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LEGAL OVERVIEW AND ANALYSIS OF THE COMMISSION'S PROPOSAL FOR A REGULATION ON PLANTS OBTAINED BY CERTAIN NEW GENOMIC TECHNIQUES, THEIR PRODUCTS, AND THEIR FOOD AND FEED

In green, remarks regarding the leaked draft
In blue, identified problems and comments

The development of new techniques for the genetic modification of organisms (hereinafter "NGT"), and more specifically **cisgenesis** and **mutagenesis**, has raised the question of whether they should be subject to European regulations on genetically modified organisms (hereinafter "GMOs"), namely Directive 2001/18/EC and Regulation (EC) No 1829/2003.

The European Court of Justice, which has dealt with this issue on several occasions (cf. CJEU, 7 février 2023, *Confédération paysanne and Others* - C-688-21 ; CJEU, 25 July 2018, *Confédération paysanne and Others* - C-528/16), has developed a technical reasoning, differentiating the practical methods used to carry out the genetic modification (in vitro/in vivo).

In this context, the European Commission has decided to issue a new legislative proposal, that aims to exempt a certain number of these genetic modification operations from the risk assessment and labelling rules.

- *Precisely, whereas the previous version of the proposal was supposed to be amending Directives 68/193/EEC (on the marketing of materials for the vegetative propagation of the vine), 1999/105/EC (on the marketing of forest reproductive materials), 2002/53/EC (on the common catalogue of varieties of agricultural plant species), 2002/55/EC (on the marketing of vegetable seeds) and Regulation (EU)2017/625 on official controls, the final version of the proposal only amends Regulation (EU) 2017/625. NGTs are therefore not submitted to clear indication in the catalogue of varieties. Specific provisions provide for information of users in the new proposal.*

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According to the Commission, targeted mutagenesis[1] and cisgenesis[2] are different from established genomic techniques because they introduce novel *features*, but no foreign genetic material from a non-crossable species (transgenesis).

The present proposal, submitted par the Commission on July 5th, intends to set out new rules specifically for plants obtained by targeted mutagenesis and cisgenesis (including intragenesis), their progeny, food and feed, and products they might be contained in.

It is first necessary to present the ground distinction and general definitions proposed by the Commission (I). Next, the rules to be applied to Category 1 NGT (II), and Category 2 NGT (III) will be exposed. Final remarks regarding the specific evaluation and administrative review entrusted to the Commission (IV) will close the present overview.

I. DEFINITIONS AND DISTINCTIONS PROPOSED

The legal basis of the proposal should first be presented (A) before exposing the general definitions (B) and basic distinctions of NGT plants (C & D) set up by the Commission.

A. Legal basis of the proposal

The EU cannot adopt an act unless it has received the competence to do so by the Treaty (principle of conferral of powers laid down in the TFEU, Article 5).

The legal basis may have an impact on how the act is adopted (ordinary legislative procedure adopted by Parliament and Council and special legislative procedure).

According to the Commission, the proposal is based on:

- Article 43 TFEU, which gives the Commission competence to submit legislative proposals implementing the common agricultural policy (CAP).
- Article 114 TFEU, which gives the EU competence to adopt measures with the aim of ensuring the good functioning of the internal market.
- Article 168(4)(b) TFEU, which gives the EU competence to adopt measures in the veterinary and phytosanitary fields, with the protection of public health as a direct objective.

[1] According to article 3, "targeted mutagenesis" means mutagenesis techniques resulting in modification(s) of the DNA sequence at precise locations in the genome of an organism.
[2] According to article 3, "cisgenesis" means techniques of genetic modification resulting in the insertion, in the genome of an organism, of an exact copy of genetic material already present in the breeders' gene pool

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Such measures shall be adopted in accordance with the ordinary legislative procedure, meaning co-adopted by EP and Council.

About Article 114 TFEU, some provisions might have an interest for our matter:

- §3: The Commission is entitled to prepare proposals "*concerning health, safety, environmental protection and consumer protection*" that will "*take as a base a high level of protection, taking account in particular of any new development based on scientific facts*". EP and Council "*will also seek to achieve these objectives*".

  - The Commission might be 'violating' the treaty by not ensuring a high level of consumers' protection considering they would not be informed in any manner on cat 1 NGTs.

B. General definition

Hereinafter, plants and products obtained by NGT will be referred to as NGT plants. Article 3 (2) of the proposal defines NGT plant as *"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*".

This means that as soon as a plant or a product contains any trace of genetic material originating from outside the breeders' gene pool, it remains entirely regulated by the GMO legislation.

According to Article 3, "'*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*;"

- 'Embryo rescue': This technique is being used to obtain viable interspecific or intergeneric hybrids. This is used when hybrid zygote is unable to develop. This technique has been successfully used in *Triticum*, *Hordeum*, *Phaseolus*, *Nicotiana*, *Gossypium*, *Lycopersicon*, *Trifolium*, *Cucurbita* and several other species.
- 'Induced polyploidy': When two species of a cross differ in chromosome number, it is necessary to match their ploidy level by doubling the chromosome of the species with low ploidy. It may enhance the chances of obtaining a zygote, which is a fertilized egg cell that results from the union of a female gamete with a male gamete.
- 'Bridge crosses': Sometimes, two species say A and C do not cross directly. In such case a third species say B which can cross with both A and C is chosen as a bridge

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species. First B is crossed with C and then the amphidiploid is crossed with A. Bridge crosses have been used in tobacco and wheat.
In tobacco, *Nicotiana repanda* can cross with *N. sylvestris* but not with *N. tabacum*. But *N. sylvestris* can cross with *N. tabacum*. For transfer of genes from *N. repanda*, *N. sylvestris* is used as a bridge species. It is first crossed with *N. repanda* and the resulting amphidiploid is crossed with *N. tabacum*.
Similarly, in wheat the cross between *Aegilops ventricosa* and *Triticum aestivum* is sterile. *T. turgidum* is used as a bridge species for transfer of genes from *Aegilops ventricosa* to *T. aestivum*.
The bridge cross is a complicated procedure and is more successful for transfer of monogenic dominant characters. This may be used when other techniques do not work in interspecific or intergeneric gene transfer.

- The possibility to go beyond the total genetic information available in one species could be questioned, as the breeder could then introduce a wide range of foreign genes into NGT plants.

C. Definition of Category 1 NGT plants

According to Article 3 of the proposal, a 'category 1 NGT plant' **is the one :**

- **that fulfils the criteria of equivalence to conventional plants set out in Annex I, or**
- **is a progeny of that NGT plant, including progeny derived by crossing of such plants**, on the condition that there are no further modifications that would make it subject to the GMO legislation.

The respect of the equivalence's criteria set out in Annex I is therefore not necessary for the progeny of Category 1 NGT plant.

- The crossing of several Category 1 NGT plants could lead to a violation of Annex I by the progenies. The only reservation that "*there are no further modifications that would make it subject to the GMO legislation*" might not be sufficient to ensure these progenies are equivalent to conventional plants.
- It would be preferable to exclude the crossing of NGT plants from the scope of Category 1, and submit it to Category 2.

As regards other rules, however, the plant coming from the **crossing of Category 1 NGTs is considered as NGT**.

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The criteria of equivalence to conventional plants is set out in Annex I as follows:

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 of the types referred to in points 1 to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.

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

(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.

- The technical and scientific basis of these provisions are not provided in the proposal.
- 20 genetic modifications is a significant number. It appears rather arbitrary. No explanation is provided for such a number. 20 genetic modifications of the types described would be considered equivalent to conventional plants, while 21 not. In fact, one genetic modification should be examined at a time. Two genetic modifications of the types described should make up an NGT plant not equivalent to convention plants.
- (1): 20 nucleotides also appears very arbitrary. No explanation is provided for such a number. If the logic based on a fixed number of modified nucleotides is conserved, a certain number of modified nucleotides should apply to all types of genetic modifications.
- (2) and (4): 'any number of nucleotides' appears very excessive.
- (3) (a) and (b): No maximum number of nucleotides is provided for here. However, 'insertion' and 'substitution' operations are foreseen. As a consequence, the maximum number of modified nucleotides provided for in (1) should also apply.
- (5): provisions between brackets are redundant and deprives (5) from its specificity.
- "sequence similarity with the targeted site" exclude the examination of any unintended mutations/modifications on other sites of the genome.

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The Commission is empowered to adopt delegated acts amending the criteria of equivalence laid down in Annex I "*in order to adapt them to scientific and technological profess".* (Art 5).

- According to Article 290 TFEU, "*A legislative act may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend* ***certain non-essential elements of the legislative act****.*"
  However, the criterion of equivalence seem to be **the most essential element of this legislative proposal**, as both definitions of cat 1 NGT and cat 2 NGT (considering that cat 2 NGTs means "a NGT plant other than a category 1 NGT plant") are based on this criterion. The very applicability of the derogations to GMO rules relies on the definition of cat 1 NGT, namely on the criterion of equivalence.

- In the leaked draft, **herbicide-tolerant crops,** even if fulfilling the notification criteria, were excluded from the regulatory route for Category 1 NGT plants.
  The official proposal does not retain this exclusion, as stated in Recital (36): "*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]*".
  The PRM proposal provides that:
  > Recital (48) *« As this Regulation aims to contribute to the sustainability of agricultural production, the competent authorities of Member States responsible for the registration of varieties should be able to* ***subject the cultivation of those varieties in their territory to cultivation conditions appropriate for avoiding those undesirable effects****. »*
  > And Art. 47 1 (f) *« where the varieties are tolerant to herbicides, they are* ***subject to cultivation conditions*** *for the production of PRM and for any other purpose, adopted pursuant to paragraph 3 or, in the case they have not been adopted, as adopted by the competent authorities responsible for registration, to avoid the development of herbicide resistance in weeds due to their use; »*
- *These provisions are not equivalent to the exclusion from the regulatory route for Category 1 NGT plants.*

D. Definition of Category 2 NGT plants

Article 3 of the Proposal defines category 2 NGT plant as every NGT plant other than a category 1 NGT plant.

Then, plant and plant products obtained by NGTs and which do not fulfill the criteria of Category 1 NGT, namely which do not fulfill the criteria of equivalence to conventional plants, nor are progeny of a such plants, are qualified as Category 2 NGT plants.

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Unlike category 1 NGT plant, the EU legislation on GMOs, **insofar as they are not derogated from by this Proposal**, shall apply to category 2 NGT plants and category 2 NGT products (Art 12).

- This legislative proposal constitutes *lex specialis* with regard to the GMO legislation.
  Recital (11) states, indeed: "*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.*"
  Lex generalis sets general provisions with a large scope of application. It is applicable as long as *lex specialis* does not derogate from it. As such, *lex specialis* shall apply in priority. What is not covered by *lex specialis* falls under *lex generalis*.
  That means, for example, that where there are no specific rules on labelling in the new Regulation, rules provided for in Reg. 1829/2003 will automatically apply to NGT plants and products.

Finally, it is to be noted that Cat. 1 and 2 **NGT plants will remain forbidden in organic farming** (article 5§2).

II. RULES TO BE APPLIED TO 'CATEGORY 1 NGT PLANTS' (CHAPTER II – ARTICLES 5 TO 11)

Whether or not they are to be placed on the marked, Category 1 NGT plant would only be submitted to a verification procedure (**A**).

A. A simple verification procedure

For plants obtained by NGT that could also occur naturally or be produced by conventional breeding techniques, or their progeny ('Category 1 NGT plants'), **a verification procedure** shall apply.

- The leaked draft named this stage of the process a "notification request".

For Category 1 NGT plants, the GMO legislation does not find application. This means that Cat. 1 NGT plants **will not require authorization, risk assessment, traceability and labelling** as GMOs, except in this regard for plant reproductive material (PMR), as **labelling is foreseen for PRM**. For these plants, only a **transparency register** would be established. As a consequence, Member States will not be allowed to ban the use and cultivation of NGT plants on their territory.

- Note that the vast majority of farmers and consumers are not aware of the existence and possible use of national and even less of European registers. For instance, the national

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variety registers and the common variety register for seeds and plant reproductive materials remain unknown to almost everyone.

The authority to whom the request should be submitted varies depending on the purpose of the release: placing on the market or not.

1. Verification procedure for the release of NGT plants for any other purpose than placing on the market (Article 6)

- **Request shall be presented to only one Member State**

When the NGT plant is not aimed to be placed on the marked, for example for field trials, it is the responsibility of the 'competent authority' of the Member State where the release is going to take place - or of the Commission in a subsidiary capacity - to determine if NGT plants belong to category 1.

If the person intends to undertake such release in more than one Member State, the person shall submit the notification to only one Member State, meaning **the national decision has EU-wide effects**.

- **Content of the request**

The verification request shall include:
- the name and address of the notifier,
- the designation and the specifications of the NGT plant,
- a description of the trait(s) and characteristic(s) which have been introduced or modified,
- a copy of studies that shall demonstrate that the plant is category 1 NGT meeting the criteria set out in Annex I - in accordance with the information requirements specified in an implementing act -,
- indication of the Member States in which the notifier intends to undertake the deliberate release,
- an identification of the parts of the request the requester demands to be treated as confidential accompanied by 'verifiable justifications'.

All the information shall be communicated for the request to be admissible.

- **Decision by one Member State**

The member State's competent authority shall prepare a **verification report** within **30 working days** on whether the plant fulfils the category 1 criteria.

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- This delay was not foreseen in the leaked draft.

The report shall be communicated to other Member States and to the Commission. "Comments" may be made within **20 days** from the date of receipt of that report.

- Other Member States had 30 days in the leaked draft.

In the absence of any comments from a Member State or the Commission, the Member State's competent authority shall adopt a **decision within 10 working days** from the expiry of the 20 days deadline, establishing whether the NGT plant fulfils the conditions.

- The deadline for the Member State to answer the request, and for others Member States to submit comments, is rather short. This raises doubts about the quality of the checks that will be carried out.

In case the Commission or a Member State makes a comment, the competent national authority **shall forward the file to the Commission.**

- If the Commission wants the lead on the decision-making, she only has to make a comment.

- In the leaked draft, the EFSA was seized to deliver a statement and had to **make the notification public**. From then, the Commission would have been up to adopt its decision.

The Commission, after having consulted the EFSA, shall prepare a draft decision, within **45 days**, declaring whether the NGT plant is a category 1. Before being adopted, the draft decision is submitted to a committee composed of member States' and the Commission's representatives, under the advisory procedure of Regulation 182/2011 (comitology).

- **At no point, the verification request is made public**. The leaked draft provided that as soon as a 'reasoned objection' was raised by another Member State or the Commission, the notification request had to be made public.
- The proposal provides for no risk assessment, no labelling for consumers (except on seed bag), and no traceability (detection methods, reference material). It would then be difficult to ensure NGT-free-farming, as detection in the field will be impossible. **Contamination with genetic modifications seems therefore unavoidable**.

- The recognition of the 'Category 1 NGT plant' status by a national decision, in the event of a verification request for any other purpose than placing on the market, **would in fact entail the possibility for the requester to then place the plant on the market**. Indeed, the procedure for the purpose of placing on the market only applies "*Where a declaration of*

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*category 1 NGT plant status referred to in Article 4(1), point (a), **has not already been made in accordance with Article 6"*** (Article 7). In other words, if the Member States authority finds that the plant is a category 1 NGT plant, thus authorize the release of the NGT for a purpose other than placing on the marked, the applicant will **no longer have to go through the placing on market procedure**.

As a consequence, going through Article 6's procedure would prevent the public from having access to the verification request submitted and to all the relevant information on the plant supplied by the requester.

2. Verification procedure for the release of the NGT plant for the purpose of placing on the market (Article 7)

When the NGT plant is to be placed on the marked, the verification decision is adopted by **the Commission**. (Article 7)

The verification request is submitted to the European Food Safety Agency (**EFSA)**, that conducts the assessment on whether the NGT plant fulfils the category 1 NGT plant criteria. It shall include the same elements as for NGT that are not intended to be placed on the marked (cf. supra). The EFSA delivers a statement within **30 working days**.

Article 11 offers the applicant the possibility to request a confidential treatment, accompanied by "verifiable justifications" assessed as appropriate by the EFSA. The article provides for a limitative list of items of information that could be granted confidential treatment, "*where the disclosure of such information is demonstrated by the requester to potentially harm its interests to a significant degree*". This right also exists when the plant is not aimed to be placed on the market.

After the EFSA's statement, the verification request and all relevant supporting information supplied by the requester **shall be made public**.

- The leaked draft provided for the publication of the information in Art 6 (for any other purpose than placing on the market) rather than in article 7.

The Commission is then empowered to adopt the decision on whether the plant is a category 1 NGT plant. Before being adopted, the draft decision is submitted to a committee composed of member States' and the Commission's representatives, under the advisory procedure of Regulation 182/2011 (comitology).

3. Publicity

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The proposed Regulation (article 9) provides that Category 1 NGT plants that have obtained a positive decision are **listed in a database**, publicly available.

- Unlike proposed in the leaked draft, the official proposal contains **no obligation** to ensure that varieties containing or consisting of a category 1 NGT plant are clearly **indicated as varieties obtained by a new genomic technique in the catalogue of varieties** (provision added to Directive 68/193/EEC on vine, Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species, Directive 2002/55/EC on vegetable seeds).

However, plant reproductive material, including for breeding and scientific purposes, when made available to third parties, shall bear a label indicating the words 'cat 1 NGT'. That means *a contrario* that **no labelling is provided for category 1 NGT plants and products** themselves when made available to consumers.

III. RULES TO BE APPLIED TO CATEGORY 2 NGT PLANTS' (CHAPTER III)

To begin with, it should be noted that **EU legislation on GMOs, insofar as it is not derogated from by the Proposal, shall apply to category 2 NGT plants and category 2 NGT products** (Art 12), unlike Category 1 NGT plant.

Therefore, category 2 NGT plants and products **remain subject to the GMO labelling requirements**. In addition to these labelling requirements, the labelling of authorized category 2 NGT products '*may also*', if desired, mention the trait(s) conveyed by the genetic modification.

However, the possibility for Member States to restrict or prohibit cultivation pursuant to Directive 2001/18 does not apply to category 2 NGT plants.

- This potentially goes against article 114 §4 et §5 TFEU:
  - §4: after the adoption of the harmonization measure, Member States may deem it "*necessary to maintain national provisions on grounds of major needs referred to in Article 36*". Art 36 refers to "*the protection of health and life of humans, animals or plants*". The provisions maintained shall not constitute a means of arbitrary discrimination or a disguised restriction on trade.
  - §5: after the adoption of the harmonization measure, Member States may deem it necessary to "*introduce national provisions based on new scientific evidence relating to the protection of the environment on grounds of a problem specific to that Member State arising after the adoption of the harmonization measure*".

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Then, as with Category 1 NGT plants, Category 2 NGT plants are not granted the same treatment if they are to be placed on the market or not, and in the latest case whether they are to be used for food or feed or not.

A. Release for any other purpose than for placing on the market (Section 1 – Article 13)

The release of any category 2 NGT plant for any other purpose than for placing on the market is subject to a **notification procedure**. (Article 13 of the Proposal)

The notification procedure is roughly the same as for standard notification procedure for GMOs set out in article 6 of directive 2001/18/EC.

The very same documents as for GMOs are required for the application to be admissible:

- a copy of the studies which have been carried out to demonstrate that the plant is an NGT plant (and that the genetic material – other than that originating from the breeders' gene pool – inserted as an intermediate step has been completely removed),
- a technical dossier supplying the information specified in Annex II necessary for carrying out the environmental risk assessment of the deliberate release of an NGT plant or combination of NGT plants;
- and the environmental risk assessment carried out.

Annex II to the Regulation specifies the information that must be supplied in the technical dossier and sets the principles and criteria applicable to carry out the environmental risk assessment. A Commission's implementing act shall also specify the criteria of the environmental risk assessment.

- **Ultimately, as explained, EU legislation on GMOs shall apply to category 2 NGT plants and category 2 NGT products insofar as it is not derogated from by this Proposal** (Art 12). Therefore, apart from Article 6(2) of directive 2001/18/EC, the other provisions are applicable. For example, it results from article 6(1) of the 2001/18/EC directive that the person willing to release a Category 2 NGT plant shall submit the application to the competent authority of the Member State where such NGT plant is to be placed on the market for the first time.

B. Release for the purpose of placing on the market NGT products other than food and feed (Section 2 – Articles 14 to 17)

The release on the market of any category 2 NGT plant, for any other purpose than food or feed shall be subject to a **notification procedure** (Article 14).

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The notification procedure follows the one applicable to the placing on the market of GMOs as or in products.

1. Content of the notification referred to in Article 13(2) of Directive 2001/18/EC

The content of the notification slightly varies as compared to GMOs. Some new requirements complete the classical information.

Are required:

- the name and address of the notifier (or its representative if the notifier is not established in the EU),
- the designation and specification of the plant,
- the scope of the notification (for what use, like cultivation),
- a copy of the studies which have been carried out and any other available material to demonstrate that the plant is an NGT plant (in accordance with a Commission's implementing act),
- "Where appropriate"[3], a monitoring plan for environmental effects,
- proposed commercial names of the products and names of category 2 NGT plants contained therein, description of how the product is intended to be used,
- methods of sampling, detection, identification, and quantification (in case where it is not feasible, the modalities to comply with analytical method requirement shall be adapted as specified in a Commission's implementing act), samples…

Furthermore, the notifier shall include information 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. *These details were not required in the leaked draft.*

Notification for both GMOs and 'Category 2 NGTs' shall also contain the environmental risk assessment (the one for NGT plant shall be made in accordance with Annex 2 containing exposure assessment and risk characterization, and a Commission's implementing act), conditions for the placing on the market of the product, a proposal for labelling[4].

[3] If the notifier considers that the NGT does not need a monitoring plan based on the results of previous tests (like: the deliberate release for any other purpose than placing on the market, section 1 / the findings of the environmental risk assessment, the characteristics of the plant or its receiving environment… (Art 14. 1. (h)).

[4] "*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*" ; Article 23 provides, in addition to GMOs requirement, for "*the labelling of authorized category 2 NGT products may also mention the trait(s) conveyed by the genetic modification*"

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- **Ultimately, as explained, EU legislation on GMOs shall apply to category 2 NGT plants and category 2 NGT products insofar as it is not derogated from by this Proposal** (Art 12). Therefore, apart from Article 6(2) of directive 2001/18/EC, the other provisions are applicable. For example, it results from article 6(1) of the 2001/18/EC directive that the person willing to release a Category 2 NGT plant shall submit the application to the competent authority of the Member State where such NGT plant is to be placed on the market for the first time.

2. Specific provision on the written consent given by MS authorities.

For the purpose of placing NGT products other than food or feed on the market, specific provisions adapt the requirements set out in Article 19 of Directive 2001/18/EC.

The written consent given by the national competent authority shell specify:

- **monitoring requirements** or state that monitoring is not required (if monitoring is not required, the report on the results of the monitoring is not needed for the application for the renewal of the consent).
- the **labelling requirements**.

After being renewed once (the consent cannot be given for a period exceeding 10 years in accordance with Art 15.4 of Directive 2001/18/EC), the consent of the national competent authority shall be valid for an **unlimited period**, unless the decision made upon the assessment report delivered at the expiry of the consent indicates that the renewal is for a limited period (under Article 17(6) or (8) of the Directive 2001/18/EC), on justified grounds (risk assessment findings).

- On precautionary ground, the validity of administrative decisions should not be unlimited, especially because the proposal does not contain any provision that would permit the **withdrawal** of the decision.

C. Placing on the market of category 2 NGT plants for food or feed use and of category 2 NGT for food and feed (Section 3 – Articles 18 to 21)

The release on the market of category 2 NGT plant for food or feed use and for food and feed, shall be subject to an authorization procedure.

The authorization request shall be presented before the competent authority of the Member State.

The requirements of Regulation (EC) No 1829/2003 on GMOs are adapted to NGTs.

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1. Application for authorization

Apart from what is already required for GMOs, and by way of derogation from the legislation on GMOs, the application for authorization shall be accompanied by:

- A copy of the studies which have been carried out to demonstrate that the plant is a NGT (here again, in accordance or compliance with some information, principles and criteria specified in Commission's implementing acts, and the safety assessment such acts will provide for).
- Methods for sampling, detection, identification, and quantification of the NGT plant (if not feasible, and if duly justified by the applicant or concluded by the European Union Reference Laboratory, the modality to comply with such requirement shall be adapted as specified in an implementing act)
- The environmental risk assessment carried out in accordance with the principles and criteria set out in Annex II and an implementing act.
- "where appropriate"[5], a monitoring plan for environmental effects and the duration of the monitoring plan;
- A proposal for labelling[6].

Authorizations are renewable. Once renewed, "*the authorization shall be valid for an unlimited period*" unless the Commission decides to renew the authorization for a limited period on justified grounds. (Art 21).

- On precautionary ground, the validity of administrative decisions should not be unlimited, especially because the Proposal does not contain any provision that would permit the **withdrawal** of the decision. safety assessment of the food or feed.
- **Safety assessment** is only required for food and feed Cat. 2 NGTs, in the form of studies demonstrating that the food or feed complies with the criteria referred to in Article 4(1) or Article 16(1) of Regulation (EC) No 1829/2003.
- Annex II seems to provide that the safety assessment is conducted in the 'plausible risk hypothesis' only. This point is unclear, however, as Article 19 (applicable to cat 2 NGTs for food or feed use / cat 2 NGTs for food and feed) provides that, for being placed on the market, the food or feed shall comply "*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***". Neither Regulation (EC) No 1829/2003 nor Article 19 of the proposed Regulation mentions any 'plausible risk hypothesis'.

[5] If the applicant considers that the NGT does not need a monitoring plan based on the results of previous tests (like: the deliberate release for any other purpose than placing on the market, section 1 / the findings of the environmental risk assessment, the characteristics of the plant or its receiving environment… (Article 19.3 (b))
[6] Under the same conditions as for Article 14

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2. Opinion of the EFSA

According to article 20, the EFSA shall deliver an opinion within **6 months** as from the receipt of a valid application on:

- the application for authorization (which is carried out by the Member State competent authority) ;
- the conformity of the particulars and documents submitted.

The EFSA shall also forward particulars to the Union reference laboratory for tests to be done (on method of detection, identification and quantification proposed by the applicant) or to assess whether the information provided by the applicant justifies the application of adapted modalities.

The opinion of the EFSA shall be substantiated. In case it is in favor of authorizing the Category 2 NGT, it shall describe the method validated by the Union reference laboratory for detection, sampling identification and quantification, as well as an indication of where appropriate reference material can be accessed. EFSA shall also make a proposal of labelling.

➢ EFSA opinion is only advisory.

D. The environmental risk assessment for Category 2 NGT plants and Category 2 NGT food and feed

Part 1 of Annex II to the proposal sets out the general principles and information on the risk assessment of category 2 NGT plants, food and feed. Accordingly, "*The environmental risk assessment shall be carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC.*"

Directive 2001/18/EC on GMOs is accompanied by two Annexes relating to the risk assessment: Annex II sets the general principles applicable, and Annex III the information necessary to carry the environmental risk assessment.

➢ As it stands, the environmental risk assessment for GMOs and NGTs shall be carried out in accordance with the same principles (Annex II to Directive 2001/18/EC that provides for objectives, general principles, a methodology and conclusions on the potential environmental impact).

However, still according to Part 1 of Annex II to the proposal, "*The type and amount of information necessary for the environmental risk assessment of category 2 NGT plants laid down in Annex III of*

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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."

- Hence, the environmental risk assessment for GMOs and NGTs **does not include the same type and amount of information.**

The risk profile is evaluated considering 5 factors:

- the characteristics of the NGT plant
- prior experience with the consumption of similar plants or their products,
- prior experience with the cultivation of the same plant species,
- the scale and conditions of the release, the intended conditions of use.

The risk assessment shall then at least consist of:

- Hazard identification and characterization;
- Exposure assessment;
- Risk characterization.

The information required for each of the latter is specified in Annex II. Concerning hazard identification and characterization, some information is required "***only 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***". The specific information is set out in Part 2 (specific information on environmental risk assessment concerning hazard identification and characterization) and 3 (specific information for the safety assessment concerning hazard identification and characterization, for food or feed) of Annex II.

- 'Plausible risk hypothesis' is not defined anywhere. However, when cat 2 NGT is intended to be placed on the market, EFSA shall deliver **pre-submission advice** on plausible risk hypothesis for the purpose of the risk assessment conducted in accordance with Annex II, under Article 22 of the Regulation. Where the potential applicant or notifier is a SME, it may notify the Authority of how it intends to address the plausible risk identified, for additional advice to be provided.

Most of the specific information required in the 'plausible risk hypothesis' for NGTs is always required for GMOs (for instance: interactions of the NGT plant with target organisms, effects on biogeochemical processes, allergenicity…).

E. Common provisions for Category 2 NGT plants and products (Section 4 – Articles 22 to 25)

1. Regulatory incentives and pre-submission advice

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Incentives shall apply to cat 2 NGT plants containing **traits relevant for sustainability**, meaning "*where at least one of the intended trait(s) of the 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.*" (Article 22 to the proposal).

Category 2 NGT may benefit from incentives when:

- the plant contains at least one trait listed in Part 1 of Annex III
- the plant does not have any trait referred to in Part 2 of that Annex.

The traits justifying the incentives are as follows:

1. Yield, including yield stability and yield under low-input conditions;
2. Tolerance/resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses and other pests;
3. Tolerance/resistance to abiotic stresses, including those created or exacerbated by climate change;
4. More efficient use of resources, such as water and nutrients;
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 fertilizers.

The Commission is empowered to adopt delegated acts amending the list 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*" (under conditions specified in Art 22. 8).

According to part 2 of Annex 3, "*Traits excluding the application of the incentives referred to in Article 22:* ***tolerance to herbicides***."

- Herbicide-tolerant cat. 2 NGT plants are excluded from the benefit of regulatory incentives.
- In the leaked draft, herbicide-tolerant cat. 2 NGT plants were already excluded from the benefit of regulatory incentives.

Request for incentives shall be submitted to the EFSA.

Incentives consist of:

- Unless the complexity of the product requires extension of time, EFSA shall delivers its opinion within 4 months, instead of 6.

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- When the applicant is a SME, it should be exempted of payment of the financial contributions to the Union Reference Laboratory and to the European network of GMO laboratories.

➢ *The leaked draft extended theses incentives to Category 2 NGTs placed on the market for uses other than food or feed.*

Pre-submission advice is also possible for:

- notifications submitted for the purpose of placing on the market of NGT products other than food and feed (Art 14)
- applications for authorization for the purpose of placing on the market of category 2 NGT plants for food or feed use and of category 2 NGT for food and feed (Art 19)

Advice is given prior to the notification or the application, for the purposes of the risk assessment conducted in accordance with Annex II:

- EFSA shall provide advice on plausible risk hypothesis identified. The advice shall not, however, cover the design of studies.
- When the potential applicant or notifier is a SME, it may notify the Authority of how it intends to address the plausible risk hypothesis, including the design of the studies it intends to perform. The Authority shall then provide advice on the notified information, **including on the design of the studies.**

Pre-submission advice is submitted to several requirement listed in article 22(4). However, the procedure is made easier for SMEs.

➢ The leaked draft provided for incentives and pre-submission advice for both NGT plants mentioned in Article 16 and Article 19 of the draft. In the official proposal, the placing on the market of cat 2 NGT products for use other than food or feed (which was Article 16 - is now Article 14) is removed from the scope of incentives but remains in the scope of pre-submission advice.

IV. SPECIFIC EVALUATION AND ADMINISTRATIVE REVIEW ENTRUSTED TO THE COMMISSION

The proposed Regulation provides for rules for specific implementing, monitoring, reporting, and evaluation requirements and administrative review entrusted to the Commission.

1. Monitoring, reporting and evaluation

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The Commission shall report on the implementation of the Regulation no sooner than three years after the first decision granting an NGT status to a plant, and thereafter every 5 years, to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

To monitor the impacts of the Regulation and for the purpose of reporting, the Commission shall establish a detailed program.

After the publication of the first report, the Commission shall carry out an evaluation of the implementation of the Regulation and its impact on human, animal health, the environment, consumer information, the functioning of the internal market, and economic, environmental, and social sustainability. A report on the main findings of such evaluation shall be presented to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

2. Administrative review

The Commission may, on its own initiative or in response to a request from a Member State or from any person directly and individually concerned, review any decision taken by EFSA.

'If appropriate', the Commission may require the EFSA to withdraw its decision or to remedy its failure to act.

- *This administrative review is new, if compared to the leaked draft.*