EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food Safety, Sustainability, and Innovation
Biotechnology

Implementation Strategy [1]

For Regulation (EU) 2026/1388 on plants obtained by certain new genomic techniques and their products

Introduction 1

Regulation (EU) 2026/1388 [2] ('NGT Regulation') entered into force on 16 July 2026 and will apply from 17 July 2028. It establishes a specific regulatory framework for plants obtained by certain new genomic techniques (NGT plants) and their products. It distinguishes between two categories of NGT plants. Category 1 NGT plants are equivalent to natural or conventionally bred plants and, upon a verification procedure, those plants and their products are exempt from the requirements of the legislation on genetically modified organisms (GMOs). Category 2 NGT plants, which harbour more complex genetic modifications, and their products will remain subject to the GMO legislation with certain adaptations, including a tailored risk assessment, the possibility to adapt arrangements to comply with analytical method performance requirements, the possibility to waive post-market environmental monitoring, and unlimited validity of authorisations upon first renewal. To address concerns about the potential impacts of NGT plant patenting, especially on breeders and farmers, the Regulation also contains provisions to increase transparency, facilitate access to NGT plant biological material and improve legal certainty in this area.

In view of the positive contribution that NGT plants and products can make to face increasing geopolitical, economic, environmental and climate challenges and considering the novelty of the approach of the NGT Regulation, as regards for example the provisions on category 1 NGT plants, the adaptations for category 2 NGT plants and the measures relating to patents, the proper and timely implementation of the NGT Regulation is a priority for the Commission services.

This implementation strategy sets out actions at Union and Member State level across eight implementation areas that are necessary for the effective and consistent application of the NGT Regulation throughout the Union. It supports coordinated

[1] This Implementation Strategy is provided for information purposes only. It does not legally bind the Commission on whether the identified actions will be pursued or on the form in which they will be pursued.

[2] Regulation (EU) 2026/1388 of the European Parliament and of the Council of 17 June 2026 on plants obtained by certain new genomic techniques and their products, and amending Regulation (EU) 2017/625 (OJ L, 2026/1388, 26.6.2026)

implementation by the Commission, Union bodies and agencies, and the Member States, and informs stakeholders and the public of planned actions.

Summary: implementation areas

Implementation area	Key actions	Finalisation (target)
Delegated and implementing acts	- Delegated act on the information required to demonstrate that a plant is an NGT plant and on the verification procedure for category 1 NGT plant status - Implementing act on notifications and applications for category 2 NGT plants and products	By application date
Guidance	- Guidance by the European Food Safety Authority on verification requests for category 1 NGT plant status and notifications and applications for category 2 NGT plants and products - Guidance by the European Union Reference Laboratory for GM Food and Feed on analytical methods for category 2 NGT plants - Information on support for NGT research and development	By application date
Member States' regulatory and administrative preparations	- Verification procedure for category 1 NGT plant status conducted at national level - Adaptation of national GMO legislation, procedures and capacity, where necessary - Preparation for controls	By application date
EU administrative preparations	- Verification procedure for category 1 NGT plant status conducted at EU level - Practical arrangements by the European Food Safety Authority on enhanced pre-submission advice for category 2 NGT plants/products - Adaptation of procedures and capacity	By application date
Patents	- Guidance by the Commission on plant intellectual property matters - Code of Conduct on patents - NGT plant patent expert group	- By application date - Q4 2027 - Q3/Q4 2026
IT systems	- Adaptation of the E-Submission Food Chain platform - Database of decisions declaring category 1 NGT plant status - Indication in the relevant information systems that a plant variety or basic material for the production of forest reproductive material contains or consists of category 1 NGT plants	By application date
Monitoring programme	Establishment of a monitoring programme	By application date
Communication and outreach	- Conference – Innovation and resilience in the agrifood chain: Regulation on plants obtained by new genomic techniques - Communication to stakeholders (potential requesters and applicants); public awareness-raising at EU and national level - Information to non-EU countries	- Q4 2026 - Continuously - Q4 2026

Implementation areas 2

2.1 Delegated and implementing acts

The NGT Regulation empowers the Commission to adopt delegated and implementing acts in the areas described below in order to provide operators and competent authorities with clear and harmonised requirements. They will be essential for the NGT Regulation to be operational (i.e. for operators to be able to submit requests for verification, notifications for deliberate release and applications for the placing on the market of food and feed, and for competent authorities to handle them). They should therefore be adopted before, or at the latest by, the date of application of the NGT Regulation.

The measures foreseen are as follows:

- **Adoption by the Commission of a delegated act on the information required to demonstrate that a plant is an NGT plant, and on the verification procedure for category 1 NGT plant status (Article 25)**

The delegated act will cover the following two elements:

— the information required to demonstrate that a plant is an NGT plant, which must be submitted both for category 1 verification and category 2 authorisation (Article 25(a)), and

— the verification procedure for category 1 NGT plant status: preparation and presentation of the verification request (including demonstration of compliance with the equivalence criteria in Annex I and the trait-based exclusion), content of the information related to patents and, where relevant, patent licensing that requesters may submit together with the verification request, content of the Member States' verification reports and content of the Commission's and Member States' decisions declaring whether a plant is a category 1 NGT plant (Article 25(b)).

NGT plants and the verification procedure for category 1 NGT plants are new concepts in the EU GMO legislation. Therefore, the act will aim to ensure legal certainty and predictability for operators and competent authorities, as well as accurate and comparable declarations of category 1 NGT plant status across Member States and at EU level. As the verification procedure is carried out at national or EU level, harmonised requirements and harmonised application of the procedure are essential to ensure equal treatment and consistent decisions.

A central element will be the application of the technical criteria of equivalence of NGT plants to conventional plants (Annex I), which define the boundary between category 1 and category 2 NGT plants. It is essential that both operators and public authorities have a common understanding of these criteria and how to demonstrate compliance with them, as they will underpin operators' long-term research and breeding investments, and

to ensure the smooth functioning of verification procedures. For the same reasons, the information requirements related to the exclusion from category 1 status of NGT plants containing certain traits (Articles 6(4), 7(3), Annex II) will also need to be further specified.

All these elements will be complemented by guidance by the European Food Safety Authority ('EFSA') (see Section 2.2).

The Commission will gather input from EFSA, the Member States, stakeholders, and the public to ensure scientific robustness and practical operability of the delegated act. The Commission will request EFSA to provide scientific and technical assistance for the delegated act, including data requirements to demonstrate fulfilment of the conditions for a plant to be considered an NGT plant and for obtaining the status of category 1 NGT plant.

The Commission will publish a 'call for evidence' (if feasible already in Q3 2026), describing the initiative and inviting stakeholders and the public to provide evidence and opinions relevant to the preparation of the act. The Commission will take the responses into account when developing the delegated act. At a later stage, the Commission will invite stakeholders and the public to provide feedback on the draft delegated act during a four-week public feedback period. As is usual Commission practice, those consultation activities will be carried out through the Have Your Say portal ([3]). The drafting process will also take into account discussions focusing on implementation aspects at the NGT conference (see Section 2.8).

The Commission will work closely with Member States experts during the preparation of the delegated act in an expert group established for that purpose in Q3 2026. The Council and the Parliament can participate as observers in the expert group and have the power to express an objection to the delegated act when adopted by the Commission within the timeframe set out in Article 290 TFEU and Article 26(6) of the NGT Regulation.

The draft delegated act will also be notified under the World Trade Organisation (WTO) Agreements on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and on Technical Barriers to Trade (TBT Agreement), for possible comments from non-EU countries.

Milestones*	- Q3 2026, mandate to EFSA to provide scientific and technical support - Q3/Q4 2026, launch call for evidence - Q3/Q4 2026, establishment of an expert group - Q2 2027, launch 4-week feedback on draft act - Q3 2027, launch expert group feedback on draft act - Q1 2028, adoption - Q1 2028, transmission to European Parliament and Council, 2-month objection period (extendable by 2 months) - Entry into force at date of application of the NGT Regulation
Actors	Commission; expert group (Member States); EFSA; European Parliament and Council (as observers in the expert group and for formal scrutiny in accordance with Article 290 TFEU); interested parties

* Indicative, non-exhaustive and may be subject to change.

([3]) https://ec.europa.eu/info/law/better-regulation/have-your-say_en

- **Adoption by the Commission of an implementing act on notifications and applications for category 2 NGT plants/products (Article 27)**

The implementing act will cover the following elements:

— the methodology and information requirements for the adapted environmental risk assessment and food and feed safety assessment (Article 27(a)),

— the preparation and the presentation of notifications and applications (Article 27(b)), including the conditions to grant an exemption from the requirement for a post-market environmental monitoring plan, and

— the adapted arrangements for complying with analytical method performance requirements (Article 27(c)).

Preparations for the implementing act will focus in particular on aspects where procedures and requirements for category 2 NGT plants differ from those for other GMOs. Where the NGT Regulation provides flexibility, the implementing act will clarify the grounds and the information required for its application, to support consistent interpretation and legal certainty, and reduce the risk of disagreements between competent authorities or delays in the authorisation process.

For the risk assessment, the NGT Regulation establishes general principles and information requirements (Annex III), while providing for flexibility on a case-by-case basis and possibility to adapt risk assessment methodologies to scientific and technical progress. The implementing act will further specify methodologies and information requirements adapted to the specific characteristics of category 2 NGT plants.

The implementing act will also develop further the conditions under which post-market environmental monitoring is not required and the justification to be provided by notifiers and applicants in this regard.

These elements will be complemented by EFSA guidance (see Section 2.2).

For analytical methods, the NGT Regulation allows adapted arrangements where identification and quantification methods are not feasible, subject to justification by the notifier/applicant. The implementing act will specify the justification required by notifiers/applicants and how arrangements to comply with analytical method performance requirements will be adapted. This element of the implementing act will be developed in close cooperation with the Commission's Joint Research Centre ('JRC'), which has been designated as the European Union Reference Laboratory for GM food and feed ('EURL GMFF'). In addition, the EURL GMFF, assisted by the European Network of GMO Laboratories ('ENGL'), will develop guidance on the minimum performance requirements for analytical methods (see Section 2.2).

The Commission will gather input from EFSA, the JRC, Member States, stakeholders, and the public. The NGT Regulation requires the Commission to consult EFSA before adopting the implementing act (Article 27). The Commission will request EFSA to provide scientific and technical assistance, including on data requirements for the notification/application, risk assessment, and exemption from post-market environmental monitoring. Input from the JRC will be requested regarding analytical methods, as outlined above.

The Commission will publish a 'call for evidence' (if feasible already in Q3 2026), describing the initiative and inviting stakeholders and the public to provide evidence and opinions relevant to the preparation of the act. The Commission will take the responses into account when developing the implementing act. At a later stage, the Commission will invite stakeholders and the public to provide feedback on the draft implementing act during a four-week public feedback period. These consultation activities will be carried out through the Have Your Say portal. The drafting process will also take into account discussions focusing on implementation aspects at the NGT conference (see Section 2.8).

Member States' experts will be involved in the preparation through the relevant regulatory committees (Regulatory Committee for Directive 2001/18/EC and Standing Committee on Plants, Animals, Food and Feed, Section Genetically Modified Food and Feed and Environmental Risk, ScoPAFF Committee). The Commission will submit the draft implementing act to the ScoPAFF Committee, for delivery of an opinion, following the examination procedure.

The draft will also be notified under the WTO SPS and TBT agreements for possible comments from non-EU countries.

Milestones*	- Q3 2026, mandate to EFSA to provide scientific and technical support - Q3/Q4 2026, launch call for evidence - Q3 2027, launch 4-week feedback on draft act - Q1 2028, vote in Committee, adoption - Entry into force at date of application of the NGT Regulation
Actors	Commission; Member States (ScoPAFF); EFSA; EURL (for analytical methods); interested parties

* Indicative, non-exhaustive and may be subject to change.

2.2 Guidance

The NGT Regulation requires EFSA and the EURL GMFF to issue guidance by the date of application (17 July 2028). The aim of the guidance is to assist requesters, notifiers and applicants in providing the scientific, technical and administrative detail needed for category 1 verification requests and category 2 applications/notifications and to ensure clarity and predictability for operators in light of the time and financial investment involved in NGT plant breeding. It will complement the delegated and implementing acts by addressing further technical aspects that do not need to be specified in those acts. The work on guidance should proceed in parallel with the preparation of the acts to ensure it is ready when the NGT Regulation starts to apply but will be finalised only after the delegated and implementing acts are adopted to ensure coherence.

The measures foreseen are as follows:

- **Development by EFSA of guidance on category 1 and category 2 NGT plants and products (Article 29(1))**

EFSA's guidance will cover:

— the preparation and presentation of category 1 NGT plant verification requests,

— the preparation and presentation of category 2 NGT plant/product notifications and applications, and

— the adapted environmental risk assessment and food and feed safety assessment for category 2 NGT plants/products.

To support the regulatory procedures concerning both category 1 and category 2 NGT plants, the guidance will assist operators by providing the scientific and technical details on how to demonstrate that a plant is an NGT plant. This may include, for example, molecular methods and data requirements to demonstrate the absence of genetic material originating from outside the gene pool for conventional breeding purposes used during breeding.

For category 1 NGT plants, guidance will, among other things and in alignment with the delegated act, assist operators by providing details on the information required from verification requesters to demonstrate compliance with the conditions for category 1 NGT plants. This will include, in particular, the scientific and technical details to demonstrate compliance with the criteria of equivalence, such as the genetic information, methodologies and quality standards.

For category 2 NGT plants, guidance will, among other things and in alignment with the implementing act, assist operators by providing further information on the specific rules introduced by the NGT Regulation. This will include in particular further detailing of the adapted risk assessment for category 2 NGT plants, and the conditions under which post-market environmental monitoring is not required and the information to be provided to demonstrate that these conditions are fulfilled. The NGT Regulation provides greater flexibility for category 2 NGT plants compared to existing GMO legislation, and guidance will help ensure that this flexibility is applied in a consistent and scientifically sound manner.

EFSA will be able to draw on its existing opinions, guidance and statements dealing with risks of GMOs and NGT plants, such as the existing risk assessment guidance for GMOs ([4]), its statement on criteria for risk assessment of NGT plants ([5]) and its safety related considerations in other recent scientific opinions on NGT plants ([6]). EFSA will also

([4]) https://www.efsa.europa.eu/en/topics/genetically-modified-organisms

([5]) EFSA Panel on Genetically Modified Organisms, Statement on criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis, EFSA Journal 2022;20(10):7618, https://doi.org/10.2903/j.efsa.2022.7618

([6]) EFSA Panel on Genetically Modified Organisms, Updated scientific opinion on plants developed through cisgenesis and intragenesis, EFSA Journal 2022;20(10):7621, https://doi.org/10.2903/j.efsa.2022.7621; EFSA Panel on Genetically Modified Organisms, Applicability of the EFSA Opinion on site-directed nucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis, EFSA Journal 2020;18(11):6299, https://doi.org/10.2903/j.efsa.2020.6299

take into account the latest scientific data on NGT plants identified through their regular literature horizon scan ([7]).

Member States and stakeholders will be able to contribute to the preparation of the guidance through EFSA's consultation activities. A public consultation is foreseen for the draft NGT guidance. Member States, in particular their national risk assessment agencies, will also be involved through EFSA's Scientific Network for Risk Assessment of GMOs (the GMO Network).

- **Development by the EURL of guidance on analytical methods for category 2 NGT plants/products (Article 29(2))**

The NGT Regulation requires the EURL GMFF, assisted by the ENGL, to publish guidance on the methods for sampling, detection, identification and quantification of category 2 NGT plants. It should focus on the adapted arrangements to comply with analytical method performance requirements in the cases where it is not feasible to provide an analytical method for identification and quantification, and it will also consider a possible adaptation of method validation arrangements, in alignment with the implementing act. The EURL GMFF will consider technical analytical method limitations described in the 2023 ENGL report on detection of plant products obtained by targeted mutagenesis and cisgenesis ([8]). The work will also build on the ENGL's guidance document "Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing" ([9]), to which a second part was added in 2023 that includes recommendations for NGT food and feed products ([10]). In accordance with the NGT Regulation, the new EURL guidance will also apply to category 2 NGT products that are not for food or feed use.

- **Information on support for NGT research and development (Article 29(4))**

The NGT Regulation requires the Commission to provide information for operators about opportunities related to NGT research and development, including the various programmes, financial mechanisms, and policies. This will build on existing information about opportunities to advance research and development in the biotechnology sector that is available on the Your Europe website, in particular its Biotech and Biomanufacturing Hub ([11]), supplementing it where necessary.

Actors	EFSA; EURL, assisted by the ENGL; Commission.

([7]) https://open.efsa.europa.eu/questions/EFSA-Q-2024-00643; https://doi.org/10.2903/j.efsa.2025.9619; https://doi.org/10.2903/j.efsa.2026.9929

([8]) European Network of GMO Laboratories, Detection of food and feed plant products obtained by targeted mutagenesis and cisgenesis, Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/007925, JRC133689.

([9]) European Network of GMO Laboratories, Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing, Publications Office of the European Union, Luxembourg, 2015, JRC95544.

([10]) European Network of GMO Laboratories, Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing – part 2, Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/63656, JRC125975.

([11]) https://europa.eu/youreurope/business/running-business/developing-business/biotech/index_en.htm

2.3 Member States' regulatory and administrative preparations

The NGT Regulation is directly applicable, but its implementation will require considerable regulatory and administrative preparation at national level. In many Member States, several authorities, agencies and administrative levels are involved. Early coordination among all concerned and timely preparation are therefore essential. Ensuring a shared understanding of the NGT Regulation, as well as of the respective roles and responsibilities of different actors at national level, will be key in making the system operational. Member States are encouraged to develop national implementation plans and share them, or details of their implementation work, with the Commission and other Member States. To support these preparations, the Commission will facilitate regular exchange with the Member States on harmonised implementation and best practices to support consistent application, in the context of the relevant regulatory committees –the ScoPAFF Committee and the Regulatory Committee for Directive 2001/18 – or in dedicated working groups.

The measures foreseen are as follows - however, they may vary between Member States, and additional measures may be required depending on the national context:

- **Establishment of a verification procedure for category 1 NGT plant status conducted at national level (Article 6); preparations to support the verification procedure conducted at EU level (Article 7)**

The NGT Regulation lays down that the procedure to verify category 1 NGT plant status is carried out by the competent authorities of the Member States if the request is submitted prior to a deliberate release for any purpose other than placing on the market, such as field trials (Article 6). A decision is taken at Union level only in case of reasoned objections to a Member State verification report. Where the verification request is submitted prior to the placing on the market of category 1 NGT products, the procedure is conducted at Union level (Article 7).

The proper operation of the verification procedure within the prescribed deadlines is a precondition for the functioning of the NGT Regulation and will be particularly relevant for operators that intend to release category 1 NGT plants for field trials. Member States must also prepare to contribute to verification procedures carried out by other Member States or at Union level, where the ScoPAFF Committee will be consulted. Member States will need to ensure the availability of sufficient scientific expertise, especially to assess the fulfilment of the conditions for category 1 NGT plants, as well as adequate administrative capacity to meet the applicable deadlines. Member States should strive for a consistent application of the verification procedures, to ensure legal certainty and predictability for operators. To this end, they should rely on the delegated act and EFSA guidance (see above Sections 2.1, 2.2), which will not only set out the required information, content of the verification reports and decisions, but also provide a common understanding e.g. on how to implement the criteria of equivalence. Work by Member States will be supported by regular exchanges on implementation in the relevant regulatory committees and working groups.

- **Adaptation of national GMO legislation, procedures and capacity, where necessary**

The NGT Regulation is directly applicable and does not require transposition. Still, Member States will need to consider whether they need to amend their national GMO legislation in particular to take account of category 1 NGT plants, in view of the fact that the EU GMO legislation is not applicable to those plants and their products (Article 5(1)).

Member States will also need to consider any necessary adaptations of their national GMO legislation to take into account the specific adaptations to the EU GMO legislation for category 2 NGT plants as a result of the special rules introduced by the NGT Regulation, in particular in relation to Directive 2001/18/EC (see Chapter III Sections 1 and 2 of the NGT Regulation). Ensuring clarity on the interaction between directly applicable provisions of the NGT Regulation and existing national transposition measures in relation to Directive 2001/18/EC will be important.

Adjustments may also be required e.g. to forms, guidance documents, internal coordination mechanisms and other administrative procedures, potentially across several levels of government. For example, procedures may need to be adapted to contribute to enhanced pre-submission advice in line with the practical arrangements that will be developed by EFSA (Article 23), or to enable shorter timelines if requested by EFSA to carry out risk assessments for GM food and feed, especially for products benefitting from the incentive of an accelerated procedure (Article 23).

National reference laboratories will need to build or adjust expertise to be able to provide expert assistance on adapted arrangements for complying with analytical method performance requirements for category 2 NGT plants for uses other than food or feed (Article 16), which may require e.g. training or adaptation of mandates. The EURL GMFF and the ENGL will allow for the necessary exchanges to support harmonised approaches in the context of their regular meetings, e.g. in the EURL annual workshop and the ENGL steering committee meetings.

Regarding plant and forest reproductive material, Member States will need to ensure that applicants seeking acceptance of a plant variety, or approval of basic material for the production of forest reproductive material, provide the relevant information on plant varieties or basic material that contain or consist of category 1 or category 2 NGT plants (see Section 2.6).

- **Preparation for controls (Article 34)**

Operators, within and outside the EU, bear primary responsibility for ensuring that products placed on the EU market (whether produced in the EU or imported) are compliant with EU legislation. Member States are responsible to carry out controls and enforcement actions, as relevant in accordance with Regulation (EU) 2017/625 on official controls ([12]). Member States must therefore prepare to ensure effective inspections and other control measures.

([12]) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

Member States will be responsible for ensuring that before category 1 NGT plants and their products are released or placed on the market, a decision confirming category 1 NGT plant status has been taken.

In practice, compliance with the new Regulation will be verified through inspections, documentary checks and -as regards category 2 NGT plants- laboratory testing. The Commission will organise exchanges with the Member States on best practices for enforcement in the relevant regulatory committees.

- **Possible additional national measures**

Should Member States consider it necessary to adopt additional measures concerning NGT plants on aspects not harmonised by the NGT Regulation, such measures should not affect aspects harmonised by Union law and should remain consistent with Union law and the objectives of the NGT Regulation. Member States should pay particular attention regarding any measures specifically targeting category 1 NGT plants, given that they are equivalent to conventional plants. Member States should notify any draft technical regulations concerning NGT plants and their products via the Technical Regulations Information System (TRIS) in accordance with Directive (EU) 2015/1535 ([13]).

Milestones – whole area	Continuously, Member States to exchange and inform on regulatory and administrative preparations, share national implementation plans if prepared, and identify challenges and best practices
Actors	Member States; support by the Commission, EFSA and EURL/ENGL.

2.4 EU administrative preparations

Beyond the adoption of delegated and implementing acts and guidance for NGT plants, the Commission, EFSA and the EURL will prepare for additional tasks by establishing new or adapting existing external and internal procedures. The Commission will ensure coordination of these administrative preparations.

The measures foreseen are as follows:

- **Establishment of a verification procedure for category 1 NGT plant status conducted at EU level (Article 7, Article 6(14))**

The Commission and EFSA must establish, in close cooperation, the EU-centralised verification procedure for requests submitted prior to the placing on the market of category 1 NGT products. They must also establish the Union procedure to resolve cases of reasoned objections during the verification procedure conducted at Member State level, prior to the deliberate release for any other purpose other than placing on the market. EFSA will, among other things, set up the internal procedures for admissibility

([13]) Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification) (OJ L 241, 17.9.2015, p. 1).

check, delivering statements on the fulfilment of the category 1 conditions, assessment of confidentiality requests and publication of information, as necessary.

- **Development by EFSA of practical arrangements on enhanced pre-submission advice for category 2 NGT plants/products (Article 23(7)); adaptation of existing practical arrangements, where necessary**

The NGT Regulation requires EFSA to adopt practical arrangements to implement the enhanced pre-submission advice for category 2 NGT plants/products benefitting from incentives. This will complement EFSA's practical arrangements for the general pre-submission advice ([14]), which is set out in Regulation (EC) No 178/2002 and will continue to apply to all NGT plants/products.

Existing practical arrangements by EFSA might have to be adapted, too, to cover general pre-submission advice, notification of studies and confidentiality regarding verification procedures for category 1 NGT plants. If after the date of application of the NGT Regulation recurrent interpretation questions occur on these matters, the Commission might also consider amending its relevant Commission notice ([15]) to include category 1 NGT plants.

- **Adaptation of procedures and capacity**

The Commission and EFSA will review their respective internal procedures in view of the new rules for NGT plants. For example, EFSA will have to prepare for the stricter deadlines for the risk assessment to be conducted for category 2 NGT plants, the accelerated procedure for risk assessment for category 2 NGT plants benefiting from incentives and to provide enhanced pre-submission advice to potential applicants for the authorisation of those plants.

For category 2 NGT food and feed, the EURL GMFF, supported by the ENGL, will be responsible for verifying if the analytical method provided by the applicant meets the minimum performance requirements. They will need to prepare for the additional task to assess any claimed unfeasibility to provide an analytical method for identification and/or quantification of category 2 NGT food and feed, in line with the implementing act and the EURL's guidance (see Section 2.2). They might also have to adapt the arrangements for performing method validation (see Section 2.2).

Actors	Commission; EFSA; EURL/ENGL.

([14]) Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission advice and public consultations, https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf

([15]) Commission Notice on the submission of notifications under Articles 13 and 17 of Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC and under the relevant provisions of Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381. C/2021/1445 (OJ C 80, 9.3.2021, p. 1).

2.5 Patents

In addition to provisions on the submission of patent information and licence declarations as part of the verification procedure for category 1 NGT plants to be included in the delegated act (see Section 2.1), the NGT Regulation includes several other provisions on measures relating to patents on NGT plants, which aim to increase transparency, facilitate access to patented biological material of NGT plants, improve legal certainty and establish a framework for monitoring and reporting ([16]). These provisions apply as from the date of entry into force of the NGT Regulation. The Commission will start the work on implementing them shortly after that date.

The measures foreseen are as follows:

- **Development by the Commission of guidance to assist operators on matters relating to plant intellectual property (Article 29(3))**

The aim of this guidance is to raise operators' awareness on the intellectual property framework relevant to plants, public organisations offering support to plant breeders on questions relating to the said framework as well as on the existing initiatives supporting transparency in relation to patented NGT plant material and access to it. The guidance is expected to provide support for SMEs in particular.

The guidance is to be published by the date of application of the NGT Regulation. The Commission will start preparing it shortly after entry into force of the NGT Regulation, in Q3/Q4 2026. As part of the process for drafting the guidance, the Commission will consult intellectual property offices of the Member States and other relevant Member State competent authorities through the NGT plant patent expert group (referred to in Article 31 – see also below in this Section), thus also enabling inputs from other relevant actors, such as the European Patent Office and the Community Plant Variety Office. The final guidance will be published on the Commission's website. After publication, the Commission will regularly check if the guidance requires updating.

Milestones*	- Q3/Q4 2026, Commission starts preparing the guidance - Q4 2027, consultation of Member States on the draft guidance - Q1 2028, publication of the guidance

* Indicative, non-exhaustive and may be subject to change.

- **Development by stakeholders of a voluntary Code of Conduct on patents; oversight, monitoring and evaluation by the Commission, in cooperation with Member States (Article 30)**

The aim of this measure is to further enhance the transparency of information relating to patents on NGT plant biological material, to facilitate breeders' access to such material under fair and reasonable conditions and to provide for increased legal certainty for breeders and farmers in relation to patent enforcement.

([16]) See also Commission's statement in the Appendix to the Communication from the Commission to the European Parliament of 23 April 2026, COM(2026) 151 final, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52026PC0151

While the development of the Code of Conduct is a voluntary and stakeholder-driven process, the Commission will closely oversee its drawing-up as well as its implementation. The Commission will aim to ensure that the process for preparing the Code is transparent and that commitments included therein are fully compliant with the existing legal framework. In addition, the Commission will aim to safeguard, where necessary, that the specific commitments developed in the context of the Code reflect a fair balance among the different interests at stake, paying particular attention to SMEs, and that the Code includes an adequate reporting framework, in order to gather the relevant data for the required evaluation by the Commission of its implementation, as required by the NGT Regulation. To achieve these objectives, the Commission will provide as necessary recommendations in the drafting process of the Code. The Commission will also provide administrative and logistical support for the participating stakeholders.

The Code is to be finalised within 18 months from the date of entry into force of the NGT Regulation. The Commission will thus initiate the work relating to the development of the Code as soon as possible after the entry into force of the NGT Regulation, in particular by inviting a wide range of stakeholders, as required by the Regulation, to participate in its drawing up and by arranging an inaugural stakeholders' meeting to discuss the process, timeline and expectations in terms of the content of the Code.

Considering the tight timeframe within which the Code is to be finalised and the different interests at stake, the Commission will support the participating stakeholders by ensuring appropriate planning for the drawing up process and regular progress meetings. It will also act as a facilitator, by encouraging the participants to overcome the obstacles that may arise, including through recommendations.

As required by the NGT Regulation, the Commission will cooperate with the Member States in its oversight of the drawing up of the Code, including through exchanges in the expert group on the effects of patents on NGT plants to be established in accordance with Article 31 of the NGT Regulation (see also below in this Section).

Once the Code of Conduct is finalised and signed by the participating stakeholders, the Commission will publish it on its website. It will encourage wide participation in the Code among operators. This could include raising awareness about the Code in the context of the verification procedure for category 1 NGT plants and to encourage requesters to sign it.

The Commission will monitor the rate of participation in, and the functioning of the Code, and will evaluate its application every 5 years. To this end, in the context of the regular reporting by participating stakeholders on the implementation of the Code, the Commission will engage in regular exchanges with them to identify issues concerning its operation, if any, and facilitate consensus among stakeholders for overcoming them.

Milestones*	- Q3/Q4 2026, invitation to stakeholders to participate in the drawing up of the Code of Conduct - Q3/Q4 2026, inaugural stakeholder meeting - Q4 2027, finalisation and signature of the Code of Conduct

* Indicative, non-exhaustive and may be subject to change.

- **Establishment and operation of an expert group on the effect of the patenting of NGT plants, assessment of the impact of NGT plant patenting (Article 31)**

The purpose of the expert group is to provide Member State support to the Commission in the monitoring and assessment of the impacts of the patenting of NGT plants, to facilitate exchanges of information and informed discussions on this matter.

The Commission will convene the NGT plant patent expert group in Q3/Q4 2026. As required by the NGT Regulation, in addition to Member States' experts, the Commission will invite the European Patent Office ('EPO') and the Community Plant Variety Office ('CPVO') to appoint an expert to the group.

The Commission will convene meetings of the expert group on a regular basis to exchange views and assist the Commission, inter alia, in the development of the guidance on intellectual property matters, on the drawing up, monitoring and evaluation of the Code of Conduct, as well as, more generally, on the impacts of the patenting of NGT plants on access to patented NGT plant biological material, transparency of the patent landscape and innovation in the field of NGT plants.

The work of the expert group will support the Commission's assessment of the impact of the patenting of NGT plants, which the Commission is to complete 1 year after the first NGT products have become available on the market and, if no follow-up measures are required following that assessment, 4 to 6 years thereafter.

Milestones*	Q3/Q4 2026, NGT plant patent expert group convened for the first time, followed by regular meetings thereafter.
Actors – whole area	Commission; Member States (experts in areas of intellectual property rights and plant breeding, such as from patent offices and plant variety offices), EPO, CPVO; stakeholders.

* Indicative, non-exhaustive and may be subject to change.

2.6 IT systems

The NGT Regulation requires the set-up and adaptation of several IT systems to ensure effective information exchange in verification procedures and enhance transparency on NGT plants. Member States may have to adapt any additional relevant national IT systems.

The measures foreseen are as follows:

- **Adaptation of the E-Submission Food Chain platform (Article 8)**

For the submission of GMO notifications and applications and the exchange of information, the Commission, EFSA, national competent authorities and applicants or notifiers use the E-Submission Food Chain Platform ('ESFC') ([17]). The Commission will

([17]) Link to the ESFC: https://webgate.ec.europa.eu/esfc; link to ESFC Training and Support for additional guidance and user manual: https://food.ec.europa.eu/horizontal-topics/general-food-law/training-and-support_en

expand it to cover also verification requests and other types of exchange of information for category 1 NGT plants, both for verification procedures conducted at national level and at EU level. The Commission will also adapt it as relevant for applications for authorisation of category 2 NGT plants and products. The timely adaptation of the ESCF is a precondition for the operation of the verification and application procedures. National competent authorities and EFSA will be invited to provide feedback during the development phase.

- **Establishment of a database of decisions declaring category 1 NGT plant status (Article 9)**

The Commission will set up a new public database as part of the Food and Feed Information Portal ([18]) for decisions declaring category 1 NGT plant status, containing the non-confidential information specified in Article 9 of the NGT Regulation, such as an identification number, the techniques used to obtain the genetic modifications, the plant traits or information on patents and licensing declarations of the patent holders.

- **Adaptation of information systems on varieties and forest reproductive material to include information on NGT plants (Article 10)**

Member States must ensure that their national catalogues of plant varieties and national lists of basic material for the production of forest reproductive material specify when a plant variety or basic material contains or consists of category 1 NGT plants and include the identification numbers of the category 1 NGT plants it has been derived from (Article 10(2), (3)). The indication of the identification number of the category 1 NGT plant or, in case of progeny, the plants it has been derived from, will enable operators to identify the relevant plant(s) in the database of category 1 NGT decisions and to access related information in that database, such as traits introduced with NGTs or information related to patents.

Today, the relevant plant variety catalogues and lists of basic material already identify GMOs. In addition, the new Regulation on forest reproductive material ([19]) requires that national registers of basic material specify that basic material contains or consists of category 2 NGT plants (Article 15 of the Regulation on forest reproductive material).

The EU plant variety catalogues, databases and information systems, in particular the EU plant variety portal ([20]) and Forest Reproductive Material Information System ([21]) will be adapted, too, to include information on plant varieties and basic material that contain or consist of category 1 NGT plants, in line with Article 10 of the NGT Regulation, and on basic material that contains or consists of category 2 NGT plants, in line with the new Regulation on forest reproductive material.

([18]) https://ec.europa.eu/food/food-feed-portal/screen/home

([19]) Regulation (EU) 2026/1392 of the European Parliament and of the Council of 20 May 2026 on the production and marketing of forest reproductive material, amending Regulations (EU) 2016/2031 and (EU) 2017/625 of the European Parliament and of the Council and repealing Council Directive 1999/105/EC (FRM Regulation), (OJ L, 2026/1392, 26.6.2026).

([20]) https://ec.europa.eu/food/plant-variety-portal/

([21]) https://ec.europa.eu/forematis/

Adaptations at EU and Member State level should be completed by the time the first NGT varieties or forest reproductive material reach the EU market.

Milestones* – whole area	- By end 2026, identification of IT needs and interfaces - Adapted ESFC operational by date of application of the NGT Regulation - Category 1 NGT database established by date of application of the NGT Regulation - Before the first NGT varieties and basic material for the production of forest reproductive material reach the market, adaptation of EU and Member State information systems for plant varieties and forest reproductive material
Actors	Commission; EFSA; Member States.

* Indicative, non-exhaustive and may be subject to change.

2.7 Monitoring programme

The NGT Regulation requires the Commission to collect information to assess the performance of the Regulation and its impacts and in order to inform implementation reports and an evaluation of the legislation. This work will allow assessing the extent to which the NGT regulation delivers on its objectives to enable innovation and make NGT plants and their products available on the EU market, ensuring safety and supporting farmers' and consumers' needs, sustainability objectives and the competitive position of EU breeders and farmers. The measure foreseen is as follows:

- **Establishment of an indicator-based monitoring programme to gather data on environmental, economic and social impacts, including sustainability-related indicators (Articles 32 and 33); specification of the respective tasks of the Commission and the Member States in collecting and analysing data and other evidence**

The indicators should support monitoring of impacts on human and animal health and the environment, consumer information, the functioning of the internal market, SMEs, the breeding sector, the organic sector, and environmental, economic and social sustainability. A broad set of indicators has already been identified in the impact assessment accompanying the proposal for the NGT Regulation ([22]), on which the programme will be based as a minimum, and which may be adapted and supplemented if necessary. Additional indicators will be added where relevant. The NGT Regulation requires to regularly review the indicators after their establishment.

As part of the programme for monitoring, the Commission is required to monitor the sustainability impacts of NGT plants with regard to positive and negative environmental, economic and social impact of the traits introduced with NGTs and the application and effects of the exclusion from category 1 status of NGT plants including tolerance to

([22]) Impact assessment report accompanying the Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625, SWD(2023) 412, Section 9.

herbicides or production of a known insecticidal substance among the intended traits conveyed by the genetic modifications.

The Commission will rely on the expertise of its JRC and the Member States to prepare the monitoring programme. First, the JRC will develop a draft, which will entail, in particular, potential indicators, identifying data needs and the options for meeting those needs, specifying data sources, developing quantitative and qualitative data collection, data analysis methods and data collection frequencies. The JRC will consider all actors in the agri-food chain (notably breeders, input providers, farmers, processors, retailers, and consumers). It will take into account stakeholders' views on areas for monitoring discussed at the NGT conference (see Section 2.8) and it will conduct regular, inclusive and transparent stakeholder consultations. The draft monitoring programme will be updated iteratively in light of feedback received from consultations with national competent authorities and stakeholders.

The final monitoring programme will contain a list of indicators and of actions to be taken to enable the Commission to fulfil the reporting obligations of the NGT Regulation. For each action, it will identify the responsible institution/actor (Commission, Member States or EFSA) to collect and analyse data and the most suitable data gathering process (data sources, data collection and data analysis methods as well as data collection frequencies).

The NGT Regulation introduces a number of novel concepts and procedures, for which there is no implementation experience to draw on. This challenge requires a careful, iterative approach in developing the indicators as explained above, where Member States and stakeholder feedback will be essential, as well as regular review of the indicators after their establishment. Both the Commission, when developing the indicators, and the Member States, when collecting the data, will be responsible for ensuring the completeness, reliability and comparability of the data collected.

The monitoring programme will not take the form of an implementing act or any other legally binding instrument, as the NGT Regulation does not provide for this. It may take the form of, for example, a Commission Recommendation or a Staff Working Document. Its effectiveness will therefore depend on the active cooperation and commitment of the responsible institutions/actors.

Milestones*	- Q3 2027, draft monitoring programme - By Q1 2028, Member State and stakeholder consultations finalised - By date of application of the NGT Regulation, formal establishment of monitoring programme
Actors	Commission; Member States (regulatory committees); EFSA; stakeholders.

* Indicative, non-exhaustive and may be subject to change

2.8 Communication and outreach

NGT plants offer new possibilities for innovation across multiple sectors of the agrifood economy. They can contribute to a more resilient and sustainable agrifood system and to the competitiveness of researchers, breeders, and farmers in the EU. With the adoption of the NGT Regulation, it is therefore important to ensure that stakeholders

(potential requesters for verification of category 1 NGT plants, notifiers and applicants for category 2 NGT plants and products) clearly understand what the new rules entail and how they will be applied in practice. A good understanding by stakeholders will promote compliance and support the smooth operation of procedures. Outreach to stakeholders will also be a tool to identify and address practical implementation issues at an early stage.

In addition, given that public awareness of NGT plants and their products currently remains limited, targeted efforts to raise awareness about the characteristics of NGT plants, their safety profiles and their applications should be pursued at EU and national levels.

The measures foreseen are as follows:

- **Conference to present the NGT Regulation and to collect input for implementation**

In the last quarter of 2026, the Commission (DG SANTE) will organise a one-day conference in Brussels on the NGT Regulation. This conference will be targeted primarily at authorities and stakeholders who will implement or apply the new rules and will also be open to the public via web streaming. It will include dedicated breakout sessions to identify practical implementation questions and challenges, which will feed into the preparation of the delegated and implementing acts, guidance, and other implementation measures as described in the sections above.

- **Awareness raising at EU and national level**

The Commission will engage in outreach to the general public on the NGT Regulation and NGT plants, for example through communication material, its website and engagement in social media. Member States are encouraged to take awareness-raising efforts at national level too. Communication should remain factual, balanced, and accessible, contributing to informed public debate and consumer understanding about NGT plants and products. Both the Commission and Member States should revise and update their websites to reflect the new regulatory framework and to provide clear and accessible information.

- **Outreach in international fora, including the WTO and the Biosafety Clearing House**

Communication at international level will promote compliance of imported products. The Commission will, as required by international law, provide information on the NGT Regulation, and on delegated and implementing acts through notifications under the WTO SPS and TBT agreements and the Biosafety Clearing House of the Cartagena Protocol. In addition, the Commission plans to organise information sessions for third countries on the NGT Regulation. It will also engage in discussions with third countries, including EFTA States, on any trade-related questions that may arise.

Milestones* – whole area	- Q4 2026, Conference - Innovation and resilience in the agrifood chain: Regulation on plants obtained by new genomic techniques - Q3 2026, information Biosafety Clearing House, SPS and TBT addendum notifications launched for NGT Regulation - Q4 2026, information session to third countries; information session in WTO Sanitary and Phytosanitary Measures Committee - Q2/Q3 2027, SPS and TBT notifications launched for draft delegated and draft implementing act
Actors	Commission; Member States.

* Indicative, non-exhaustive and may be subject to change.

Conclusion 3

The NGT Regulation establishes a new framework that will enable innovative plant breeding in the EU. By facilitating the development of plants that are, for example, more resilient to climate change and require fewer inputs such as water, fertilisers and pesticides, it can support competitiveness of both breeders and farmers while contributing to broader sustainability goals. At the same time, it will reduce administrative burden, while ensuring high safety standards for NGT plants and products. Turning these objectives into tangible benefits will depend on effective and timely implementation.

Implementation of the NGT Regulation entails a degree of novelty and complexity. NGT plants and their two categories are a new concept in the GMO legislation. For category 1 NGT plants entirely new procedures are introduced and for category 2 NGT plants the GMO procedures are modified. Several implementation measures are foreseen to ensure the harmonised and smooth implementation of these new concepts and procedures (delegated and implementing acts, guidance), which will also depend on appropriate administrative preparations at EU and national level.

Given that several aspects of the NGT Regulation operate partly at national level and partly at Union level, ensuring coherent implementation is particularly important, demanding close coordination among the Commission, EFSA, EURL GMFF, Member States and other actors involved. It is also important to ensure the smooth interplay between the different levels of legislation and guidance, i.e. the NGT Regulation, the delegated and implementing acts, the guidance documents, and applicable legislation and guidance in related areas, such as the General Food Law. Implementation challenges may also include analytical enforcement limitations, potential data limitations for monitoring in early years, interactions with plant reproductive material legislation, and societal and political sensitivities.

These issues will be addressed through coordinated efforts by all actors involved, timely adoption of delegated and implementing acts and guidance, continuous monitoring of progress and communication engagement at Union and national level.

The implementation of the patent-related provisions in the NGT Regulation will require early and continuous Commission actions, namely overseeing the drawing-up of a Code

of Conduct, monitoring and assessing its functioning, preparing the patent guidance as well as convening and managing an NGT plant patent expert group. These actions will require regular engagement with stakeholders, and cooperation with the Member States through the NGT plant patent expert group. Lastly, the NGT Regulation provides for several obligations on the part of the Commission to monitor and evaluate the measures relating to NGT plant patents and to assess the impact of NGT plant patenting. Should the evaluation of the Code of Conduct reveal that it is not properly functioning, or the assessment of the impacts of NGT plant patents show negative impacts occurring, the Commission will take appropriate action to address the issues identified, including the submission of legislative proposals, where appropriate.

Image credits: Icons made by Freepik, Eucalyp, GeekClick, Iconjam, and Vectors Market from www.flaticon.com