GeneBEcon

Regulatory Options for New Genomic Techniques in the European Union

Technical Report

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ABBREVIATIONS

Abbreviation	Definition
CJEU	Court of Justice of the European Union
DNSH	Do not significant harm
EC	European Commission
ECHA	European Chemicals Agency
EU	European Union
EFSA	European Food Safety Authority
ERA	Environmental Risk Assessment
FAO	Food and Agriculture Organization
GMO	Genetically Modified Organism
IPR	Intellectual Property Rights
JRC	Joint Research Centre
MAAs	Mycosporine-like Amino Acids
NGT	New Genomic Techniques
PMEM	Post Market Environmental Monitoring
PMM	Post-Market food/feed Monitoring
REA	Research Executive Agency
ODM	Oligonucleotide-Directed Mutagenesis
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SDN	Site-Directed Nucleases

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1. About the GeneBEcon Project

GeneBEcon - capturing the potential of Gene editing for a sustainable BioEconomy
GeneBEcon is an ambitious Horizon Europe-funded project, which examines the innovation potential of gene editing to enable a sustainable bioeconomy in Europe. Through the application of this technology in potato and microalgae, GeneBEcon intends to promote energy-efficient, low-input, and zero-pollution agricultural production and clean industrial processing.

New Genomic Techniques (NGTs) represent a powerful toolbox which is complementary to traditional breeding techniques and contributes to alleviating current pressing challenges such as pollution and climate change. However, these techniques do not yet reach their full potential in Europe. GeneBEcon will advance research and innovation, acting on two fronts: through new gene editing developments at the technological level, as well as considering social, economic, and regulatory dimensions.

Among NGTs, gene editing holds the greatest potential for contributing to the ambitious objectives of the European Green Deal, the 2030 Climate Target Plan, and the Circular Economy Action Plan. Nonetheless, risks and benefits must be assessed to ensure that gene editing innovations, just like any other type of innovation, are developed in a responsible, inclusive, and transparent way. GeneBEcon aims to address these concerns and propel Europe towards a cleaner, more sustainable and zero-pollution agricultural and industrial production.

GeneBEcon will construct a toolbox for gene editing using potato and microalgae as case studies and it will assess regulatory options in terms of data requirements for risk assessment, analyse the economic impact and consider societal perceptions. The gene-edited potato will be virus-resistant to enable reduced use of pesticides in potato cultivation, and it will produce a higher quality starch allowing a more environmentally friendly potato starch processing saving up to 75,000 tonnes of chemicals and 7.5 GWh of energy in the EU every year. Likewise, gene-edited microalgae will allow resource-efficient and clean production of industrially relevant compounds and the repurposing of microalgae residual biomass as animal feed.

GeneBEcon has a budget of 5.5 million Euros and a duration of three years as of 1 September, 2022. GeneBEcon is executed by a multidisciplinary consortium with leading scientists from 11 European countries and in interdisciplinary collaboration with stakeholders.

Partners:

Swedish University of Agricultural Sciences, Sweden – Project Coordinator
XPRO Consulting Limited, Cyprus
SolEdits AB, Sweden
Latvijas Universitate, Latvia
FN3PT/inov3PT, France
INRAE, France
Euroseeds, Belgium
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2. Introduction

New Genomic Techniques (NGTs) represent a toolbox of modern plant breeding techniques that can facilitate the development of energy-saving, low-input and reduced-pollution agricultural production and industrial processing of raw materials, contributing to sustainability and a circular bioeconomy (FAO, 2022). In addition, policymakers in the EU have recognised that the technological progress with NGTs has triggered a discussion about regulatory innovation to ensure that the regulations are proportionate and non-discriminatory, fit for purpose, and ensure safe and sustainable use of new products (EC, 2021).

In Europe, regulatory uncertainty reduces investment in NGTs at several levels, including research, innovation, product development and scaling-up of production processes (Purnhagen & Wesseler, 2019). Despite the judgement by the Court of Justice of the European Union (CJEU) on the "mutagenesis" exemption (C-528/16, 2018, hereinafter "mutagenesis judgment"), plant breeding companies emphasise the uncertainty of future regulatory oversight, including timelines for product approvals (Jorasch, 2020). In the mutagenesis judgment, the Court had ruled that GMOs obtained by using mutagenesis techniques developed after 2001 would not be exempted from the application of Directive 2001/18/EC[1] (hereinafter Directive). As a result, most NGT products are considered regulated GMOs in the EU (Purnhagen, 2019; Purnhagen et al., 2018). The development and uptake of new technologies in society is a multifaceted process that includes different regulatory, economic, social, and technological drivers which interact in various ways. Over the past three decades, molecular and genetic technologies have given rise to social controversies and regulatory impediments in many parts of the world, including the EU (Smith et al., 2021).

Amending the current GMO legislation for NGTs (for an overview of the current regulatory status, see Molitorisová et al., 2023) with a focus on targeted mutagenesis and cisgenesis is central to applying NGTs to develop products that benefit society safely and sustainably as aimed by the regulatory framework for food innovation (Monaco & Purnhagen, 2022).

Developments in biotechnology, namely the possibility of targeted changes within the plant genome (without the usage of exogenous genomic markers that would be needed to identify the applied breeding method), as well as a lack of definitions of key legal terms, add to regulatory uncertainty. The study conducted by the European Commission (EC) on NGT (EC, 2021) mentions the need for flexibility and proportionality, together with the need to develop proportionate NGT-specific risk assessment procedures adapted to the risk profiles

[1] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106, 17.4.2001, 1-39.

of plants resulting from NGTs, as the current regulatory system involves implementation and enforcement challenges.

To address this regulatory uncertainty, we, in the GeneBEcon project, define and discuss six different regulatory options for NGT products, including the following aspects: (A) Authorisation; (B) Post-approval / Post-market-requirements; (C) Labelling; (D) Traceability; (E) Implication (EU / International / Liability / Economic Impact), and (F) Future Proof. We also assess the regulatory options for contained use (e.g., use of NGT microorganisms in fermenters or hydroponic facilities (Wesseler et al., 2022)), sole import authorisation from third countries into the EU, including enforcement at EU borders, full authorisation including cultivation inside the EU, along with control of unauthorised NGT organisms. All those aspects also interact with consumer preferences.

In the following chapters, the options are described, and they may be utilised for scientific assessment for their “fit for purpose.” Policymakers may also find them useful as a starting point for discussing the regulatory design of potential laws and regulations on NGTs.

In Genome Editing, nucleases are guided by sequence-specific guide RNA (gRNA) (CRISPR/Cas) or proteins (zinc finger nucleases, TALENs) to induce targeted breaks within the plant genome. The genomic changes within the target side occur during the repair of those breaks, which can be achieved by mistakes from natural repair mechanism (SDN-1), homologues templates (SDN-2) or templates with homologues ends (SDN-3) (see Box 1 for explanations). This paper considers products produced via site-directed nucleases (SDN-1 and SDN-2), oligonucleotide-directed mutagenesis (ODM), and cisgenesis via SDN-3. Our classification follows up on the FAOs classification (FAO, 2022).

Box 1. Site-directed nucleases, oligonucleotide-directed mutagenesis[2]

SDN-1: Techniques using site-directed nucleases with the objective of generating localised random base pair changes, short random deletions or insertions (indels) as a result of an error in the cell gene repair mechanism based in non-homologous end joining pathway (NHEJ). No exogenous DNA repair template is used in these applications.

SDN-2: Techniques using site-directed nucleases with the objective of generating a localised predefined point mutation or deletion/addition by co-introducing a repair DNA template that is homologous to the targeted area. Repairing is achieved by homologous recombination (HR). SDN-2 generates changes spanning a few base pairs in genetic elements (promoters, coding sequences, etc.) that pre-exist in the host genome.

SDN-3: Techniques using site-directed nucleases with the objective of generating a localised insertion of a predefined DNA-Sequence by co-introducing a repair DNA template that has homologous ends to the targeted area. Repairing is achieved by homologous recombination (HR). SDN-3 can be used to introduce genetic material found within the species or in a sexually compatible species (cisgenesis or intragenesis) but also from other species (transgenesis). Transgenic approaches are out of the scope of this exercise because they clearly fall under the scope of the current GMO definition of Directive 2001/18.

Cisgenesis and Intragenesis: They are genetic modifications involving genetic material obtained from outside the host organism and transferred to the host using various delivery strategies; the incorporated sequences contain an exact copy (cisgenesis) or a re-arranged copy (intragenesis) of sequences already present in the species or in a sexually compatible species

Transgenesis: The process of introducing gene(s) from a different, sexually incompatible species into the genome of a given cell and the propagation of such gene(s) thereafter (Taken from EFSA Scientific Opinion of 18.10.22[3])

ODM: A non-transgenic base pair-specific precision gene editing platform that employs a specific oligonucleotide, typically 20-100 bp in length, to produce a single DNA base change in the plant genome

[2] FAO. 2022. Gene editing and agrifood systems. Rome. https://doi.org/10.4060/cc3579en (last accessed 06.02.2023)

[3] EFSA, in its 2022 opinion (https://doi.org/10.2903/j.efsa.2022.7621), based its definitions on the JRC technical report of 2021 (https://op.europa.eu/en/publication-detail/-/publication/5a661f2b-a180-11eb-b85c-01aa75ed71a1/language-en) which differs from the EFSA opinion from 2012 (https://www.efsa.europa.eu/en/efsajournal/pub/2561).

3. Regulatory Options

The six regulatory options to be discussed are illustrated in the subsequent chapters. Some options are inspired by already existing legislation in other parts of the world (for an overview, see Buchholzer & Frommer, 2022; Eriksson et al., 2019). For a quick overview, the six main regulatory criteria (rows) are shown for the six options (columns) on the next page.

The six regulatory criteria can be explained as follows:

A. Authorisation:

Lays down the scope of the legislation and includes the necessary steps which must be taken by applicants in order to fulfil the requirements of the authorisation procedure.

B. Post-Approval Requirements:

Lays down which conditions and requirements are expected to be fulfilled by applicants after product authorisation.

C. Labelling:

Lays down the labelling requirements foreseen by the option.

D. Traceability:

Lays down the traceability requirements foreseen by the option.

E. Implications:

Explains the implication the option has on the EU and International market, as well as the liability and economic impact.

F. Future-Proof:

States whether the option can be considered future-proof in terms of flexibility for new scientific developments.

Table 1: Regulatory Options Matrix

Options / Criteria	1. Status Quo	2. Explore current GMO legislation for further possibilities	3. Regulatory differentiation of NGT plants according to their risk profiles	4. Trait-based Regulation	5. Foreign DNA as a regulatory trigger	6. REACH-like legislation
A. Authorisation	Required for all GMOs	Lower data requirements	No authorisation, but a notification is required for "conventional-like" NGT-plants	EU-wide authorisation only for organisms with novel traits	Not required, if no foreign DNA present	Mandatory registration, authorisation required only for products with high concerns
B. Post–approval requirements	Required	Required	Not required for “conventional-like” NGT-plants	No PMEM and no location registers	No PMEM and no location registers for products without foreign DNA	Standard market surveillance by member states only
C. Labelling	Mandatory labelling as GMO	Mandatory labelling as GMO	For “conventional-like” NGT-plants: information in Common Catalogue of Varieties	None (Category “GMO” would effectively cease to exist entirely)	No labelling for organisms without foreign DNA	Required
D. Traceability	Required	Required	Not required for “conventional-like” NGT-plants	None	None for organisms without foreign DNA	Required
E. Implications	Liability for environmental damages	Liability for environmental damages	No special liability provisions for “conventional-like” NGT-plants	No special liability for any organisms	No special liability for organisms without foreign DNA	Shared responsibilities between authorities and applicants
F. Future-Proof	Not flexible	Not flexible	Flexible	Flexible	Flexible	Flexible

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3.1 Option 1: Status Quo

The Directive defines the term GMO[4], sets broad and general protection goals and defines exemptions. It is regarded as a horizontal “GMO law”, which means that it entails general legal provisions applicable to other GMO legislations. During the pre-market authorisation procedure, GMOs are evaluated case-by-case, focusing on potential risks. Applying the rationales of the CJEU’s judgment, NGT-derived organisms would be considered regulated GMOs. In this option, we presume that future CJEU judgments would not further clarify the regulatory status of NGT organisms.

A. Authorisation

Trans-, cisgenic, intragenic and genome-edited microorganisms and higher plants are GMOs within the Directive's scope.

The authorisation procedure includes a risk assessment. A detection method that uniquely identifies the regulated product must be submitted upon application to the competent authority. If there is no technical possibility to identify the modification, the application is unlikely to meet basic regulatory requirements and is unlikely to be authorised.

GMO authorisation will apply the procedure as it currently stands. This includes decision-making following the rules of the committee procedure and a final Commission decision in case a qualified majority cannot be reached.

B. Post-approval requirements

Post-market environmental monitoring (PMEM [5]), post-market food/feed monitoring (PMM[6], case dependent), and for the scope of cultivation, coexistence measures and (partially public) location registers are required for any GMO. Due to Article 26b of the Directive, introduced by Directive (EU) 2015/412[7], Member States can opt out of cultivating an authorised GMO plant. This option would foresee no changes.

[4] According to Art. 2.1 Directive "genetically modified organism (GMO)" means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination."

[5] Annex VII B, Monitoring Plan, further specified in EFSAs Guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants (https://doi.org/10.2903/j.efsa.2011.2316).

[6] Art. 7 of the Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed, OJ L 157, 8.6.2013, 1-48.

[7] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory, OJ L 68, 13.3.2015, 1-8.

C. Labelling

Requirements as set out in section 2 of Regulation (EC) No 1829/2003[8] will remain.

D. Traceability

Requirements will remain as they are under Article 4, Regulation (EC) No 1830/2003[9].

E. Implication (EU / International / Liability / Economic Impact)

Under this option, damages, such as environmental or economic damages, caused by any occupational use of GMOs lead to liability, according to Directive 2004/35/EC[10]. Furthermore, national provisions on liability will apply. However, as it is challenging to identify the mutation leading to liability, constant uncertainty concerning liability will remain.

F. Future Proof

The wording of this option cannot be considered sufficiently flexible to account for technological change.

[8] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L 268, 18.10.2003, 1-23.
[9] Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, OJ L 268, 18.10.2003, 24-28.
[10] Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage, OJ L 143, 30.4.2004, 56-75.

3.2 Option 2: Explore current GMO legislation for potential adjustment

The Directive, as interpreted by the CJEU, remains unchanged. The existing provisions for delegated acts and regulatory leeways will be used to facilitate the usage of NGTs.

The GMO definition remains unchanged; options of interpretation within the existing legislation will be exploited. Authorities would request less experimental data for the risk assessment than the status quo. Implementing Regulation (EU) No. 503/2013 could be amended within the framework set by Regulation (EC) No. 1829/2003. For plants produced by cisgenesis and intragenesis, the next authorisation step would require less event-specific data for the risk assessment. The opt-out possibility will remain, allowing EU Member States to restrict or prohibit cultivation in their territory. These options will be limited to policy interventions which do not require an ordinary legislative procedure, according to Art. 294 TFEU[11].

From the perspective of the applicant, the alleviation of the authorisation procedure would have limited to no effect, as the product would still be subject to the opt-out possibility of Member States.

The technical Annexes from II onwards of the Directive, laying down which information is necessary for the ERA and the notifications, could be amended.

A. Authorisation

These changes could decrease the time needed for authorisation and facilitate investments in the authorisation of new GMOs, as it would require less data to be collected and analysed and, therefore, the potential to decrease approval time.

The Directive and the Regulation (EC) No. 1829/2003 would be amended to facilitate the authorisation of GMO marketing, cultivation, and use as food and feed; e.g., the application procedure would focus on only the most relevant data. Furthermore, certain GM microorganisms (e.g. microalgae) would be added to Annex II Part C Dir. 2009/41/EC[12] on the contained use of GMMs.

[11] Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union Consolidated version of the Treaty on European Union Consolidated version of the Treaty on the Functioning of the European Union Protocols Annexes to the Treaty on the Functioning of the European Union Declarations annexed to the Final Act of the Intergovernmental Conference which adopted the Treaty of Lisbon, signed on 13 December 2007, OJ C 202, 7.6.2016, 1-388.

[12] Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified microorganisms, OJ L 125, 21.5.2009, 75-97.

Targeted risk assessment should be based on the credible hypothesis to harm. EFSA Risk Assessment Guidance[13] would be revised.

Annex II would be changed to allow relaxed Environmental Risk Assessment (ERA) requirements.

A detection method that uniquely identifies the regulated product must be submitted upon application. However, if there is not yet the technical possibility to detect the modification, the application will not meet basic regulatory requirements.

B. Post-approval requirements

Post-market requirements would change according to changes and amendments in relevant legislation, such as in Regulations (EC) No. 1829/2003 and (EC) No. 1830/2003. PMM, PMEM, and for the scope of cultivation coexistence measures together with (partially public) location registers would still be required. Depending on the classification of the product, coexistence measures apply.

According to article 26b of the Directive (EU) 2015/412, the opt-out option would still be in place, so Member States could choose to opt out of cultivation.

C. Labelling

Labelling requirements would remain untouched.

D. Traceability

Traceability requirements would remain untouched.

E. Implications (EU / International / Liability / Economic Impact)

Under this option, damages, such as environmental or economic damages, caused by any occupational use of genetically modified organisms can lead to liability, according to Directive 2004/35/EC. Furthermore, national provisions on liability regarding the use of GMOs will apply.

F. Future Proof

The wording of this option cannot be considered sufficiently flexible to account for technological change.

[13] EFSAs Guidance for risk assessment of food and feed from genetically modified plants (https://doi.org/10.2903/j.efsa.2011.2150).

3.3 Option 3: Regulatory differentiation of NGT plants according to their risk profiles

This approach envisages the forthcoming regulation of NGTs according to their risk profile. These profiles are determined in an official case-by-case verification process.

This approach excludes those NGT plants from the risk assessment that have a "conventional-like" risk profile. These are plants with DNA modifications commonly occurring in nature or through conventional breeding or NGT plants in which the genetic modification has a lower likelihood to occur by conventional breeding or natural processes but for which no credible hypothesis to harm could be verified.

Applications of NGTs that result in transgenic plants would remain covered by the existing GMO legislation.

NGT plants, having a lower likelihood to occur by conventional breeding or natural processes and for which a credible hypothesis to harm was verified and which are not transgenic, would undergo a targeted assessment according to the verified hypothesis to harm.

A. Authorisation

The official case-by-case verification process prescribed in a future EU regulation is based on a clear set of defined and agreed information requirements and strict timelines.[14] and mutual recognition of decisions between Member States[15]. “Conventional-like” NGT plants would not need special pre-market authorisation.

B. Post-approval requirements

PMM, PMEM, and coexistence requirements would be obsolete for conventional-like products or NGT plants. For products not having a conventional-like risk profile, all GMO post-marketing measures would stay in place.

[14] Similar consultation procedures in countries that have also been assessed in the Commission study implemented timelines between 45 and 80 days for the procedure up to the issuing of a declaration of conformity by the responsible authorities.

[15] The qualification of food is essential because non-novel food, in principle, does not require prior authorisation from the European Commission to enter the European market. Food business operators must verify whether the food they intend to place on the market falls within the scope of the Novel Foods Regulation. Where they are unsure whether a food they intend to place on the market within the Union falls within the scope of this Regulation, they shall consult the Member State where they first intend to place the novel food. This process is set out in Commission Implementing Regulation (EU) 2018/456 of 19 March 2018 on the procedural steps of the consultation process for determination of novel food status in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, OJ L 77, 20.3.2018, 6-13 ("Implementing Regulation 2018/456").

C. Labelling

With conventional-like NGT products meeting the criteria of the verification process, under the national variety registration authority, the developer has to provide information as a "tick box" statement ("this is a variety resulting from NGTs") in the technical questionnaire for variety registration. This should be supplemented by the decision of the competent authority that carried out the verification confirming the regulatory status of the variety. In addition, the information included in the technical questionnaire for variety registration as to the above would become public as part of the national catalogue of varieties and the EU Common Catalogue of varieties[16].

For products not having a conventional-like risk profile and that would consequently be considered GMOs, labelling requirements would remain.

D. Traceability

For conventional-like NGT products meeting the criteria of the verification process, traceability requirements would be obsolete.

For products not having a conventional-like risk profile, traceability requirements would remain.

E. Implication (EU / International / Liability / Economic Impact)

For conventional-like NGT products meeting the criteria of the verification process, liability requirements for conventional products remain.

For products not having a conventional-like risk profile, current liability provisions on GMOs would remain. This system would be similar to systems already implemented in a growing number of countries around the world which consider conventional-like NGT products as non-GMO. In addition, it would avoid enforcement challenges, given border controls for imports.

F. Future Proof

The wording of this option can be considered sufficiently flexible to account for technological change.

[16] Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species, OJ L 193, 20.7.2002, 1-11; Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed, OJ L 193, 20.7.2002, 33-59.

3.4 Option 4: Trait-based Regulation

This option focuses on regulating the final product and its characteristics/phenotype, not on the production method. It follows a trait-based regulation, i.e., the regulatory status of an organism is not determined by how it has been produced but rather by its (phenotypical) traits and their novelty. The category of "GMO" will practically cease to exist since "GMOs", even transgenic ones, would not be treated differently from organisms created by other methods since the sole entry point for the regulation would be the phenotypical traits.

Traits or combinations of traits that have not been observed so far in the species (novelty) were historically regulated within the ambit of the Novel Food Regulation (EU) 2015/2283[17]. Now, these would be inside the scope of such a trait-based regulation and require notification with the competent authority. The competent authority would check whether the "novel trait" of the concrete organism offers potential risks originating from, e.g., new herbicide tolerances, new antimicrobial resistances, new pest resistances, new constituents that lead to elevated allergenicity or different nutritional properties or other properties that could negatively affect the environment or the health of consumers/animals. Such potential risks would trigger a thorough risk assessment. There may also be categories of traits that are generally considered not risky – e.g., when plants with new traits do not produce new constituents (e.g. reduced pod-shattering, non-browning properties). Such traits, even if yet unknown in the species in question, would therefore not lead to the requirement for a thorough risk assessment.

This model has significant similarities to the regulatory regime of Canada. It would require more extensive legal changes because it affects not only the current GMO regulatory system but also the registration process of varieties currently considered conventional, as laid down in the seed marketing directives.

A. Authorisation

There would be an EU-wide mandatory regulation.

The authorisation procedure would depend on the organism's genetic properties and traits, and there would be a uniform authorisation procedure along objective criteria.

The approval would be granted through an independent decision by a central EU authority responsible for risk assessment and risk management.

[17] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, OJ L 327, 11.12.2015, 1-22.

B. Post-approval requirements

Post-market requirements would change according to amendments in relevant legislation. However, there would be no requirements for PMEM and coexistence measures with (partially public) location registers.

C. Labelling

There would not be special labelling requirements. There might be optional labelling, e.g., as a novel food.

D. Traceability

Apart from the general traceability requirements, e.g., in the General Food Law, there would be no additional requirements.

E. Implication (EU / International / Liability / Economic Impact)

Liability provisions for conventional products would apply. Entry of products onto neighbouring fields would not constitute damage per se since the legal category of "GMO" would cease to exist.

F. Future Proof

The wording of this option can be considered sufficiently flexible to account for technological change.

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3.5 Option 5: Foreign DNA as the regulatory trigger

This option is based on the notion that a level of accepted risk already exists in conventional plant breeding (and in dealing with microorganisms) that in the past did not trigger regulatory action since there were no significant detrimental effects observed. Organisms with comparable risks to conventionally produced organisms should thus not be specifically regulated. Except for viruses and viroids, only organisms with foreign DNA (i.e., transgenic organisms) would continue to be specifically regulated.

Foreign DNA is defined as DNA not derived from the gene pool of the recipient organism, encompassing the sum of all genomes of organisms that can exchange genes, even if only by classical breeding methods (so-called “breeder's gene pool” with regard to plants). This established concept of the “breeders gene pool” leads to a model that would not regulate “multiplexed” organisms or organisms created by cis- or intragenesis. This differs from the “novel combination of DNA” trigger used in the models in many South American countries like Argentina.

The competent authority would only need to be consulted if the organism either contains a transgene (for which the current EU rules on GMOs would apply) or if foreign DNA was used in the production process, in which case the authority needs to determine the absence of foreign DNA with data provided by the applicant.

A. Authorisation

There would be an EU-wide regulation. Depending on the breeding process, there would be necessary screening for foreign DNA based on data delivered by an applicant and case-by-case confirmatory testing by national/EU reference laboratories. It would take 60 days and be conducted by a competent national authority.

If no foreign DNA is present in the organisms, the authorisation procedure would be equal to conventional products.

B. Post-approval / post-market-requirements

There would be no PMEM requirements and no risk assessment for all plants and microorganisms that do not bear foreign DNA. Coexistence measures together with (partially public) location registers would stay in place for transgenic organisms.

C. Labelling

There would be no special labelling requirements for non-transgenic NGT products.

D. Traceability

There would be no special traceability requirements for non-transgenic NGT products.

E. Implication (EU / International / Liability / Economic Impact)

Current liability rules for GMOs would stay in place for transgenic organisms. Liability rules for NGT-organisms without foreign DNA would not differ from the ones for conventional products.

F. Future Proof

The wording of this option can be considered sufficiently flexible to account for technological change.

3.6 Option 6: REACH-like legislation

REACH (EC) No 1907/2006[18]) stands for the "registration, evaluation, authorisation and restriction of chemicals" and follows the "no data, no market" principle. It further aims to stimulate innovations and competitiveness in the industry. A regulatory option taking the REACH example as a basis would put the responsibility of revealing safety information and managing its risks solely on the applicants. Producers would have to register the genetically modified product in a central database run by an EU authority (similar to the procedure with chemicals by ECHA), which would become a focal point for applicants. Regarding plants, one option would be to either expand the common catalogue of plant varieties or create a new plant variety catalogue for this purpose. The information would be publicly stored and made available to an EU authority, similar to chemicals by ECHA.

There would be a classification of organisms based on their level of risk. There would be no opt-out possibility for Member States, but different enforcement mechanisms (e.g., market surveillance) based on Member State law and European Union law would apply. Therefore, an implementing act will determine the regulatory trigger - for example, organisms with genetic modifications by NGT.

A. Authorisation

Manufacturers and importers would have to register their products with an EU authority and submit a dossier in which information such as risks and hazards are identified, and details are provided on how they would be controlled. There would be no cross-requirement to register a modification in cases where it has already been registered and approved. Without such registration, no import and no placing on the market by other means would be possible.

The EU authority checks the completeness of the dossier and assesses the risk profile in a second step. If the organism poses a high risk (product of high concern but potentially acceptable risk), it is placed on a "candidate list", from which it cannot be taken unless given authorisation.

Should a product pose solely unacceptable risks towards people and their health or the environment, it could be banned. In line with WTO law, the level of unacceptable risk is to be determined at a political level.

[18] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, OJ L 396, 30.12.2006, 1.

B. Post-approval / post-market-requirements

After an organism is registered or approved, the product information will be published in a public register. Member States will conduct market surveillance following national and European Union laws.

C. Labelling

The specific GMO labelling requirements would remain.

D. Traceability

Traceability needs to be established.

E. Implication (EU / International / Liability / Economic Impact)

Each Member State should establish its enforcement mechanisms

F. Future Proof

The wording of this option can be considered sufficiently flexible to account for technological change.

4. Summary

At EU level, the consensus seems to grow regarding the amendment of the current GMO regulation for NGTs with a focus on targeted mutagenesis and cisgenesis. We have provided six options considering the potential regulatory design of such changes. These options also cover the widest spectrum of possibilities, ranging from working within the framework of the current legislation (Option 1) to streamlining NGT regulatory design with one of the other acts on risk regulation in the EU (Option 6). We included in the development of our six regulatory options for NGTs the following regulatory tools: (A) Authorisation; (B) Post-approval / Post-market-requirements; (C) Labelling; (D) Traceability; (E) Implications as Incentives (EU / International / Liability / Economic Impact); and (F) Future Proof.

Further research may utilise these options as objects of research to determine their "fit for purpose."

The six regulatory options can be described as follows:

Table 2: Overview of Regulatory Options

Option 1	Status Quo
Option 2	Explore current GMO legislation for further possibilities
Option 3	Regulatory differentiation of NGT plants according to their risk profiles
Option 4	Trait-based Regulation
Option 5	Foreign DNA as a regulatory trigger
Option 6	REACH-like legislation

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