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From:	Presidency
To:	Delegations
Subject:	Regulation on new genomic techniques (NGT) *– Revised Presidency text*

With a view to the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) on 20 January 2025, delegations will find in annex a revised Presidency text.

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

The Presidency has based its revisions on the text prepared for the meeting of the Permanent Representatives Committee on 7 February 2024 (doc. 16714/23). New changes (i.e. those that were not introduced in doc. 16714/23) have been marked with yellow highlight.

ANNEX

2023/0226 (COD)

Draft

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 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 targeted ~~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~~

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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).

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

~~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 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

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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.

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 ([14]), and transboundary movements of these organisms ~~NGT plants~~ to third countries are regulated by Regulation (EC) No 1946/2003 ([15]) (taken together, 'the Union GMO legislation').

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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

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 Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75).

15 Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movement of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

(5) In its judgment in case C-528/16 *Confédération paysanne and Others*[16] 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[17], requested the Commission to submit, by 30 April 2021, a study in light of that judgment regarding the status of novel genomic 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 ([18]) 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 European Union Reference Laboratory for GM Food and Feed (EURL), in collaboration with the European Network of GM Laboratories (ENGL) stressed that products that have identifical DNA sequence but have been developed either naturally or by conventional breeding or by

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16 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.

17 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 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).

18 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.

using certain new genomic techniques cannot be distinguished by analytical methods ([19]). 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 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.

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[19] European Network of GMO Laboratories (ENGL), Detection of food and feed plant products obtained by new mutagenesis techniques, 26 March 2019 (JRC116289); 13 June 2023 (JRC133689; EUR 31521 EN).

(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 of equivalence ~~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 by ~~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[2021]; 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 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,

~~[20] 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.~~

~~[21] 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.~~

continuous sequences of genetic material from the breeders´ gene pool should be included in the criteria of equivalence ~~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[2223].

(14 ter) Herbicide tolerant plants are bred to be intentionally tolerant to herbicides, in order to be cultivated in combination with the use of those herbicides. If such cultivation is not done under appropriate conditions, it may lead to development of weeds resistant to those herbicides or to the need to increase of quantities of herbicides applied, regardless of the breeding technique, with the risk of a negative impact on human and animal health and the environment In addition, the Farm to Fork Strategy proposes specific targets to reduce the use of pesticides by 2030. This Regulation should also contribute to these objectives. Therefore, the development and use of NGT plants that include tolerance to herbicides among the intended traits conveyed by the genetic modification should be followed up and these plants should remain subject to authorization, traceability, and monitoring requirements. Therefore, NGT plants that include tolerance to herbicides among the intended traits conveyed by the genetic modification should be subject to the provisions for category 2 NGT plants.

(14 quater) Subject to exclusions, patents may be granted on any inventions, whether products or processes, in accordance with Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights[24]. According to Article 28 of the agreement, where the subject matter of a patent is a product, that patent grants its owner exclusive rights to that product, while where the subject matter of a patent is a process, that patent grants its owner both exclusive rights to that process and to the product obtained directly from that process.

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22 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.

23 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.

24 World Trade Organization; Agreement on Trade-Related Aspects of Intellectual Property Rights. Available online: https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm

(14 quinquies) The balance between effective protection of invention and stimulation of research and development and the expectations of breeders to have free access to varieties for the development of new varieties should be maintained.

(14 sexies) Free access to all varieties for the purpose of breeding or discovering and developing of new varieties known as breeders' exemption is guaranteed by Union rules on Community plant variety rights which aims to ensure freedom of action and is known to promote innovation in European plant breeding. It also provides “open access” to the biodiversity needed to produce new varieties. This legal framework ensures that diversity is maintained in the European seed market.

(14 septies) Patents whose subject matter is a process (process patents) can protect basic techniques by which biological material is produced, modified or processed, or they can protect methods of introducing specific characteristics in the biological material that result in a particular trait. In order to strike a balance between protection of innovations in the field of basic technologies and the freedom to use the broadest possible pool of material for breeding purposes, it is justified to differentiate between process patents protecting basic technologies and process patents that result in a specific characteristic (trait).

(14 octies) Striking a balance between the legitimate interests of innovators seeking protection and the legitimate interests of third parties seeking access to breeding material requires that additional conditions apply to the placing on the market of plant reproductive material of category 1 NGT plants protected by one or more product patents or process patents where the process results in a specific characteristic (trait).

(14a) Since category 1 NGT plants encompass~~es~~ plants that are equivalent to plants occurring naturally or ~~produced~~ obtained 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 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 of equivalence ~~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 of equivalence ~~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 knowledge and technical progress following the adoption of this Regulation.

(15) All NGT plants that are not category 1 NGT plants ('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~~ conditions for category 1 NGT plants, 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 ([25]) 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([26]) 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. Moreover, in certain circumstances it may be necessary for Member States to adopt

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[25] 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).

[26] 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).

appropriate measures on their territory to avoid the unintended presence of category 1 NGT plants in organic agriculture, in particular in areas with specific geographical conditions, such as certain Mediterranean island Member States and insular regions, in accordance with Article 29(7) of Regulation (EU) 2018/848.

(24 bis) An additional labelling requirement for NGT 1 plant reproductive material which is protected by a patent followed by the inclusion of such information in the commercial documentation of such material and in the databases where it is offered for sale and in the catalogues of varieties referred to in Article 3 of Directive 2002/53/EC[27] on the common catalogue of varieties of agricultural plant species shall be provided in order to ensure traceability, transparency and choice for breeders using NGT 1 plant reproductive material in breeding programmes and will distinguish between patented and non-patented NGT 1 plant reproductive material.

(24 ter) In certain cases, such as placing on the market of category 1 plant reproductive material protected by a patent, it may be necessary for Member States to take appropriate measures on their territory to prevent the unintended use of patented category 1 plant reproductive material for cultivation in all or part of their territory, for reasons related to the socio-economic impact of the presence of patented plant reproductive material on the market on the breeding sector and agricultural policy objectives.

(24 quater) The verification whether a plant is protected by one or more product patents or process patents where the process results in a specific characteristic (trait) requires research in multiple databases established by various patent offices. A patent application can also be published after a verification request has been filed. Published patent applications limit the freedom to use the plant reproductive material and as such shall constitute an obstacle to the placing on the market of such material. Therefore, Member States need to be able to inform the Commission about patents or patent applications that would be an obstacle to granting a verification decision.

(24 quinquies) Surrender of a patent at the patentee's request is final, therefore if a patent is lapsed so that category 1 NGT plant reproductive material can be placed on the market, the surrender of a patent should not take place until the category 1 NGT status is confirmed. A

[27] Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (OJ L 193, 20.7.2002, p. 1).

patentee can also decide to surrender the patent at a later date. Therefore the procedures for confirmation of the category 1 NGT status and the verification that the plant reproductive material is not protected by one or more product patents or process patents where the process results in a specific characteristic (trait) should be separate.

(24 sexies) A patent belonging to a third party or a patent application filed by a third party are also an obstacle to issuing a decision that would allow to place category 1 NGT plant reproductive material on the market. Therefore, the requester needs to have an opportunity to take steps in order to remove patent protection, also in cases when the patent verification request was granted in one or more Member States or a patent application was published. In particular the requester should also have the ability to suspend a verification procedure for this purpose.

(24 septies) The revocation of a decision declaring that the plant is not protected by one or more product patents or process patents where the process results in a specific characteristic (trait) and that no application for such a patent was published in any Member State may have severe consequences not only for the requester, but also for third parties who in good faith obtain and use the plant reproductive material. Therefore the revocation of such a decision should be done with due consideration given to proportionality, diligence of the requester and legitimate interests of the stakeholders involved, and only if it is in the public interest.

(24 octies) The Commission should have the ability to remove plant reproductive material from the market if it has been placed on the market in violation of the provisions of this regulation, even if the requester did not seek to obtain a decision stating that such material was not protected by a product patent or a process patent, where the process results in a specific characteristic (trait), or if an application for such a decision was rejected, or if such a decision was revoked.

(25) Category 2 NGT plants and their products should remain subject to the requirements of the Union GMO legislation given that on the basis of current scientific and technical knowledge, their risks need to be assessed. Special rules should be provided in order to adapt the procedures and certain other rules laid down in Directive 2001/18/EC and Regulation (EC) No 1829/2003 to the specific nature of category 2 NGT plants and the differing levels of risk that they may pose.

(26) Category 2 NGT plants and their products, in order to be released into the environment or placed on the market, should remain subject to a consent or authorisation in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003. However, given the wide variety of those category 2 NGT plants, the amount of information necessary for the risk assessment will vary on a case-by-case basis. The Authority, in its scientific opinions on plants developed through cisgenesis and intragenesis[28] and on plants developed through targeted mutagenesis[29] recommended flexibility in data requirements for the risk assessment of these plants. Based on the Authority's 'Criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis' ([30]), considerations on the history of safe use, familiarity for the environment and the function and structure of the modified/inserted sequence(s) should assist in determining the type and amount of data required to perform the risk assessment of those category 2 NGT plants. It is therefore necessary to establish general principles and information requirements ~~criteria~~ for the risk assessment of these plants, while providing for flexibility and possibility to adapt risk assessment methodologies to scientific and technical progress.

(27) Requirements on the content of notifications for consent for the placing on the market of products, ~~containing or consisting of GMOs~~ other than food or feed, containing or consisting of GMOs, and on the content of applications for authorisation for the placing on the market

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28 EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins E, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Naegeli H, Nogué F, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Casacuberta, J, Fernandez Dumont A, Gennaro A, Lenzi, P, Lewandowska A, Munoz Guajardo IP, Papadopoulou N and Rostoks N, 2022. 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.

29 EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Mullins E, Nogué F, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Casacuberta J, Gennaro A, Paraskevopoulos K, Raffaello T and Rostoks N, 2020. Applicability of the EFSA Opinion on site-directed nucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis. EFSA Journal 2020;18(11):6299, 14 pp. https://doi.org/10.2903/j.efsa.2020.6299.

30 EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins E, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Naegeli H, Nogué F, Rostoks N, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Fernandez A, Gennaro A, Papadopoulou N, Raffaello T and Schoonjans R, 2022. Statement on criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis. EFSA Journal 2022;20(10):7618, 12 pp. https://doi.org/10.2903/j.efsa.2022.7618.

of genetically modified food and feed are laid down in different pieces of legislation. To ensure consistency between the notifications for consent and applications for authorisation for category 2 NGT products, the content of such notifications and applications should be the same, except those concerning the assessment of food and feed safety assessment as these are only relevant to category 2 NGT food and feed.

(28) The European Union Reference Laboratory for GM Food and Feed (EURL), in collaboration with the European Network of GM Laboratories (ENGL), ~~concluded that analytical testing is not considered feasible for all products obtained by targeted mutagenesis and cisgenesis~~ has identified analytical challenges and limitations associated with the identification and quantification of certain plants and products obtained by targeted mutagenesis and cisgenesis ([31]). For example, w~~W~~hen the introduced modifications of the genetic material are not specific to the NGT plant in question, they do not allow the differentiation of the NGT plant from conventional plants. In such cases, an analytical method should still be provided by the notifier or applicant, but, if duly justified, the modalities to comply with analytical method performance requirements should be adapted. ~~In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the notifier or the applicant, the modalities to comply with analytical method requirements should be adapted.~~ This should be done in the implementing acts adopted pursuant to this Regulation. Provision should also be made for the EURL, assisted by the ENGL, to adopt guidance for applicants on the minimum performance requirements for analytical methods. Modalities for performing method validation may also be adapted.

(29) Directive 2001/18/EC requires a monitoring plan for environmental effects of GMOs after their deliberate release or placing on the market but provides for flexibility as to the design of the plan taking into account the environmental risk assessment, the characteristics of the GMO, of its expected use and of the receiving environment. This requirement for a monitoring plan should apply as a rule to category 2 NGT plants. However, g~~G~~enetic modifications in category 2 NGT plants may range from changes only needing a limited risk assessment to complex alterations requiring a more thorough analysis of potential risks. Therefore, it should be possible for the competent authority not to require post-market monitoring ~~requirements~~ for environmental effects of category 2 NGT plants where duly

[31] European Network of GMO Laboratories (ENGL), Detection of food and feed plant products obtained by new mutagenesis techniques, 26 March 2019 (JRC116289); 13 June 2023 (JRC133689; EUR 31521 EN)

justified, based on the results of any previous release of the category 2 NGT plant, the findings of the environmental risk assessment, the characteristics of the category 2 NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment~~, in accordance with the implementing act concerning the notifications and applications adopted pursuant this Regulation~~. ~~should be adapted in the light of the environmental risk assessment and the experience in field trials, the characteristics of the NGT plant concerned, the characteristics and scale of its expected use, in particular any history of safe use of the plant and the characteristics of the receiving environment. Therefore, a monitoring plan for environmental effects should not be required if the category 2 NGT plant is unlikely to pose risks that need monitoring, such as indirect, delayed or unforeseen effects on human health or on the environment.~~

(29a) Provision should be made for the Authority to adopt guidance to assist the notifier or the applicant in the preparation and the presentation of the notification and the application, including as regards the monitoring plan for environmental effects.

(30) For reasons of proportionality, ~~after~~ upon a first renewal of the authorisation, the authorisation should be valid for an unlimited period, unless decided differently at the time of that renewal based on the risk assessment and the available information on the category 2 NGT plant concerned, subject to reassessment when new information has become available.

(31) For reasons of legal certainty and good administration, the timeline for the Authority to deliver its opinion on an application for authorisation should only be extended when additional information is necessary to carry out the assessment of the application, and the extension should not be longer than the originally foreseen time limit unless it is justified by the nature of the data or exceptional circumstances.

(32) To increase transparency and consumers' information, operators should be allowed to complement the labelling of category 2 NGT products as GMO with information on the trait(s) conferred by the genetic modification. In order to avoid misleading or confusing indications, a proposal for such a labelling should be provided in the notification for consent or in the application for authorisation and should be specified in the consent or in the authorisation decision.

(33) Regulatory incentives should be offered to potential notifiers or applicants for category 2 NGT plants and their products containing traits with the potential to contribute to a

sustainable agri-food system, in order to steer the development of category 2 NGT plants towards such traits. The criteria to trigger these incentives should focus on broad trait categories with the potential to contribute to sustainability (such as those linked to tolerance or resistance to biotic and abiotic stresses, improved nutritional characteristics or increased yield) and should be based on the contribution to the value for sustainable cultivation and use as defined in [Article 52(1) of 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[32]]. The applicability of the criteria across the EU does not allow a narrower definition of traits to focus on specific issues or address local and regional specificities.

(34) Incentives should consist in an accelerated procedure for risk assessment as regards applications handled by a fully centralised procedure (category 2 NGT plants for food or feed use and category 2 NGT food and feed ~~food and feed products~~) and enhanced pre-submission advice to help developers prepare the dossier for the purpose of the environmental and food and feed safety assessments, without affecting the general provisions on pre-submission advice, notification of studies and consultation of third parties pursuant to Articles 32a, 32b and 32c of Regulation (EC) No 178/2002([33]). The submission of evidence demonstrating compliance with regulatory requirements in the context of a notification or an application for authorisation remains the notifier's or applicant's responsibility.

(35) Additional incentives should be afforded when the notifier or applicant is a small or medium-sized enterprise (SME), to promote access to the regulatory procedures by these enterprises, support diversification of developers of category 2 NGT plants and encourage the development by small breeders of crop species and traits by means of NGTs, by granting fee waivers for the validation of detection methods to SMEs and more extensive pre-submission advice covering also the design of studies to be carried out for the purpose of risk assessment.

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32 COM(2023) 414 final

33 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031 1.2.2002, p. 1).

(36) Herbicide tolerant plants are bred to be intentionally tolerant to herbicides, in order to be cultivated in combination with the use of those herbicides. If such cultivation is not done under appropriate conditions, it may lead to development of weeds resistant to those herbicides or to the need to increase of quantities of herbicides applied, regardless of the breeding technique. For this reason, category 2 NGT plants featuring herbicide-tolerant traits should not be eligible for incentives under this framework. However, this Regulation should not take other specific measures on herbicide tolerant NGT plants, because such measures are taken horizontally 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].

(37) ~~In order to enable NGT plants to contribute to the sustainability objectives of the Green Deal and the Farm to Fork and Biodiversity Strategies, cultivation of NGT plants in the Union should be facilitated. This requires predictability for breeders and farmers as regards the possibility to cultivate such plants in the Union. Therefore, the possibility for Member States to adopt measures restricting or prohibiting the cultivation of category 2 NGT plants in all or part of their territory, set out in Article 26b of Directive 2001/18/EC would undermine those goals.~~ Directive 2001/18/EC provides the possibility for Member States to restrict or prohibit the cultivation of GMOs on their territory and to take appropriate measures to avoid the unintended presence of GMOs in other products, taking into account *inter alia* the diversity of farming systems and natural and economic conditions, such as those pertaining to islands. Those provisions continue to apply to category 2 NGT plants, given that experience has shown that cultivation of genetically modified plants is an issue with strong national, regional and local dimensions. In this context, the Commission will continue gathering and coordinating relevant information to complement and update, as necessary, the guidelines on coexistence.

(38) ~~The special rules laid down in this Regulation concerning the authorisation procedure for category 2 NGT plants are expected to result in more cultivation in the Union of category 2 NGT plants compared to the situation so far under the current Union GMO legislation. That renders necessary for Member States' public authorities to define coexistence measures to balance the interests of producers of conventional, organic and GM genetically modified plants and thereby allow producers a choice between different types of production, in line with the Farm to Fork Strategy's target of 25 % of agricultural land under organic farming by 2030. The diversity of farming systems and natural and economic conditions in the EU~~

~~such as insularity, need to be taken into consideration when defining these measures, that need to be proportionate to the objective pursued. In some cases, depending on economic and natural conditions, it may be necessary to exclude the cultivation of these plants from large areas. This possibility should rest on a demonstration that, for those areas, other measures are not sufficient to prevent the unintended presence of genetically modified plants in conventional or organic crops. The Commision should continue gathering and coordinating relevant information to complement and update as necessary the guidelines on coexistance referred to in Article 26a(2) of Directive 2001/18/EC.~~

(39) To achieve the goal of ensuring the effective functioning of the internal market, NGT plants and their ~~related~~ products should benefit from the free movement of goods, provided they comply with the requirements of other Union law.

(40) Given the novelty of the NGTs, it will be important to monitor closely the development and presence on the market of NGT plants and their products and evaluate any accompanying impact on human and animal health, the environment, and environmental, economic and social sustainability. Information should be collected regularly and within five years after the adoption of the first decision allowing the deliberate release or the marketing of NGT plants or ~~NGT~~ their products in the Union, the Commission should carry out an evaluation of this Regulation to measure the progress made towards the availability of NGT plants containing such characteristics or properties on the EU market.

(41) In order to provide a high level of protection of health and environmental protection in relation to NGT plants and ~~NGT~~ their products, requirements arising from this Regulation should apply in a non-discriminatory manner to products originating in the Union and imported from third countries.

(41 bis) This Regulation is without prejudice to the application of relevant provisions of Union and national law on public access to documents.

(42) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States but can be better achieved at Union level, so that NGT plants and ~~NGT~~ their products may circulate freely within the internal market, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(43) The types of NGT plants developed and the impact of certain traits on environmental, social and economic sustainability are continuously evolving. Therefore, based on the available evidence of such developments and impacts, the Commission should be empowered in accordance with Article 290 of the Treaty on the Functioning of the European Union to adapt the list of traits that should be incentivized or discouraged to achieve the goals of the Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies.~~2~~

(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 ([34]). 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 also on the basis of relevant reports which the Commission may be required to publish prior to adopting delegated acts.

(45) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the information required to demonstrate that a NGT plant is a category 1 NGT plant, as regards the preparation and the presentation of the notification for that determination, as regards the content of the verification reports and of the decision, and as regards the methodology and information requirements for the environmental risk assessments of category 2 NGT plants and the safety assessment of category 2 NGT food and ~~NGT~~ feed, in accordance with the principles and factors ~~criteria~~ laid down in this Regulation. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council([35]).

(46) The Commission should regularly collect information in order to assess the performance of the legislation in achieving the development and availability of NGT plants and ~~NGT~~ their

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

[35] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

products in the market that can contribute to the objectives of the Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies and in order to inform an evaluation of the legislation. A broad set of indicators have been identified[36] and should be periodically reviewed by the Commission. The indicators should support monitoring of potential risks to health or the environment of category 2 NGT plants and their ~~related NGT~~ products, impact of NGT plants on environmental, economic and social sustainability as well as impact on organic agriculture and on consumers acceptance of NGT products. A first monitoring report should be presented three years after the first NGT plants or their products have been notified/authorised, to ensure that enough data is available after full implementation of the new legislation, and at regular intervals thereafter. The Commission should carry out an evaluation of this Regulation two years after the first monitoring report has been published, in order to allow for the impact of the first products going through the verification or authorisation to fully materialise.

(46a) Directive 98/44/EC on the legal protection of biotechnological inventions sets out principles regarding the patentability of biological material including plants. In order to be able to take possible action in case of adverse impacts of patented NGT plants, the Commission should ~~assess, as part of a broader market analysis,~~ conduct a study on the impact that the patenting of plants and related licensing and transparency practices may have on innovation in plant breeding, on breeders' access to plant genetic material and techniques and on the availability of plant reproductive material to farmers as well as the overall competitiveness of the EU plant breeding industry. For the same reason, the Commission should establish an expert group on the effect of the patenting of NGT plants. It is important to ensure that farmers and breeders have access to techniques and material to promote the diversity of plant reproductive material, such as seeds, at affordable prices, while also strongly supporting innovation in both conventional and organic plant breeding by preserving investment incentives.

(46b) Stakeholders raised concerns that patents on NGT plants may limit the access of breeders to those plants. Article 27(c) of the Agreement on a Unified Patent Court[37] already provides

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[36] Impact assessment report accompanying the Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625, SWD(2023) 412

[37] Agreement on a Unified Patent Court (OJ C 175, 20.6.2013, p. 1).

that rights conferred by a patent shall not extend to the use of biological material for the purpose of breeding or discovering and developing other plant varieties.

(47) Certain references to provisions of the Union GMO legislation in Regulation (EU) 2017/625 of the European Parliament and of the Council ([38]) need to be amended to include the specific provisions in this legislation applicable to NGT plants.

(48) Since the application of this Regulation requires the adoption of implementing acts, it should be deferred in time to allow for the adoption of such measures,

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 and ~~or~~ feed, containing or consisting of such plants ('NGT products').

[38] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

Article 2

Scope

This Regulation shall apply to:

(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.

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([39]) 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*[40]];

(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;

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[39] 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).

[40] COM(2023) 414 final

(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;

~~(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, and does not include tolerance to herbicides among the intended traits conveyed by the genetic modification, 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;

(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];

(16) ‘patent’ means either a patent granted pursuant to the national law of a Member State, or a European patent or European patent with unitary effect within the meaning of Regulation (EU) No 1257/2012[41];

(17) ‘product patent’ means a patent whose subject matter is a product consisting of or containing biological material;

(18) ‘process patent’ means a patent whose subject matter is a process by means of which biological material is produced, processed or used.

Article 4

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

[41] Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection (OJ L 361, 31.12.2012, p. 1).

1. 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 plant or 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.

2. If, following a patent verification request in accordance with Article 7 bis, the plant is the object of a decision of the Commission finding that it is not protected by one or more product patents or process patents, where the process results in a specific characteristic (trait) or patents for use of biotechnological material, where the use results in a specific characteristic (trait) of the NGT 1 plant, and that no application for such a patent was published in any Member State, Articles 7 ter and 10 bis shall not apply.

CHAPTER II

Category 1 NGT plants and category 1 NGT products

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 conditions set out in Article 3(7)(a) ~~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;~~

(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.

3 bis. Articles 32b and 32c(2) of Regulation (EC) No 178/2002 shall not apply.

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 meets the conditions set out in Article 3(7)(a) ~~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 conditions set out in Article 3(7)(a) ~~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 objection~~s~~ 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.

9. In cases where ~~a comment is~~ a reasoned objection~~s are~~ is 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 objection~~s~~ 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 objection~~s~~, 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 <u>for requests submitted</u> 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.

2 bis. Articles 32b and 32c(2) of Regulation (EC) No 178/2002 shall not apply.

3. The Authority shall acknowledge receipt of the verification request to the requester without undue 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 meets the conditions set out in Article 3(7)(a) ~~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 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*.

Article 7 bis

Procedure for verification whether a plant is protected by product patents or process patents

1. To obtain the decision confirming that the plant reproductive material is not protected by one or more patents referred to in Article 4(2), the person intending to place on the market reproductive material of a category 1 NGT plant shall submit to the Commission a request for such a decision ('patent verification request').

2. The patent verification request 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:

(a) the name and the address of the requester, and the decision referred to in Article 6(8) or 6(10) if it has been issued;

(b) a summary of a systematic review, which has been carried out by the requester to demonstrate that the NGT 1 plant is not protected by one or more patents referred to in Article 4(2), thus protecting the plant, and to demonstrate that there are no published patent applications for such patents in one or more Member States of the European Union. This summary shall include information about the sources that were consulted;

(c) a declaration that neither the requester nor their parent or subsidiary have filed any yet unpublished applications for patents referred to in Article 4(2) that would result in patent protection of the plant in question in one or more Member States of the European Union;

(d) a declaration that neither the requester nor their parent or subsidiary will seek patent protection of the plant in question in the future in one or more Member States of the European Union;

(e) if the systematic review referred to in letter (b) indicates the existence of patents or published patent applications or if the requester cannot make the declaration referred

to in letter (c), due to extant patents or patent applications, they shall include, where appropriate:

(i) duly confirmed copies of motions to surrender all the patents that would otherwise constitute an obstacle to the confirmation of lack of patent protection in all applicable patent offices; or

(ii) duly confirmed copies of motions retracting patent applications in cases where the patents were not granted yet;

(f) other necessary documents, in particular documents confirming that the requester or a third party filing such motions is empowered to file the motions referred to in letter (e), in particular:

(i) binding contracts between the requester and a third party;

(ii) necessary consents, particularly of other patentees or other parties holding rights over the patents or patent applications;

(iii) powers of attorney, mandates or other declarations necessary to make binding decisions with regard to the patents or patent applications in question;

(g) 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 in the case where the requester has not yet obtained confirmation of NGT status in accordance with Article 6 or 7 and has applied for product patent(s) or process patent(s) where the process results in a specific characteristic (trait) in one or more Member States and the application has not yet been published.

4. If the patent verification request does not contain all the necessary information or documents, it shall be declared inadmissible if the shortcomings are not successfully remedied within 30 working days from the receipt of the notification indicating the shortcomings issued by the Commission. In particular, when the summary is deemed insufficient to perform the verification, the Commission can request the full systematic review referred to in paragraph 2(b). The Commission shall inform the requester and the

Member States without undue delay of the inadmissibility of the patent verification request and shall provide reasons of its decision.

5. If the patent verification request is deemed admissible, the Commission shall verify that the NGT plant is not protected by one or more patents referred to in Article 4(2), or whether any application for such a patent that would protect the plant has been published in any Member State. On the basis of this examination the Commission shall prepare a verification report. The verification report referred to in the previous sentence shall be transmitted to the requester and the Member States within 30 working days from the determination that the request is admissible.

6. Member States may make reasoned objections to a verification report confirming that the decision referred to in Article 4(2) can be issued, only in the case where they can indicate specific patents or patent applications that would protect the plant contrary to the statement of the requester or the verification report. The Commission shall deem inadmissible any objections that do not indicate specific patents or patent applications mentioned in the previous sentence. The reasoned objections shall be made within 30 working days from the receipt of the verification report and be transmitted to the requester without undue delay.

7. In the absence of reasoned objections from a Member State, within 15 working days from the expiry of the deadline referred to in paragraph 6, the Commission shall adopt a decision. The Commission shall transmit the decision without undue delay to the requester and the Member States. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

8. Within 30 working days from the receipt of a verification report indicating that the criteria for issuing the confirmation decision mentioned in Article 4(2) are not met, or from the receipt of a reasoned objection referred to in paragraph 6, the requester can submit to the Commission a response to the verification report or reasoned objection, by, where appropriate, presenting explanations as to why they maintain that those criteria are met, or proving that they or a third party resigned from the patent protection or withdrew the patent application.

9. Within 30 working days from the receipt of a verification report indicating that the criteria for issuing the confirmation decision mentioned in Article 4(2) are not met, or from the receipt of a reasoned objection referred to in paragraph 6, the requester can request to

suspend the procedure for up to 6 months from the delivery of the decision accepting the request to allow them to take necessary steps to meet the criteria for issuing the confirmation decision mentioned in Article 4(2). Within that period the requester shall submit information, indicating how they addressed the issues mentioned in the verification report or the reasoned objections, along with a motion to resume the proceedings. The Commission shall resume the proceedings without undue delay, after the receipt of the motion.

10. Within 45 days from the receipt of the response or additional information mentioned in paragraph 8, or from the resumption of proceedings or from the expiry of the term of suspension mentioned in paragraph 9, the Commision shall, taking the new information provided and the explanations into account, adopt a decision. The Commission shall transmit the decision without undue delay to the requester and the Member States. The decision shall be adopted in accordance with the procedure referred to in Article 28 (2).

11. The patent verification request mentioned in paragraph 1 can be filed at any time, unless:

(a) a decision referred to in Article 4(2) is already in force; or

(b) a procedure regulated in this Article is already running; or

(c) the procedure has been suspended according to paragraph 9 or 12.

12. The procedure regulated in this Article can be suspended at any time, at the request of the requester, if the procedures regulated in Articles 6 or 7 with regard to the same plant have not come to a conclusion. The Commission shall resume the procedure at the request of the requester without undue delay. If such a request to resume is not filed within 30 days from the final conclusion of the procedures regulated in Articles 6 or 7, the Commission shall terminate the procedure regulated in this Article.

13. The Commission shall publish a summary of the decisions referred to in paragraphs 7 and 10 in the Official Journal of the European Union.

Article 7 ter

Measures regarding restrictions and prohibitions of patent protected reproductive material of category 1 NGT plants

1. A Member State may adopt measures restricting or prohibiting use for cultivation of reproductive material of a category 1 NGT plant that has not obtained the decision referred to in Article 4(2) in all or part of its territory.

2. The measures referred to in paragraph 1 shall be based on grounds related to:

(a) socio-economic impacts, including the economic impact on the breeding sector;

(b) agricultural policy objectives.

Those grounds may be invoked individually or in combination, depending on the particular circumstances of the Member State, region or area in which those measures will apply.

3. A Member State intending to adopt measures pursuant to paragraph 1 of this Article shall first communicate a draft of those measures and the corresponding grounds invoked to the Commission. During a period of 75 days starting from the date of such communication:

(a) the Member State concerned shall refrain from adopting and implementing those measures;

(b) the Member State concerned shall ensure that operators refrain from planting the NGT plants concerned; and

(c) the Commission may make any comments it considers appropriate.

4. On expiry of the 75-day period referred to in paragraph 3, the Member State concerned may adopt the measures either in the form originally proposed, or as amended to take account of any non-binding comments received from the Commission. Those measures shall be communicated to the Commission, the other Member States and the requester without undue delay.

5. Member States shall make available to the public information on measures adopted restricting the use for cultivation of reproductive material of a category 1 NGT plant referred to in paragraph 1.

6. A Member State may repeal the measures adopted pursuant to paragraph 1 on all or part of its territory. The Member State shall without undue delay notify the Commission, the other Member States and the requester of this decision.

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 7 bis 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~~.~~;

(g) the decision referred to in Article 4(2), as appropriate;

(h) the decision referred to in Article 11 bis, as appropriate.

The database may also contain the information on the measures adopted by Member States pursuant to Article 7 ter.

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 10 bis

Labelling and transparency of information on reproductive material of a category 1 NGT plant referred to in Article 4(2)

1. The reproductive material of a category 1 NGT plant that has not obtained the decision referred to in Article 4(2) shall be labelled according to Article 10, followed by the additional information, accordingly, 'patent protected' or 'patent pending'.

2. Member States shall ensure that varieties of category 1 NGT plants protected by patents referred to in Article 4(2), whose status has been confirmed under Article 6 or 7, are clearly described in national catalogues of varieties referred to in Article 3 of Directive 2002/53/EC.

3. Information mentioned in paragraph 2 must appear in the accompanying commercial documentation and catalogues in which these varieties are entered.

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;

(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.

Article 11 bis

Revocation of the patent verification decision and removal of patent protected category 1 NGT plant reproductive material from the market

1. The Commission may revoke the decision referred to in Article 4(2) granted according to Article 7 bis paragraph 7 or 10, if the revocation is in the public interest, and if:

(a) the requester intentionally or negligently provided the competent authority with false or incomplete information regarding the lack of product patents protecting the plant or lack of process patents where the process results in a specific characteristic (trait), thus protecting the plant, or the lack of published patent applications for such patents or the lack of unpublished, filed patent applications, where the requester or the requester's parent or a subsidiary is at least one of the patentees in such an application; or

(b) the requester has filed for one or more patents referred to in Article 4(2) that would protect the category 1 NGT plant in question in any Member State; or

(c) a third party has filed for one or more patents referred to in Article 4(2) that would protect the category 1 NGT plant in question in any Member State; or

(d) the surrender of a patent or retraction of a published patent application proved unsuccessful, particularly if it was a result of actions of the requester or their parent or subsidiary.

2. In the decision to revoke, referred to in paragraph 1, the Commission may order the removal of the reproductive material of the category 1 NGT plant in question from the market.

3. The Commission may also order the removal from the market of category 1 NGT plant reproductive material if it was placed on the market when the decision referred to in Article 4(2), regarding the category 1 NGT plant in question, was not in force when the reproductive material of such a plant was placed on the market.

4. The decision to revoke the decision referred to in paragraphs 2 and 3 shall be adopted in accordance with the procedure referred to in Article 28(2).

CHAPTER III

Category 2 NGT plants and category 2 NGT products

Article 12

Status of Category 2 NGT plants and category 2 NGT products

The rules which apply to GMOs in Union legislation in so far as they are not derogated from by this Regulation, shall apply to category 2 NGT plants and category 2 NGT products.

SECTION 1

DELIBERATE RELEASE OF CATEGORY 2 NGT PLANTS FOR ANY OTHER PURPOSE THAN FOR PLACING ON THE MARKET

Article 13

Content of the notification referred in Article 6 of Directive 2001/18/EC

As regards the deliberate release of a category 2 NGT plant for any other purpose than placing on the market, the notification referred to in Article 6(~~1~~2) of Directive 2001/18/EC shall include:

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

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

(c) a technical dossier supplying the information specified in Annex II necessary to carry out the environmental risk assessment of the deliberate release of a NGT plant or combination of NGT plants:

(i) general information including information on personnel and training;

(ii) information relating to the category 2 NGT plant(s);

(iii) information relating to the conditions of release and the potential receiving environment;

(iv) information on the interactions between the category 2 NGT plant(s) and the environment;

(v) a plan for monitoring in order to identify effects of the category 2 NGT plant(s) on human health or the environment;

(vi) where relevant, information on control, remediation methods, waste treatment and emergency response plans;

(vii) an identification of the parts of the notification and any other supplementary information that the notifier requests to be treated as confidential, accompanied by verifiable justification, pursuant to Article 25 of Directive 2001/18/EC;

(viii) a summary of the dossier;

(d) the environmental risk assessment carried out in accordance with the principles and ~~criteria~~ information set out in Parts 1 and 2 of Annex II and with the implementing act adopted in accordance with Article 27, point (c).

SECTION 2

PLACING ON THE MARKET OF CATEGORY 2 NGT PRODUCTS FOR OTHER USES THAN FOOD OR FEED

Article 14

Content of the notification referred to in Article 13 of Directive 2001/18/EC

1. As regards the placing on the market of category 2 NGT products other than food and feed, the notification referred to in Article 13(2) of Directive 2001/18/EC, without prejudice to

any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002, shall contain:

(a) name and address of the notifier and of its representative established in the Union (if the notifier is not established in the Union);

(b) designation and specification of the category 2 NGT plant;

(c) scope of the notification:

(i) cultivation;

(ii) other uses (to be specified in the notification);

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

(e) the environmental risk assessment carried out in accordance with the principles and ~~criteria~~ information set out in Parts 1 and 2 of Annex II and with the implementing act adopted in accordance with Article 27, point (c);

(f) the conditions for the placing on the market of the product, including specific conditions of use and handling;

(g) with reference to Article 15(4) of Directive 2001/18/EC, a proposed period for the consent, which should not exceed 10 years;

(h) ~~where appropriate,~~ a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC, including a proposal for the time-period of the monitoring plan; this time-period may be different from the proposed period for the consent. By way of derogation from the first sentence, a monitoring plan shall not be required where the notifier duly justifies that it is not needed, based on the results of any release notified in accordance with Section 1, the findings of the environmental risk assessment, the characteristics of the category 2 NGT plant, the characteristics

and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted pursuant to Article 27, point (d), and the guidance referred to in Article 29(1); ~~If, based on the results of any release notified in accordance with Section 1, the findings of the environmental risk assessment, the characteristics of the NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted in accordance with Article 27, point (d), the notifier considers that the NGT plant does not need a monitoring plan, the notifier may propose not to submit a monitoring plan;~~

(i) a proposal for labelling which shall comply with the requirements laid down in point A.8. of Annex IV to Directive 2001/18/EC, Article 4(6) of Regulation (EC) No 1830/2003 and Article 23 of this Regulation;

(j) proposed commercial names of the products and names of category 2 NGT plants contained therein, and a proposal for a unique identifier for the category 2 NGT plant, developed in accordance with Commission Regulation (EC) No 65/2004 ([42]). After the consent any new commercial names should be provided to the competent authority of the Member State;

(k) description of how the product is intended to be used. Differences in use or management of that product compared to similar non-genetically modified products shall be highlighted;

(l) methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the category 2 NGT plant. ~~In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies,~~

——As regards identification and quantification, if duly justified by the notifier, the modalities to comply with analytical method performance requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2);

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[42] Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

(m) samples of the category 2 NGT plant and their control samples, and information as to the place where the reference material can be accessed;

(n) where applicable, the information to be provided for the purpose of complying with Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;

(o) an identification of the parts of the notification and any other supplementary information that the notifier requests to be treated as confidential, accompanied by verifiable justification, pursuant to Article 25 of Directive 2001/18/EC and Articles 39 to 39e of Regulation (EC) No 178/2002;

(p) a summary of the dossier in a standardised form.

2. The notifier shall include in this notification information on data or results from releases of the same category 2 NGT plant or the same combination of category 2 NGT plants previously or currently notified and/or carried out by the notifier either inside or outside the Union.

3. The competent authority of the Member State that prepares the assessment report referred to in Article 14 of Directive 2001/18/EC shall examine the notification for compliance with paragraphs 1 and 2.

Article 15

Specific provisions on monitoring

The written consent referred to in Article 19 of Directive 2001/18/EC shall either specify monitoring requirements, as described in Article 19(3) point (f) or state that monitoring is not required. Article 17(2), point (b), of Directive 2001/18/EC shall not apply if monitoring is not required by the consent.

Article 15 bis

Specific provision on analytical method requirements

1. Where appropriate, the competent authority of the Member State that prepares the assesment report may request expert assistance from the relevant national reference laboratories referred to in Regulation (EU) 2017/625 to assess whether the information provided by the applicant according to Article 14(1), point (l), justifies the application of adapted modalities to comply with analytical method performance requirements.
2. The national reference laboratory may request expert assistance from the European Union Reference Laboratory referred to in Article 32 of Regulation (EC) No 1829/2003.

Article 16

Labelling in accordance with Article 23

In addition to Article 19(3), point (e), of Directive 2001/18/EC, the written consent shall specify the labelling in accordance with Article 23 of this Regulation.

Article 17

Duration of the validity of the consent ~~after~~ upon renewal

1. The consent granted under Part C of Directive 2001/18/EC shall, ~~after~~ upon the first renewal in accordance with Article 17 of Directive 2001/18/EC, be valid for an unlimited period, unless the decision referred to in Articles 17(6) or (8) or 18(2) provides that the renewal is for a limited period, on justified grounds based on the findings of the risk assessment carried out pursuant to this Regulation and on experience with the use, including results of monitoring, if so specified in the consent.

2. The last sentence in Article 17(6) and (8) of Directive 2001/18/EC shall not apply.

SECTION 3

PLACING ON THE MARKET OF CATEGORY 2 NGT PLANTS FOR FOOD OR FEED USE AND OF CATEGORY 2 NGT FOOD AND FEED

Article 18

Scope

This Section shall apply to:

(a) category 2 NGT plants for food use or for feed use;

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

(c) feed containing, consisting of or produced from category 2 NGT plants ('category 2 NGT feed').

Article 19

Specific provisions on the application for authorisation referred to in Articles 5 and 17 of Regulation (EC) No 1829/2003

1. By way of derogation from Articles 5(3), point (e), and 17(3), point (e), of Regulation (EC) No 1829/2003, and without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002, an application for authorisation of a category 2 NGT plant for food or feed use, or category 2 NGT food or feed shall be accompanied by a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out and any other available material to demonstrate that:

   (a) 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);

(b) the food or the feed complies with the criteria referred to in Article 4(1) or Article 16(1) of Regulation (EC) No 1829/2003, respectively, based on a safety assessment of the food or feed carried out in accordance with the principles and ~~criteria~~ information laid down in Parts 1 and 3 of Annex II to this Regulation and with the implementing act adopted in accordance with Article 27, point (c).

2. By way of derogation from Articles 5(3), point (i), and 17(3), point (i), of Regulation (EC) No 1829/2003, an application for authorisation shall be accompanied by methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the category 2 NGT plant and, where applicable, for the detection, ~~and~~ identification and quantification of the category 2 NGT plant in the NGT food or feed produced from it.

~~In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies,~~ As regards identification and quantification, if duly justified by the applicant or concluded by the European Union Reference Laboratory referred to in Article 32 of Regulation (EC) No 1829/2003 during the procedure referred to in Article 20(4), the modalities to comply with analytical method performance requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2);

3. By way of derogation from Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, in the case of category 2 NGT plants or food or feed containing or consisting of category 2 NGT plants, the application shall also be accompanied by:

(a) the environmental risk assessment carried out in accordance with the principles and ~~criteria~~ information set out in Parts 1 and 2 of Annex II and with the implementing act adopted in accordance with Article 27, point (c);

(b) ~~where appropriate,~~ a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan. This duration may be different from the duration of the authorisation. By way of derogation from the first sentence, a monitoring plan shall

not be required where the applicant duly justifies that it is not needed, based on the results of any release notified in accordance with Section 1, the findings of the environmental risk assessment, the characteristics of the category 2 NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted pursuant to Article 27, point (d), and the guidance referred to in Article 29(1). ~~If, based on the results of any release notified in accordance with Section 1, the findings of the environmental risk assessment, the characteristics of the NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted in accordance with Article 27, point (d), the applicant considers that the NGT plant does need a monitoring plan, the applicant may propose not to submit a monitoring plan.~~

4. The application shall also contain a proposal for labelling in accordance with Article 23.

Article 20

Specific provisions on the opinion of the Authority

1. By way of derogation from Article 6(1) and (2) and Article 18(1) and (2) of Regulation (EC) No 1829/2003, the Authority shall deliver an opinion on the application for authorisation referred to in Article 19 of this Regulation within six months as from the receipt of a valid application.

Where the Authority or the competent authority of the Member State carrying out the environmental risk assessment or the safety assessment of the food or feed pursuant to Article 6(3), points (b) and (c) and Article 18(3), points (b) and (c) of Regulation (EC) No 1829/2003 considers that additional information is necessary, the Authority, or the ~~national~~ competent authority of the Member State through the Authority, shall ask the applicant to submit that information within a specified time limit. In that case, the six months period shall be extended by that additional period. The extension shall not exceed six months unless it is justified by the nature of the data requested or by exceptional circumstances.

2. In addition to the tasks referred to in Article 6(3) and Article 18(3) of Regulation (EC) No 1829/2003, the Authority shall verify whether all the particulars and documents submitted by the applicant are in conformity with Article 19 of this Regulation.

3. By way of derogation from Article 6(3), point (d), and Article 18(3), point (d), of Regulation (EC) No 1829/2003, the Authority shall forward to the European Union ~~r~~Reference ~~l~~Laboratory referred to in Article 32 of Regulation (EC) No 1829/2003 the particulars referred to in Article 19(2) of this Regulation and in Article 5(3), point (j), and Article 17(3), point (j), of Regulation (EC) No 1829/2003.

4. The European Union ~~r~~Reference ~~l~~Laboratory shall test and validate the method of detection, identification and quantification proposed by the applicant in accordance with Article 19(2) or assess whether the information provided by the applicant justifies the application of adapted modalities to comply with detection method requirements referred to in that paragraph.

5. By way of derogation from Article 6(5), point (f), and Article 18(5), point (f), of Regulation (EC) No 1829/2003, in the event of an opinion in favour of authorising the food or the feed, the opinion shall also include:

   (a) the method, validated by the European Union ~~r~~Reference ~~l~~Laboratory, for detection, including sampling, ~~and, where applicable,~~ identification and quantification of the category 2 NGT plant and, where applicable, for the detection, ~~and~~ identification and quantification of the category 2 NGT plant in the NGT food or feed produced from it, and a justification of any adaptation of the analytical method performance requirements in the cases referred to in Article 19(2), subparagraph 2;

   (b) an indication of where appropriate reference material can be accessed.

6. In addition to the particulars mentioned in Article 6(5), point (d) and Article 18(5), point (d) of Regulation (EC) No 1829/2003, the opinion shall also include a proposal for labelling in accordance with Article 23 of this Regulation.

Article 21

Duration of the validity of the authorisation ~~after~~ upon renewal

By way of derogation from Article 11(1) and Article 23(1) of Regulation (EC) No 1829/2003, ~~after~~ upon the first renewal, the authorisation shall be valid for an unlimited period, unless the Commission decides to renew the authorisation for a limited period, on justified grounds based on

the findings of the risk assessment carried out pursuant to this Regulation and on experience with the use, including results of monitoring, if so specified in the authorisation.

SECTION 4

COMMON PROVISIONS FOR CATEGORY 2 NGT PLANTS AND CATEGORY 2 NGT PRODUCTS

Article 22

Incentives for category 2 NGT plants and category 2 NGT products containing traits relevant for sustainability

1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least one of the intended trait(s) of the category 2 NGT plant conveyed by the genetic modification is contained in Part 1 of Annex III and it does not have any traits referred to in Part 2 of that Annex.

2. The following incentives shall apply to applications for authorisation submitted in accordance with Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19:

   (a) by way of derogation from Article 20(1), subsection (1) of this Regulation, the Authority shall deliver its opinion on the application within 4 months from the receipt of a valid application, unless the complexity of the product requires application of the time limit referred to in Article 20(1). The time limit shall be extendable under the conditions set out in Article 20(1), subsection (2);

   (b) where the applicant is a SME, it shall be exempted from the payment of the financial contributions to the European Union Reference Laboratory and to the European Network of GMO Laboratories referred to in Article 32 of Regulation (EC) No 1829/2003.

3. The following pre-submission advice for the purposes of the risk assessment conducted in accordance with Annex II shall, in addition to Article 32a of Regulation (EC) No 178/2002, apply prior to notifications submitted in accordance with Article 13 of Directive

2001/18/EC in conjunction with Article 14 and to applications for authorisation submitted in accordance with Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19:

(a) the staff of the Authority shall, at the request of a potential applicant or notifier, provide advice on ~~plausible~~ the risk hypotheses that the potential applicant or notifier has identified to be tested in the risk assesment ~~based on the properties of a plant, product or hypothetical plant or product, that need to be addressed~~ by providing the information under Parts 2 and 3 of Annex II~~. The advice shall not, however, cover the design of studies to address the risk hypotheses~~;

(b) the advice referred to in point (a) shall not cover the design of studies to address the risk hypotheses unless the advice concerns guidance documents developed by the Authority in which study design is addressed. By way of derogation from the first sentence, where the potential applicant or notifier is a SME, it may notify the Authority of how it intends to address the ~~plausible~~ risk hypotheses referred to in point (a) that it has identified to be tested in the risk assesment ~~based on the properties of a plant, product or hypothetical plant or product~~, including the design of the studies it intends to perform in accordance with the requirements laid down Parts 2 and 3 of Annex II. The Authority shall provide advice on the notified information, including on the design of the studies.

4. The pre-submission advice referred to in paragraph 3 shall comply with the following requirements:

(a) it shall be without prejudice and non-committal as to any subsequent assessment of applications or notifications by the Panel on Genetically Modified Organisms of the Authority. The staff of the Authority providing the advice shall not be involved in any preparatory scientific or technical work that is directly or indirectly relevant to the application or notification that is the subject of the advice;

(b) for potential notifications in accordance with Article 13 of Directive 2001/18/EC in conjunction with Article 14 and for potential applications under Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19 concerning a category 2 NGT plant to be used as seeds or other plant reproductive material, the pre-submission advice shall be provided by the Authority together, or in close

collaboration with the competent authority of the Member State to which the notification or application is going to be submitted;

(c) the Authority shall make public without delay a summary of the pre-submission advice once an application or notification has been considered valid. Articles 38(1a) of Regulation (EC) No 178/2002 shall apply *mutatis mutandis*;

(d) potential applicants or notifiers demonstrating that they are a SME can request the pre-submission advice referred to in paragraph 3, point (a), at different points in time.

5. Any request for the incentives shall be submitted to the Authority at the time of request of advice referred to in paragraph 3 or the application referred to in Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19, and accompanied by the following information:

(a) the information necessary to establish that the intended trait(s) conveyed by the genetic modification of the category 2 NGT plant meet the conditions referred to in paragraph 1;

(b) where applicable, the information necessary to demonstrate the (potential) applicant or notifier is a SME;

(c) for the purpose of paragraph 3, information on the aspects listed in Part 1 of Annex II as far as it can already be provided and any other relevant information.

6. Article 25 of Directive 2001/18/EC and Article 30 of Regulation (EC) No 1829/2003 shall apply to information submitted under this article to the Authority, as appropriate.

7. The Authority shall lay down the practical arrangements to implement paragraphs (3) to (6), including the verification that the category 2 NGT plant meets the conditions referred to in paragraph 1.

8. The Commission is empowered to adopt delegated acts in accordance with Article 26 amending the lists of traits of NGT plants laid down in Annex III in order to adapt them to advances in scientific and technological progress and or to new evidence relating to the impact on sustainability of those traits, subject to the following conditions:

(a) the Commission shall take into account the monitoring of the impacts of this Regulation in accordance with Article 30(3);

(b) the Commission shall conduct and publish an up-to-date scientific literature review of the impacts on environmental, social and economic sustainability of the trait(s) it intends to add to or delete from the list in Annex III;

(c) where applicable, the Commission shall take into account the results of monitoring which was carried out in accordance with Article 14, point (h), or Article 19(3), of category 2 NGT plants harbouring the trait(s) conveyed by their genetic modification.

Article 23

Labelling of authorised category 2 NGT products

In addition to the labelling requirements referred to in Article 21 of Directive 2001/18/EC, Articles 12, 13, 24 and 25 of Regulation (EC) No 1829/2003, and Article 4(6) to (7) of Regulation (EC) No 1830/2003, and without prejudice to the requirements under other Union legislation, the labelling of authorised category 2 NGT products may also mention the trait(s) conveyed by the genetic modification, as specified in the consent or the authorisation pursuant to Sections 2 or 3 of Chapter III of this Regulation. Where use is made of this provision, the label shall mention all the traits of the category 2 NGT plant conveyed by the genetic modification.

~~*Article 24*~~

~~**Measures to avoid the unintended presence of category 2 NGT plants**~~

~~Member States shall take appropriate measures~~ as regards cultivation of category 2 NGT plants with ~~the aim of avoiding~~ to avoid the unintended presence of category 2 NGT plants in products ~~crops not subject to Directive 2001/18/EC or Regulation (EC) No 1829/2003.~~

~~The Commission shall complement and update the guidelines referred to in Article 26a(2) of Directive 2001/18/EC, as appropriate.~~

~~*Article 25*~~

~~**Cultivation**~~

~~Article 26b of Directive 2001/18/EC shall not apply to category 2 NGT plants.~~

CHAPTER IV

FINAL PROVISIONS

Article 26

Exercise of the delegation

1. The power to adopt the delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt the delegated acts referred to in Article 5(3) and Article 22(8) shall be conferred on the Commission for a period of 5 years from *[date of entry into force of this Regulation]*. The Commission shall draw up a report in respect of the delegation of power not later than 9 months before the end of the 5-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than 3 months before the end of each period.

3. The delegations of power referred to in Article 5(3) and Article 22(8) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making([43]).

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

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to ~~Articles~~ Article 5(3) and Article 22(8) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or of the Council.

Article 27

Implementing acts

The Commission shall adopt implementing acts concerning:

(a) the information required to demonstrate that a plant is a NGT plant;

(b) the preparation and the presentation of the verification requests, and the content of the verification reports and of the decisions referred to in Articles 6 and 7;

(c) the methodology and information requirements for the environmental risk assessment of category 2 NGT plants and the safety assessments of category 2 NGT food and feed, in accordance with the principles and factors ~~criteria~~ laid down in Annex II;

(d) the application of Articles 14 and 19, including rules concerning the preparation and the presentation of the notification or application;

(e) adapted modalities to comply with analytical method performace requirements referred to in Article 14(1), point (l), and Article 19(2).

Before adopting the implementing acts referred to in points (a) to (d), the Commission shall consult the Authority. The implementing acts shall be adopted in accordance with the procedure referred to in Article 28(3).

Article 28

Committee procedure

1. The Commission shall be assisted by the committee set up by Article 58 of Regulation (EC) No 178/2002.

2. Where reference is made to this paragraph, Article 4 of Regulation (EC) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EC) No 182/2011 shall apply.

Article 29

Guidance

1. Before the date of application of this Regulation, the Authority shall publish detailed guidance to assist the notifier or the applicant in the preparation and the presentation of the notifications and the application referred to in Chapters II and III and for the implementation of Annex II.

2. Before the date of application of this Regulation, the European Union Reference Laboratory for Genetically Modified Food and Feed established pursuant to Article 32 of Regulation (EC) No 1829/2003, assisted by the European Network of GMO Laboratories, shall publish detailed guidance to assist the notifier or the applicant for the application of Article 14(1), point (l), and Article 19(2).

Article 30

Monitoring, reporting and evaluation

1. No sooner than three years and no later than five years after the first decision is adopted in accordance with Article 6(8) or (10) or Article 7(6) or in accordance with Sections 2 or 3 of Chapter III, whichever is the earliest, and thereafter every five years, the Commission shall forward to the European Parliament, the Council, the European Economic and Social

Committee and the Committee of the Regions a report on the implementation of this Regulation.

2. The report shall also address any ethical issues that have arisen with the application of this Regulation.

3. For the purpose of the reporting referred to in paragraph 1, the Commission, by *[24 months after the date of entry into force of this Regulation]* at the latest, shall establish, after consulting the competent authorities of the Member States in accordance with Directive 2001/18/EC and Regulation (EC) No 1829/2003, a detailed programme for monitoring, based on indicators, the impact of this Regulation. It shall specify the action to be taken by the Commission and by the Member States in collecting and analysing the data and other evidence.

4. No sooner than two years and no later than three years after the publication of the first report referred to in paragraph 1 the Commission shall carry out an evaluation of the implementation of this Regulation and its impact on human and animal health, the environment, consumer information, the functioning of the internal market, small or medium-sized enterprises (SMEs), the organic sector, and economic, environmental and social sustainability.

5. The Commission shall present a report on the main findings of the evaluation referred to in paragraph 4 to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

Article 30 bis

NGT patent expert group and the study on the impact of patenting practices

~~The Commission shall conduct a study on the impact that the patenting of plants and related licensing and transparency practices may have on innovation in plant breeding, on breeders' access to plant genetic material and techniques and on availability of plant reproductive material to farmers as well as the overall competitiveness of the EU plant breeding industry.~~

~~The Commission shall report on its findings not later than 31 December 2025 and, in view of the outcomes of the study, the Commission shall inform on measures to follow-up or, if appropriate, submit a proposal.~~

1. As from the date of entry into force of this regulation, the Commission shall establish an expert group on the effect of patents on NGT plants (the 'NGT patent expert group').

2. The NGT patent expert group shall survey and exchange information on a regular basis as regards the effect of patent law and the implementation practice on access to modified genetic resources, transparency of the patent landscape and innovation in the field of NGT plants. The NGT patent expert group shall in particular survey the patent licensing practices for the breeding and marketing of NGT plants protected by a patent, ongoing patent application procedures on NGT plants and patent enforcement practices vis à vis farmers and, if available, case-examples thereof.

3. The NGT patent expert group shall be constituted in accordance with Commission Decision C(2016) 3301 final of 30 May 2016 establishing the horizontal rules on the creation and operation of Commission expert groups. Each Member State may appoint a delegation of maximum two experts to the NGT patent expert group. The experts shall have knowledge and experience in the areas covered by this Regulation and in the area of intellectual property rights, including their impact on the market. The European Patent Office may also appoint one expert to the NGT patent expert group.

4. The Commission shall conduct a study on the impact that the patenting of plants, as well as related licensing and transparency practices, may have on innovation in plant breeding, on breeders' access to plant genetic material and techniques and on the availability of plant reproductive material to farmers as well as the overall competitiveness of the EU plant breeding industry. The study shall include, in particular, an evaluation of the conditions necessary to ensure the access of breeding companies using new genomic techniques that qualify as micro, small or medium-sized enterprises in accordance with Commission Recommendation 2003/361/EC to patented modified genetic resources in fair, transparent and predictable terms, including whether they should be granted commercial access to those resources free of cost. When carrying out the study and considering the appropriate follow-up actions, the Commission shall take into account the findings of the NGT patent expert group. The Commission shall report on its findings one year after entry into force of this Regulation~~no later than 31 December 2025~~.

5. ~~From the 1 January 2026 on, t~~The NGT patent expert group may continue working for as long as necessary after the completion of the study referred to in paragraph 4.

6. In view of the outcomes of the study referred to in paragraph 4, the Commission shall inform on measures to follow-up, and in particular, if appropriate, submit a proposal addressing any identified issues such as negative impacts on breeders or farmers. If the Commission considers there is no need to submit a proposal, it shall inform the Parliament and the Council of the reasons.

Article 31

References in other Union legislation

With regard to category 2 NGT plants, references in other Union legislation to Annex II or Annex III to Directive 2001/18/EC shall be construed as references to Parts 1 and 2 of Annex II to this Regulation.

Article 32

Administrative review

Any decision taken under, or failure to exercise, the powers vested in the Authority by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person directly and individually concerned.

To this effect a request shall be submitted to the Commission within two months from the day on which the party concerned became aware of the act or omission in question.

The Commission shall prepare a draft decision within two months requiring, if appropriate, the Authority to withdraw its decision or to remedy its failure to act.

Article 33

Amendments to Regulation (EU) 2017/625

Article 23 of Regulation (EU) 2017/625 is amended as follows:

(1) in paragraph 2, point (a)(ii) is replaced by the following:

‘(ii) the cultivation of GMOs for food and feed production and the correct application of the plan for monitoring referred to in Article 13(2), point (e), of Directive

2001/18/EC, in Article 5(5), point (b), and Article 17(5), point (b), of Regulation (EC) No 1829/2003 and in Articles 14(1), point (h) and 19(3), point (b) of Regulation [*reference to this Regulation*];';

(2) in paragraph 3, point (b) is replaced by the following:

'(b) the cultivation of GMOs for food and feed production and the correct application of the plan for monitoring referred to in Article 13(2), point (e), of Directive 2001/18/EC, in Article 5(5), point (b), and Article 17(5), point (b), of Regulation (EC) No 1829/2003 and in Articles 14(1), point (h) and 19(3), point (b) of Regulation [*reference to this Regulation*];'.

Article 34

Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

2. It shall apply from [*24 months from the date of entry into force of this Regulation*].

3. Article 30 bis shall apply from the entry into force of this regulation.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

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;

(2) deletion of any number of nucleotides;

Criteria specific to the use of cisgenesis:

(3) 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:

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

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

(4) targeted inversion of a sequence of any number of nucleotides.~~;~~

~~(5) 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.~~

ANNEX II

Risk assessment of category 2 NGT plants and category 2 NGT food and feed

Part 1 of this Annex describes the general principles to be followed to perform the environmental risk assessment of category 2 NGT plants referred to in Article 13, points (c) and (d), Article 14(1), point (e), and Article 19(3), point (a), and the safety assessment of category 2 NGT food and feed referred to in Article 19(1), point (b). Part 2 describes specific information for the environmental risk assessment of category 2 NGT plants and Part 3 describes specific information for the safety assessment of category 2 NGT food and feed.

Part 1- General principles and information

The environmental risk assessment shall be carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC.

The type and amount of information necessary for the environmental risk assessment of category 2 NGT plants laid down in Annex III of Directive 2001/18/EC and for the food and feed safety assessment of category 2 NGT food and feed shall be adapted on a case by case basis ~~to their risk profile~~. Factors to be considered include:

(a) the characteristics of the category 2 NGT plant, in particular the trait(s) introduced, the function of the modified or inserted ~~genome~~ genomic sequence(s) and the function of any gene disrupted by the inserted ~~genome~~ genomic sequence(s) ~~insertion of a cisgene or parts thereof~~;

(b) prior experience with the consumption of the same plant species or plant species exhibiting similar traits or in which similar genomic sequences have been modified, inserted or disrupted, ~~similar plants~~ or their products;

(c) prior experience with the cultivation of the same plant species or plant species exhibiting similar traits or in which similar ~~genome~~ genomic sequences have been modified, inserted or disrupted;

(d) the scale and conditions of the release;

(e) the intended conditions of use of the category 2 NGT plant;~~.~~

(f) the potential receiving environment.

The environmental risk assessment of category 2 NGT plants and the risk assessment of category 2 NGT food and ~~NGT~~ feed shall consist of the following:

(a) problem formulation including hazard identification and hazard characterisation;

(b) exposure characterisation ~~assessment~~;

(c) risk characterisation;~~.~~

(d) risk management strategies, as applicable;

(e) overall risk evaluation and conclusion.

The following information shall always be required:

(a) hazard identification and hazard characterisation

(i) information relating to the recipient plant or, where appropriate, to the parental plants;

(ii) molecular characterisation.

The information shall be provided by collating already available data from scientific literature or from other sources or generating scientific data where necessary by performing appropriate experimental or bioinformatic studies.

(b) exposure characterisation ~~assessment~~

Information shall be provided on the likelihood of each identified potential adverse effect. This shall be evaluated taking into consideration, as relevant, the characteristics of the receiving environment(s), the scale and conditions of release, the intended function, the dietary role, the expected level of use of the food and feed in the EU and the scope of the application for authorisation.

(c) risk characterisation

The applicant shall base its risk characterisation of category 2 NGT plants and foods and feed on information from hazard identification, hazard characterisation and exposure assessment. The risk shall be characterised by combining, for each potential adverse effect, the magnitude with the likelihood of that adverse effect occurring to provide a quantitative or semi quantitative estimation of the risk. Where relevant, the uncertainty for each identified risk shall be described and, where possible, expressed in quantitative terms.

~~Any i~~Information on hazard identification and hazard characterisation specified under Parts 2 and 3 shall only be required ~~if the specific characteristics and the intended use of the category 2 NGT~~

~~plant or category 2 NGT food or feed give rise to a plausible~~ when necessary to address the risk hypothesis for the category 2 NGT plant or category 2 NGT food or feed ~~that can be addressed utilising the specified information~~.

Part 2 - Specific information for the environmental risk assessment of category 2 NGT plants concerning hazard identification and hazard characterisation

(1) Analysis of agronomic, phenotypic and compositional characteristics

(2) Persistence and invasiveness, including any selective advantage and disadvantage

(3) Potential gene transfer

(4) Interactions of the category 2 NGT plant with target organisms

(5) Interactions of the category 2 NGT plant with non-target organisms

(6) Impacts of the specific cultivation, management and harvesting techniques

(7) Effects on biogeochemical processes

(8) Effects on human and animal health

Part 3–Specific information for the safety assessment of category 2 NGT food and feed concerning hazard identification and hazard characterisation

(1) Analysis of agronomic, phenotypic and compositional characteristics

(2) Toxicology

(3) Allergenicity

(4) Nutritional assessment

ANNEX III

Traits referred to in Article 22

Part 1

Traits justifying the incentives referred to in Article 22:

(1) improved yield, including yield stability and yield under low-input conditions;

(2) tolerance/resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses, insects and other pests;

(3) tolerance/resistance to abiotic stresses, including adaptation to climate change conditions ~~those created or exacerbated by climate change~~;

(4) more efficient use of natural resources, such as water and nutrients;

(4 bis) reduced need for external inputs, such as plant protection products and fertilisers;

(5) characteristics that enhance the sustainability of storage, processing and distribution;

(6) improved quality or nutritional characteristics;

(7) bioremediation. ~~reduced need for external inputs, such as plant protection products and fertilisers.~~

Part 2

Traits excluding the application of the incentives referred to in Article 22: tolerance to herbicides.