EUROPEAN
COMMISSION

Brussels, XXX
[…](2016) XXX draft

COMMISSION DIRECTIVE (EU) .../...

of XXX

amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms

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amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[1], and in particular Article 27 thereof,

Whereas:

(1) In October 2010, the European Food Safety Authority (EFSA) adopted a scientific opinion establishing guidance on the environmental risk assessment (e.r.a.) of genetically modified plants[2] ('the Guidance'), following a request from the Commission, in March 2008, to revise the previous guidelines of EFSA.

(2) According to Article 3 of Directive (EU) 2015/412 of the European Parliament and of the Council[3], the Commission must update the Annexes to Directive 2001/18/EC by 3 April 2017, in accordance with Article 27 of that Directive, as regards the e.r.a., with a view to incorporating and building upon the Guidance.

(3) At its meeting on 4 December 2008, the Council adopted conclusions on Genetically Modified Organisms ("GMOs") stressing the need to update and strengthen the environmental risk assessment of GMOs, in particular concerning the assessment of long-term environmental effects.

(4) The essential elements of the Guidance should be incorporated in the relevant Annexes to Directive 2001/18/EC in order to adapt them to technical progress and in the light of the experience gained in the e.r.a of genetically modified plants. Focussing on the essential elements of the Guidance is necessary to preserve the respective roles of the Directive and of the Guidance, as well as to leave sufficient flexibility to EFSA for updating its Guidance in the future. This approach is also consistent with the general principle set out in Annex II to Directive 2001/18/EC that the e.r.a. should be carried out on a case-by-case basis. The fact that certain parts of the Annexes do not apply only to genetically modified plants should also be taken into account.

(5) Adaptations of the Annexes to Directive 2001/18/EC to technical progress other than the incorporation of the essential elements of the Guidance should also be carried out.

(6) Part C of Annex II, concerning the methodology of the e.r.a., should be updated to incorporate key elements of the Guidance, while taking into account the fact that this

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1 OJ L 106, 17.4.2001, p. 1, as last amended by Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory (JO L 68, 13.3.2015, p. 1).

2 EFSA Journal 2010;8(11):1879

3 Cf footnote 1

part of Annex II applies to all GMOs and not to genetically modified plants only. In particular, it should be clarified that the e.r.a. should identify and characterise both intended and unintended effects of the genetic modification, more specific provisions are needed concerning delayed effects, certain requirements should be introduced concerning the quality and transparency of the studies provided in the e.r.a. and the case of stacked transformation events should be addressed. The comprehensive step-by-step assessment approach consisting of six steps described in the Guidance should also be mirrored in the section concerning the steps in the e.r.a.

(7) Part D of Annex II applies to the conclusions of the e.r.a. and contains two distinct parts, concerning GMOs other than higher plants (section D.1) and genetically modified higher plants (section D.2) respectively. The Guidance considers seven specific areas of risk to be addressed in the e.r.a. of genetically modified plants in order to draw conclusions. The structure and content of section D.2 of Annex II should therefore be updated to reflect these seven areas of risk.

(8) Where the e.r.a. concerns a genetically modified plant, the scope of the e.r.a. should be consistent with the respective scopes of Directive 2001/18/EC and of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market[4]. The environmental risk assessment of the use of a plant protection product on a genetically modified plant falls under the scope of the latter legislation and should not be carried out as part of the e.r.a. performed under Directive 2001/18/EC.

(9) Annex III B lists the information required in notifications concerning releases of genetically modified higher plants and applies to both notifications for the purpose of placing on the market ("Part C notifications") and notifications for other purposes than placing on the market ("Part B notifications"). Its structure, content and level of detail should be amended to ensure consistency with the Guidance. As most of the changes induced by the Guidance concern the e.r.a. of Part C notifications, and in the interest of clarity and simplification for the notifiers and the competent authorities, it is appropriate to modify the structure of Annex III B by separating the requirements concerning these notifications from the requirements concerning Part B notifications.

(10) The vast majority of the requests for authorisation of the placing on the market of genetically modified plants are submitted in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council[5]. In the interest of simplification, it is therefore appropriate to align, to the extent possible, the order of the items required for Part C notifications in Annex III B with the order followed in Commission Implementing Regulation (EU) No 503/2013[6].

(11) Annex IV sets out additional information requirements for Part C notifications only. The requirements set out in this Annex concerning detection methods should be updated in the light of technical progress, notably concerning the submission by notifiers of the reference material.

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4 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L309, 24.11.2009, p. 1).

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).

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 L157, 08.06.2013, p.1).

(12) The measures provided for in this Directive are in accordance with the opinion of the Committee set up under Article 30 of Directive 2001/18/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes II, III, III B and IV to Directive 2001/18/EC are amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [*18 months from the date of entry into force*] at the latest. They shall forthwith communicate to the Commission the text of those provisions.

   When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Union.*

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER

EUROPEAN
COMMISSION

Brussels, XXX
[…](2016) XXX draft

ANNEX 1

ANNEX

to Commission Directive amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms

ANNEX

to Commission Directive amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms

1. In Annex II, section C is replaced by the following:

"C. Methodology

C.1. General and specific considerations for the e.r.a.

1. *Intended and Unintended Effects*

The e.r.a shall identify and characterise the intended and unintended effects of the genetic modification with respect to possible adverse impacts on human and animal health and the environment.

Intended effects are those that are designed to occur and which fulfil the original objectives of the genetic modification.

Unintended effects are consistent (non-transient) differences between the GMO and its appropriate comparator, which go beyond the intended effect(s) of introducing the genetic modification.

2. *Delayed effects*

For notifications under part C of this Directive the e.r.a shall include an assessment of the potential delayed environmental effects in the form of a desk based study based on one or more of the following;

- evidence from previous experiences;
- available data sets/literature;
- mathematical models predictions

and shall be relevant to the receiving environment(s) and intended use(s) of the GMO(s).

3. *Data*

To carry out an e.r.a. the notifier shall generate the necessary data. Where applicable, data already available from scientific literature may be used.

Information from any previous releases of the same or similar genetically modified organisms and organisms with similar traits and their biotic and abiotic interaction with similar receiving environments shall be considered in the e.r.a, subject to Article 6(3) and Article 13(4) of this Directive, as appropriate.

Data provided in the e.r.a shall comply with the following requirements:

(a) The use of data generated outside Europe shall be justified with regard to relevance to European receiving environment(s).

(b) Study protocols shall provide sufficient statistical power to inform the e.r.a. The results from the studies shall be comprehensive. The raw data shall be provided in an electronic format and be suitable for carrying out statistical or other analysis.

(c) Toxicological studies carried out to assess risk(s) to human and/or animal health e.g. due to accidental consumption, shall be conducted in facilities which comply with the:

(i) requirements of Directive 2004/10/EC; or

(ii) 'OECD Principles on Good Laboratory Practice' (GLP), if carried out outside the Union

The applicant shall provide evidence to demonstrate such compliance.

(d) Where appropriate, studies other than toxicological studies, shall:

(i) comply with the principles of Good Laboratory Practice (GLP) laid down in Directive 2004/10/EC; or

(ii) be conducted by organisations accredited under the relevant ISO standard.

(e) Selection of sites for field studies shall be representative of the receiving environments where the GMO(s) may be released and shall be justified explicitly.

(f) The choice of non-genetically modified comparator shall be appropriate for the relevant receiving environment(s), have a genetic background comparable to the GMO and shall be justified explicitly.

4. Stacked transformation events

For the e.r.a. of GMOs containing stacked transformation events obtained by conventional crossing of organisms containing one or several transformation event(s) the notifier shall provide an e.r.a. for each single transformation event or refer to already submitted notifications in accordance with, as appropriate, Article 6(3) or Article 13(4).

The notifier shall consider the potential for progeny of the GMO containing various sub combinations of the transformation events to occur and assess the need to consider sub combinations of the higher stack in the risk assessment.

The e.r.a. of GMOs containing stacked transformation events shall include an assessment of the following aspects;

(a) stability of the transformation events;

(b) expression of the transformation events;

(c) potential additive, synergistic or antagonistic effects resulting from the combination of the transformation events

C.2. Characteristics of the GMO

The notifier shall take into account the relevant technical and scientific details regarding characteristics of:

- the recipient or parental organism(s);

- the genetic modification(s), be it inclusion or deletion of genetic material, and relevant information on the vector and the donor;
- the GMO;
- the intended release or use including its scale;
- the potential receiving environment(s) into which the GMO will be released and into which the transgene may spread; and
- the interaction(s) between these.

Information on the recipient, donor, vector, genetic modification and the GMO shall be independent of the environment and the conditions of the release.

C.3. Steps in the e.r.a.

The e.r.a. referred to in Articles 4, 6, 7 and 13 shall be conducted following the six steps below:

1. Problem formulation including hazard identification:

Any characteristics of the GMOs linked to the genetic modification that may result in adverse effects on human health or the environment shall be identified. A comparison of the characteristics of the GMO(s) with those of the non-modified organism under corresponding conditions of the release or use, will assist in identifying the particular potential adverse effects arising from the genetic modification. It is important not to discount any potential adverse effect on the basis that it is unlikely to occur.

Potential adverse effects of GMOs will vary from case to case, and may include:

- disease to humans including allergenic or toxic effects (see for example items II.A.11. and II.C.2(i) in Annex III A, and I.B.1.(h) and II.B.1.(h) in Annex III B);
- disease to animals and plants including toxic, and where appropriate, allergenic effects (see for example items II.A.11. and II.C.2(i) in Annex III A, and I.B.3(f) and II.B.4(g) in Annex III B);
- effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations (see for example items IV B 8, 9 and 12 in Annex III A);
- altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors;
- compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes;
- conferring resistance to antibiotics used in human or veterinary medicine (see for example items II.A.11(e) and II.C.2(i)(iv) in Annex III A);
- effects on biogeochemistry(biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material (see for example items II.A.11(f) and IV. B.15 in Annex III A, and I.B.3(e) and II.B.4(f) in Annex III B).

Adverse effects may occur directly or indirectly through exposure pathways which may include:

- the spread of the GMO(s) in the environment,
- the transfer of the inserted genetic material to other organisms, or the same organism whether genetically modified or not,
- phenotypic and genetic instability,
- interactions with other organisms,
- changes in management, including, where applicable, in agricultural practices.

Where potential adverse effects are identified, the problem formulation shall consequently:

- define assessment endpoints that are representative of the protection goals;
- formulate testable hypotheses that are clearly phrased and easily transferable to data to be generated or evaluated;
- define measurement endpoints as measurement units for both hazard and exposure;
- define the magnitude of tolerable effect;
- consider possible uncertainties (e.g. knowledge gaps, methodological limitations).

2. *Hazard characterisation*

The magnitude of the consequences of each potential adverse effect shall be evaluated. This evaluation shall assume that such an adverse effect will occur. The e.r.a shall consider that the magnitude of the consequences is likely to be influenced by the receiving environment(s) into which the GMO(s) is (are) intended to be released and the scale and conditions of the release.

The evaluation shall be expressed where possible in quantitative terms.

If expressed in qualitative terms a categorical description (e.g. high, moderate, low or negligible) shall be used and an explanation of the scale of effect represented by each description provided.

3. *Exposure characterisation*

The likelihood or probability of each identified potential adverse effect occurring shall be evaluated to provide a qualitative or quantitative assessment of the exposure. A qualitative assessment shall be further defined using an appropriate scale (e.g. the categorical descriptions may refer to a sequential range within a numerical scale 0-1). The characteristics of the receiving environment(s), and the scope of the application shall be taken into consideration (e.g. the placing on the market for uses other than cultivation).

4. *Risk characterisation*

The risk shall be characterised by combining the magnitude of the consequences of a hazard and the likelihood of the adverse effects occurring to provide a quantitative or semi quantitative estimation of the risk.

Where relevant the uncertainty for each identified risk shall be described and expressed in quantitative terms.

5. *Risk management strategies*

A risk management strategy to manage the identified risks and reduce them to a level of no concern shall be defined.

The risk management strategies shall be described in terms of reducing the hazard and/or exposure and the consequent reduction in overall risk shall be quantified (when possible) and shall be proportionate to the protection goals in the identified receiving environments, the scale and conditions of the release and the levels of uncertainty identified in the e.r.a.

6. *Overall risk evaluation and conclusions*

An evaluation of the overall risk of the GMO(s) shall be made taking into account the results of the risk characterisation (step 4), the proposed risk management strategies (step 5) and the associated levels of uncertainty.

The overall risk evaluation and conclusions shall determine the requirements for the Post Market Environmental Monitoring (PMEM) plan of the GMO(s) and the monitoring of the efficacy of the proposed risk management measures."

2. In Annex II, the title and the first subparagraph of section D are replaced by the following:

"D. Conclusions on the specific areas of risk of the e.r.a.

Conclusions on the potential environmental impact in relevant receiving environments from the release or the placing on the market of GMOs shall be drawn on each of the points listed in sections D1 or D2, on the basis of an e.r.a. carried out in accordance with the principles outlined in section B and following the methodology described in section C, and on the basis of the information required pursuant to Annex III."

3. In Annex II, section D.2. is replaced by the following:

"D.2. In the case of genetically modified higher plants (GMHP)

1. Persistence and invasiveness including plant to plant gene flow.
2. Plant to micro-organisms gene transfer
3. Interactions of the GM plant with target organisms
4. Interactions of the GM plant with non-target organisms
5. Impacts of the specific cultivation, management and harvesting techniques

   The conclusions on this area of risk shall not address the environmental impacts of the use of plant protection products on the GMHP, as those impacts are assessed under Regulation (EC) No 1107/2009 of the European Parliament and of the Council.
6. Effects on biogeochemical processes
7. Effects on human and animal health."

4. Annex III is replaced by the following:

"ANNEX III

INFORMATION REQUIRED IN THE NOTIFICATION

A notification referred to in part B or part C of the Directive shall include, as appropriate, the information set out below in the sub-Annexes including an e.r.a. carried out in accordance with Annex II.

Not all the subsets of information listed in sub-Annexes shall be required in every notification. A given subset of information shall not be required where it is not relevant or necessary in the context of the notification concerned. The notifier shall provide a justification for any subset of information they do not provide.

The level of detail required for each subset of information may also vary according to the nature and the scale of the proposed release.

For each required subset of information, the following shall be provided:

(i) the summaries and results of the studies referred to in the notification, including an explanation about their relevance to e.r.a. where applicable;

(ii) annexes where detailed information on those studies is provided including a description of the methods and materials used or the reference to standardised or internationally recognised methods and the name of the body or bodies responsible for carrying out the studies.

Future developments in genetic modification may necessitate adapting this Annex to technical progress or developing guidance notes on this Annex. Further differentiation of information requirements for different types of GMOs, for example perennial plants and trees, single celled organisms, fish or insects, or for particular use of GMOs like the development of vaccines, may be possible once sufficient experience with notifications for the release of particular GMOs has been gained in the Community.

Annex III A applies to releases of all types of genetically modified organisms other than higher plants. Annex III B applies to release of genetically modified higher plants.

The term 'higher plants' means plants which belong to the taxonomic group Spermatophytae (Gymnospermae and Angiospermae).

In addition to the information set out in the sub-Annexes:

(i) The notification shall contain a checklist demonstrating that the information required under the applicable sub-Annex is complete;

(ii) In accordance with Article 25(2), notifiers may indicate the information in the notification that should be treated as confidential and shall, in such cases, provide verifiable justification."

5. Annex III B is replaced by the following:

"ANNEX III B

INFORMATION REQUIRED IN NOTIFICATIONS CONCERNING RELEASES OF GENETICALLY MODIFIED HIGHER PLANTS (GMHPs) (GYMNOSPERMAE AND ANGIOSPERMAE)

I. INFORMATION REQUIRED IN NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6 AND 7

A. GENERAL INFORMATION

1. Name and address of the notifier (company or institute),
2. Name, qualifications and experience of the responsible scientist(s),
3. Title of the project
4. Designation and specification of the genetically modified plant
5. Information relating to the release
   (a) Purpose of the release
   (b) Foreseen date(s) and duration of the release
   (c) Method by which the genetically modified plants will be released
   (d) Method for preparing and managing the release site, prior to, during and post release, including cultivation practices and harvesting methods
   (e) Approximate number of plants (or plants per m2).
6. Information relating to the site of release
   (a) Location and size of the release site(s).
   (b) Description of the release site ecosystem, including climate, flora and fauna.
   (c) Proximity to officially recognised biotopes or protected areas which may be affected.

B. SCIENTIFIC INFORMATION

All the subsets of information listed below shall be provided in the notification, except where the notifier can justify that a specific subset is not relevant or necessary in the context of the notification concerned.

1. Information relating to (a) the recipient or (b) (where appropriate) parental plants
   (a) Complete name:
      (i) family name
      (ii) genus
      (iii) species
      (iv) subspecies
      (v) cultivar/breeding line
      (vi) common name.
   (b) Geographical distribution and cultivation of the plant within the European Union.
   (c) Information concerning reproduction:
      (i) mode(s) of reproduction
      (ii) specific factors affecting reproduction, if any
      (iii) generation time.

(d) Sexual compatibility with other cultivated or wild plant species, including the distribution in Europe of the compatible species.

(e) Survivability:

(i) ability to form structures for survival or dormancy

(ii) specific factors affecting survivability, if any.

(f) Dissemination:

(i) ways and extent of dissemination (for example an estimation of how viable pollen and/or seeds declines with distance)

(ii) specific factors affecting dissemination, if any.

(g) 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.

(h) Other potential interactions, relevant to the GMO, of the plant with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

2. Molecular characterisation

(a) Information relating to the genetic modification

(i) Description of the methods used for the genetic modification.

(ii) Nature and source of the vector used.

(iii) Source of the nucleic acid(s) used for transformation, size, and intended function of each constituent fragment of the region intended for insertion.

(b) Information relating to the genetically modified plant

(i) General description of the trait(s) and characteristics which have been introduced or modified.

(ii) Information on the sequences actually inserted/deleted:

- size and copy number of all detectable insert(s), both partial and complete and methods used for its/their characterisation;
- the organisation and sequence of the inserted genetic material at each insertion site in a standardised electronic format;
- in case of deletion, size and function of the deleted region(s) whenever possible;
- subcellular location(s) of the insert(s) in the plant cells (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its/their determination;

(iii) Information on the expression of the insert:

- the method(s) used for expression analysis together with their performance characteristics;
- information on the developmental expression of the insert during the lifecycle of the plant;
- parts of the plant where the insert/modified sequence are expressed;

(iv) Genetic stability of the insert and phenotypic stability of the GMHP.

(c) Conclusions of the molecular characterisation

3. Information on specific areas of risk

(a) Any change to the ability of the GMHP to become more persistent and/or invasive, including the ability to transfer genetic material to other plants.

(b) Any change to the ability of the GMHP to transfer genetic material to microorganisms.

(c) Mechanism of interaction between the genetically modified plant and target organisms (if applicable).

(d) Potential changes in the interactions of the GMHP with non-target organisms resulting from the genetic modification.

(e) Potential interactions with the abiotic environment.

(f) Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification.

(g) Conclusions on the specific areas of risk

4. Information on control, monitoring, postrelease and waste treatment plans

(a) Any precautions taken:

(i) distance(s) from sexually compatible plant species, both wild relatives and crops

(ii) any measures to minimise/prevent dispersal of any reproductive organ of the GMHP (for example pollen, seeds, tuber).

(b) Description of methods for postrelease treatment of the site.

(c) Description of postrelease treatment methods for the genetically modified plant material including wastes.

(d) Description of monitoring plans and techniques.

(e) Description of any emergency plans.

(f) Methods and procedures to protect the site.

5. Description of detection and identification techniques for the genetically modified plant.

6. Information about previous releases of the genetically modified plant, if applicable.

II. INFORMATION REQUIRED IN NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLE 13

A. GENERAL INFORMATION

1. Name and address of the notifier (company or institute),
2. Name, qualifications and experience of the responsible scientist(s).
3. Designation and specification of the GMHP.
4. Scope of the notification.
   (a) Cultivation/ Growing
   (b) Other uses

B. SCIENTIFIC INFORMATION

All the subsets of information listed below shall be provided in the notification, except where the notifier can justify that a specific subset is not relevant or necessary in the context of the notification concerned.

1. Information relating to (a) the recipient or (b) (where appropriate) parental plants
   (a) Complete name:
      (i) family name
      (ii) genus
      (iii) species
      (iv) subspecies
      (v) cultivar/breeding line
      (vi) common name.
   (b) Geographical distribution and cultivation area of the plant within the European Union.
   (c) Information concerning reproduction:
      (i) mode(s) of reproduction
      (ii) specific factors affecting reproduction, if any
      (iii) generation time.
   (d) Sexual compatibility with other cultivated or wild plant species, including the distribution in Europe of the compatible species.
   (e) Survivability:
      (i) ability to form structures for survival or dormancy
      (ii) specific factors affecting survivability, if any.
   (f) Dissemination:
      (i) ways and extent of dissemination (for example an estimation of how viable pollen and/or seeds declines with distance)
      (ii) specific factors affecting dissemination, if any.

(g) 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.

(h) Other potential interactions, relevant to the GMO, of the plant with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

2. Molecular characterisation

(a) Information relating to the genetic modification

(i) Description of the methods used for the genetic modification.

(ii) Nature and source of the vector used.

(iii) Source of the nucleic acids(s) used for transformation, size, and intended function of each constituent fragment of the region intended for insertion.

(b) Information relating to the genetically modified plant

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

(ii) Information on the sequences actually inserted/deleted:

- size and copy number of all detectable inserts, both partial and complete, and methods used for its characterisation;
- the organisation and sequence of the inserted genetic material at each insertion site in a standardised electronic format;
- in case of deletion, size and function of the deleted region(s) whenever possible;
- subcellular location(s) of the insert(s) (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its/their determination;
- 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.
- sequence information in a standardised electronic format for both 5' and 3' flanking regions at each insertion site;
- Open Reading Frames (hereafter referred to as 'ORFs' and defined as any nucleotide sequence that contains a string of codons that is uninterrupted by the presence of a stop codon in the same reading frame) 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).

(iii) Information on the expression of the insert:

- the method(s) used for expression analysis together with their performance characteristics;
- information on the developmental expression of the insert during the lifecycle of the plant;
- parts of the plant where the insert/modified sequence are expressed;
- potential unintended expression of new ORFs identified under the sixth indent of point (ii), which raise a safety concern;
- protein expression data, including the raw data, obtained from field trials and related to the conditions in which the crop is grown;
- expression data with regard to the stacking of transformation events by conventional crossing. On a case-by-case basis, and where concerns arise, additional information may be necessary.

(iv) Genetic stability of the insert and phenotypic stability of the GMHP.

(c) Conclusions of molecular characterisation

3. Comparative analysis

(a) Choice of conventional counterpart and additional comparators

(b) Choice of representative site locations

(c) Experimental design and statistical analysis of data from field trials for comparative analysis

(i) Description of field trial design

(ii) Description of relevant aspect of the receiving environments

(iii) Statistical analysis

(d) Selection of plant material and compounds for analysis, if applicable.

(e) Comparative analysis of agronomic and phenotypic characteristics, if applicable.

(f) Comparative analysis of composition, if applicable.

(g) Conclusions of comparative analysis

4. Specific information for each area of risk

For each of the seven areas of risk referred to in Section D.2 of Annex II the notifier shall first describe the pathway to harm explaining in a chain

of cause and effect how the deployment of the GMHP could lead to harm, taking into account both hazard and exposure.

(a) Persistence and invasiveness including plant to plant gene flow

(i) Assessment of the potential for the GMHP to become persistent (e.g. volunteer populations) and/or invasive (e.g. feral populations) or transmit transgene(s) to relatives and the environmental consequences thereof, based on:

- Whether the GHMP or its progeny can grow, hybridise, reproduce or overwinter in EU conditions and in relevant receiving environments.
- Whether the GMHP can form feral populations in semi-natural habitats, or if sexually compatible wild relatives are likely to be recipients of transgenes.
- Whether the presence of the GM trait in either feral crop plant or a compatible relative causes an alteration in fitness, or increases the range of habitats in which the plant may survive and reproduce.
- Intended and unintended differences between the GMHP and its conventional counterpart in their potential to establish, grow, reproduce, hybridise, and overwinter, form feral populations, demonstrate fitness

(ii) Conclusions on impacts of persistence and invasiveness including plant-to-plant gene flow

(b) Plant to micro-organism gene transfer

(i) .Assessment of the potential impact of transfer and/or long-term establishment of newly inserted DNA from the GM-plants to microorganisms.

(ii) Assessment of the potential impact of the transfer of newly inserted DNA for human and animal health and the environment.

(iii) Conclusions on impacts of plant to microorganism gene transfer.

(c) Interactions of the GMHP with target organisms

(i) Assessment of the potential immediate and/or delayed environmental impact(s) resulting from undesired changes in the direct and indirect interactions between the GMHP and target organisms.

(ii) Assessment of the potential immediate and/or delayed environmental impact(s) resulting from the development of resistance of the target organism to the expressed

protein based on the history of development of resistance to conventional pesticides and/or transgenic plants expressing similar traits.

(iii) Conclusions on interactions of the GMHP with target organisms.

(d) Interactions of the GMHP with non-target organisms (NTOs)

(i) Assessment of the possible immediate and/or delayed environmental impact(s) resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of a representative subset of species of herbivores, predators, parasitoids, parasites and pathogens, entomopathogenic organisms, pollinators, decomposers and plant symbionts (where applicable), and taking into account the potential impact(s) on relevant ecosystem services.

(ii) Conclusions on interactions of the GMHP with non-target organisms

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

(i) For GMHPs for cultivation, assessment of the possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP.

(ii) Conclusions on impacts of the specific cultivation, management and harvesting techniques

(f) Effects on biogeochemical processes

(i) Assessment of the possible immediate and/or delayed effects on biogeochemical processes in the production site, which comprises the soil, plants, animals and microorganisms within the area in which the GM plant is to be grown (e.g. an agricultural field).

(ii) Assessment of the possible immediate and/or delayed effects on biogeochemical processes in the wider environment, which comprises land, water and air outside the production site, with which the GM plant and its management might interact.

(iii) Conclusions on effects on biogeochemical processes

(g) Effects on human and animal health

(i) Assessment of possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into contact with the GMHP

release(s) (products such as pollen or dust from processed plants).

(ii) For GMHPs not destined for human consumption but where the recipient or parental organism(s) may be considered for human consumption the likelihood of accidental intake.

(iii) Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from the unintended or accidental exposure to the GMO and products derived from it.

(iv) Conclusions on the effects on human and animal health

(h) Overall risk evaluation and conclusions

5. Description of detection and identification techniques for the GMHP.

6. Information about previous releases of the GMHP, if applicable.

6. In Annex IV, points 1 and 7 of section A are replaced by the following:

"1. proposed commercial names of the products and names of GMOs contained therein, and a proposal for a unique identifier for the GMO, developed in accordance with Commission Regulation (EC) No 65/2004[1]. After the consent any new commercial names should be provided to the competent authority,";

"7. methods for detection, identification and, where appropriate, quantification of the transformation event; samples of the GMO(s) and their control samples, and information as to the place where the reference material can be accessed. Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register(s) referred to in Article 31(2) should be identified,".

[1] Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p5).