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ANNEX 1

ANNEX

to 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

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

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 chosen 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 be relevant to the receiving environment(s) and intended use(s) of the GMO(s) and shall include an assessment of the potential delayed environmental effects in the form of a desk based study using one or more of the following;

– evidence from previous experiences;

– available data sets/literature;

– mathematical models predictions.

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 GMOs 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) or Article 13(4). 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) Toxicological studies carried out to assess risk(s) to human or animal health 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.

(c) 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.

(d) Information on the study protocols and the results obtained from the studies referred to points (b) and (c) shall be comprehensive and include the raw data in an electronic format, suitable for carrying out statistical or other analysis.

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

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 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:

The problem formulation shall:

– define assessment endpoints that are representative of the protection goals;

– identify the hazards;

– describe the pathway to harm;

– 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, including knowledge gaps and methodological limitations.

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. Potential adverse effects shall not be discounted on the basis that they are 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;

– disease to animals and plants, including toxic, and, where appropriate, allergenic effects;

– effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations;

– 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.

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.

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 ("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, which may notably consist in a numerical scale from 0 to1. The characteristics of the receiving environment(s), and the scope of the application shall be taken into consideration.

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 or the exposure, or both, 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."

(b) 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."

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

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

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

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

The notifications referred to in Parts B and C of the Directive shall include the information set out in the applicable sub-Annex, including an e.r.a. carried out in accordance with Annex II. Annex III A applies to releases of all types of genetically modified organisms other than higher plants. Annex III B applies to release of GMHP.

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 it does 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 Union.

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), the notification may indicate the information in the notification that should be treated as confidential and shall, in such cases, provide verifiable justification."

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. Designation and specification of the GMHP

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 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 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 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 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 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 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 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 ability of the GMHP to become more persistent 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 GMHP 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, post-release 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 or prevent the dispersal of any reproductive organ of the GMHP (for example pollen, seeds, tuber).

(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) Methods and procedures to protect the site.

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 or 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 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 area 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 (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 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 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, 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;

– nucleotide sequence that contains a string of codons that is uninterrupted by the presence of a stop codon in the same reading frame (Open Reading Frames, hereafter referred to as '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).

(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 and, where concerns arise, additional information.

(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 or invasive or to transmit transgene(s) to relatives and the environmental consequences thereof.

(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 or long-term establishment of newly inserted DNA from the GMHP 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 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 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 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.

(i) Assessment of the possible immediate and 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 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 delayed effects on biogeochemical processes in the production site, which

comprises the soil, plants, animals and microorganisms within the area in which the GMHP is to be grown;

(ii) Assessment of the possible immediate and delayed effects on biogeochemical processes in the wider environment, which comprises land, water and air outside the production site, with which the GMHP 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 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 delayed effects on animal health and consequences for the feed/food chain resulting from the unintended or accidental exposure to the GMHP 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.

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[1]. After the consent any new commercial names should be provided to the competent authority,

(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,".

[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, p. 5)."