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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject:	Position of the Council at first reading with a view to the adoption of a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their products, and amending Regulation (EU) 2017/625

REGULATION (EU) 2026/…

OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of …

on plants obtained by certain new genomic techniques and their 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 and 114 and Article 168(4), point (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[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure[3],

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1 OJ C, C/2024/893, 6.2.2024, ELI: http://data.europa.eu/eli/C/2024/893/oj.

2 OJ C, C/2024/3674, 26.6.2024, ELI: http://data.europa.eu/eli/C/2024/3674/oj.

3 Position of the European Parliament of 24 April 2024 (OJ C, C/2025/3751, 17.9.2025, ELI: http://data.europa.eu/eli/C/2025/3751/oj) and position of the Council at first reading of … (not yet published in the Official Journal). Position of the European Parliament of … (not yet published in the Official Journal) and decision of the Council of …

Whereas:

(1) Since 2001, when Directive 2001/18/EC of the European Parliament and of the Council[4] regulating 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 of organisms at targeted locations.

[4] 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, ELI: http://data.europa.eu/eli/dir/2001/18/oj).

(2) NGTs are a diverse group of techniques, which can be used in various ways to achieve different results and products. They can result in organisms with modifications equivalent to those which can be obtained by conventional breeding methods or in organisms with more complex modifications. NGTs include targeted mutagenesis and cisgenesis, including intragenesis, which introduce genetic modifications without transgenesis, that is without inserting genetic material from non-crossable species. Targeted mutagenesis and cisgenesis rely only on the gene pool for conventional breeding purposes, also known as the breeders' gene pool, which is the total genetic information that is available for conventional breeding, including genetic information from distantly related plant species that can be crossed with the target species by using advanced conventional breeding techniques, excluding genetic modification techniques other than those listed in Annex I B to Directive 2001/18/EC. The European Food Safety Authority (the 'Authority'), in its 2012 scientific opinion addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function, and the High Level Group of the Commission's Scientific Advice Mechanism, in its 2017 explanatory note entitled 'New techniques in agricultural biotechnology', provided an overview of the state of those conventional breeding techniques.

(3) Targeted mutagenesis techniques result in one or more modifications of the DNA sequence at targeted locations in the genome of an organism. Cisgenesis techniques result in the insertion, into the genome of an organism, of genetic material already present in the gene pool for conventional breeding purposes. The genetic material can be incorporated as a continuous (exact) copy (cisgenesis in the strict sense), or as a re-arranged copy of sequences already present in the gene pool for conventional breeding purposes (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 in respect of site-directed modifications also make it possible to target the insertion of continuous DNA sequences other than complete genes (for example promoters or regulatory sequences) from the gene pool for conventional breeding purposes 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 gene pool for conventional breeding purposes.

(4) There is ongoing public and private research using NGTs on a wider variety of crops and traits compared to those obtained by transgenesis authorised in the Union or globally. 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, plants with improved nutrient and water-use efficiency, plants with higher yields and resilience and plants with improved quality characteristics. Those types of new plants, coupled with the fairly easy and speedy applicability of NGTs, could deliver benefits to farmers, consumers and the environment. Thus, NGTs have the potential to contribute to the innovation and sustainability goals of the European Green Deal and of the Farm to Fork, Biodiversity, Adaptation to Climate Change and Bioeconomy strategies, to global food security and to the Union’s strategic autonomy.

(5) The deliberate release into the environment ('deliberate release') 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 those organisms, are subject to Directive 2001/18/EC, to Regulation (EC) No 1830/2003 of the European Parliament and of the Council[5] and, in the case of food and feed, also to Regulation (EC) No 1829/2003 of the European Parliament and of the Council[6], while the contained use of plant cells is subject to Directive 2009/41/EC of the European Parliament and of the Council[7], and transboundary movements of these organisms to third countries are regulated by Regulation (EC) No 1946/2003 of the European Parliament and of the Council[8] (taken together, 'the Union GMO legislation').

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5 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, ELI: http://data.europa.eu/eli/reg/2003/1830/oj).

6 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, ELI: http://data.europa.eu/eli/reg/2003/1829/oj).

7 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, ELI: http://data.europa.eu/eli/dir/2009/41/oj).

8 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, ELI: http://data.europa.eu/eli/reg/2003/1946/oj).

(6) In its judgment in Case C-528/16[9], the Court of Justice 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.

(7) The Council, in Decision (EU) 2019/1904[10], 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 in view of the outcomes of the study.

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9 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.

10 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, ELI: http://data.europa.eu/eli/dec/2019/1904/oj).

(8) The Commission's 2021 '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' 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 their products, including food and feed. In particular, the study concluded that the authorisation procedure and risk assessment requirements for GMOs under the Union GMO legislation are not adapted to the variety of potential organisms and products that can be obtained by certain NGTs, namely targeted mutagenesis and cisgenesis, including intragenesis, and that those 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 for products of such plants. In certain cases, genetic modifications introduced by these techniques are indistinguishable with analytical methods from natural mutations or from genetic modifications introduced by conventional breeding techniques, whereas the distinction is generally possible for genetic modifications introduced by transgenesis. The European Network of GMO Laboratories (ENGL) with the support of the European Union Reference Laboratory for Genetically Modified Food and Feed (EURL GMFF), in its 2023 report 'Detection of food and feed plant products obtained by targeted mutagenesis and cisgenesis', stressed that products that have identical DNA sequences but have been developed either naturally or by conventional breeding or by using certain NGTs cannot be distinguished by analytical methods. 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.

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

(10) On the basis of current scientific and technical knowledge, in particular on safety aspects, this Regulation should apply only to GMOs that are plants, namely 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 cover only plants obtained by certain NGTs, namely targeted mutagenesis and cisgenesis, including intragenesis ('NGT plants'), but not by other NGTs. Such plants do not carry genetic material from non-crossable species. Genetically modified plants produced by other NGTs that introduce into an organism genetic material from non-crossable species, that is by transgenesis, should remain subject to the Union GMO legislation rather than to this Regulation, given that such 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.

(11) The legal framework for NGT plants and their products 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 effective functioning of the internal market for the plants and products concerned, 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 NGT plants and their products, including food and feed, so as to contribute to the innovation and sustainability goals of the European Green Deal and the Farm to Fork, Biodiversity, Adaptation to Climate Change and Bioeconomy strategies, and to enhance the competitiveness of the Union agri-food sector at Union and world level. By following those objectives, this Regulation will contribute to the integrated and unifying ‘One Health’ approach.

(12) This Regulation should constitute *lex specialis* with regard to the Union GMO legislation. It should introduce specific provisions for NGT plants and their products. However, in the absence of specific rules in this Regulation, NGT plants and their products 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 of the European Parliament and of the Council[11] regarding official controls or the legislation on certain products such as plant and forest reproductive material.

(13) In keeping with the Union GMO legislation, this Regulation should include within its scope NGT plants and their products, namely food and feed containing, consisting of or produced from NGT plants, and products, other than food and feed, containing or consisting of NGT plants ('NGT products'). Plant reproductive material, including forest reproductive material, falls within the scope of this Regulation both as a 'plant', namely when it is deliberately released, and as a 'product', namely when it is placed on the market, including for the purposes of cultivation.

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

(14) 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 posed by NGT plants and NGT products or lack thereof.

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

(16) NGT plants that could also occur naturally or be produced 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. Therefore, in respect of category 1 NGT plants, this Regulation should derogate in full from the Union GMO legislation and from provisions in other Union legislation that apply to GMOs. Similarly, the products of category 1 NGT plants (‘category 1 NGT products’) should not be subject to that legislation or those provisions. All NGT plants other than category 1 NGT plants (‘category 2 NGT plants’) and NGT products related to such plants (‘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.

(17) In order to ensure legal certainty, this Regulation should set out the criteria to ascertain if an 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 fulfilment of those criteria before NGT plants or NGT products are deliberately released or placed on the market, as category 1 NGT plants or products. The criteria of equivalence should be fulfilled in the plant that is to be deliberately 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 that is to be deliberately released or placed on the market should not be relevant for the verification of the criteria of equivalence. Those criteria should be objective and based on up-to-date scientific knowledge. They should cover the types and extent of genetic modifications that can be observed in nature or in plants obtained by conventional breeding techniques and should include upper limits for the size of genetic modifications, the number of genetic modifications per protein-coding sequence and the overall number of genetic modifications per NGT plant. As regards the number of genetic modifications, the criteria of equivalence should reflect the complexity of plant genomes. Therefore, the upper limit for the total number of individual modifications per plant for the plant to qualify as a category 1 NGT plant should be proportionate to the number of genome copies (‘ploidy’) of the plant.

(18) Current scientific knowledge indicates that targeted mutagenesis and cisgenesis can lead to genetic modifications that are similar to mutations occurring naturally 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 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 in the light of the Authority's assessment that novel hazards can be associated with intragenic plants compared with cisgenic, in the strict sense, and conventionally bred plants, as explained in its scientific opinion of 2012 addressing the safety assessment of plants developed through cisgenesis and intragenesis and its updated scientific opinion of 2022 on plants developed through cisgenesis and intragenesis. 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, in the strict sense, and not intragenic.

(19) 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 can lead to the development of weeds resistant to those herbicides or to the need to increase the quantity 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 that objective. Therefore, the development and use of NGT plants that include tolerance to herbicides among the traits intended to be conveyed by the genetic modifications should be followed up and such plants should remain subject to authorisation, traceability and monitoring requirements. Therefore, NGT plants that include tolerance to herbicides among the traits intended to be conveyed by the genetic modifications should be excluded from category 1 status, and should therefore be subject to the provisions on category 2 NGT plants.

(20) Traits intended to be conveyed by the genetic modifications that support the production of a known insecticidal substance should also be considered as excluding NGT plants from category 1 status. Such traits are aimed at killing insect pests, but can also have adverse effects on beneficial insects such as pollinators. Plants that are developed to include such traits should therefore be subject to the provisions on category 2 NGT plants.

(21) 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 on category 1 NGT plants without the need to go through the verification procedure prior to their deliberate release or placing on the market. Conversely, the progeny deriving from the application of targeted mutagenesis or cisgenesis to a category 1 NGT plant should be subject to the procedure to verify the fulfilment of the criteria of equivalence prior to its deliberate release or placing on the market as a category 1 NGT plant. If those criteria are not met, the progeny should be deliberately released or placed on the market only as a category 2 NGT plant.

(22) Since category 1 NGT plants and products are not to be subject to Union rules concerning GMOs, and in the interest of legal certainty for operators and of transparency, a declaration of category 1 NGT plant status should be obtained prior to the deliberate release or the placing on the market of such plants or products.

(23) The declaration of category 1 NGT plant status should be obtained prior to any deliberate release of a category 1 NGT plant for any purpose other 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 those field trials. When no field trials are to take place in the territory of the Union, operators should obtain that declaration before placing a category 1 NGT product on the market.

(24) 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 an NGT plant and that it fulfils the criteria of equivalence. In addition, the requester should provide a declaration that none of the traits intended to be conveyed by the genetic modifications corresponds to traits excluding NGT plants from category 1 status. Requesters should also provide scientific evidence substantiating the relation between the introduced genetic modifications and the traits intended to be conveyed by those genetic modifications based on, inter alia, relevant scientific literature, information related to any plants already developed or marketed featuring similar genetic modifications and traits, and any existing data gathered during the breeding process or from releases in third countries. All material used to provide the evidence should be up to date and should reflect the latest stage of development of the plant.

(25) In the interest of legal certainty for operators, and in order to improve transparency for breeding activities, prior to deliberate release or the placing on the market, requesters should submit information describing the extent to which a plant for which the verification of category 1 NGT plant status has been requested benefits from any type of patent protection. Requesters should act 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 plant status, which is based solely on scientific equivalence criteria and the exclusion of certain traits.

(26) 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 under fair and reasonable conditions and providing information on the willingness to license should contribute to the development of new varieties, and further encourage the development and placing on the market of category 1 NGT plants and products. To that end, it should be possible for the patent holder, irrespective of whether it is the requester, to confirm its willingness to license their patent under fair and reasonable conditions, such as those referred to in licensing platforms. That information should be provided by the requester on a voluntary basis in the context of the verification procedure for category 1 NGT plants. A requester that is the patent holder should provide information clarifying the intent to license or not, and to participate in voluntary licensing platforms or not.

(27) The fact that a notification for consent under Directive 2001/18/EC or an application for authorisation under Regulation (EC) No 1829/2003 has been submitted 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 this Regulation.

(28) Since the conditions for a plant to qualify as a category 1 NGT plant are unrelated to the type of activity that requires the deliberate release of the category 1 NGT plant, a declaration of category 1 NGT plant status made prior to its deliberate release for any purpose other 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 procedure for the verification of category 1 NGT plant status for requests submitted prior to field trials should be conducted by the competent authorities of Member States, as this would be less administratively burdensome for operators, and a decision should be taken at Union level only if the Commission or the competent authorities of other Member States make reasoned objections to the verification report as regards the fulfilment of the conditions for category 1 NGT plants. 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 declarations of category 1 NGT plant status.

(29) The Commission, the Authority and the competent authorities of the Member States should be subject to appropriate deadlines to ensure that declarations of category 1 NGT plant status are made within a reasonable time.

(30) Decisions declaring 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 of such decisions and for the purpose of labelling of plant reproductive material derived from them.

(31) Category 1 NGT plants and products should remain subject to any regulatory framework that applies to conventionally bred plants and their products. As is the case for conventional plants and products, category 1 NGT plants and 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 can 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 of the European Parliament and of the Council[12], the emergency measures concerning plant reproductive material of varieties of agricultural plant species under Article 16(2) and Article 18 of Council Directive 2002/53/EC[13] and of varieties of vegetable species under Article 16(2) and Article 18 of Council Directive 2002/55/EC[14], and other safeguard measures in Union legislation governing the placing on the market of products, such as medicinal products, cosmetic products, and fertilisers. In addition, 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 to be novel food and will thus fall within the scope of Regulation (EU) 2015/2283 of the European Parliament and of the Council[15] and be subject to a risk assessment in that context.

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12 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 31, 1.2.2002, p. 1, ELI: http://data.europa.eu/eli/reg/2002/178/oj).

13 Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (OJ L 193, 20.7.2002, p. 1, ELI: http://data.europa.eu/eli/dir/2002/53/oj).

14 Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed (OJ L 193, 20.7.2002, p. 33, ELI: http://data.europa.eu/eli/dir/2002/55/oj).

15 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, ELI: http://data.europa.eu/eli/reg/2015/2283/oj).

(32) This Regulation should not impede progress towards achieving the Farm to Fork and Biodiversity strategies' target of 25 % of agricultural land under organic farming by 2030. Regulation (EU) 2018/848 of the European Parliament and the Council[16] 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 I B to that Directive. 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 NGTs with the principles of organic production requires further consideration. The use of category 1 NGT plants should therefore be prohibited in organic production until such further consideration takes place.

[16] 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, ELI: http://data.europa.eu/eli/reg/2018/848/oj).

(33) Organic production chains are, with the exceptions set out in Regulation (EU) 2018/848, already separated from conventional production chains in order to avoid the unintended presence in organic production of conventional material not authorised. 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 products in organic production should not constitute non-compliance with Regulation (EU) 2018/848. Moreover, in certain circumstances it could be necessary for Member States to adopt appropriate measures on their territory to avoid the unintended presence of category 1 NGT plants in organic agriculture, in particular in areas with specific geographical conditions, such as certain Mediterranean island Member States and insular regions, in accordance with Article 29(7) of Regulation (EU) 2018/848.

(34) Provision should be made to ensure transparency as regards the use of category 1 NGT plant varieties in order to ensure that production chains that wish to remain free from NGT plants and NGT products can do so, and thereby safeguard consumer trust. NGT plants that have obtained a declaration of category 1 NGT plant status should be listed in a publicly available database. That database should contain, inter alia, information on the techniques used to obtain the traits. For transparency reasons, the patent information and the licence declarations 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 limited only to what the requester was aware of. To ensure traceability, transparency and choice for operators, during research and plant breeding, when selling plant reproductive material to farmers or making it available to third parties in any other way, plant reproductive material of category 1 NGT plants should be labelled as such.

(35) Since category 2 NGT plants and products are to 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, they remain subject to the authorisation, labelling, and traceability requirements of that legislation. 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 continues to apply to category 2 NGT plants given that experience has shown that cultivation of genetically modified plants is an issue with strong national, regional and local dimensions and taking into account, inter alia, the diversity of farming systems and natural and economic conditions, such as those pertaining to islands.

(36) 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 might pose.

(37) Where category 2 NGT plants and products are to be deliberately released or placed on the market, they should remain subject to a consent or authorisation and other provisions, including provisions 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 category 2 NGT plants, the amount of information necessary for the risk assessment will vary on a case-by-case basis. The Authority recommended flexibility in data requirements for the risk assessment of plants obtained through cisgenesis and targeted mutagenesis in its scientific opinions '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' of 2020 and 'Updated scientific opinion on plants developed through cisgenesis and intragenesis' of 2022. On the basis of the Authority's statement on 'criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis' of 2022, considerations on the history of safe use, familiarity for the environment and the function and structure of the modified or inserted sequences should assist in determining the type and amount of data required to perform the risk assessment of category 2 NGT plants. It is therefore necessary to establish general principles and 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.

(38) Requirements on the content of notifications for consent for the placing on the market of products, for uses other than food or feed, containing or consisting of GMOs, and on the content of applications for authorisation for the placing on the market of GMOs for food or feed use and of genetically modified food and feed are laid down in different pieces of Union 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 as those are relevant only to category 2 NGT food and feed.

(39) The ENGL, with the support of the EURL GMFF, has identified analytical challenges and limitations associated with the identification and quantification of certain plants and products obtained by targeted mutagenesis and cisgenesis. 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 that NGT plant from conventional plants. In such cases, an analytical method should still be provided by the notifier or applicant, but, if duly justified, it should be possible to adapt the arrangements for complying with analytical method performance requirements. Provision should also be made for the EURL GMFF, assisted by the ENGL, to adopt guidance for applicants on the minimum performance requirements for analytical methods. It should also be possible to adapt the arrangements for performing method validation.

(40) Directive 2001/18/EC requires a monitoring plan for environmental effects of GMOs after their deliberate release or placing on the market, but provides for flexibility as to the design of the plan, taking into account the environmental risk assessment, the characteristics of the GMO, its expected use and 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 could 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 for environmental effects of category 2 NGT plants where duly justified, on the basis of the results of any previous release of the category 2 NGT plant in the Union, 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.

(41) 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.

(42) For reasons of proportionality, the consent or authorisation should, upon its first renewal, be valid for an unlimited period, unless decided otherwise at the time of that renewal on the basis of the risk assessment and the available information on the category 2 NGT plant or category 2 NGT product concerned, subject to reassessment when new information has become available.

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

(44) To increase transparency and information for consumers, it should be possible for operators to complement the labelling of category 2 NGT products as GMOs with information on the traits conveyed by the genetic modifications, provided that such information concerns all such traits. In order to avoid misleading or confusing indications, a proposal for such 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.

(45) Regulatory incentives should be offered to applicants, potential applicants and potential notifiers for category 2 NGT plants and products with traits, intended to be conveyed by genetic modifications, 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 their contribution to the value for sustainable cultivation and use. The applicability of those criteria across the Union does not allow a narrower definition of traits to focus on specific issues or address local and regional specificities.

(46) Incentives should consist in an accelerated procedure for risk assessment as regards applications handled through a fully centralised procedure, in the case of category 2 NGT plants for food or feed use and category 2 NGT food and feed, and in enhanced pre-submission advice to help developers prepare the dossier for the purposes of the environmental risk assessment and food and feed safety assessment, 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. The submission of evidence demonstrating compliance with regulatory requirements in the context of a notification for consent or an application for authorisation should remain the responsibility of the notifier or of the applicant.

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

(48) Category 2 NGT plants including herbicide-tolerant traits should not be eligible for incentives under this Regulation.

(49) To ensure the effective functioning of the internal market, NGT plants and NGT products should benefit from the free movement of goods, provided that they comply with the requirements of Union law.

(50) Member States should be responsible for ensuring compliance with this Regulation. For instance, they should ensure that NGT plants, before being deliberately released or placed on the market in the Union, have obtained a declaration of category 1 NGT plant status, if they meet all the relevant requirements, or a consent or authorisation for category 2 NGT plant or product. Where NGT plants and NGT 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 accordance with that Regulation, including for imports. Relevant data generated in the performance of such official controls and other official activities should be taken into account by the Commission in the monitoring of the sustainability impact of NGT plants carried out pursuant to this Regulation.

(51) To ensure a high level of protection for health and the environment, while keeping the Union competitive, this Regulation should apply equally to NGT plants and NGT products originating in the Union and those imported from third countries. Therefore, importing NGT plants and NGT products from third countries should not be prohibited as long as they meet the requirements set out in this Regulation.

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

(53) In order to reflect the rapid evolution of scientific and technical knowledge in the areas of plant science and plant breeding, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU) should be delegated to the Commission in respect of adapting the criteria of equivalence to scientific and technical progress as regards the types and extent of genetic modifications which can occur naturally or through conventional breeding. That empowerment should be used only to the extent justified by available evidence of advances in scientific knowledge and technical progress following the adoption of this Regulation.

(54) The types of NGT plants developed and the impact of certain traits on environmental, social and economic sustainability are continuously evolving. Therefore, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of adapting the lists of traits that should be incentivised or discouraged in category 2 NGT plants to scientific and technological progress or to new evidence relating to the impact on sustainability of those traits.

(55) In order to maintain a high level of transparency, to take into account scientific and technological progress and to ensure that the requirements concerning verification requests are proportionate, the power to adopt acts in accordance with Article 290 TFEU 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 and the content of the patent information, of the licence declarations, of the verification reports and of the decisions taken in the context of the verification procedure.

(56) 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[17]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. It is of particular importance that the consultations be carried out also on the basis of relevant reports which the Commission may be required to publish prior to adopting delegated acts.

[17] OJ L 123, 12.5.2016, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj.

(57) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards, where the verification procedure is conducted at Union level, decisions declaring whether the NGT plant is a category 1 NGT plant, as regards the notification or application for category 2 NGT plants, as regards the methodology and information requirements for the environmental risk assessments of category 2 NGT plants and the safety assessment of category 2 NGT food and feed, in accordance with the principles and factors laid down in this Regulation, and as regards adapted arrangements for complying with analytical method performance requirements. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[18].

(58) 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, where the procedure is conducted at Union level, the advisory procedure should be used for the adoption of such implementing decisions, supported by scientific and technical assistance by the Authority.

[18] 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, ELI: http://data.europa.eu/eli/reg/2011/182/oj).

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

(60) 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 of conduct include commitments by patent owners to provide clear and publicly accessible information on patents, to license patents under fair and reasonable conditions, and to seek the amicable settlement of patent disputes with breeders that are SMEs and with farmers in the case of unintentional minor presence of patented biological material in their fields. In the latter case, patent owners could consider refraining from enforcing their patent rights. The Commission should also aim that the code of conduct 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, it should take appropriate actions including, where 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.

(61) Directive 98/44/EC of the European Parliament and of the Council[19] sets out principles regarding the patentability of biological material, including plants. In order to be able to take action in the event of adverse impacts of the patenting of NGT plants, the Commission should conduct an assessment on the impact that such patenting and related licensing and transparency practices could 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 on the overall competitiveness of the Union's 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 ongoing evaluation of Council Regulation (EC) No 2100/94[20] will also consider the coherence of 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, where appropriate, proposing legislative measures.

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19 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ L 213, 30.7.1998, p. 13, ELI: http://data.europa.eu/eli/dir/1998/44/oj).

20 Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (OJ L 227, 1.9.1994, p. 1, ELI: http://data.europa.eu/eli/reg/1994/2100/oj).

(62) Stakeholders raised concerns that patents relating to NGT plants might limit the access of breeders to those plants for the purpose of developing other plant varieties. In this regard, Article 27, point (c), of the Agreement on a Unified Patent Court[21] 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 those 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 consistent application across the Union.

(63) 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[22] and Article 53, point (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.

21 OJ C 175, 20.6.2013, p. 1.
22 OJ C 411, 8.11.2016, p. 3.

(64) Breeders can benefit from guidance on matters relating to plant intellectual property. The Commission should therefore publish such guidance to assist operators, in particular breeders.

(65) 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 could arise for non-self-reproducing products. This is one of the relevant factors 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 of the European Parliament and of the Council[23] 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. That requirement is to apply when determining the appropriate enforcement measures, procedures and remedies in such situations.

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[23] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157, 30.4.2004, p. 45, ELI: http://data.europa.eu/eli/dir/2004/48/oj).

(66) Given the novelty of the NGTs, it will be important to monitor closely the development and presence on the market of NGT plants and NGT products and evaluate any accompanying intended and unintended impact on human and animal health and the environment, including on biodiversity, and impact on environmental, economic and social sustainability, as well as impact on organic agriculture and on consumers' acceptance of NGT products. To support that monitoring, a broad set of indicators have been identified in the impact assessment accompanying the proposal for this Regulation and should be periodically reviewed by the Commission.

(67) The Commission should regularly collect information in order to assess the performance of this Regulation and measure the progress made towards the availability on the internal market of NGT plants and NGT products that can contribute to the achievement of the innovation and sustainability goals of the European Green Deal and of the Farm to Fork, Biodiversity, Adaptation to Climate Change and Bioeconomy strategies and in order to inform an evaluation of this Regulation. A first implementation report should be presented between three and seven years after the first NGT plants or NGT products have gone through the verification procedure, have received consent or have been authorised in order to ensure that enough data is available after full implementation of this Regulation, and at regular intervals thereafter. The Commission should carry out an evaluation of this Regulation between two and three years after publishing the first implementation report, in order to allow for the impact of the first products going through the verification or authorisation to fully materialise.

(68) Certain references to provisions of the Union GMO legislation in Regulation (EU) 2017/625 need to be amended to include the specific provisions of this Regulation applicable to NGT plants.

(69) Since the objectives of this Regulation, namely to ensure a high level of protection of human and animal health and the environment and the effective functioning of the internal market in relation to NGT plants and NGT products, while enhancing innovation, sustainability and competitiveness, cannot be sufficiently achieved by the Member States but can be better achieved at Union level, 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.

(70) Since the application of this Regulation requires the adoption of implementing and delegated acts, it should be deferred in time to allow for their adoption,

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 of the environment, in accordance with the precautionary principle, and the effective functioning of the internal market in relation to plants obtained by certain new genomic techniques, to food and feed containing, consisting of or produced from such plants, and to products, other than food and feed, containing or consisting of such plants, while enhancing innovation, sustainability and competitiveness.

This Regulation lays down specific rules for the deliberate release into the environment, for any purpose other than placing on the market of such plants, and for the placing on the market of such food and feed and other products.

Article 2

Scope

This Regulation applies to:

(a) NGT plants;

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

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

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

Article 3

Definitions

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

(1) ‘organism’ means an organism as defined in Article 2, point (1), of Directive 2001/18/EC;

(2) ‘genetically modified organism’ or ‘GMO’ means a genetically modified organism as defined in Article 2, point (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;

(3) ‘deliberate release’ means deliberate release as defined in Article 2, point (3), of Directive 2001/18/EC;

(4) ‘placing on the market’ means placing on the market as defined in Article 2, point (4), of Directive 2001/18/EC;

(5) ‘food’ means food as defined in Article 2 of Regulation (EC) No 178/2002;

(6) ‘feed’ means feed as defined in Article 3, point (4), of Regulation (EC) No 178/2002;

(7) ‘plant’ means a plant as defined in Article 2, point (1), of Regulation (EU) 2016/2031 of the European Parliament and of the Council[24];

(8) ‘plant reproductive material’ means plants capable of, and intended for, producing entire plants;

(9) ‘NGT plant’ means a genetically modified plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, and not containing any genetic material originating from outside the gene pool for conventional breeding purposes that might have been temporarily inserted during the development of that plant;

(10) ‘targeted mutagenesis’ means mutagenesis techniques resulting in one or more modifications of the DNA sequence at targeted locations in the genome of an organism;

(11) ‘cisgenesis’ means techniques of genetic modification resulting in the insertion, into the genome of an organism, of genetic material already present in the gene pool for conventional breeding purposes;

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

(12) ‘gene pool for conventional breeding purposes’ means the total genetic information available in one species and in other taxonomic species with which that species can be crossed, including by using advanced techniques such as embryo rescue, induced polyploidy and bridge crosses;

(13) ‘category 1 NGT plant’ means an NGT plant that:

(a) fulfils the criteria of equivalence to conventional plants set out in Annex I and does not include any trait listed in Annex II among the traits intended to be conveyed by the genetic modifications; or

(b) is the progeny of NGT plants as referred to in point (a), including progeny obtained by crossing of such plants, and contains no further modifications obtained through targeted mutagenesis, cisgenesis or other techniques that would make it subject to Directive 2001/18/EC or Regulation (EC) No 1829/2003;

(14) ‘category 2 NGT plant’ means an NGT plant other than a category 1 NGT plant;

(15) ‘NGT plant for food use’ means an NGT plant that may be used as food or as a source material for the production of food;

(16) ‘NGT plant for feed use’ means an NGT plant that may be used as feed or as a source material for the production of feed;

(17) ‘produced from NGT plants’ means derived, in whole or in part, from NGT plants, but not containing or consisting of NGT plants;

(18) ‘NGT product’ means food and feed containing, consisting of or produced from NGT plants, and products, other than food and feed, containing or consisting of such plants;

(19) ‘category 1 NGT product’ means an NGT product where the NGT plant it contains, consists of or is produced from is a category 1 NGT plant;

(20) ‘category 2 NGT product’ means an NGT product where the NGT plant it contains, consists of or is produced from is a category 2 NGT plant;

(21) ‘small or medium-sized enterprise’ or ‘SME’ means an SME within the meaning of Commission Recommendation 2003/361/EC[25];

(22) ‘chimeric protein’ means a protein 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 purpose other than placing on the market, and placing on the market of NGT products

Without prejudice to other requirements of Union law:

(a) a category 1 NGT plant may be deliberately released for any purpose other than placing on the market only if the plant is:

(i) a category 1 NGT plant as referred to in Article 3, point (13)(a), and has obtained a decision declaring that status in accordance with Article 6 or 7; or

[25] Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: http://data.europa.eu/eli/reco/2003/361/oj).

(ii) a category 1 NGT plant as referred to in Article 3, point (13)(b), and is the progeny of plants as referred to in point (i) of this point;

(b) a category 1 NGT product may be placed on the market only if the plant concerned fulfils at least one of the conditions laid down in point (a) of this Article;

(c) a category 2 NGT plant may be deliberately released for any purpose other than placing on the market only if it has been granted consent in accordance with Chapter III, Section 1;

(d) a category 2 NGT product may be placed on the market only if it has been granted consent or has been authorised in accordance with Chapter III, Section 2 or 3.

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 fulfil the conditions of Article 4, point (a), or to category 1 NGT products that fulfil the conditions of Article 4, point (b).

2. For the purposes of Regulation (EU) 2018/848, the rules set out in Article 5, point (f)(iii), and Article 11 of that Regulation, including Article 11(2) and (3) thereof as regards labelling pursuant to Article 10(1) of this Regulation, 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 of Regulation (EU) 2018/848 or in agricultural ingredients for processed organic food authorised in accordance with Article 25 of that Regulation, 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 to scientific and technological progress, to the extent justified by advances in scientific knowledge as regards the types and extent of genetic modification which can occur naturally or through conventional breeding.

When adopting delegated acts under this paragraph, 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 genetic modification which can occur naturally or through conventional breeding. The report must justify that, following the intended amendment to 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.

When preparing delegated acts under this paragraph, the Commission shall take into account any relevant new or updated scientific opinions from the European Food Safety Authority (the ‘Authority’).

Article 6

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

1. To obtain the declaration of category 1 NGT plant status referred to in Article 4, point (a)(i), of this Regulation before undertaking a deliberate release of an NGT plant for any purpose other than placing on the market, the person intending to undertake the deliberate release shall submit a request to verify whether the conditions set out in Article 3, point (13)(a), of this Regulation 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, 3 and 4 of this Article and the delegated act adopted in accordance with Article 25, point (b) of this Regulation.

2. Where a person intends to undertake the deliberate release as referred to in paragraph 1 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 shall be submitted in accordance with standard data formats, where they exist, in accordance with 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 traits and characteristics which have been introduced or modified;

(d) a copy of the studies, including relevant DNA sequence information, and any other available material to demonstrate that:

(i) the plant is an NGT plant, including information on the techniques used to obtain it as well as information that it does not contain any genetic material originating from outside the 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 laid down in the delegated act adopted in accordance with Article 25, point (a);

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

(e) in the cases referred to in paragraph 2 of this Article, 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, in accordance with Article 11 of this Regulation.

4. The verification request shall also include a declaration that none of the traits intended to be conveyed by the genetic modifications is listed in Annex II. The declaration shall be accompanied by scientific evidence, available at the time of submission of the request, substantiating the relation between the introduced genetic modifications and the traits intended to be conveyed by those genetic modifications.

5. Together with the verification request, 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.

6. Together with the verification request and the patent information referred to in paragraph 5, the requester may submit a written declaration of the holder of a patent identified under paragraph 5 confirming the patent holder's willingness to license 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 patent holder, it shall submit a written declaration clarifying whether:

   (a) it is willing to license the protected subject matter under fair and reasonable conditions in all Member States where it is entitled to grant such a licence; and

   (b) it is, or intends to become, a member of relevant and appropriate licensing platforms.

7. The patent information referred to in paragraph 5 and the licence declarations referred to in paragraph 6 shall not be subject to verification and shall have only declaratory value.

8. The competent authority shall acknowledge receipt of the verification request, the patent information referred to in paragraph 5 and, where applicable, the licence declarations referred to in paragraph 6 to the requester without undue delay, stating the date of receipt, and shall make them available to the Commission and to the other Member States without undue delay.

9. If the verification request does not contain all the necessary information, or if the patent information referred to in paragraph 5 or, where the requester is the holder of a patent identified under paragraph 5, the licence declaration referred to in paragraph 6 is missing, the competent authority shall declare the verification request inadmissible within 30 working days of the date of its receipt. The competent authority shall inform the requester, the Commission and the other Member States without undue delay of the inadmissibility of the verification request and shall provide the reasons of its decision.

10. If the verification request is not declared inadmissible in accordance with paragraph 9 of this Article, the competent authority shall verify whether the NGT plant fulfils the conditions set out in Article 3, point (13)(a), and prepare a verification report within 30 working days of the date of receipt of that verification request. The competent authority shall make available the verification report to the Commission and to the other Member States without undue delay.

11. The Commission and the other Member States may make reasoned objections to the verification report as regards the fulfilment of the conditions set out in Article 3, point (13)(a), within 20 days of the date of receipt of that report.

12. In the absence of any reasoned objection from the Commission or a Member State, the competent authority that prepared the verification report shall adopt, within 10 working days of the expiry of the deadline referred to in paragraph 11, a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, to the Commission and to the other Member States.

13. Where the Commission or the Member States make reasoned objections within the deadline referred to in paragraph 11, the competent authority that prepared the verification report shall forward those reasoned objections to the Commission and to the other Member States without undue delay.

14. In the cases referred to in paragraph 13 of this Article, the Commission, after having consulted the Authority, shall prepare an implementing decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days of the expiry of the deadline referred to in paragraph 11 of this Article, taking the reasoned objections received into account. That implementing decision shall be adopted in accordance with the procedure referred to in Article 28(2).

15. Where the Authority is consulted in accordance with paragraph 14 of this Article, 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 delivered in the framework of the consultation, with the exception of any information to which the Member State competent authority has granted confidential treatment in accordance with Article 11.

16. The Commission shall publish a summary of the decisions referred to in paragraphs 12 and 14 in the *Official Journal of the European Union*.

Article 7

Procedure for the verification 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, point (a)(i), has not already been made in accordance with Article 6, to obtain such a declaration before placing on the market an NGT product, the person intending to place the product on the market shall submit a verification request to the Authority in accordance with paragraphs 2 and 3 of this Article and the delegated act adopted in accordance with Article 25, point (b).

2. The verification request shall be submitted in accordance with standard data formats, where they exist, in accordance with 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 traits and characteristics which have been introduced or modified;

(d) a copy of the studies, including relevant DNA sequence information, and any other available material to demonstrate that:

(i) the plant is an NGT plant, including information on the techniques used to obtain it as well as information that it does not contain any genetic material originating from outside the 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 laid down in the delegated act adopted in accordance with Article 25, point (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, in accordance with Article 11 of this Regulation and Article 39 of Regulation (EC) No 178/2002.

3. The verification request shall also include a declaration that none of the traits intended to be conveyed by the genetic modifications is listed in Annex II. The declaration shall be accompanied by scientific evidence, available at the time of submission of the request, substantiating the relation between the introduced genetic modifications and the traits intended to be conveyed by those genetic modifications.

4. Together with the verification request, 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.

5. Together with the verification request and the patent information referred to in paragraph 4, the requester may submit a written declaration of the holder of a patent identified under paragraph 4 confirming the patent holder's willingness to license 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 patent holder, it shall submit a written declaration clarifying whether:

(a) it is willing to license the protected subject matter under fair and reasonable conditions in all Member States where it is entitled to grant such a licence; and

(b) it is, or intends to become, a member of relevant and appropriate licensing platforms.

6. The patent information referred to in paragraph 4 and the licence declarations referred to in paragraph 5 shall not be subject to verification and shall have only declaratory value.

7. The Authority shall acknowledge receipt of the verification request, the patent information referred to in paragraph 4 of this Article and, where applicable, the licence declarations referred to in paragraph 5 of this Article to the requester without undue delay, stating the date of receipt, and shall make them available to the Commission and to the Member States without undue delay. It shall 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.

8. If the verification request does not contain all the necessary information or if the patent information referred to in paragraph 4 or, where the requester is the holder of a patent identified under paragraph 4, the licence declaration referred to in paragraph 5 is missing, the Authority shall declare the verification request inadmissible within 30 working days of the date of its receipt. The Authority shall inform the requester, the Commission and the Member States without undue delay of the inadmissibility of the verification request and shall provide the reasons of its decision.

9. If the verification request is not declared inadmissible in accordance with paragraph 8 of this Article, the Authority shall deliver a statement on whether the NGT plant fulfils the conditions set out in Article 3, point (13)(a), within 30 working days of the date of receipt of that verification request. It shall make the statement available to the Commission and to 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.

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

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

Article 8

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

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

Article 9

Database of decisions declaring 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(12) and (14) and Article 7(10).

   The database shall contain the following information:

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

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

   (c) a summarised description of the techniques used to obtain the genetic modifications;

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

   (e) an identification number;

   (f) where available, the statement of the Authority, as referred to in Article 6(15) and Article 7(9);

   (g) the decision referred to in Article 6(12) or (14), or Article 7(10), as applicable;

(h) the patent information referred to in Article 6(5) and Article 7(4); and

(i) the licence declarations referred to in Article 6(6) and Article 7(5), where applicable.

The database shall be publicly available online.

2. Should there be any change in the patent information referred to in paragraph 1, point (h), or the licence declarations referred to in paragraph 1, point (i), the requester, acting to the best of its 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 transparency of information

1. Plant reproductive material, including for breeding and scientific purposes, that contains or consists of category 1 NGT plants and is made available to third parties, whether in return for payment or free of charge, shall bear a label with the indication ‘NGT-1’, followed by the identification numbers of the NGT plants it has been derived from.

2. The competent authorities shall include the indication that a variety contains or consists of category 1 NGT plants, and the identification numbers of the category 1 NGT plants it has been derived from, in the catalogues of varieties referred to in Council Directive 68/193/EEC[26], Directive 2002/53/EC, Directive 2002/55/EC and Council Directive 2008/90/EC[27].

3. The competent authorities shall include the indication that basic material intended for the production of forest reproductive material of the 'tested' category contains or consists of category 1 NGT plants, and the identification numbers of the category 1 NGT plants it has been derived from, in the national lists referred to in Council Directive 1999/105/EC[28].

4. The indication that plant reproductive material contains or consists of category 1 NGT plants, and the identification numbers of the category 1 NGT plants it has been derived from, shall be included in any database and marketing documentation where the plant reproductive material is offered.

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26 Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine (OJ L 93, 17.4.1968, p. 15, ELI: http://data.europa.eu/eli/dir/1968/193/oj).

27 Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants intended for fruit production (OJ L 267, 8.10.2008, p. 8, ELI: http://data.europa.eu/eli/dir/2008/90/oj).

28 Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material (OJ L 11, 15.1.2000, p. 17, ELI: http://data.europa.eu/eli/dir/1999/105/oj).

Article 11

Confidentiality

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

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

3. The Member State 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 requester demonstrates that the disclosure of such information would potentially harm the requester's interests to a significant degree:

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

   (b) DNA sequence information; and

   (c) breeding patterns and strategies.

4. Where the Member State competent authority assesses the confidentiality request, it 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. The Commission, the Authority and Member States 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. If the requester withdraws the verification request referred to in Article 6 or 7, the Commission, the Authority and Member States shall respect the confidentiality as granted by the Member State competent authority or the Authority in accordance with this Article. Where the verification request is withdrawn before the Member State competent authority or the Authority has decided on the corresponding confidentiality request, the Commission, the Authority and Member States 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 PURPOSE OTHER THAN PLACING ON THE MARKET

Article 13

Notification referred to in Article 6 of Directive 2001/18/EC

As regards the deliberate release of a category 2 NGT plant for any purpose other 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, including relevant DNA sequence information, and any other available material to demonstrate that the plant is an NGT plant, including information on the techniques used to obtain it as well as information that it does not contain any genetic material originating from outside the 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 laid down in the delegated act adopted in accordance with Article 25, point (a);

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

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

(ii) information relating to each NGT plant;

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

(iv) information on the interactions between each NGT plant and the environment;

(v) a plan for monitoring in order to identify effects of each NGT plant 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, in accordance with Article 25 of Directive 2001/18/EC;

(viii) a summary of the dossier;

(d) an environmental risk assessment carried out in accordance with the principles and information set out in Parts 1 and 2 of Annex III and with the implementing act adopted in accordance with Article 27, first paragraph, point (a).

SECTION 2

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

Article 14

Notification referred to in Article 13 of Directive 2001/18/EC

1. As regards the placing on the market of category 2 NGT products for uses other than food or feed, the notification referred to in Article 13(1) of Directive 2001/18/EC shall contain, 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 notifier and, if the notifier is not established in the Union, of its representative established in the Union;

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

   (c) scope of the notification:

      (i) cultivation; or

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

(d) a copy of the studies, including relevant DNA sequence information, and any other available material to demonstrate that the plant concerned is an NGT plant, including information on the techniques used to obtain it as well as information that it does not contain any genetic material originating from outside the 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 laid down in the delegated act adopted in accordance with Article 25, point (a);

(e) the environmental risk assessment carried out in accordance with the principles and information set out in Parts 1 and 2 of Annex III and with the implementing act adopted in accordance with Article 27, first paragraph, point (a);

(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 shall not exceed 10 years;

(h) 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, which may be different from the proposed period for the consent; however, a monitoring plan shall not be required where the notifier duly justifies that it is not needed on the basis of 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 concerned, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted in accordance with Article 27, first paragraph, point (b), of this Regulation and the guidance referred to in Article 29(1) of this Regulation;

(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 24 of this Regulation;

(j) proposed commercial names of the products and names of the 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[29]; after the consent, any new commercial names shall be provided to the competent authority;

[29] 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, ELI: http://data.europa.eu/eli/reg/2004/65/oj).

(k) a description of how the product is intended to be used; differences in use or management of that product compared to similar products not containing or consisting of genetically modified organisms shall be highlighted;

(l) methods for sampling – including references to existing official or standardised sampling methods – , detection, identification and quantification of the category 2 NGT plant concerned; where the notifier duly justifies that it is not feasible to provide an analytical method for identification and quantification, the arrangements for complying with analytical method performance requirements shall be adapted as set out in the implementing act adopted in accordance with Article 27, first paragraph, point (c), and the guidance referred to in Article 29(2);

(m) samples of the category 2 NGT plant concerned, 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[30];

(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, in accordance with Article 25 of Directive 2001/18/EC;

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

30 OJ L 201, 31.7.2002, p. 50, ELI: http://data.europa.eu/eli/prot/2002/628/oj.

2. The notifier shall include in the notification information on data or results from deliberate releases of the same category 2 NGT plant or the same combination of category 2 NGT plants previously or currently notified or carried out by the notifier, whether within 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 of this Article.

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), of that Directive, 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 16

Specific provision on analytical method performance requirements

Where appropriate, the competent authority of the Member State that prepares the assessment report referred to in Article 14 of Directive 2001/18/EC 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 notifier in accordance with Article 14(1), point (l), of this Regulation justifies the application of adapted arrangements for complying with analytical method performance requirements.

Article 17

Labelling in accordance with Article 24

In addition to the labelling referred to in Article 19(3), point (e), of Directive 2001/18/EC, the written consent shall specify the labelling in accordance with Article 24 of this Regulation.

Article 18

Duration of the validity of the consent upon renewal

1. Consent granted under Part C of Directive 2001/18/EC shall, upon the first renewal in accordance with Article 17 of that Directive, be valid for an unlimited period, unless the decision referred to in Article 17(6) or (8) or Article 18(2) of that Directive 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 second sentence of Article 17(6) and the second sentence of Article 17(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 19

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, including food 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 20

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 Article 5(3), point (e), and Article 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 which have been carried out, including relevant DNA sequence information and, where available, independent, peer-reviewed studies, and any other available material to demonstrate that:

   (a) the plant is an NGT plant, including information on the techniques used to obtain it as well as information that it does not contain any genetic material originating from outside the 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 laid down in the delegated act adopted in accordance with Article 25, point (a);

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

2. By way of derogation from Article 5(3), point (i), and Article 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, identification and quantification of the category 2 NGT plant in the NGT food or feed.

Where the applicant duly justifies, or where the European Union Reference Laboratory (EURL) established by Article 32, first paragraph, of Regulation (EC) No 1829/2003 concludes during the procedure referred to in Article 21(4) of this Regulation, that it is not feasible to provide an analytical method for identification and quantification, the arrangements for complying with analytical method performance requirements shall be adapted as set out in the implementing act adopted in accordance with Article 27, first paragraph, point (c), of this Regulation and the guidance referred to in Article 29(2) of this Regulation.

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

(a) an environmental risk assessment carried out in accordance with the principles and information set out in Parts 1 and 2 of Annex III to this Regulation and with the implementing act adopted in accordance with Article 27, first paragraph, point (a), of this Regulation;

(b) 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, which may be different from the duration of the authorisation.

The monitoring plan referred to in the first subparagraph, point (b), of this paragraph shall not be required where the applicant duly justifies that it is not needed on the basis of 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 Article 27, first paragraph, point (b), of this Regulation and the guidance referred to in Article 29(1) of this Regulation.

4. The application for authorisation shall contain a proposal for labelling in accordance with Article 24.

Article 21

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 20 of this Regulation within six months of the date of receipt of a valid application.

   Where the Authority or the competent authority of the Member State carrying out the environmental risk assessment or the food or feed safety assessment 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 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-month 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 20 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 EURL the particulars referred to in Article 20(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 EURL shall test and validate the method of detection, identification and quantification proposed by the applicant in accordance with Article 20(2). If the applicant justifies the application of adapted arrangements for complying with analytical method performance requirements, the EURL shall carry out an assessment of whether the claimed unfeasibility is justified. That assessment shall be 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 granting an authorisation, the opinion shall also include:

   (a) the method, validated by the EURL, for detection, including sampling, and, where applicable, identification and quantification of the category 2 NGT plant and detection, identification and quantification of the category 2 NGT plant in the NGT food or feed, and a justification of any adaptation of the arrangements for complying with the analytical method performance requirements in the cases referred to in Article 20(2), second subparagraph, of this Regulation;

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

6. In addition to the proposals for labelling referred to in in Article 6(5), point (d), and Article 18(5), point (d), of Regulation (EC) No 1829/2003, the opinion shall include a proposal for labelling in accordance with Article 24 of this Regulation.

Article 22

Duration of the validity of the authorisation upon renewal

By way of derogation from Article 11(1) and Article 23(1) of Regulation (EC) No 1829/2003, 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 23

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

1. The incentives set out in this Article shall apply to category 2 NGT plants and category 2 NGT products where at least one of the traits of the category 2 NGT plant intended to be conveyed by the genetic modifications is contained in Part 1 of Annex IV and that plant does not have any of the traits referred to in Part 2 of that Annex.

2. The following incentives shall apply to applications for authorisation submitted in accordance with Article 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 20 of this Regulation:

   (a) by way of derogation from Article 21(1), first subparagraph, of this Regulation, the Authority shall deliver its opinion on the application within four months of the date of receipt of a valid application, unless the complexity of the product requires application of the time limit referred to in Article 21(1) of this Regulation; both time limits may be extended under the conditions set out in Article 21(1), second subparagraph of this Regulation;

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

3. In addition to the pre-submission advice referred to in Article 32a of Regulation (EC) No 178/2002, pre-submission advice for the purposes of the risk assessment conducted in accordance with Annex III to this Regulation shall be provided in accordance with this paragraph prior to notifications submitted in accordance with Article 13 of Directive 2001/18/EC in conjunction with Article 14 of this Regulation and to applications submitted in accordance with Article 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 20 of this Regulation.

The staff of the Authority shall, at the request of a potential applicant or potential notifier, provide advice on the risk hypotheses that the potential applicant or potential notifier has identified to be tested in the risk assessment by providing the information under Parts 2 and 3 of Annex III to this Regulation.

That advice 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. However, where the potential applicant or potential notifier is an SME, it may notify the Authority of how it intends to address the risk hypotheses referred to in the second subparagraph that it has identified to be tested in the risk assessment, including the design of the studies it intends to perform in accordance with the requirements laid down in Parts 2 and 3 of Annex III. 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 notifications or applications 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 and potential applications 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; Article 38(1a) of Regulation (EC) No 178/2002 shall apply *mutatis mutandis*;

(d) a potential notifier or potential applicants that is an SME can request the pre-submission advice at different points in time.

5. The Authority shall verify whether the conditions set out in paragraph 1 of this Article are met. Any request for incentives shall be submitted to the Authority at the time of request of advice referred to in paragraph 3 of this Article or the application referred to in Article 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 20 of this Regulation, and accompanied by the following information:

(a) the information necessary to establish that the category 2 NGT plant meets the conditions referred to in paragraph 1;

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

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

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

7. The Authority shall lay down the practical arrangements to implement paragraphs 3 to 6.

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 IV in order to adapt them to scientific and technological progress 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 32(2);

(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 traits it intends to add to or delete from the lists in Annex IV;

(c) where applicable, the Commission shall take into account the results of monitoring which was carried out in accordance with Article 14(1), point (h), or Article 20(3), point (b), in respect of category 2 NGT plants harbouring the traits conveyed by their genetic modifications.

Article 24

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), (7) and (8) 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 traits conveyed by the genetic modifications, as specified in the consent or the authorisation pursuant to Section 2 or 3 of this Chapter. Where use is made of this provision, the label shall mention all the traits of the category 2 NGT plant conveyed by the genetic modifications.

Chapter IV

Final provisions

Article 25

Information requirements

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

(a) the 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 referred to in Article 6(5) and Article 7(4), the content of the licence declarations referred to in Article 6(6) and Article 7(5), 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), Article 23(8) and Article 25 shall be conferred on the Commission for a period of five 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 nine months before the end of the five-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 three months before the end of each period.

3. The delegations of power referred to in Article 5(3), Article 23(8) and Article 25 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.

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 Article 5(3), Article 23(8) or Article 25 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 two 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 methodology and information requirements for the environmental risk assessment of category 2 NGT plants and the safety assessment of category 2 NGT food and feed, in accordance with the principles and factors laid down in Annex III;

(b) the application of Articles 14 and 20, including rules concerning the preparation and the presentation of the notification or application;

(c) adapted arrangements for complying with analytical method performance requirements referred to in Article 14(1), point (l), and Article 20(2).

Those implementing acts shall be adopted in accordance with the procedure referred to in Article 28(3).

Before adopting the implementing acts referred to in the first subparagraph, points (a) and (b), the Commission shall consult the Authority.

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 (EU) No 182/2011 shall apply.

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

Article 29

Guidance

1. By … [24 months from the date of entry into force of this Regulation], the Authority shall publish detailed guidance to assist requesters, notifiers and applicants in the preparation and the presentation of the verification requests, the notifications and the applications referred to in Chapters II and III and for the implementation of Annex III.

2. By … [24 months from the date of entry into force of this Regulation], the EURL, assisted by the ENGL, shall publish detailed guidance to assist the notifier or the applicant for the application of Article 14(1), point (l), and Article 20(2).

3. By … [24 months from the date of entry into force 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 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.

4. By … [24 months from the date of entry into force 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 30

Code of conduct

1. The Commission, in cooperation 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 ('code of conduct').

2. 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 Union;

   (b) arrangements for the licensing of patents under fair and reasonable conditions, including through the voluntary platforms 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 licence 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, contain indicators to measure the achievement of those objectives, take due account of the needs and interests of all interested parties at Union level, including plant breeders and farmers, and provide 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 licences granted under the arrangements referred to in paragraph 3, point (b). 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, as referred to in paragraphs 1 to 5.

7. By … [seven years from the date of entry into force of this Regulation] and every five 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 to 5 and of the monitoring referred to in paragraph 6. In this context, the Commission shall also assess if and to what 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, where 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 by … [18 months from the date of entry into force of this Regulation].

Article 31

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

1. The Commission shall establish an expert group on the effect of the patenting of NGT plants (the ‘expert group’).

2. The expert group shall assist the Commission and exchange information on a regular basis as regards the assessment conducted by the Commission in accordance with paragraph 4 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 concerning NGT plants and patent enforcement practices vis-à-vis farmers and, if available, examples of cases thereof.

3. The expert group shall be constituted in accordance with 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 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 expert group.

4. The Commission shall regularly assess 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 patented plant biological material, traits and techniques, and breeders' ability to conduct experimentation;

(c) farmers' access to plant reproductive material, 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) the risk of litigation involving farmers or breeders in situations where patented plant biological material may appear in their crops or products due to accidental presence or similarity, without intentional use of the patented plant biological 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 plant biological material.

5. The first of the assessments referred to in paragraph 4 shall be conducted one year after NGT products have become available on the Union market.

6. The assessment referred to in paragraph 4 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 of granting access for free to such material.

7. When carrying out the assessment referred to in paragraph 4 and when considering the appropriate follow-up actions the Commission shall take into account the findings of the 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.

8. The assessment referred to in paragraph 4 shall be published and made accessible to the public.

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

10. 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.

11. 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 four years and no later than six years after the publication of the first assessment.

Article 32

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(12) or (14) or Article 7(10) or in accordance with Section 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. The report shall also address any ethical issues that have arisen with the application of this Regulation.

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

3. 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, 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.

4. The Commission shall present a report on the main findings of the evaluation referred to in paragraph 3 to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

Article 33

Sustainability

1. As part of the programme for monitoring referred to in Article 32(2), the Commission and Member States shall monitor the sustainability impact of NGT plants, in particular by considering:

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

(b) the application and effects of the exclusion from category 1 status of NGT plants including traits listed in Annex II among the traits intended to be conveyed by the genetic modifications.

Specific indicators shall be established for this purpose in accordance with Article 32(2) and shall be regularly reviewed. The programme for monitoring shall collect data from multiple sources, which may include information provided during the verification procedure for category 1 NGT plants, during the notification and authorisation procedures for category 2 NGT plants and products, or during variety registration procedures, relevant databases and marketing documentation for NGT plant reproductive material, literature, and case studies focusing on traits introduced in NGT plants, as well as data originating from official controls as referred to in Article 34.

2. The Commission shall include the outcome of the work referred to in paragraph 1 of this Article in the implementation reports referred to in Article 32(1), and in the evaluation referred to in Article 32(3). 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, where appropriate, the outcome of the work referred to in paragraph 1 in relevant strategies concerning a sustainable agrifood system and the bioeconomy, such as those aimed at supporting research, innovation and development activities.

Article 34

Member State 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 the release of an NGT plant or the placing on the market of an NGT product that does 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 applies, the official controls and other official activities shall be planned and performed in accordance with that Regulation.

Article 35

References in other Union legislation

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

Article 36

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 on request from a Member State or from any person directly and individually concerned.

A request to this effect shall be submitted to the Commission within two months of the date on which the Member State or person concerned became aware of the decision or failure to exercise the powers in question.

The Commission shall, within two months of the submission of the request, take a decision requiring, if appropriate, the Authority to withdraw its decision or to remedy its failure to exercise the powers.

Article 37

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 Article 14(1), point (h), and Article 20(3), point (b), of Regulation (EU) 2026/… of the European Parliament and of the Council*;

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* Regulation (EU) 2026/… of the European Parliament and of the Council of … on plants obtained by certain new genomic techniques and their products, and amending Regulation (EU) 2017/625 (OJ L, …, ELI: …)+.’;

(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 Article 14(1), point (h), and Article 20(3), point (b), of Regulation (EU) 2026/…++;’.

+ OJ: Please insert in the text the number, and in the footnote the number, the date of publication and the publication reference of this Regulation.

++ OJ: Please insert the number of this Regulation.

Article 38

Entry into force and application

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

It shall apply from … [24 months from the date of entry into force of this Regulation]. However, Articles 29, 30 and 31 shall apply from … [the date of entry into force of this Regulation].

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

Done at …,

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

ANNEX I

Criteria of equivalence of NGT plants to conventional plants

An NGT plant is considered equivalent to conventional plants if the genetic modifications introduced by the new genomic techniques meet the following conditions:

(1) In the case of plants obtained by targeted mutagenesis, the genetic modifications are the following:

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

(b) deletion of any number of nucleotides.

The number of those genetic modifications does not exceed a limit of three for each protein-coding sequence, taking into account that genetic modifications in introns and regulatory sequences are not subject to that limit.

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

(a) consist of one or more 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; and

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

(i) they result in a combination of DNA sequences that occurs in the gene pool for conventional breeding purposes;

(ii) they do not lead to interruptions of endogenous genes, including interruptions that create chimeric proteins.

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

ANNEX II

Traits referred to in Article 3, point (13)(a), that exclude NGT plants from category 1 status

(1) Tolerance to herbicides

(2) Production of a known insecticidal substance

ANNEX III

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

The objective of a risk assessment is to identify and evaluate, on a case-by-case basis, 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 20(3), point (a), and the safety assessment of category 2 NGT food and feed referred to in Article 20(1), point (b). Part 2 describes specific information for the environmental risk assessment of category 2 NGT plants. Part 3 describes specific information for the safety assessment of category 2 NGT food and feed.

Part 1

General principles and information

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

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

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

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

(c) prior experience with the cultivation of plants of the same species or of a species exhibiting similar traits or in which similar 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 concerned;

(f) the potential receiving environment.

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

(a) hazard identification and characterisation;

(b) exposure characterisation;

(c) risk characterisation;

(d) risk management strategies, where applicable;

(e) overall risk evaluation and conclusion.

The following information shall always be required:

(A) Hazard identification and hazard characterisation

Information relating to the recipient plant or, where appropriate, to the parental plants and information relating to molecular characterisation shall be provided by collating available data from scientific literature or from other sources or by generating scientific data, where necessary by performing appropriate experimental or bioinformatic studies.

Information on hazard identification and hazard characterisation specified under Parts 2 and 3 shall be required only if it is necessary for addressing the risk hypothesis for the category 2 NGT plant or category 2 NGT food or feed.

(B) Exposure 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, the scale and conditions of release, the intended function, the dietary role, the expected level of use of the food and feed in the Union and the scope of the application for authorisation.

(C) Risk characterisation

The applicant shall base the risk characterisation of category 2 NGT plants or category 2 NGT food or 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.

Part 2

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

(1) Analysis of agronomic, phenotypic and compositional characteristics

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

(3) Potential gene transfer

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

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

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

(7) Effects on biogeochemical processes

(8) Effects on human and animal health

Part 3

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

(1) Analysis of agronomic, phenotypic and compositional characteristics

(2) Toxicology

(3) Allergenicity

(4) Nutritional assessment

ANNEX IV

Traits referred to in Article 23

Part 1

Traits justifying the incentives referred to in Article 23:

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

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

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

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

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

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

(7) improved quality or nutritional characteristics;

(8) bioremediation.

Part 2

Traits excluding the application of the incentives referred to in Article 23:

tolerance to herbicides.