Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625

(1) Since 2001, when Directive 2001/18/EC of the European Parliament and of the Council ([32]), on the deliberate release of genetically modified organisms (GMOs) into the environment was adopted, significant progress in biotechnology has led to the development of new genomic techniques (NGTs), most prominently genome editing techniques that enable changes to be made to the genome at precise locations. ***Major advances in genetic engineering have already contributed to the widespread use of marker-assisted selection, which makes itpossible to identify and mobilise interesting genes that are present in biodiversity.***

(2) NGTs constitute a diverse group of genomic techniques, and each of them can be used in various ways to achieve different results and products. They can result in organisms with modifications equivalent to what can be obtained by conventional breeding methods or in organisms with more complex modifications. Among NGTs, targeted mutagenesis and cisgenesis (including intragenesis) introduce genetic modifications without inserting genetic material from non-crossable species (transgenesis). They rely only on the breeders' gene pool, i.e. the total genetic information that is available for conventional breeding including from distantly related plant species that can be crossed by advanced breeding techniques. Targeted mutagenesis techniques result in modification(s) of the DNA sequence at ***targeted*** locations in the genome of an organism. Cisgenesis techniques result in the insertion, in the genome of an organism, of genetic material already present in the breeders' gene pool. Intragenesis is a subset of cisgenesis resulting in the insertion in the genome of a rearranged copy of genetic material composed of two or more DNA sequences already present in the breeders' gene pool.

(3) There is ongoing public and private research using NGTs on a wider variety of crops and traits compared to those obtained through transgenic techniques authorised in the Union or globally([33]). This includes plants with improved tolerance or resistance to plant diseases and pests***, tolerance to herbicides***, plants with improved tolerance or resistance to climate change effects and environmental stresses, improved nutrient and water-use efficiency, plants with higher yields and resilience and improved quality characteristics. These types of new plants, coupled with the fairly easy and speedy applicability of those new techniques, could deliver benefits to farmers, consumers and to the environment. Thus, NGTs have the potential to contribute to the innovation and sustainability goals of the European Green Deal ([34]) and of the 'Farm to Fork' ([35]), Biodiversity ([36]) and Adaptation to Climate Change([37]) Strategies, to global food security ([38]), the Bioeconomy Strategy ([39]) and to the Union's strategic autonomy ([40]).

(4) The deliberate release into the environment of organisms obtained by NGTs, including products containing or consisting of such organisms, as well as the placing on the market of food and feed produced from these organisms, are subject to Directive 2001/18/EC and, Regulation (EC) No 1830/2003 (10) of the European Parliament and of the Council and, in the case of food and feed, also to Regulation (EC) No 1829/2003 (11), while the contained use of plant cells is subject to Directive2009/1/EC, and transboundary movements of NGT

plants to third countries are regulated by Regulation (EC) No 1946/2003 ('the Union GMO legislation').

(5) In its judgment in case C-528/16 Confédération paysanne and Others12 the Court of Justice of the European Union held that GMOs obtained by means of new techniques/methods of mutagenesis that had appeared or had been mostly developed since Directive 2001/18/EC was adopted could not be considered excluded from the scope of that Directive.

(6) The Council, in Decision (EU) 2019/190413, requested the Commission to submit, by 30 April 2021, a study in light of that judgment regarding the status of novel genomic techniques under Union law, and a proposal (accompanied by an impact assessment), if appropriate, depending on the conclusions of the study.

(7) The Commission's study on new genomic techniques (14) concluded that the Union GMO legislation is not fit for the purpose of regulating the deliberate release of plants obtained by certain NGTs and the placing on the market of related products including food and feed. In particular, the study concluded that the authorisation procedure and risk assessment requirements for GMOs under the Union GMO legislation are not adapted to the variety of potential organisms and products that can be obtained with some NGTs, namely targeted mutagenesis and cisgenesis (including intragenesis), and these requirements can be disproportionate or inadequate. The study showed that this is particularly the case for plants obtained by these techniques, given the amount of scientific evidence that is already available, in particular on their safety. Furthermore, the Union GMO legislation is difficult to implement and enforce for plants obtained by targeted mutagenesis and cisgenesis and related products. In certain cases, genetic modifications introduced by these techniques are indistinguishable with analytical methods from natural mutations or from genetic modifications introduced by conventional breeding techniques, whereas the distinction is generally possible for genetic modifications introduced by transgenesis. The Union GMO legislation is also not conducive to developing innovative and beneficial products that could contribute to sustainability, food security and resilience of the agri-food chain.

(8) ***Category 1 NGT plants and products*** obtained by targeted mutagenesis and cisgenesis and related products ***shall not be subject to the rules and requirements of the Union GMO legislation and to provisions in other Union legislation that apply to GMOs***. ***Targeted mutagenesis Category 1 NGT plants and products shall be exempted in Directive 2001/18/EC Annex 1 B like other mutagenecis methods.***

(9) Based on the current scientific and technical knowledge in particular on safety aspects, this Regulation should be limited to GMOs that are plants, i.e. organisms in the taxonomic groups Archaeplastida or Phaeophyceae***. Available knowledge on other organisms, such as*** microorganisms, fungi and animals***, should be reviewed with a view to future legislative initiatives on this***. For the same reason, this Regulation should only cover plants obtained by certain NGTs: targeted mutagenesis and cisgenesis (including intragenesis) (hereinafter 'NGT plants'), but not by other new genomic techniques. Such NGT plants do not carry genetic material from non-crossable species. GMOs produced by other new genomic techniques that introduce into an organism genetic material from non-crossable species (transgenesis) should remain subject only to the Union GMO legislation, given that the resulting plants might bear specific risks associated to the transgene.

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

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

(12) The potential risks of NGT plants vary, ranging from risk profiles similar to conventionally-bred plants to various types and degrees of hazards and risks that might be similar to those of plants obtained by transgenesis. This Regulation should therefore lay down special rules to adjust the risk assessment and risk management requirements according to the potential risks or lack thereof posed by NGT plants and NGT products.

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

(13.a) ***NGT plants with the potential to persist, reproduce or spread in the environment, within or beyond the fields, should be evaluated with highest scrutiny in respect to their impact on nature and the environment.***

(14) NGT plants that could also occur naturally or be produced by conventional breeding techniques and their progeny ***~~obtained by conventional breeding techniques~~*** ('category 1 NGT plants') should be treated as plants that have occurred naturally or have been produced by conventional breeding techniques, given that they are equivalent and that their risks are comparable, thereby derogating in full from the Union GMO legislation and GMO related requirements in sectoral legislation. In order to ensure legal certainty, this Regulation should set out the criteria to ascertain if a NGT plant is equivalent to naturally occurring or conventionally bred plants and lay down a procedure for competent authorities to verify and take a decision on the fulfillment of those criteria, prior to the release or placing on the market of NGT plants or NGT products. Those criteria should be objective and based on science. They should cover the type and extent of genetic modifications that can be observed in nature or in organisms obtained with conventional breeding techniques and should include thresholds for both size and number of genetic modifications to the genome of NGT plants. Since scientific and technical knowledge evolves rapidly in this area, the Commission should be empowered in accordance with Article 290 of the Treaty on the

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

(14.a) ***In view of the high complexity of plant genomes, the criteria for considering that a NGT plant is equivalent to naturally occurring or conventionally bred plants should reflect the diversity of plants genomic size and their characteristics. Polyploid plants contain more than two homologous chromosomes. Within this, tetraploid, hexaploid, and octoploid have 4, 6 and 8 sets of chromosomes respectively. Polyploid plants tend to exhibit greater numbers of genetic modifications compared to monoploid plants. Based on this any limit to the total number of individual modifications per plant should reflect the plants "ploidy", meaning the number of chromosomes set in a plant.***

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

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

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

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

(***18a new***) ***In order to effectively select new varieties that help the agricultural sector increase food security, as well as sustainability, adaptation and resilience to the consequences of climate change, it is necessary to consider the specificity of polyploid plants, i.e. those that***

contain more than two genomes. For such plants, the maximum number of genetic modifications allowed for inclusion in category 1 NGT should be proportionate to the number of genomes they contain.

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

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

(21) Decisions declaring the category 1 NGT plant status should assign an identification number to the NGT plant concerned in order to ensure transparency and traceability of such plants when they are listed in the database***. The information listed shall include information on the technique(s) used to obtain the trait(s)***.

(22) Category 1 NGT plants should remain subject to any regulatory framework that applies to conventionally bred plants. As is the case for conventional plants and products, those NGT plants and their products will be subject to the applicable sectoral legislation on seed and other plant reproductive material, food, feed and other products, and horizontal frameworks, such as the nature conservation legislation and environmental liability. In this regard, category 1 NGT food featuring a significantly changed composition or structure that affects the nutritional value, metabolism or level of undesirable substances of the food will be considered as novel food and thus fall into the scope of Regulation (EU) 2015/2283 of the European Parliament and of the Council (15) and will be risk assessed in that context.

(23) Regulation (EU) 2018/848 of the European Parliament and the Council on organic production and labelling of organic products and repealing Council Regulation (EC) 834/2007(20) prohibits the use of GMOs and products from and by GMOs in organic production. It defines GMOs for the purposes of that Regulation by reference to Directive 2001/18/EC, excluding from the prohibition GMOs which have been obtained through the techniques of genetic modification listed in Annex 1.B of Directive 2001/18/EC. As a result, category 2 NGT plants will be banned in organic production. However, it is necessary to clarify the status of category 1 NGT plants for the purposes of organic production. ***Currently, the compatibility of the use of new genomic techniques with the principles of organic production requires further consideration.*** The use of category 1 NGT plants should therefore be prohibited in organic production***, until further consideration.***

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

(25) Category 2 NGT plants should remain subject to the requirements of the Union GMO legislation given that on the basis of current scientific and technical knowledge, their risks need to be assessed. Special rules should be provided in order to adapt the procedures and

certain other rules laid down in Directive 2001/18/EC and Regulation (EC) No 1829/2003 to the specific nature of category 2 NGT plants and the differing levels of risk that they may pose.

(26) Category 2 NGT plants and products, in order to be released into the environment or placed on the market, should remain subject to a consent or authorisation in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003. However, given the wide variety of those NGT plants, the amount of information necessary for the risk assessment will vary on a case-by-case basis. The Authority, in its scientific opinions on plants developed through cisgenesis and intragenesis17 and on plants developed through targeted mutagenesis18 recommended flexibility in data requirements for the risk assessment of these plants. Based on the Authority's 'Criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis' (19), considerations on the history of safe use, familiarity for the environment and the function and structure of the modified/inserted sequence(s) should assist in determining the type and amount of data required to perform the risk assessment of those NGT plants. It is therefore necessary to establish general principles and criteria for the risk assessment of these plants, while providing for flexibility and possibility to adapt risk assessment methodologies to scientific and technical progress.

(27) Requirements on the content of notifications for consent for the placing on the market of products containing or consisting of GMOs other than food or feed and on the content of applications for authorisation for the placing on the market of genetically modified food and feed are laid down in different pieces of legislation. To ensure consistency between the notifications for consent and applications for authorisation for category 2 NGT products, the content of such notifications and applications should be the same, except those concerning the assessment of food and feed safety assessment as these are only relevant to category 2 NGT food and feed.

(28) The European Union Reference Laboratory for GM Food and Feed (EURL), in collaboration with the European Network of GM Laboratories (ENGL), concluded that analytical testing is not considered feasible for all products obtained by targeted mutagenesis and cisgenesis (20). When the introduced modifications of the genetic material are not specific to the NGT plant in question, they do not allow the differentiation of the NGT plant from conventional plants. In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the notifier or the applicant, the modalities to comply with analytical method requirements should be adapted. This should be done in the implementing acts adopted pursuant to this Regulation. Provision should also be made for the EURL, assisted by the ENGL, to adopt guidance for applicants on the minimum performance requirements for analytical methods. Modalities for performing method validation may also be adapted.

(29) Directive 2001/18/EC requires a monitoring plan for environmental effects of GMOs after their deliberate release or placing on the market but provides for flexibility as to the design of the plan taking into account the environmental risk assessment, the characteristics of the GMO, of its expected use and of the receiving environment. Genetic modifications in category 2 NGT plants may range from changes only needing a limited risk assessment to complex alterations requiring a more thorough analysis of potential risks. Therefore, post-market monitoring requirements for environmental effects of category 2 NGT plants should be adapted in the light of the environmental risk assessment and the experience in field trials, the characteristics of the NGT plant concerned, the characteristics and scale of its expected use, in particular any history of safe use of the plant and the characteristics of the receiving environment. ***In view of the precautionary principle***, a monitoring plan for environmental effects should ***always*** be required ***when consent is first given. It should***

only be possible to waive the requirement for monitoring upon the renewal of consent, provided that it has been demonstrated that the category 2 NGT plant ***does not*** pose risks that need monitoring, such as indirect, delayed or unforeseen effects on human health or on the environment.

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

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

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

(33) Regulatory incentives should be offered to potential notifiers or applicants for category 2 NGT plants and products containing traits with the potential to contribute to a sustainable agri-food system, in order to steer the development of category 2 NGT plants towards such traits. The criteria to trigger these incentives should focus on broad trait categories with the potential to contribute to sustainability (such as those linked to tolerance or resistance to biotic and abiotic stresses, improved nutritional characteristics or increased yield) and should be based on the contribution to the value for sustainable cultivation and use as defined in [Article 52(1) of the Commission's Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of plant reproductive material in the Union21]. The applicability of the criteria across the EU does not allow a narrower definition of traits to focus on specific issues or address local and regional specificities.

(34) Incentives should consist in an accelerated procedure for risk assessment as regards applications handled by a fully centralised procedure (food and feed products) and enhanced pre-submission advice to help developers prepare the dossier for the purpose of the environmental and food and feed safety assessments, without affecting the general provisions on pre-submission advice, notification of studies and consultation of third parties pursuant to Articles 32a, 32b and 32c of Regulation (EC) No 178/2002(22).

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

(36) Herbicide tolerant plants are bred to be intentionally tolerant to herbicides, in order to be cultivated in combination with the use of those herbicides. If such cultivation is not done under appropriate conditions, it may lead to development of weeds resistant to those herbicides or to the need to increase of quantities of herbicides applied, regardless of the

breeding technique. For this reason, NGT plants featuring herbicide-tolerant traits should not ***fall within the scope*** of the ***category 1 NGTs*** ~~***be eligible for incentives under this framework. However, this Regulation should not take other specific measures on herbicide tolerant NGT plants, because such measures are taken horizontally in [the Commission's Proposal for a Regulation***~~ of the ~~***European Parliament and of the Council on the production and marketing of plant reproductive material in the Union]***~~.

(37) In order to enable NGT plants to contribute to the sustainability objectives of the Green Deal and the Farm to Fork and Biodiversity Strategies, cultivation of NGT plants in the Union should be facilitated. This requires predictability for breeders and farmers as regards the possibility to cultivate such plants in the Union. Therefore, ***it should not be possible*** for Member States to adopt measures restricting or prohibiting the cultivation of category 2 NGT plants in all or part of their territory, set out in Article 26b of Directive 2001/18/EC***, as this*** would undermine those goals.

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

(39) To achieve the goal of ensuring the effective functioning of the internal market ***and*** the free movement of ***NGT plant products across the EU, the deliberate release of NGT plants and placing on the market of NGT products should be based on the harmonized*** requirements ***and procedures laid down in this Regulation, leading to the adoption of a decision uniformly applicable to all Member States. Member States shall not unilaterally derogate from the provisions set out in this Regulation in a way that would restrict, prohibit or hinder the free movement, placing on the market and deliberate release of NGT plants or related products within the territory of the*** Union.

(40) Given the ***ongoing*** development ***of new genomic techniques, the Commission*** should ***carry out an evaluation*** within five years after the adoption of the first decision allowing the deliberate release or the marketing of NGT plants or NGT products in the Union***. This*** evaluation ***should*** measure the progress made towards the availability of NGT plants ***or NGT products*** containing such characteristics or properties on the EU market***, with the aim of further improving this Regulation***.

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

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

(43) The types of NGT plants developed and the impact of certain traits on environmental, social and economic sustainability are continuously evolving. Therefore, based on the available evidence of such developments and impacts, ***fully taking into account the precautionary principle,*** the Commission should be empowered in accordance with Article 290 of the

Treaty on the Functioning of the European Union to adapt the list of traits that should be incentivized or discouraged to achieve the goals of the Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies.'

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

(45) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the information required to demonstrate that a NGT plant is a category 1 NGT plant, as regards the preparation and the presentation of the notification for that determination, and as regards the methodology and information requirements for the environmental risk assessments of category 2 NGT plants and of NGT food and NGT feed, in accordance with the principles and criteria laid down in this Regulation. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council(24).

(45a new) The European Parliament has called for the EU and its Member States not to grant patents on biological material and to safeguard the freedom to operate and the breeders' exemption for varieties. It should be ensured that breeders have full access to the genetic material of NGT plants, which by definition are not transgenic plants. Access to genetic materials can best be secured when the right of patent holders is exhausted in the hand of the breeder (breeder's exemption). As current provisions do not provide for a full breeder's exemption in patent law, it should be ensured that patents should not restrict the use of NGT plants by breeders and farmers. Hence, these plants should not be subject to patent legislation, but should for the protection of intellectual property solely be subject to the Community Plant Variety Rights (CPVR) system, as laid down in Council Regulation (EC) No 2100/94, which allows the use of the breeder's exemption. NGT plants, their derived seed, their plant material, associated genetic material such as genes and gene sequences, and plant traits should therefore be excluded from patentability. The exclusion from patentability should be applied in a consistent manner across legislation. Furthermore, in order to avoid that patents could be granted or patent applications could be submitted between the date of the entry into force of this Regulation and the application of its provisions, it should be ensured that the plant material is excluded from patentability from the day of entry into force of this Regulation. For patents already granted or pending patent applications covering plant material, the effects of patents should be further limited. In addition, the Commission should assess and address, in the announced forthcoming study, how the broader problem of patents being granted, directly or indirectly, on plant material despite previous efforts to close loopholes, should be further addressed. The assessment should address in particular the role and impact of patents on breeders' and farmers' access to plant reproductive material, seed diversity and affordable prices, as well as on innovation and in particular on opportunities for SMEs. The report of the Commission should be accompanied by the appropriate legislative proposals in order to ensure further necessary changes to the intellectual property rights framework.

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

products in the market that can contribute to the objectives of the Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies and in order to inform an evaluation of the legislation. A broad set of indicators have been identified25 and should be periodically reviewed by the Commission. The indicators should support monitoring of potential risks to health or the environment of category 2 NGT plants and related NGT products, impact of NGT plants on environmental, economic and social sustainability as well as impact on organic agriculture and on consumers acceptance of NGT products. A first monitoring report should be presented three years after the first products have been notified/authorised, to ensure that enough data is available after full implementation of the new legislation, and at regular intervals thereafter. The Commission should carry out an evaluation of this Regulation two years after the first monitoring report has been published, in order to allow for the impact of the first products going through the verification or authorisation to fully materialise.

(47) Certain references to provisions of the Union GMO legislation in Regulation (EU) 2017/625 of the European Parliament and of the Council (26) need to be amended to include the specific provisions in this legislation applicable to NGT plants.

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

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation, ***in accordance with the precautionary principle*** lays down specific rules for the deliberate release into the environment for any other purpose than placing on the market of plants obtained by certain new genomic techniques ('NGT plants') and for the placing on the market of food and feed containing, consisting of or produced from such plants, and of products, other than food or feed, containing or consisting of such plants, ***ensuring a high level of protection of human and animal health and the environment***.

Article 2

Scope

This Regulation shall apply to:

(1) NGT plants;

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

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

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

Article 3

Definitions

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

(1) the definitions of 'organism', 'deliberate release' and 'placing on the market' set out in Directive 2001/18/EC, those of 'food' and 'feed' set out in Regulation (EC) No 178/2002, that of 'traceability' set out in Regulation (EC) No 1830/2003, that of 'plant' set out in Regulation (EU) 2016/2031 of the European Parliament and of the Council(27) and that of 'plant reproductive material' set out in [*the Commission's Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of plant reproductive material in the Union28*];

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

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

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

(5) 'cisgenesis' means techniques of genetic modification resulting in the insertion, in the genome of an organism, of genetic material already present in the breeders' gene pool;

(6) 'gene pool ***for conventional breeding purposes***' means the total genetic information available in one species and other taxonomic species with which it can or cross-bred, using advanced techniques such as embryo rescue, induced polyploidy and bridge crosses;

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

- **a.** fulfils the criteria of equivalence to conventional plants, set out in Annex I, or
- **b.** is progeny of the NGT plant(s) referred to in point (a), including progeny derived by crossing of such plants, on the condition that there are no further modifications that would make it subject to Directive 2001/18/EC or Regulation 1829/2003;

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

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

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

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

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

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

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

(15)‘small or medium sized enterprise (SME)’ means a SME within the meaning of Commission Recommendation 2003/361/EC2 .

(15a) ‘One Health Approach’ means an integrated, unifying approach that aims to sustainably balance and optimise the health of people, animals, plants and ecosystems. It recognises that the health of humans, domestic and wild animals, plants, and the wider environment including ecosystems are closely interlinked and inter-dependent;

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

Article 4

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

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

(1) the plant is a category 1 NGT plant and
   - **a.** has obtained a decision declaring that status in accordance with Article 6 or 7; or
   - **b.** is progeny of plant(s) referred to in point (a) ***on the condition that the criteria of equivalence set out in Annex 1 are still satisfied*** ; or

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

(new) The implementation, enforcement and application of this Regulation shall not have the object or effect of preventing or impeding imports from third countries of NGT plants and products that meet the same standards as those laid down in this Regulation.

Article 4a (new)

Exclusion from patentability

NGT plants, plant material, parts thereof, genetic information and process features they contain shall not be patentable.

CHAPTER II
Category 1 NGT plants and category 1 NGT products

Article 5

Status of category 1 NGT plants

1. The rules which apply to GMOs in Union legislation shall not apply to category 1 NGT plants.
2. For the purposes of Regulation (EU) 2018/848, the rules set out in its Article 5(f), point (iii), and ***Article*** 11 shall apply to category 1 NGT plants and to products produced from or by such plants. ***[7 years after the entry into force of this Regulation], the European Commission shall present a report on the evolution of the consumers' and producers' perception, accompanied, where appropriate, by a legislative proposal.***
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, ***taking into account potential associated risks and functional consequences in the verification procedure*** in order to adapt them to ***the latest*** scientific and technological ***development*** as regards the types and extent of modifications which can occur naturally or through conventional breeding.

(3a New) The adventitious or technically unavoidable presence of category 1 NGT plants, reproductive material or parts thereof in organic production, or in non-organic products authorized in organic production in accordance with Article 24 and 25 Regulation (EU) 2018/848, shall not constitute a non-compliance of that Regulation.

Article 6

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

1. To obtain the declaration of category 1 NGT plant status referred to in Article 4(1), point (a), before undertaking a deliberate release of a NGT plant for any other purpose than placing on the market, the person intending to undertake the deliberate release shall submit a request to verify whether the criteria set out in Annex I ***at least one of the traits referred to in Annex III part 1 and the exclusion criteria in Annex III part 2*** are met ('verification request'). ***That request shall be submitted*** to the competent authority designated in accordance with Article 4(4) of Directive 2001/18/EC of the Member State within whose territory the release is to take place in accordance with paragraphs 2 and 3 and the ***delegated*** act adopted in accordance with Article ***6(11a), point (b)***.
2. Where a person intends to undertake such a deliberate release simultaneously in more than one Member State, that person shall submit the verification request to the competent authority of one of those Member States.
3. The verification request referred to in paragraph 1 shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, and shall include, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002:

    a. the name and the address of the requester;
    b. the designation and specification of the NGT plant;

c. a description of the trait(s) and characteristics which have been introduced or modified***, including information on the technique or techniques used to obtain the trait or the traits and including disclosure of the sequence of genetic modification;***

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

i. the plant is a NGT plant, including that it does not contain any genetic material originating from outside the ***gene pool for conventional breeding purposes*** where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the ***delegated*** act adopted in accordance with Article ***6(11a), point (a);***

ii. the NGT plant meets the criteria set out in Annex I***, at least one of the traits in Annex III part 1 and the exclusion criteria of Annex III part 2***;

(da new) the denomination of the variety

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

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

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

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

6. If the verification request is not deemed inadmissible in accordance with paragraph 5, the competent authority shall verify whether the NGT plant fulfils the criteria set out in Annex I and prepare a verification report within 30 working days from the date of receipt of a verification request. The competent authority ***may, where appropriate, consult with the European Food Safety Authority ('EFSA') while*** preparing the verification report. The competent authority shall make available the verification report to the other Member States and to the Commission without undue delay.

7. The other Member States and the Commission may make ***reasoned objections*** to the verification report, as regards the fulfilment of the criteria set out in Annex I, within 20 days from the date of receipt of that report. ***These reasoned objections must solely refer to the criteria as set out in Annex I and Annex III and shall include a scientific justification.***

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

9. In cases where a ***reasoned objection*** is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall ***make*** the ***reasoned objections publicly available*** without undue

delay.

10. The Commission, after having consulted the Authority, shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the ***reasoned objections***, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).
11. The Commission shall publish a summary of the decisions referred to in paragraphs 8 and 10 in the Official Journal of the European Union.

(11a new). ***The Commission is empowered to adopt delegated acts in accordance with Article 26 supplementing this Regulation in order to establish***

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

(b) the preparation and the presentation of the verification requests referred to in Articles 6 and 7.

Article 7

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

1. Where a declaration of category 1 NGT plant status referred to in Article 4(1), point (a), has not already been made in accordance with Article 6, to obtain such a declaration before placing on the market a NGT product, the person intending to place the product on the market shall submit a verification request to the Authority in accordance with paragraph 2 and the implementing act adopted in accordance with Article 27, point (b).
2. The verification request referred to in paragraph 1 shall be submitted to the Authority in accordance with standard data formats, where they exist, pursuant to Article 39f of Regulation (EC) No 178/2002, and shall include, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002:
    a. the name and the address of the requester;
    b. the designation and specification of the NGT plant;

    ba new. the denomination of the variety;

    (c) a description of the trait(s) and characteristics which have been introduced or modified ***including information on the technique or techniques used to obtain the trait or the traits and including disclosure of the sequence of genetic modification;***

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

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

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

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

3. The Authority shall acknowledge receipt of the verification request to the requester without delay, stating the date of receipt. It shall make available the verification request to the Member States and to the Commission without undue delay and make public the verification request, relevant supporting information and any supplementary information supplied by the requester, in accordance with article 38(1) of Regulation (EC) No 178/2002, after omission of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 11 of this Regulation.
4. If the verification request does not contain all the necessary information, it shall be declared inadmissible by the Authority within 30 working days within the date of receipt of a verification request. The Authority shall inform the requester, the Member States and the Commission without undue delay of the inadmissibility of the verification request and shall provide the reasons of its decision.
5. If the verification request is not deemed inadmissible in accordance with paragraph 4, the Authority shall deliver its statement on whether the NGT plant fulfils the criteria set out in Annex I within 30 working days from the date of receipt of a verification request. The Authority shall make available the statement to the Commission and the Member States. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its statement public, after omission of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 11 of this Regulation.
6. The Commission shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 30 working days from the date of receipt of the statement of the Authority, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

7. The Commission shall publish ***the final*** decision in the Official Journal of the European Union ***and shall publish, in a dedicated and publicly available webpage, its draft decision and the reasoned objections referred to in Article 6.***

Article 8

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

NOT AMENDED

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

Article 9

Database of decisions declaring the category 1 NGT plant status

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

   The database shall contain the following information:
   (a) name and the address of the requester;
   (b) the designation ***and specification*** of the category 1 NGT plant;

   (b a new) the denomination of the variety ;

   (c) a summarised description of the technique(s) used to obtain the genetic modification;
   (d) a description of the trait(s) and characteristics which have been introduced or modified;
   (e) an identification number, and

   (e a new) If provided, the opinion or statement of EFSA, as referred to in Article 6 (10) and Article 7(5), and

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

2. The database shall be publicly available***, and in on line format.***

Article 10

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

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

Article 11

Confidentiality

NOT AMENDED

1. The requester referred to in Articles 6 and 7 may submit a request to the Member State competent authority or to the Authority, as appropriate, to treat certain parts of the information submitted under this Title as confidential, accompanied by verifiable justification, in accordance with paragraphs 3 and 6.
2. The competent authority or the Authority, as appropriate, shall assess the confidentiality request referred to in paragraph 1. EN 33 EN
3. The competent authority or the Authority, as appropriate, may grant confidential treatment only with respect to the following items of information, upon verifiable justification, where the disclosure of such information is demonstrated by the requester to potentially harm its interests to a significant degree:

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

4. The competent authority or the Authority, as appropriate, shall, after consultation with the requester, decide which information is to be treated as confidential and shall inform the requester of its decision.
5. Member States, the Commission and the Authority shall take the necessary measures to ensure that confidential information notified or exchanged under this Chapter is not made public.
6. The relevant provisions of Articles 39e and 41 of Regulation (EC) No 178/2002 shall apply mutatis mutandis.
7. In the event of a withdrawal of the verification request by the requester, Member States, the Commission and the Authority shall respect the confidentiality as granted by the competent authority or the Authority in accordance with this Article. Where the withdrawal of the verification request takes place before the competent authority or the Authority has decided on the relevant confidentiality request, Member States, the Commission and the Authority shall not make public the information for which confidentiality has been requested.

CHAPTER III

Category 2 NGT plants and category 2 NGT products

Article 12

Status of Category 2 NGT plants and category 2 NGT products

NOT AMENDED

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

SECTION 1

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

Article 13

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

NOT AMENDED

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

(a) the name and the address of the notifier;
(b) a copy of the studies, which have been carried out and any other available material to demonstrate that the plant is a NGT plant, including that it does not contain any genetic material originating from outside the breeders' gene pool where such genetic material has been

temporarily inserted during the development of the plant, in accordance with the information requirements specified in the implementing act adopted in accordance with Article 27, point (a);

(c) a technical dossier supplying the information specified in Annex II necessary to carry out the environmental risk assessment of the deliberate release of a NGT plant or combination of NGT plants:
   i. general information including information on personnel and training;
   ii. information relating to the category 2 NGT plant(s);
   iii. information relating to the conditions of release and the potential receiving environment;
   iv. information on the interactions between the category 2 NGT plant(s) and the environment;
   v. a plan for monitoring in order to identify effects of the category 2 NGT plant(s) on human health or the environment;
   vi. where relevant, information on control, remediation methods, waste treatment and emergency response plans;
   vii. an identification of the parts of the notification and any other supplementary information that the notifier requests to be treated as confidential, accompanied by verifiable justification, pursuant to Article 25 of Directive 2001/18;
   viii. a summary of the dossier;

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

SECTION 2

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

Article 14

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

NOT AMENDED

1. As regards the placing on the market of category 2 NGT products other than food and feed, the notification referred to in Article 13(2) of Directive 2001/18/EC, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002, shall contain:

(a) name and address of the notifier and of its representative established in the Union (if the notifier is not established in the Union);
(b) designation and specification of the category 2 NGT plant;
(c) scope of the notification:
   i. cultivation;
   ii. other uses (to be specified in the notification);
(d) a copy of the studies, which have been carried out and any other available material to demonstrate that the plant is a NGT plant, including that it does not contain any genetic material originating from outside the breeders' gene pool where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the implementing act adopted in accordance with Article 27, point (a);
(e) the environmental risk assessment carried out in accordance with the principles and criteria set out in Parts 1 and 2 of Annex II and with the implementing act adopted in accordance with Article 27, point (c);

(f) the conditions for the placing on the market of the product, including specific conditions of use and handling;
(g) with reference to Article 15(4) of Directive 2001/18/EC, a proposed period for the consent, which should not exceed 10 years;
(h) where appropriate, a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC, including a proposal for the timeperiod of the monitoring plan; this time-period may be different from the proposed period for the consent. If, based on the results of any release notified in accordance with Section 1, the findings of the environmental risk assessment, the characteristics of the NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted in accordance with Article 27, point (d), the notifier considers that the NGT plant does not need a monitoring plan, the notifier may propose not to submit a monitoring plan;
(i) a proposal for labelling which shall comply with the requirements laid down in point A.8. of Annex IV to Directive 2001/18/EC, Article 4(6) of Regulation (EC) No 1830/2003 and Article 23 of this Regulation;
(j) proposed commercial names of the products and names of category 2 NGT plants contained therein, and a proposal for a unique identifier for the category 2 NGT plant, developed in accordance with Commission Regulation (EC) No 65/2004 (29). After the consent any new commercial names should be provided to the competent authority;
(k) description of how the product is intended to be used. Differences in use or management of that product compared to similar non-genetically modified products shall be highlighted;
(l) methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the NGT plant. In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the notifier, the modalities to comply with analytical method requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2);
(m) samples of the category 2 NGT plant and their control samples, and information as to the place where the reference material can be accessed;
(n) where applicable, the information to be provided for the purpose of complying with Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;
(o) an identification of the parts of the notification and any other supplementary information that the notifier requests to be treated as confidential, accompanied by verifiable justification, pursuant to Article 25 of Directive 2001/18/EC and Articles 39 to 39e of Regulation (EC) No 178/2002;
(p) a summary of the dossier in a standardised form.

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

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

Article 15

Specific provisions on monitoring

NOT AMENDED

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

~~Article 16~~

~~**Labelling in accordance with Article 23**~~

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

Article 17

Duration of the validity of the consent after renewal

NOT AMENDED

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

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

SECTION 3

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

Article 18

Scope

NOT AMENDED

This Section shall apply to:

(a) category 2 NGT plants for food use or for feed use;
(b) food containing, consisting or produced from category 2 NGT plants or containing ingredients produced from category 2 NGT plants (‘category 2 NGT food’);
(c) feed containing, consisting or produced from category 2 NGT plants (‘category 2 NGT feed’).

Article 19

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

NOT AMENDED

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

(a) the plant is a NGT plant, including that it does not contain any genetic material originating from outside the breeders' gene pool where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the implementing act adopted in accordance with Article 27, point (a);
(b) the food or the feed complies with the criteria referred to in Article 4(1) or Article 16(1) of Regulation (EC) No 1829/2003, respectively, based on a safety assessment of the food or feed carried out in accordance with the principles and criteria laid down in Parts 1 and 3 of Annex II to this Regulation and with the implementing act adopted in accordance with Article 27, point (c).

2. By way of derogation from Articles 5(3), point (i), and 17(3), point (i), of Regulation (EC) No 1829/2003, an application for authorisation shall be accompanied by methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the NGT plant and, where applicable, for the detection and identification of the NGT plant in the NGT food or feed.
In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the applicant or concluded by the European Union Reference Laboratory referred to in Article 32 of Regulation (EC) No 1829/2003 during the procedure referred to in Article 20(4), the modalities to comply with analytical method requirements shall be adapted as specified in the EN 38 EN implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2);

3. By way of derogation from Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, in the case of category 2 NGT plants or food or feed containing or consisting of category 2 NGT plants, the application shall also be accompanied by:
(a) the environmental risk assessment carried out in accordance with the principles and criteria set out in Parts 1 and 2 of Annex II and with the implementing act adopted in accordance with Article 27, point (c);
(b) where appropriate, a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan. This duration may be different from the duration of the authorisation. If, based on the results of any release notified in accordance with Section 1, the findings of the environmental risk assessment, the characteristics of the NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted in accordance with Article 27, point (d), the applicant considers that the NGT plant does need a monitoring plan, the applicant may propose not to submit a monitoring plan.

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

Article 20

Specific provisions on the opinion of the Authority

NOT AMENDED

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

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

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

3. By way of derogation from Article 6(3), point (d), and Article 18(3), point (d), of Regulation (EC) No 1829/2003, the Authority shall forward to the Union reference laboratory referred to in Article 32 of Regulation (EC) No 1829/2003 the particulars referred to in Article 19(2) of this Regulation and in Article 5(3), point (j), and Article 17(3), point (j), of Regulation (EC) No 1829/2003. EN 39 EN

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

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

(a) the method, validated by the Union reference laboratory, for detection, including sampling, and, where applicable, identification and quantification of the NGT plant and detection and identification of the NGT plant in the NGT food or feed, and a justification of any adaptation of the method in the cases referred to in Article 19(2), subparagraph 2;
(b) an indication of where appropriate reference material can be accessed.

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

Article 21

Duration of the validity of the authorisation after renewal

NOT AMENDED

By way of derogation from Article 11(1) and Article 23(1) of Regulation (EC) No 1829/2003, after the first renewal, the authorisation shall be valid for an unlimited period, unless the Commission decides to renew the authorisation for a limited period, on justified grounds based on the findings of the risk assessment carried out pursuant to this Regulation and on experience with the use, including results of monitoring, if so specified in the authorisation.

SECTION 4

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

Article 22

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

1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least one of the intended trait(s) of the NGT plant conveyed by the genetic modification is contained in ***Article 51(1) of Regulation (2023/0227)*** and it does not have any traits referred to in Part 2 of that Annex.
2. The following incentives shall apply to applications for authorisation submitted in accordance with Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19:
    - **a.** by way of derogation from Article 20(1), subsection (1) of this Regulation, the Authority shall deliver its opinion on the application within 4 months from the receipt of a valid application, unless the complexity of the product requires application of the time limit referred to in Article 20(1). The time limit shall be extendable under the conditions set out in Article 20(1), subsection (2); EN 40 EN
    - **b.** where the applicant is a SME, it shall be exempted from the payment of the financial contributions to the Union Reference Laboratory and to the European Network of GMO Laboratories referred to in Article 32 of Regulation (EC) No 1829/2003.
3. The following pre-submission advice for the purposes of the risk assessment conducted in accordance with Annex II shall, in addition to Article 32a of Regulation (EC) No 178/2002, apply prior to notifications submitted in accordance with Article 13 of Directive 2001/18/EC in conjunction with Article 14 and to applications for authorisation submitted in accordance with Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19:
    - **a.** the staff of the Authority shall, at the request of a potential applicant or notifier, provide advice on plausible risk hypotheses that the potential applicant or notifier has identified based on the properties of a plant, product or hypothetical plant or product, that need to be addressed by providing the information under Parts 2 and 3 of Annex II. The advice shall not, however, cover the design of studies to address the risk hypotheses;
    - **b.** where the potential applicant or notifier is a SME, it may notify the Authority of how it intends to address the plausible risk hypotheses referred to in point (a) that it has identified based on the properties of a plant, product or hypothetical plant or product, including the design of the studies it intends to perform in accordance with the

requirements laid down Parts 2 and 3 of Annex II. The Authority shall provide advice on the notified information, including on the design of the studies.

4. The pre-submission advice referred to in paragraph 3 shall comply with the following requirements:
    - **a.** it shall be without prejudice and non-committal as to any subsequent assessment of applications or notifications by the Panel on Genetically Modified Organisms of the Authority. The staff of the Authority providing the advice shall not be involved in any preparatory scientific or technical work that is directly or indirectly relevant to the application or notification that is the subject of the advice;
    - **b.** for potential notifications in accordance with Article 13 of Directive 2001/18/EC in conjunction with Article 14 and for potential applications under Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19 concerning a category 2 NGT plant to be used as seeds or other plant reproductive material, the pre-submission advice shall be provided by the Authority together, or in close collaboration with the competent authority of the Member State to which the notification or application is going to be submitted;
    - **c.** the Authority shall make public without delay a summary of the presubmission advice once an application or notification has been considered valid. Articles 38(1a) shall apply mutatis mutandis;
    - **d.** potential applicants or notifiers demonstrating that they are a SME can request the pre-submission advice referred to in paragraph 3, point (a), at different points in time.
5. Any request for the incentives shall be submitted to the Authority at the time of request of advice referred to in paragraph 3 or the application referred to in Articles 5 EN 41 EN or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19, and accompanied by the following information:
    - **a.** the information necessary to establish that the intended trait(s) conveyed by the genetic modification of the category 2 NGT plant meet the conditions referred to in paragraph 1;
    - **b.** where applicable, the information necessary to demonstrate the (potential) applicant or notifier is a SME;
    - **c.** for the purpose of paragraph 3, information on the aspects listed in Part 1 of Annex II as far as it can already be provided and any other relevant information.
6. Article 26 of Directive 2001/18/EC and Article 30 of Regulation (EC) No 1829/2003 shall apply to information submitted under this article to the Authority, as appropriate.
7. The Authority shall lay down the practical arrangements to implement paragraphs (3) to (6).
8. The Commission is empowered to adopt delegated acts in accordance with Article 26 amending the lists of traits of NGT plants laid down in Annex III in order to adapt them to scientific and technological progress and to new evidence relating to the impact on sustainability of those traits, subject to the following conditions:
    - **a.** the Commission shall take into account the monitoring of the impacts of this Regulation in accordance with Article 30(3);
    - **b.** the Commission shall conduct an up-to-date scientific literature review of the impact on environmental, social and economic sustainability of the trait(s) it intends to add to or delete from the list in Annex III;
    - **c.** where applicable, the Commission shall take into account the results of monitoring which was carried out in accordance with Article 14, point (h), or Article 19(3), of NGT plants harbouring the trait(s) conveyed by their genetic modification.

Article 23

Labelling of authorised category 2 NGT products

NOT AMENDED

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

Article 24

Measures to avoid the unintended presence of category 2 NGT plants

Member States ***may*** take appropriate measures to avoid the unintended presence of category 2 NGT plants in products not subject to Directive 2001/18 or Regulation 1829/2003***, only in the event that the category 2 NGT plants are able to be detected, identified and quantified by analytical method. These provisions shall not apply to category 1 NGT plants and category 1 NGT products.***

Article 25

Cultivation

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

CHAPTER IV

FINAL PROVISIONS

Article 26

Exercise of the delegation

1. The power to adopt the delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt the delegated acts referred to in Article 5(3), ***Article 6(11a)*** and Article 22(8) shall be conferred on the Commission for a period of 5 years from [date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than 9 months before the end of the 5-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than 3 months before the end of each period.
3. The delegations of power referred to in Article 5(3), ***Article 6(11a)*** and Article 22(8) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day

following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making(30).

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

6. A delegated act adopted pursuant to Articles Article 5(3), ***Article 6(11a)*** and Article 22(8) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or of the Council.

Article 27

Implementing acts

The Commission shall adopt implementing acts concerning:

~~***(a) the information required to demonstrate that a plant is a NGT plant;***~~
~~***(b) the preparation and the presentation of the verification requests referred to in Articles 6 and 7;***~~

(c) the methodology and information requirements for the environmental risk assessment of category 2 NGT plants and the safety assessments of category 2 NGT food and feed, in accordance with the principles and criteria laid down in Annex II;
(d) the application of Articles 14 and 19, including rules concerning the preparation and the presentation of the notification or application;
(e) adapted modalities to comply with analytical method requirements referred to in Article 14(1), point (l), and Article 19(2).

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

Article 28

Committee procedure

NOT AMENDED

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

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

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

Article 29

Guidance

NOT AMENDED

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

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

Article 30

Monitoring, reporting and evaluation

1. No sooner than three years after the first decision is adopted in accordance with Article 6(8) or (10) or Article 7(6) or in accordance with Sections 2 or 3 of Chapter III, whichever is the earliest, and thereafter every five years, the Commission shall forward to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the implementation of this Regulation.
2. The report shall also ***identify and*** address any ***biodiversity and environmental, human and animal health, socio-economic, changes to agronomic practices and*** ethical issues that ***may*** have arisen with the application of this Regulation.
3. For the purpose of the reporting referred to in paragraph 1, the Commission, by [24 months after the date of entry into force of this Regulation] at the latest, shall establish, after consulting the competent authorities of the Member States in accordance with Directive 2001/18/EC and Regulation (EC) No 1829/2003, a detailed programme for monitoring, based on indicators, the impact of this Regulation, ***including the intended and unintended effects and systematic effects on the environment, biodiversity and ecosystems.*** It shall specify the action to be taken by the Commission and by the Member States in collecting and analysing the data and other evidence.
4. No sooner than two years 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, and economic, environmental and social sustainability.
5. The Commission shall present a report on the main findings of the evaluation referred to in paragraph 4 to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

5 a (new). The Commission shall by June 2025 present a report to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the role and impact of patents on breeders' and farmers' access to varied plant reproductive material, as well as on innovation and particularly on the opportunities for SMEs. The report shall assess whether further legal provisions are necessary in addition to those provided for in Article 4a and Article 33a of this Regulation. Where appropriate to ensure breeders' and farmers' access to plant reproductive material, seed diversity and affordable prices, the report shall be accompanied by a legislative proposal to address further necessary adjustments in the intellectual property framework.

5a (new). By 2024, the Commission shall produce a report evaluating the specificities and needs for other sectors not covered in this legislation, such as microorganisms, including a proposal for further policy action.

5b (new). Every 4 years, the Commission shall assess the equivalence criteria established in Annex I and, if necessary, update them through a delegated act as referred to in Article 5, paragraph 3.

Article 31

References in other Union legislation

NOT AMENDED

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

Article 32
Administrative review
NOT AMENDED

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

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

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

Article 33
Amendments to Regulation (EU) 2017/625
NOT AMENDED

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

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

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

Article 33a (new)
Amendments to Directive 98/44/EC

1. Article 4 of Directive 98/44/EC on the legal protection of biotechnological inventions is amended as follows:

In paragraph 1, points (c) and (d) are added:

'(c) NGT plants, plant material, parts thereof, genetic information and process features they contain, as defined in Regulation (EU) .../... [insert reference to this Regulation];
(d) plants, plant material, parts thereof, genetic information and process features they contain that can be yielded by techniques excluded from the scope of Directive 2001/18/EC as listed in Annex
I B to that directive.'

Paragraph 4 is added:
'4. Paragraph 2 and 3 shall be without prejudice to the exclusions from patentability covered in paragraph 1.'

Article 34

Entry into force and application

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

2. It shall apply from [*24 months from the date of entry into force of this Regulation*]. ***Article 4a and Article 33a shall apply from the date of entry into force.***

ANNEX I

Criteria of equivalence of NGT plants to conventional plants

A NGT plant is considered equivalent to conventional plants ***if the following conditions*** referred to in points 1 ***and 1a are met.***

(1) The number of the following genetic modifications, which can be combined with each other, does not exceed 3 per any protein-coding sequence (mutations in introns and regulatory sequences are excluded from this limit):

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

(b) deletion of any number of nucleotides;

(1 a new) The following genetic modifications, which can be combined with each other, do not create a chimeric protein that is not present in species from the gene pool for breeding purposes or does not interrupt an endogenous gene;

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

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

(c) ***inversion or translocation of continuous endogenous DNA sequences existing in the gene pool for breeding purposes***

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

~~(3) on the condition that the genetic modification does not interrupt an endogenous gene:~~

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

~~b. targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;~~

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

~~(5) any other targeted modification of any size, on the condition that the resulting DNA sequences already occur (possibly with modifications as accepted under points (1) and/or (2)) in a species from the breeders' gene pool.~~

ANNEX II

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

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

Part 1- General principles and information

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

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

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

(aa new) characteristics of the recipient plant (i.a. allergenicity; potential for gene flow; weed potential; ecological function);

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

(d) the scale and conditions of the release;
(e) the intended conditions of use of the NGT plant.

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

(a) hazard identification and characterisation;
(b) exposure assessment;
(c) risk characterisation.

The following information shall always be required:

(a) hazard identification and characterisation
    (i) information relating to the recipient plant or, where appropriate, to the parental plants;
    (ii) molecular characterisation.

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

(b) exposure assessment

    Information shall be provided on the likelihood of each identified potential adverse effect. This shall be evaluated taking into consideration, as relevant, the EN 3 EN characteristics of the receiving environment(s), the intended function, the dietary role, the expected level of use of the food and feed in the EU and the scope of the application for authorisation.

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

Any information on hazard identification and characterisation specified under Parts 2 and 3 shall only be required if the specific characteristics and the intended use of the category 2 NGT plant or category 2 NGT food or feed give rise to a plausible risk hypothesis that can be addressed utilising the specified information.

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

(1) Analysis of agronomic, phenotypic and compositional characteristics
(2) Persistence and invasiveness
(3) Potential gene transfer
(4) Interactions of the NGT plant with target organisms
(5) Interactions of the NGT plant with non-target organisms
(6) Impacts of the specific cultivation, management and harvesting techniques
(6a new) Impacts on organic cultivation
(7) Effects on biogeochemical processes
(8) Effects on human and animal health
(8a new) Effects on protecting and conserving biodiversity

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

(1) Analysis of agronomic, phenotypic and compositional characteristics

(2) Toxicology

(3) Allergenicity

(4) Nutritional assessment

ANNEX III

Traits referred to in Article *6 and Article* **22**

Part 1

Traits justifying the incentives referred to in Article 22:

(1) yield, including yield stability and yield under low-input conditions, ***provided that this traits also contributes to either point (2), (3) or (4) of this Annex***;

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

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

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

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

(6) improved quality or nutritional characteristics;

(7) reduced need for external inputs, such as plant protection products and fertilisers, ***if it does not contradict with Annex III part 2***.

Part 2

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

ANNEX IIIa (new)

In-door safety assessment

A Cat.1 NGT plant is considered safe, without having to go through field trials, if the following confined experiments have been undertaken and provide evidence that:

(1) the whole genome sequencing and profiling shows the intended and unintended genetic modifications have not adversely modified the function of one or more genes; and

(2) the whole transcriptome sequencing realized on the relevant part of the plant shows the intended and unintended genetic modifications have not adversely modified biochemical pathways, leading in particular to adverse compositional consequences, verified e.g. through gene ontology analysis; and

(3) biochemical metabolite (metabolomics) and protein (proteomics) profiling realized on the relevant part of the plant shows the intended and unintended genetic modifications have not induced an increase in the levels of known toxins or allergens or the production by the plant of toxic or allergenic novel biochemicals or proteins for the plant itself, any other forms of life it is known to interact with or bound to consume it.