

### 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<sup>(40)</sup> and that of ‘plant reproductive material’ set out in [the *Commission’s Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of plant reproductive material in the Union*<sup>41</sup>];
- (1a) ‘genetically modified organism’ or ‘GMO’ means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC;
- (2) ‘NGT plant’ means a ~~genetically modified~~ plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the breeders’ gene pool that temporarily may have been inserted during the development of the NGT plant;
- ~~(3) ‘genetically modified organism’ or ‘GMO’ means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC;~~
- (4) ‘targeted mutagenesis’ means mutagenesis techniques resulting in modification(s) of the DNA sequence at ~~precise~~ targeted locations in the genome of an organism;

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<sup>40</sup> Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

<sup>41</sup> COM(2023) 414 final

- (5) ‘cisgenesis’ means techniques of genetic modification resulting in the insertion, in the genome of an organism, of genetic material already present in the breeders’ gene pool. The genetic material may be incorporated as a continuous (exact) copy (cisgenesis in the strict sense) or a re-arranged copy of sequences already present in the breeder’s gene pool (intragensis, also considered a subset of cisgenesis in a broader sense);
- (6) ‘breeders’ gene pool’ means the total genetic information available in one species and other taxonomic species with which it can be cross-bred, including by using advanced techniques such as embryo rescue, induced polyploidy and bridge crosses;
- (7) ‘provisional category 1 NGT plant’ means a NGT plant that meets the requirements of Article 4(1), point 1a and b;
- (a) — ~~fulfils the criteria of equivalence to conventional plants, set out in Annex I, and does not include tolerance to herbicides among the intended traits conveyed by the genetic modification, or~~
- (b) — ~~is progeny of the NGT plant(s) referred to in point (a), including progeny obtained derived by crossing of such plants, on the condition that there are no further modifications that would make it subject to Directive 2001/18/EC or Regulation 1829/2003;~~
- (7a) ‘category 1 NGT plant’ means a NGT plant that meets the requirements of Article 4(2), point 1a, b and c;
- (8) ‘category 2 NGT plant’ means a NGT plant other than a category 1 NGT plant, whether its status is provisional or not either a NGT plant other than a category 1 NGT plant or a category 1 NGT plant that does not meet the requirements of Article 4(1)(b) and (c);
- (9) ‘NGT plant for food use’ means a NGT plant that may be used as food or as a source material for the production of food;

- (10) 'NGT plant for feed use' means a NGT plant that may be used as feed or as a source material for the production of feed;
- (11) 'produced from a NGT plant' means derived, in whole or in part, from a NGT plant, but not containing or consisting of a NGT plant;
- (12) 'NGT product' means ~~a product, other than food and feed, containing or consisting of a NGT plant and~~ food and feed containing, consisting of or produced from ~~such a plant~~ NGT plants, and other products other than food and feed containing or consisting of such plants;
- (13) 'category 1 NGT product' means a NGT product where the NGT plant it contains, consists of or, in the cases of food or feed, is produced from, is a category 1 NGT plant;
- (14) 'category 2 NGT product' means a NGT product where the NGT plant it contains, consists of or, in the cases of food or feed, is produced from, is a category 2 NGT plant;
- (15) 'small or medium sized enterprise (SME)' means a SME within the meaning of Commission Recommendation 2003/361/EC<sup>2</sup>;
- (16) 'patent' means either a patent granted pursuant to the national law of a Member State, or a European patent or European patent with unitary effect within the meaning of Regulation (EU) No 1257/2012;
- (17) 'product patent' means a patent whose subject matter is a product consisting of or containing biological material, as opposed to a patent whose subject matter is a process by means of which biological material is produced, processed or used.

#### *Article 4*

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

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

- (1) the plant is a category 1 NGT plant and
- (a)(i) \_\_\_\_\_ has obtained a decision declaring that status in accordance with Article 6 or 7; or
- (b)(a)(ii) \_\_\_\_\_ is progeny of plant(s) referred to in point (a); ~~or~~ and
- ~~(b) is not protected by one or more patents or published patent applications in one or more Member States of the European Union, or the holders of such patents or patent applications commit not to exercise their rights on the NGT plant in the European Union as long as it is declared category 1 NGT plant status; and~~
- ~~\_\_\_\_\_ (e) does not include tolerance to herbicides among the intended traits conveyed by the genetic modification; or~~
- (2) the plant is a category 2 NGT plant, ~~and has been granted consent or has been authorised,~~ in accordance with Chapter III, Section 1.
2. Without prejudice to other requirements of Union law, a NGT product may only be placed on the market, if:
- (1) the plant is a category 1 NGT plant and
- (a)(i) \_\_\_\_\_ has obtained a decision declaring that status in accordance with Article 6 or 7; or
- (a)(ii) \_\_\_\_\_ is progeny of plant(s) referred to in point (a); and
- (b) does not include tolerance to herbicides among the intended traits conveyed by the genetic modification; and
- (c) has obtained a decision in accordance with Article 6bis or 7 declaring that the product is not protected by one or more product patents or published product patent applications in one or more Member States of the European Union; or
- (2) the plant is a category 2 NGT plant, and has been granted consent or has been authorised, in accordance with Chapter III, Section 2 or 3.

## CHAPTER II

### Category 1 NGT plants and category 1 NGT products

#### Article 5

##### Status of category 1 NGT plants and category 1 NGT products

1. The rules which apply to GMOs in Union legislation shall not apply to category 1 NGT plants that fulfill the condition of Article 4(1), point 1, or Article 4(2), point 1, and their NGT products.
2. For the purposes of Regulation (EU) 2018/848, the rules set out in its Articles 5 (f) (iii) and 11 shall apply to category 1 NGT plants and to products produced from or by such plants.
3. The Commission is empowered to adopt delegated acts in accordance with Article 26 amending the criteria of equivalence of NGT plants to conventional plants laid down in Annex I in order to adapt them to scientific and technological progress, to the extent justified by advances in scientific knowledge, as regards the types and extent of modifications which can occur naturally or through conventional breeding. This empowerment shall be subject to the following conditions:
  - (a) The Commission shall publish a report to justify that, on the basis of scientific evidence, the criteria of equivalence laid down in Annex I no longer reflect what can occur naturally or through conventional breeding. The report shall include an up-to-date scientific literature review as regards the types and extent of modification that can occur naturally or through conventional breeding.
  - (b) Where applicable, the Commission shall take into account any relevant new or updated scientific opinions from the Authority.

*Article 6*

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

1. To obtain the declaration of category 1 NGT plant status referred to in Article 4(1), point ~~1(a)(1)(a)~~, before undertaking a deliberate release of a NGT plant for any other purpose than placing on the market, the person intending to undertake the deliberate release shall submit a request to verify whether the conditions set out in Article 4(1), point 1 (a) and (b), ~~3(7)(a)~~ criteria set out in Annex I are met ('verification request') to the competent authority designated in accordance with Article 4(4) of Directive 2001/18/EC of the Member State within whose territory the release is to take place in accordance with paragraphs 2 and 3 and the implementing act adopted in accordance with Article 27, point (b).
2. Where a person intends to undertake such a deliberate release simultaneously in more than one Member State, that person shall submit the verification request to the competent authority of one of those Member States.
3. The verification request referred to in paragraph 1 shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, and shall include, ~~without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002:~~
  - (a) the name and the address of the requester;
  - (b) the designation and specification of the NGT plant;
  - (c) a description of the trait(s) and characteristics which have been introduced or modified;
  - (d) a copy of the studies, which have been carried out and any other available material to demonstrate that:

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

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

~~(iii) the NGT plant is not protected by one or more patents or published patent applications in one or more Member States of the European Union, or the holders of such patents or patent applications commit not to exercise their rights on the NGT plant in the European Union as long as it is declared category I NGT plant status;~~

~~Article 32b of Regulation (EC) No 178/2002 shall not apply;~~

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

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

~~(g) a declaration by the requester stating that:~~

~~(i) to the best of their knowledge, the plant is not protected by one or more patents or covered by one or more patent applications in one or more Member States of the European Union where the holders of such patents or patent applications have not made the commitment of exercising their rights on the NGT plant in the European Union as long as it is declared category I NGT plant status; and~~

~~(ii) they commit not to file patent applications on the NGT plant as regards one or more Member States of the European Union as long as they pursue a category I NGT plant status.~~

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

~~3 ter. — At the time of submitting the verification request the requester shall include in that request information demonstrating that they or another person have deposited a sample of biological material of the NGT plant with a public depository institution, where it can be made available to any person upon request after the category 1 NGT plant status has been obtained. The requester shall indicate the depository institution and the accession number of the deposited biological material. Where the biological material has been deposited by a person other than the requester, the name and address of the depositor shall be stated in the verification request and accompanied by a document providing evidence that the depositor has authorised the requester to refer to the deposited biological material in the request and has given their unreserved and irrevocable consent to the deposited material being made available to the public after the category 1 NGT plant status has been obtained.~~

4. The competent authority shall acknowledge receipt of the verification request to the requester without undue delay, stating the date of receipt. It shall make available the request, ~~accompanied by an English translation,~~ to the other Member States and to the Commission without undue delay.
5. If the verification request does not contain all the necessary information, it shall be declared inadmissible by the competent authority within 30 working days within the date of receipt of a verification request. The competent authority shall inform the requester, the other Member States and the Commission without undue delay of the inadmissibility of the verification request and shall provide the reasons of its decision.
6. If the verification request is not deemed inadmissible in accordance with paragraph 5, the competent authority shall verify whether the NGT plant meets the conditions set out in Article 4(1), point 1 (a) and (b), 3(7)(a) fulfils the criteria set out in Annex I and prepare a verification report within 30 working days from the date of receipt of a verification request. The competent authority shall make available the verification report to the other Member States and to the Commission without undue delay.

7. The other Member States and the Commission may make ~~comments~~ reasoned objections to the verification report, as regards the fulfillment of the conditions set out in Article 4(1), point 1 (a) and (b), 3(7)(a) criteria set out in Annex I, within 20 days from the date of receipt of that report.
8. In the absence of any ~~comments~~ reasoned 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 provisional category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.
9. In cases where ~~a comment is a~~ reasoned objections are ~~is~~ made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the ~~the comment(s)~~ reasoned objections to the other Member States and to the Commission without undue delay.
10. The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring whether the NGT plant is a provisional category 1 NGT plant within 45 working days from the date of receipt of the ~~comment(s)~~ reasoned objections, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).
- 10 bis. Where the provisional status of category 1 NGT plant has been granted, the verification report, referred to in paragraph 6, including the elements in paragraph 3, shall be published by the Commission within 30 days.
11. The Commission shall publish a summary of the decisions referred to in paragraphs 8 and 10 in the *Official Journal of the European Union*.

Article 6bis

**Verification procedure to obtain a category 1 NGT plant status for requests submitted prior to the placing on the market of NGT products that have obtained a provisional category 1 NGT plant status**

1. Where a declaration of category 1 NGT plant status referred to in Article 4(1), point 1(a)(i), has already been made in accordance with Article 6, to obtain a declaration referred to in Article 4(2), point 1(c), before placing on the market a NGT product, the person intending to place the product on the market shall submit an additional verification request to the same Member State 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 Member State in accordance with standard data formats, where they exist, pursuant to Article 39f of Regulation (EC) No 178/2002, and shall include:
  - (a) the name and the address of the requester;
  - (b) the decision referred to in Article 6(8) or 6(10);
  - (c) a summary of a systematic review, which has been carried out by the requester to demonstrate that the NGT plant is not protected by one or more product patents or published product patent applications in one or more Member States of the European Union. This summary shall include information about the sources that were consulted;
  - (d) 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;

(e) a declaration by the requester stating that:

(i) to the best of their knowledge, the plant is not protected by one or more product patents or covered by one or more product patent applications in one or more Member States of the European Union; and

(ii) they commit not to file product patent applications on the NGT plant as regards one or more Member States of the European Union and not to disclose any information to third parties on the NGT plant for the purpose of pursuing patent protection as long as they pursue a category 1 NGT plant status.

3. The Member State shall acknowledge receipt of the verification request to the requester without undue delay, stating the date of receipt.
4. If the verification request does not contain all the necessary information, it shall be declared inadmissible by the Member State within 30 working days within the date of receipt of a verification request. The Member State shall inform the requester 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 Member State shall adopt a decision on whether the NGT plant meets the conditions set out in Article 4(2), point 1(c), and declaring whether the NGT plant is a category 1 NGT plant that may be placed on the market, within 30 working days from the date of receipt of a verification request. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.
6. Where the status of category 1 NGT plant that may be placed on the market has been granted, the decision, referred to in paragraph 5, including the elements in paragraph 2, shall be published by the Commission within 30 days.
7. The Commission shall publish a summary of the decision in the Official Journal of the European Union.

*Article 7*

**Verification procedure to obtain a of category 1 NGT plant status for requests submitted prior to the placing on the market of NGT products that have not obtained a provisional category 1 NGT status**

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

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

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

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

~~(iii) the NGT plant is not protected by one or more patents or published patent applications in one or more Member States of the European Union, or the holders of such patents or patent applications commit not to exercise their rights on the NGT plant in the European Union as long as it is declared category I NGT plant status;~~

~~Article 32b of Regulation (EC) No 178/2002 shall not apply.~~

~~(da) a summary of a systematic review which has been carried out to demonstrate that the NGT plant is not protected by one or more product patents or published product patent applications in one or more Member States of the European Union. This summary shall include information about the sources that were consulted;~~

(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;

(f) a declaration by the requester stating that:

(i) to the best of their knowledge, the plant is not protected by one or more product patents or covered by one or more product patent applications in one or more Member States of the European Union where the holders of such patents or patent applications have not made the commitment of exercising their rights on the NGT plant in the European Union as long as it is declared category 1 NGT plant status; and

(ii) they commit not to file product patent applications on the NGT plant as regards one or more Member States of the European Union and not to disclose any information to third parties on the NGT plant for the purpose of pursuing patent protection as long as they pursue a category 1 NGT plant status.

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

2 ter. At the time of submitting the verification request the requester shall include in that request information demonstrating that they or another person have deposited a sample of biological material of the NGT plant with a public depository institution, where it can be made available to any person upon request after the category 1 NGT plant status has been obtained. The requester shall indicate the depository institution and the accession number of the deposited biological material. Where the biological material has been deposited by a person other than the requester, the name and address of the depositor shall be stated in the verification request and accompanied by a document providing evidence that the depositor has authorised the requester to refer to the deposited biological material in the request and has given their unreserved and irrevocable consent to the deposited material being made available to the public after the category 1 NGT plant status has been obtained.

3. The Authority shall acknowledge receipt of the verification request to the requester without undue delay, stating the date of receipt. It shall make available the verification request to the Member States and to the Commission without undue delay and make public the verification request, relevant supporting information and any supplementary information supplied by the requester, in accordance with article 38(1) of Regulation (EC) No 178/2002, after omission of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 11 of this Regulation.

4. If the verification request does not contain all the necessary information, it shall be declared inadmissible by the Authority within 30 working days within the date of receipt of a verification request. The Authority shall inform the requester, the Member States and the Commission without undue delay of the inadmissibility of the verification request and shall provide the reasons of its decision.
5. If the verification request is not deemed inadmissible in accordance with paragraph 4, the Authority shall deliver its statement on whether the NGT plant meets the conditions set out in Article 4(2), point 1, 4(1) 3(7)(a) fulfils the criteria set out in Annex I within 30 working days from the date of receipt of a verification request. The Authority shall make available the statement to the Commission and the Member States. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its statement public, after omission of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 11 of this Regulation.
6. The Commission shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 30 working days from the date of receipt of the statement of the Authority, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).
- 6 bis. Where the status of category 1 NGT plant has been granted, the statement, referred to in paragraph 5, including the elements in paragraph 2, shall be published by the Commission within 30 days.
7. The Commission shall publish a summary of the decision in the *Official Journal of the European Union*.

*Article 8*

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

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

*Article 9*

**Database of decisions declaring the category 1 NGT plant status**

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

The database shall contain the following information:

- (a) name and the address of the requester;
- (b) the designation of the category 1 NGT plant;
- (c) a ~~summarised~~ detailed description of the technique(s) used to obtain the genetic modification;
- (d) a description of the trait(s) and characteristics which have been introduced or modified;
- (e) an identification number, and
- (f) the decision referred to in Article 6(8) or (10), and Article 7(6), as appropriate.;
- ~~(g) information relating to the sample referred to in Articles 6(3ter) and 7(2ter) and the depositary institution from which the sample can be made available.~~

2. The database shall be publicly available.

#### *Article 10*

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

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

#### *Article 11*

#### **Confidentiality**

1. The requester referred to in Articles 6 and 7 may submit a request to the Member State competent authority or to the Authority, as appropriate, to treat certain parts of the information submitted under this ~~Title~~ Chapter as confidential, accompanied by verifiable justification, in accordance with paragraphs 3 and 6.
2. The competent authority or the Authority, as appropriate, shall assess the confidentiality request referred to in paragraph 1.
3. The competent authority or the Authority, as appropriate, may grant confidential treatment only with respect to the following items of information, upon verifiable justification, where the disclosure of such information is demonstrated by the requester to potentially harm its interests to a significant degree:
  - (a) items of information referred to in points (a), (b) and (c) of Article 39(2) of Regulation (EC) No 178/2002;
  - (b) DNA sequence information; and
  - (c) breeding patterns and strategies.

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

*Article 11 bis*

**Revocation of category 1 NGT plant status for plants and their products**

The Commission may revoke the category 1 NGT status of the plant if it is shown that the category 1 NGT plant status was granted based on incorrect or misleading information related to product patents, whether submitted intentionally or negligently.

The Commission may also revoke the category 1 NGT status of the plant if a product patent application, held filed by a third party as regards one or more Member States of the European Union which covers the plant, is granted published after the request for verification to obtain category 1 NGT plant status has been submitted.

The Commission may also revoke the category 1 NGT status of the plant if the holders of patents or patent applications exercise their rights on the NGT plant in the European Union, where a commitment not to exercise those rights as referred in Articles 6(3)(d)(iii) and 7(2)(d)(iii) was submitted with the request for verification to obtain category 1 NGT plant status.

The decision to revoke the category 1 NGT status of the plant shall be adopted in accordance with the procedure referred to in Article 28(2).

This is without prejudice to the possibility for a competent authority or the Commission to revoke the category 1 NGT status of the plant on any other legitimate grounds.

The modalities related to the revocation of the category 1 NGT plant status shall be set out in the implementing act adopted in accordance with Article 27, point (ba).

## CHAPTER III

### Category 2 NGT plants and category 2 NGT products

#### *Article 12*

#### **Status of Category 2 NGT plants and category 2 NGT products**

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

#### SECTION 1

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

*Article 13*

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

As regards the deliberate release of a category 2 NGT plant for any other purpose than placing on the market, the notification referred to in Article 6(4~~2~~) of Directive 2001/18/EC shall include:

- (a) the name and the address of the notifier;
- (b) a copy of the studies, which have been carried out and any other available material to demonstrate that the plant is a NGT plant, including that it does not contain any genetic material originating from outside the breeders' gene pool where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the implementing act adopted in accordance with Article 27, point (a);
- (c) a technical dossier supplying the information specified in Annex II necessary to carry out the environmental risk assessment of the deliberate release of a NGT plant or combination of NGT plants:
  - (i) general information including information on personnel and training;
  - (ii) information relating to the category 2 NGT plant(s);
  - (iii) information relating to the conditions of release and the potential receiving environment;
  - (iv) information on the interactions between the category 2 NGT plant(s) and the environment;
  - (v) a plan for monitoring in order to identify effects of the category 2 NGT plant(s) on human health or the environment;
  - (vi) where relevant, information on control, remediation methods, waste treatment and emergency response plans;

- (vii) an identification of the parts of the notification and any other supplementary information that the notifier requests to be treated as confidential, accompanied by verifiable justification, pursuant to Article 25 of Directive 2001/18/EC;
- (viii) a summary of the dossier;
- (d) the environmental risk assessment carried out in accordance with the principles and ~~criteria~~ information set out in Parts 1 and 2 of Annex II and with the implementing act adopted in accordance with Article 27, point (c).

## **SECTION 2**

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

#### *Article 14*

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

1. As regards the placing on the market of category 2 NGT products other than food and feed, the notification referred to in Article 13(2) of Directive 2001/18/EC, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002, shall contain:
  - (a) name and address of the notifier and of its representative established in the Union (if the notifier is not established in the Union);
  - (b) designation and specification of the category 2 NGT plant;
  - (c) scope of the notification:
    - (i) cultivation;
    - (ii) other uses (to be specified in the notification);

- (d) a copy of the studies, which have been carried out and any other available material to demonstrate that the plant is a NGT plant, including that it does not contain any genetic material originating from outside the breeders' gene pool where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the implementing act adopted in accordance with Article 27, point (a);
- (e) the environmental risk assessment carried out in accordance with the principles and ~~criteria~~ information set out in Parts 1 and 2 of Annex II and with the implementing act adopted in accordance with Article 27, point (c);
- (f) the conditions for the placing on the market of the product, including specific conditions of use and handling;
- (g) with reference to Article 15(4) of Directive 2001/18/EC, a proposed period for the consent, which should not exceed 10 years;
- (h) ~~where appropriate~~, a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC, including a proposal for the time-period of the monitoring plan; this time-period may be different from the proposed period for the consent. By way of derogation from the first sentence, a monitoring plan shall not be required where the notifier duly justifies that it is not needed, based on the results of any release notified in accordance with Section 1, the findings of the environmental risk assessment, the characteristics of the category 2 NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted pursuant to Article 27, point (d), and the guidance referred to in Article 29(1); ~~If, based on the results of any release notified in accordance with Section 1, the findings of the environmental risk assessment, the characteristics of the NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted in accordance with Article 27, point (d), the notifier considers that the NGT plant does not need a monitoring plan, the notifier may propose not to submit a monitoring plan;~~

- (i) a proposal for labelling which shall comply with the requirements laid down in point A.8. of Annex IV to Directive 2001/18/EC, Article 4(6) of Regulation (EC) No 1830/2003 and Article 23 of this Regulation;
  - (j) proposed commercial names of the products and names of category 2 NGT plants contained therein, and a proposal for a unique identifier for the category 2 NGT plant, developed in accordance with Commission Regulation (EC) No 65/2004 <sup>(42)</sup>. After the consent any new commercial names should be provided to the competent authority of the Member State;
  - (k) description of how the product is intended to be used. Differences in use or management of that product compared to similar non-genetically modified products shall be highlighted;
  - (l) methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the category 2 NGT plant. ~~In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies,~~
- As regards identification and quantification, if duly justified by the notifier, the modalities to comply with analytical method performance requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2);
- (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;

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

- (n) where applicable, the information to be provided for the purpose of complying with Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;
  - (o) an identification of the parts of the notification and any other supplementary information that the notifier requests to be treated as confidential, accompanied by verifiable justification, pursuant to Article 25 of Directive 2001/18/EC and Articles 39 to 39e of Regulation (EC) No 178/2002;
  - (p) a summary of the dossier in a standardised form.
2. The notifier shall include in this notification information on data or results from releases of the same category 2 NGT plant or the same combination of category 2 NGT plants previously or currently notified and/or carried out by the notifier either inside or outside the Union.
3. The competent authority of the Member State that prepares the assessment report referred to in Article 14 of Directive 2001/18/EC shall examine the notification for compliance with paragraphs 1 and 2.

#### *Article 15*

#### **Specific provisions on monitoring**

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

*Article 15 bis*

**Specific provision on analytical method requirements**

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

*Article 16*

**Labelling in accordance with Article 23**

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

*Article 17*

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

1. The consent granted under Part C of Directive 2001/18/EC shall, ~~after~~ upon the first renewal in accordance with Article 17 of Directive 2001/18/EC, be valid for an unlimited period, unless the decision referred to in Articles 17(6) or (8) or 18(2) provides that the renewal is for a limited period, on justified grounds based on the findings of the risk assessment carried out pursuant to this Regulation and on experience with the use, including results of monitoring, if so specified in the consent.
2. The last sentence in Article 17(6) and (8) of Directive 2001/18/EC shall not apply.

## SECTION 3

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

#### *Article 18*

##### **Scope**

This Section shall apply to:

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

#### *Article 19*

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

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

- (a) the plant is a NGT plant, including that it does not contain any genetic material originating from outside the breeders' gene pool where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the implementing act adopted in accordance with Article 27, point (a);
- (b) the food or the feed complies with the criteria referred to in Article 4(1) or Article 16(1) of Regulation (EC) No 1829/2003, respectively, based on a safety assessment of the food or feed carried out in accordance with the principles and ~~criteria~~ information laid down in Parts 1 and 3 of Annex II to this Regulation and with the implementing act adopted in accordance with Article 27, point (c).
2. By way of derogation from Articles 5(3), point (i), and 17(3), point (i), of Regulation (EC) No 1829/2003, an application for authorisation shall be accompanied by methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the category 2 NGT plant and, where applicable, for the detection, ~~and identification~~ and quantification of the category 2 NGT plant in the NGT food or feed produced from it.
- ~~In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, As regards identification and quantification,~~ if duly justified by the applicant or concluded by the European Union Reference Laboratory referred to in Article 32 of Regulation (EC) No 1829/2003 during the procedure referred to in Article 20(4), the modalities to comply with analytical method performance requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2);
3. By way of derogation from Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, in the case of category 2 NGT plants or food or feed containing or consisting of category 2 NGT plants, the application shall also be accompanied by:

- (a) the environmental risk assessment carried out in accordance with the principles and ~~criteria~~ information set out in Parts 1 and 2 of Annex II and with the implementing act adopted in accordance with Article 27, point (c);
- (b) ~~where appropriate~~, a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan. This duration may be different from the duration of the authorisation. By way of derogation from the first sentence, a monitoring plan shall not be required where the applicant duly justifies that it is not needed, based on the results of any release notified in accordance with Section 1, the findings of the environmental risk assessment, the characteristics of the category 2 NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted pursuant to Article 27, point (d), and the guidance referred to in Article 29(1). ~~If, based on the results of any release notified in accordance with Section 1, the findings of the environmental risk assessment, the characteristics of the NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted in accordance with Article 27, point (d), the applicant considers that the NGT plant does need a monitoring plan, the applicant may propose not to submit a monitoring plan.~~
4. The application shall also contain a proposal for labelling in accordance with Article 23.

#### *Article 20*

##### **Specific provisions on the opinion of the Authority**

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

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

2. In addition to the tasks referred to in Article 6(3) and Article 18(3) of Regulation (EC) No 1829/2003, the Authority shall verify whether all the particulars and documents submitted by the applicant are in conformity with Article 19 of this Regulation.
3. By way of derogation from Article 6(3), point (d), and Article 18(3), point (d), of Regulation (EC) No 1829/2003, the Authority shall forward to the European Union ~~Reference~~ Laboratory referred to in Article 32 of Regulation (EC) No 1829/2003 the particulars referred to in Article 19(2) of this Regulation and in Article 5(3), point (j), and Article 17(3), point (j), of Regulation (EC) No 1829/2003.
4. The European Union ~~Reference~~ Laboratory shall test and validate the method of detection, identification and quantification proposed by the applicant in accordance with Article 19(2) or assess whether the information provided by the applicant justifies the application of adapted modalities to comply with detection method requirements referred to in that paragraph.
5. By way of derogation from Article 6(5), point (f), and Article 18(5), point (f), of Regulation (EC) No 1829/2003, in the event of an opinion in favour of authorising the food or the feed, the opinion shall also include:

- (a) the method, validated by the European Union Reference Laboratory, for detection, including sampling, ~~and, where applicable,~~ identification and quantification of the category 2 NGT plant and, where applicable, for the detection, and identification and quantification of the category 2 NGT plant in the NGT food or feed produced from it, and a justification of any adaptation of the analytical method performance requirements in the cases referred to in Article 19(2), subparagraph 2;
- (b) an indication of where appropriate reference material can be accessed.
6. In addition to the particulars mentioned in Article 6(5), point (d) and Article 18(5), point (d) of Regulation (EC) No 1829/2003, the opinion shall also include a proposal for labelling in accordance with Article 23 of this Regulation.

#### *Article 21*

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

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

### **SECTION 4**

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

*Article 22*

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

1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least one of the intended trait(s) of the category 2 NGT plant conveyed by the genetic modification is contained in Part 1 of Annex III and it does not have any traits referred to in Part 2 of that Annex.
2. The following incentives shall apply to applications for authorisation submitted in accordance with Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19:
  - (a) by way of derogation from Article 20(1), subsection (1) of this Regulation, the Authority shall deliver its opinion on the application within 4 months from the receipt of a valid application, unless the complexity of the product requires application of the time limit referred to in Article 20(1). The time limit shall be extendable under the conditions set out in Article 20(1), subsection (2);
  - (b) where the applicant is a SME, it shall be exempted from the payment of the financial contributions to the European Union Reference Laboratory and to the European Network of GMO Laboratories referred to in Article 32 of Regulation (EC) No 1829/2003.
3. The following pre-submission advice for the purposes of the risk assessment conducted in accordance with Annex II shall, in addition to Article 32a of Regulation (EC) No 178/2002, apply prior to notifications submitted in accordance with Article 13 of Directive 2001/18/EC in conjunction with Article 14 and to applications for authorisation submitted in accordance with Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19:

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

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

- (a) it shall be without prejudice and non-committal as to any subsequent assessment of applications or notifications by the Panel on Genetically Modified Organisms of the Authority. The staff of the Authority providing the advice shall not be involved in any preparatory scientific or technical work that is directly or indirectly relevant to the application or notification that is the subject of the advice;
- (b) for potential notifications in accordance with Article 13 of Directive 2001/18/EC in conjunction with Article 14 and for potential applications under Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19 concerning a category 2 NGT plant to be used as seeds or other plant reproductive material, the pre-submission advice shall be provided by the Authority together, or in close collaboration with the competent authority of the Member State to which the notification or application is going to be submitted;

- (c) the Authority shall make public without delay a summary of the pre-submission advice once an application or notification has been considered valid. Articles 38(1a) of Regulation (EC) No 178/2002 shall apply *mutatis mutandis*;
  - (d) potential applicants or notifiers demonstrating that they are a SME can request the pre-submission advice referred to in paragraph 3, point (a), at different points in time.
5. Any request for the incentives shall be submitted to the Authority at the time of request of advice referred to in paragraph 3 or the application referred to in Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19, and accompanied by the following information:
- (a) the information necessary to establish that the intended trait(s) conveyed by the genetic modification of the category 2 NGT plant meet the conditions referred to in paragraph 1;
  - (b) where applicable, the information necessary to demonstrate the (potential) applicant or notifier is a SME;
  - (c) for the purpose of paragraph 3, information on the aspects listed in Part 1 of Annex II as far as it can already be provided and any other relevant information.
6. Article ~~25~~6 of Directive 2001/18/EC and Article 30 of Regulation (EC) No 1829/2003 shall apply to information submitted under this article to the Authority, as appropriate.
7. The Authority shall lay down the practical arrangements to implement paragraphs (3) to (6), including the verification that the category 2 NGT plant meets the conditions referred to in paragraph 1.
8. The Commission is empowered to adopt delegated acts in accordance with Article 26 amending the lists of traits of NGT plants laid down in Annex III in order to adapt them to advances in scientific and technological progress and or to new evidence relating to the impact on sustainability of those traits, subject to the following conditions:

- (a) the Commission shall take into account the monitoring of the impacts of this Regulation in accordance with Article 30(3);
- (b) the Commission shall conduct and publish an up-to-date scientific literature review of the impacts on environmental, social and economic sustainability of the trait(s) it intends to add to or delete from the list in Annex III;
- (c) where applicable, the Commission shall take into account the results of monitoring which was carried out in accordance with Article 14, point (h), or Article 19(3), of category 2 NGT plants harbouring the trait(s) conveyed by their genetic modification.

*Article 23*

**Labelling of authorised category 2 NGT products**

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

*Article 24*

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

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

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

*Article 25*

**Cultivation**

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

**CHAPTER IV**

**FINAL PROVISIONS**

*Article 26*

**Exercise of the delegation**

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

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making<sup>(43)</sup>.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to ~~Articles~~ Article 5(3) and Article 22(8) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or of the Council.

#### *Article 27*

#### **Implementing acts**

The Commission shall adopt implementing acts concerning:

- (a) the information required to demonstrate that a plant is a NGT plant;
- (b) the preparation and the presentation of the verification requests, and the content of the verification reports and of the decisions referred to in Articles 6, 6bis and 7;
- (ba) the application of Article 11bis;
- (c) the methodology and information requirements for the environmental risk assessment of category 2 NGT plants and the safety assessments of category 2 NGT food and feed, in accordance with the principles and factors ~~criteria~~ laid down in Annex II;

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<sup>43</sup> OJ L 123, 12.5.2016, p. 1.

- (d) the application of Articles 14 and 19, including rules concerning the preparation and the presentation of the notification or application;
- (e) adapted modalities to comply with analytical method performace requirements referred to in Article 14(1), point (l), and Article 19(2).

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

#### *Article 28*

##### **Committee procedure**

1. The Commission shall be assisted by the committee set up by Article 58 of Regulation (EC) No 178/2002.
2. Where reference is made to this paragraph, Article 4 of Regulation (EC) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 5 of Regulation (EC) No 182/2011 shall apply.

#### *Article 29*

##### **Guidance**

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

2. Before the date of application of this Regulation, the European Union Reference Laboratory for Genetically Modified Food and Feed established pursuant to Article 32 of Regulation (EC) No 1829/2003, assisted by the European Network of GMO Laboratories, shall publish detailed guidance to assist the notifier or the applicant for the application of Article 14(1), point (l), and Article 19(2).
3. The Commission shall publish guidelines for the purpose of assisting operators, in particular breeders, in navigating the plant intellectual property landscape. The Commission shall consult the competent intellectual property offices of the Member States when drafting the guidelines. The guidelines shall at least specify:
  - (a) existing plant licencing platforms and their members;
  - (b) existing public organisations that have the purpose of assisting SMEs with intellectual property-related questions;
  - (c) existing databases allowing operators to identify the intellectual property rights which apply to plant;
  - (d) the relevant obligations on intellectual property rights-holders to grant compulsory licences;
  - (e) the existing exemptions from intellectual property rights open to plant breeders.

### *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.