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

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

4. No sooner than two years 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, the organic sector, and economic, environmental and social sustainability.

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

Article 30 bis

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

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

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

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

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

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

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

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

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

Article 31

References in other Union legislation

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

Article 32

Administrative review

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

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

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

Article 33

Amendments to Regulation (EU) 2017/625

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

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

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

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

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

Article 34

Entry into force and application

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

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

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

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

Done at Brussels,

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

ANNEX I

Criteria of equivalence of NGT plants to conventional plants

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

Criteria specific to the use of targeted mutagenesis:

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

(2) deletion of any number of nucleotides;

Criteria specific to the use of cisgenesis:

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

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

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

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

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

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

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

ANNEX II

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

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

Part 1- General principles and information

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

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

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

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

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

(d) the scale and conditions of the release;

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

(f) the potential receiving environment.

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

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

(b) exposure characterisation ~~assessment~~;

(c) risk characterisation;~~.~~

(d) risk management strategies, as applicable;

(e) overall risk evaluation and conclusion.

The following information shall always be required:

(a) hazard identification and hazard characterisation

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

(ii) molecular characterisation.

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

(b) exposure characterisation ~~assessment~~

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

(c) risk characterisation

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

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

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

(1) Analysis of agronomic, phenotypic and compositional characteristics

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

(3) Potential gene transfer

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

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

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

(7) Effects on biogeochemical processes

(8) Effects on human and animal health

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

(1) Analysis of agronomic, phenotypic and compositional characteristics

(2) Toxicology

(3) Allergenicity

(4) Nutritional assessment

ANNEX III

Traits referred to in Article 22

Part 1

Traits justifying the incentives referred to in Article 22:

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

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

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

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

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

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

(6) improved quality or nutritional characteristics;

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

Part 2

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