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INFORMATION NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee (Part 1)
Subject:	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 *- Analysis of the final compromise text with a view to agreement*

Delegations will find in annex the text reflecting the political agreement reached at the trilogue on 3 December 2025 on the abovementioned proposal, before legal-linguistic revision. The text is the same in substance as that in the fourth column of the four-column table set out in document 16661/25.

ANNEX

2023/0226 (COD)

Draft

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on plants obtained by certain new genomic techniques and their ~~food and feed~~*products*, 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 ~~precise~~***targeted*** 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 state of these conventional*** breeding techniques. Targeted mutagenesis techniques result in modification(s) of the DNA sequence at ~~precise~~***targeted*** 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~~***The*** genetic material ~~composed of two or~~

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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***

~~more DNA~~***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 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 ~~through~~***by*** 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

[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.

Deal ([5]) and of the 'Farm to Fork' ([6]), Biodiversity ([7]) and Adaptation to Climate Change([8]) Strategies, to 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 ~~2009/1/EC~~***2009/41/EC ([14])***, and transboundary

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

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

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

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

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).***

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

(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 ~~with~~***by*** 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

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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).***

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.

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 Network of GMO Laboratories (ENGL), with the support of the European Union Laboratory for GM Food and Feed (EURL), stressed that products that have identifical DNA sequence but have been developed either naturally or by conventional breeding or by 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

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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).***

products, while addressing the specificity of NGT plants. ***A precautionary and science-based approach should guide their governance.*** This legal framework should enable the development and placing on the market of ***NGTs*** plants ***and their products***, ***including*** food and feed ~~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. ***Through these objectives, this Regulation contributes to the integrated and unifying 'One Health' approach.***

(11) This Regulation constitutes lex specialis with regard to the Union GMO legislation. It introduces specific provisions for NGT plants and ~~NGT~~***their*** 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 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 under the term 'plant' (when it is deliberately released into the environment) and under the term 'product' (when it is placed on the market, including for the purpose of 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 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') 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)*** and lay down a procedure for competent authorities to verify and take a decision on the ~~fulfillment~~***fulfilment*** of those criteria, prior to the release or placing on the market of NGT plants or NGT products. ***The criteria should be fulfilled in the plant intended to be released or placed on the market as a category 1 NGT plant. Any genetic modifications temporarily introduced during the development of the NGT plant and removed from the plant intended to be released or placed on the market should not be relevant for the verification of the criteria.*** Those criteria should be objective and based on ~~science~~***up-to-date scientific knowledge***. They should cover the type and extent of genetic modifications that can be observed in nature or in organisms obtained ~~with~~***by*** conventional breeding techniques and should include thresholds for ~~both size and~~***the size of genetic modifications, the*** number of genetic modifications ~~to the genome of 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~~***per protein-coding sequence and the overall number*** of genetic modifications ***per NGT plants. As regards the latter, the criteria for considering that a NGT plant is equivalent to a naturally occurring or conventionally bred plant should reflect the complexity of plant genomes*** ~~that can occur in nature or through conventional breeding~~. ***Therefore, the limit to the total number of individual modifications per plant for inclusion in category 1 NGT should be proportionate to the number of genome copies ("ploidy") of the plant.***

(14a) 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 gene pool for conventional breeding purposes is also possible through conventional breeding. The scientific literature also shows differences in the size of these individual genetic modifications and in the number of genetic modifications per plant, considering also for the latter the ploidy level of the plant. On this basis, targeted substitutions and insertions of limited size, deletions of any size, larger substitutions with, and insertions of, continuous sequences of genetic material from the gene pool for conventional breeding purposes, as well as inversions and translocations of continuous endogenous DNA sequences should be included in the criteria of equivalence. In addition, those criteria should contain certain conditions in order to exclude intragenic plants, including those that produce chimeric proteins, from category 1 NGT plants since novel hazards can be associated with intragenic plants compared with cisgenic and conventionally bred plants[2021]. To this effect, the criteria for plants obtained by cisgenesis should exclude genetic modifications that lead to interruptions of endogenous genes, unless they result in a combination of DNA sequences that occurs in the gene pool for conventional breeding purposes and can therefore be considered cisgenic and not intragenic.

(14b) 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,

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

21 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.

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.

(14c) Traits supporting the production of a known insecticidal substance, should be considered as an exclusion criterion from category 1 NGT. Such traits are aimed at killing insect pests, but they may also have adverse effects on beneficial insects such as pollinators. Based on the latter, plants that are developed to include such traits should be subject to the provisions of category 2 NGT plants.

(14d) Since category 1 NGT plants encompass plants that are equivalent to plants occurring naturally or obtained by conventional breeding and that should be treated in the same way as those plants, 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 that has obtained declaration of that status, including the result of the crossing of such a category 1 NGT plant with a conventionally bred plant, or of the crossing of two such category 1 NGT plants, or their respective progeny, 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, 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.

(14e) 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 criteria of equivalence 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. ***For the same reason, in order to improve transparency for breeding activities prior to deliberate release, including placing on the market, requesters should submit declarations describing the extent to which a plant for which the verification of NGT 1 status has been requested benefits from any type of patent protection. Requesters should make such declarations to the best of their knowledge, providing any relevant information of which they are aware. At the same time, the existence of patent protection should not determine the eligibility of the plant for category 1 NGT status, which is based solely on scientific equivalence criteria.***

(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) Requesters for a declaration of category 1 NGT plant status should demonstrate that the plant is a category 1 NGT plant. To this end, they should carry out studies and provide any other available material to demonstrate that the plant is a NGT plant and that it fulfills the criteria of equivalence to conventional plants. Requesters should also provide scientific evidence substantiating the relation between the introduced genetic modifications and the intended traits based on, inter alia, relevant scientific literature, information related to any plants already developed or marketed featuring similar genetic modifications and traits, any existing data gathered during the breeding process or from releases in third countries. The requester should also provide a declaration that the intended traits do not correspond to traits excluding NGT plants from category 1

status. All material used to provide the evidence should be up-to-date and should reflect the latest stage of development of the plant.

(17b) The balance between effective protection of invention and stimulation of research and development on the one hand and wide access to varieties serving the development of new varieties on the other hand should be maintained. Making patents on category 1 NGT plants available to breeders on fair and reasonable conditions and providing information on the willingness to licence should contribute to the development of new varieties, and to further encourage the development and placing on the market of category 1 NGT plants and their products obtained by NGTs. To that end, it should be possible for the patent holder, irrespective of whether it is the requester, to confirm their willingness to license their patent under fair and reasonable conditions, such as those referred to in licensing platforms, among others. This information should be provided by the requester on a voluntary basis, in the context of category 1 NGT verification procedure. Where the requester is the patent holder, they should provide information clarifying the intent to licence or not, and to participate in voluntary licensing platforms.

(17c) 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 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~~***appropriate*** 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 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 products, those NGT plants and their products will be subject to the applicable sectoral legislation on seed and other plant reproductive material, food, feed and other products, and horizontal frameworks, such as the nature conservation legislation and environmental liability. In this regard, ***safeguard measures necessary to protect human and animal health and the environment may be taken under the applicable Union legislation, including the emergency measures concerning food and feed under Articles 53 and 54 of Regulation (EC) No 178/2002, the emergency measures concerning plant reproductive material of varieties of agricultural plant species under Articles 16(2) and 18 of Directive 2002/53/EC and of varieties of vegetable species under Articles 16(2) and 18 of Directive 2002/55/EC, and other safeguard measures in Union legislation governing the placing on the market of products, such as medicinal products, cosmetic products, and fertilisers. Also,*** 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 ~~(22)~~ and will be risk assessed in that context.

(23) ***This Regulation should not impede progress towards the Farm to Fork Strategy and the EU Biodiversity Strategies target of 25% of agricultural land under organic farming by 2030.*** 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(**23**) 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. ***Currently, the compatibility of*** the use of new genomic techniques ~~is currently incompatible~~ with the ~~concept~~***principles*** of organic production ~~in the Regulation (EC) 2018/848 and with consumers' perception of organic products~~***requires further consideration***. The use of category 1 NGT plants should therefore be ~~also~~ prohibited in organic production***, until such further consideration takes place***.

(23a) Organic production chains are, with the exceptions set out in Regulation (EU) 2018/848, already separated from conventional production chains so that unintended presence is avoided. To keep the burden for organic producers proportionate, by applying the same precautionary measures as those already applied to conventional plants and products not authorised in organic production, the adventitious or technically unavoidable presence of category 1 NGT plants and their products in organic production should not constitute non-compliance with Regulation (EU) 2018/848. Moreover, in certain circumstances it may be necessary for Member States to adopt appropriate measures on their territory to

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~~22~~ 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).

23 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).

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) 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 ***including information on the technique or techniques used to obtain the trait or traits. For transparency reasons, the patent information and the declarations as provided by the requester should also be included in the database and be kept up-to-date, without any responsibility on the part of the Commission for the accuracy of that information and subject to the caveat that this information is only limited to what the requester was aware of***. 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.

(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~~***In particular, they*** 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~~***remain subject*** to the ~~specific nature of~~***authorisation, labelling, and traceability requirements. The possibility for Member States to restrict or prohibit cultivation of GMOs on their territory and to take appropriate measures to avoid the unintended presence of GMOs in other products also continue to apply to*** category 2 NGT plants ~~and the differing levels of risk that they may pose~~***, given that experience has shown that cultivation of genetically modified plants is an issue with strong national, regional and local dimensions and taking into account inter alia the diversity of farming systems and natural and economic conditions, such as those pertaining to islands***.

(25a) However, 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 ***and other provisions, including on measures necessary to protect human and animal health and the environment such as modification, suspension and revocation of authorisation and emergency measures,*** 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[24] and on plants developed through targeted mutagenesis[25] 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' ([26]), 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

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24 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.

25 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.

26 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.

~~criteria~~***information requirements*** 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***, other than food or feed,*** containing or consisting of GMOs ~~other than food or feed~~***,*** and on the content of applications for authorisation for the placing on the market 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~~***has identified*** analytical ~~testing is not considered feasible for all~~***challenges and limitations associated with the identification and quantification of certain plants and*** products obtained by targeted mutagenesis and cisgenesis ([27]). ***For example,*** when 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 ~~where it is not feasible to provide~~***,*** an analytical method ~~that detects, identifies and quantifies, if duly justified~~***should still be provided*** by the notifier or ~~the~~ applicant***, but, if duly justified***, the modalities to comply with analytical method ***performance*** 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

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[27] 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)

GMO, of its expected use and of the receiving environment. ***In view of the precautionary principle this requirement for a monitoring plan should apply as a rule to category 2 NGT plants. However,*** genetic 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 ~~should be adapted~~***where duly justified, based on the results of any previous release of the category 2 NGT plant*** in the ~~light~~***Union, the findings*** of the environmental risk assessment ~~and the experience in field trials~~, the characteristics of the ***category 2*** 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 or 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~~***it*** should be ~~allowed~~***possible for operators*** to complement the labelling of category 2 NGT products as GMO with information on the ~~trait~~***traits*** conferred by the genetic modification***, provided that this information concerns all traits***. 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[28]]. 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 ~~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([29]). ***The submission of evidence demonstrating compliance with regulatory requirements in the context of a notification for consent 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

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28 ~~-~~COM(2023) 414 final

29 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).

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.

(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.~~

~~(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 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.~~

(39) To achieve the goal of ensuring the effective functioning of the internal market, NGT plants and ~~related~~***their*** 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 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.

(40a) Member States should be responsible for ensuring compliance with this Regulation. For instance, they should ensure that NGT plants, being released or placed on the Union market, have obtained a category 1 NGT plant status decision, if they meet all the relevant requirements, or a category 2 NGT plant consent or authorisation. Where NGT plants and their products fall within the scope of the rules referred to in Article 1(2) of Regulation (EU) 2017/625, Member States should plan and perform official controls and other official activities in compliance with that Regulation, including for imports. Relevant data generated in the performance of official controls in accordance with Regulation (EU) 2017/625 should be taken into account by the Commission in the monitoring of the sustainability impacts of NGT plants as provided in Article 30b.

(41) ~~In order to provide~~***To ensure*** a high level of protection ~~of~~***for*** health and ~~environmental protection in relation to NGT plants and NGT products, requirements arising from~~***the environment, while keeping the Union competitive,*** this Regulation should apply ~~in a non-discriminatory manner to~~***equally to NGT plants and*** products originating in the Union and ***those*** imported from third countries. ***Therefore, importing NGT plants and products from third countries should not be prohibited as long as they meet the requirements set out in this Regulation.***

(41a) 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~~***lists*** of traits that should be incentivized or discouraged ***in category 2 NGT plants*** to achieve the goals of the Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies.~~2~~

(43a) In order to maintain a high level of transparency and information, to take into account scientific progress and to simplify verification requests, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the information required to demonstrate that a plant is an NGT plant, as well as of the preparation and the presentation of the verification requests, the content of the patent information, the content of the license declaration, the content of the verification reports and the content of the decisions taken in the context of the verification procedure.

(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 ([30]). 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

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

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 ***or application for category 2 NGT plants,*** ~~for that determination, and~~ as regards the methodology and information requirements for the environmental risk assessments of category 2 NGT plants ~~and of~~ ***and the safety assessment of category 2*** NGT food and ~~NGT~~ feed, in accordance with the principles and ~~criteria~~***factors*** laid down in this Regulation***, and as regards adapted modalities to comply with analytical method requirements***. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council([31]).

(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*** 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[32] and should be periodically reviewed by the Commission. The indicators should support monitoring of ~~potential risks to~~***intended and unintended impact on human and animal*** health ~~or~~***and*** the environment ~~of category 2 NGT plants and related NGT products,~~***, including on biodiversity, and*** impact ~~of NGT plants~~ on environmental, economic and social sustainability ***of NGT plants and their products,*** 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

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[31] 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).

[32] ***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

~~notified/authorised~~***notified or 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 conduct an assessment 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 biological 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, in particular small and medium sized breeders, and the potential risks of market concentration. For the same reason, the Commission should establish an expert group on the effect of the patenting of NGT plants. The on-going evaluation of Regulation (EC) No 2100/94 on Community Plant Variety Rights will also consider the coherence between patents and plant variety rights, including any relevant provisions on the interface between them, such as Article 92 of that Regulation. 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. To this end, the Commission should take appropriate actions including, if appropriate, proposing legislative measures.

(46b) Stakeholders raised concerns that patents on NGT plants may limit the access of breeders to those plants for purposes of developing other plant varieties. In this regard, Article 27(c) of the Agreement on a Unified Patent Court already provides that the rights conferred by a patent do not extend to the use of biological material for the purpose of breeding, or discovering and developing other plant varieties. It is important that all Member States address the mentioned concerns and ensure legal certainty for plant breeders by taking appropriate steps to implement a corresponding limitation to patent rights in their national patent laws, to ensure its coherent application across the Union.

(46c) Under Directive 98/44/EC, as interpreted by Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions and Article 53(b) of the European Patent Convention, patents are not to be granted in respect of plants exclusively obtained by means of an essentially biological process. To ensure that patents on plants made by technical methods do not extend to plants that have been produced by essentially biological processes and carry the same characteristics, the European Patent Office requires that a disclaimer be included in the patent. Therefore, for a plant obtained by technical processes, the part of the patent claim defining exactly what is to be protected is required to specify that the patent does not include plants produced by essentially biological processes.

(46d) Breeders can benefit from guidance to help them navigate the plant intellectual property landscape. The Commission should therefore publish guidance to assist operators, in particular breeders, in navigating the plant intellectual property landscape.

(46e) Breeders should have a broad understanding of, and opportunities to benefit from, the various programmes, mechanisms and policies designed to support research and development in the area of new genomic techniques. The Commission should therefore publish information for operators about the opportunities to benefit from the various programmes, financial mechanisms and policies designed to support research and development in the area of new genomic techniques.

(46f) In accordance with Directive 98/44/EC, the holder of the patent is to be entitled to prohibit the use of patented self-reproducing material in situations analogous to those where it would be permitted to prohibit the use of patented, non-self-reproducing products. However, situations where the unintentional or accidental presence of patented biological material of NGT plants occurs during agricultural activity by farmers, as a result of natural self-replication through cross-pollination, are not comparable to the situations that may arise for non-self-reproducing products. This is a relevant factor when determining whether a patent on an NGT plant has been infringed in such situations. Even if it is concluded that a patent infringement has occurred, Directive 2004/48/EC lays down the framework for the enforcement of intellectual property rights and requires, inter alia, that measures, procedures and remedies provided by Member States be proportionate and applied in such a manner as to avoid the

creation of barriers to legitimate trade and to provide for safeguards against their abuse. This requirement applies when determining the appropriate enforcement measures, procedures, and remedies in these situations.

(46g) The Commission, in cooperation with the Member States, should oversee the drawing up of a Union-level code of conduct to support transparency on patents on plant biological material, breeders' access to such material and legal certainty for breeders and farmers. The Commission should aim that the code include commitments by patent owners to provide clear and publicly accessible patent information, to license patents on fair and reasonable terms, and to seek the amicable settlement of patent disputes with breeders that are SMEs, and farmers in case of unintentional minor presence of patented biological material in their fields. In the latter case, patent owners may consider refraining from enforcing their patent rights. The Commission should also aim that the code include commitments by voluntary licensing platforms to promote cost-attractive participation for SMEs, standard licence agreements and fair mechanisms for resolving disagreements. The Commission should monitor and evaluate the rate of participation in and the functioning of the code of conduct, and, if the evaluation observes constant or aggravated non-compliance with the provisions covered in the code of conduct, the Commission should take appropriate actions including, if appropriate, proposing legislative measures to safeguard the good functioning of the sector, in particular access to patented NGT plant biological material for primary users, including farmers.

(47) Certain references to provisions of the Union GMO legislation in Regulation (EU) 2017/625 of the European Parliament and of the Council ([33]) need to be amended to include the specific provisions in this legislation applicable to NGT plants.

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[33] 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

(48) Since the application of this Regulation requires the adoption of implementing ***and delegated*** 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 *and objectives*

This Regulation aims to ensure a high level of protection of human and animal health and the environment, in accordance with the precautionary principle, and the effective functioning of the internal market in relation to NGT plants and NGT products, while enhancing innovation, sustainability and competitiveness.

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

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;

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).

(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([34]) 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[35]];

(1a) 'genetically modified organism' or 'GMO' means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC;

(2) 'NGT plant' means a genetically modified plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the ~~breeders'~~ gene pool ***for conventional breeding purposes*** 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;~~

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[34] 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).

[35] COM(2023) 414 final

(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 ***for conventional breeding purposes'***;

(6) '~~breeders'~~ gene pool ***for conventional breeding purposes***' 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 traits in Annex Ia among the intended trait(s) conveyed by the genetic modification(s), or*** ~~or~~

(b) is progeny of the NGT plant(s) referred to in point (a), including progeny ~~derived~~***obtained*** by crossing of such plants, on the condition that there are no further modifications ***obtained through targeted mutagenesis or cisgenesis or other techniques*** that would make it subject to Directive 2001/18/EC or ~~Regulation 1829/2003~~***Regulation (EC) No 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 ***NGT plants, and products other than food and feed containing or consisting of such plants*** ~~such a plant~~;

(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].

(15b) “Chimeric protein” means proteins created through the joining of two or more genes or parts of genes that originally coded for separate proteins.

Article 4

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

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

(1) the plant is a category 1 NGT plant and ***has obtained a decision declaring that status in accordance with Article 6 or 7; or***

(1a) the plant is progeny of plant(s) referred to in point (1) and is a category 1 NGT plant as defined in Article 3(7)(b); or

~~(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*** ~~and~~ has been authorised in accordance with Chapter III.

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 conditions of articles 4(1) or 4(1a) and their NGT products***.

2. For the purposes of Regulation (EU) 2018/848, the rules set out in its Articles 5 (f) (iii) and ***Article*** 11 shall apply to category 1 NGT plants and to products produced from or by such plants. ***However, the adventitious or technically unavoidable presence of category 1 NGT plants, including plant reproductive material, and products produced from or by such plants, in organic production, or in non-organic substances and products authorised in organic production in accordance with Article 24, or in agricultural ingredients for processed organic food, authorised in accordance with Article 25 of Regulation (EU) 2018/848, shall not constitute non-compliance with that Regulation.***

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 ***those criteria*** ~~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. The Commission shall also justify in the report that, following the proposed amendment of Annex I, NGT plants meeting the equivalence criteria will remain equivalent to plants occurring naturally or obtained through conventional

breeding in terms of similarity of genetic modifications and similarity of potential risk.

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

Article 6

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

1. To obtain the declaration of category 1 NGT plant status referred to in Article 4(1), point (a), before undertaking a deliberate release of a NGT plant for any other purpose than placing on the market, the person intending to undertake the deliberate release shall submit a request to verify whether the ~~criteria~~***conditions*** set out in ~~Annex I~~***Article 3(7)(a)*** 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~~***delegated*** act adopted in accordance with Article ~~27, point~~ ***25a***(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)~~ ***or traits*** and characteristics which have been introduced or modified;

(d) a copy of the studies, ~~which have been carried out~~***including relevant DNA sequence information,*** and any other available material to demonstrate that:

(i) the plant is a NGT plant, including ***information on the technique or techniques used to obtain it, and information*** that it does not contain any genetic material originating from outside the ~~breeders'~~ gene pool ***for conventional breeding purposes*** where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the ~~implementing~~***delegated*** act adopted in accordance with Article ~~27, point (a);~~***25a(a).***

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

(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.

3a. Together with the verification request referred to in paragraph 1, the requester shall submit information, to the best of its knowledge, on patents or published patent applications including one or more claims on the biological material of the NGT plant, or declare the absence of such patents or published patent applications.

3b. The requester may submit a written declaration of the holder of a patent identified under paragraph 3a confirming their willingness to licence the protected subject matter under fair and reasonable conditions in all Member States where the patent holder is entitled to grant such a licence (licence declaration). If the requester is the holder of a patent which extends to the NGT plant, they shall submit a written declaration clarifying whether they are willing to licence the protected subject matter under fair and reasonable conditions in all Member States where the patent holder is entitled to grant such a licence. If the requester is the holder of a patent which extends to the NGT plant, they shall also submit a written declaration stating whether they are, or intend to become, a member of relevant and appropriate licensing platforms.

3c. ***The patent information and the licence declaration shall not be subject to verification and shall only have declaratory value.***

3d. ***The verification request referred to in paragraph 1 shall also include a declaration that the intended trait(s) are not listed in Annex Ia. The declaration shall be accompanied by scientific evidence substantiating the relation between the introduced genetic modification(s) and the intended trait(s), available at the time of submission of the request.***

4. The competent authority shall acknowledge receipt of the verification request***, the patent information and the licence declaration, where applicable,*** to the requester without undue delay, stating the date of receipt. It shall make available the request***, the patent information and the licence declaration, where applicable,*** to the other Member States and to the Commission without undue delay.

5. If the verification request does not contain all the necessary information***, the information referred to in paragraph 3a and, where applicable, paragraph 3b***, it shall be declared inadmissible by the competent authority within 30 working days within the date of receipt of a verification request. The competent authority shall inform the requester, the other Member States and the Commission without undue delay of the inadmissibility of the verification request and shall provide the reasons of its decision.

6. If the verification request is not deemed inadmissible in accordance with paragraph 5, the competent authority shall verify whether the NGT plant fulfils the ~~criteria~~***conditions*** set out in ~~Annex I~~***Article 3(7)(a)*** 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),*** within 20 days from the date of receipt of that report.

8. In the absence of any ~~comments~~***reasoned objection*** 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~~***reasoned objection*** 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 to the other Member States and*** to the Commission without undue delay.

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

10a. Where the Authority is consulted in accordance with paragraph 10, it shall make public the verification request, relevant supporting information and any supplementary information supplied by the requester, the reasoned objections, as well as its statement, with the exception of any information to which the Member State competent authority has granted confidential treatment in accordance with Article 11.

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

Article 7

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

1. Where a declaration of category 1 NGT plant status referred to in Article 4(1), point (a), has not already been made in accordance with Article 6, to obtain such a declaration before placing on the market a NGT product, the person intending to place the product on the market shall submit a verification request to the Authority in accordance with paragraph 2 and the ~~implementing~~***delegated*** act adopted in accordance with Article ~~27, point~~ ***25a***(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)~~ ***or traits*** and characteristics which have been introduced or modified;

(d) a copy of the studies, ~~which have been carried out~~***including relevant DNA sequence information,*** and any other available material to demonstrate that:

(i) the plant is a NGT plant, including ***information on the technique or techniques used to obtain it, and information*** that it does not contain any genetic material originating from outside the ~~breeders'~~ gene pool ***for conventional breeding purposes*** where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the ~~implementing~~***delegated*** act adopted in accordance with Article ~~27, point~~ ***25a***(a);

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

(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.

2a. Together with the verification request referred to in paragraph 1, the requester shall submit information, to the best of its knowledge, on patents or published patent applications including one or more claims on the biological material of the NGT plant, or declare the absence of such patents or published patent applications.

2b. The requester may submit a written declaration of the holder of a patent identified under paragraph 2a confirming their willingness to licence the protected subject matter under fair and reasonable conditions in all Member States where the patent holder is entitled to grant such a licence (licence declaration). If the requester is the holder of a patent which

extends to the NGT plant, they shall submit a written declaration clarifying whether they are willing to licence the protected subject matter under fair and reasonable conditions in all Member States where the patent holder is entitled to grant such a licence. If the requester is the holder of a patent which extends to the NGT plant, they shall also submit a written declaration stating whether they are, or intend to become, a member of relevant and appropriate licensing platforms.

2c. The patent information and the licence declaration shall not be subject to verification and shall only have declaratory value.

2d. The verification request referred to in paragraph 1 shall also include a declaration that the intended trait(s) are not listed in Annex Ia. The declaration shall be accompanied by scientific evidence substantiating the relation between the introduced genetic modification(s) and the intended trait(s), available at the time of submission of the request.

3. The Authority shall acknowledge receipt of the verification request***, the patent information and the licence declaration, where applicable,*** to the requester without ***undue*** delay, stating the date of receipt. It shall make available the verification request***, the patent information and the licence declaration, where applicable,*** 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***, the information referred to in paragraph 2a and, where applicable, paragraph 2b***, it shall be declared inadmissible by the Authority within 30 working days within the date of receipt of a verification request. The Authority shall inform the requester, the Member States and the Commission without undue delay of the inadmissibility of the verification request and shall provide the reasons of its decision.

5. If the verification request is not deemed inadmissible in accordance with paragraph 4, the Authority shall deliver its statement on whether the NGT plant fulfils the ~~criteria~~***conditions*** set out in ~~Annex I~~***Article 3(7)(a)*** 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 8

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

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

Article 9

Database of decisions declaring the category 1 NGT plant status

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

The database shall contain the following information:

(a) name and the address of the requester;

(b) the designation ***and specification*** 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~~***;***

(ea) where available, the statement of EFSA, as referred to in Article 6 (10) and Article 7(5); and

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

(fa) the patent information referred to in Article 6(3a) and Article 7(2a);

(fb) the declarations referred to in Article 6(3b) and Article 7(2b), where applicable.

2. The database shall be publicly available ***online***.

2a. Should there be any change in the information referred to in paragraph 1 letter (fa) or letter (fb), the requester, acting to the best of their knowledge, shall without undue delay inform the Commission of such a change. The Commission shall update the database accordingly.

Article 10

Labelling of category 1 NGT plant reproductive material, including breeding material*, and the transparency of information*

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.

The indication that a variety contains or consists of a category 1 NGT plant, and the identification number of the category 1 NGT plant(s) it has been derived from, shall be included in the catalogues of varieties referred to in Directive 2002/53/EC, Directive 2002/55/EC, Directive 68/193/EEC, and Directive 2008/90/EC, and in any data bases and marketing documentation where the plant reproductive material is offered. The indication that basic material intended for the production of forest reproductive material of the 'tested' category contains or consists of a

category 1 NGT plant, and the identification number of the category 1 NGT plant(s) it has been derived from, shall be included in the national lists referred to in Directive 1999/105/EC.

Article 11

Confidentiality

1. The requester referred to in ~~Articles 6 and 7~~ ***Article 6*** may submit a request to the Member State competent authority***, and the requester referred to in Article 7 may submit a request*** ~~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. ***Where the Authority assesses the confidentiality request, it shall apply the procedure set out in Article 39b of Regulation (EC) No 178/2002.***

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.

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) 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~~ ***including relevant DNA sequence information,*** and any other available material to demonstrate that the plant is a NGT plant,

including ***information on the technique or techniques used to obtain it, and information*** that it does not contain any genetic material originating from outside the ~~breeders'~~ gene pool ***for conventional breeding purposes*** where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the ~~implementing~~***delegated*** act adopted in accordance with Article ~~27, point~~ ***25a***(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~~***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~~ ***including relevant DNA sequence information,*** and any other available material to demonstrate that the plant is a NGT plant, including ***information on the technique or techniques used to obtain it, and information*** that it does not contain any genetic material originating from outside the ~~breeders'~~ gene pool ***for conventional breeding purposes*** where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the ~~implementing~~***delegated*** act adopted in accordance with Article ~~27, point~~ ***25a***(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. ~~If~~***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 ~~in accordance with~~***pursuant to*** 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~~***and the guidance referred to in Article 29(1)***;

(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 ([36]). 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;

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[36] 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).

(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, 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);

(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 15a

Specific provision on analytical method requirements

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 Article 32 of Regulation (EC) 1829/2003 or in Article 100 of 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.~~

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 ~~Article~~***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 ***relevant DNA sequence information and***, 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 ***information on the technique or techniques used to obtain it, and information*** that it does not contain any genetic material originating from outside the ~~breeders'~~ gene pool ***for conventional breeding purposes*** where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the ~~implementing~~***delegated*** act adopted in accordance with Article ~~27, point~~ ***25a***(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.

In cases where it is not feasible to provide an analytical method that ~~detects,~~ identifies and quantifies, 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. ~~If~~***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 ~~in accordance with~~***pursuant to*** 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~~***and the guidance referred to in Article 29(1)***.

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 Reference 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 Reference 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~~***. If*** the applicant justifies the application of adapted modalities to comply with ~~detection~~***analytical*** method ***performance*** requirements ~~referred to in that paragraph~~***, the European Union Reference Laboratory shall carry out the assessment of the claimed unfeasibility, which shall be justified and made public***.

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 Reference Laboratory, for detection, including sampling, and, where applicable, identification and quantification of the ***category 2*** NGT plant and detection and identification of the ***category 2*** NGT plant in the NGT food or feed, 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 ~~based on the properties of a plant, product or hypothetical plant or product, that need~~ to be ~~addressed~~***tested in the risk assesment*** 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 ~~based on the properties of a plant, product or hypothetical plant or product~~***to be tested in the risk assesment***, 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)~~***Article 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. ***The Authority shall verify whether the conditions set out in paragraph 1 are met.*** 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 ~~26~~***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).

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 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 make public*** an up-to-date scientific literature review of the impact 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 to avoid the unintended presence of category 2 NGT plants in products not subject to Directive 2001/18 or Regulation 1829/2003.~~

~~*Article 25*~~

~~**Cultivation**~~

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

CHAPTER IV
FINAL PROVISIONS

Article 25a

Information requirements

The Commission is empowered to adopt delegated acts in accordance with Article 26 supplementing this Regulation concerning:

(a) Information required to demonstrate that a plant is an NGT plant.

(b) The preparation and the presentation of the verification requests, the content of the patent information, the content of the license declaration, the content of the verification reports and the content of the decisions referred to in Articles 6 and 7.

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)~~ ***Articles 5(3), 22(8) and 25a*** 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)~~***Articles 5(3), 22(8) and 25a*** 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([37]).

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)~~***5(3), 22(8) and 25a*** 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 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 ~~criteria~~***factors*** 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 ***performance*** requirements referred to in Article 14(1), point (l), and Article 19(2).

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

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).

2a. Before the date of application of this Regulation, the Commission shall publish, and thereafter review and update if needed, guidance for the purpose of assisting operators, in particular breeders and farmers, on matters relating to plant intellectual property. The Commission shall consult the competent intellectual property offices of the Member States when drafting the guidance. The guidance shall be updated, if needed, and include information on:

(a) plant licensing platforms;

(b) public organisations that have the purpose of assisting plant breeders with intellectual property-related questions;

(c) databases allowing operators to identify the intellectual property rights which apply to a given plant;

(d) basic information on intellectual property rights relevant to plants, including on conditions for obtaining protection, rights conferred and their limitations, as well as compulsory cross-licensing.

2b. Before the date of application of this Regulation, the Commission shall publish information for operators, with particular emphasis on breeders, about the opportunities to benefit from the various programmes, financial mechanisms and policies designed to support research and development in the area of new genomic techniques.

Article 29a
Code of conduct

1. The Commission, in co-operation with the Member States, shall oversee the drawing up of a code of conduct at Union level to enhance the transparency of information relating to patents on plant biological material, to facilitate breeders' access to such material and to enhance legal certainty for breeders and farmers.

2. To achieve this aim, the Commission shall invite the owners of patents relating to NGT plants, representatives of voluntary platforms for the licensing of patents on plant biological material, plant breeder and farmer organisations as well as other civil society organisations and other interested parties, as appropriate, to participate on a voluntary basis in the drawing up of the code of conduct.

3. The Commission shall aim that the code of conduct include the following commitments by patent owners:

(a) the provision of clear, comprehensive and publicly accessible information on patents and patent applications covering biological material incorporated in plant varieties placed on the market in the EU;

(b) the modalities for licensing of patents in fair and reasonable conditions, including through voluntary platforms for the licensing of plant biological material referred to in paragraph 2;

(c) the amicable settlement of patent disputes involving breeders which are SMEs, or involving farmers in the case of unintentional minor presence of patented biological material in their fields.

4. The Commission shall aim that the code of conduct include the following commitments by voluntary platforms for the licensing of plant biological material:

(a) cost-attractive fees for participation in the platforms to facilitate participation in the platforms by breeders which are SMEs.

(b) standard license agreements.

(c) fair and impartial mechanisms for settling disagreements on licensing fees.

5. The Commission shall aim that the code of conduct set out its objectives, contains indicators to measure the achievement of those objectives, takes due account of the needs and interests of all interested parties at Union level, including plant breeders and farmers, and provides a reporting framework to ensure that participants annually report to the Commission on any measures taken to implement the code of conduct and their outcomes, including aggregated information on licenses granted on patents referred to in point b) of paragraph 3. The Commission may provide recommendations to operators in the drawing up of the code of conduct.

6. The Commission shall monitor the rate of participation in and the functioning of the code of conduct and the achievement of its aims referred to in paragraphs 1 to 5.

7. By [5 years from the date of entry into application of this Regulation] and every 5 years thereafter, the Commission shall publish a report on the evaluation of the functioning of the code of conduct. In its evaluation, the Commission shall examine the results of the drawing up of the code of conduct referred to in paragraphs 1-5 and of the monitoring referred to in paragraph 6. In this context, the Commission shall also assess if and to which extent provisions covered in the code of conduct have been infringed and if the code of conduct has ensured fair and reasonable access to patented NGT plant

biological material. The report shall be accompanied, if appropriate, by legislative proposals to safeguard the good functioning of the sector, in particular access to patented NGT plant biological material for primary users, including farmers.

8. The code of conduct shall be ready at the latest [18 months after entry into force of this regulation].

Article 30

Monitoring, reporting and evaluation

1. No sooner than three ***years and no later than seven*** 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 breeding sector, the organic sector,*** and economic, environmental and social sustainability.
The Commission's evaluation shall also assess the impact of the application of this Regulation and, in particular, of Article 5(2) on the organic sector, including the

perception thereof of organic operators and consumers.

The evaluation shall also examine whether the implementation of this Regulation creates any administrative, economic, or practical burdens for organic operators, including any effects on their ability to rely on existing compliance assurance mechanisms.

On the basis of the evaluation, the Commission shall submit, where appropriate, a legislative proposal to the European Parliament and to the Council.

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 30a

NGT plant patent expert group and the assessment on the impact of NGT plant patenting

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 'expert group').

2. The expert group shall assist the Commission and exchange information on a regular basis as regards the survey conducted by the Commission on 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 expert group shall in particular assist the Commission on surveying 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. That delegation 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 and the Community Plant Variety Office may each appoint one expert to the NGT patent expert group.

4. The Commission shall regularly conduct an assessment on the impact that the patenting of NGT plants, traits and techniques as well as related licensing and transparency practices, have in the Union on:

(a) innovation in plant breeding;

(b) breeders' access to plant biological material, patented traits and techniques, and breeders' ability to conduct experimentation;

(c) farmers' access to reproductive material of plants, including the price of available products and other commercially available propagating material, as well as their rights to use farm-saved seeds and propagating materials.

(d) potential litigation involving farmers or breeders in situations where patented biological material may appear in their crops or products due to accidental presence or similarity, without intentional use of the patented material;

(e) competition in the plant-breeding sector, in particular from the perspective of small and medium-sized breeders, while considering the potential risks of market concentration; and

(f) transparency and legal certainty regarding patented biological material.

5. The assessment shall be conducted one year after products obtained through new genomic techniques have become available on the Union market. The assessment shall also include an evaluation of the necessary conditions to ensure that the Union breeding sector using new genomic techniques has a fair and reasonable access to patented plant biological material, exploring the possibility to grant access for free to such material.

6. When carrying out the assessment and when considering the appropriate follow-up actions the Commission shall take into account the findings of the NGT patent expert group as well as the reporting from the Union breeding sector. To this end, the Commission shall invite the Union breeding sector to report on its experience with commercial access to patented plant biological material. The assessment shall be published and made accessible to the public.

7. The NGT patent expert group may continue working for as long as necessary after the completion of the assessment referred to in paragraph 4.

8. If the assessment referred to in paragraph 4 reveals significant barriers to access to patented plant biological material, undue restrictions on experimentation, negative effects on breeders and farmers, increased market concentration, reduced diversity in seed supply, insufficient transparency, or other evidence that the system is not functioning smoothly, the Commission shall, where appropriate, submit legislative proposals to set up mandatory conditions or safeguards.

9. If the Commission considers that, on the basis of the assessment referred to in paragraph 4, no follow-up measures are necessary, it shall inform the European Parliament and the Council thereof and shall repeat the assessment as defined in paragraph 4 no sooner than 4 years and no later than 6 years after the publication of the first assessment. Paragraphs 5 and 6 shall apply.

Article 30b

Sustainability

1. As part of the programme for monitoring referred to in Article 30(3), the Commission and the Member States shall monitor the sustainability impacts of NGT plants, in particular by considering:

(a) positive and negative environmental, economic and social impact of the traits introduced with NGTs;

(b) the application and effects of the exclusion from category 1 status of NGT plants featuring intended traits listed in Annex Ia.

Specific indicators shall be established for this purpose in accordance with Article 30(3) and shall be regularly reviewed. The programme shall collect data from multiple sources, which may include information provided during the verification procedures for category 1 NGT plants or during the authorisation procedure for category 2 NGT plants, variety registration procedures, relevant databases and marketing documentation for NGT plant reproductive material, literature, and cases studies focusing on traits introduced in NGT plants, as well as data originating from official controls as referred to in Article 30c.

2. The Commission shall include the outcome of the work referred to in paragraphs 1 and 2 in the implementation reports referred to in Article 30(1), and in the evaluation referred to in Article 30(4). The evaluation shall also assess the need for further measures intended to promote the development of NGT plants with traits contributing to environmental, economic and social sustainability.

3. The Commission and Member States may consider, when appropriate, the outcome of the work referred to in paragraphs 1 and 2 in relevant strategies concerning a sustainable agrifood system and the bioeconomy, such as those related to support research, innovation and development activities.

Article 30c

Member States controls

Member States shall ensure that the competent authorities organise inspections and other control measures as appropriate, to ensure compliance with this Regulation. In the event of a release of a NGT plant or placing on the market of a NGT product that do not meet the requirements of Article 4, the Member State concerned shall ensure that necessary measures are taken to terminate the release or placing on the market, to initiate remedial action if necessary, and to inform the public, the Commission and other Member States.
Where Regulation (EU) 2017/625 (Official Controls Regulation) applies, the controls and other official activities shall be planned and performed in accordance with that Regulation.

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].

2a. Articles 29, 29a and 30a 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

~~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~~ ***if the*** genetic modifications ~~of the types referred to in points 1 to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.~~***introduced by the new genomic technique(s) meet the following conditions:***

(1) ~~substitution or insertion of no more than 20 nucleotides;~~ ***In the case of plants obtained by targeted mutagenesis, the number of the following genetic modifications, does not exceed 3 per each protein-coding sequence taking into account that genetic modifications in introns and regulatory sequences are excluded from this limit:***

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

(b) deletion of any number of nucleotides;

(2) In the case of plants obtained by cisgenesis, the genetic modifications:

(a) consist of any of the following types:

(i) insertion of continuous DNA sequences existing in the gene pool for conventional breeding purposes;

(ii) substitution of endogenous DNA sequences with continuous DNA sequences existing in the gene pool for conventional breeding purposes;

(iii) inversion or translocation of continuous endogenous DNA sequences ;

(b) and fulfil one or both of the following conditions:

~~(3)~~***(i)*** ~~on the condition that~~ ***they result in a combination of DNA sequences that occurs in*** the ~~genetic modification does not interrupt an endogenous gene:~~ ***gene pool for conventional breeding purposes; or***

~~(a)~~***(ii)*** ~~targeted insertion of a contiguous DNA sequence existing in the breeder's gene pool;~~***they do not lead to interruptions of endogenous genes, including those interruptions that create chimeric proteins.***

~~(2)~~ ~~deletion of any number of nucleotides;~~

(3) The genetic modifications referred to in points 1 and 2 in any combination do not exceed the number of 20 per monoploid genome.

~~(b) targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder'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 already occur (possibly with modifications as accepted under points (1) and/or (2)) in a species from the breeders' gene pool.~~

Annex Ia

Traits referred to in Article 3(7)(a) that exclude NGT plants from category 1 status

(1) tolerance to herbicides

(2) production of a known insecticidal substance

Annex II

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

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

The objective of a risk assessment is, on a case-by-case basis, to identify and evaluate potential adverse effects of the category 2 NGT plant or category 2 NGT food or feed, either direct or indirect, immediate or delayed, on human, animal health and the environment, including on biodiversity.

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 I

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 ~~to their risk profile~~***on a case by case basis***. 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 insertion of a cisgene or parts thereof;

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

(ea) 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) hazard identification and characterisation;

(b) exposure ~~assessment~~***characterisation***;

(c) risk characterisation~~.~~***;***

(ca) risk management strategies, as applicable;

(cb) 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 ~~assessment~~ ***characterisation***

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

Part II

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 III

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

~~Traits referred to in Article 22~~

Part I

Part 1

Traits justifying the incentives referred to in Article 22:

(1) 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 and other pests;

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

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

(4a) 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) ~~reduced need for external inputs, such as plant protection products and fertilisers~~***bioremediation***.

Part II

Part 2

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

tolerance to herbicides.