Proposal for discussion on actions to improve the exemption mechanism for genetically modified plants under Directive 2001/18/EC

This document contains a proposal for discussion on actions to improve the exemption mechanism for genetically modified plants under Directive 2001/18/EC.

The main aim is to initiate a discussion on whether EU authorities can share the view that the Directive should not apply to plants resulting from the use of New Plant Breeding Techniques (NPBTs), provided these plants are at least equally safe as plants obtained by traditional breeding. Moreover, this proposal outlines for discussion a potential means to achieve this.

This document consists of 5 paragraphs.

- Firstly, the rationale for this proposal is introduced (§1).
- This is followed by an explanation on the need for a policy review and short term action in the field of *plant* breeding (§2).
- Subsequently, the guiding principles for drafting the proposal are introduced (§3).
- In §4 the proposal for amendment of Annex IB to Directive 2001/18/EC is provided.
- Finally, the justification for the proposal is provided (§5).

The Netherlands would welcome a discussion among Member States, Competent Authorities and the European Commission and invites any feedback, as appropriate, on this proposal for action.

§ 1. Introduction

Directive 2001/18/EC regulates the introduction of genetically modified (GM) organisms into the environment. Since 2001, new genetic modification techniques have been developed at a rapid pace. When applied to *plants*, these techniques enable faster, more precise and more directed results than conventional breeding techniques, both in terms of product-oriented output steering as well as process control. These new methods provide innovative opportunities that enable responses to important societal challenges such as more sustainable agricultural practices, combatting climate change, feed and food supply, product diversity, and the transition towards a circular (bio-based) economy. Moreover, they may enable the development of more robust crop plants vis a vis pests and diseases and a higher product quality for consumers, as well as more opportunities for bio-based industries. These developments call for re-assessing the proportionality of the regulatory framework in as far as it is currently in place, for genetically modified *plants*.

Many national competent authorities in the EU consider products obtained by New Plant Breeding Techniques (NPBTs) as falling within the scope of the Directive, although others question the legal status of such products in relation to Directive 2001/18/EC. A lengthy and unresolved debate about this issue has been going on for many years without sufficient progress. In the meantime, plant breeders indicate that their companies are currently hampered by predominantly three impediments:

1. The regulatory framework has a disproportionate effect in terms of costs, duration and predictability of market authorisation procedures – especially for small and medium-sized enterprises – preventing the use of innovative technologies in the EU;
2. Process-based triggers stemming from the definition of a GMO and requiring authorisations for that GMO, are not likely to have added value in terms of biosafety, and lead to administrative costs;
3. Lack of clarity and legal certainty leads to an increased disharmonisation as regards the application of the Directive to products resulting from the use of NPBTs.

Consistent policy approaches are therefore required to improve the functioning of the internal market in Europe in conformity with the aim of the Directive, at the same time ensuring safety for human health and the environment.

The European Court of Justice has, in the meantime, been requested to provide more clarity regarding the interpretation of Annex I B of the Directive (case C-528/16) with regard to mutagenesis. The European Commission has indicated it will not provide a legal interpretation of NPBTs. It will wait for the Court's ruling. However, the Dutch authorities see no need to await the Court's rulings on the interpretation of European legislation for initiating a policy debate on NPBTs.

To the contrary, the Dutch authorities see a pressing need to address the underlying issues at stake in the short term, which includes making the implementation of the Directive more workable in view of ongoing technical and scientific developments.

The main aim is to initiate a discussion on whether EU authorities can share the view that the Directive should not apply to plants resulting from the use of New Plant Breeding Techniques (NPBTs), provided these plants are at least equally safe as plants obtained by traditional breeding.

Neither scientific nor legal interpretations have so far yielded a harmonised approach towards NPBTs, nor has Annex IB ever been updated to technical progress so far. An unexplored option that may be considered for this purpose, is amending the exemption *mechanism*, by amending Annex IB. The Netherlands therefore present this proposal for discussion as a potential way forward.

§ 2. Policy review and short term action on NPBTs are warranted

Article 3 of the Directive states that the Directive (including the authorisation requirement) shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B.

In the past 17 years, since its establishment in 2001, Annex I B has not been adapted, even though many technical and scientific developments have occurred since then. In view of currently existing scientific knowledge and technological developments, national competent authorities from Member States need to decide whether or not the terminology used and the content of the Annex still reflect the actual technical and scientific *status quo* or whether adjustments are needed. It is observed that neither policy development by EU Authorities nor the exemption mechanism under the Directive are keeping pace with these continued technical developments in the field of plant breeding. Therefore, the Netherlands initiated a policy review process, triggered by

recent scientific advice[1] that urges for taking action. In the short run, the Dutch authorities see a pressing need for taking action on NPBTs, in particular in relation to the existing mechanism for exemptions under the Directive.

The aforementioned court case may, in due course, provide a legally binding interpretation of the currently existing exemption mechanism under the Directive regarding the term "mutagenesis". However, the Court's decision will not address the full range of NPBTs, nor is it likely to take into account future developments in plant breeding. Moreover, the current mechanism for exemptions contains a framework in which every new technique or application thereof that might fulfil the conditions for being included in the Annex, has to be assessed on a case-by-case basis. In case of any intention for amending Annex I B, a co-decision procedure needs to be initiated by the Commission since Annex I B does not fall within the scope of Article 27 of the Directive. This makes it rather cumbersome and time-consuming to keep Annex I B up to date with scientific knowledge and technical progress. Therefore there seems to be a merit in reshaping this exemption mechanism in order to make it function more effectively and efficiently. This could also contribute to resolving the abovementioned difficulties experienced in the field of plant breeding. Furthermore it allows for an update in accordance with the current understanding of science and technological developments in a way that also encompasses future developments.

§ 3. Guiding principles for reviewing the exemption mechanism

Annex I B contains techniques that are exempted based on their long safety record (see recital 17 of the Directive[2]), provided they fulfil the technical conditions mentioned in Annex I B, *i.e.* mutagenesis and cell fusion.

In view of the technical and scientific developments since the establishment of the Directive, the Annex can be considered to be outdated. Moreover, the Directive does not contain a procedure for reviewing and updating the Annex, nor any indication of how to apply the criterion 'long safety record' as referred to in recital 17 of the Directive.

The Netherlands considers it therefore necessary to review the existing exemption mechanism, with regards to *plants only*. The limitation to plants is based on the fact that the currently outdated mechanism predominantly hampers innovation in plant breeding. Moreover, the existing framework of selection and quality control in the plant breeding sector, as well as the mandatory plant variety registration, provide additional safeguards that do not exist as such in other areas. These additional safeguards enable specifically for GM plants a review of the exemption mechanism.

This proposal is based on the following guiding principles:

1. The definition of a genetically modified organism (GMO) of article 2 of the Directive should remain unchanged and should be applied in its full extent.
2. For regulatory efficiency and in view of the urgency to resolve the outstanding issue, amending the Directive should remain limited to Annex IB.

[1] *Trend Analysis Biotechnology 2016*, COGEM (http://www.cogem.net/index.cfm/en/publications/publication/trend-analysis-biotechnology-2016?q=&category=trend-analysis&from=30-09-1998&to=03-08-2017&order=relevance)

[2] ¨This Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record.¨

3. A review process for periodical adaptations to technological progress should be designed.
4. For genetically modified plants, science-based criteria should be developed for inclusion in the annex in a manner that allows any person to determine whether or not the Directive applies to the GMOs resulting from the use of any technique.
5. The Directive aims to regulate deliberate releases of GMOs and not the process used for developing a GMO. For justifying an exemption of the applicability of the directive, safety for human health and the environment should be sufficient ground. This safety predominantly depends on the product (GMO) itself, whilst the process used to obtain the product is less relevant considering the subsequent selection process, as has been demonstrated for traditionally bred products.
6. Workability, predictability, consistency and legal certainty of the exemption mechanism should be ensured.
7. Technological developments and innovation for applications for which safety to human health and the environment is sufficiently ensured, should be enabled.
8. The burden of proof for justifying compliance with the exemption criteria should be placed on actors that are making use of the exemption.

Bearing in mind these guiding principles, a reviewed exemption mechanism should be developed that meets the following conditions:

- The mechanism applies to all genetically modified plants, irrespective of the process used to obtain them. It therefore contains a more product-based approach than currently exists.
- The mechanism must ensure harmonised application thereof in order to ensure another aim of the Directive, which is to improve the EU's internal market by ensuring a level playing field.
- Rather than assessing new techniques or applications thereof on a case-by-case basis, the mechanism must be developed in a manner exempting GMOs based on generally formulated conditions and criteria, hence avoiding the need for the regulator to review Annex I B each time a new technique or application occurs.
- Any person claiming a justified use of the exemption mechanism, including any applicable conditions thereof, shall be responsible for providing supporting evidence to the relevant authorities at their request.

A reviewed exemption mechanism can only be workable if it is based on scientifically sound and clear criteria and conditions. In the next paragraph, a proposal for a revised Annex I B is provided that meets the principles and conditions described above.

The Netherlands would welcome a discussion among Member States, Competent Authorities and the European Commission on this proposal for action, and invites feedback. For further information, please contact Ms. Annemiek van Waterschoot via annemiek.van.waterschoot@minienm.nl.

§ 4. Proposal for a revised exemption mechanism

Please note that the text below is explicitly intended for discussion and describes how potentially an amendment of Annex IB could be formulated.

¨(…)

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 of the European Parliament and of the Council establishes a comprehensive legal framework for the authorisation of genetically modified organisms (GMOs), which does not apply to such organisms obtained through the techniques of genetic modification listed in Annex I B;
(2) Annex I B of this Directive has never been adapted to technical progress, since its establishment in 2001;
(3) Scientific knowledge and technical progress have developed to an extent that requires a revision of Annex I B;
(4) 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 the exemption mechanism as provided by Annex I B;
(5) Growing and continued lack of clarity and legal certainty impede a smooth and harmonised implementation of this Directive, especially regarding its applicability with regard to new plant breeding techniques;
(6) Avoidance of unnecessary costs related to lengthy and relatively unpredictable market authorisation procedures requires a revised exemption mechanism, provided in Annex I B;
(7) Directive 2001/18/EC should therefore be amended accordingly;

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Annex I B of Directive 2001/18/EC shall be replaced by 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 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.

Signature

Annex

Annex I B

TECHNIQUES REFERRED TO IN ARTICLE 3

I. Techniques of genetic modification as referred to in article 3, to which this Directive shall not apply, shall only yield organisms resulting from the use thereof in as far as these organisms no longer contain recombinant nucleic acid molecules that are used for or during modification and do not contain genetically modified organisms other than those produced by one or more of the techniques, methods or applications referred to in this annex.

II. As regards the non-applicability of this Directive to the techniques referred to in this annex, any person deliberately releasing a genetically modified organism obtained with these techniques, shall, at the request of the Commission or a competent authority of a Member State, provide without undue delay a written justification as regards the fulfilment of the provisions of this annex.

III. Without prejudice to the above conditions, techniques referred to in article 3 are:

A) the following techniques, methods or applications thereof:
   (1) conventional random mutagenesis methods using ionising radiation or mutagenic chemical agents;
   (2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods;

B) techniques, methods or applications thereof resulting in plants, provided that:
   (1) no other genetic material is introduced into the resulting plant than genetic material from the same plant species or from a plant species with which it can exchange genetic material through traditional breeding methods, and
   (2) recombinant nucleic acid molecules that are used for or during modification are no longer present in the resulting plant that is meant for deliberate introduction into the environment.

IV. Every five years the Commission, following consultation with relevant stakeholders and in collaboration with the competent authorities of the Member States, shall review this annex. The first review shall be completed by 1 January 2023.¨

§ 5. Justification

This paragraph contains a justification of the proposed changes to the currently existing legislation.

1) In this proposal, the content of Annex I B is defined by article 3 of the Directive, meaning that the Annex can only contain techniques of genetic modification as referred to in article 3, to which the Directive shall not apply.

   The Directive does not define "techniques of genetic modification". During the past years discussions have taken place about the question what constitutes a "technique of genetic modification". In order to obtain clarity and legal certainty, either this term should be defined or it should be used in its broadest sense.

   It is proposed to do the latter and subsequently focus on criteria for the products resulting from modification techniques used, rather than specifying what is to be understood by a technique of genetic modification.

2) The proposal fully includes the content of the current Annex I B in terms of organisms to which the Directive shall not apply. Although, for plants, the content of part A) may be considered to be covered as well by part B), for the sake of consistency and clarity it has been included in this proposal for legal certainty reasons. However, in order to improve the wording of it, particularly in relation to terminology that may be multi-interpretable, it is proposed to introduce a more specific wording for mutagenesis, as has been done in this proposal. The adjusted wording is in line with the explanation note provided by the Scientific Advice Mechanism in 2017 at the request of the European Commission.[3]

   The adjusted wording merely aims to clarify and does not in any way pre-empt the outcome of the case that is before the European Court of Justice regarding the interpretation of Annex I B of the Directive with regard to mutagenesis (case C-528/16). The proposal includes under part A) (1) the currently exempted technique "mutagenesis" but specifies it as: conventional random mutagenesis methods using ionising radiation or mutagenic chemical agents. Other techniques that could be considered more directed forms of mutagenesis, and for which the European Court of Justice is asked to decide whether or not these fall under the term mutagenesis, are hence excluded from part A)(1) of the proposal. These directed mutagenesis techniques used in plants are, however, covered under part B). Hence, if the European Court of Justice decides that mutagenesis must be interpreted in a narrow manner (part A) (1)), this proposal is congruent with that outcome. On the other hand, in case the Court decides mutagenesis must be interpreted in a broader manner, part B) of this proposal encompasses that outcome as well for plants. The possible need for inclusion of other mutagenesis methods in part A) or other organisms than plants in part B) fully depends on the outcome of the court case.

3) This proposal also includes the technical criterion applicable to the scope of the annex, that is currently already included in the existing Annex I B. The existing annex only applies to organisms resulting from the use of techniques of genetic modification in as far as these specific organisms do not involve the use of:

[3] New Techniques in Agricultural Biology, http://ec.europa.eu/research/sam/index.cfm?pg=agribiotechnology.

a. recombinant nucleic acid molecules, or
b. genetically modified organisms other than those produced by one or more of the techniques, methods or applications referred to in Annex I B.

In this proposal, the words “involve the use of” have been replaced by “contain” in order to introduce a product oriented approach, based on the aforementioned guiding principles.

In order to ensure that techniques are included in their broadest sense, the term “techniques, methods or applications” is used, in line with recital 17 of the Directive, whereas the current legislation refers to “techniques/methods”. This is solely done in order to avoid interpretation difficulties about whether or not a technical means (technique, method or application) should be considered to be a technique or not.

In line with answers from EFSA to questions of the European Commission[4], in this proposal a recombinant nucleic acid molecule is considered to be a molecule that is not generated by natural recombination and is generated by joining two or more nucleic acid molecules and which can replicate after its transfer into a living cell.

4) For the purpose of Annex I B, criteria in this proposal have been focused on the organisms resulting from modification techniques used, rather than specifying what is or what is not a technique of genetic modification. This enables an exemption mechanism – without amending the definition of a GMO – based on a product-based approach as opposed to the process-based approach, as is currently applicable.

5) As opposed to part A), part B) of this proposal only applies to plants that are genetically modified and fulfil the conditions provided therein. The reason for this limitation of scope to plants, as is also explained under the guiding principles for this proposal, is the associated breeding and selection process and the mandatory plant variety registration framework that all new and commercially bred plant varieties are subjected to. These frameworks have demonstrated to result in plants and plant varieties that are considered and have been demonstrated to be safe.

6) As regards the criterion embedded in part B (2), the purpose thereof is to ensure that recombinant nucleic acid molecules resulting from the modification process are no longer present in the organism. This includes the recombinant nucleic acid sequence itself as well as fragments thereof.

For legal certainty, enforceability and predictability, it is essential to establish a cut-off limit for enabling practical detection of recombinant nucleic acid molecules in plants, used for or during the modification. For this purpose reference is made to the term "recombinant nucleic acid molecules" as currently used in Annex IB of Directive 2001/18/EC and Annex II Part A of Directive 2009/41/EC. In line with these Directives and with the EFSA answers, referred to under 3) above, a recombinant nucleic acid molecule is considered to be created outside the cells through the formation of a new combination of genetic material or nucleic acid

[4] ref. letter 15 October 2015, ref EW/Age/Ago/MR/lg(2015) – out – 14680359

molecules[5]. As regards part B)(1) of this proposal, the main underlying assumption is that scientifically it can be justified that plants, obtained in a manner in which all conditions of part B) are fulfilled, can also be obtained through traditional breeding methods[6]. Techniques fulfilling the criteria of this proposal are considered to enable similar changes in the plant genome as can be obtained with traditional breeding methods. The current practice of traditional breeding and the mandatory plant variety registration yield plants that are considered to be safe for human health and the environment. Genetically modified plants that are obtained through techniques referred to under part B) must therefore, when a similar selection process and quality control framework are applied as is the case during traditional breeding, and provided a successful plant variety registration is accomplished, be considered equally safe for human health and the environment.

Traditional breeding methods to improve plant production by crossing superior plants with other compatible plants has been performed for thousands of years. The last 60 years, genes have been specifically mutated by mutagenesis using chemical compounds or irradiation, followed by screening of populations for the desirable traits. Traditional plant breeding techniques, including conventional mutagenesis, translocation breeding and intergeneric crosses, are intrinsically very non-specific[7]. However, due to subsequent screening and selection processes, followed by mandatory variety registration, traditionally bred plant varieties are generally regarded as safe. Plants that comply with the criteria under part B) are plants in which only DNA is introduced that can also be obtained by intergeneric crossing, or mutations that are similar to or more specific than those induced by classical mutagenesis, and that can also be obtained by traditional breeding. This is followed by a similar screening and selection process, including mandatory variety registration, as for plants obtained through traditional breeding. Therefore plants that meet the criteria under part B) can be considered equally safe as plants obtained by traditional breeding[6].

7) This proposal shall have no consequence for the applicability of other EU-legislation on organisms to which Directive 2001/18/EC shall not apply due to exemption on the basis of Annex I B. These organisms remain GMOs as defined in the Directive hence similarly as under the current legislation.

8) As regards the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms it is noted that Regulation 1830/2003 defines a GMO as “genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex

[5] As regards the number of nucleotides constituting a new combination of genetic material or nucleic acid molecules, it may be considered – in line with the views of a majority of EU experts participating in the NPT-working group (New Techniques Working Group (2012) Final Report, European Commission) – that in order to form such a new combination, a nucleotide sequence of at least 20 bp is required. Although a minority of experts felt at the time that, in view of the definition of a GMO, the replacement of one single nucleotide in a nucleic acid molecule could be interpreted as producing a recombinant nucleic acid, the weight of this difference of opinion among experts becomes less relevant in view of the product-oriented approach of this proposal for Annex I B.

[6] http://edepot.wur.nl/141713 van der Wiel al, 2010

[7] Hartung and Schiemann, 2014, http://onlinelibrary.wiley.com/doi/10.1111/tpj.12413/full

I B to Directive 2001/18/EC". Similarly, all organisms to which the Directive shall not apply, based on this proposal, also do not need to be labelled.

9) Directive 2015/412/EU amends 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. To GMOs falling within the scope of Annex I B of Directive 2001/18/EC, however, the requirements of that Directive do not apply. Therefore, the possibility for the Member States to restrict or prohibit the cultivation of these exempted GMOs in their territory cannot be based on Directive 2001/18/EC. Hence, for those exempted GMOs, a Member State that wishes to ban or restrict their cultivation in its territory has to initiate national legislative measures to that extent, in accordance with the provisions of the Treaty on the Functioning of the European Union.

10) As also mentioned above (under 2), plants obtained by conventional random mutagenesis methods and cell fusion as mentioned under part A) can also be considered to be covered by the criteria under part B): in case of mutagenesis by irradiation or chemicals, there is no involvement of recombinant nucleic acid molecules or introduction of new DNA. Also, fusion of plant cells does not involve the use of recombinant nucleic acid molecules. Fusion of plant cells leads to a situation where complete genomes of different plant cells are fused. Under the conditions of part A) (2), only genomes are fused from plants that can exchange genetic material through traditional breeding methods.

11) Organisms obtained by agro-infiltration *sensu stricto*, RNA-dependent DNA methylation and reverse breeding are created by using recombinant nucleic acid molecules that are only transiently present in the plant cells [8]. These organisms can therefore be considered to meet the criteria as described under part B) if it is demonstrated that the resulting plants no longer contain recombinant nucleic acid molecules.

    In organisms obtained by cisgenesis, DNA from the same plant or closely related species (cisgene) is introduced, often involving the use of recombinant nucleic acid molecules. These organisms can be considered to meet the criteria as described under part B), provided that the introduced DNA originates from species that can exchange genetic material through traditional breeding methods and it is demonstrated that such organisms do not contain recombinant nucleic acid molecules.

12) Organisms obtained by gene-editing techniques such as oligo-directed mutagenesis (ODM) and site directed nucleases such as CRISPR-Cas, Zinc finger, TALEN and meganucleases result in specific, targeted mutations which are created by using recombinant nucleic acid molecules that are only transiently present in the plant cells. These organisms can be considered to meet the criteria of part B), provided it can be demonstrated that these organisms no longer contain recombinant nucleic acid molecules used for modification.

[8] New Techniques Working Group (2012) Final Report, European Commission;
LUSSER, M.; PARISI, C.; PLAN, D. & RODRIGUEZ-CEREZO, E (2011): New plant breeding techniques. State-of-the-art and prospects for commercial development. Rep. EUR 24760 EN. European Commission - Joint Research Centre, Institute for Prospective Technological Studies. (http://ftp.jrc.es/EURdoc/JRC63971.pdf)