Proposal by AFBV and WGG for amendments to GMO legislation

This proposal is a working document not for broad distribution, intended to elicit comments in order to serve as a basis for further discussion.

The text colored in blue reflects current wording of the Directive that is not modified by this amendment.

Draft Amendment to EC Directive 2001/18 based on Netherlands 2017 proposal

10 February 2020

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to (…)

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Directive 2001/18/EC (hereinafter 'The Directive') of the European Parliament and of the Council establishes a comprehensive legal framework for the deliberate release and placing on the market of genetically modified organisms (GMOs);

(2) The rules laid down in The Directive do not apply to such organisms obtained through the techniques listed in Annex I A, Part 2 and Annex I B;

(3) Annex I A has never been adapted to new technical progress and scientific knowledge, since its establishment in 2001;

(4) New genetic modification techniques, which have been in development for more than 20 years and are known as genome editing, have emerged and have demonstrated significant potential for genetic improvement. Scientific reports show that these techniques have a level of safety comparable to mutagenesis and traditional breeding techniques;

(5) Scientific knowledge and technical progress have developed to an extent that requires a revision of Articles 2 and 3 as well as Annex I A and the creation of a new Annex I C. This Annex I C should exclude from the scope of The Directive certain categories of organisms obtained through genome editing techniques which permit precise and targeted modifications of the genome without insertion of recombinant nucleic acid sequences;

(6) The aim to enhance the functioning of the European internal market and improve opportunities for innovation, while protecting human health and the environment, underpins the need for revising Annex IA in order to include genome editing techniques in Part 1 and create a new Annex I C in order to exclude certain categories of organisms obtained through genome editing techniques;

(7) Growing and continued lack of clarity and legal certainty impede a smooth and harmonised implementation of The Directive, especially regarding its applicability with regard to new breeding techniques which lead to genome editing;

(8) To substantiate the excluded status of an organism under The Directive, adapted mechanisms are required to confirm applicability of the new exemptions under new Annex I C;

(9) In order to avoid unjustified discrimination between otherwise indistinguishable products obtained by genome editing and traditional breeding methods, all of which do not contain any recombinant nucleic acids, modifications to The Directive should constitute a full harmonization measure for GMOs as well as organisms that are excluded or exempted under revised Annex I

A, under Annex IB and new Annex I C, with such excluded or exempted organisms to be treated the same way as those obtained through traditional breeding methods;

(10) The Directive should therefore be amended accordingly;

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Paragraph (2) of Article 2 of The Directive is replaced by Article 3 below. Article 3 of The Directive is replaced by Article 4 below. Annex I A of The Directive is replaced by revised Annex I A below. A new Annex I C included below is added to The Directive.

Article 2

This amendment to The Directive constitutes a full harmonization measure for GMOs as well as organisms excluded under Article 2 (Annex I A, Part 3) or exempted under Article 3 (Annexes I B and I C), with all excluded or exempted organisms to be regulated only in the same manner as organisms derived from traditional breeding methods.

Article 3

Paragraph (2) of Article 2 of The Directive is replaced as follows:

(2) " genetically modified organism (GMO) " means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination

Within the terms of this definition:

(a) genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1;

(b) the techniques listed in Annex I A, part 2, are not considered to result in genetic modification;

(c) the organisms described in Annex I A, Part 3, are excluded from the scope of The Directive.

Article 4

Article 3 of The Directive is replaced as follows

Exemptions

1. This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B.

2. This Directive shall not apply to the carriage of genetically modified organisms by rail, road, inland waterway, sea or air.

3. After confirmation on a case by case basis by a competent authority of a Member State, in accordance with the terms and conditions defined in Annex I C, The Directive shall not apply to certain categories of organisms obtained by techniques of genetic modification identified in

revised Annex I A, Part 1, Point 4, and described in Annex I C, which Annex can be revised from time to time in accordance with the mechanism described in Article 5 below.

Article 5

Not later than once every five years, following consultation with relevant stakeholders and in collaboration with the competent authorities of the Member States, the Commission shall report to the EU Parliament on the evolution of scientific knowledge and technical progress and, if necessary, shall propose a revision of these Annexes. The first such report and eventual proposed revision shall be completed by 1 January 2025.

Article 6

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this amendment to The 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 amendment to The 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 amendment to The Directive.

3. Regulations (EC) 1829/2003, (EC) 1830/2003 and (EC) 1946/2003 are amended to reflect the replacement of Paragraph (2) of Article 2 and Article 3 of The Directive and the addition of Annex I C to The Directive.

Article 7

This amendment to The Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

Article 8

This amendment to The Directive is addressed to the Member States.

Signature

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Revised Annex I A

ANNEX I A

TECHNIQUES REFERRED TO IN ARTICLE 2(2)

PART 1

Techniques of genetic modification referred to in Article 2(2) (a) are inter alia:

(1) Recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;

(2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;

(3) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

(4) genome editing techniques, a group of technologies that allow the targeted modification of genetic information by adding (insertion of), removing (deletion of), or exchanging (replacement of) nucleotides at a specific location in the genome of the recipient organism.

PART 2

Techniques referred to in Article 2(2)(b) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules :

(1) in vitro fertilisation;

(2) natural processes such as: conjugation, transduction, transformation;

(3) polyploidy induction;

PART 3

The organisms covered by Article 3 paragraph 2 (c) of this amendment to The Directive, called “null segregants”, are progeny of a GMO parental line from which the recombinant nucleic acid sequence(s) present in the parent has(ve) been removed through sexual crossing or a molecular excision mechanism, as well as any other exogenous sequences at the excision site.

The GMO can be either a GMO parent of the initial cross, a GMO line used for the molecular excision or a GMO line used as an intermediary in the production of the final organism.

However, if a null segregant has been obtained by using a technique listed in Annex I A, Part 1, Point 4, it shall be regulated in accordance with the terms and conditions of Annex I C.

New Annex I C

The text of this Annex has been written primarily with the intention to cover plants; it can be further adapted, if necessary and as appropriate, to animals and microorganisms.

ANNEX I C

As used herein, the term 'natural gene pool' refers to the gene pool of a plant species defined as all of the genes and alleles (i.e., different versions of the same gene) obtained from plants which can exchange genes by sexual crossing as well as from distantly related plant species with which genes can be exchanged by sexual crosses using traditional breeding techniques. The terms 'Editing' or 'edited' refer to the application of 'genome editing' techniques.

TECHNIQUES REFERRED TO IN ARTICLE 3, paragraph 3

Certain categories of plants, described below and obtained through use of the techniques described in Annex I A, Part 1, Point 4, are excluded from the scope of The Directive, provided that if recombinant nucleic acid sequences have been used in the editing process these recombinant nucleic acid sequences have been entirely removed from the modified organism. Additional categories may be added at a later date in accordance with the mechanism described in Article 5 of this amendment to The Directive, if justified by the evolution of scientific knowledge and technical progress.

a. Categories of plants to be excluded:

(1) Category 1: A plant having a native allele that has been edited to reproduce a functionality associated with a known allele present in its natural gene pool;

(2) Category 2: A plant having a native allele that has been edited to reproduce a functionality associated with a known allele present in a plant species that is outside the plant's natural gene pool;

(3) Category 3: A plant having a native allele that has been edited to reproduce a new functionality, of which the sequence modifications obtained by genome editing are of the same type as those which can be obtained by spontaneous or induced mutagenesis; and

(4) Category 4: A plant in which a gene known and present in its natural gene pool has been inserted into a targeted site of its genome.

With respect to all of the above categories, it is possible, through genome editing, to have in the same plant several edited alleles (or inserted genes). In such cases each edited allele (or inserted gene) shall be analysed independently according to the above-defined criteria. If all of the edited alleles or inserted genes fall under the same category, the plant belongs to such category. If the edited alleles or inserted genes belong to different categories, the plant must comply with each relevant category in order to be excluded. If a new edit is undertaken upon a different allele of a plant which has previously been determined to be excluded, only confirmation of exclusion for the new allele shall be required of the notifier.

b. Obtaining confirmation of the exclusion from The Directive of an edited plant:

Confirmation of the exclusion of an edited plant must be obtained by the notifier. The confirmation process is adapted to the exclusion category.

1. Procedure for submitting the confirmation request

- The notifier shall file its confirmation request with the competent authority of the Member State in charge of GMO regulations;
- The request for confirmation is made by the notifier whenever it wishes to benefit from the exclusion and remove its plant from the scope of The Directive;
- The exclusion decision for an edited plant shall be valid for all progeny of such plant containing the same edit and binding upon all Member States;
- Once the confirmation of exclusion is obtained, any variety obtained using the edited plant shall be subject to seed and plant variety regulations applicable to relevant crop species in the same manner as any variety obtained through traditional breeding techniques, including registration in the common catalogues of varieties of agricultural plant and vegetable species which can be marketed in the European Union.

2. Contents of the confirmation request application

The information requirements to be supplied by the notifier shall be adapted to the plant category:

a. *Standard requirements for all categories*:

(i) Name of the notifier and contact information;

(ii) Taxonomic description of the plant which has been edited or in which a gene has been inserted;

(iii) Technique used and main steps that have been followed, including, if applicable, whether or not an intermediate GMO was produced in the editing process, and the modalities of elimination of any inserted recombinant nucleic acid sequence, and confirmation of the elimination of any such inserted sequence (null segregant).

b. *Requirements that are Category specific*:

- For Categories 1 and 2:

(i) Taxonomic description of the plant containing the model allele and a description of the model allele;

(ii) Description of the edit realized in the final plant (addition, deletion or replacement) and confirmation that the resulting edited sequence has been obtained and comparison of the functionality of the model and edited alleles.

- For Category 3:

(i) Description of the new allele and its functionality obtained after genome editing and available background information on the reasons that led to editing such allele (research work, for example);

(ii) Description of the edit realized in the final plant (addition, deletion or replacement) and confirmation that the resulting edited sequence and its functionality have been obtained.

- For Category 4:
  (i) Taxonomic description of the donor plant containing the inserted gene and a description of such gene;
  (ii) Confirmation of the sequence of the inserted gene in comparison to the original gene before insertion;
  (iii) Confirmation that the inserted gene is located at the site targeted by genome editing.

c. *Any information supplied by the notifier for which it wishes to claim confidentiality must be marked "Confidential".*

3. Processing time

The processing time by the competent authority of a Member State to determine whether or not an edited plant falls under one of the four Categories for exclusion should be no more than sixty days.