DIRECTIVES

COMMISSION DIRECTIVE (EU) 2018/350

of 8 March 2018

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) Directive 2001/18/EC sets out requirements for the environmental risk assessment of genetically modified organisms ('GMOs').

(2) On 4 December 2008, the Council adopted Conclusions on GMOs stressing the need to update and strengthen the environmental risk assessment of GMOs, in particular concerning the assessment of long-term environmental effects.

(3) Following a request from the Commission, the European Food Safety Authority (EFSA) adopted in October 2010 a Scientific opinion establishing guidance on the environmental risk assessment of genetically modified plants ([2]) ('the Guidance'), which is a revision of the previous guidance. Other guidance documents issued by EFSA and by the European Medicines Agency are relevant to the environmental risk assessment of GMOs other than plants.

(4) Article 3 of Directive (EU) 2015/412 of the European Parliament and of the Council ([3]) provides that by 3 April 2017 the Commission has to update the Annexes to Directive 2001/18/EC as regards the environmental risk assessment with a view to incorporating and building upon the Guidance, which is not legally binding.

(5) In order to adapt to technical progress and taking into account the experience gained in the environmental risk assessment of genetically modified plants, the essential elements of the Guidance should be incorporated in Directive 2001/18/EC. In doing so, the principle that the environmental risk assessment should be carried out on a case-by-case basis should be respected.

(6) The Guidance was essentially designed for notifications for the purpose of placing on the market ('Part C notifications') of genetically modified plants, while Annex II to Directive 2001/18/EC applies to both Part C notifications and notifications for other purposes than placing on the market ('Part B notifications'). Therefore, certain requirements resulting from the incorporation of the Guidance in Annex II should only apply to Part C notifications, as they would be irrelevant or disproportionate in the context of Part B notifications, which essentially concern experimental releases.

(7) Part C of Annex II to Directive 2001/18/EC concerns the methodology of the environmental risk assessment. It should be updated in order to incorporate, in particular, the terminology used to describe the six steps of the assessment approach as described in the Guidance.

([1]) OJ L 106, 17.4.2001, p. 1.
([2]) *EFSA Journal* 2010;8(11):1879.
([3]) 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 (OJ L 68, 13.3.2015, p. 1).

(8) Part D of Annex II to Directive 2001/18/EC applies to the conclusions of the environmental risk assessment and contains two distinct sections, 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 environmental risk assessment 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 those areas of risk.

(9) Where the environmental risk assessment concerns a genetically modified plant made tolerant to a herbicide, its scope should be consistent with Directive 2001/18/EC. The environmental risk assessment of the use of a plant protection product, including its use on a genetically modified plant, falls under the scope of Regulation (EC) No 1107/2009 of the European Parliament and of the Council ([1]) and will be carried out at Member State level to take into account the specific agricultural conditions.

(10) Annex III B to Directive 2001/18/EC lists the information required in notifications concerning releases of genetically modified higher plants and applies to both Part C notifications and 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 environmental risk assessment 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 Part C notifications from the requirements concerning Part B notifications.

(11) The 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 ([2]). In the interest of simplification, it is therefore appropriate to align, to the extent possible, the order of the pieces of information required for Part C notifications in Annex III B to Directive 2001/18/EC with the order followed in Commission Implementing Regulation (EU) No 503/2013 ([3]).

(12) Annex IV to Directive 2001/18/EC sets out additional information requirements only for Part C notifications. The requirements set out in that Annex concerning detection methods should be updated in the light of technical progress, in particular as regards the submission by notifiers of the reference material.

(13) 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 29 September 2019 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.

([1]) 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 L 309, 24.11.2009, p. 1).

([2]) 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).

([3]) 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).

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 twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 8 March 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Directive 2001/18/EC is amended as follows:

(1) Annex II is amended as follows:

(a) Section C is replaced by the following:

'C. **Methodology**

Guidance issued by the European Food Safety Authority is available for the implementation of this section for Part C notifications.

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

1. *Intended and unintended changes*

As part of the identification and evaluation of the potential adverse effects referred to in Section A, the e.r.a shall identify the intended and unintended changes resulting from the genetic modification and shall evaluate their potential to cause adverse effects on human health and on the environment.

Intended changes resulting from the genetic modification are changes that are designed to occur and which fulfil the original objectives of the genetic modification.

Unintended changes resulting from the genetic modification are consistent changes which go beyond the intended change(s) resulting from the genetic modification.

Intended and unintended changes can have either direct or indirect, and either immediate or delayed effects on human health and on the environment.

2. *Long-term adverse effects and cumulative long-term adverse effects in the e.r.a. of Part C notifications*

Long-term effects of a GMO are effects resulting either from a delayed response by organisms or their progeny to long-term or chronic exposure to a GMO or from an extensive use of a GMO in time and space.

The identification and evaluation of the potential long-term adverse effects of a GMO on human health and on the environment shall take into account the following:

(a) the long-term interactions of the GMO and the receiving environment;

(b) the characteristics of the GMO which become important on a long-term basis;

(c) data obtained from repeated deliberate releases or placings on the market of the GMO over a long period.

The identification and evaluation of the potential cumulative long-term adverse effects referred to in the introductory part of Annex II shall also take into account the GMOs deliberately released or placed on the market in the past.

3. *Quality of the data*

In order to carry out an e.r.a. for a notification under Part C of this Directive, the notifier shall collate already available data from scientific literature or from other sources, including monitoring reports, and shall generate the necessary data by performing, where possible, appropriate studies. Where applicable, the notifier shall justify in the e.r.a. why generating data by studies is not possible.

The e.r.a. for notifications under Part B of the Directive shall be based at least on already available data from scientific literature or from other sources and may be supplemented by additional data generated by the notifier.

Where data generated outside Europe is provided in the e.r.a., its relevance to receiving environment(s) in the Union shall be justified.

Data provided in the e.r.a for notifications under part C of this Directive shall comply with the following requirements:

(a) where toxicological studies carried out to assess risk to human or animal health are provided in the e.ra., the notifier shall provide evidence to demonstrate that they were conducted in facilities which comply with:

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

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

(b) where studies other than toxicological studies are provided in the e.r.a., they shall:

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

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

(iii) in the absence of a relevant ISO standard, be conducted in accordance with internationally recognised standards;

(c) information on the results obtained from the studies referred to in points (a) and (b) and on the study protocols used shall be reliable and comprehensive and shall include the raw data in an electronic format suitable for carrying out statistical or other analysis;

(d) the notifier shall specify, where possible, the size of effect that each study performed intends to detect and justify it;

(e) the selection of sites for field studies shall be based on relevant receiving environments in view of the potential exposure and impact that would be observed where the GMO may be released. The selection shall be justified in the e.r.a.;

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

4. *Stacked transformation events in Part C notifications*

The following shall apply to the e.r.a. of a GMO containing stacked transformation events in Part C notifications:

(a) the notifier shall provide an e.r.a. for each single transformation event in the GMO or refer to already submitted notifications for those single transformation events;

(b) the notifier shall provide an assessment of the following aspects:

(i) the stability of the transformation events;

(ii) the expression of the transformation events;

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

(c) where the progeny of the GMO can contain various subcombinations of the stacked transformation events, the notifier shall provide a scientific rationale justifying that there is no need to provide experimental data for the concerned subcombinations, independently of their origin, or, in the absence of such scientific rationale, shall provide the relevant experimental data.

C.2. Characteristics of the GMO and of the releases

The e.r.a. 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 insertion 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 characteristics.

Relevant information from previous releases of the same or similar GMOs and organisms with similar traits and their biotic and abiotic interaction with similar receiving environments, including information resulting from the monitoring of such organisms, shall be considered in the e.r.a., subject to Article 6(3) or Article 13(4).

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

The e.r.a. referred to in Articles 4, 6, 7 and 13 shall be conducted for each relevant area of risk referred to in Section D1 or in Section D2 in accordance with the following six steps:

1. *Problem formulation including hazard identification*

The problem formulation shall:

(a) identify any changes in the characteristics of the organism, linked to the genetic modification, by comparing the characteristics of the GMO with those of the chosen non-genetically modified comparator under corresponding conditions of release or use;

(b) identify potential adverse effects on human health or the environment which are linked to the changes that have been identified under point (a) above;

Potential adverse effects shall not be discounted on the basis that they are unlikely to occur.

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

— effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations leading to a potential decline in biodiversity,

— altered susceptibility to pathogens facilitating the dissemination of infectious diseases 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,

— effects on biogeochemistry (biogeochemical cycles), including carbon and nitrogen recycling through changes in soil decomposition of organic material,

— disease affecting humans, including allergenic or toxic reactions,

— disease affecting animals and plants, including toxic, and, in the case of animals, allergenic reactions, where appropriate.

Where potential long-term adverse effects of a GMO are identified, they shall be assessed in the form of desk based studies using, where possible, one or more of the following:

(i) evidence from previous experiences;

(ii) available data sets or literature;

(iii) mathematical modelling;

(c) identify relevant assessment endpoints.

Those potential adverse effects that could impact the identified assessment endpoints shall be considered in the next steps of the risk assessment;

(d) identify and describe the exposure pathways or other mechanisms through which adverse effects may occur.

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

— the spread of the GMO(s) in the environment,

— the transfer of the inserted genetic material to the same organism or other organisms, whether genetically modified or not,

— phenotypic and genetic instability,

— interactions with other organisms,

— changes in management, including, where applicable, in agricultural practices;

(e) formulate testable hypotheses, and define relevant measurement endpoints, to allow, where possible, a quantitative evaluation of the potential adverse effect(s);

(f) consider possible uncertainties, including knowledge gaps and methodological limitations.

2. *Hazard characterisation*

The magnitude 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 is likely to be influenced by the receiving environment(s) into which the GMO is intended to be released and by the scale and conditions of the release.

Where possible, the evaluation shall be expressed in quantitative terms.

Where the evaluation is expressed in qualitative terms, a categorical description ("high", "moderate", "low" or "negligible") shall be used and an explanation of the scale of effect represented by each category shall be provided.

3. *Exposure characterisation*

The likelihood or probability of each identified potential adverse effect occurring shall be evaluated to provide, where possible, a quantitative assessment of the exposure as a relative measure of probability, or otherwise a qualitative assessment of the exposure. The characteristics of the receiving environment(s) and the scope of the notification shall be taken into consideration.

Where the evaluation is expressed in qualitative terms, a categorical description ("high", "moderate", "low" or "negligible") of the exposure shall be used and an explanation of the scale of effect represented by each category shall be provided.

4. *Risk characterisation*

The risk shall be characterised by combining, for each potential adverse effect, the magnitude with the likelihood of that adverse effect occurring to provide a quantitative or semi quantitative estimation of the risk.

Where a quantitative or semi quantitative estimation is not possible, a qualitative estimation of the risk shall be provided. In that case, a categorical description ("high", "moderate", "low" or "negligible") of the risk shall be used and an explanation of the scale of effect represented by each category shall be provided.

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

5. *Risk management strategies*

Where risks are identified that require, on the basis of their characterisation, measures to manage them, a risk management strategy shall be proposed.

The risk management strategies shall be described in terms of reducing the hazard or the exposure, or both, and shall be proportionate to the intended reduction of the risk, the scale and conditions of the release and the levels of uncertainty identified in the e.r.a.

The consequent reduction in overall risk shall be quantified where possible.

6. *Overall risk evaluation and conclusions*

A qualitative and, where possible, quantitative evaluation of the overall risk of the GMO shall be made taking into account the results of the risk characterisation, the proposed risk management strategies and the associated levels of uncertainty.

The overall risk evaluation shall include, where applicable, the risk management strategies proposed for each identified risk.

The overall risk evaluation and conclusions shall also propose specific requirements for the monitoring plan of the GMO and, where appropriate, the monitoring of the efficacy of the proposed risk management measures.

For notifications under Part C of the Directive, the overall risk evaluation shall also include an explanation of the assumptions made during the e.r.a. and of the nature and magnitude of uncertainties associated with the risks, and a justification of the risk management measures proposed.'

(b) The title and the introductory paragraph 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 for each relevant area of risk listed in Section D1 for GMOs other than higher plants or Section D2 for genetically modified higher plants, 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.'

(c) Section D.2 is replaced by the following:

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

"Higher plants" shall mean plants which belong to the taxonomic group Spermatophytae (Gymnospermae and Angiospermae).

1. Persistence and invasiveness of the GMHP, including plant to plant gene transfer

2. Plant to micro-organisms gene transfer

3. Interactions of the GMHP with target organisms

4. Interactions of the GMHP with non-target organisms

5. Impacts of the specific cultivation, management and harvesting techniques

6. Effects on biogeochemical processes

7. Effects on human and animal health.'

(2) Annex III is replaced by the following:

'*ANNEX III*

INFORMATION REQUIRED IN THE NOTIFICATION

Notifications referred to in Parts B and C of this Directive shall, as a rule, include the information set out in Annex III A, for GMOs other than higher plants, or in Annex III B, for genetically modified higher plants.

The provision of a given subset of information listed in Annex III A or in Annex III B shall not be required where it is not relevant or necessary for the purposes of risk assessment in the context of a specific notification, in view especially of the characteristics of the GMO, of the scale and conditions of the release or of its intended conditions of use.

The appropriate level of detail 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) for notifications referred to in Part C of this Directive, Annexes with detailed information on those studies, 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 Union.'

(3) 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. Information relating to the release

(a) Purpose of the release

(b) Foreseen date(s) and duration of the release

(c) Method by which the GMHP 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 m^2).

5. 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) Presence of sexually compatible wild relatives or cultivated plant species.

(d) Proximity to officially recognised biotopes or protected areas which may be affected.

B. **Scientific information**

1. Information relating to the recipient plant or, where appropriate, to the parental plants

(a) Complete name:

(i) family name

(ii) genus

(iii) species

(iv) subspecies

(v) cultivar or breeding line

(vi) common name.

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

(ii) specific factors affecting dissemination, if any.

(g) Where a plant species is not normally grown in the Union, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

(h) Potential interactions of the plant, that are relevant to the GMHP, 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 GMHP

(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 insert(s) and methods used for its/their characterisation,

— in case of deletion, size and function of the deleted region(s),

— 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) Parts of the plant where the insert is 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 persistence or invasiveness of the GMHP, and its ability to transfer genetic material to sexually compatible relatives and the adverse environmental effects thereof.

(b) Any change to the ability of the GMHP to transfer genetic material to microorganisms and the adverse environmental effects thereof.

(c) Mechanism of interaction between the GMHP and target organisms (if applicable) and the adverse environmental effects thereof.

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

(e) Potential changes in agricultural practices and management of the GMHP resulting from the genetic modification and the adverse environmental effects thereof.

(f) Potential interactions with the abiotic environment and the adverse environmental effects thereof.

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

(h) Conclusions on the specific areas of risk.

4. Information on control, monitoring, post-release and waste treatment plans

(a) Any measures taken, including:

(i) spatial and temporal isolation from sexually compatible plant species, both wild and weedy relatives and crops;

(ii) any measures to minimise or prevent the dispersal of any reproductive part of the GMHP.

(b) Description of methods for post-release treatment of the site.

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

(d) Description of monitoring plans and techniques.

(e) Description of any emergency plans.

(f) Description of the methods and procedures to:

(i) avoid or minimise the spread of the GMHPs beyond the site of release;

(ii) protect the site from intrusion by unauthorised individuals;

(iii) prevent other organisms from entering the site or minimise such entries.

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

6. Information about previous releases of the GMHP, 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

(b) Other uses (to be specified in the notification).

B. **Scientific information**

1. Information relating to the recipient plant or, where appropriate, to the parental plants

(a) Complete name:

(i) family name

(ii) genus

(iii) species

(iv) subspecies

(v) cultivar/breeding line

(vi) common name.

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

(c) Information 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 the Union 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;

(ii) specific factors affecting dissemination, if any.

(g) Where a plant species is not normally grown in the Union, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

(h) Potential interactions of the plant, that are relevant to the GMHP, 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) Description of the trait(s) and characteristics which have been introduced or modified.

(ii) Information on the sequences actually inserted or 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),

— 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, 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,

— bioinformatic analysis using up-to-date databases, to investigate possible interruptions of known genes,

— all Open Reading Frames, (hereafter referred to as "ORFs") within the insert (either due to rearrangement or not) and those created as a result of the genetic modification at the junction sites with genomic DNA. ORF is defined as a nucleotide sequence that contains a string of codons that is uninterrupted by the presence of a stop codon in the same reading frame,

— bioinformatic analysis using up-to-date databases, to investigate possible similarities between the ORFs and known genes which may have adverse effects,

— primary structure (amino acid sequence) and, if necessary, other structures, of the newly expressed protein,

— bioinformatic analysis using up-to-date databases, to investigate possible sequence homologies and, if necessary, structural similarities between the newly expressed protein and known proteins or peptides which may have adverse effects.

(iii) Information on the expression of the insert:

— method(s) used for expression analysis together with their performance characteristics,

— information on the developmental expression of the insert during the life cycle of the plant,

— parts of the plant where the insert/modified sequence is expressed,

— potential unintended expression of new ORFs identified under the seventh indent of point (ii), which raise a safety concern,

— protein expression data, including the raw data, obtained from field studies and related to the conditions in which the crop is grown.

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

(c) Conclusions of molecular characterisation

3. Comparative analysis of agronomic and phenotypic characteristics and of composition

(a) Choice of conventional counterpart and additional comparators.

(b) Choice of sites for field studies.

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

(i) Description of field studies design

(ii) Description of relevant aspect of the receiving environments

(iii) Statistical analysis.

(d) Selection of plant material for analysis, if relevant.

(e) Comparative analysis of agronomic and phenotypic characteristics.

(f) Comparative analysis of composition, if relevant.

(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 release of the GMHP could lead to harm, taking into account both hazard and exposure.

The notifier shall submit the following information, except where it is not relevant in view of the intended uses of the GMO:

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

(i) Assessment of the potential for the GMHP to become more persistent or invasive and the adverse environmental effects thereof;

(ii) Assessment of the potential for the GMHP to transmit transgene(s) to sexually compatible relatives and the adverse environmental effects thereof;

(iii) Conclusions on the adverse environmental effect(s) of persistence and invasiveness of the GMHP including the adverse environmental effect(s) of plant-to-plant gene transfer.

(b) Plant to micro-organism gene transfer

(i) Assessment of the potential for transfer of newly inserted DNA from the GMHP to microorganisms and the adverse effects thereof;

(ii) Conclusions on the adverse effect(s) of the transfer of newly inserted DNA from the GMHP to microorganisms for human and animal health and the environment;

(c) Interactions of the GMHP with target organisms, if relevant

(i) Assessment of the potential for changes in the direct and indirect interactions between the GMHP and target organisms and the adverse environmental effect(s);

(ii) Assessment of the potential for evolution of resistance of the target organism to the expressed protein (based on the history of evolution of resistance to conventional pesticides or transgenic plants expressing similar traits) and any adverse environmental effect(s) thereof;

(iii) Conclusions on adverse environmental effect(s) of interactions of the GMHP with target organisms.

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

(i) Assessment of the potential for direct and indirect interactions of the GMHP with non-target organisms, including protected species, and the adverse effect(s) thereof.

The assessment shall also take into account the potential adverse effect(s) on relevant ecosystem services and on the species providing those services.

(ii) Conclusions on adverse environmental effect(s) of 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 changes in the specific cultivation, management and harvesting techniques used for the GMHP and the adverse environmental effect(s) thereof;

(ii) Conclusions on adverse environmental effect(s) of the specific cultivation, management and harvesting techniques.

(f) Effects on biogeochemical processes

(i) Assessment of the changes in the biogeochemical processes within the area in which the GMHP is to be grown and in the wider environment, and the adverse effects thereof;

(ii) Conclusions on adverse effects on biogeochemical processes.

(g) Effects on human and animal health

(i) Assessment of potential direct and indirect interactions between the GMHP and persons working with or coming into contact with the GMHPs, including through pollen or dust from a processed GMHP, and assessment of the adverse effects of those interactions on human health;

(ii) For GMHPs not destined for human consumption, but where the recipient or parental organism(s) may be considered for human consumption, assessment of the likelihood of and possible adverse effects on human health due to accidental intake;

(iii) Assessment of the potential adverse effects on animal health due to accidental consumption of the GMHP or of material from that plant by animals;

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

(h) Overall risk evaluation and conclusions.

A summary of all the conclusions under each area of risk shall be provided.

The summary shall take into account the risk characterisation in accordance with steps 1 to 4 of the methodology described in Section C.3 of Annex II and the risk management strategies proposed in accordance with point 5 of Section C.3 of Annex II.

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

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

(4) Section A of Annex IV is amended as follows:

(a) point 1 is 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 (*). After the consent any new commercial names should be provided to the competent authority,

(*) 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, p. 5).'

(b) point 7 is replaced by the following:

'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,'.