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From:	Presidency
To:	Delegations
Subject:	Regulation on new genomic techniques (NGT) – Revised Presidency compromise text on Articles 1-11 and Annex I

With a view to the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) on 14 November 2023, delegations will find in annex a revised Presidency compromise text on Articles 1-11 and Annex I.

In comparison to doc. 15205/23, this REV 1 covers also Article 5(3) and Annex I, and it includes amendments to Recitals 14 ff. and 44 as well as Annex I. All other recitals and articles are unchanged.

Changes with respect to the Commission proposal have been marked with underline for insertions and ~~strikethrough~~ for deletions.

New changes (i.e. those that were not introduced in a previous document) have been marked with blue highlight, and those specific to this REV 1 with green highlight.

ANNEX

2023/0226 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on plants obtained by certain new genomic techniques and their products ~~food and feed~~, and amending Regulation (EU) 2017/625

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 114 and 168(4) (b) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Since 2001, when Directive 2001/18/EC of the European Parliament and of the Council ([1]), on the deliberate release of genetically modified organisms (GMOs) into the environment was adopted, significant progress in biotechnology has led to the development of new

[1] 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 (OJ L 106, 17.4.2001, p. 1).

genomic techniques (NGTs), most prominently genome editing techniques that enable changes to be made to the genome at targeted ~~precise~~ locations.

(2) NGTs constitute a diverse group of genomic techniques, and each of them can be used in various ways to achieve different results and products. They can result in organisms with modifications equivalent to what can be obtained by conventional breeding methods or in organisms with more complex modifications. Among NGTs, targeted mutagenesis and cisgenesis (including intragenesis) introduce genetic modifications without inserting genetic material from non-crossable species (transgenesis). They rely only on the breeders' gene pool, i.e. the total genetic information that is available for conventional breeding including from distantly related plant species that can be crossed by advanced conventional breeding techniques (excluding genetic modification techniques other than those listed in Annex I B of Directive 2001/18/EC). The European Food Safety Authority ('the Authority'), in its scientific opinion on plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases[2] and the High Level Group of the Commission´s Scientific Advice Mechanism in its Explanatory note on New techniques in agricultural biotechnology[3] provide an overview of the ~~current~~ state of these conventional breeeding techniques. Targeted mutagenesis techniques result in modification(s) of the DNA sequence at precise locations in the genome of an organism. Cisgenesis techniques result in the insertion, in the genome of an organism, of genetic material already present in the breeders' gene pool. ~~Intragenesis is a subset of cisgenesis resulting in the insertion in the genome of a rearranged copy of genetic material composed of two or more DNA sequences already present in the breeders' gene pool.~~ The genetic material may be incorporated as a continuos (exact) copy (cisgenesis in the strict sense) or a re-arranged copy of sequences already present in the breeder´s gene pool (intragenesis, also considered a subset of cisgenesis in a broader sense). Intragenic plants result from the use of intragenesis techniques, but can be also obtained by ~~through~~ cisgenesis techniques in the strict sense. In the latter case, new developments of site-directed modification also offer the possibility to target the insertion of continuous DNA sequences

[2] EFSA Panel on Genetically modified organisms (GMO); Scientific opinion addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function. EFSA Journal 2012;10(10):2943. [31 pp.] doi:10.2903/j.efsa.2012.2943. Available online: https://www.efsa.europa.eu/en/efsajournal/pub/2943.

[3] European Commission, Directorate-General for Research and Innovation, *New techniques in agricultural biotechnology*, Publications Office, 2017, https://data.europa.eu/doi/10.2777/574498

other than complete genes (for example promoters or regulatory sequences), from the breeders' gene pool at specific loci in the genome. When the insertion of such fragments occurs within an endogenous gene, interrupting it, this leads to the formation of a rearranged gene in the recipient plant and, as such, the plant should also be considered intragenic, except in those particular cases in which the resulting DNA sequences in the recipient plant already occur in species from the breeder´s gene pool.

(3) There is ongoing public and private research using NGTs on a wider variety of crops and traits compared to those obtained by ~~through~~ transgenic techniques authorised in the Union or globally([4]). This includes plants with improved tolerance or resistance to plant diseases and pests, plants with improved tolerance or resistance to climate change effects and environmental stresses, improved nutrient and water-use efficiency, plants with higher yields and resilience and improved quality characteristics. These types of new plants, coupled with the fairly easy and speedy applicability of those new techniques, could deliver benefits to farmers, consumers and to the environment. Thus, NGTs have the potential to contribute to the innovation and sustainability goals of the European Green Deal ([5]) and of the 'Farm to Fork' ([6]), Biodiversity ([7]) and Adaptation to Climate Change([8]) Strategies, to

[4] Insights and solutions stemming from EU-funded research and innovation projects on plant breeding strategies may contribute to address detection challenges, ensure traceability and authenticity, and promote innovation in the area of new genomic techniques. More than 1,000 projects were funded under the Seventh Framework Programme and successor Horizon 2020 programme with an investment of over 3 billion Euros. Horizon Europe support to new collaborative research projects on plant breeding strategies is also ongoing, SWD(2021) 92.

[5] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal, COM/2019/640 final.

[6] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A Farm to Fork Strategy for a fair, healthy and environmentally friendly food system, COM/2020/381 final.

[7] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, EU Biodiversity Strategy for 2030: Bringing nature back into our lives, COM/2020/380 final.

[8] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions forging a Climate-Resilient Europe - The New EU Strategy on Adaptation to Climate Change, COM(2021) 82 final

global food security ([9]), the Bioeconomy Strategy ([10]) and to the Union's strategic autonomy ([11]).

(4) The deliberate release into the environment of organisms obtained by NGTs, including products containing or consisting of such organisms, as well as the placing on the market of food and feed produced from these organisms, are subject to Directive 2001/18/EC and, Regulation (EC) No 1830/2003 ([12]) of the European Parliament and of the Council and, in the case of food and feed, also to Regulation (EC) No 1829/2003 ([13]), while the contained use of plant cells is subject to Directive 2009/41/EC, and transboundary movements of these organisms ~~NGT plants~~ to third countries are regulated by Regulation (EC) No 1946/2003 (taken together, 'the Union GMO legislation').

(5) In its judgment in case C-528/16 *Confédération paysanne and Others*[14] the Court of Justice of the European Union held that GMOs obtained by means of new techniques/methods of mutagenesis that had appeared or had been mostly developed since Directive 2001/18/EC was adopted could not be considered excluded from the scope of that Directive.

(6) The Council, in Decision (EU) 2019/1904[15], requested the Commission to submit, by 30 April 2021, a study in light of that judgment regarding the status of novel genomic

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9 Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, Safeguarding food security and reinforcing the resilience of food systems, COM (2022) 133 final; Food and Agriculture Organisation of the United Nations (FAO), 2022, Gene editing and agrifood systems, Rome, ISBN 978-92-5-137417-7.

10 European Commission, Directorate-General for Research and Innovation, A sustainable bioeconomy for Europe – Strengthening the connection between economy, society and the environment: updated bioeconomy strategy, Publications Office, 2018, https://data.europa.eu/doi/10.2777/792130.

11 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Trade Policy Review - An Open, Sustainable and Assertive Trade Policy, COM(2021)66 final.

12 Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

13 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).

14 Judgement of the Court of Justice of 25 July 2018, Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt, C-528/16, ECLI:EU:C:2018:583.

15 Council Decision (EU) 2019/1904 of 8 November 2019 requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the

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techniques under Union law, and a proposal (accompanied by an impact assessment), if appropriate, depending on the conclusions of the study.

(7) The Commission's study on new genomic techniques ([16]) concluded that the Union GMO legislation is not fit for the purpose of regulating the deliberate release of plants obtained by certain NGTs and the placing on the market of related products including food and feed. In particular, the study concluded that the authorisation procedure and risk assessment requirements for GMOs under the Union GMO legislation are not adapted to the variety of potential organisms and products that can be obtained by ~~with~~ some NGTs, namely targeted mutagenesis and cisgenesis (including intragenesis), and these requirements can be disproportionate or inadequate. The study showed that this is particularly the case for plants obtained by these techniques, given the amount of scientific evidence that is already available, in particular on their safety. Furthermore, the Union GMO legislation is difficult to implement and enforce for plants obtained by targeted mutagenesis and cisgenesis and related products. In certain cases, genetic modifications introduced by these techniques are indistinguishable with analytical methods from natural mutations or from genetic modifications introduced by conventional breeding techniques, whereas the distinction is generally possible for genetic modifications introduced by transgenesis. The Union GMO legislation is also not conducive to developing innovative and beneficial products that could contribute to sustainability, food security and resilience of the agri-food chain.

(8) It is therefore necessary to adopt a specific legal framework for GMOs obtained by targeted mutagenesis and cisgenesis and related products when deliberately released into the environment or placed on the market.

(9) Based on the current scientific and technical knowledge in particular on safety aspects, this Regulation should be limited to GMOs that are plants, i.e. organisms in the taxonomic groups Archaeplastida or Phaeophyceae, excluding microorganisms, fungi and animals for which the available knowledge is more limited. For the same reason, this Regulation should only cover plants obtained by certain NGTs: targeted mutagenesis and cisgenesis (including intragenesis) (hereinafter 'NGT plants'), but not by other new genomic techniques. Such NGT plants do not carry genetic material from non-crossable species. GMOs produced by

status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study (OJ L 293, 14.11.2019, p. 103).

16 Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16, SWD(2021) 92 final.

other new genomic techniques that introduce into an organism genetic material from non-crossable species (transgenesis) should remain subject only to the Union GMO legislation, given that the resulting plants might bear specific risks associated to the transgene. Moreover, there is no indication that current requirements in the Union GMO legislation for GMOs obtained by transgenesis need adaptation at the present time.

(10) The legal framework for NGT plants should share the objectives of the Union GMO legislation to ensure a high level of protection of human and animal health and of the environment and the good functioning of the internal market for the concerned plants and their products, while addressing the specificity of NGT plants. This legal framework should enable the development and placing on the market of plants~~,~~ and their products (including food and feed) obtained by ~~with~~ NGTs ~~containing, consisting of or produced from NGT plants and other products containing or consisting of NGT plants ('NGT products')~~ so as to contribute to the innovation and sustainability objectives of the European Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies and to enhance the competitiveness of the Union agri-food sector at Union and world level.

(11) This Regulation constitutes *lex specialis* with regard to the Union GMO legislation. It introduces specific provisions for NGT plants and their ~~NGT~~ products. However, where there are no specific rules in this Regulation, NGT plants and their products ~~(including food and feed)~~ obtained from them should remain subject to the requirements of the Union GMO legislation and the rules on GMOs in sectoral legislation, such as Regulation (EU) 2017/625 on official controls or the legislation on certain products like plant and forest reproductive material.

(11a) In keeping with the Union GMO legislation, this Regulation should include under its scope NGT plants~~,~~ and their products (food and feed containing, consisting of or produced from such NGT plants, and ~~other~~ products, other than food and feed, containing or consisting of such NGT plants, ~~(~~ hereinafter 'NGT products'). Plant reproductive material, including forest reproductive material, falls under the scope of this Regulation both ~~as a~~ under the term 'plant' (when it is deliberately relased into the environment ~~for any purpose other than the placing on the market~~) and ~~as a~~ under the term 'product' (when it is placed on the market, including for the purpose of ~~commercial~~ cultivation).

(12) The potential risks of NGT plants vary, ranging from risk profiles similar to conventionally-bred plants to various types and degrees of hazards and risks that might be similar to those

of plants obtained by transgenesis. This Regulation should therefore lay down special rules to adjust the risk assessment and risk management requirements according to the potential risks or lack thereof posed by NGT plants and NGT products.

(13) This Regulation should distinguish between two categories of NGT plants.

(14) ~~NGT~~ "Category 1 NGT plants" are ~~includes~~ plants that could also occur naturally or be produced by conventional breeding techniques ~~and their progeny obtained by conventional breeding techniques ('category 1 NGT plants')~~. This category should be treated in the same way as plants that have occurred naturally or have been produced by conventional breeding techniques, given that they are equivalent and that their risks are comparable, thereby derogating in full from the Union GMO legislation and GMO-related requirements in sectoral legislation. In order to ensure legal certainty, this Regulation should set out the criteria to ascertain if a NGT plant is equivalent to naturally occurring or conventionally bred plants (criteria for category 1 NGT plant) and lay down a procedure for competent authorities to verify and take a decision on the fulfillment of those criteria, prior to the release or placing on the market of NGT plants or NGT products. Those criteria should be objective and based on up-to-date scientific knowledge ~~science~~. They should cover the type and extent of genetic modifications that can be observed in nature or in organisms obtained with conventional breeding techniques and should include thresholds for both size and number of genetic modifications to the genome of NGT plants. ~~Targeted substitutions and insertions of limited size, deletions and targeted inversions of any size as well as larger targeted substitutions with, and insertions of, continuous sequences of genetic material from the breeder´s gene pool should be included in the criteria for category 1 NGT plants, under certain conditions to exclude intragenic plants. Novel hazards can be associated with intragenic plants compared with cisgenic and conventionally bred plants[17][18], therefore intragenic plants should remain subject to the Union GMO legislation and be excluded from the criteria for category 1 NGT plants. Since scientific and technical knowledge evolves rapidly in this area, the Commission should be empowered in accordance with Article 290 of~~

~~[17] EFSA Panel on Genetically Modified Organisms (GMO); Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. EFSA Journal 2012;10(2):2561, 33 pp. doi:10.2903/j.efsa.2012.2561. Available online: https://www.efsa.europa.eu/en/efsajournal/pub/2561.~~

~~[18] EFSA Panel on Genetically Modified Organisms ; Updated scientific opinion on plants developed through cisgenesis and intragenesis. EFSA Journal 2022;20(10):7621, 33 pp. https://doi.org/10.2903/j.efsa.2022.7621.~~

~~the Treaty on the Functioning of the European Union to update these criteria in light of scientific and technical progress as regards the type and extent of genetic modifications that can occur in nature or through conventional breeding.~~

(14 bis) Current scientific knowledge indicates that targeted mutagenesis and cisgenesis techniques can lead to genetic modifications that are similar to mutations occurring spontaneously in nature or as a result of conventional breeding techniques. These mutations include substitutions, insertions (including duplications, translocations and inversions) and deletions of nucleotides in the DNA. Furthermore, insertion of genetic material from the breeders´ gene pool is also possible through crossing or conventional breeding. The scientific literature also shows differences in the size of these invidual genetic modifications and in the number of genetic modifications per plant, considering also for the latter the ploidy level of the plant. In addition, the efficiency varies between breeding techniques. On this basis, targeted substitutions and insertions of limited size, deletions and targeted inversions of any size as well as larger targeted substitutions with, and insertions of, continuous sequences of genetic material from the breeders´ gene pool should be included in the criteria for category 1 NGT plant. In addition, those criteria should include certain conditions in order to exclude intragenic plants from category 1 NGT plants since novel hazards can be associated with intragenic plants compared with cisgenic and conventionally bred plants[19][20].

(14a) Since category 1 NGT plants encompass~~es~~ plants that are equivalent to plants occurring naturally or produced by conventional breeding and that should be treated in the same way as those plants, ~~also~~ their progeny obtained by conventional breeding techniques should also be treated accordingly and be included under category 1 NGT plants. Therefore, the progeny deriving from the application of conventional breeding techniques to a category 1 NGT plant, including the result of the crossing of a category 1 NGT plant with a conventionally bred plant, or of the crossing of two category 1 NGT plants, should remain subject to the provisions of category 1 NGT plants without the need to go through the verification

[19] EFSA Panel on Genetically Modified Organisms (GMO); Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. EFSA Journal 2012;10(2):2561, 33 pp. doi:10.2903/j.efsa.2012.2561. Available online: https://www.efsa.europa.eu/en/efsajournal/pub/2561.

[20] EFSA Panel on Genetically Modified Organisms ; Updated scientific opinion on plants developed through cisgenesis and intragenesis. EFSA Journal 2022;20(10):7621, 33 pp. https://doi.org/10.2903/j.efsa.2022.7621.

procedure, prior to their release or placing on the market. Conversely, the progeny deriving from the application of targeted mutagenesis or cisgenesis to a category 1 NGT plant shall be subject to the procedure to verify the fulfillment of the criteria for category 1 NGT plants, prior to its release or placing on the market as category 1 NGT plant. If those criteria are not met, the progeny can be released or placed on the market only as category 2 NGT plant.

(14b) Since scientific and technical knowledge evolves rapidly in this area, the Commission should be empowered in accordance with Article 290 of the Treaty on the Functioning of the European Union to update the~~se~~ criteria for category 1 NGT plants in light of scientific and technical progress as regards the type and extent of genetic modifications that can occur in nature or through conventional breeding. This empowerment should only apply to the extent justified by available evidence of advances in scientific knowldege and technical progress following the adoption of this Regulation.

(15) All NGT plants that are not category 1 ('category 2 NGT plants') and their products (hereinafter 'category 2 NGT products') should remain subject to the requirements of the Union GMO legislation because they feature more complex sets of modifications to the genome.

(16) Category 1 NGT plants and their products (hereinafter 'category 1 NGT products') should not be subject to the rules and requirements of the Union GMO legislation and to provisions in other Union legislation that apply to GMOs. For legal certainty for operators and transparency, a declaration of the category 1 NGT plant status should be obtained prior to deliberate release, including the placing on the market.

(17) This declaration should be obtained prior to any deliberate release of any category 1 NGT plants for any other purpose than placing on the market, such as for field trials that are to take place in the territory of the Union, since the criteria are based on data that is available before the field trials and does not depend on these field trials. When no field trials are to take place in the territory of the Union, operators should obtain that declaration before placing the category 1 NGT product on the market.

(17a) The fact that a notification for consent or an application for authorisation has been submitted under Union GMO legislation does not preclude the subsequent submission of a request to obtain a declaration of category 1 NGT plant status for the same plant or product under the present regulation.

(18) Since the criteria for considering that a NGT plant is equivalent to naturally occurring or conventionally bred plants are unrelated to the type of activity that requires the deliberate release of the category 1 NGT plant, a declaration of the category 1 NGT plant status made prior to its deliberate release for any other purpose than placing on the market in the territory of the Union should also be valid for the placing on the market of related category 1 NGT products. In view of the high uncertainty existing at the field trial stage about the product reaching the market and the likely involvement of smaller operators in such releases, the verification procedure of category 1 NGT plant status prior to field trials should be conducted by ~~national~~ competent authorities of Member States as this would be less administratively burdensome for operators, and a decision should be taken at Union level only in case there are ~~comments~~ reasoned objections to the verification report, as regards the fulfillment of the criteria set out in Annex I, by ~~other national~~ competent authorities of other Member States. Where the verification request is submitted prior to the placing on the market of category 1 NGT products, the procedure should be conducted at Union level in order to ensure effectiveness of the verification procedure and consistency of the category 1 NGT plant status declarations.

(19) The competent authorities of the Member States, the Commission and the ~~European Food Safety~~ Authority ~~('the Authority')~~ should be subject to strict deadlines to ensure that category 1 NGT plant status declarations are made within a reasonable time.

(20) The verification of category 1 NGT plant status is of technical nature and does not involve any risk assessment or risk management considerations and the decision on the status is only declaratory. Therefore, when the procedure is conducted at Union level, such implementing decisions should be adopted by the advisory procedure, supported by scientific and technical assistance by the Authority.

(21) Decisions declaring the category 1 NGT plant status should assign an identification number to the category 1 NGT plant concerned in order to ensure transparency and traceability of such plants when they are listed in the database and for the purpose of labelling of plant reproductive material derived from them.

(22) Category 1 NGT plants should remain subject to any regulatory framework that applies to conventionally bred plants. As is the case for conventional plants and their products, those category 1 NGT plants and their category 1 NGT products will be subject to the applicable sectoral legislation on ~~seed and other plant reproductive material,~~ food, feed and ~~other~~

products other than food and feed, such as seed and other plant reproductive material, and horizontal frameworks, such as the nature conservation legislation and environmental liability. In this regard, category 1 NGT food featuring a significantly changed composition or structure that affects the nutritional value, metabolism or level of undesirable substances of the food will be considered as novel food and thus fall into the scope of Regulation (EU) 2015/2283 of the European Parliament and of the Council ([21]) and will be risk assessed in that context.

(23) Regulation (EU) 2018/848 of the European Parliament and the Council on organic production and labelling of organic products and repealing Council Regulation (EC) 834/2007([22]) prohibits the use of GMOs and products from and by GMOs in organic production. It defines GMOs for the purposes of that Regulation by reference to Directive 2001/18/EC, excluding from the prohibition GMOs which have been obtained through the techniques of genetic modification listed in Annex 1.B of Directive 2001/18/EC. As a result, category 2 NGT plants will be banned in organic production. However, it is necessary to clarify the status of category 1 NGT plants for the purposes of organic production. The use of new genomic techniques is currently incompatible with the concept of organic production in the Regulation (EC) 2018/848 and with consumers' perception of organic products. The use of category 1 NGT plants should therefore be also prohibited in organic production.

(24) Provision should be made to ensure transparency as regards the use of category 1 NGT plant varieties, to ensure that production chains that wish to remain free from NGTs can do so and thereby safeguard consumer trust. NGT plants that have obtained a category 1 NGT plant status declaration should be listed in a publicly available database. To ensure traceability, transparency and choice for operators, during research and plant breeding, when selling seed to farmers or making plant reproductive material available to third parties in any other way, plant reproductive material of category 1 NGT plants should be labelled as category 1 NGT.

[…]

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21 Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

22 Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (OJ L 150, 14.6.2018, p. 1).

(44) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ([23]). In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. It is of particular importance that the consultations be carried out on the basis of relevant reports which the Commission may be required to publish prior to adopting delegated acts.

[…]

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation lays down specific rules for the deliberate release into the environment for any other purpose than placing on the market of plants obtained by certain new genomic techniques ('NGT plants') and for the placing on the market of food and feed containing, consisting of or produced from such plants, and of products, other than food or feed, containing or consisting of such plants ('NGT products').

Article 2

Scope

This Regulation shall apply to:

[23] OJ L 123, 12.5.2016, p. 1

(1) NGT plants;

(2) food containing, consisting of or produced from NGT plants, or containing ingredients produced from NGT plants;

(3) feed containing, consisting or produced from NGT plants;

(4) products, other than food and feed, containing or consisting of NGT plants.

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Article 3

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) the definitions of 'organism', 'deliberate release' and 'placing on the market' set out in Directive 2001/18/EC, those of 'food' and 'feed' set out in Regulation (EC) No 178/2002, that of 'traceability' set out in Regulation (EC) No 1830/2003, that of 'plant' set out in Regulation (EU) 2016/2031 of the European Parliament and of the Council([24]) and that of 'plant reproductive material' set out in [the *Commission's Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of plant reproductive material in the Union*[25]];

(1a) 'genetically modified organism' or 'GMO' means a 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 I B to Directive 2001/18/EC;

(2) 'NGT plant' means a ~~genetically modified~~ plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the breeders' gene pool that temporarily may have been inserted during the development of the NGT plant;

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24 Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

25 COM(2023) 414 final

~~(3) 'genetically modified organism' or 'GMO' means a 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 I B to Directive 2001/18/EC;~~

(4) 'targeted mutagenesis' means mutagenesis techniques resulting in modification(s) of the DNA sequence at ~~precise~~ targeted locations in the genome of an organism;

(5) 'cisgenesis' means techniques of genetic modification resulting in the insertion, in the genome of an organism, of genetic material already present in the breeders' gene pool. The genetic material may be incorporated as a continuous (exact) copy (cisgenesis in the strict sense) or a re-arranged copy of sequences already present in the breeder´s gene pool (intragenesis, also considered a subset of cisgenesis in a broader sense);

(6) 'breeders' gene pool' means the total genetic information available in one species and other taxonomic species with which it can be cross-bred, including by using advanced techniques such as embryo rescue, induced polyploidy and bridge crosses;

(7) 'category 1 NGT plant' means a NGT plant that:

(a) fulfils the criteria of equivalence to conventional plants, set out in Annex I, or

(b) is progeny of the NGT plant(s) referred to in point (a), including progeny obtained ~~derived~~ by crossing of such plants, on the condition that there are no further modifications that would make it subject to Directive 2001/18/EC or Regulation 1829/2003;

(8) 'category 2 NGT plant' means a NGT plant other than a category 1 NGT plant;

(9) 'NGT plant for food use' means a NGT plant that may be used as food or as a source material for the production of food;

(10) 'NGT plant for feed use' means a NGT plant that may be used as feed or as a source material for the production of feed;

(11) 'produced from a NGT plant' means derived, in whole or in part, from a NGT plant, but not containing or consisting of a NGT plant;

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(12) 'NGT product' means ~~a product, other than food and feed, containing or consisting of a NGT plant and~~ food and feed containing, consisting of or produced from ~~such a plant~~ NGT plants, and ~~other~~ products other than food and feed containing or consisting of such plants;

(13) 'category 1 NGT product' means a NGT product where the NGT plant it contains, consists of or, in the cases of food or feed, is produced from, is a category 1 NGT plant;

(14) 'category 2 NGT product' means a NGT product where the NGT plant it contains, consists of or, in the cases of food or feed, is produced from, is a category 2 NGT plant;

(15) 'small or medium sized enterprise (SME)' means a SME within the meaning of Commission Recommendation 2003/361/EC[2].

Article 4

Deliberate release of NGT plants for any other purpose than placing on the market and placing on the market of NGT products

Without prejudice to other requirements of Union law, a NGT plant may only be deliberately released into the environment for any other purpose than placing on the market, and a NGT product may only be placed on the market, if:

(1) the plant is a category 1 NGT plant and

(a) has obtained a decision declaring that status in accordance with Article 6 or 7; or

(b) is progeny of plant(s) referred to in point (a); or

(2) the plant is a category 2 NGT plant, and has been granted consent or has been authorised, in accordance with Chapter III.

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CHAPTER II

Category 1 NGT plants and category 1 NGT products

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Article 5

Status of category 1 NGT plants and category 1 NGT products

1. The rules which apply to GMOs in Union legislation shall not apply to category 1 NGT plants that fulfill the condition of article 4(1) and their NGT products.

2. For the purposes of Regulation (EU) 2018/848, the rules set out in its Articles 5 (f) (iii) and 11 shall apply to category 1 NGT plants and to products produced from or by such plants.

3. The Commission is empowered to adopt delegated acts in accordance with Article 26 amending the criteria of equivalence of NGT plants to conventional plants laid down in Annex I in order to adapt them to scientific and technological progress, to the extent justified by advances in scientific knowledge, as regards the types and extent of modifications which can occur naturally or through conventional breeding. This empowerment shall be subject to the following conditions:

   (a) The Commission shall publish a report to justify that, on the basis of scientific evidence, the criteria of equivalence laid down in Annex I no longer reflect what can occur naturally or through conventional breeding. The report shall include an up-to-date scientific literature review as regards the types and extent of modification that can occur naturally or through conventional breeding.

   (b) Where applicable, the Commission shall take into account any relevant new or updated scientific opinions from the Authority.

Article 6

Verification procedure of category 1 NGT plant status for requests submitted prior to the deliberate release for any other purpose than placing on the market

1. To obtain the declaration of category 1 NGT plant status referred to in Article 4(1), point (a), before undertaking a deliberate release of a NGT plant for any other purpose than placing on the market, the person intending to undertake the deliberate release shall submit a request to verify whether the criteria set out in Annex I are met ('verification request') to the competent authority designated in accordance with Article 4(4) of Directive 2001/18/EC of the Member State within whose territory the release is to take place in accordance with paragraphs 2 and 3 and the implementing act adopted in accordance with Article 27, point (b).

2. Where a person intends to undertake such a deliberate release simultaneously in more than one Member State, that person shall submit the verification request to the competent authority of one of those Member States.

3. The verification request referred to in paragraph 1 shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, and shall include~~, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002~~:

   (a) the name and the address of the requester;

   (b) the designation and specification of the NGT plant;

   (c) a description of the trait(s) and characteristics which have been introduced or modified;

   (d) a copy of the studies, which have been carried out and any other available material to demonstrate that:

      (i) the plant is a NGT plant, including that it does not contain any genetic material originating from outside the breeders' gene pool where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the implementing act adopted in accordance with Article 27, point (a);

      (ii) the NGT plant meets the criteria set out in Annex I;

   Article 32b of Regulation (EC) No 178/2002 shall not apply;

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(e) in the cases referred to in paragraph 2, an indication of the Member States in which the requester intends to undertake the deliberate release;

(f) an identification of the parts of the verification request and any other supplementary information that the requester demands to be treated as confidential, accompanied by verifiable justification, pursuant to Article 11 of this Regulation and Article 39 of Regulation (EC) No 178/2002.

4. The competent authority shall acknowledge receipt of the verification request to the requester without undue delay, stating the date of receipt. It shall make available the request, accompanied by an English translation, to the other Member States and to the Commission without undue delay.

5. If the verification request does not contain all the necessary information, it shall be declared inadmissible by the competent authority within 30 working days within the date of receipt of a verification request. The competent authority shall inform the requester, the other Member States and the Commission without undue delay of the inadmissibility of the verification request and shall provide the reasons of its decision.

6. If the verification request is not deemed inadmissible in accordance with paragraph 5, the competent authority shall verify whether the NGT plant fulfils the criteria set out in Annex I and prepare a verification report within 30 working days from the date of receipt of a verification request. The competent authority shall make available the verification report to the other Member States and to the Commission without undue delay.

7. The other Member States and the Commission may make ~~comments~~ reasoned objections to the verification report, as regards the fulfillment of the criteria set out in Annex I, within 20 days from the date of receipt of that report.

8. In the absence of any ~~comments~~ reasoned objections from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

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9. In cases where ~~a comment is~~ reasoned objections are made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the ~~the comment(s)~~ reasoned objections to the other Member States and to the Commission without undue delay.

10. The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the ~~comment(s)~~ reasoned objections, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

11. The Commission shall publish a summary of the decisions referred to in paragraphs 8 and 10 in the *Official Journal of the European Union*.

Article 7

Verification procedure of category 1 NGT plant status for requests submitted prior to the placing on the market of NGT products

1. Where a declaration of category 1 NGT plant status referred to in Article 4(1), point (a), has not already been made in accordance with Article 6, to obtain such a declaration before placing on the market a NGT product, the person intending to place the product on the market shall submit a verification request to the Authority in accordance with paragraph 2 and the implementing act adopted in accordance with Article 27, point (b).

2. The verification request referred to in paragraph 1 shall be submitted to the Authority in accordance with standard data formats, where they exist, pursuant to Article 39f of Regulation (EC) No 178/2002, and shall include~~, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002~~:

   (a) the name and the address of the requester;

   (b) the designation and specification of the NGT plant;

   (c) a description of the trait(s) and characteristics which have been introduced or modified;

(d) a copy of the studies, which have been carried out and any other available material to demonstrate that:

(i) the plant is a NGT plant, including that it does not contain any genetic material originating from outside the breeders' gene pool where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the implementing act adopted in accordance with Article 27, point (a);

(ii) the NGT plant meets the criteria set out in Annex I;

Article 32b of Regulation (EC) No 178/2002 shall not apply.

(e) an identification of the parts of the verification request and any other supplementary information that the requester demands to be treated as confidential, accompanied by verifiable justification, pursuant to Article 11 of this Regulation and Article 39 of Regulation (EC) No 178/2002.

3. The Authority shall acknowledge receipt of the verification request to the requester without delay, stating the date of receipt. It shall make available the verification request to the Member States and to the Commission without undue delay and make public the verification request, relevant supporting information and any supplementary information supplied by the requester, in accordance with article 38(1) of Regulation (EC) No 178/2002, after omission of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 11 of this Regulation.

4. If the verification request does not contain all the necessary information, it shall be declared inadmissible by the Authority within 30 working days within the date of receipt of a verification request. The Authority shall inform the requester, the Member States and the Commission without undue delay of the inadmissibility of the verification request and shall provide the reasons of its decision.

5. If the verification request is not deemed inadmissible in accordance with paragraph 4, the Authority shall deliver its statement on whether the NGT plant fulfils the criteria set out in Annex I within 30 working days from the date of receipt of a verification request. The Authority shall make available the statement to the Commission and the Member States. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall

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make its statement public, after omission of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 11 of this Regulation.

6. The Commission shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 30 working days from the date of receipt of the statement of the Authority, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

7. The Commission shall publish a summary of the decision in the *Official Journal of the European Union*.

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Article 8

System of exchange of information between Member States, the Commission and the Authority

The Commission shall set up and maintain an electronic system for the submission of verification requests in accordance with Articles 6 and 7 and the exchange of the information under this ~~Title~~ Chapter.

Article 9

Database of decisions declaring the category 1 NGT plant status

1. The Commission shall establish and maintain a database listing the decisions declaring the category 1 NGT plant status adopted in accordance with Article 6(8) and (10) and Article 7(6).

   The database shall contain the following information:

   (a) name and the address of the requester;

   (b) the designation of the category 1 NGT plant;

   (c) a summarised description of the technique(s) used to obtain the genetic modification;

(d) a description of the trait(s) and characteristics which have been introduced or modified;

(e) an identification number, and

(f) the decision referred to in Article 6(8) or (10), and Article 7(6), as appropriate.

2. The database shall be publicly available.

Article 10

Labelling of category 1 NGT plant reproductive material, including breeding material

Plant reproductive material, including for breeding and scientific purposes, that contains or consists of category 1 NGT plant(s) and is made available to third parties, whether in return for payment or free of charge, shall bear a label indicating the words 'cat 1 NGT', followed by the identification number of the NGT plant(s) it has been derived from.

Article 11

Confidentiality

1. The requester referred to in Articles 6 and 7 may submit a request to the Member State competent authority or to the Authority, as appropriate, to treat certain parts of the information submitted under this ~~Title~~ Chapter as confidential, accompanied by verifiable justification, in accordance with paragraphs 3 and 6.

2. The competent authority or the Authority, as appropriate, shall assess the confidentiality request referred to in paragraph 1.

3. The competent authority or the Authority, as appropriate, may grant confidential treatment only with respect to the following items of information, upon verifiable justification, where the disclosure of such information is demonstrated by the requester to potentially harm its interests to a significant degree:

(a) items of information referred to in points (a), (b) and (c) of Article 39(2) of Regulation (EC) No 178/2002;

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(b) DNA sequence information; and

(c) breeding patterns and strategies.

4. The competent authority or the Authority, as appropriate, shall, after consultation with the requester, decide which information is to be treated as confidential and shall inform the requester of its decision.

5. Member States, the Commission and the Authority shall take the necessary measures to ensure that confidential information notified or exchanged under this Chapter is not made public.

6. The relevant provisions of Articles 39e and 41 of Regulation (EC) No 178/2002 shall apply mutatis mutandis.

7. In the event of a withdrawal of the verification request by the requester, Member States, the Commission and the Authority shall respect the confidentiality as granted by the competent authority or the Authority in accordance with this Article. Where the withdrawal of the verification request takes place before the competent authority or the Authority has decided on the relevant confidentiality request, Member States, the Commission and the Authority shall not make public the information for which confidentiality has been requested.

[…]

ANNEX I

Criteria of equivalence of NGT plants to conventional plants

A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications per monoploid genome of the types referred to in points 1 to ~~5~~4, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.

Criteria specific to the use of targeted mutagenesis:

(1) substitution or insertion of no more than 20 nucleotides;

deletion of any number of nucleotides;

Criteria specific to the use of cisgenesis:

on the condition that the genetic modification does not interrupt an endogenous gene or that the resulting combination of DNA sequences in the recipient plant already occurs in a species from the breeders' gene pool:

~~targeted~~ insertion of a ~~contiguous~~ continuous DNA sequence existing in the breeders'~~s~~ gene pool;

~~targeted~~ substitution of an endogenous DNA sequence with a ~~contiguous~~ continuous DNA sequence existing in the breeders'~~s~~ gene pool;

targeted inversion of a sequence of any number of nucleotides.;

~~any other targeted modification of any size, on the condition that the resulting DNA sequences in the recipient plant already occur (possibly with modifications as accepted under points (1) and/or (2)) in a species from the breeders' gene pool:.~~

~~(a) targeted insertion of a continuos DNA sequence existing in the breeders' gene pool;~~

~~(b) targeted substitution of an endogenous DNA sequence with a continuous DNA sequence existing in the breeders' gene pool.~~

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