additional information to EFSA contains confidential information, a public access version should also be submitted.

Following the confidentiality decision by the EC, the applicant should provide a CD-ROM containing the final public access version of the application to EFSA. The CD-ROM should bear the date of the confidentiality decision.

2.2. Language

An application should be written in idiomatic English. The text should be carefully checked for errors. Peer-reviewed articles and published reports in languages other than English should be accompanied by translations of the relevant parts.

2.3. Electronic version

2.3.1. Format and label of the CD-ROMs

The provided CD-ROM(s) should be clearly labelled and include the following information:

- name of the GM plant event and plant species;
- EFSA application identification code (once provided)
- name of company;
- date of submission;
- submission type:
    - first submission (CC1)
    - updated versions (CC2... CCx)
    - valid version
    - additional information;
- CI, non-CI, or public access version;
- CD-ROM number (applicable only if more than one CD-ROM is submitted per application, e.g. "CD-ROM 1 of 2").

2.3.2. File format, size and name

All documents cited in Part I and Part II should be provided preferably as portable document format (PDF), should be accessible to allow reading, printing, word searching and copying of text from the file using Adobe® Acrobat® Standard software. Text and figures of all parts of an application should be fully legible. Other software format types, such as Word, Excel and GenBank, are acceptable for specific files and they should fulfil the same criteria as required for PDF files. Sequence information is preferably submitted in GenBank format including the annotation information.

[8] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents. OJ L 145, 31.5.2001, p. 43–48.

The documents should be formatted for standard DIN A4 (210 x 297 mm) paper. The recommended font of text is Times New Roman or Arial, 11-12 points for normal text and 9-10 points for footnotes. All fonts used in the document should be embedded in the PDF files to ensure that they are always readable and searchable.

The size of documents should be limited to 25 MB. In case a study report exceeds 1000 pages the applicant should consider dividing into separate documents. If this is not possible, the study report in the paper version, doe not need to include long appendices (*e.g.* raw data), which will be asked by EFSA if needed.

File names specified in Table 1 should be used. For other files, names should be concise and informative and contain no more than 40 characters including spaces. File and folder names should not include the following special characters: \ / : * ? \" < > | #.

All documents should be well structured and include a table of content. On each page of the application, the file name, company name, GM plant event name, and page number should be included in the header or footer. To improve navigation through PDF documents the use of bookmarks and hyperlinks is encouraged.

2.4. Standard units and abbreviations

The International System of Units (SI)[9] must be used. For the naming of chemical compounds and for chemical quantities, units and symbols, the applicants should follow the International Union of Pure and Applied Chemistry (IUPAC) nomenclature[10]. Gene and protein names should respect nomenclature and style of the relevant species. Chemical substances (e.g. herbicide) should be indicated including the trade name and the active substance.

It is advisable to use only the GM event name in Part II, but to include also its trade name in Part VII.

Acronyms and abbreviations should be defined when first mentioned and should be listed at the beginning of Part II.

3. Specifics on the different parts of the application

3.1. Part I – General information

Requirements on the structure and content of Part I can be found in Annex I of Implementing Regulation (EU) No 503/2013. Part I is used by EFSA for both completeness check (see the corresponding spread-sheet in Appendix A) and risk assessment purposes. All information should include sufficient details and should be clearly referenced.

3.2. Part II – Scientific information

Part II should be structured according to Annex I of Implementing Regulation (EU) No 503/2013. Part II is used by EFSA for both completeness check (see the corresponding spread-sheets Appendix A) and risk assessment purposes. All requirements of Part II should be addressed in the application. The ERA section should be structured according to the EFSA GMO Panel Guidance on the ERA of GM plants (EFSA, 2010a).

3.2.1. Content and requirement of Part II

The scientific content of chapters and sections in the document "Main_text_[Application_identification code].pdf" (see Table 1) should comply with the requirements laid down in Annex II of Implementing Regulation (EU) No 503/2013.

[9] http://www.bipm.org/utils/common/pdf/si_brochure_8_en.pdf
[10] http://www.iupac.org/

Specific topics are addressed in the following EFSA guidance documents:

- Guidance for risk assessment of food and feed from GM plants (EFSA, 2011a)
- Guidance on selection of comparators for the risk assessment of GM plants and derived food and feed (EFSA, 2011b)
- Guidance on the post-market environmental monitoring (PMEM) of GM plants (EFSA, 2011c)
- Guidance on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed (EFSA, 2011d)
- Guidance on the ERA of GM plants (EFSA, 2010a)
- Statistical considerations for the safety evaluation of GMOs (EFSA, 2010b)
- Scientific opinion on the assessment of allergenicity of GM plants and microorganisms and derived food and feed (EFSA, 2010c)
- Scientific opinion on the assessment of potential impacts of GM plants on non-target organisms (EFSA, 2010d)
- Scientific opinion on guidance for the risk assessment of GM plants used for non-food or non-feed purposes (EFSA, 2009)
- Safety and nutritional assessment of GM plants and derived food and feed: The role of animal feeding trials (EFSA, 2008)

Part II should be a complete stand-alone document, containing all information required for the risk assessment. The information presented in main text, appendices, tables and figures should be coherent. If a requirement of Implementing Regulation (EU) No 503/2013 does not apply for certain part(s) of an application, the applicant should justify the omission of such data. All studies are expected to be of high quality and quality assurance documentations should be provided. Raw data of all studies performed by the applicant should be provided in a suitable electronic format.

Appendix C specifies data to be provided for the comparative analysis of the GM plant agronomic/phenotypic characteristics. Appendices D to F refer to the data generated in support of the ERA. Appendix D is required for applications on GM plants expressing insect resistance traits. The four tables provided in Appendix E should be used to summarise the studies on non-target organisms (NTOs) used to support the ERA. Appendix F is required for each experimental study submitted for the ERA. All compiled appendices D to F should be saved in the folder Appendices as the subfolder ERA_Appendices D to F (see Table 1).

3.2.2. Data presentation – figures and tables

Applicants are encouraged to use figures and tables to illustrate experimental data. The resolution and quality of images should be sufficient to enable the non-equivocal interpretation of the data. Examples for MC and FF data presentation can be found in Appendix B. Schematic summaries of data supporting the comparative analysis of the GM plant agronomic/phenotypic characteristics and ERA data are given in Appendix C and Appendices D-F, respectively.

Figure preparation: Each figure is expected to have a self-explanatory title and a legend, to be numbered according to its appearance, and to be cited in the text. No specific feature within an image can be enhanced, obscured, moved, removed or introduced. Adjustment of brightness, contrast or colour balance can be applied only to the whole image, provided that this does not obscure, eliminate or miss-represent any information. The grouping or consolidation of images from multiple sources must be explicitly acknowledged in the figure and in its legend.

Table preparation: Each table is expected to have a self-explanatory title and a legend as appropriate, to be numbered according to the order of its appearance, and to be cited in the text.

3.2.3. Citations and reference list

All published and unpublished studies provided in Part II should be clearly cited. Citations should be presented in an alphabetical reference list at the end of the document. Applicants are recommended to include also an overview table of all studies and reports carried out at the beginning of the main text. An example of such an overview table is provided in Table 1 of Appendix B.

3.2.3.1. Published studies, proceedings, reports, guidelines and legislation

Citations should be derived from file names. Published study should be cited as (Johnson et al., 2010) or (Johnson and van Cauwelaert, 2009). Examples for the formatting of references in the reference list can be found in Section 3.2.3.3. EndNote style files are available upon request.

The following format should be applied to the reference list:

- no full stops after author initials and no commas between author last name and initial(s);
- "and" between the penultimate and final author;
- when the last name starts with 'van', 'de', etc., alphabetise the names according to the preposition (e.g. van Cauwelaert comes under „v");
- comma between the end of the author(s) name(s) and the year, and full stop after the year.
- journal names are preferably written in full and in regular font (no italics, no underline, etc.). abbreviated journal names should be avoided;
- the volume number (where applicable) shall be followed by a comma;
- the issue or band number shall not be provided unless necessary to identify the publication. If included it shall be followed by a comma;
- a page range shall be inserted (e.g. 42-46), for certain references the total number of pages (pp.) are indicated (e.g. 75 pp.), or for single page references the page (p.) where the reference is found (e.g. p. 18);
- full stop at the end of each reference;
- two or more works by the same author(s) cited at the same time (in alphabetical order), the author(s) surname(s) should not be repeated and the years be separated by a comma, from the oldest to the most recent (Smith et al., 2007, 2008) or (Johnson, 2006, 2007; Smith et al., 2007a, b).

3.2.3.2. Unpublished studies

Citations should be derived from file names. EFSA recommends citing an unpublished study such as (Appendix xx). These unpublished studies should be listed in an overview table. Examples are given in Tables 1-3 of the Appendix B.

3.2.3.3. Examples for the formatting of references in the reference list

Journal articles:

Icoz I and Stotzky G, 2008. Fate and effects of insect-resistant Bt crops in soil ecosystems. Soil Biology and Biochemistry 40, 559-586.

Unpublished studies carried out by applicants: (if authors' names not claimed to be confidential):

Smith DK and Cramer JL, 2009. Updated bioinformatics evaluation of the CP4 EPSPS protein. [Applicant name] Technical Report, [Report number], 1-22.

Appendix 4, Updated bioinformatics evaluation of the CP4 EPSPS protein. [Applicant name] Technical Report, [Report number], 1-22.

Book:

Gregory N and Grandin T, 2007. Animal welfare and the meat market. CABI, Wallingford, UK, 185 pp.

Book section:

Bookers E, Heutinck L, van Reened C and Wolthuis-Fillerup M, 2007. Application of risk assessment to animal welfare. In: Animal welfare and the meat market. Eds Gregory NG and Grandin T. CABI, Wallingford, UK, 12-21.

Proceedings/Conference paper:

Bookers E, Heutinck L, van Reened C and Wolthuis-Fillerup M, 2008. Veal calves generalize their response across familiar and unfamiliar persons in a repeatable on-farm fear of humans test. Proceedings of the 4th International Workshop on the Assessment of Animal Welfare at Farm and Group Level (WAFL), Ghent, Belgium, 34-35.

Thesis:

Lund V, 2002. Ethics and animal welfare in organic animal husbandry: An interdisciplinary approach. Thesis (PhD), Swedish University of Agricultural Sciences, Uppsala, Sweden. 79 pp.

Online document:

BAS (Bristol Aquarists Society), online. Background information about goldfish. available at http://www.bristol-aquarists.org.uk/goldfish/info/info.htm

Brosowski J, 1999, online. Animal Diversity Web. *Dicentrarchus labrax*. University of Michigan, available at http://animaldiversity.ummz.umich.edu/site/accounts/information/Dicentrarchus_labrax.html

3.3. Part III – Cartagena protocol

Requirements on the structure and content of Part III can be found in Annex I of Implementing Regulation (EU) No 503/2013. EFSA checks the presence of Part III in a complete application, but does not evaluate the content.

3.4. Part IV – Labelling

Requirements on the content of Part IV can be found in Annex I of Implementing Regulation (EU) No 503/2013. EFSA checks the presence of Part IV in a complete application, but does not evaluate the content.

Based on the outcome of the risk assessment, EFSA may provide recommendations to the EC for the labelling of a GM food or feed product.

3.5. Part V – Methods of detection, sampling and identification and reference material

Part V falls within the remit of the European Union Reference Laboratory (EURL) as referred to in Article 32 of Regulation (EC) No 1829/2003. Requirements on the content of Part V can be found in Annex I of Implementing Regulation (EU) No 503/2013. Information and requirements of the EURL-GMFF can be consulted at its website.

Part V should consist of two files: one summarising the information provided to EURL, including information on where the reference material can be accessed; the other documenting the submission of the samples, reagents and methods to the EURL-GMFF (see Appendix G).

3.6. Part VI – Additional information to be provided for GM plants and/or food/feed containing or consisting of GM plants

Requirements on the content of Part VI can be found in Annex I of Implementing Regulation (EU) No 503/2013.

3.7. Part VII – Summary of applications

Requirements on the structure and content of Part VII can be found in Annex I of Implementing Regulation (EU) No 503/2013.

Any confidential information should be excluded as this part will be published on the EFSA Register of Questions (see Sections 1.4 and 1.6). Please be reminded that during the completeness check phase, an updated version should be sent to EFSA together with the revised application.

3.8. Part VIII -Administrative documents

Part VIII of the application shall contain all administrative documents related to the application. The list of documents and the standardised naming for the files are listed in Table 3.

Table 2: List of administrative documents and their recommended file names

File name	File content
01-Letter_to_MS_submission.pdf or 01-Letter_to_EC_submission.pdf	Cover letter accompanying the submission of the application
02a-Confidentiality_Data_protection.pdf 02b-Confidential_name_list.pdf	Agreement on confidentiality and data protection A list of names to be treated as confidential
03a-Access_letter_event1.pdf 03b-Access_letter_event2.pdf 03c…….etc.	For GM plants containing stacked events: Letter(s) granting consent of access to applications for concerned single events (see Section 3.8.1).
04-CClist.exl	Completeness checklist: filled by the applicant (Appendix A)
05-DoConformity.pdf	Declaration of Conformity between the paper and electronic versions of the application

3.8.1. Letter "consent of access"

If an application refers to data already provided in another application previously submitted to EFSA (as in the case of applications for stacked events) a letter of "consent of access" from the applicant is required. This letter authorises EFSA and all MS CA to use the data previously submitted. Such consent letter should be provided independently for each concerned application.

3.8.2. Completeness checklist

The completeness checklist (see Appendix A) for the sections concerning molecular characterisation, food and feed risk assessment have been aligned with Implementing Regulation (EU) No 503/2013. This checklist consists of eight spreadsheets, corresponding to Parts I to VIII of a GM plant application. This checklist, filled out by applicants, is used by EFSA during the completeness check phase to ensure that (i) GM plant applications follow the required structure, and (ii) all required information and documents are provided.

4. Applications for GM plants containing stacked events

In accordance with Implementing Regulation (EU) No 503/2013, the risk assessment of each single transformation event in GM plants containing events stacked by conventional crossing is a pre-requisite for the risk assessment of the stack and when submitting applications, the applicant shall provide a risk assessment of each single transformation event or refer to already submitted

applications. As clarified by the EC[11], single events should be subject to separate and stand-alone applications. Such references must precise in detailing the section, page number, appendix, figure, name of the relevant reports and information.

The evaluation of applications for GM plants containing stacked events builds on the knowledge acquired during the risk assessment of all the involved single events. Therefore, EFSA will start the risk assessment of an application for GM plants containing stacked events only after the risk assessment of the respective single events is completed. In line with Implementing Regulation (EU) No 503/2013, applications for GM segregating crops should include all sub-combinations independently of their origin and not yet authorised.

5. Applications for renewal authorisations

All applications submitted under Articles 5, 11, 17 and 23 of Regulation (EC) No 1829/2003 should follow the structure specified in section 2.1 of this submission guidance. It is important to note that the EFSA GMO Panel is preparing Guidance for renewal authorisations of existing GMO products submitted under Articles 11 and 23 of Regulation (EC) No 1829/2003.

USEFUL WEBSITES

EFSA Register of Questions: http://registerofquestions.efsa.europa.eu/roqFrontend.

Community Reference Laboratory for GM food and feed: http://gmo-crl.jrc.ec.europa.eu

EU authorisation procedure for GMOs: http://ec.europa.eu/food/plant/gmo/authorisation/index_en.htm

EU register of GM food and feed: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

EFSA GMO Extranet: https://sciencenet.efsa.europa.eu/portal/server.pt

EFSA Journal: http://www.efsa.europa.eu/en/efsajournal.htm

Minutes of EFSA GMO Panel plenary meetings: http://www.efsa.europa.eu/en/gmo/gmomeetings.htm

Minutes of EFSA GMO Panel WG meetings: http://www.efsa.europa.eu/en/gmo/gmowgs.htm

REFERENCES

EFSA (European Food Safety Authority), 2006. Guidance document for the risk assessment of genetically modified plants and derived food and feed. The EFSA Journal 2006, 374, 1-115.

EFSA (European Food Safety Authority), 2008. Safety and nutritional assessment of GM plants and derived food and feed: The role of animal feeding trials. Food and Chemical Toxicology 46 (2008) S2–S70. The EFSA Journal 2008, 1057, 2-70.

EFSA (European Food Safety Authority), 2009. Scientific opinion on guidance for the risk assessment of genetically modified plants used for non-food or non-feed purposes. The EFSA Journal 2009, 1164, 1-42.

EFSA Panel on Genetically Modified Organisms (GMO), 2010a. Guidance on the environmental risk assessment of genetically modified plants. EFSA Journal 2010;8(11):1879, 111 pp. doi:10.2903/j.efsa.2010.1879

EFSA Panel on Genetically Modified Organisms (GMO), 2010b. Statistical considerations for the safety evaluation of GMOs. EFSA Journal 2010;8(1):1250, 59 pp. doi:10.2903/j.efsa.2010.1250

EFSA Panel on Genetically Modified Organisms (GMO), 2010c. Scientific opinion on the assessment of allergenicity of GM plants and microorganisms and derived food and feed. EFSA Journal 2010;8(7):1700, 168 pp. doi:10.2903/j.efsa.2010.1700

[11] EC letter to EuropaBio [Ref. Ares (2013)3227877-11/10/2013]

EFSA Panel on Genetically Modified Organisms (GMO), 2010d. Scientific Opinion on the assessment of potential impacts of genetically modified plants on non-target organisms. EFSA Journal 2010;8(11):1877, 72 pp. doi:10.2903/j.efsa.2010.1877

EFSA Panel on Genetically Modified Organisms (GMO), 2011a. Guidance for risk assessment of food and feed from genetically modified plants. EFSA Journal 2011; 9(5):2150, 37 pp. doi:10.2903/j.efsa.2011.2150

EFSA Panel on Genetically Modified Organisms (GMO), 2011b. Guidance on selection of comparators for the risk assessment of genetically modified plants and derived food and feed. EFSA Journal 2011;9(5):2149, 20 pp. doi:10.2903/j.efsa.2011.2149

EFSA Panel on Genetically Modified Organisms (GMO), 2011c. Guidance of the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. EFSA Journal 2011;9(8):2316, 40 pp. doi:10.2903/j.efsa.2011.2316

EFSA Scientific Committee, 2011d. Guidance on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed. EFSA Journal 2011;9(12):2438, 21 pp. doi:10.2903/j.efsa.2011.2438

APPENDICES

Appendices A, C, D, E, F described below are available in electronic format on EFSA website.

A. COMPLETENESS CHECKLIST

The completeness checklist contains eight spreadsheets, corresponding to each of the eight parts of an application package. The completed document should be submitted in XLS format and included in Part VIII.

B. EXEMPLAR FIGURES AND TABLES FOR PART II

Appendix B contains examples of figures and tables to present data on molecular characterisation and food and feed risk assessment. These figures and tables should not be viewed as precise templates. Other formats are accepted, provided that the aim is achieved. They should be included in Part II.

C. SCHEMATIC SUMMARY OF FIELD TRIALS

Appendix C is a schematic summary for each field trial conducted to support the comparative analysis of agronomic and phenotypic characteristics. They should be included in Part II.

D. SCHEMATIC SUMMARY OF INSECT RESISTANCE MANAGEMENT-RELATED INFORMATION

Appendix D is requested for GM plant applications covering GM plants expressing insect resistance traits for cultivation in the EU. The applicant should include it in the subfolder ERA_Appendices D to F.

E. SCHEMATIC SUMMARY OF NTO STUDIES

Appendix E consists of four parts, each requesting specific information on the NTO studies submitted as part of the GM plant application. The applicant should include it in the subfolder ERA_Appendices D to F.

- Part 1: Overview of NTO studies performed or commissioned by the applicant;
- Part 2: Overview of NTO studies published in peer-reviewed journals and used by the applicant in support of NTO risk assessment;
- Part 3: Summary of laboratory studies performed or commissioned by the applicant to support the NTO risk assessment;
- Part 4: Summary of field studies performed or commissioned by the applicant to support the NTO risk assessment.

F. SCHEMATIC SUMMARY OF STATISTICAL DESIGN AND ANALYSIS FOR EACH ERA-RELATED STUDY

For each experimental study submitted in support of the ERA, the applicant should compile a separate Appendix F. All completed Appendices should be included in the subfolder ERA_Appendices D to F.

G. PROOF OF ACKNOWLEDGEMENT OF RECEPTION BY EURL-GMFF

Appendix G contains an “Acknowledgement of reception of samples, reagents and methods” used by EURL-GMFF. A copy of such document for a specific GM event should be included in Part V.

ABBREVIATIONS

CI:	Confidential Information
CA:	National Competent Authority
CC:	Completeness Check
CD-ROM:	Compact Disk - Read Only Memory
EURL-GMFF:	European Union Reference Laboratory for GM Food and Feed
EC:	European Commission
EU:	European Union
EFSA:	European Food Safety Authority
ENV:	Environment
ERA:	Environmental Risk Assessment
FF:	Food and Feed
GM:	Genetically Modified
GMO:	Genetically Modified Organisms
MC:	Molecular Characterisation
MS:	Member State
MS CA	National Competent Authority of a Member State
non-CI:	Non-Confidential Information
WG:	Working Group

			For EFSA use	
General requirements as outlined in the EFSA submission guidance (version 3) for GM plants	**Yes, provided**	**Not applicable**	**EFSA agrees**	EFSA comments/questions to applicants
A GM plant applicant consists of the following eight parts				
Part I - Genernal information	☐	☐	☐	
Part II Scientific information	☐	☐	☐	
Part III – Cartagena Protocol	☐	☐	☐	
Part IV – Labelling proposal	☐	☐	☐	
Part V – Detection and validation methods	☐	☐	☐	
Part VI – Additional information	☐	☐	☐	
Part VII – Summary	☐	☐	☐	
Part VIII – Administrative documents	☐	☐	☐	
In case of a stacked application, letter(s) of consent of access for all single events	☐	☐	☐	
Statement of conformity between electronic and paper copy	☐	☐	☐	
Submission data package				
1 electronic copy	☐	☐	☐	
1 paper copy	☐	☐	☐	
Declaration of Conformity between the paper and electronic versions of the application	☐	☐	☐	
Passwords of CDs or files (if applicable) are provided	☐	☐	☐	
CD(s) are labelled as described in section 2.4.1of the submission guidance	☐	☐	☐	
File format, size and name				
DNA sequence information in Gen Bank format including annotation information	☐	☐	☐	
File size smaller than 25 MB	☐	☐	☐	

General requirements

	☐	☐	☐	
Files are word searchable	☐	☐	☐	
All files named as described in section 2.1 of the submission guidance	☐	☐	☐	
Files names shorter than 40 characters	☐	☐	☐	
Confidential information				
At submission, Confidential (CI) from non-confidential information (non-CI) are stored on separate CDs	☐	☐	☐	
At submission, CI and non-CI are stored on the same CD, but organised in separate folders.	☐	☐	☐	
Files containing confidential information contain "CI" in the file names (e.g. "Appendix_5_CI.pdf")	☐	☐	☐	
main text does NOT contain CI	☐	☐	☐	
If authors' names are claimed as confidential, they are not included in the citation	☐	☐	☐	
A list, containing all the names to be treated as confidential information, is provided to EFSA	☐	☐	☐	
Citations and References				
References are listed in alphabetical order at the end of Part II	☐	☐	☐	
Citations of published studies in line with the formatting requirements of the Submission guidance section 3.2.3.	☐	☐	☐	
Citations of unpublished studies in line with the formatting requirements of the Submission guidance section 3.2.3.	☐	☐	☐	
Citation, reference and file names are consistent throughout all documentation	☐	☐	☐	

Comments (up to 500 characters) *Please insert your comments here*		

			For EFSA use	
Part I - General information	**Yes, provided**	**Not applicable (justification provided in Part I)**	**EFSA agrees**	EFSA comments/questions to applicants
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 EFSA	☐	☐	☐	
3. Designation and specification of the GM plant and its products	☐	☐	☐	
4. Scope of the application is clearly indicated	☐	☐	☐	
Where an application is limited to either food or feed use, it shall contain a verifiable justification explaining why the authorisation shall not cover both uses in accordance with Article 27 of Regulation (EC) No 1829/2003	☐	☐	☐	
For GM plants containing stacked transformation events (segregating crops), the list of all sub-combinations not yet authorised is included in the scope of the application	☐	☐	☐	
5. Unique identifier: : a proposal for a unique identifier for the GM plant developed in accordance with Regulation (EC) No 65/2004	☐	☐	☐	
6. Where applicable, a detailed description of the method of production and manufacturing.	☐	☐	☐	
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.	☐	☐	☐	
Comments (up to 500 characters) *Please insert your comments here*				

			For EFSA use only	
Part II - Scientific Information	**Yes, provided**	**Not applicable**	**EFSA agrees**	EFSA comments/questions to applicants
Applicants should filled out the completeness checklist when preparing a GM plant application. Only one box should be checked in each row.	Information provided	If this box is checked, a justification should be included in the main text of Part II	Using the filled-out completeness checklist, EFSA verifies that all information is present in Part II; the information provided is in line with the Implementing Regulation (EU) No 503/2013; and the data presentation is in line with the EFSA submission guidance.	
Specific requirements for the performance of studies for applications submitted under Articles 5(3) and 17(3), as outlined in the Implementing Regulation (EU) No 503/2013				
Information on the study protocols and the results obtained from all studies is comprehensive and include the raw data in an electronic format, suitable for carrying out statistical or other analysis.	☐	☐	☐	
Toxicological studies shall be conducted in facilities which comply with the				
(a) requirements of Directive 2004/10/EC; or	☐	☐	☐	
(b) 'OECD Principles on Good Laboratory Practice' (GLP), if carried out outside the Union.	☐	☐	☐	
Evidence to demonstrate such compliance is provided.	☐	☐	☐	
Studies, other than toxicological studies, shall				
(a) comply with the principles of Good Laboratory Practice (GLP) laid down in Directive 2004/10/EC; or	☐	☐	☐	
(b) be conducted by organisations accredited under the relevant ISO standard.	☐	☐	☐	
Considerations for Part II as outlined in the EFSA Submission Guidance				
Overview table of all Appendices and key references is provided (for example see Table 1 in Appendix B of the Submission Guidance)	☐	☐	☐	
Study overview table (for example see Table 2 in Appendix B of the Submission Guidance)	☐	☐	☐	
Specific considerations as outlined in Annex II of the Implementing Regulation (EU) No 503/2013				
Insertion of marker genes and other nucleic acid(s) sequences not essential to achieve the desired trait				

Clear indication if the GM plant contains antibiotic resistance marker gene(s) or other non essential sequences	☐	☐	☐	
Risk assessment of genetically modified food and feed containing stacked transformation events				
The GM plant contains stacked transformation events obtained by conventional crossing	☐	☐	☐	
- applications on single events are clearly referrenced in this application	☐	☐	☐	
- for segregating crops, this application includes all sub-combinations independently of their origin which have not yet been authorised	☐	☐	☐	
- this application contains a scientific rationale justifying that there is no need to provide experimental data for the concerned sub-combinations or, in the absence of such scientific rationale, contains the experimental data	☐	☐	☐	
- for non-segregating crops, this application covers only the combination which is to be placed on the market	☐	☐	☐	
The GM plant contains transformation events that are combined by other means such as co- and retransformation	☐	☐	☐	
Scientific requirements for the risk assessment of GM food and feed as outlined in Annex II of the Implementing Regulation (EU) No 503/2013				
A. Hazard identification and characterisation				
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 or strain	☐	☐	☐	
(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 and/or allergenicity	☐	☐	☐	

(d) Data on the past and present use of the recipient organism. This information should include:	☐	☐	☐	
- the history of safe use for consumption as food and/or feed	☐	☐	☐	
- how the plant is typically cultivated, transported and stored	☐	☐	☐	
- whether special processing is required to make the plant safe to eat	☐	☐	☐	
- the description of the normal role of the plant in the diet (e.g. 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)	☐	☐	☐	
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				
(a) method of genetic transformation including relevant references	☐	☐	☐	
(b) the recipient plant material	☐	☐	☐	
(c) the species and strain of *Agrobacterium* and other microbes	☐	☐	☐	
(d) helper plasmids	☐	☐	☐	
(e) source of carrier nucleic acids	☐	☐	☐	
1.2.1.2 Nature and source of vector used				
(a) physical map of the functional elements and	☐	☐	☐	
- physical map of other plasmid/vector components	☐	☐	☐	
- relevant information needed for the interpretation of the molecular analyses	☐	☐	☐	
- indication of the region intended for insertion	☐	☐	☐	
(b) a table identifying:	☐	☐	☐	
- each component of the plasmid/vector	☐	☐	☐	
- its size	☐	☐	☐	
- its origin	☐	☐	☐	
- its intended function	☐	☐	☐	
1.2.1.3 Source of nucleic acid(s) used for transformation, size and intended function of each constituent fragment of the region intended for insertion				
Information on the donor organism(s); for each donor organism this shall comprise of:				
- taxonomic classification;	☐	☐	☐	
- history of use regarding food and feed safety	☐	☐	☐	

Information on the nucleic acid(s) sequence(s) intended to be inserted	☐	☐	☐	
Information regarding the function of the nucleic acid region(s)	☐	☐	☐	
(a) the complete sequence of the nucleic acid(s) intended to be inserted;including	☐	☐	☐	
- information on any deliberate alteration(s) to the corresponding sequence(s) in the donor organism(s)	☐	☐	☐	
(b) the history of safe use of the gene product(s) arising from the regions intended for insertion	☐	☐	☐	
(c) data on the possible relationship of the gene products with known toxins, anti-nutrients and allergens	☐	☐	☐	
Discussion whether the nature of the donor organism(s) or the nucleic acid sequence(s) may trigger any safety issue	☐	☐	☐	
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				
Description of the introduced trait(s), of the resulting changes on phenotype and metabolism of the plant	☐	☐	☐	
If the trait is herbicide tolerance, information on the mode of action of the active substance and its metabolism in the plant.	☐	☐	☐	
1.2.2.2 Information on the sequences actually inserted/deleted				
(a) copy number of all detectable inserts, both complete and partial, and	☐	☐	☐	
the size of all detectable inserts, both complete and partial; this is typically determined by Southern analysis	☐	☐	☐	

If Southern analyses is used:				
- probe/restriction enzyme combinations shall provide complete coverage of sequences that could be inserted into the GM plant, such as any parts of the plasmid/vector or any carrier or foreign nucleic acid(s) remaining in the GM plant	☐	☐	☐	
- analyses shall span the entire transgenic locus/loci as well as the flanking sequences and	☐	☐	☐	
- include appropriate controls	☐	☐	☐	
(b) the organisation of the inserted genetic material at each insertion site	☐	☐	☐	
- sequence of the inserted genetic material at each insertion site in a standardised electronic format	☐	☐	☐	
- identifying changes in the inserted sequences compared to the sequence intended for insertion	☐	☐	☐	
c) in the case of deletion(s), size and function of the deleted region(s)	☐	☐	☐	
d) sub-cellular location(s) of insert(s) and methods for its/their determination	☐	☐	☐	
e) sequence information in a standardised electronic format for 5’ flanking regions at each insertion site	☐	☐	☐	
- sequence information in a standardised electronic format for 3’ flanking regions at each insertion site	☐	☐	☐	
- identification of interruptions of known genes	☐	☐	☐	
- bioinformatic analyses using up-to-date databases to perform both intraspecies and interspecies similarity searches	☐	☐	☐	
In case of stacked events: safety assessment of potential interactions between any unintended modification at each insertion site	☐	☐	☐	
f) ORFs created as a result of the genetic modification either at the junction sites with genomic DNA or due to internal rearrangements of the insert(s).	☐	☐	☐	
- ORFs analysed between stop codons, not limiting their lengths	☐	☐	☐	
- Bioinformatic analyses to investigate possible similarities with known toxins or allergens using up-to-date databases	☐	☐	☐	

- The characteristics and versions of the databases	☐	☐	☐	
Bioinformatic overview table (for example see Table 3 in Appendix B)	☐	☐	☐	
Further analyses (such as transcription analysis), if needed	☐	☐	☐	
1.2.2.3 Information on the expression of the insert(s)				
Overview table - Field trial for protein expression analyses (for example see Table 4 in Appendix B)	☐	☐	☐	
To investigate intended and unintended changes at the protein, RNA and/or metabolite levels; Following elements are provided:				
a) The method(s) used for expression analysis	☐	☐	☐	
- the performance characteristics	☐	☐	☐	
b) Information on developmental expression of the insert during the life cycle of the plant	☐	☐	☐	
c) Parts of the plant where the insert/modified sequences are expressed;	☐	☐	☐	
d) Characterise potential unintended expression of new ORFs identified under point 1.2.2.2(f) which raise a safety concern	☐	☐	☐	
e) Protein expression data obtained from field trials and related to the conditions in which the crop is grown	☐	☐	☐	
- including raw data	☐	☐	☐	
- data on expression levels from those parts of the plant used for food and feed purposes	☐	☐	☐	
- expression of target genes in other parts of the plant when tissue-specific promoters are used and when relevant for the safety assessment	☐	☐	☐	
- protein expression data from three growing sites or from one site over three seasons	☐	☐	☐	
Depending on the nature of the insert specific RNA(s) or metabolite(s) shall be analysed	☐	☐	☐	
For silencing approaches by RNAi expression, potential ‘off target’ genes should be searched by in silico analysis	☐	☐	☐	
- assess if the genetic modification affects the expression of other genes which raise safety concerns	☐	☐	☐	

f) With regards to stacked events by conventional crossing:				
- provide expression data to assess potential interactions between the events, which may raise any additional safety concerns over protein and trait expression compared to the single transformation events	☐	☐	☐	
- the comparison carried out with data obtained from plants grown in the same field trial	☐	☐	☐	
- on a case-by-case basis, and where concerns arise, additional information is provided.	☐	☐	☐	
1.2.2.4 Genetic stability of the insert and phenotypic stability of the GM plant				
(a) Demonstrate the genetic stability of the transgenic locus(i) using appropriate molecular approaches,and	☐	☐	☐	
demonstrate the phenotypic stability of the introduced trait(s), and	☐	☐	☐	
demonstrate inheritance pattern(s) of the introduced trait(s)	☐	☐	☐	
- demonstrate stability over multiple (normally five - first and last generation is sufficient) generations or vegetative cycles	☐	☐	☐	
- source of the material used for the analysis is specified	☐	☐	☐	
- data analysed using appropriate statistical methods	☐	☐	☐	
(b) In case of stacked events:				
establish that each transformation event in the stacked event has the same molecular properties as the single transformation events	☐	☐	☐	
establish that each transformation event in the stacked event has the same characteristics as the single transformation events	☐	☐	☐	
compare plant materials representative of those designed for commercial production with original transformation events, including:	☐	☐	☐	
- sequence comparison of inserts obtained from the single events and the stacked events	☐	☐	☐	
- sequence comparison of the flanking regions obtained from the single events and the stacked events	☐	☐	☐	
provide adequate justification for the plant materials used	☐	☐	☐	

	☐	☐	☐	
1.2.2.5. Potential risk associated with horizontal gene transfer				
Assess the probability of horizontal gene transfer and any potential associated risk when intact and functional nucleic acid(s) remains in the genetically modified food and feed:	☐	☐	☐	
- from the product to humans	☐	☐	☐	
- from the product to animals	☐	☐	☐	
- from the product to micro-organisms	☐	☐	☐	
1.2.3 Conclusions of the molecular characterisation				
Conclusion on the structure of the insert	☐	☐	☐	
Conclusion on the expression of the insert	☐	☐	☐	
Conclusion on the stability of intended trait(s)	☐	☐	☐	
Indicate whether the molecular characterisation of the genetic modification(s) raises safety concerns with regard to the interruption of endogenous genes or regulatory sequences.	☐	☐	☐	
Identify whether the genetic modification(s) raise(s) any issues regarding the potential for producing proteins/substances other than those intended and in particular new toxins or allergens	☐	☐	☐	
Identify potential unintended changes that shall be addressed in the relevant complementary parts of the safety assessment	☐	☐	☐	
Comments (up to 500 characters) *Please insert your comments here*				
1.3. Comparative analysis				
1.3.1 Choice of the conventional counterpart and additional comparators				
A breeding scheme (pedigree) in relation to the GM plant, the conventional counterpart and, where appropriate, additional comparator(s) (for example see Appendix B)	☐	☐	☐	
- together with an adequate justification of their selection	☐	☐	☐	

- qualitative and quantitative data to support the history of safe use of the conventional counterpart	☐	☐	☐	
For vegetatively propagated crops				
- conventional counterpart shall, in principle, be the near-isogenic variety used to generate the transgenic line	☐	☐	☐	
- additional comparator(s)	☐	☐	☐	
For crops that reproduce sexually				
- conventional counterpart shall have a genetic background comparable to the GM plant.	☐	☐	☐	
- When using back-crossing, a conventional counterpart with a genetic background that is as close as possible to the GM plant is selected.	☐	☐	☐	
- (optional) an additional comparator having a closer genetic background to the GM plant than the conventional counterpart (such as a negative segregant)	☐	☐	☐	
For herbicide tolerant genetically modified plants				
- the GM plant exposed to the intended herbicide	☐	☐	☐	
- the conventional counterpart treated with conventional herbicide management regimes	☐	☐	☐	
- the GM plant treated with the same conventional herbicide management regimes	☐	☐	☐	
For stacked transforamtion events				
In case that it is not possible to use a conventional counterpart with a genetic background as close to the GM plant as with conventional counterpart normally used for single transformation events, reasoned justification on the choice of the conventional counterpart and assess its limitations for the risk assessment, are provided.	☐	☐	☐	
Single parental GM lines or GM lines containing a sub-combination of the stacked transformation events for which an application has been submitted or negative segregants derived from these genetically modified lines may also be included as additional comparators.	☐	☐	☐	

- if so, detailed information justifying the choice of additional comparators is provided.	☐	☐	☐	
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				
Specific protocols for experimental design				
Field trial(s) are performed for the production of material for the comparative analysis	☐	☐	☐	
Each field trial shall meet the following requirements:				
- all test materials are randomised to plots within a single field at each site, in a completely randomised or randomised block experimental design	☐	☐	☐	
- the choice of non-GM reference varieties is appropriate for the chosen sites, and is justified explicitly.	☐	☐	☐	
- at least six different non-GM reference varieties are used over the entire set of field trials	☐	☐	☐	
- the different sites selected for the field trials reflect the different meteorological and agronomic conditions under which the crop is to be grown; the choice is explicitly justified.	☐	☐	☐	
- a minimum of eight sites	☐	☐	☐	
- the field trials may be conducted in a single year, or spread over multiple years.	☐	☐	☐	
- if the sites cover a restricted range of growing conditions, the field trials are replicated over more than one year.	☐	☐	☐	
The field trials are adequately described, giving information on important parameters such as management of the field before sowing, date of sowing, soil type, herbicide use, climatic and other cultivation/environmental conditions during growth and time of harvest, as well as the conditions during storage of the harvested material.	☐	☐	☐	
Each site shall meet the following requirements:				
- the test materials consiste of GM plants, conventional counterpart and, where appropriate, additional comparator(s)	☐	☐	☐	
- the test materials are identical between replicates	☐	☐	☐	

	☐	☐	☐	
- unless explicitly justified for not doing so, at least three appropriate non-GM reference varieties	☐	☐	☐	
- non-GM reference varieties have a known history of safe use	☐	☐	☐	
- non-GM reference varieties are identical between replicates	☐	☐	☐	
- the number of replications is four or more	☐	☐	☐	
- if only two appropriate reference varieties are available at a particular site, then the replication is six at that site;	☐	☐	☐	
- if only one appropriate reference variety is available at a particular site, then the replication is eight at that site.	☐	☐	☐	
When the GM plant is tested together with other GM plants of the same crop species to produce material for the comparative assessment, the following two conditions are met:				
(i) the conventional counterpart and, where appropriate, additional comparator(s) always occur together with the GM plant in the same block;	☐	☐	☐	
(ii) all the different GM plants and their comparator(s) and all the non-GM reference varieties used for the equivalence test are fully randomized within each block.	☐	☐	☐	
If the number of plots per block required for such a field trial were to exceed 16, then a partially balanced incomplete block design may be used, to reduce the number of plots per block, by excluding some of the GM plants and their appropriate comparator(s) from each block. This is done, provided that the following two conditions are met:				
(i) the conventional counterpart always occurs together with its particular GM plant in the same block;	☐	☐	☐	
(ii) all of the non-GM reference varieties appear in each of the incomplete blocks and are fully randomised with the plants and their comparator(s).	☐	☐	☐	
1.3.2.2 Statistical analysis				
Analysis of data is presented in a clear format, using standardised scientific units.	☐	☐	☐	
The raw data and the programming code used for the statistical analysis are given in an editable form.	☐	☐	☐	
The natural scale or another scale has been used for the endpoint response variables.	☐	☐	☐	

When data transformation is applied, any difference between the GM material and any other test material are interpreted as a ratio on the natural scale.	☐	☐	☐	
For each endpoint, a test of difference and a test of equivalence are carried out				
In testing for difference, the null hypothesis is that there is no difference between the GMO and its conventional counterpart	☐	☐	☐	
- Where additional comparator(s) are used, a test of difference is carried out between the GM plant and each of the additional comparator(s)	☐	☐	☐	
In testing for equivalence, the null hypothesis is that the difference between the GMO and the set of reference varieties is at least as great as a specified minimum size	☐	☐	☐	
- Rejection of the null hypothesis is required in order to conclude that the GMO and the set of reference varieties are unambiguously equivalent for the endpoint considered	☐	☐	☐	
- The equivalence limits used for the test of equivalence represent appropriately the range of natural variation expected for reference varieties with a history of safe use	☐	☐	☐	
The total variability of each endpoint observed in the field trials are estimated and partitioned using appropriate statistical models in order to derive two sets of confidence limits and to set a lower and upper equivalence limit based on the variability observed among the non-GM reference varieties, one to be used in the test of difference; the other and the equivalent limits to be used in the test of equivalence.	☐	☐	☐	
A linear mixed statistical models is used to calculate both sets of confidence limits	☐	☐	☐	
- the random factors for model 1 are, but not necessarily be restricted to, those representing the variation: (i) between the test materials; (ii) in the interaction between the test materials and the indicator variable I; (iii) between sites; and (iv) between blocks within sites.	☐	☐	☐	
- Model 2 is identical to model 1 except that the random factor representing the interaction between the test materials and the indicator variable I is omitted	☐	☐	☐	

- The fixed factor for both models have as many levels as there are test materials and represent the contrasts between the means of the test materials.	☐	☐	☐	
- The set of non-GM reference varieties is considered as a single level of the fixed factor.	☐	☐	☐	
- For the difference test, the component of the fixed factor of interest is the single degree-of-freedom contrast between the GM plant and its conventional counterpart.	☐	☐	☐	
- For the equivalence test, the component of the fixed factor of interest is the single degree-of-freedom contrast between the GM plant and the set of non-GM reference varieties.	☐	☐	☐	
- Both the difference test and the equivalence test are implemented using the correspondence between hypothesis testing and the construction of confidence limits.	☐	☐	☐	
- In equivalence testing, the approach used shall follow the two one-sided tests (TOST) methodology by rejecting the null hypothesis of non-equivalence when the both confidence limits fall between the equivalence limits.	☐	☐	☐	
- The choice of 90% confidence limits corresponds to the customary 95% level for statistical testing of equivalence.	☐	☐	☐	
- The results of the difference and equivalence tests are represented visually for all the endpoints simultaneously, on a single graph or a few graphs.	☐	☐	☐	
- The graph(s) show the line of zero difference between the GM material and its conventional counterpart and, for each endpoint: the lower and upper adjusted equivalence limits; the mean difference between the genetically modified material and its conventional counterpart; and the confidence limits for this difference.	☐	☐	☐	
- The line of zero difference on the logarithmic scale corresponds to a multiplicative factor of unity on the natural scale.	☐	☐	☐	
- The horizontal axis is labelled with values that specify the change on the natural scale.	☐	☐	☐	
- In the case of logarithmic transformation, changes of 2x and ½x will appear equally spaced on either side of the line of zero difference.	☐	☐	☐	

- When, in addition to the conventional counterpart, another test material is used as comparator, the mean difference between the GM material and that comparator, its confidence limits and its adjusted equivalence limits shall be displayed on the graph(s) , for all such additional comparators, by referring this to the same zero baseline as defined by the conventional counterpart.	☐	☐	☐	
For reporting, full details are given for each endpoint analysed, listing				
(a) the assumptions underlying the analysis	☐	☐	☐	
(b) full specification of the mixed models chosen, including fixed and random effects	☐	☐	☐	
(c) results of any test of interaction between the test materials and sites	☐	☐	☐	
(d) fixed effects, together with the appropriate estimated residual variation with which they are compared, and variance components for the random factors;	☐	☐	☐	
(e) estimated degrees of freedom	☐	☐	☐	
(f) any other relevant statistics	☐	☐	☐	
A. Regarding test of difference, each outcome from the graph is categorised and the respective appropriate conclusion is drawn	☐	☐	☐	
B. Regarding test of equivalence, each outcome from the graph is categorised, and the respective appropriate conclusion is drawn.	☐	☐	☐	
Despite the expected proportion of spurious significant differences, report and discuss all significant differences observed between the GMcrop, its conventional counterpart and, where applicable, any other test material, focusing on their biological relevance.	☐	☐	☐	
A discussion on the likely impact of other growing conditions not tested in the field trial is provided	☐	☐	☐	
In the case of significant difference and/or lack of equivalence for any particular endpoint, further statistical analysis is carried out to assess whether there are interactions between any of the test materials and site.	☐	☐	☐	
	☐	☐	☐	

- Whatever approach is adopted, details are given, for each endpoint analysed, listing:	☐	☐	☐	
(a) the assumptions underlying the analysis,	☐	☐	☐	
and, when appropriate: (b) degrees of freedom,	☐	☐	☐	
(c) the estimated residual variation for each source of variation, and variance components,	☐	☐	☐	
(d) any other relevant statistics.	☐	☐	☐	
Discussion of these additional analyses, which are intended to aid the interpretation of any significant differences found and to study potential interactions between test materials and other factors.	☐	☐	☐	
1.3.3 Selection of material and compounds for analysis				
The material to be used for the comparative assessment are selected while taking into account the uses of the GM plant and the nature of the genetic modification.	☐	☐	☐	
In the case of herbicide tolerant GM plants, three test materials are used: the GM plant exposed to the intended herbicide; the conventional counterpart treated with conventional herbicide management regimes; and the GM plant treated with the same conventional herbicide management regimes.	☐	☐	☐	
Analysis is carried out on the raw agricultural commodity.	☐	☐	☐	
Additional analysis of processed products are conducted, where appropriate, and on a case-by-case basis	☐	☐	☐	
The sampling, analysis and preparation of the tested material are carried out according to appropriate quality standards.	☐	☐	☐	
The quality standards applied are referenced.	☐	☐	☐	
1.3.4 Comparative analysis of composition				
The specific analyses are tailored to the plant species, and include a detailed assessment appropriate to the intended effect of the genetic modification, the considered nutritional value and use of the plant.	☐	☐	☐	
Compounds selection refers to OECD consensus documents, and includes at least				

- proximates (including moisture and total ash)	☐	☐	☐	
- key macro- and micro-nutrients	☐	☐	☐	
particular attention paid to key nutrients such as proteins, carbohydrates, lipids/fats, fibre, vitamins and minerals	☐	☐	☐	
vitamins and minerals which are present at nutritionally significant levels and/or which make nutritionally significant contributions to the diet	☐	☐	☐	
a fatty acid profile is included for oil-rich plants (main individual saturated, mono-unsaturated and poly-unsaturated fatty acids)	☐	☐	☐	
an amino acid profile (individual protein amino acids and main non-protein amino acids) for plants used as an important protein source	☐	☐	☐	
- anti-nutritional compounds	☐	☐	☐	
The concentrations of anti-nutritional compounds are assessed according to plant species and the proposed use of the food and feed product	☐	☐	☐	
- key toxins inherently present in the recipient plant which may adversely affect human/animal health depending on their toxic potency and levels	☐	☐	☐	
The concentrations of key toxins are assessed according to plant species and the proposed use of the food and feed product	☐	☐	☐	
- already identified allergens	☐	☐	☐	
- other secondary plant metabolites characteristic for specific crop plant species	☐	☐	☐	
- analysis of plant cell wall components for the vegetative parts of plants used for feed purposes	☐	☐	☐	
The characteristics of the introduced trait triggers further analysis of specific compounds including metabolites of potentially modified metabolic pathways.	☐	☐	☐	
If so, inclusion of compounds other than the key nutrients, key toxins, anti-nutrients and allergens identified by the OECD consensus documents and justify the selection of these compounds	☐	☐	☐	

1.3.5 Comparative analysis of agronomic and phenotypic characteristics				
The protocols of these field trials follow the specifications set out in Section 1.3.2.	☐	☐	☐	
A comparison between the GM plant and its conventional counterpart	☐	☐	☐	
- identification of unintended effects resulting from the genetic modification	☐	☐	☐	
- address plant biology and agronomic traits, including common breeding parameters (such as yield, plant morphology, flowering time, day degrees to maturity, duration of pollen viability, response to plant pathogens and insect pests, sensitivity to abiotic stress)	☐	☐	☐	
Where transformation events are stacked by conventional crossing, there may also be changes to agronomic and phenotypic characteristics.				
Phenotypic characteristics and agronomic properties of stacked transformation events are assessed in field trials	☐	☐	☐	
Where appropriate, additional information on agronomic traits of the stacked transformation events from additional field trials	☐	☐	☐	
1.3.6 Effects of processing				
Description of the different processing technologies in sufficient detail, paying special attention to the steps which may lead to significant changes in the product content, quality or purity.	☐	☐	☐	
Assessment of whether or not the processing and/or preserving technologies applied are likely to modify the characteristics of GM end products compared with their respective conventional counterpart.	☐	☐	☐	
When genetic modification targets metabolic pathways resulting in changes in the concentration of non-protein substances or in new metabolites (such as in nutritionally enhanced foods), processed products are assessed. On a case-by-case basis, additional experimental data shall be submitted.			☐	
	☐	☐		

Scientific rationale for the risk assessment of these products.	☐	☐	☐	
Depending on the product, information on the composition, level of undesirable substances, nutritional value and metabolism, as well as on the intended use	☐	☐	☐	
Depending on the nature of the newly expressed protein(s), assessment on the extent to which the processing steps lead to the concentration or to the elimination, denaturation and/or degradation of these protein(s) in the final product	☐	☐	☐	
1.3.7 Conclusions				
The conclusion of the comparative analysis clearly states:				
(a) whether agronomic and phenotypic characteristics of the GM plant are, except for the introduced trait(s), different to the characteristics of its conventional counterpart and/or equivalent to the reference varieties, taking into account natural variation;	☐	☐	☐	
(b) whether compositional characteristics of the GM food and feed are, taking into account natural variation, different to the characteristics of its conventional counterpart and/or equivalent to the reference varieties, except for the introduced trait(s);	☐	☐	☐	
(c) characteristics for which the GM plant or the GM food and feed are different to the characteristics of its conventional counterpart and/or not equivalent to the reference varieties taking into account natural variation, which need further investigation;	☐	☐	☐	
(d) whether, in the case of transformation events stacked by conventional crossing, there are indications of interactions between the combined transformation events.	☐	☐	☐	
Comments (up to 500 characters) *Please insert your comments here*				

1.4 Toxicological assessment				
1.4.1 Testing of newly expressed proteins				
Evaluation of all newly expressed proteins shall include:				
(a) A molecular and biochemical characterisation of the newly expressed protein, including				
- determination of the primary structure	☐	☐	☐	
- molecular weight	☐	☐	☐	
- studies on post-translational modifications	☐	☐	☐	
- a description of its function	☐	☐	☐	
- evaluation of potential interaction with other plant constituents	☐	☐	☐	
In the case of newly expressed enzymes, information on the enzyme activities, including				
- temperature and pH range for optimum activity	☐	☐	☐	
- substrate specificity	☐	☐	☐	
- possible reaction products	☐	☐	☐	
(b) An up-to-date search for homology				
- to proteins known to cause adverse effects, such as toxic proteins	☐	☐	☐	
- to proteins exerting a normal metabolic or structural function	☐	☐	☐	
The database(s) and the methodology used to carry out the search are specified	☐	☐	☐	
(c) A description of the stability of the protein under relevant processing and storage conditions and the expected treatment of the food and feed.				
- influences of temperature and pH changes	☐	☐	☐	
- potential modification(s) of the proteins (such as denaturation) and/or production of stable protein fragments generated through such treatments	☐	☐	☐	
(d) Data concerning the resistance of the newly expressed protein to proteolytic enzymes (such as pepsin).				
- Stable breakdown products are characterised and evaluated with regard to the potential to cause adverse health effects linked to their biological activity	☐	☐	☐	

(e) A repeated dose 28-day oral toxicity study with the newly expressed protein in rodents.				
As regards proteins expressed in the GM plant, in the case where the history of safe use for consumption as food and/or feed of both the plant and the newly expressed proteins is duly documented, specific toxicity testing is not required.				
If so, to provide necessary information regarding the history of safe use of the proteins	☐	☐	☐	
As regards proteins expressed in the GM plant, where specific testing is required				
The tested protein is the one expressed in the GM plant	☐	☐	☐	
If, due to the lack of sufficient amount of test materials from the plant, a protein produced by micro-organisms is used, the structural, biochemical and functional equivalence of this microbial substitute to the newly expressed plant protein is demonstrated.				
by comparisons of the molecular weight, amino acid sequence, post-translational modification, immunological reactivity and,	☐	☐	☐	
by, in the case of enzymes, the enzymatic activity	☐	☐	☐	
In case of differences between the plant expressed protein and its microbial substitute, the significance of these differences for the safety studies are evaluated.	☐	☐	☐	
When the genetic modification results in the expression of two or more proteins in the genetically modified plant and when, based on scientific knowledge, a possibility of synergistic or antagonistic interactions of safety concerns is identified				
Studies with combined administration of proteins are performed.	☐	☐	☐	
When appropriate depending on the outcome of the 28-day toxicity study, further targeted investigations are provided.	☐	☐	☐	
1.4.2 Testing of new constituents other than proteins				
Risk assessment of identified new constituents other than proteins. This shall include, on a case-by-case basis:				
- evaluation of their toxic potency	☐	☐	☐	
- evaluation of the need of toxicological testing as well as	☐	☐	☐	
- determination of their concentration in GM food and feed	☐	☐	☐	

To establish the safety of new constituents having no history of safe use for consumption in food and feed, the applicant shall provide information analogous to that described in the EFSA Guidance for submissions for food additive evaluations of 16 August 2012 and Commission Regulation (EC) No 429/2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. This includes the submission of information on a core set of studies such as				
- on metabolism/toxicokinetics	☐	☐	☐	
- sub-chronic toxicity	☐	☐	☐	
- genotoxicity	☐	☐	☐	
- chronic toxicity	☐	☐	☐	
- carcinogenicity	☐	☐	☐	
- reproduction and developmental toxicity	☐	☐	☐	
- any other appropriate type of study	☐	☐	☐	
1.4.3 Information on altered levels of food and feed constituents				
This section applies only in the case where the intended or unintended effect of the genetic modification would result in an alteration of the levels of food and feed constituents beyond the natural variation.				
A detailed risk assessment based on the knowledge of the physiological function and/or toxic properties of the altered levels of food and feed constituents such as macro- and micronutrients, anti-nutrients, and natural toxins as well as other secondary plant metabolites,	☐	☐	☐	
to determine if, and to what extent, the need of additional toxicological tests with whole GM food/feed on selected 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 GM food/feed				
A 90-day feeding study with whole food and feed in rodents is performed for a single transformation event or for stacked transformation events which are not obtained by conventional crossing.	☐	☐	☐	
GM plant containing stacked transformation events obtained by conventional crossing				

A 90-day feeding study with whole food and feed in rodents is performed for each of the single transformation event.	☐	☐	☐	
A 90-day feeding study with whole food and feed in rodents with the GM plant containg the stacked transformation events is included, where indications of potential adverse effects are identified (i) the stability of the inserts, (ii) the expression of the inserts and (iii) the potential synergistic or antagonistic effects resulting from the combination of the transformation events.	☐	☐	☐	
The toxicity study design with GM food and feed should follow OECD TG 408 with adaptation				
Minimum of two test doses and a negative control	☐	☐	☐	
The highest dose is the maximum achievable without causing nutritional imbalance; the lowest dose is above the anticipated human/target animal intake level	☐	☐	☐	
The GM food and feed analysed is relevant to the product to be consumed	☐	☐	☐	
For herbicide tolerant GM plants, the tested material comes from the GM plant exposed to the intended herbicide	☐	☐	☐	
Information on natural variation of test parameters is derived from historical background data	☐	☐	☐	
Statistical analysis focuses on the detection of possible differences between the test material and its control.	☐	☐	☐	
A power analysis to estimate a sample size capable of detecting a pre-specified biologically relevant effect size with a specified power and significance level	☐	☐	☐	
1.4.4.2 Animal studies with respect to reproductive and developmental toxicity testing				
Discussion on the need to perform such studies, based on outcome from Sections 1.4.1, 1.4.2, 1.4.3 and 1.4.4.	☐	☐	☐	
Reproductive or developmental toxicity test	☐	☐	☐	
1.4.4.3 Other animal studies to examine the safety and the characteristics of GM food and feed (see also Sections 1.6.1 and 1.6.2)				
Discussion on the need to perform such studies, based on outcome from Sections 1.4.1, 1.4.2, 1.4.3 and 1.4.4.	☐	☐	☐	

Feeding studies with target animal species, focusing on the safety of new constituents, on the identification and characterisation of unintended effects, and on the nutritional impact of any intentional, substantial, compositional modifications of the GM plant	☐	☐	☐	
Plant materials used in such studies are suitable for diet inclusion and can be nutritionally matched to a suitable control diet	☐	☐	☐	
1.4.4.4 Interpretation of relevance of animal studies				
Evaluation of effects observed in the animal trials to identify potential consequences for human and animal health. Attention is paid to the following:				
- effects specific for the test animal, but not for humans	☐	☐	☐	
- dose-response relationships in parameters that have changed	☐	☐	☐	
- when a difference is noted only at the highest dose applied, other factors are considered to determine whether there is a relationship with treatment.	☐	☐	☐	
- information on the background variability in a given parameter	☐	☐	☐	
- evaluation of changes occurring in animals of one gender in tests where animals of both genders are used	☐	☐	☐	
- identify possible inter-relationships between observed changes in single parameters	☐	☐	☐	
- supportive data, including in vitro and in silico experiments, to explain the observed effect	☐	☐	☐	
1.4.5 Conclusion of the toxicological assessment				
The conclusion of the toxicological assessment shall indicate whether:				
(a) potential adverse effects identified in other parts of the safety assessment have been confirmed or discarded;	☐	☐	☐	
(b) the available information on the newly expressed protein(s) and other new constituents resulting from the genetic modification gives indications of potential adverse effects in particular, whether and at which dose levels adverse effects were identified in specific studies;	☐	☐	☐	

(c) the information on natural constituents of which the levels are different from those in its conventional counterpart provides indications of potential adverse effects, in particular, whether and at which dose levels adverse effects were identified in specific studies;	☐	☐	☐	
(d) adverse effects have been identified from the studies made on the whole genetically modified food and feed and at which dose levels.	☐	☐	☐	
Evaluate the result of the toxicological assessment in the light of anticipated intake of the GM food and feed	☐	☐	☐	
Comments (up to 500 characters) *Please insert your comments here*				
1.5 Allergenicity assessment				
1.5.1 Assessment of allergenicity of the newly expressed protein				
Verification whether the source of the transgene is allergenic	☐	☐	☐	
When the introduced genetic material is obtained from wheat, rye, barley, oats or related cereal grains, assessment of the newly expressed proteins for a possible role in the elicitation of gluten-sensitive enteropathy or other enteropathies which are not IgE-mediated.	☐	☐	☐	
For stacked transformation events, assessment of any potential for increased allergenicity to humans and animals that may arise from additive, synergistic or antagonistic effects of the gene products.	☐	☐	☐	

A weight of evidence approach, followed in the assessment of possible allergenicity of the newly expressed protein(s), includes:				
a) Amino acid sequence homology comparison between the newly expressed protein and known allergens				
- a search for sequence homologies and/or structural similarities to identify potential IgE cross-reactivity	☐	☐	☐	
- quality and the comprehensiveness of the databases are state of the art	☐	☐	☐	
- the alignment-based criterion meets the minimal requirement, i.e. 35 % sequence identity to a known allergen over a window of at least 80 amino acids.	☐	☐	☐	
- Sequence alignment parameters used in the analysis, including calculation of percent identity (PID) on a window of 80 amino acids with gaps	☐	☐	☐	
- for assessing short peptidic fragments such as ORFs, a search for sequences of contiguous identical or chemically similar amino acid residue can be conducted.	☐	☐	☐	
(b) Specific serum screening				
Specific serum screening shall be performed when:				
i) the source of the introduced gene is considered allergenic, even if no sequence homology of the newly expressed protein to a known allergen is demonstrated; or	☐	☐	☐	
ii) the source is not known to be allergenic, but there are indications of a relationship between the newly expressed protein and a known allergen, based on sequence homology or structure similarity.	☐	☐	☐	
Specific serum screening study report using individual sera from individuals with a proven and well-characterised allergy to the source or to the potentially cross-reacting allergen using relevant immunochemical tests.	☐	☐	☐	
(c) Pepsin resistance and *in vitro* digestibility tests				
Pepsin resistance test performed under standardised conditions.	☐	☐	☐	

The digestibility of the newly expressed proteins in specific segment of the population may be assessed using *in vitro* digestibility tests using different conditions than those used in the pepsin resistance test.	☐	☐	☐	
Additional *in vitro* digestibility tests to take into account the impact of the possible interaction between the protein and other components of the matrix, as well as the effects of the processing.	☐	☐	☐	

Depending on the outcome of the *in vitro* digestibility test, a comparison of the intact, the heat-denatured and the pepsin-digested proteins for IgE binding.	☐	☐	☐	
(d) Additional tests				
in vitro cell based assays or in vivo tests on animal models	☐	☐	☐	
1.5.2 Assessment of allergenicity of the GM food or feed				
When the recipient plant is known to be allergenic,				
assessment of any potential change in the allergenicity of the GM food or feed by comparison of the allergen repertoire with that of its conventional counterpart, in particular, the potential over-expression of natural endogenous allergens.	☐	☐	☐	
Where available, information on the prevalence of allergy in persons working with, coming into contact with or in the vicinity of GM plant cultivation.	☐	☐	☐	
1.5.3 Adjuvanticity				
When known functional aspects of the newly expressed protein or structural similarity to known strong adjuvants may indicate possible adjuvant activity, assessment of the possible role of these proteins as adjuvants.	☐	☐	☐	
Information on the interactions with other constituents of the food matrix and/or processing which may alter the structure and bioavailability of the adjuvants	☐	☐	☐	
1.5.4 Conclusion of the allergenicity assessment				
The conclusion of the allergenicity assessment shall indicate:				
(a) whether the novel protein(s) is likely to be allergenic;	☐	☐	☐	
(b) whether the GM food or feed is likely to be more allergenic than its conventional counterpart.	☐	☐	☐	
When there is a likelihood of increased allergenicity due to the genetic modification, the GM food or feed is further characterised in the light of its anticipated intake.	☐	☐	☐	
Proposal of appropriate conditions for placing on the market (such as post-market monitoring and labelling).	☐	☐	☐	

Comments (up to 500 characters) *Please insert your comments here*				
1.6 Nutritional assessment				
1.6.1 Nutritional assessment of the genetically modified food				
Determination of the necessity to perform nutritional studies for GM food	☐	☐	☐	
When nutritional studies are conducted, the control diet(s) include the conventional counterpart and where appropriate additional comparator(s).	☐	☐	☐	
In the case of herbicide tolerant GMd plants, the tested material should come from the GM plant exposed to the intended herbicide.	☐	☐	☐	
In cases where an altered bioavailability needs to be established and may raise concern for sub-population(s), the level of the nutrient in the food shall be determined, taking into account all the different forms of the compound.	☐	☐	☐	
The selection of test methods for bioavailability depends on the nutrient or other constituent, the food containing these constituents, as well as the health, nutritional status and dietary practices of the specific population(s) anticipated to consume the food.	☐	☐	☐	
1.6.2 Nutritional assessment of the genetically modified feed				
Determination of the necessity to perform nutritional studies for GM feed	☐	☐	☐	
When nutritional studies are conducted, the control diet(s) include the conventional counterpart and where appropriate additional comparator(s).	☐	☐	☐	
When GM feed with improved nutritional characteristics, feeding studies with target animal of food producing species are conducted to assess the impact on the feed.	☐	☐	☐	

When GM plants modified for improved content and bioavailability of nutrients, studies with target food producing animal species are conducted to determine the bioavailability of individual nutrients in the GM plant compared to its conventional counterpart.	☐	☐	☐	
When GM plants with traits to enhance animal performance through increased nutrient density (such as increased oil content) or an enhanced level of a specific nutrient (such as an essential amino acid or a vitamin), an appropriate control diet using its conventional counterpart is formulated by supplementing it with the specific nutrient to the extent of the change effected in the GM plant.	☐	☐	☐	
Co-products (such as oilseeds meals) of GM plants may be compared with co-products produced from the conventional counterpart.	☐	☐	☐	
When appropriate, feeding studies in food producing animals to demonstrate that the nutritionally improved GM plant fulfils the expected nutritional value				
The exact experimental design and statistical approaches depends on the targeted animal species, type of plant trait(s) studied and the size of the expected effect.	☐	☐	☐	

Target animal feeding studies - species and duration:				
- span the growing and/or finishing period to slaughter for chickens, pigs, and cattle for fattening, or	☐	☐	☐	
- a major part of a lactation cycle for dairy cows, or	☐	☐	☐	
- laying cycle for laying hens or quails	☐	☐	☐	
- for feedstuffs intended only for aquaculture, growth studies conduct with aquatic species such as carp, catfish, salmonidae or typical herbivores.	☐	☐	☐	
The experimental diets are formulated in such a way that the key measured endpoints are responsive to a difference in the quantity and/or availability of the nutrient in question.	☐	☐	☐	
Endpoint measurements shall vary with the target species used in the study, but shall include feed intake, body weight, animal performance and bioavailability of nutrients.	☐	☐	☐	
1.6.3 Conclusion of the nutritional assessment				
Indication whether the GM food and feed is nutritionally equivalent to its conventional counterpart, taking natural variations into account.	☐	☐	☐	
Evaluation the result of the nutritional assessment in the light of anticipated intake of the GM food and feed.	☐	☐	☐	
Comments (up to 500 characters) *Please insert your comments here*				
1.7 Standardised guidelines for toxicity tests				
Toxicity tests use internationally agreed guidelines and test methods described by Council Regulation (EC) No 440/2008	☐	☐	☐	
Where necessary, they are used in a possibly adapted form for GMO toxicological testing	☐	☐	☐	
2. Exposure assessment - Anticipated intake/extent of use				
An estimate of the expected intake is provided for the nutritional evaluation.	☐	☐	☐	

Information to be provided:				
- the intended function, the dietary role, and the expected level of use of the GM food and feed in the EU	☐	☐	☐	
- the expected range of concentrations of newly produced proteins or existing plant proteins deliberately modified in the GM food(s) and feed(s) to be placed on the market	☐	☐	☐	
- recent developments in methodologies and appropriate consumption data are used	☐	☐	☐	
- describe any assumptions made in the exposure assessment	☐	☐	☐	
- on the basis of representative consumption data for products obtained from the respective conventional plants, estimation of the anticipated average and maximum intake of the GM food and feed.	☐	☐	☐	
- data on import and production quantities may provide additional information for the intake assessment	☐	☐	☐	
- probabilistic methods may be used to determine ranges of plausible values rather than single values or point estimates.	☐	☐	☐	
- identify and consider particular groups of the EU population with an expected higher exposure and consider this higher exposure within the risk assessment	☐	☐	☐	
- expected intake of these constituents shall be estimated taking into account the influences of processing, storage and expected treatment of the food and feed in question.	☐	☐	☐	
- in cases where the GM has resulted in an altered level of a natural constituent, or if a new constituent occurs naturally in other food and feed products, the anticipated change in total intake of this constituent is assessed considering realistic as well as worst case intake scenarios.	☐	☐	☐	
- information on known or anticipated human/animal intake of analogous GM food and feed and on other routes of exposure to the respective new and natural constituents, including amount, frequency and other factors influencing exposure	☐	☐	☐	

Comments (up to 500 characters) *Please insert your comments here*				
3. Risk characterisation				
3.1 Introduction				
Risk characterisation shall be carried out in an integrative manner:				
- based on data from hazard identification, hazard characterisation, and on exposure/intake data.	☐	☐	☐	
- Depending on the issue and the available data, perform a qualitative and, where possible, quantitative risk characterisation.	☐	☐	☐	
- comprehensive by considering all the available evidence from several analysis.	☐	☐	☐	
- demonstrate that the hazard identification and hazard characterisation are complete.	☐	☐	☐	
- discuss the quality of existing data and information. The discussion shall clearly indicate how this body of information has been taken into account in the determination of the final risk characterisation.	☐	☐	☐	
- estimate uncertainties associated to each test as well as to the different stages of the risk assessment, quantify them to the possible extent	☐	☐	☐	
- a distinction made between uncertainties that reflect natural variations in biological parameters and variation amongst different species' responses.	☐	☐	☐	
- the conditions for the estimated risk, and associated uncertainties, are as precise as possible.	☐	☐	☐	
- consider indications resulting from the risk characterisation that may require specific activities for post-market monitoring of GM food and feed.	☐	☐	☐	
3.2 Issues to be considered for risk characterisation				

3.2.1 Molecular characterisation	☐	☐	☐	
3.2.1 Comparative analysis	☐	☐	☐	
3.2.3 Food and feed safety in relation to intake	☐	☐	☐	
3.3 The result of risk characterisation				
The final risk characterisation shall clearly demonstrates that				
(a) The GM food and feed has no adverse effects on human and animal health	☐	☐	☐	
(b) The GM food does not differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer	☐	☐	☐	
(c) The GM food does not mislead the consumer;	☐	☐	☐	
(d) The GM feed does not harm or mislead the consumer by impairing the distinctive features of the animal products	☐	☐	☐	
(e) The GM feed does not differ from the feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for animals or humans	☐	☐	☐	
clearly indicate what assumptions have been made during the risk assessment in order to predict the probability of occurrence and severity of adverse effect(s) in a given population, and the nature and magnitude of uncertainties associated with establishing these risks	☐	☐	☐	
include detailed information justifying the inclusion or not of a proposal for labelling in the application	☐	☐	☐	
4. Post-market monitoring on the genetically modified food or feed				
Based on the outcome of the risk assessment, discussion on the necessity to provide a post-market monitoring (PMM) proposal.	☐	☐	☐	
Post-market monitoring should only be considered in cases where, notwithstanding the fact that the safety of genetically modified food and feed has been demonstrated, it is appropriate to confirm the expected consumption, the application of conditions of uses or identified effects.				

A PMM is proposed to confirm: (a) that specific recommendations of uses are followed by the consumer/animal owner;	☐	☐	☐	
(b) the predicted consumption of the genetically modified food or feed; or	☐	☐	☐	
(c) the relevance and intensity of effects and unintended effects detected during the pre-market risk assessment which can only be further characterised by post-market monitoring	☐	☐	☐	
The PMM strategies are described	☐	☐	☐	
The PMM is accompanied by adequate justification and a thorough description of the selected methodologies including aspects related to the analysis of the collected information	☐	☐	☐	
Comments (up to 500 characters) *Please insert your comments here*				
Scientific requirements for the environmental assessment as outlined in the EFSA guidance on the ERA of GM plants (2010)				
5. Environmental Assessment				
General approach of the ERA				
ERA is science-based, transparent and performed on a case-by-case basis	☐	☐	☐	
- follows a systematic approach (6 steps, 7 areas of risks)	☐	☐	☐	
- follows a comparative approach	☐	☐	☐	
- addresses uncertainties	☐	☐	☐	
The ERA considers				
- immediate and/delayed, direct and indirect effects	☐	☐	☐	
- intended effects	☐	☐	☐	
- unintended effects (*event-specific*) taking into account the data collected/generated from	☐	☐	☐	

i) the molecular characterisation	☐	☐	☐	
ii) the compositional analysis	☐	☐	☐	
iii) the agronomic and phenotypic characterisation	☐	☐	☐	
iv) the GM plant-environment interactions taking into account *in planta* data	☐	☐	☐	
The ERA considers the scope of the application and the different levels and routes of exposure to the GM plant	☐	☐	☐	
The issues outlined in the EFSA ERA guidance chapters 2.3.1 - choice of comparator, 2.3.2- receiving environment, 2.3.3 - general statistical principles, 2.3.4 - long-term effects and 2.3.5 - risk assessment of GM plants containing stacked transformation events should be considered throughout the ERA. EFSA does not expect a dedicated section on these chapters in the submitted application.				
Choice of comparators				
Description of comparator(s)	☐	☐	☐	
For GM plants containing single events				
Assessment of similarities and differences in the interaction of the GM plant and the environment in relation to conventional counterpart (where feasible and appropriate)	☐	☐	☐	
For vegetatively propagated crops, the conventional counterpart shall, in principle, be the non-GM near-isogenic line	☐	☐	☐	
For sexually reproducing crops, the conventional counterpart shall have a genetic background as close as possible to the GM plant under assessment	☐	☐	☐	
For GM plants containing stacked events				
The conventional counterpart, if available, should be used as the comparator	☐	☐	☐	
If the conventional counterpart not available,				
- non GM line derived from the breeding scheme used to develop the GM plant	☐	☐	☐	
- non GM line with agronomic properties as similar as possible to the GM plant containing the stacked events	☐	☐	☐	
The following information is provided				

- Breeding scheme of the GM plant	☐	☐	☐	
- Breeding scheme of all chosen comparator(s)	☐	☐	☐	
- Justification for the selection of the comparator(s)	☐	☐	☐	
- Details and justification of treatments and management regimes	☐	☐	☐	
Receiving environments				
The relevant receiving environment(s) is/are described including the following:				
- characteristics of the receiving environments	☐	☐	☐	
- representative management systems	☐	☐	☐	
- range of relevant biotic and abiotic interactions	☐	☐	☐	
Justification of representativeness of the receiving environments	☐	☐	☐	
Justification of representativeness of the selected management systems	☐	☐	☐	
Consideration of a worst-case scenario	☐	☐	☐	
Consideration of the presence of other GM plants in the same receiving environments	☐	☐	☐	
Justification that the generated data are relevant for other receiving environments and risk conclusions are valid for other receiving environments	☐	☐	☐	
General statistical principles				
An overview of statistical design and analysis for each study presented in the ERA part of the application	☐	☐	☐	
For each ERA related study, Appendix F -ERA-statistical design and analysis is compiled	☐	☐	☐	
Consideration of uncertainties				
- Discussion of the level of uncertainty in the ERA in comparison with the current uncertainties displayed in the scientific literature	☐	☐	☐	
- Description of the types of uncertainties encountered and considered during the different risk assessment steps (steps 1 to 5)	☐	☐	☐	

- Description of the relative importance of these types of uncertainties and their influence on the assessment outcome	☐	☐	☐	
- Highlight and quantification as far as possible of uncertainties inherent in the different steps of the ERA	☐	☐	☐	
- Definition as precisely as possible of the terms for the expression of risks and associated uncertainties	☐	☐	☐	
Long-term effects				
Potential long-term effect(s) are identified and described by a desk study in the 7 areas of risk (chapters 3.1-3.7 of the ERA guidance document) and classified according to	☐	☐	☐	
- category 1 of long-term effects: result of chronic exposure	☐	☐	☐	
- category 2 of long-term effects: result of increase in spatial and temporal complexity	☐	☐	☐	
The long-term effects are addressed in each specific area of risk including	☐	☐	☐	
- methods, approaches and data sets used to reach conclusions	☐	☐	☐	
- the basis of and justification for the conclusions	☐	☐	☐	
- cross-link to parts of the post-market environmental monitoring (PMEM) plan designed to observe possible long-term effects	☐	☐	☐	
Specific areas of risks				
5.1. Persistence and invasiveness including plant-to-plant gene flow				
5.1.1 Step 1: Problem formulation				
A problem formulation is given including				
identification of potential hazards	☐	☐	☐	
identification of pathways of exposure (plant / environment)	☐	☐	☐	
identification of aspects of the environment to be protected (protection goals)	☐	☐	☐	
risk hypothesis to be tested	☐	☐	☐	

definition of assessment & measurement endpoints	☐	☐	☐	
definition of acceptable effect size (limits of concern)	☐	☐	☐	
information on the conditions of the production systems and relevant semi-natural and natural habitats	☐	☐	☐	
5.1.2 Step 2: Hazard characterisation				
Species-specific background information				
Description of the parental species including information on				
- the reproductive biology	☐	☐	☐	
- the characteristics associated with weediness and invasiveness	☐	☐	☐	
- the factors limiting persistence and invasiveness	☐	☐	☐	
- the hybridisation and introgression potential with any sympatric compatible relatives	☐	☐	☐	
Stage 1: Event-specific information on				
- the seed germination characteristics (see Appendix C ERA agronomic characteristics)	☐	☐	☐	
- the phenotype under agronomic conditions	☐	☐	☐	
For each field trial the following Appendices are compiled:	☐	☐	☐	
Appendix C ERA agronomic characteristics	☐	☐	☐	
Appendix F ERA statistical design and analysis	☐	☐	☐	
- the reproductive biology of the GM plant	☐	☐	☐	
- the potential for seed persistence leading to volunteer occurrence	☐	☐	☐	
Conclusions of stage 1 assessment				
Potential unintended effects, resulting from the transformation process, have been shown not to alter the fitness of the GM plant compared to the conventional counterpart in stage 1?	☐	☐	☐	
if YES, then GM trait specific information can be used in the subsequent stages	☐	☐	☐	

For plants that can either reproduce or overwinter in the EU consideration of stage 2	☐	☐	☐	
For plants that can either reproduce or overwinter: Stage 2: *Trait-specific* information				
The applicant has addressed the following questions (see Figure 4 of the ERA guidance document 2010)				
a) Will the GM plant be more persistent than conventional counterpart under agricultural conditions?	☐	☐	☐	
b) Will the GM trait increase the fitness of the GM plant or compatible relative under agricultural conditions?	☐	☐	☐	
c) Can the GM plant form feral populations under EU conditions?	☐	☐	☐	
d) Can the GM plant hybridise with sympatric compatible relatives outside production systems?	☐	☐	☐	
Conclusions of stage 2 assessment	☐	☐	☐	
If feral populations are likely and/or if hybridisation is plausible: Stage 3: *Trait-specific* information				
The applicant has addressed the following questions (see Figure 4 of the ERA guidance document 2010)				
a) Will the GM trait alter the fitness of feral plants or compatible relatives in semi-natural habitats?	☐	☐	☐	
b) Will the GM trait alter the range of feral plants or populations of compatible relatives?	☐	☐	☐	
Conclusions of stage 3 assessment	☐	☐	☐	
If altered fitness or the ability to occupy new niches are demonstrated: Stage 4: *Trait-specific* information				
The applicant has addressed the following question (see Figure 4 of the ERA guidance document 2010)				
a) Will the GM trait caused populations of feral plants or compatible relatives to change in size?	☐	☐	☐	
Conclusions of stage 4 assessment	☐	☐	☐	
5.1.3 Step 3: Exposure characterisation				
Exposure characterisation for each hazard identified in step 3.1.1 and 3.1.2	☐	☐	☐	
Identification and description of pathway(s) of exposure	☐	☐	☐	

5.1.4: Step 4: Risk characterisation				
Risk characterisation is provided for all identified risks	☐	☐	☐	
Information on the acceptability of the characterised risk(s) (within the range defined as acceptable during the problem formulation)	☐	☐	☐	
5.1.5: Step 5: Risk management strategies				
Information on whether any risk management strategies are needed	☐	☐	☐	
If needed, proposal and definition of the management strategies	☐	☐	☐	
Assessment of efficacy and reliability of each management strategy	☐	☐	☐	
Information on the expected reduction in risk associated with the management strategies	☐	☐	☐	
Cross link with PMEM taking into account risk management strategies	☐	☐	☐	
5.1.6: Step 6: Conclusions				
- the impact of the GM plant and/or hybridising relatives in the production systems	☐	☐	☐	
- the impact of the GM plant and/or hybridising relatives in semi-natural and natural habitats	☐	☐	☐	
- the acceptability of the anticipated harm	☐	☐	☐	
- the risk management strategies needed to mitigate any harm	☐	☐	☐	
Comments (up to 500 characters) *Please insert your comments here*				
5.2. Plant to micro-organisms gene transfer				
5.2.1 Step 1: Problem formulation				
A problem formulation is given including				
	☐	☐	☐	

identification of potential hazards	☐	☐	☐	
identification of pathways of exposure (plant / environment)	☐	☐	☐	
identification of aspects of the environment to be protected (protection goals)	☐	☐	☐	
risk hypothesis to be tested	☐	☐	☐	
definition of assessment & measurement endpoints	☐	☐	☐	
definition of acceptable effect size (limits of concern)	☐	☐	☐	
The problem formulation should focus on				
- the molecular characterization of the DNA sequence inserted, including promoters is given	☐	☐	☐	
- the presence of antibiotic marker gene (ARM)	☐	☐	☐	
- the homologies between inserted plant DNA sequences and DNA sequences from relevant microbial recipients	☐	☐	☐	
- the presence of recipient micro-organisms for transgenic DNA in the receiving environment(s)	☐	☐	☐	
- Selective conditions enhancing the probability of dissemination and maintenance of the genetic material from the GM plant in natural microbial communities	☐	☐	☐	
- the persistence of the GM plant material after harvest	☐	☐	☐	
- the potential for long-term establishment of the genetic material from the GM plants in natural microbial communities	☐	☐	☐	
5.2.2 Hazard characterisation				
Characterisation of each hazard identified in step 3.2.1	☐	☐	☐	
Assessment of prevalence and distribution of genes	☐	☐	☐	
5.2.3 Step 3: Exposure characterisation				
Exposure characterisation for each hazard identified in step 3.2.1 and 3.2.2	☐	☐	☐	
Exposure characterisation is taking into account				
- the sub-cellular location and copy number of the recombinant DNA	☐	☐	☐	

- the environmental routes of exposure of the GM plants and the recombinant DNA	☐	☐	☐	
- the stability of the DNA in the relevant environment(s)	☐	☐	☐	
The exposure characterisation is considering the different routes of exposure in the receiving environment(s):				
- the plant production system	☐	☐	☐	
- the food and feed chain	☐	☐	☐	
- the gastro-intestinal system	☐	☐	☐	
5.2.4: Step 4: Risk characterisation				
Risk characterisation is provided for each identified risk, e.g. by estimating				
- the estimated probability of occurrence	☐	☐	☐	
- any positive selection pressure in receiving environment	☐	☐	☐	
- the magnitude of the consequences of the adverse effect(s)	☐	☐	☐	
5.2.5: Step 5: Risk management strategies				
Information on whether any risk management strategies are needed	☐	☐	☐	
If needed, proposal and definition of the management strategies	☐	☐	☐	
Assessment of efficacy and reliability of each management strategy	☐	☐	☐	
Information on the expected reduction in risk associated with the management strategies	☐	☐	☐	
Cross link with PMEM taking into account risk management strategies	☐	☐	☐	
5.2.6: Step 6: Conclusions				
Conclusions taking into account any proposed risk management strategie(s)	☐	☐	☐	
The potential impacts are also evaluated for indirect effects on biogeochemical cycles	☐	☐	☐	

Comments (up to 500 characters) *Please insert your comments here*				
5.3 Interactions between the GM plant and target organisms				
5.3.1 Step 1: Problem formulation				
Description of the target organisms	☐	☐	☐	
A problem formulation is given including				
identification of potential hazards	☐	☐	☐	
identification of pathways of exposure (plant / environment)	☐	☐	☐	
identification of aspects of the environment to be protected (protection goals)	☐	☐	☐	
risk hypothesis to be tested	☐	☐	☐	
definition of assessment & measurement endpoints	☐	☐	☐	
definition of acceptable effect size (limits of concern)	☐	☐	☐	
5.3.2 Step 2: Hazard characterisation				
Evaluation of the potential hazards identified in step 1 e.g. for the target organisms to develop resistance	☐	☐	☐	
Background information on				
- the biology, life cycle, ecology and/or behaviour of the target organisms	☐	☐	☐	
- the resistance mechanisms	☐	☐	☐	
- the heritability and linkages to virulence, fitness and selective advantage	☐	☐	☐	
- the distribution of the target organism and its resistant populations in European environments	☐	☐	☐	
- the host range of the target organism	☐	☐	☐	
- the population genetics and epidemiology of susceptible and resistant target organisms	☐	☐	☐	

- the frequency of resistant individuals or resistance allele(s)	☐	☐	☐	
- the mode of action of the transgenic products towards the target organisms	☐	☐	☐	
- the baseline susceptibility of the target organisms to the transgenic products	☐	☐	☐	
Various scenarios are considered, including a worst case scenario	☐	☐	☐	
5.3.3 Step 3: Exposure characterisation				
Data characterising the exposure of target organisms to the GM plants should include				
- expression level of the transgenic products in plant tissues consumed by TO	☐	☐	☐	
- estimation of the levels of intake of the transgenic product(s) at various development stages of the target organisms	☐	☐	☐	
- influence of the expression level and its variability on the interaction between the GM plant and the target organism	☐	☐	☐	
- proportion of the population of the target organisms exposed to the GM plant in the receiving environment(s)	☐	☐	☐	
- baseline frequency of resistant individuals or resistance/virulence alleles	☐	☐	☐	
- deployment of other GM plants expressing similar traits in the receiving environment	☐	☐	☐	
5.3.4: Step 4: Risk characterisation				
Risk characterisation is provided for each identified risk identified, e.g.				
- evolving resistance	☐	☐	☐	
- developing undesired changes in the interaction between the target plant pathogens and the GM plants in the receiving environment(s)	☐	☐	☐	
5.3.5: Step 5: Risk management strategies				
Information on whether any risk management strategies are needed	☐	☐	☐	
If needed, proposal and definition of the management strategies	☐	☐	☐	

Assessment of efficacy and reliability of each management strategy	☐	☐	☐	
Information on the expected reduction in risk associated with the management strategies	☐	☐	☐	
An IRM plan is presented	☐	☐	☐	
Annex II-ERA-IRM is compiled	☐	☐	☐	
Cross link with PMEM taking into account risk management strategies	☐	☐	☐	
5.3.6: Step 6: Conclusions				
Conclusions taking into account any proposed risk management strategie(s)	☐	☐	☐	
Comments (up to 500 characters) *Please insert your comments here*				
5.4 Interactions of the GM plant with non-target organisms (NTOs)				
5.4.1 Step 1: Problem formulation				
The following elements are considered				
- the plant and the objective of the inserted trait(s) are clearly described	☐	☐	☐	
- the receiving environments are clearly described	☐	☐	☐	
- the selected NTO focal species are clearly described	☐	☐	☐	
- the selected NTO focal species are commonly present in European environments	☐	☐	☐	
- if the NTOs are NOT commonly present in European environments, are justifications provided?	☐	☐	☐	
A problem formulation is given including				
identification of potential hazards	☐	☐	☐	
identification of pathways of exposure of NTOs to plant/plant products)				

identification of aspects of the environment to be protected (protection goals)	☐	☐	☐	
risk hypothesis to be tested	☐	☐	☐	
definition of assessment & measurement endpoints	☐	☐	☐	
definition of acceptable effect size (limits of concern)	☐	☐	☐	
Was the stepwise approach (Figure 5 of the ERA GD 2010) followed to select focal NTO species to be tested ?	☐	☐	☐	
According to this stepwise approach, did you address the following questions				
step 1: identification of NT functional groups likely to be exposed to the GM plant	☐	☐	☐	
step 2:categorisation of NT species from identified functional groups	☐	☐	☐	
did you also consider endangered NT species or species of economic/cultural value?	☐	☐	☐	
step 3: ranking species based on the ecological criteria	☐	☐	☐	
step 4: final selection of focal species	☐	☐	☐	
5.4.2 Step 2: Hazard characterisation				
Was a tiered approach followed to assess effects on NTO?	☐	☐	☐	
Did you test <u>at least one</u> focal NTO species per functional group identified?	☐	☐	☐	
Did you provide tier 1a studies?	☐	☐	☐	
Did you provide tier 1b (in planta) studies?	☐	☐	☐	
Did you provide tier 2 studies?	☐	☐	☐	
If not, justification provided	☐	☐	☐	
Did you provide tier 3 studies?	☐	☐	☐	
If not, justification provided	☐	☐	☐	
For each tier study provided, please indicate the selected assessment and measurements endpoints, the experimental details of the study and the trigger values to move between tiers (see Appendix E)	☐	☐	☐	
Appendix E - ERA NTO	☐	☐	☐	
	☐	☐	☐	

	☐	☐	☐	
Appendix F - ERA statistical design and analysis	☐	☐	☐	
Did you also assess unintended effects based on a weight-of-evidence approach?	☐	☐	☐	
Did you consider the following data?				
(1) molecular data	☐	☐	☐	
(2) compositional data	☐	☐	☐	
(3) data from agronomic & phenotypic field trials	☐	☐	☐	
(4) GM plant-environment interactions taking into account *in planta* data	☐	☐	☐	
Did you provide field-generated data from outside EU?	☐	☐	☐	
5.4.3 Step 3: Exposure characterisation				
The exposure of NTO to the newly inserted product(s)/GM plant is evaluated, considering the	☐	☐	☐	
(0) scope of the application,	☐	☐	☐	
(1) characteristics of the NTO (e.g. spatial distribution, trophic levels, feeding habits)	☐	☐	☐	
(2) characteristics of the GM plant, its transgene(s) and the products thereof (e.g. spatial distribution, pollen dispersal & deposition, time/location of pollen, shed, product concentration in the various parts of the plant over the growing season)	☐	☐	☐	
(3) characteristics of the host plant(s) (e.g. range and spatial distribution of host plants)	☐	☐	☐	
(4) and other external factors (e.g. rainfall, agricultural management practices)	☐	☐	☐	
5.4.4: Step 4: Risk characterisation				
Risk characterisation is provided for each identified risk.	☐	☐	☐	
Specific characterization and quantification of the identified risk(s) for each selected endpoint				
(1) in the production site of the GM plant?	☐	☐	☐	
(2) outside the production site in different habitats where relevant exposure of sensitive NTO may occur?	☐	☐	☐	

5.4.5: Step 5: Risk management strategies				
Information on whether any risk management strategies are needed	☐	☐	☐	
If needed, proposal and definition of the management strategies	☐	☐	☐	
Assessment of efficacy and reliability of each management strategy	☐	☐	☐	
Information on the expected reduction in risk associated with the management strategies	☐	☐	☐	
Cross link with PMEM taking into account risk management strategies	☐	☐	☐	
Were the management strategies designed for worst-case scenario of high exposure?	☐	☐	☐	
Do they comply with common principles of good agricultural practices like crop rotations, integrated pest management?	☐	☐	☐	
5.4.6: Step 6: Conclusions				
The conclusions are provided, taking into account any proposed risk management strategie(s)				
(1) in the production site of the GM plant	☐	☐	☐	
(2) outside the production site in different habitats where relevant exposure of sensitive NTO may occur?	☐	☐	☐	
Conclusion on intended effects on NTOs	☐	☐	☐	
Conclusion on unintended effects on NTOs	☐	☐	☐	
Comments (up to 500 characters) *Please insert your comments here*				
5.5 Impacts of the specific cultivation, management and harvesting techniques				
5.5.1 Step 1: Problem formulation				
A problem formulation is given including				
	☐	☐	☐	

identification of potential hazards	☐	☐	☐	
identification of pathways of exposure (plant / environment)	☐	☐	☐	
identification of aspects of the environment to be protected (protection goals)	☐	☐	☐	
risk hypothesis to be tested	☐	☐	☐	
definition of assessment & measurement endpoints	☐	☐	☐	
definition of acceptable effect size (limits of concern)	☐	☐	☐	
Identification of the various representative management and production systems in which the GM plant might be introduced	☐	☐	☐	
Identification of potential changes of receiving environment(s) and management and production systems which are foreseeable in the near future	☐	☐	☐	
Description how the introduction of the GM plant might alter the existing management and production systems, taking into consideration direct and indirect effects	☐	☐	☐	
Identification of relevant assessment endpoints representing the aspects of the environment(s) that need to be protected from adverse effects due to changes in cultivation, management and harvesting techniques.	☐	☐	☐	
Identification of the potential adverse effects that may result from the changes in management and production systems in a range of different environments, taking account of anticipated future changes in agriculture associated with other drivers	☐	☐	☐	
5.5.2 Step 2: Hazard characterisation				
For each representative management and production system: Identification of the possible environmental adverse effects due to the change in management practices and cultivation practices, including the cultivation of other plants	☐	☐	☐	
- Consideration of the potential impact of the GM plant on the cultivation of other plants and of its consequences.	☐	☐	☐	
- Consequences of risk management measures identified in other chapter sections are being considered ;	☐	☐	☐	

Information on the potential long-term and indirect environmental impacts of the management and production systems in countries where the GM plant is/has been grown (even outside EU)	☐	☐	☐	
Models are used to support the risk assessment	☐	☐	☐	
5.5.3 Step 3: Exposure characterisation				
3 scenarios for exposure characterisation are considered				
- a "field level" or "substitution" scenario is described	☐	☐	☐	
- a "landscape scenario" or "typical" scenario is described	☐	☐	☐	
- a "worst-case" scenario is described	☐	☐	☐	
A "fourth" scenario is described considering the potential adoption of other GM plants in the receiving environment	☐	☐	☐	
Models are used to support the scenario analysis	☐	☐	☐	
5.5.4: Step 4: Risk characterisation				
Risk characterisation is provided for each scenario analysis, e.g. assessment as to whether the specific GM management practices cause greater, similar or lower adverse environmental effects than the current management and production systems they are likely to replace	☐	☐	☐	
Models are used to complement applicant's statement and clarify uncertainties	☐	☐	☐	
5.5.5: Step 5: Risk management strategies				
Information on whether any risk management strategies are needed	☐	☐	☐	
If needed, proposal and definition of the management strategies	☐	☐	☐	
Assessment of efficacy and reliability of each management strategy	☐	☐	☐	
Information on the expected reduction in risk associated with the management strategies	☐	☐	☐	
Cross link with PMEM taking into account risk management strategies	☐	☐	☐	
Information on whether				

- the proposed management and production systems are consistent with the environmental protection goals and	☐	☐	☐	
- the strategies proposed do not pose more harm than non-GM management strategies	☐	☐	☐	
Models are used to complement applicant's statement and clarify uncertainties	☐	☐	☐	
5.5.6: Step 6: Conclusions				
Conclusions taking into account any proposed risk management strategie(s)	☐	☐	☐	
The conclusions are taking into account effects of further potential changes in the receiving environment(s) and farming systems	☐	☐	☐	
Comments (up to 500 characters) *Please insert your comments here*				
5.6 Effects on biogeochemical processes				
5.6.1 Step 1: Problem formulation				
A problem formulation is given including				
identify potential hazards	☐	☐	☐	
identify pathways of exposure (plant / environment)	☐	☐	☐	
identify aspect of the environment to be protected (protection goals)	☐	☐	☐	
formulate risk hypothesis to be tested	☐	☐	☐	
define assessment & measurement endpoints	☐	☐	☐	
define acceptable effect size (limits of concern)	☐	☐	☐	
Identify if GM plants and their associated management have potential adverse effects on biogeochemical processes compared to the effects of a range of current production systems (link to 5.5)	☐	☐	☐	

- at production site	☐	☐	☐	
- in the wider environment	☐	☐	☐	
5.6.2 Step 2: Hazard characterisation				
An assessment is provided whether the hazard identified in step 1 would have additional adverse effects relative to current production practice	☐	☐	☐	
5.6.3 Step 3: Exposure characterisation				
The exposure of the hazard characterised in step 2 are discussed	☐	☐	☐	
The assessment of the GM plant and its management affecting biogeochemical processes in the production site is provided	☐	☐	☐	
The assessment of the GM plant and its management affecting biogeochemical processes in the wider environment is provided	☐	☐	☐	
The assess the potential exposure to GM plant products through manure or organic plant matter, (imported as fertilizer or soil amendment derived from faeces animal fed GMO) or derived from other bioproducts of industrial processes is provided	☐	☐	☐	
5.6.4: Step 4: Risk characterisation				
Risk characterisation is provided for each risk identified and is carried out both at the production site and in the wider environment	☐	☐	☐	
The risk characterisation demonstrates that the GM plant and its management do not have more adverse effects on biogeochemical cycles than any present system	☐	☐	☐	
5.6.5: Step 5: Risk management strategies				
Information on whether any risk management strategies are needed	☐	☐	☐	
If yes, the management strategies are proposed and defined	☐	☐	☐	
The efficacy and reliability of each management strategy are discussed	☐	☐	☐	

The final level of risk, after applying the management strategies, is provided	☐	☐	☐	
Cross link with PMEM taking into account risk management strategies	☐	☐	☐	
5.6.6 Step 6: Conclusions				
The conclusions are provided, taking into account any risk management strategies	☐	☐	☐	
The conclusions consider in both production site and the wider environment	☐	☐	☐	
The conclusions consider long-term effects of adverse changes in biogeochemical processes and address indirect effects on biogeochemical processes as a consequences of altered production practices related to GM plant	☐	☐	☐	
5.7. Effects on human and animal health				
The issue is considered in the application	☐	☐	☐	
Reference is given to the food and feed safety assessment	☐	☐	☐	
If the application is for non-food or non-feed purposes, reference is given to the EFSA GMO Panel guidance document (EFSA, 2009)	☐	☐	☐	
5.8. Overall risk evaluation and conclusions				
The overall evaluation of the risk of the GM plant in the receiving environment(s) is provided	☐	☐	☐	
The overall evaluation is taking into account				
- the risk characterisation	☐	☐	☐	
- any risk management strategies proposed	☐	☐	☐	
- assumptions made during the ERA	☐	☐	☐	
- nature and magnitude of the uncertainties associated	☐	☐	☐	
Cross link with PMEM taking into account risk management strategies	☐	☐	☐	
6. PMEM				
Plan for General Surveillance (GS)	☐	☐	☐	

	☐	☐	☐	
Consideration of the scope of the application and the level of exposure	☐	☐	☐	
The GS plan relies on the following tools:				
- GMO-focused systems like farmer questionnaires	☐	☐	☐	
- existing monitoring networks	☐	☐	☐	
- literature review	☐	☐	☐	
Identification of risk(s) or critical uncertainty during the ERA	☐	☐	☐	
A Case-Specific Monitoring (CSM) plan is provided considering the risk(s) identified during the ERA including any uncertainty on risk management measures	☐	☐	☐	
An Insect-Resistant Management (IRM) plan is provided	☐	☐	☐	
If yes,	☐	☐	☐	
- Appendix D - ERA IRM is compiled	☐	☐	☐	
- A strategy for managing resistance (e.g. High dose/Refuge) is provided	☐	☐	☐	
- A proposal to monitor the implementation of resistance management measures is provided	☐	☐	☐	
- A proposal to monitor the change in susceptibility of target pests is provided	☐	☐	☐	
Information on data quality, management and statistical analyses	☐	☐	☐	
Reporting the results of monitoring on an annual basis	☐	☐	☐	
Review and adaptation proposed	☐	☐	☐	
Comments (up to 500 characters) *Please insert your comments here*				
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 GM food and feed covered by the application is included in the application.	☐	☐	☐	
This systematic review is 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.	☐	☐	☐	
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 of the Implementing Regulation, a thorough analysis of the respective studies and plausible explanations for the observed discrepancies are provided.	☐	☐	☐	

End of this spreadsheet

			For EFSA use only	
Part III - Cartagena Protocol	**Yes, provided**	**Not applicable (justification provided in Part III)**	**EFSA agrees**	EFSA comments/questions to applicants
For GM plants containing stacked transformation events (segregating crops), the information provided in Part III includes all sub-combinations not yet authorised	☐	☐	☐	
(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	☐	☐	☐	
1. Identification of characteristics which may cause adverse effects	☐	☐	☐	

	☐	☐	☐	
2. Evaluation of the potential consequences of each adverse effect, if it occurs	☐	☐	☐	
3. Evaluation of the likelihood of the occurence of each identified potential adverse effect	☐	☐	☐	
4. Estimation of the risk posed by each identified characteristic of the GMO(s)	☐	☐	☐	
5. Application of management strategies for risks from the deliberate release or marketing of GMO(s)	☐	☐	☐	
6. Determination of the overall risk of the GMO(s)	☐	☐	☐	
(k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate	☐	☐	☐	
Comments (up to 500 characters) *Please insert your comments here*				

			For EFSA use only	
Part IV - Labelling	**Yes, provided**	**Not applicable (justification provided in Part IV)**	**EFSA agrees**	EFSA comments/questions to applicants
For GM plants containing stacked transformation events (segregating crops), the information provided in Part IV includes all sub-combinations not yet authorised	☐	☐	☐	
(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	☐	☐	☐	
Comments (up to 500 characters) *Please insert your comments here*				

			For EFSA use only	
Part V - Methods of detection, sampling and reference materials	**Yes, provided**	**Not applicable (justification provided in Part V)**	**EFSA agrees**	EFSA comments/questions to applicants
A copy of the completed form for the submission of those samples to the EURL and proof of sending to the EURL	☐	☐	☐	
Reference to the place where the reference material can be accessed shall be provided in the application.	☐	☐	☐	
Proof of reception by the EURL-GMFF about samples, reagents and methods (Appendix G)	☐	☐	☐	
Comments (up to 500 characters) *Please insert your comments here*				

			For EFSA use only	
Part VI - Additional information to be provided for GM plants and/or food/feed containing or consisting of GM plants	**Yes, provided**	**Not applicable (justification provided in Part VI)**	**EFSA agrees**	EFSA comments/questions to applicants
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.	☐	☐	☐	
Comments (up to 500 characters) *Please insert your comments here*				

			For EFSA use only	
Part VII - Summary	**Yes, provided**	**Not applicable (justification provided in Part VII)**	EFSA agrees	EFSA comments/questions to applicants
1. General Information				
1.1 Details of application				
(a) Member State of application	☐	☐	☐	
(b) Application number	☐	☐	☐	
(c) Name of the product (commercial and 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 oGM plants	☐	☐	☐	
☐ Food produced from GM plants or containing ingredients produced from GM plantscontaining or consisting of genetically modified plants	☐	☐	☐	
(b) Genetically modified feed				
☐ Feed containing or consisting of GM plants	☐	☐	☐	
☐ Feed produced from GM plants	☐	☐	☐	
(c) GM plants for food and feed uses				
☐ Products other than food and feed containing or consisting of GM 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	☐	☐	☐	
If yes, specify	☐	☐	☐	
1.5. Has the GM plant been notified under Part B of Directive 2001/18/EC?	☐	☐	☐	
Yes	☐	☐	☐	
If no, provide risk analysis data	☐	☐	☐	
1.6. Has the GM plant or derived products been previously notified for marketing in the Union under Part C of Directive 2001/18/EC?				
No	☐	☐	☐	
If yes, 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	☐	☐	☐	
If yes, specify	☐	☐	☐	
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 Articles 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. Inforamtion 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 GM 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 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 GM 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) Sub-cellular 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 GM plant	☐	☐	☐	
3.2.5. Information (for environmental safety aspects) on how the GM plant differs from the recipient plant in:				
(a) Mode(s) and/or rate of reproduction	☐	☐	☐	
(b) Dissemination	☐	☐	☐	
(c) Suvivability	☐	☐	☐	
(d) Other differences	☐	☐	☐	
3.2.6. Any change to the ability of the GM 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 and feed constituents	☐	☐	☐	
(d) Testing of the whole GM food and feed	☐	☐	☐	
6. Allergenicity				
(a) Assessment of allergenicity of the newly expressed protein	☐	☐	☐	
(b) Assessment of allergenicity of the whole GM plant	☐	☐	☐	
7. Nutritional assessment				
(a) Nutritional assessment of GM food	☐	☐	☐	
(b) Nutritional assessment of GM feed	☐	☐	☐	
8. Exposure assessment - Anticipated intake/extent of use	☐	☐	☐	
9. Risk characterisation	☐	☐	☐	
10. Post-market monitoring of GM food or feed	☐	☐	☐	

11. Environmental assessment				
11.1. Mechanism of interaction between the GM plant and target organisms	☐	☐	☐	
11.2. Potential changes in the interactions of the GM 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 GM plant and target organisms	☐	☐	☐	
(e) Interactions of the GM 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 environmetnal risk assessment and monitoring	☐	☐	☐	
(c) Case-specific GM plant monitoring (approach, strategy, method and analysis)	☐	☐	☐	
(d) General surveillance of the impact of the GM plant (approach, strategy, method and analysis)	☐	☐	☐	
(e) Reporting the results of monitoring	☐	☐	☐	
13. Detection and identification techniques for the GM plant	☐	☐	☐	
14. Information relating to previous releases of the GM plant (for ERA aspects)				

14.1. History of previous releases of the GM plant notified under Part B of the Directive 2001/18/EC and under Part B of Directive 90/220/EEC by the same notifier				
(a) Notification number	☐	☐	☐	
(b) Conclusions of post-release monitoring	☐	☐	☐	
(c) Results of the release in respect to any risk to human health and the environment (submitted to the Competent Authority according to Article 10 of Directive 2001/18/EC)	☐	☐	☐	
14.2. History of previous releases of the GM plant carried out outside the Community by the same notifier				
(a) Release country	☐	☐	☐	
(b) Authority overseeing the release	☐	☐	☐	
(c) Release site	☐	☐	☐	
(d) Aim of the relaese	☐	☐	☐	
(e) Duration of the release	☐	☐	☐	
(f) Aim of post-releases monitoring	☐	☐	☐	
(g) Duration of post-releases monitoring	☐	☐	☐	
(h) Conclusions of post-releases monitoring	☐	☐	☐	
(i) Results of the release in respect to any risk on human health and the environment	☐	☐	☐	

APPENDIX B: EXAMPLES OF FIGURES AND TABLES FOR PART II

This appendix contains examples of the types of figures and tables that may be included in an application. Figures and tables are useful to provide an overview of studies in the application and snap-shots of each study, to add clarity to parts of a study with illustrations, and to streamline the risk assessment process. These figures and tables should not be viewed as precise templates as the data in each application differs. They are non-binding, omission of certain details in the exemplar tables or figures does not mean these data are not necessary, for example, the fatty acid analysis in Table 2 contains only a limited number of fatty acids. Other formats of these figures and tables will be accepted, provided that the same aim is achieved.

Table of contents

Table 1: Example of a general overview table of data provided in the Part II of an application indicating the title of the studies, the section they relate to and the type of information they contain. This table should be provided as a separate appendix. Every time additional information is provided, this table should be updated and provided as a separate appendix.

SECTION	NAME	TITLE	RELATED SECTION IN PART II	AUTHOR NAMES ON THE STUDY TO BE KEPT CONFIDENTIAL (YES/NO)	INFORMATION[1]
	Main text (no additional info needs to be added)				
Non-CI Appendices	e.g. Appendix X	e.g. Molecular characterisation of insert	e.g. A.2.1		New document[2]
					From Apxx[3]-flanking
					Updated study[4]
CI Appendices					
References[5]					

[1] Some additional information to clarify the way information can be provided is given in footnotes
[2] This analyses can be found in the current application
[3] This study has also been provided in the frame of applicationXX
[4] A study had been provided in the frame of a previous application but has been updated in the current application
[5] No description is expected, except for key studies they should be added (maximum 10)

Table 2: Example of application overview table focussing on study reports based on an application for herbicide tolerance GM maize. This table should be provided as a separate appendix. Every time additional information is provided, this table should be updated and provided as a separate appendix.

A. GM plant containing single event

APPLICATION IDENTIFICATION CODE (EVENT NAME)				
	Single event		Comparators	
	event name		conventional counterpart	commercial varieties
newly expressed proteins	protein A	protein B	n.a.	n.a.
Traits			n.a.	n.a.
Breeding tree	(Appendix xx Pxx)		(Appendix xx Pxx)	
Scope 1. Food ☐ 1.1 GM plants for food use ☐ 1.2 Food containing or consisting of GM plants ☐ 1.3 Food produced from GM plant s or containing ingredients produced from GM plants 2. Feed ☐ 2.1 GM plants for feed use ☐ 2.2 Feed containing or consisting of GM plants ☐ 2.3 Feed produced from GM plants 3. GM plants for environmental release ☐ 3.1 Import and processing ☐ 3.2 Seeds and plant propagating material for cultivation in Europe				
Anticipated uses and products	(Appendix xx page xx)			
MOLECULAR CHARACTERISATION • Information on the zygosity of the insert in the to be commercialised plant e.g. F1 hybrid hemizygous for the newly introduced genes • Information on the biology of the crop (self- or cross-pollinator)				
Insert structure and backbone presence (sequence)				
(Appendix xx) • Number of Inserts & copy number of the *newly introduced gene A gene B* • No backbone sequence present or partial vector backbone present (including following elements x & y) • name of the gene promoter driving expression of *gene A* and *gene B*			negative control used in Southern analyses:e.g. near-isogenic NGMx/NGMy or commercial hybrid xx	n.a.
Ref to sequence				
(Appendix xx)				
Bioinformatic analyses				
Ref to bioinformatic overview table				
(Appendix xx): Flanking sequence (Appendix xx): ORF analyses				
Stability/integrity (Segregation)				
(Appendix xx) Genetic stability • stable insertion in nucleus confirmed by PCR and Southern on x generations (Fn, BCx). (Appendix xx) Phenotypic stability			negative control used in Southern and PCR analyses e.g. near-isogenic	n.a.

APPLICATION IDENTIFICATION CODE (EVENT NAME)			
	Single event	Comparators	
	event name	conventional counterpart	commercial varieties
• consistent expression level of proteins A and B in x generations (Fn, BCx). • segregation analysis of on x generations (Fn, BCx).		NGMx/NGMy or commercial hybrid xx	
Protein expression			
Ref to protein field trial overview table			
(Appendix xx) Field trial year (production plan ID) -country, nr sites, x hybrid (NGMx(BCxFx)/NGMy & NGMz(BCxFx)/NGMy) - zygosity of the insert in the analysed plants and a detailed description on the grain content if segregation occurs -leaves (developmental stage xx and xx), roots, pith, silk, pollen, whole plants at anthesis stage and kernels. -treated and untreated with targeted herbicide regime (Appendix xx) Field trial year (production plan ID) -country, nr sites, (NGMx(BCxFx)/NGMy) -leaves (developmental stage xx and xx), roots (developmental stage xx and xx), whole plants at four growth stages, kernels, piths, silk, pollen. -treated and untreated with targeted herbicide regime		control (e.g. near-isogenic NGMx/NGMy) used to test specificity of antibody	n.a.
Other molecular studies			
(Appendix xx) e.g. RT-PCR on ORF3		negative control e.g. near-isogenic NGMx/NGMy	n.a.
Rationale if certain studies were not deemed needed or not in line with EFSA GMO Panel guidelines			
e.g. Genetic stability was only shown in 4 generations due to the long generation time of the species (see main text page xx)			
COMPARATIVE ANALYSIS			
Compositional analysis			
(Appendix xx) Field trial year (country, nr sites, production plan ID) • NGMx(BCxFx)/NGMy (BCxFx) • Herbicide regime ☐ sprayed ☐ unsprayed ☐ not applicable • nr parameter analyzed in forage ○ Proximate (ash, fat, moisture, protein, carbohydrates, ADF, NDF) ○ mineral (Ca, P) ○ allergens • nr parameter analyzed in grain ○ proximates (ash, fat, moisture, protein, carbohydrates, ADF, NDF) ○ minerals (Ca, copper, Fe,Mg, manganese, P, potassium, selenium, Na, Zn) ○ amino acids composition (18) ○ fatty acides (16:0 Palmitic, 18:0 Stearic, 18:1 Oleic, 18:2 Linoleic, 18:3 Linolenic) ○ vitamins (A, B1, B2, B3, B6, B9, E) ○ secondary metabolites and anti nutrients (ferulic acid, p-coumaric acid, inositol, phytic acid, trypsin inhibitor, furfural, raffinose) ○ allergens		near-isogenic NGMx/ NGMy	nr. commercial hybrid + ranges of natural variation (ILSL, 2006) (OECD, 2002)
(add info year-mon-date Appendix xx) Field trial year (country, nr sites, production plan ID)		near-isogenic NGMz/ NGMy	nr. commercial hybrid

APPLICATION IDENTIFICATION CODE (EVENT NAME)			
	Single event	Comparators	
	event name	conventional counterpart	commercial varieties

• NGMx/NGMy(BCxFx)
• treated or untreated with target herbicide
• nr parameter analyzed in forage (as 200x)
• nr parameter analyzed in grain (more than 200x)
  ○ proximate (+ starch)
  ○ minerals (as 200x)
  ○ amino acids composition (as 200x)
  ○ fatty acids (+ 20:0 arachidic, 20:1 eicosenoic, 22:0 behenic)
  ○ vitamins (as 200x)
  ○ secondary metabolites and anti nutrients (as 200x)
			+ ranges of natural variation (ILSL, 2006) (OECD, 2002)

Agronomic traits & phenotypic stability			
(Appendix xx) Field trial year (country, nr sites, production plan ID) • NGMx/NGMy(BCxFx) • nr agronomic traits • nr disease trait were evaluated. Not all traits were recorded at all locations.		near-isogenic NGMy/ NGMx	nr. commercial hybrid
(add info year-mon-date Appendix xx) statistical analysis • statistical code • raw data			
TOXICITY			
Bioinformatics of newly expressed proteins to Toxin databases			
Ref to bioinformatic overview table • (Appendix xx) BLASTP to Genbank non-redundant xx 201x			
Equivalence between microbial recombinant protein vs. plant protein			
(Appendix xx) Amino acid comparison • alignment indicated on pxx (Appendix xx) comparison protein A produced by *E.coli* to the leaf extract • bacterial strain used for producing recombinant protein • plant tissue from which the native protein was extracted • list type of analysis (e.g., concentration, purity, immunoreactivity, molecular weight, glycosylation and N-terminal aa and insecticidal activity was determined by SDS-PAGE, western, peptide mass mapping analysis, N-terminal sequence, glycosylation analysis, insect bioassay, etc). (Appendix xx) protein A produced by *E.coli vs* the plant extract (Appendix xx) protein B produced by *E.coli* vs the plant extract • bacterial strain used for producing recombinant protein • plant tissue from which the native protein was extracted • list type of analysis (e.g., concentration, purity, immunoreactivity, molecular weight, glycosylation and N-terminal aa and insecticidal activity was determined by SDS-PAGE, western, peptide mass mapping analysis, N-terminal sequence, glycosylation analysis, insect bioassay, etc)		leaf extract from e.g., a negative segregant	n.a.
Acute oral toxicity test			
(Appendix xx) protein A • protein source: e.g., *E.coli* • duration: e.g., 14 days • dosage: e.g., 0 and 1250 mg protein / kg body weight • animals (species, number): e.g., inbred mice (nr. Female + nr. male) • negative control: e.g., corn oil			
(Appendix xx) protein B • as above			
Repeated-dose oral toxicity test			

APPLICATION IDENTIFICATION CODE (EVENT NAME)			
	Single event	Comparators	
	event name	conventional counterpart	commercial varieties
(Appendix xx) protein A • protein source: e.g., *E.coli* • duration: e.g., 14 days • dosage: e.g., 0, 200, 1000 and 5000 mg protein / kg body weight • animals (species, number): e.g., inbred mice (nr. Female + nr. male) • negative control: e.g., corn oil			
(Appendix xx) protein B • as above			
90-day animal feeding study			
(Appendix xx) • F2 grain NGMy/ NGMx(BCxFx) • dosage: e.g., 10 or 41.5% of grain • animals (species, number): e.g., inbred mice (Nr F + Nr M) • diet component analysis • statistical analysis: gm impact, gender impact		near-isogenic NGMy/ NGMx	nr. commercial hybrid
Other toxicity studies			
(Appendix xx)			
Rationale if certain studies were not deemed needed or not in line with EFSA GMO Panel guidelines			
e.g. why certain toxicity tests are not necessary (see main text page xx)			
ALLERGENICITY			
Bioinformatics of newly expressed proteins to Allergen databases			
Reference to bioinformatic overview table • (Appendix xx) e.g., FARRP 201x			
Proteolytic degradation			
(Appendix xx) *in vitro* SGF digestibility assay (pH xx) on protein A (Appendix xx) *in vitro* SGF digestibility assay (pH xx) on protein B (Appendix xx) *in vitro* SIF digestibility assay on protein A (Appendix xx) *in vitro* SIF digestibility assay on protein B • specify the host e.g. bacterial strain used for producing recombinant protein			
In vitro IgE binding assay			
(Appendix xx)			
Other immunological studies			
(Appendix xx)			
Rationale if certain studies were not deemed needed or not in line with EFSA GMO Panel guidelines			
e.g. why certain immunological tests are not necessary (see main text page xx)			
NUTRITIONAL ASSESSMENT			
Exposure			
(Technical dossier pxx) anticipated intake of proteins A and B from consuming crop xx in EU (Appendix xx pxx) Exposure assessment for fatty acids • concentration of the fatty acids measured from refined oil • consumption data base • recipe calculation			

APPLICATION IDENTIFICATION CODE (EVENT NAME)			
	Single event	Comparators	
	event name	conventional counterpart	commercial varieties
• population • dietary estimate (g/d, E%): average intake, percentile consumer • nutritional impact at EU level			
Nutritional assessment by animal study			
(Appendix xx) e.g. broiler study • F2 grain NGMx/ NGMy(BCxFx) • dosage • animals (species, number): e.g., each genotype used Nr F + Nr M [nr birds/pen x nr pens], in total nr • diet component analysis • statistical analysis: gm impact, gender impact		isogenic NGMx/ NGMy	nr. commercial variety
Other nutritional studies			
(Appendix xx)			
Rationale if certain studies were not deemed needed or not in line with EFSA GMO Panel guidelines			
e.g. why certain nutritional tests are not necessary (see main text page xx)			
ERA			
please fill in the Appendices D, E, F, G			

Note: 1) for data generated in other relevant application, please indicate the EFSA application identification code.
2) please distinguish "not applicable (n.a.)" from "not provided (n.p.)", for the latter a justification shall be included.
3) a laboratory study shall be always cleared referred in the table, a reference includes (author name, year, study ID).
4)NGMx/NGMy is a example of genetic background of a GM maize hybrid.
5)BCxFx refers to the number of backcrosses and the number of selfing during plant breeding.

B. GM plant containing stacked events

APPLICATION IDENTIFICATION CODE (EVENT NAME)						
	Stacked event	Comparators for the stacked event		Single events (obligatory) / Parent events (if available)		
Event name	A x B x …	conventional counterpart	commercial varieties	A	B	… (add one column for each additional event)
newly expressed proteins		n.a.	n.a.			
traits		n.a.	n.a.			
Breeding tree	(Appendix xx page xx)	(Appendix xx page xx)				
Scope						
1. Food ☐ 1.1 GM plants for food use ☐ 1.2 Food containing or consisting of GM plants ☐ 1.3 Food produced from GM plant s or containing ingredients produced from GM plants 2. Feed ☐ 2.1 GM plants for feed use ☐ 2.2 Feed containing or consisting of GM plants ☐ 2.3 Feed produced from GM plants 3. GM plants for environmental release ☐ 3.1 Import and processing ☐ 3.2 Seeds and plant propagating material for cultivation in Europe						
Anticipated uses and products (Appendix xx Pxx)						
ISSUES CONSIDERED DURING THE SAFETY ASSESSMENT OF GM PLANTS CONTAINING STACKED EVENTS						
Assessment of interaction(s)						
(Appendix xx) list arguments in bullet points, indicate laboratory studies with clear reference						
Assessment of sub-combinations						
(Appendix xx) list arguments in bullet points, indicate laboratory studies with clear reference						

APPLICATION IDENTIFICATION CODE (EVENT NAME)						
	Stacked event	Comparators for the stacked event		Single events (obligatory) / Parent events (if available)		
Event name	A x B x …	conventional counterpart	commercial varieties	A	B	… (add one column for each additional event)
MOLECULAR CHARACTERISATION						
• Information on the zygosity of the insert in the to be commercialised plant e.g. F1 hybrid hemizygous for the newly introduced genes • Information on the biology of the crop (self- or cross-pollinator)						
Insert structure						
insert structure/backbone sequence	(Appendix xx) Integrity inserts: via method	Control description	n.a.	Nr of inserts/nr of copies/backbone	Nr of inserts/nr of copies/backbone	…
Sequence						
	E.g. See single	n.a.	n.a.	Ref to current or previous dossier where the studies can be found	Ref to current or previous dossier where the studies can be found	…
Bioinformatic analyses Ref to bioinformatic overview table						
Flanking sequence	Updated in this dossier/ up-to date in previous… (see singles)	n.a.	n.a.	Ref to current or previous dossier where the most up-to-date studies can be found	Ref to current or previous dossier where the most up-to-date studies can be found	…
ORF analysis	Updated in this dossier/ up-to date in previous… (see singles)	n.a.	n.a.	Ref to current or previous dossier where the most up-to-date studies can be found	Ref to current or previous dossier where the most up-to-date studies can be found	…
Stability/integrity						
Genotypic	(Appendix xx) Method & Number of generations	control	n.a.	Method & Number of generations	Method & Number of generations	…
Phenotypic	(Appendix xx) Method & Number of generations		n.a.	Method & Number of generations	Method & Number of generations	…
Protein expression Ref to protein field trial overview table						
	(Appendix xx)	(Appendix xx)	n.a.	(Appendix xx)	(Appendix xx)	…

APPLICATION IDENTIFICATION CODE (EVENT NAME)						
	Stacked event	Comparators for the stacked event		Single events (obligatory) / Parent events (if available)		
Event name	A x B x …	conventional counterpart	commercial varieties	A	B	… (add one column for each additional event)
Year(s) (+ location and nr of sites) of studies in current application	Year(s) (+ location and nr of sites)	Control used to test specificity of antibody		Year(s) (+ location and nr of sites)	Year(s)(+ location and nr of sites)	
List tissues that were analyzed	List tissues that were analyzed	n.a.	n.a.	List tissues that were analyzed	List tissues that were analyzed	
Other relevant info (zygosity of the insert in the analysed plant, indicate if inserts segregate in the analysed grain/seed, specific treatment)	specific treatment	n.a.	n.a.	specific treatment	specific treatment	
Raw/data production plan ID	Reference	n.a.	n.a.	Reference	Reference	
Data in related dossiers	n.a.	n.a.	n.a.	(APxx, Appendix xx) Year(s) (+ nr of sites)	(APxx, Appendix xx) Year(s) (+ nr of sites)	
Other molecular studies						
Rationale if certain studies were not deemed needed or not in line with EFSA GMO Panel guidelines						
COMPARATIVE ANALYSIS						
Compositional analysis						
(Appendix xx) Field trial year (country, nr. site, production ID) (Appendix xx) compositional analysis (Appendix xx) statistical analysis nr parameter in forage • NGMx/NGMy(BCxFx) • list parameters • nr parameter in grain B020x/B971x(BCxFx) list parameters	Herbicide regime ☐ sprayed ☐ unsprayed ☐ not applicable field trial (country, nr. of sites, production plan ID) Statistical analysis ☐ statistical code ☐ raw data	Herbicide regime ☐ sprayed ☐ unsprayed ☐ not applicable field trial (country, nr. of sites, production plan ID) Statistical analysis ☐ statistical code ☐ raw data	Nr. commercial varieties Herbicide regime ☐ sprayed ☐ unsprayed ☐ not applicable field trial (country, nr. of sites, production plan ID) Statistical analysis ☐ statistical code ☐ raw data	Herbicide regime ☐ sprayed ☐ unsprayed ☐ not applicable field trial (country, nr. of sites, production plan ID) Statistical analysis ☐ across location ☐ per site	Herbicide regime ☐ sprayed ☐ unsprayed ☐ not applicable field trial (country, nr. of sites, production plan ID) Statistical analysis ☐ across location ☐ per site	…
Agronomic traits & phenotypic stability						

APPLICATION IDENTIFICATION CODE (EVENT NAME)						
	Stacked event	Comparators for the stacked event		Single events (obligatory) / Parent events (if available)		
Event name	A x B x …	conventional counterpart	commercial varieties	A	B	… (add one column for each additional event)
(Appendix xx) Field trial year (country, nr. site, production ID) (Appendix xx) agronomic study • NGMx/NGMy(BCxFx) • nr agronomic traits • nr disease trait	Herbicide regime ☐ sprayed ☐ unsprayed ☐ not applicable field trial (country, nr. of sites, production plan ID)	Herbicide regime ☐ sprayed ☐ unsprayed ☐ not applicable field trial (country, nr. of sites, production plan ID)	Nr. commercial varieties Herbicide regime ☐ sprayed ☐ unsprayed ☐ not applicable field trial (country, nr. of sites, production plan ID)	Herbicide regime ☐ sprayed ☐ unsprayed ☐ not applicable field trial (country, nr. of sites, production plan ID)	Herbicide regime ☐ sprayed ☐ unsprayed ☐ not applicable field trial (country, nr. of sites, production plan ID)	…
TOXICITY						
Bioinformatics of newly expressed proteins to Toxin databases						
Reference to bioinformatic overview table • (Appendix xx) BLASTP to e.g., Genbank non-redundant xx 201x	Database name & version	n.a.	n.a.	Database name & version of the last update	Database name & version of the last update	…
Equivalence between microbial recombinant protein vs. plant protein						
(Appendix xx) based on data of single events		n.a.	n.a.	• bacterial strain used for producing recombinant protein • plant tissue from which the native protein was extracted	• bacterial strain used for producing recombinant protein • plant tissue from which the native protein was extracted	… •
Acute oral toxicity test						
(Appendix xx) assessment in light of data of single events	• protein source • duration • dosage • animals (species, number) • negative control	n.a.	n.a.	• protein source • duration • dosage • animals (species, number)	• protein source • duration • dosage • animals (species, number)	… •

APPLICATION IDENTIFICATION CODE (EVENT NAME)						
	Stacked event	Comparators for the stacked event		Single events (obligatory) / Parent events (if available)		
Event name	A x B x …	conventional counterpart	commercial varieties	A	B	… (add one column for each additional event)
Repeated-dose oral toxicity test						
(Appendix xx) assessment in light of data of single events	• protein source • duration • dosage • animals (species, number) • negative control	n.a.	n.a.	• protein source • duration • dosage • animals (species, number)	• protein source • duration • dosage • animals (species, number)	… •
90-day animal feeding study						
(Appendix xx)	• diet component • duration • dosage • animals (species, number)	• diet component • duration • dosage • animals (species, number)	• diet component • duration • dosage • animals (species, number)	• diet component • duration • dosage • animals (species, number)	• diet component • duration • dosage • animals (species, number)	… •
Other toxicity studies						
(Appendix xx) e.g., assessment of synergistic or antagonistic toxicity by combining newly expressed proteins	• protein source • duration • dosage • animals (species, number) • negative control	n.a.	n.a.	n.a.	n.a.	…
Rationale if certain studies were not deemed needed or not in line with EFSA GMO Panel guidelines						
ALLERGENICITY						
Bioinformatics of newly expressed proteins to Allergen databases						
Reference to bioinformatic overview table • (Appendix xx) e.g., FARRP 201x	Database name & version	n.a.	n.a.	Database name & version of the last update	Database name & version of the last update	…
Proteolytic degradation						

APPLICATION IDENTIFICATION CODE (EVENT NAME)						
	Stacked event	Comparators for the stacked event		Single events (obligatory) / Parent events (if available)		
Event name	A x B x …	conventional counterpart	commercial varieties	A	B	… (add one column for each additional event)
(Appendix xx) assessment in light of data of single events		n.a.	n.a.	specify the host e.g. bacterial strain used for producing recombinant protein • *in vitro* SGF • *in vitro* SIF	specify the host e.g. bacterial strain used for producing recombinant protein • *in vitro* SGF • *in vitro* SIF	… •
In vitro IgE binding assay						
(Appendix xx)						
Other immunological studies						
(Appendix xx)						
Rationale if certain studies were not deemed needed or not in line with EFSA GMO Panel guidelines						
NUTRITIONAL ASSESSMENT						
Exposure						
(Technical dossier pxx) anticipated intake of proteins A, B… from consuming crop xx in EU (Appendix xx pxx) Exposure assessment for fatty acids • concentration of the fatty acids measured from refined oil • consumption data base • recipe calculation • population • dietary estimate (g/d, E%): average intake, percentile consumer • nutritional impact at EU level		n.a.	n.a.			
Nutritional assessment by animal study						
(Appendix xx) e.g. broiler study	• diet component • duration • dosage • animals (species,	• diet component • duration • dosage • animals (species,	• diet component • duration • dosage • animals (species,	• diet component • duration • dosage • animals (species,	• diet component • duration • dosage • animals (species,	… •

APPLICATION IDENTIFICATION CODE (EVENT NAME)						
	Stacked event	Comparators for the stacked event		Single events (obligatory) / Parent events (if available)		
Event name	A x B x …	conventional counterpart	commercial varieties	A	B	… (add one column for each additional event)
	number)	number)	number)	number)	number)	
Other nutritional studies						
(Appendix xx)						
Rationale if certain studies were not deemed needed or not in line with EFSA GMO Panel guidelines						
ERA						
please fill in the Appendices D, E, F, G						

Note: 1) for data generated in other relevant application, please indicate the EFSA application identification code.
2) please distinguish "not applicable (n.a.)" from "not provided (n.p.)", for the latter a justification shall be included.
3) a laboratory study shall be always cleared referred in the table, a reference includes (author name, year, study ID).
4) NGMx/NGMy is a example of genetic background of a GM maize hybrid.
5) BCxFx refers to the number of backcrosses and the number of selfing during plant breeding.

Table 3: Example of overview table on bioinformatic analyses. This table/these tables should be included or in the main text, or in the specific studies of the Part II of an application, or as a separate appendix. In case the bioinformatic analysis is updated these tables should be amended.

Since the risk assessment performed by the EFSA GMO Panel may not start immediately after validity for applications for GM plants including the scope cultivation and applications for GM plants containing stacked events for which single event(s) have not been risk assessed, for these types of applications, the completeness check of the bioinformatic analyses will be limited to checking if the application includes: (1) a summary of the results, (2) an overview of the studies, related to the different aspects (flanking sequences, ORFs, newly expressed proteins, see below), and (3) a clear and correct reference where the studies (including the outputs) can be found. In the case of applications for GM plants containing stacked events, it will be accepted that bioinformatic studies are not included in the technical dossier in case they have been summarised and properly referred to in the main text. Please note that other formats of overview tables will be accepted as long as the information to be included in the example formats is summarised.

A. GM plant containing single event

Flanking sequences (both against DNA and protein databases)							
General Database[1]	Date[2]	Algorithms[3]	Ref. to place in dossier[4]	EST Database1*	Date2	Algorithms[3]	Ref. to place in dossier[4]
Nucleotide[1]							
Protein[1]							
ORF analyses ☐ insert-plant (a) / ☐ insert-insert (b)* / ☐ whole insert (c)							
Allergen database[1]	Date[2]	Algorithms[3]	Ref. to place in dossier[4]	General (and toxin*) database1	Date2	Algorithms[3]	Ref. to place in dossier[4]
(a)							
Newly expressed proteins							
Allergen database[1]	Date[2]	Algorithms[3]	Ref. to place in dossier[4]	General or toxin-database1	Date2	Algorithms[3]	Ref. to place in dossier[4]
Protein 1							
Protein 2							

1. e.g. Genbank non-redundant nucleotide, Genbank non-redundant protein, Genbank general/plant/species EST, FARRP vs. xx (including version and using official name)
2. release date of the version of the database used for the analysis
3. algorithm e.g. BLASTn, BLASTx, BLASTp, FASTA, ... and indicate if default settings were used and if not which parameter was adjusted
4. application number, place in dossier (e.g. technical dossier, additional information with date); citation and internal reference number

* include specifics in the table only when applicable and provided

B. GM plant containing stacked events

	Flanking sequences (both against DNA and protein databases)							
	General Database[1]	Date[2]	Algorithms[3]	Ref. to place in dossier[4]	EST Database[1*]	Date[2]	Algorithms[3]	Ref. to place in dossier[4]
event 1	Nucleotide[1]							
	Protein[1]							
event 2	Nucleotide[1]							
	Protein[1]							
event 3	Nucleotide[1]							
	Protein[1]							

	ORF analyses ☐ insert-plant (a) / ☐ insert-insert (b)* / ☐ whole insert (c)							
	Allergen database[1]	Date[2]	Algorithms[3]	Ref. to place in dossier[4]	General (and toxin*) database[1]	Date[2]	Algorithms[3]	Ref. to place in dossier[4]
event 1 (a)								
event 1 (b)								
event 2								
event 3								

	Newly expressed proteins							
	Allergen database[1]	Date[2]	Algorithms[3]	Ref. to place in dossier[4]	General or toxin-database[1]	Date[2]	Algorithms[3]	Ref. to place in dossier[4]
protein 1								
protein 2								
protein...								

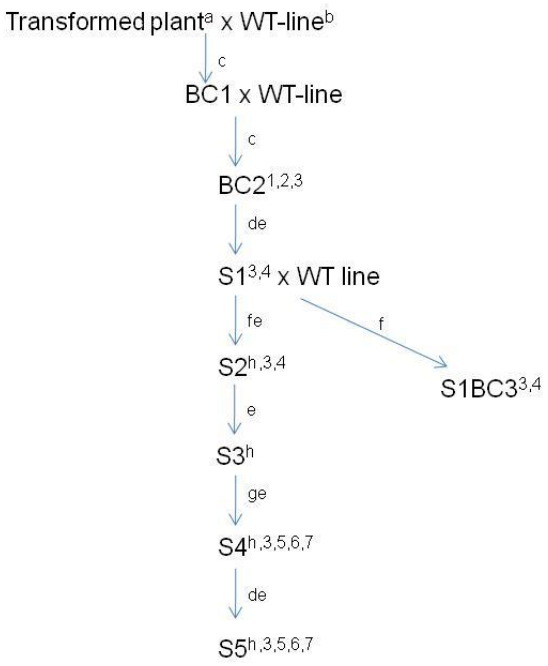
1. e.g. Genbank non-redundant nucleotide, Genbank non-redundant protein, Genbank general/plant/species EST, FARRP vs. xx (including version and using official name
2. release date of the version of the database used for the analysis
3. algorithm e.g. BLASTn, BLASTx, BLASTp, FASTA, ... and indicate if default settings were used and if not which parameter was adjusted
4. application number, place in dossier (e.g. technical dossier, additional information with date); citation and internal reference number

* include specifics in the table only when applicable and provided

Table 4: Example of a summary table related to a field trial for the protein expression analyses. This table/these tables should be included in the specific study reports of the Part II of an application

For each field trial (site) carried out to analyse the protein expression levels of the GM plant (including the controls such as GM plants containing single/related stacked events and/or non-GM comparator) a summary data sheet must be filled out. Therefore in one application multiple sheets may be required. Consider including tables for field trials described in previous or related applications submitted to EFSA.

Field trial ID			
Protein(s) analysed	A	B	…
Method of analysis (indicate if methods are identical between different field trials)			
Season			
Country/state/region (nr of sites)			
GM analysed with identification code, generation and genetic background			
Comparator(s) (non-GM; single events; parental lines-including genetic background)			
GM specific treatment(s)(such as specific herbicide)			
Tissues sampled/developmental stage (number of replicates)			
All tissues were analysed for each sites (if not please indicate)			
Report reference			
Production plan reference			
Raw data reference and kind of statistical analyses			
Reference where argumentation of choose of sites can be found			
Reference where argumentation of choose of tissues can be found			



Legend: a: variety x was used for transformation
b: cytopasmic male sterile line/self-incompatible/monogerm
c: plants sprayed with herbicide to kill off null-segregants
d: different plants used (indicate if segregating or not)
e: selfing/self fertilised
f: single plant used (zygosity for the traits)
g: homozygous generation

Nr in tree	Experiment	comparator	Ref*
1	Sequencing of insert and flanking sequences		
2	Southern analysis (characterisation insert)		
3	Southern analysis (stability)		
4	Segregation analysis		
5	Protein expression analyses		
6	Compositional field trials		
7	Agronomic and phenotypic fiels trials		
8	Tox feeding trials (grain produced by indicated generation)		
9	Nutritional feeding trials (grain produced by indicated generation)		
10	...		
11			

* Hyperlinks are encouraged.

Figure 1: Example of a breeding tree. This figure should be included or in the main text, or as a separate annex, if applicable. In case an additional generation was created and used in a study the figure should be amended.

Examples of Southern data representation

Similar figures and tables should be included or in the main text, or in the specific study report.

Table 5: A summary of genetic elements on the plasmid and in the insert

Genetic element	Size	Location	Description, function and reference	

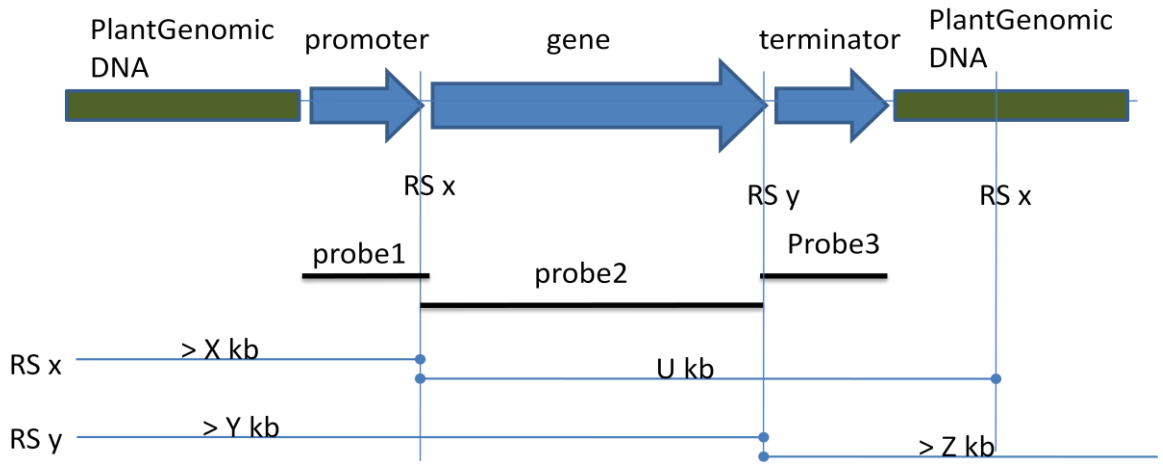


Figure: schematic representation of the insert and the flanking sequences in event x.
Identified on the map are from top to bottom:
genetic elements, restriction sites of enzymes used during the Southern analysis, the used probes and the expected fragment length
Abbreviations RS restriction site

Figure 2: A schematic representation of the insert

To support the Southern analysis EFSA requests that a schematic overview of the insert (final structure in the plant including any rearrangements/duplications/deletions) showing the position of the genetic elements, restriction sites, different probes/primers and the length of the different expected fragments is included.

Table 6: A table with expected and observed fragments, including the information in which figure they can be found.

	Probe 1		Probe 2	
	Restriction enzyme(s) combination A	**Restriction enzyme(s) combination B**	**Restriction enzyme(s) combination A**	**Restriction enzyme(s) combination B**
Expected fragment				
Observed band				
Figure				

Please provide this for both samples and positive controls.

EFSA identification code for the application (event name)

Appendix C1

Schematic summary of data for field or greenhouse trial for agronomic and phenotypic characteristics within a season (single event)

A schematic summary should be provided for each field trial conducted for the comparative analysis of agronomic and phenotypic characteristics.
It should be stored in the folder Appendices.

Study report of field trial (e.g. Appendix X or author et al. (year)):	**Season (year) and dates:** **Location (country):** **Number of sites:** **Number of replicates:** **Type of plot design:** **Statistical power analysis:** *specify the name of the Appendix F ERA statistical design and analysis*
Field trial design: ☐ **same as field trial for compositional analysis** ☐ **different**	
Field trial objective:	

1. Information on the tested plant material		
Plant material	**Identification code in study report**	**Replicates**
GM plant		
Comparator(s)		
1.		
….		
Reference varieties		
1.		
…		

3. Treatments				
Treatment Code	Genotype and name	Specification of treatment (herbicide, insecticide, other)	…	…
1. Treatment 1				
….				
n. Treatment n				

4. Information on agronomic and phenotypic characteristics (Field trials)			
Agronomic characteristic	**Evaluation time**	**Evaluation description** *Please specify how observations were evaluated and quantified (e.g. unit of measurement)*	**Raw data provided**
1. Plant establishment and vigour			☐ Yes ☐ No
2. Time of flowering and maturity			☐ Yes ☐ No
3. Growth			☐ Yes ☐ No
4. Plant height			☐ Yes ☐ No
5. Dry matter production			☐ Yes ☐ No
6. Seed			☐ Yes ☐ No
7. Yield characteristics			☐ Yes ☐ No
8. Vernalisation requirement			☐ Yes ☐ No
9. Attractiveness to pollinators			☐ Yes ☐ No
10. Pollen shed & viability			☐ Yes ☐ No
11. Pollen compatibility & morphology			☐ Yes ☐ No
12. Others			☐ Yes ☐ No

5. Information on biotic and abiotic stressor(s) tested		
Biotic or abiotic stressors	**Characteristics analysed**	**Raw data provided**
1. Insect incidence		☐ Yes ☐ No
2. Diseases observation		☐ Yes ☐ No
3. Abiotic stressors		☐ Yes ☐ No
4. Others		☐ Yes ☐ No

6. Dormancy and germination assessment and pollen morphology and viability assessment		
	Dormancy and germination	Pollen morphology and viability

Reference to study		
Type of study		
Control		
Germination endpoint		
Replicates		
Summary of analyses		
Differences observed		
Biological relevance		
…		
Conclusions		
For EFSA use		

7. Summary of analysis from Tables 1 to 6							
Agronomic and phenotypic characteristics				**Environmental observations**			
Statistically significant differences	*Please specify*	**Biological relevance**	*Please specify*	**Differences observed**	*Please specify*	**Biological relevance**	*Please specify*
Combined sites		Combined sites		Combined sites			
Individual sites		Individual sites		Individual sites			
…		…		…			
Conclusions							
For EFSA use							

Appendix C2

Schematic summary of data for field or greenhouse trial for agronomic and phenotypic characteristics within a season (GM plant containing stacked transformation events)

A schematic summary should be provided for each field trial conducted for the comparative analysis of agronomic and phenotypic characteristics.
It should be stored in the folder Appendices.

Study report of field trial (e.g. Appendix X or author et al. (year)):	**Season (year) and dates:** **Location (country):** **Number of sites:** **Number of replicates:** **Type of plot design:** **Statistical power analysis:** *specify the name of the Appendix F ERA statistical design and analysis*
Field trial design:	☐ **same as field trial for compositional analysis** ☐ **different**
Field trial objective:	

1. Information on the tested plant material		
Plant material	**Identification code in study report**	**Replicates**
GM plant containing stacked events ABC		
GM single event A		
GM single event B		
GM single event C		
…		
Comparator(s)		
1.		
….		
Reference varieties		
2.		
…		

3. Treatments				
Treatment Code	Genotype and name	Specification of treatment (herbicide, insecticide, other)	…	…
1. Treatment 1				
….				
n. Treatment n				

4. Information on agronomic and phenotypic characteristics				
Agronomic characteristic	**Evaluation time**	**Evaluation description** *Please specify how observations were quantified (e.g. unit of measurement)*	**Raw data provided**	**Comparison data single/stacked events**
1. Plant establishment and vigour			☐ Yes ☐ No	*Please specify if observations differed from data obtained on each single event (including assessment of biological relevance)*
2. Time of flowering and maturity			☐ Yes ☐ No	
3. Growth			☐ Yes ☐ No	
4. Plant height			☐ Yes ☐ No	
5. Dry matter production			☐ Yes ☐ No	
6. Seed			☐ Yes ☐ No	
7. Yield characteristics			☐ Yes ☐ No	
8. Vernalisation requirement			☐ Yes ☐ No	
9. Attractiveness to pollinators			☐ Yes ☐ No	
10. Pollen shed & viability			☐ Yes ☐ No	
11. Pollen compatibility & morphology			☐ Yes ☐ No	
12. Others			☐ Yes ☐ No	

5. Information on biotic and abiotic stressor(s) tested			
Biotic or abiotic stressors	**Characteristics analysed**	**Raw data provided**	**Comparison data single/stacked events**
1. Insect incidence		☐ Yes ☐ No	*Please specify if observations differed*

			from data obtained on each single event
2. Diseases observation		☐ Yes ☐ No	
3. Abiotic stressors		☐ Yes ☐ No	
4. Others		☐ Yes ☐ No	

6. Dormancy and germination assessment and pollen morphology and viability assessment		
	Dormancy and germination	Pollen morphology and viability
Reference to study		
Type of study		
Control		
Germination endpoint		
Replicates		
Summary of analyses		
Differences observed		
Biological difference		
…		
Conclusions		
For EFSA use		

7. Summary of analysis from Tables 1 to 6							
Agronomic and phenotypic characteristics (see 4.)				**Environmental observations (see 5. and 6.)**			
Statistical differences	*Please specify*	**Biological relevance**	*Please specify*	**Differences observed**	*Please specify*	**Biological relevance**	*Please specify*
Combined sites		Combined sites		Combined sites			
Individual sites		Individual sites		Individual sites			
…		…		…			
Conclusions							
For EFSA use							

EFSA identification code for the application (event name)

Appendix D

Schematic summary of information for Insect Resistance Management

Appendix E is requested for applications of GM insect resistant plants with the scope "seeds and plant propagating material for cultivation in the EU. The compiled appendix should be stored in the folder Appendices, subfolder ERA_Appendices D to F.

1. Information on the target specific spectrum
List of target insect species
1. [name target organism]
2.
n.

2. IRM plan and structure	
The IRM plan is	
High dose/refuge strategy	☐ Yes ☐ No
Medium to low dose / refuge strategy	☐ Yes ☐ No
Data on concentration of the insecticidal protein(s) in the GM plant are provided	☐ Yes ☐ No
Data on proportion of target insects killed by the GM plant are provided	☐ Yes ☐ No
Size of the refuge provided	☐ Yes ☐ No
The IRM plan includes	
A monitoring for any potential evolution of resistance	☐ Yes ☐ No
An educational programme	☐ Yes ☐ No
A remedial action plan	☐ Yes ☐ No

3. Underlying assumptions	
Data on occurrence of resistance alleles in target insect population are provided	☐ Yes ☐ No
Data on frequency of resistance alleles to the insecticidal proteins are provided	☐ Yes ☐ No
If not provided, data are provided on o Efficacy of the GM plant in controlling target insects o Baseline susceptibility in the target insect	 ☐ Yes ☐ No ☐ Yes ☐ No
Mating occur randomly between resistant and susceptible insects	☐ Yes ☐ No
Data on mating and dispersal behaviour are provided	☐ Yes ☐ No

Data on inheritance of resistance alleles (dominant, partially or fully recessive), including dominance value h, are provided	☐ Yes ☐ No
Duration (i.e. number of generations) of susceptibility of target insects is considered	☐ Yes ☐ No
Modelling prediction are used	☐ Yes ☐ No

EFSA identification code for the application (event name)

Appendix E

Schematic summary of NTO studies (laboratory, greenhouse, field trials)

This Appendix is structured in the following four parts:

- Part 1: Overview of NTO studies performed or commissioned by the applicant to support the NTO risk assessment
- Part 2: Overview of NTO studies published in peer-reviewed journals and used by the applicant in support of the NTO risk assessment
- Part 3: Summary of confined studies performed or commissioned by the applicant to support the NTO risk assessment
- Part 4: Summary of field studies performed or commissioned by the applicant to support the NTO risk assessment

The completed Appendix should be included in the folder Appendices, subfolder ERA_Appendices D to F.

PART 1 – Overview of NTO studies performed or commissioned by the applicant to support the NTO risk assessment

	Invertebrates								**Others (e.g., fish, birds, microorganisms)**	
	Natural enemies (predators & parasitoids)		**Pollinators**		**Herbivores (including species of conservation concern)**		**Decomposers**			
	Type	**Reference**	**Type**	**Reference**	**Type**	**Reference**	**Type**	**Reference**	**Type**	**Reference**
Study A	Tier 1a	Specify appendix X or author et al. (year)	Tier 1a	Specify appendix X or author et al. (year)	Tier 1a	Specify appendix X or author et al. (year)	Tier 1a	Specify appendix X or author et al. (year)	Tier 1a	Specify appendix X or author et al. (year)
		...		...		...		...		...
Study B	Tier 1b	Specify appendix X or author et al. (year)	Tier 1b	Specify appendix X or author et al. (year)	Tier 1b	Specify appendix X or author et al. (year)	Tier 1b	Specify appendix X or author et al. (year)	Tier 1b	Specify appendix X or author et al. (year)
		...		...		...		...		...
Study C	Tier 2	Specify appendix X or author et al. (year)	Tier 2	Specify appendix X or author et al. (year)	Tier 2	Specify appendix X or author et al. (year)	Tier 2	Specify appendix X or author et al. (year)	Tier 2	Specify appendix X or author et al. (year)
		...		...		...		...		...
Study D	Tier 3	Specify appendix X or author et al. (year)	Tier 3	Specify appendix X or author et al. (year)	Tier 3	Specify appendix X or author et al. (year)	Tier 3	Specify appendix X or author et al. (year)	Tier 3	Specify appendix X or author et al. (year)
		...		...		...		...		...
For EFSA use										

PART 2 – Overview of NTO studies published in peer-reviewed journals and used by the applicant in support of the NTO risk assessment

	Invertebrates								**Others (e.g., fish, birds, microorganisms)**	
	Natural enemies (predators & parasitoids)		**Pollinators**		**Herbivores (including species of conservation concern)**		**Decomposers**			
	Type	**Reference**	**Type**	**Reference**	**Type**	**Reference**	**Type**	**Reference**	**Type**	**Reference**
Study A	Tier 1a	Specify appendix X or author et al. (year)	Tier 1a	Specify appendix X or author et al. (year)	Tier 1a	Specify appendix X or author et al. (year)	Tier 1a	Specify appendix X or author et al. (year)	Tier 1a	Specify appendix X or author et al. (year)
		...		...		...		...		...
Study B	Tier 1b	Specify appendix X or author et al. (year)	Tier 1b	Specify appendix X or author et al. (year)	Tier 1b	Specify appendix X or author et al. (year)	Tier 1b	Specify appendix X or author et al. (year)	Tier 1b	Specify appendix X or author et al. (year)
		...		...		...		...		...
Study C	Tier 2	Specify appendix X or author et al. (year)	Tier 2	Specify appendix X or author et al. (year)	Tier 2	Specify appendix X or author et al. (year)	Tier 2	Specify appendix X or author et al. (year)	Tier 2	Specify appendix X or author et al. (year)
		...		...		...		...		...
Study D	Tier 3	Specify appendix X or author et al. (year)	Tier 3	Specify appendix X or author et al. (year)	Tier 3	Specify appendix X or author et al. (year)	Tier 3	Specify appendix X or author et al. (year)	Tier 3	Specify appendix X or author et al. (year)
		...		...		...		...		...
For EFSA use										

PART 3 – Summary of confined studies performed or commissioned by the applicant to support the NTO risk assessment (note: the table is to be completed for each funcional group studied)

Criteria	**Natural enemies (predators & parasitoids) / pollinators / herbivores / decomposers / others (e.g., cultural services, fish, birds, microorganisms)**		
Reference	Specify appendix X or author et al. (year)	Specify appendix X or author et al. (year)	Specify appendix X or author et al. (year)
Type of study	Tier 1a	Tier 1b	Tier 2
Hypothesis under test	Specify in words	Specify in words	Specify in words
Effects observed	Report observed effects (if any)	Report observed effects (if any)	Report observed effects (if any)
Species name (Order: Family)	Specify (e.g., *Poecilus cupreus* (Coleoptera: Carabidae))	Specify	Specify
Common name	Specify	Specify	Specify
Species of conservation concern (e.g., rare and protected species, or species of aesthetic or cultural value)	Specify	Specify	Specify
Focal or surrogate species	Specify	Specify	Specify
Source of test organisms	In-house colony / Purchased from commercial suppliers / Field collected	In-house colony / Purchased from commercial suppliers / Field collected	In-house colony / Purchased from commercial suppliers / Field collected
Development stage of test organism	Specify	Specify	Specify
Measurement endpoints	Specify measurement endpoints (e.g., survival, development rate, fertility)	Specify measurement endpoints (e.g., survival, development rate, fertility)	Specify measurement endpoints (e.g., survival, development rate, fertility)
Test duration	Specify	Specify	Specify
Test substance	Specify (e.g., pure Cry1Ab protein)	Specify transformation event + plant tissue (e.g., pollen, leaves, roots)	Specify transformation event + plant tissue (e.g., pollen, leaves, roots)
Expression level of novel trait	Specify for relevant plant part (e.g., µg/g Cry1Ab dry weight in pollen)	Specify for relevant plant part (e.g., µg/g Cry1Ab dry weight in pollen)	Specify for relevant plant part (e.g., µg/g Cry1Ab dry weight in pollen)
Nominal dose of test substance, with unit	Specify (e.g., µg/mL)	Specify (e.g., µg/mL)	Specify (e.g., µg/mL) if relevant
Purity of test substance	Specify purity level (e.g., 95%)	NA	NA
Bioequivalence of test substance	Specify if bioequivalence was demonstrated and, if so, how	Specify if bioequivalence was demonstrated and, if so, how (if no event-specific material is used)	Specify if bioequivalence was demonstrated and, if so, how (if no event-specific material is used)
Biological activity of test	Specify if biological activity was	Specify if biological activity was	Specify if biological activity was

substance before and after preparation of diet	demonstrated and, if so, how (note: if biological activity was demonstrated before the assay was conducted, then describe storage conditons)	demonstrated and, if so, how note: if biological activity was demonstrated before the assay was conducted, then describe storage conditons)	demonstrated and, if so, how (if relevant)
Stability of test substance	Specify level of stability and how it was determined	Specify level of stability and how it was determined	Specify level of stability and how it was determined (if relevant)
Exposure of test organisms to test substance	Specify level of exposure (e.g., maximum hazard dose, using expected environmental concentration based on expression data generated in EU field trials)	Specify level of exposure	Specify level of exposure
Route of in-field exposure	Specify	Specify	Specify
Feeding conditions	Choice / No choice / Ad libitum / Fixed dose	Choice / No choice / Ad libitum / Fixed dose	Choice / No choice / Ad libitum / Fixed dose
Negative control	Specify negative control(s) used	Specify negative control(s) used (e.g., near-isogenic line)	Specify negative control(s) used (e.g., near-isogenic line)
Positive control	Specify positive control(s) used	Specify positive control(s) used (if relevant)	Specify positive control(s) used (if relevant)
Number of replications	Specify	Specify	Specify
Number of test organisms per treatment	Specify	Specify	Specify
Number + nature of treatments	Specify	Specify	Specify
Statistical power determined prospectively	Yes / No	Yes / No	Yes / No
Reference to Appendix G ERA statistical design and analysis	Specify the name of the Appendix	Specify the name of the Appendix	Specify the name of the Appendix
For EFSA use			

PART 4 – Summary of field studies performed or commissioned by the applicant to support the NTO risk assessment (note: the table is to be completed for each single field experiment)

Criteria	**Appendix X or author et al. (year)**				
Hypothesis under test	Specify in words				
Functional groups for which comprehensive data were obtained	Natural enemies (predators & parasitoids): Yes / No	Pollinators: Yes / No	Herbivores: Yes / No	Decomposers: Yes / No	Others (e.g., cultural services, fish, birds, microorganisms): Yes / No
Abundant species	List most abundant species for which comprehensive data were recorded	List most abundant species for which comprehensive data were recorded	List most abundant species for which comprehensive data were recorded	List most abundant species for which comprehensive data were recorded	List most abundant species for which comprehensive data were recorded
Measurement endpoints	Specify variables recorded, with units (e.g., abundance)	Specify variables recorded, with units (e.g., abundance)	Specify variables recorded, with units (e.g., abundance)	Specify variables recorded, with units (e.g., abundance)	Specify variables recorded, with units (e.g., abundance)
Effects observed	Report which effects (if any) were observed	Report which effects (if any) were observed	Report which effects (if any) were observed	Report which effects (if any) were observed	Report which effects (if any) were observed
Location	Specify continent, country, region and nearby city				
Study year	Specify				
Number of cropping seasons + years covered	Specify				
Duration per growing season	Specify				
Single plot size	Specify (in hectares)				
Number of replications	Specify (e.g., number of plots, blocks, fields)				
Experimental/plot design	Specify (e.g., split-plots, random blocks, separate fields)				
Buffer size + nature	Specify (e.g., dimesion of borders surrounding the plots, interplot distances, type of buffer (e.g., plant species, bare ground))				
Sampling methods	Specify (e.g., pitfall traps, sweep netting, sticky traps, visual counts)	Specify	Specify	Specify	Specify
Sampling frequency	Specify	Specify	Specify	Specify	Specify
Sampling pattern	Specify (e.g., intersects, random)	Specify	Specify	Specify	Specify
GM event + variety name	Specify (transformation event of the crop tested + transgenic hybrid or variety name)				
Management context for	Specify active substances applied as well as timing and frequency of application (including sprays, soil granules or seed coating)				

GM plant					
Conventional counterpart	Specify (e.g., near-isogenic line)				
Reference varieties	Specify name of reference varieties (if used)				
Management context for comparators	Specify active substances applied as well as timing and frequency of application (including sprays, soil granules or seed coating)				
Biodiversity estimates	Specify which ones (if appropriate)				
Reference to Appendix G ERA statistical design and analysis	Specify the name of the Appendix				
For EFSA use					

EFSA identification code for the application (event name)
XXXX

Appendix F

Schematic summary of statistical design and analysis for each ERA study

A schematic summary should be provided for each study conducted for the environmental risk assessment.
All complied appendices should be included in the folder Appendices, subfolder ERA_Appendices D to F.

Study report (e.g. [author] et al. (YYYY)):	**Field trial** ☐ **Semi-field trial** ☐ **Laboratory** ☐ **Tier study** tier 1a ☐ tier 1b ☐ tier 2 ☐ tier 3 ☐
	Equivalence test ☐ **Difference test** ☐

1. Presentation of data	**Comments**	**Provided**	**Not provided**	**Not relevant**
Results are clearly presented, using standardized scientific units		☐	☐	☐
Raw data are provided		☐	☐	☐
Programming code used for the statistical analysis are present in an edible form		☐	☐	☐
Test materials are randomized to the experimental units		☐	☐	☐
The study is performed in accordance with international standards and protocols		☐	☐	☐
An experimental design protocol is provided		☐	☐	☐
An statistical analysis protocol is provided		☐	☐	☐
The mean, confidence limits and all equivalence limits are displayed on a graph		☐	☐	☐

2. Requirement for General Statistical Principles				
List explicitly *in words* all the questions that the study was designed to address		☐	☐	☐
Re-stated each question *in formal terms*, including precise null hypothesis that was tested to answer the question		☐	☐	☐
Clear description and justification of each assumptions made		☐	☐	☐
A proof of difference is provided		☐	☐	☐

A proof of equivalence is provided		☐	☐	☐
For studies that use extra comparators, separate difference tests (between the GM plant and each of its different comparators) and separate equivalence tests (between the GM plant and each of its different comparators) are reported similarly		☐	☐	☐

3. Requirement for each measurement endpoint				
Clear description of each measurement endpoint are provided		☐	☐	☐
"Limits of concern" for each measurement endpoints are described		☐	☐	☐
If limits of concern for lower-tier studies are less than for higher-tier studies, justification is provided		☐	☐	☐
Effect size desired to detect with the study is given and justification is provided		☐	☐	☐
Minimum effect size relevant on the receiving environment(s) given and justification provided		☐	☐	☐
Statement on how the chosen effect size relates to the limit of concern through the minimum relevant ecological effect that is deemed biological relevant is provided		☐	☐	☐
When many measurement endpoints have been included in a study (*e.g.* where the endpoints represent several NTO species), the results of all endpoints for which sufficient records have been obtained are reported, not just those deemed to be of particular biological or statistical interest.		☐	☐	☐

4. Requirement for equivalence and difference test				
For the equivalence test, limit of concern are stated explicitly		☐	☐	☐
Statistical power if given		☐	☐	☐
The difference test has sufficient statistical power and justification are provided		☐	☐	☐
Power of each measurement endpoint of each difference test are provided at the planning stage of the study		☐	☐	☐

5. Additional requirement for field trials				
Minimum levels of abundance of each taxa samples are described and justified (NTO field trials)		☐	☐	☐

The level of within-site replication is linked to the power analysis		☐	☐	☐
Justification of the selection of the different sites for the field trials is provided		☐	☐	☐
Each field trial is replicated over at least two years, each field trial over at least three sites. If not, justification is provided		☐	☐	☐
Field trials are performed in Europe		☐	☐	☐
Field trials are not performed in Europe and justification are provided		☐	☐	☐

6. Reporting				
All significant differences observed are reported and discussed; focusing on their biological difference		☐	☐	☐
For simultaneous texts of difference and equivalence, each outcome from the graph is categorized and the respective appropriate conclusion drawn.		☐	☐	☐
Analysis addressed all field trials simultaneously and is based on the full dataset from all sites		☐	☐	☐
Each analysis has the potential to identify any interactions between sites and years and the test materials; for each measurement endpoint studied, explicit statement concerning the presence or absence of any such interactions is provided; if interactions are found, the possible reasons for their existence and the implications for the inferences drawn from the trials are discussed.		☐	☐	☐
A table or graph giving, for each site and year and for each (transformed) measurement endpoint, the means and standard errors of means of the GM plant and its conventional counterpart(s), and any other test material, where applicable is provided.		☐	☐	☐

DG JRC I3	**Record for Quality System**	EURL European Union Reference Laboratory for GM Food & Feed
R19GP7/EURL Date: 25/11/2011 Revision. 5	**Reception of Samples, Reagents and Methods**	Page 1 / 1

From Molecular Biology and Genomics Unit **tel: +39 0 332 78 5856**
European Commission - Joint Research Centre - IHCP **fax: +39 0 332 78 6159**
21027 ISPRA (VA) Italy ***JRCI04/MBG/GVDE/ARES (2999) 999999***

To : Applicant **fax: Fax App. Contact**
Applicant **Email: *email App. Contact***
Adress of the applicant (contact) File No. Code EURL GMFF
Ref. EFSA:

We have received the following goods, in relation with the file in reference:

Samples on 31/12/9999 / type reception / condition of reception
List of Samples received

Reagents on 31/12/9999 / type reception / condition of reception
List of Reagents received

Methods and documents on 31/12/9999 / type reception / condition of reception
List of Documents received

Eventual additive information

Name responsible reception
Sample delivery Officer
31/12/9999

This document is not a recognition of the quantity and/or quality of samples and reagents provided. EURL-GMFF will experimentally assess the quality and quantity of material and the performance of the method(s). The laboratory will use these products in accordance with the Regulation EU 1829/2003. EURL-GMFF will not sign and return any other acknowledgement of receipt.

A copy of this document is sent to EFSA GMO.Secretariat.Applications@efsa.europa.eu