GeneBEcon

Deliverable D1.6

NGT Policy Directions

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Legal disclaimer

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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
Danish Technological Institute, Denmark
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2. Executive Summary

This report discusses various regulatory, economic, social and ethical aspects in relation to the use of new genomic techniques (NGTs) for a sustainable, circular and zero-waste bioeconomy in Europe. Through the work with gene editing in potato and in microalgae, the EU-funded GeneBEcon project aims at contributing to a positive development in terms of environmental impact, farm and industrial economy, and consumer awareness. A virus-resistant potato will reduce the use of pesticides applied on European farmlands, whereas an optimised starch quality in the tubers will reduce the need for chemical processing. A microalgae strain tailored to produce high-value compounds will provide an economic and renewable source of industrial products, whereas the residual microalgae will enable a more sustainable poultry production in Europe.

Acknowledging that the current legislation on genetically modified organisms (GMOs) in the EU is not fit for purpose for some NGTs and their resulting products, the European Commission (EC) has presented a proposal for a new NGT Regulation. The proposal suggests two different categories of NGT products, based on whether the product is considered equivalent to conventional plants (category 1) or not (category 2). GeneBEcon has defined six different regulatory options for further analysis, to provide policy- and decision-makers with robust scientific data on their respective impacts. The EC Regulation proposal´s Category 1 would be covered by option 3 ("*Regulatory differentiation according to risk profile*") or option 5 ("*Foreign DNA as a regulatory trigger*"), whereas Category 2 products would be placed under option 2 ("*Explore current GMO legislation*").

Based on the two case studies potato and microalgae, the regulatory options were examined for their effects on the biosafety data requirements. It is considered that no additional data requirements beyond the molecular information are necessary to conclude on their conventional-like safety profile and that regulatory options 3 or 5 would be sufficient for adequate protection of human health and the environment. GeneBEcon also examines the regulatory options for their respective potential socio-economic impact. The preliminary, qualitative assessment shows that option 3 or 5 have economic benefits. Options 4 and 6 ("*REACH-like legislation*") may also be suitable, however they entail a greater uncertainty.

GeneBEcon applies Responsible Research and Innovation (RRI) and Systems Mapping Approach (SMA) to include the perspectives and insights of a diverse group of stakeholders. A first SMA workshop mapped and clustered the elements of potato and microalgae production, processing and consumption into four subsystems: ecological, economic, social and regulatory. A first RRI workshop identified pertinent weaknesses and threats for NGT products in Europe, with the purpose of turning these into strengths and opportunities. Stakeholder input in the project´s RRI/SMA process will contribute to the development of an action plan for NGT product introduction in society.

The work of GeneBEcon is embedded in different ethical considerations, such as the balance of the precautionary principle with the need for innovation; public perception and informed consent; and the role of scientific advice in policy-making. It is therefore important to "bridge the gap" between the laboratory, the field, and consumers and other stakeholders. The EC proposal for new NGT Regulation is currently being discussed in the European Parliament and the Council. GeneBEcon addresses many important aspects that are relevant for the ongoing legislative discussion as well as the accompanying broader societal debate and that may be taken into consideration by EU and Member State policy- and decision-makers. To facilitate the distilling of key points, each section of the report is concluded with a "take-home message".

3. Glossary

Term	Description / Definition
conventional breeding	Conventional breeding employs cross-breeding, including by using advanced techniques such as embryo rescue, induced polyploidy and bridge crosses including the total genetic information available in one species and other taxonomic species.
foreign DNA	Genetic material that is not part of the breeders genepool (the total genetic information available in one species and other taxonomic species with which is accessible for conventional breedings) .
gene editing	Alteration of the genetic material of a living organism by inserting, replacing, or deleting a DNA sequence, resulting in modification(s) of the DNA sequence at precise locations in the genome of an organism
Genetically Modified Organism	Definition in the European Union as per Directive 2001/18/EC: "*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.*"
microalgae	Organisms that are autotrophic, mostly unicellular, and can grow in aquatic environments.
mutagenesis	Process by which the genetic information of an organism is changed resulting in modification(s) of the DNA sequence (insertions, deletions, inversions, substitutions)
mycosporine-like amino acids	UV light-absorbing compounds produced by several organisms such as lichens, fungi, algae and cyanobacteria.
New Genomic Techniques	Definition by the European Commission: "*techniques that are capable of altering the genetic material of an organism and that have emerged or have been developed since 2001, when the current legislation on genetically modified organisms (GMOs) was adopted.*"
potyvirus	Large genus of plant viruses causing significant losses in a wide range of crops.
Precautionary Principle	Definition by the European Commission: "*Whether or not to invoke the precautionary principle is a decision exercised where scientific information is insufficient, inconclusive, or uncertain and where there are indications that the possible effects on the environment, or human, animal or plant health may be potentially dangerous and inconsistent with the chosen level of protection*"
recombination	Process by which pieces of DNA are broken and recombined to produce new combinations.
Responsible Research and Innovation	Term used by the European Union's Framework Programmes to describe scientific research and technological development processes that take into account effects and potential impacts on the environment and society.
systems mapping	Creation of visual depictions of a system, such as its relationships and feedback loops, actors and trends.

4. Introduction

In the European Union (EU), genetically modified organisms (GMOs) are regulated primarily by three legal acts: Directive 2001/18/EC[1] (the "GMO Directive"), and Regulations (EC) No 1829/2003[2] and No 1830/2003.[3] The GMO Directive defines a GMO as "*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*". The regulatory measures include a risk assessment prior to authorisation, the actual authorisation procedure and post-authorisation, labelling and traceability requirements, coexistence measures and post-market monitoring. In cases of new information or potential risks, safeguard clauses allow member states to take emergency measures to protect human health and the environment. Member states also have the right to restrict or prohibit the cultivation of authorized GMOs within their territories under Directive (EU) 2015/412.[4] The public and stakeholders are given the opportunity to comment on GMO applications during the authorization process. Following the Court of Justice of the European Union (CJEU) ruling in 2018 in Case C528/16[5], all organisms and products derived from new genomic techniques (NGTs) are considered regulated GMOs in the EU.

These regulatory measures lead to a **lengthy process** and carry considerable **economic costs**, as well as substantial **administrative burden**, for the developers of GMOs and their derived products.[6] In addition, the authorisation procedure itself means that the **prospect of market approval is uncertain**. In fact, consumers in the EU have little, or no, direct experience with GMO-derived products as only one GM crop is authorised for cultivation in the EU, while the majority of the products that have been authorised for import are for feed purpose.[7]

The European Commission (EC) has recently presented a **proposal for new Regulation** on plants produced by certain NGTs.[8] Such regulatory changes will have an impact on the incentives to invest, the prospect for market approval, marketability, and by extension on the perception of the public and business stakeholders, for NGT products in the EU.

This report describes the **directions of the GeneBEcon work** assessing NGT regulatory options, biosafety data requirements, economic impact, and public perceptions. These aspects are illustrated using cases in potato and microalgae and their respective value chains. Currently in Europe, the debate about GMOs and NGT products is often polarized.[9] The project aims to understand the complex interrelationships between scientific, social, regulatory, economic, and environmental factors that influence the development of, and debate about, NGT products, all of which is in part described in this report.

Take-home message:

Regulatory measures need to be balanced in terms of proportionality in risk assessment, predictability and cost for developers, and flexibility for scientific developments, while not jeopardising their purpose of protecting human health and the environment. GeneBEcon will contribute to striking that balance for the products of new genomic techniques.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32001L0018
[2] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32003R1829
[3] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32003R1830
[4] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32015L0412
[5] https://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=C-528/16
[6] Smart RD et al (2016). Trends in approval times for genetically engineered crops in the United States and the European Union. Journal of Agricultural Economics, doi: 10.1111/1477-9552.12171
[7] https://webgate.ec.europa.eu/dyna2/gm-register/
[8] https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en
[9] Montenegro de Wit, M. (2020). Democratizing CRISPR? Stories, practices, and politics of science and governance on the agricultural gene editing frontier. Elementa: Science of the Anthropocene, *8*(9).

5. NGT policy developments

The EC proposal[10] for a new regulation suggests a verification procedure for plants and products resulting from targeted mutagenesis and cisgenesis. If the compliance of NGT plants with certain equivalence criteria, listed in Annex I (see Box 1), is confirmed by relevant authorities, these plants and their products will be considered conventional-like (Category 1), to which the rules of the EU GMO legislation will not apply. Seeds of Category 1 NGT plants would need to be labelled as such. Category 1 NGT plants will remain subject to any regulatory framework that applies to conventionally bred plants. If NGT plants and products do not meet the equivalence criteria of Category 1, they will be considered Category 2 and will be subject to an adapted GMO risk assessment as well as GMO detection, traceability, and labelling requirements. Although Category 1 plants and products are deemed "conventional-like", both categories of NGT plants and products will not be allowed for organic farming. Figure 1 illustrates the entire set of categories of plants and products across the breeding spectrum, with their respective regulatory requirements, that would result if the EC proposal is adopted in its current form.

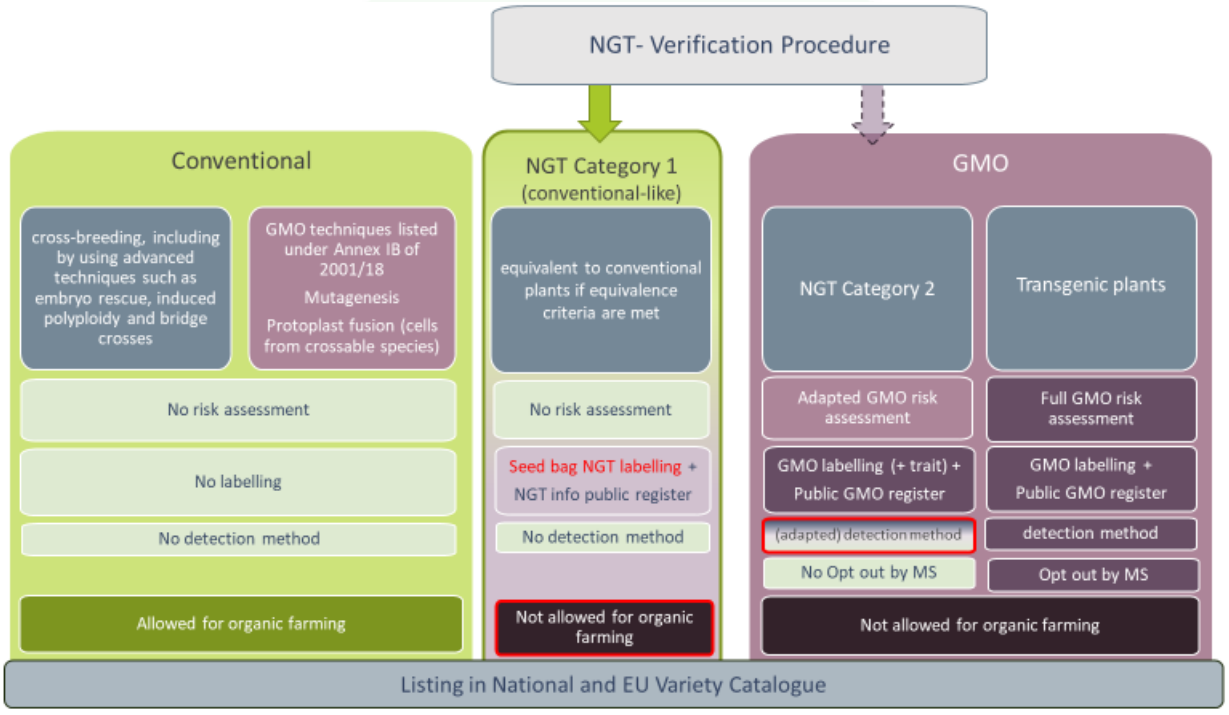

Figure 1. Regulation of plant breeding techniques in the EU as proposed by the EU Commission 5th July 2023. Figure provided by Euroseeds.

The verification process would be based on molecular data that confirms that the product meets the Equivalence Criteria for Category 1. It will not include a risk assessment and Category 1 NGT plants and products will not require a detection method. Nevertheless, other Member States and the Commission could provide comments to the draft verification report of a national competent authority. This could lead to a prolongation of the verification process and trigger an assessment by EFSA and the Commission, as well as a voting by Member States, before the Commission can take a final decision on the verification.

[10] EUR-Lex - 52023PC0411 - EN - EUR-Lex (europa.eu)

The authorization procedure for Category 2 NGT plants and products will be based on molecular data on the genetic modifications and can require additional data for composition, phenotype, as well as toxicity/allergenicity if the problem formulation gives rise to a plausible risk hypothesis. Category 2 NGT plants also require a detection method that complies with the requirements for GMO detection methods. In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, and duly justified by the notifier or the applicant, the modalities to comply with analytical method requirements can be adapted. The labelling of category 2 NGT products as GMO can be complemented with information on the conferred trait.

The proposal also foresees regulatory incentives to potential notifiers or applicants for Category 2 NGT plants and products presenting traits with the potential to contribute to a sustainable agri-food system, with the aim to steer the development of Category 2 NGT plants towards such traits. Traits enabling regulatory incentives include increases in yield, tolerance/resistance to biotic and abiotic stresses, more efficient use of water and nutrients, enhanced sustainability of storage, processing and distribution, and improved quality or nutritional characteristics. Herbicide tolerance traits will not benefit from regulatory incentives.

Box 1.

Annex I – Equivalence Criteria

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

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

(2) deletion of any number of nucleotides;

(3) on the condition that the genetic modification does not interrupt an endogenous gene:

(a) targeted insertion of a contiguous DNA sequence existing in the breeder's gene pool;

(b) targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;

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

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

Numerous countries outside of the EU have already made a decision on how to regulate different types of NGT plants. If the future EU NGT legislation differs from that of important trading partners, it will have an impact on trade and on the compliance with EU law.

Take-home message:

The European Commission proposal for new regulation on plants resulting from certain new genomic techniques will, if adopted, lead to several different categories of breeding products that are all subject to different regulatory requirements. It is important to consider the implications in terms of proportionality and similar regulatory conditions for identical products, regulatory certainty and predictability, and the potential impact on international trade.

6. GeneBEcon case studies

Through the work with gene editing in potato and in microalgae, GeneBEcon aims at contributing to sustainability and a circular bioeconomy, having a direct positive impact on the environment, the economy of farmers and companies, and the well-being of consumers.

6.1 Gene-edited potato

The **EU Zero Pollution Action Plan** – a key deliverable of the European Green Deal – emphasizes the role of biotechnology to reduce the use of pesticides in agriculture. To this end, GeneBEcon will contribute by using gene editing to develop a virus-resistant potato that requires less pesticides in agricultural production (Figure 2). Europe is the second largest grower of potatoes worldwide. The production of potato amounts in the EU-27 to 122 million tonnes per year, of which 19 million tonnes is used for processing and it employes over 23,000 people alone in the European potato processors.[11]

This scale makes resistance breeding in potato highly prioritised as a means to reduce the dependence on hazardous pest control in conventional and organic agriculture. Among the many pathogens causing problems on potatoes, the potyvirus PVY is one of the most important globally.[12] By inducing broad resistance to PVY through designed gene edits, the use of pesticides to tackle the virus spread by aphids can be significantly reduced. Losses due to virus diseases are not only restricted to direct losses of plant products but are also associated with indirect financial losses such as increased production costs, cost of control and management of disease (virus control, certification, inspection, virus testing and management tools). It is estimated that a 1% increase of PVY incidence results in a 180 kg per hectare reduction of yield, or $18 per hectare revenue loss.[13] Virus-resistant potato cultivars would potentially reduce the amount of insecticides in the total EU potato production (1.7 million hectares) with about 850,000 kg of active ingredient and secure the income of about 1.5 million famrs. The **Farm to Fork (F2F) strategy** of the European Green Deal[14] targets a 50% reduction of chemical pesticides by 2030. F2F identifies new innovative techniques, including biotechnology, as potentially important to help achieving this goal. GeneBEcon will contribute by using gene editing to develop a virus-resistant potato that requires less pesticides in agricultural production.

The **EU Bioeconomy Strategy** points to the importance of the advances in life sciences and biotechnology to develop new biobased materials, of high economic value, that will phase out fossil carbon, reduce greenhouse gas emissions and steer the industry towards renewable resources.[15] GeneBEcon will contribute by delivering biobased industrial raw materials from potato. Potato is the third most important starch crop in terms of volume in Europe. The EU production of potato starch reached 1.157 M tonnes and a value of EUR 344 million in 2019.[16] Downstream of extraction, a major part of the starch is modified by physical and chemical processes to yield qualities suitable for specific food and technical applications. A starch quality that is optimised already in the potato tuber in the field will be developed by gene editing in GeneBEcon. This is expected to eliminate the need for downstream chemical processing and increase the storage stability of end products, saving up to 75,000 tonnes of chemicals and 7.5 GWh of energy in EU every year.[17] This potato starch is likely to have economic benefits not only to the starch companies, but also to farmers that will cultivate potato with added value due to the increased quality.

[11] https://euppa.eu/_library/_files/EUPPA_Sustainability_Report_2021_online.pdf
[12] Glais, L et al (2017). in Potato virus Y: biodiversity, pathogenicity, epidemiology and management. 43-76, Springer International.
[13] Nolte P et al (2004). Effect of seedborne potato virus Y on performance of Russet Burbank, Russet Norkotah and Shepody potato. Plant Disease, 88(3).
[14] https://ec.europa.eu/food/horizontal-topics/farm-fork-strategy_en
[15] https://knowledge4policy.ec.europa.eu/publication/sustainable-bioeconomy-europe-strengthening-connection-between-economy-society_en
[16] Eurostat, 2019.
[17] Source: Lyckeby starch company

Figure 2. Field trial with gene-edited starch potato in south Sweden. Photo: Mariette Andersson.

Take-home message:

The gene-edited potato developed in GeneBEcon will carry valuable traits and will be available for incorporation into elite breeding material. This can allow potato farmers to safeguard production with reduced pesticide input, thereby improving their economy and reducing pollution. Potato starch companies will in turn benefit from varieties producing higher quality starch that requires less chemical processing and energy.

6.2 Gene-edited microalgae

The other type of biobased industrial material that GeneBEcon is developing, and which contributes to the **EU Bioeconomy Strategy**, is high-value compounds that can be produced by microalgae strains modified through gene editing. Microalgae are an exciting source of high value compounds such as proteins with a high content of essential amino acids, omega-3 fatty acids, antioxidant pigments such as β-carotene and astaxanthin, vitamins, and much more. So far, microalgae are mainly marketed as whole/extruded biomass to supplement food or feed and there are only few high-quality products such as astaxanthin oleoresin or β-carotene that are successfully marketed. Many microalgae are capable of accumulating mycosporine-like amino acids (MAA), which have high utilisation potential in pharmaceuticals and industry. It is shown that sunscreens containing 0.1% MAA are as efficient as sunscreens containing 1% UVA and 4% UVB filters. MAAs are naturally produced in wildtype microalgae, but at low levels, and it is expected that gene-edited microalgae can lead to significant increases of MAAs' production levels. The market of sunscreens in 2019 was 8.5 Billion USD and it is forecasted to reach 10.7 Billion USD by 2024. Another intended use of MAAs in industry could be UV-resistant, low-brittle plastic.

Photosynthetic microalgae have the ability to convert atmospheric CO2 into organic compounds (including bioactive molecules). This production system can be an important part of a circular bioeconomy as it enables all-year production using low energy and other inputs, (e.g., residual products from other industries such as surplus heat and industrial wastewater), while simultaneously reducing pressure on

terrestrial ecosystems and agricultural land use. In addition, their ability to sequester CO_2 at a high rate has attracted much attention as a sustainable solution to reduce and mitigate global CO_2 emissions. The size of the global microalgae production is ~25,000 tonnes per year (dry matter) with a biomass market price between 20-50 €/kg (for *Chlorella*).[18] In Europe, there are currently about 480 companies producing microalgae and the production is still rather small on a global scale but increasing rapidly.

Further contributing to the **EU Circular Economy Action Plan**[19] is the use of the microalgae side stream (after extraction of high-value compounds) as poultry feed. This means that all aspects of the microalgae innovation chain, which includes the production of gene-edited microalgae, the step-wise upscaling in bioreactors (Figure 3), the biochemical profiling and extraction of the high-value compounds, and the valorization of the residual biomass as added-value feed additive, are in line with the concepts of a zero-waste production and circular bioeconomy. Currently the main protein sources in chicken feed include legume seeds and their by-products. An increase in microalgae production resulting from the advances promoted by GeneBEcon would generate a replacement of the protein source by 2% in the chicken feed, and a gain of 173k€, 11.2M€, 92.8M€ would be obtained in Belgium, Europe and worldwide, respectively, in case of a 5% implementation in the sector. In addition to proteins, microalgae contain multiple bioactive compounds such as omega-3 fatty acids and pigments that might lead to beneficial animal health and welfare, even when added at low levels to feeds.

Take-home message:

The gene-edited microalgae developed in GeneBEcon are expected to be of great value to the bioeconomy by providing the pharmaceutical and cosmetics industry with high-quality products. Any repurposing of residues from the microalgae production into nutritious poultry feed will benefit the poultry value chain and contribute to zero-waste circular economy.

Figure 3. Microalgae contained production facilities.

[18] Fernández et al (2021). The role of microalgae in the bioeconomy. N. Biotechnol. 61, 99–107.
[19] https://ec.europa.eu/environment/strategy/circular-economy-action-plan_en

7. Policy options and associated impacts

In the EU, regulatory uncertainty reduces investment in NGTs at several levels, including research, innovation, product development and scaling-up of production processes.[20] Experts estimate that it would cost $9 million less to bring a genome-edited crop to market if it were not regulated as a GMO[21]. A study conducted by the European Commission (EC) on NGT regulation mentions the need for flexibility and proportionality, together with the need to develop proportionate NGT-specific risk assessment procedures adapted to the risk profiles of plants resulting from NGTs, as the current regulatory system involves implementation and enforcement challenges.[22]

7.1 Regulatory options

To address this regulatory uncertainty, GeneBEcon has defined six different **regulatory options for NGT products** (Table 1), considering the following regulatory criteria: authorisation; post-approval/post-market-requirements; labelling; traceability; implication (EU/international/liability/economic impact), and future proof.[23] The analyses on the biosafety assessment (subsection 7.2) and the socio-economic impact (subsection 7.3) are projected against these six regulatory options.

	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
Authorisation	Required for all GMOs	Lower data requirements	No autorisation, but a notification is required for «conventional-like» NGT plants	EU-wide autorisation only for organisms with novel traits	Not required, if no foreign DNA present	Mandatory registration, autorisation required only for products with high concerns
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
Labelling	Mandatory labelling as GMO	Mandatory labelling as GMO	For «conventional-like» NGT plants : information in Common	None (Category «GMO» would effectively cease to exist)	No labelling for organisms without foreign DNA	Required

[20] Purnhagen KP & Wesseler JH (2019). Maximum vs minimum harmonisation: What to expect from the institutional and legal battles in the EU on gene editing technologies. Pest Management Science, 75(9), 2310–2315.
[21] Lassoued, R., Phillips, P. W. B., Smyth, S. J., & Hesseln, H. (2019). Estimating the cost of regulating genome edited crops: Expert judgment and overconfidence. GM Crops & Food, 10(1), 44–62. https://doi.org/10.1080/21645698.2019.1612689
[22] European Commission. (2021). Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16. Commission staff working document SWD (2021) 92 final, 117.
[23] https://genebecon.eu/wp-content/uploads/2023/02/Technical_Report_Regulatory_Options_17.02.23.pdf

			Catalogue of Varieties			
Traceability	Required	Required	Not required for «conventional-like» NGT plants	None	None for organisms without foreign DNA	Required
Implications	Liability for environmental damage	Liability for environmental damage	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
Future-proof	Not flexible	Not flexible	Flexible	Flexible	Flexible	Flexible

Table 1. The six regulatory options for NGT-derived plants that are developed and assessed in GeneBEcon.

7.2 Assessment of biosafety data requirements

The GeneBEcon project examines six regulatory options for NGT-derived plants and products (including the current GMO regulation, i.e. status quo) and their respective effects in terms of regulatory requirements under the GMO law (Figure 4). The regulatory options differ in the extent to which the applicant has to produce **data prior to authorization or registration**. The differences in data requirements under the six options are due to different regulatory triggers (e.g. the "conventional-like" character, the introduced trait, or with absence of foreign DNA). Authorization criteria guide to different authorization and post-approval profiles with different data requirements e.g. for risk assessment. The pre-assessment data are for determining the regulatory pathway and are – depending on the regulatory option – used either only internally by the developer or are forwarded to the authority to decide on the authorization profile.

A thorough case-specific risk assessment is *inter alia* required if the NGT-derived plant is either not conventional-like (3rd option), has a potentially hazardous new trait (4th option); contains foreign DNA (5th option); or is classified as being highly hazardous (6th option). An authorization is only granted if no unacceptable risk is identified by the result of an (case specific) risk assessment as shown in Figure 4. The six regulatory options influence the parameters for the economic modeling, which affect the wider economic implications of NGT governance policies. By comparing possible costs for the applicant under the different regulatory options, GeneBEcon will determine the best options to **balance safety and innovation**.

The different regulatory options are applied to the **two case studies** of GeneBEcon (section 5) to evaluate whether or not those options are fit for purpose in practical application. Considering that the NGT potato and microalgae are in their expected R&D phase, general and broader data requirements (qualitative and semi-quantitative) according to the six options could already be identified for a potential placing on the market phase. Although specific for the two case studies on microalgae and potato, the data requirements in principle can be applied to various NGT applications for other plant species.

The current project stage already allows for a **qualitative conclusion** on the safety assessment of the NGT potato and microalgae: Based on the information generated by GeneBEcon, the conventional-like character and/or the absence of foreign DNA in the potato lines or *Chlorella* strains are the key factors. **There is sufficient evidence that potential risks do not exceed putative risks of their conventional counterparts**.[24] The performed or planned modifications in potato are expected to produce varieties with an arguably low potential for hazards that can be compared to conventional plants already cultivated and/or

[24] EFSA 2022, Leopoldina/DFG 2023, ZKBS 2023; OECD Consensus Documents on potato.

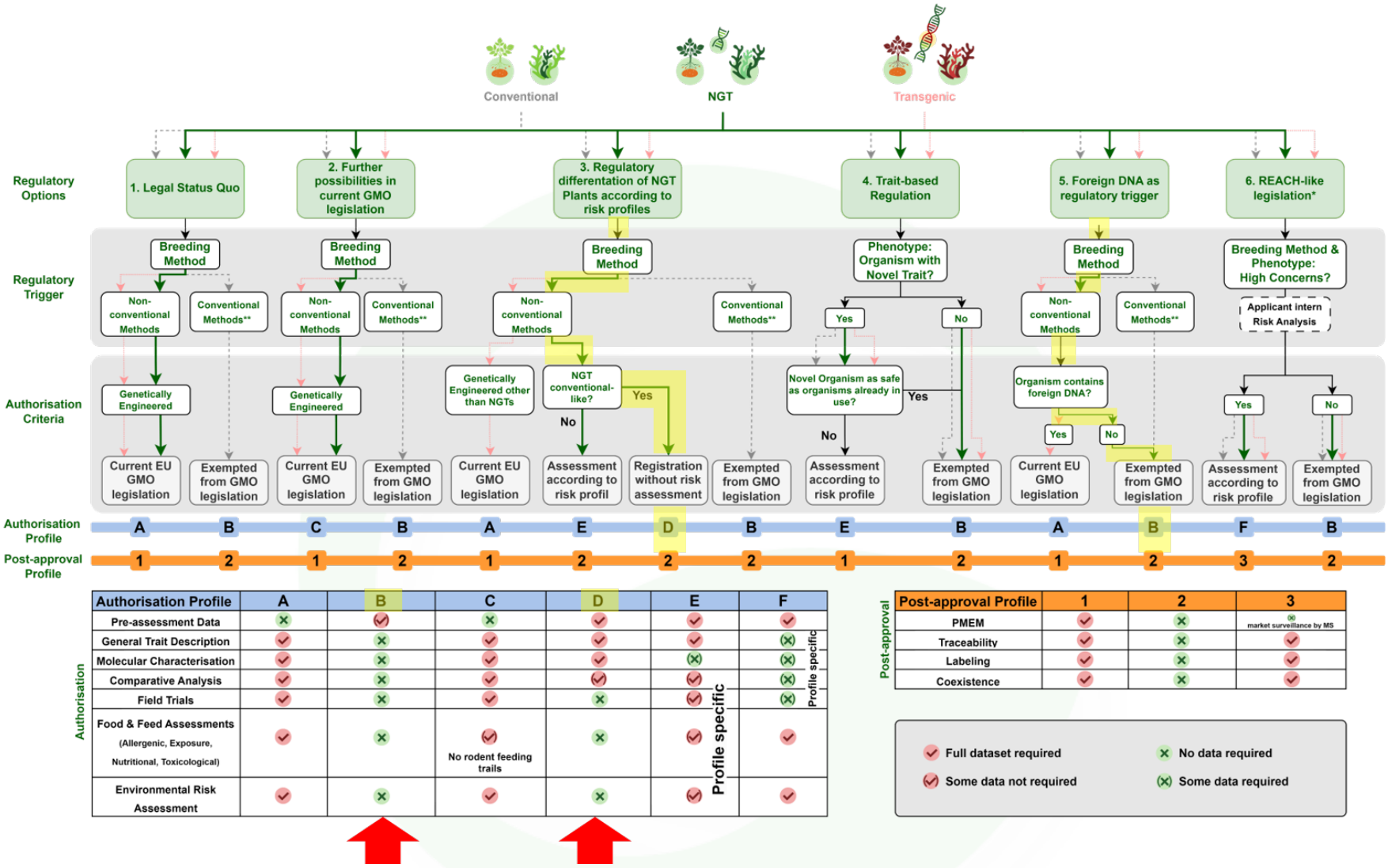

Figure 4. Data requirements for the risk assessment of NGT plants under the six regulatory options in the GeneBEcon project. The six regulatory options address different regulatory approaches for the risk assessment of NGT plants. Red arrows cover Category 1 & 2 plants of the EU Commission proposal.

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released on the market. The modifications in microalgae are likely to be - from the regulator's perspective - products with an arguably low potential for hazards and not higher than the risk potential of non-NGT microalgae. In case the product would not only be used as feed, the microalgae could also potentially fall under the Novel Food Regulation and likely to be considered safe to consume when compared to *Chlorella* varieties already on the market as food or feed.[25] The increased production of naturally occurring MAAs by NGT methods, without introducing functional transgenic sequences, is not likely to lead to an increased risk. For the microalgae, which are mostly produced in closed systems,[26] an environmental risk assessment would seem disproportionate. However, cultivation in (enclosed) open pond systems have been considered in the estimation of data requirements for the risk assessment of NGT microalgae of GeneBEcon. While microalgae, as a diverse collection of prokaryotic and eukaryotic unicellular organisms, are not covered by the current EC NGT proposal (section 5), the GeneBEcon options can be applied to strains of the eukaryotic microalgae *Chlorella*.

Overall, the GeneBEcon project has not found that additional data requirements, apart from the molecular information, are necessary. It is sufficient to either confirm the conventional-like character (in GeneBEcon option 3, which is comparable to the NGT category 1 in the EC proposal,[27]) or prove the absence of foreign DNA as needed in GeneBEcon option 5. Additional data requirements for the risk assessment of the GeneBEcon potato and microalgae would not increase the safety of those products but increase and potentially exceed the cost that developers are able, or willing, to invest. Authorization profiles D in case of 3rd option or B in case of 5th option (see Figure 4) seem to be appropriate. Recommendations for post-approval profiles are dependent on socio-economic considerations. Profile 2 is sufficient from a pure biosafety point of view.

Category 1 plants from the **current EU Commission draft proposal** (see Figure 1) are best covered by GeneBEcon option 3 or option 5, whereas Category 2 plants are best placed under GeneBEcon option 2. However, the corresponding authorization profiles are still not sufficiently determined on the EU level, and therefore **GeneBEcon offers valuable information to select the best practise**.

Take-home message:

Based on the current qualitative information generated, the gene-edited potato and microalgae are likely to present a similar safety profile as their conventional, or non-NGT, counterparts. The data requirements under GeneBEcon regulatory profiles B or D are considered sufficient to conclude on the biosafety of gene-edited potato and microalgae. This implies that the precautionary principle does not need to be invoked for certain NGT products

7.3 Socio-Economic impact

GeneBEcon assesses the six regulatory options with respect to their potential **socio-economic impact**. Different types of regulations can either facilitate or hinder the diffusion of NGTs and thus the impact on the bioeconomy.[28] Mandatory traceability and labeling systems along the value chain could lead to economic losses for farmers and hinder the adoption of NGT-derived products.[29] Uncertainty and ambivalence about labeling NGT-derived products as GMOs may reduce consumers' willingness to pay for these products. Researchers have shown that absence ("non-GMO") and presence ("contains GMOs") of labeling systems reduce the market share of GM foods, but the reduction is greater in the latter case.[30]

[25] https://webgate.ec.europa.eu/fip/novel_food_catalogue/#
[26] Araújo, R et al. (2021): Current Status of the Algae Production Industry in Europe: An Emerging Sector of the Blue Bioeconomy. In: *Front. Mar. Sci.* 7, S. 626389. DOI: 10.3389/fmars.2020.626389.
[27] Regulation on new genomic techniques (NGT) – Technical paper on the rationale for the equivalence criteria in Annex I, EU KOM 2023.
[28] Bartkowski, B., Theesfeld, I., Pirscher, F., & Timaeus, J. (2018). Snipping around for food: Economic, ethical and policy implications of CRISPR/Cas genome editing. Geoforum, 96, 172–180. https://doi.org/10.1016/j.geoforum.2018.07.017
[29] Schneider, K., Barreiro-Hurle, J., Kessel, G., Schouten, H., Vossen, J., Strassemeyer, J., & Rodriguez-Cerezo, E. (2023). Economic and environmental impacts of disease-resistant crops developed with cisgenesis. Publications Office of the European Union. https://data.europa.eu/doi/10.2760/715646
[30] Kim, Y., Kim, S., & Arora, N. (2022). GMO Labeling Policy and Consumer Choice. Journal of Marketing, 86(3), 21–39. https://doi.org/10.1177/00222429211064901

The worldwide advancement of NGT-derived products and their regulation can heavily impact the trade relations of the EU. The trade between countries and regions has long been affected by one-sided trade barriers and subsequent retaliations. For example, GMO approval asynchronicity led to a long-lasting dispute, with maize exports from the US to China dropping by 85%.[31] Regulatory asynchronicity can be a severe hurdle in international trade and may cause considerable economic damage to breeders, farmers, and traders along the value chain. The six different regulatory options potentially affect the bioeconomy of the EU. Even though we do not yet have quantitative data, we present here some initial qualitative conclusions.

For the status quo (**option 1**), regulatory costs and uncertainty lead to high research and development (R&D) costs for plant breeders.[32] Trade disruptions are expected, as NGT-derived products intended for import and covered by GMO legislation must comply with EU approval requirements, which differ significantly from those of certain key EU trading partners.[33] Labeling and traceability requirements impose additional costs on imports into the EU, which could be passed on to consumers. Trade between the EU and countries with a similar approval process will continue to be affected due to the persistence of high barriers to entry. Trade with countries where NGT products remain unregulated and untraceable could either cease altogether or be deemed illegal, rather than just facing increased trade barriers. The potential loss of trade opportunities due to the inability to penetrate export markets, the high costs of authorization and the lack of return on investment for companies and institutions developing new products would jeopardize any positive economic impact of this option.

Option 2 has a very similar potential socio-economic impact. However, minor adjustments to the existing legislation could be seen as a start towards a more accessible regulatory framework, with fewer barriers for importers in terms of data requirements. However, this may not be sufficient to achieve an approach in line with important trading partners such as Argentina or Brazil.

With **option 3**, the trade barriers between the EU and countries that adopted similar frameworks would be significantly reduced for plants with a low risk profile. Companies and research institutions might consider the EU as a more attractive place to conduct R&D and develop NGT plants as authorisation costs would decrease. By lowering regulatory costs, increasing the potential return on investments, and streamlining the R&D process, the willingness to invest in developing more traits simultaneously could increase the positive effect on crop improvement.[34]

The economic impact of **option 4** differs from the previous options because trade barriers would depend on the potential risks posed by the novel trait. New low-risk crops would have easier access to the EU market. While intra-EU R&D, including testing, would be facilitated, EU exporting producers would have to face trading partners with more restrictive regulations.

Option 5 eliminates most types of import barriers for plants that do not contain foreign DNA. It would also increase investment in research and development of more traits at the same time, which could increase the positive impact on crop improvement and sustainability efforts. EU-based companies would face the reverse challenge of adapting exported products to comply with stricter regulatory frameworks imposed by certain trading partners.

[31] Gocht, A., Consmüller, N., Thom, F., & Grethe, H. (2021). Economic and Environmental Consequences of the ECJ Genome Editing Judgment in Agriculture. Agronomy, 11(6), Article 6. https://doi.org/10.3390/agronomy11061212
[32] Jorasch, P. (2020). Potential, Challenges, and Threats for the Application of New Breeding Techniques by the Private Plant Breeding Sector in the EU. Frontiers in Plant Science, 11. https://www.frontiersin.org/articles/10.3389/fpls.2020.582011
[33] Eriksson D, et al (2019). A comparison of the EU regulatory approach to directed mutagenesis with that of other jurisdictions, consequences for international trade and potential steps forward. New Phytologist, 222(4): 1673-1684, https://doi.org/10.1111/nph.15627
[34] Kalaitzandonakes, N., Willig, C., & Zahringer, K. (2023). The economics and policy of genome editing in crop improvement. The Plant Genome, 16(2), e20248. https://doi.org/10.1002/tpg2.20248

Trade barriers for the low-risk NGT-derived equipment in **Option 6** would be low, as general registration would allow trade between trading partners with similar regulatory frameworks, while potentially raising trade barriers for companies exporting to countries with more stringent regulatory requirements. It would also facilitate investment in research and access to the EU market. However, the extent of trade barriers between jurisdictions with similar regulatory frameworks would ultimately depend on their specific definitions and characterizations of what they consider to be high and low risk.[35]

Take-home message:

An interim assessment demonstrates economic benefits of GeneBEcon regulatory options 3 or 5 compared to options 1 or 2. The adopted approval processes would reduce costs and promote R&D investments in new crop improvements using NGTs. The trade with Option 4 and 6 might be superior as well, but there is a greater uncertainty of implementing such approaches. Option 3 and 5 would therefore facilitate R&I and with this contribute to the overall objectives of the Green Deal and ist Farm to Fork Strategy which highlight the importance of innovation.

[35] Purnhagen K, et al (2023). Options for Regulating New Genomic Techniques for Plants in the European Union. Nature Plants, https://doi.org/10.1038/s41477-023-01570-2

8. Stakeholder insights

8.1 Systems mapping of the GeneBEcon cases

An important objective of GeneBEcon is to apply a **systems mapping approach**. By including the **perspectives and insights of a diverse group of stakeholders**, GeneBEcon evaluates the benefits and risks of introducing NGT-derived products in European agriculture and bioeconomy and analyses the consequences across the value chains. In a series of three system mapping workshops (2023, 2024, 2025), GeneBEcon will illustrate the complex interrelationships among scientific, social, regulatory, economic, and environmental factors that influence the debate about and the development of NGTs. The systems approach visualises this complexity with a systems map. By taking a holistic approach to understand these interconnections, potential (unintended) consequences, benefits and risks of gene editing will be identified.

In the first systems mapping workshop (Figure 5), the potato and microalgae cases were used as a starting point, identifying important elements of their production, processing and consumption. These elements were subsequently clustered in **four 'subsystems': the ecological, the economic, the social and the regulatory**. The possible impacts of introducing NGTs to these subsystems were then evaluated under two different scenarios: a "status quo" scenario where the current regulatory situation remains unchanged, and a "regulatory change" scenario enabling NGT products to obtain market approval.

The whole system would be directly or indirectly impacted when the use of NGTs would become common practice. Some of the preliminary conclusions on the status quo scenario are that it will retain an assured safety assessment, consumers will keep being properly informed through liability and traceability regimes, and no backlash in public opinion and consumer behaviour is expected. On the other hand, it would result in missed opportunities for the sustainable agriculture and bioeconomy, an R&D brain drain, and a competitive disadvantage and loss of marketing power relative to international trading partners.

For the regulatory change scenario, a key benefit is the potential contribution to a sustainable bioeconomy, healthier food due to a resource extensive and less time consuming design of plant products delivering environmental benefits, and more socio-economic opportunities and choices for breeders, farmers, industry and consumers. The costs for labelling and marketing would be reduced. On the other hand, extra costs for patents and new investments could lead to higher seed prices. Most of the identified risks stem from the social subsystem. There is a risk of public opinion backlash and any NGT introduction must be done with great care, in particular as the industry is often not seen as a trustworthy actor.[36] Therefore, a transition plan for NGTs introduction is necessary. Legal uncertainties may also arise, in particular if no traceability system exists, and farmers and consumers would not be able to choose based on preference. Therefore, a transition plan for NGTs introduction is necessary. GeneBEcon is working with stakeholders to define such NGTs transition plan under its RRI activities.

Take-home message:

New genomic techniques have a big potential to positively contribute to the bioeconomy system in Europe. The use of NGTs should be done with careful considerations because it can have intented and unintended effects (positive or negative) on the system. The best approach to study the potential consequences is by involving a group of stakeholders with diverse backgrounds and expertise.

[36] Huffman, W. E., Rousu, M., Shogren, J. F., & Tegene, A. (2004). Who do consumers trust for information: the case of genetically modified foods?. American Journal of Agricultural Economics, 86(5), 1222-1229.

Figure 5. GeneBEcon Systems Mapping workshop, Brussels, 01.03.2023.

8.2 Applying Responsible Research and Innovation for transitioning to NGT Category 1

GeneBEcon is applying the principles of Responsible Research and Innovation (RRI) in its research and innovation activities through **anticipation and reflection** of regulatory and scientific developments, **diversity and inclusion** by actively engaging a wide range of stakeholder organisations, **openness and transparency** with its activities and results, and **responsiveness and adaptive change** through three RRI engagement and co-creation workshops. The first RRI workshop already started a co-creation process, which will continue in 2024 and be finalised in 2025.

The goal of these workshops, and their intermediary work, is to actively engage stakeholder organisations to co-create an **NGT Transition Action plan** for increasing NGT desirability and use in agriculture, food industry and the bioeconomy. This RRI co-creation process started by investigating the current NGT "As-is" situation in Europe through a SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis. The priorities among weaknesses and threats were deliberated with stakeholders, to turn them into strengths and opportunities respectively with I-SMART actions. The I-SMART actions that will be specified in the final version of the NGT Transition Action Plan will be specific, measurable, assignable, realistic, time-bound (SMART) and have an impact (I-) on social objectives. The social objectives are in line with the F2F strategy, sustainable bioeconomy for Europe and the Circular Economy Action Plan.

The co-creation process will highlight the enablers, barriers and necessary actions of transitioning from the current regulatory status quo to a new regulatory situation for NGT-derived plants and products. The target groups of the NGTs Transition Action Plan are policy makers, agricultural and bioeconomy stakeholder organisations.

Take-home message:

NGT innovations bring change to value chains and perceptions, prompting regulatory and societal changes in attitudes and behaviours towards agricultural and biotechnology sustainability. In order for NGT innovation to succeed, these changes must be managed through a transition action plan.

9. Ethical considerations

The work of GeneBEcon is embedded in a number of different ethical aspects related to scientific and technological innovation, some of which are balancing each other. Whereas the **precautionary principle**, is guiding many EU policies, as an approach to risk management, there is a need to strike an appropriate balance to **innovation**, which by definition is the generation of something novel and thereby to a certain extent untested. Ideally there will be no conflict between the two principles. The European Group on Ethics in Science and New Technologies has explained in a report from 2021 that "*The use of the precautionary approach (or principle) has had a significant impact on the choice not to use genetically modified plants in Europe, even though there is little evidence of serious or irreversible damage to the widespread use of these crops in the rest of the world. Whilst there are strong proponents of the use of precaution in order to protect the environment, others argue that the concept has been used as a vehicle to stop progress*."[37] Whereas **protection from harm** is of top priority, it is also very important to safeguard the **freedom of research** and of entrepreneurial activities which will allow society to improve and thrive.

9.1 Public perceptions

There is ample evidence that NGT food products can be beneficial to the environment, to the sustainability of agricultural production, and to human health. Evidence also points to similar risk profiles of similar products, regardless of which technique (e.g. conventional, gene editing) these are derived from. The social value of freedom of choice not only takes into account the subjective freedom of the consumer, but is also based on "**informed consent**", which provides transparent scientific grounds for this. A mandatory labeling of NGTs as GMOs would entail the problem that it is not clear to the consumer that these techniques are different. In this respect, the consumer's freedom of choice must also take into account their right to make an *informed choice*.

It is important to find out what factors affect **consumers´ willingness to pay** and demand for NGT food products. To this end, GeneBEcon is studying public perceptions through consumer surveys in five countries. Analysis of public desirability of NGT food products in the GeneBEcon project considers consumers' perceptions and stakeholders' positions in addition to costs and benefits, and risk analysis of NGTs relative to products obtained by traditional breeding.

9.2 The role of science in policy-making

Informing policy through evidence is more than simply providing policymakers with the facts and the results of scientific research. The research performers also need to engage directly with the target groups and understand their perspectives and values; anticipate the policy needs and provide evidence in a timely manner; and assess the quality and robustness of the evidence. An ethical dilemma arises though between **knowledge-based and interest-based regulation**. The former is necessary for reasons of equal treatment and the comparability of breeding methods. However, in order to prevent conflicts of interest that prevent a political compromise, it is therefore appropriate to create exceptions for certain interests, such as that of organic farming, even if these are not convincing from a scientific point of view.

GeneBEcon implements **RRI for informed policy-making**. Through the workshops described in section 8, different stakeholders (including policy-makers) are engaged in mutually supportive discussions about the role of gene editing in society. These discussions serve to illustrate that the gene-edited potato and microalgae developed in GeneBEcon deliver the expected gains, that there are no safety concerns, and that the technology is robust and works as intended, and also that production systems (field cultivation,

[37] https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/6d9879f7-8c55-11eb-b85c-01aa75ed71a1

open pond, closed systems etc.) that include NGT-derived organisms can co-exist with production systems that do not include these.

Take-home message:

NGT innovations bring changes in plant research and breeding and the resulting products aim at contributing to the improvement of the environment and human well-being. However, they also entail various ethical considerations that need to be addressed to facilitate an enabling regulatory environment and a sense of acceptance among those who use products derived from these technologies, including farmers and consumers.

10. Conclusions and future outlook

The EC proposal for new NGT Regulation[38], which is briefly described in Section 5, is currently (as of December 2023) being negotiated in the European Parliament and the Council. It is difficult to predict what will be the outcome of these negotiations. The EU-funded GeneBEcon project works on many important aspects that are relevant for this legislative process and that may be taken into consideration by EU and Member State policy- and decision-makers.

GeneBEcon contributes to advancing the state-of-the-art of NGT technology through the development of a gene editing toolbox. Based on its implementation in the two case studies of potato and microalgae (section 6), the robustness and predictability of the technology will be demonstrated. There is generally a sense of confidence among the scientific research community and developers that the technology works as intended and that the outcome ”is in our hands”. It is a long road, however, from scientific progress in the laboratory to building a credible and convincing story that will appeal to the public. Public discussions must work not only on facts but also on perceptions.

Looking back at the EU GMO legislation, it was built on the concept of novelty; that the regulated products are such that do not occur naturally.[39] NGTs, on the other hand, are anticipated to close the gap between what is artificial and what occurs naturally. If we look closer at some products of for example gene editing, we see that they are in fact indistiguishable from naturally occurring products or from those that result from conventional breeding.

It is indisputable from the past two decades that assessment costs and authorisation delays resulting from the implementation of the EU GMO legislation are substantial. The question now is if, to what extent, and by which criteria, the products of new technologies will be covered by similar regulatory measures – in particular as some of these may not be considered “unnatural” in any sense of the word. The EC legal proposal appears to take certain steps in the direction of acknowledging this “conventional-like” or “natural” status of certain NGT products, however the question remains to what extent a knowledge-based vs. interest-based regulatory approach will be aimed for.

[38] EUR-Lex - 52023PC0411 - EN - EUR-Lex (europa.eu)
[39] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32001L0018

RRI Questionnaire

RRI Questionnaire

Question	Answer
1. How the RRI concept has been considered in the completed work?	RRI is relevant for informed policy-making and this is exactly what this Deliverable is about. We provide here a condensed version of some of the preliminary results from GeneBEcon and put them into context of several different EU policies, in particular those relating to the development of new technology such as gene editing.
2. Have stakeholders been consulted during the work?	Yes
a. How?	The Stakeholder Advisory Board members and the Ethical Board members have been asked to review the Deliverable.
b. What inputs have been obtained during the interaction with the stakeholders?	Feedback and comments on the draft report.
c. Have these inputs changed the considerations of the work?	Yes, we have addressed some comments, including those on the regulatory situation in non-European countries, on closing the gap between natural and artificial, on consumer trust in the food industry, on informed consent, and on knowledge-based vs. interest-based regulation.
3. In involving stakeholders, did you have to explain the science behind the work? Please explain how you did this.	No
4. Explain the Ethical procedures you are following in the course of the completed work.	As this is an important Deliverable showcasing much of the work in the project, we have consulted all project partners and asked for feedback on the texts. We have asked the Ethical Board members to review the near-final version of the Deliverable. We are aiming for a neutral and objective role in providing scientific results as input for policy developments in the European Union.
5. Have you considered any gender issues in the work?	No
a. Which ones?	-
b. How did they affect the work and/ or results?	-
6. What kind of open science actions have you included in the work and results?	This is a public deliverable that will be made openly available via e.g. the GeneBEcon website.
7. In this Deliverable/ Milestone, what kind of governance/ regulation issues do you foresee?	This Deliverable aims at providing scientific evidence as input to the policy developments on new genomic techniques (incl gene editing) in the EU. We hope that any potential new legislation on NGTs in the EU will take scientific aspects on benefits, safety, economic impact, and innovation potential into consideration.

a. What kind of change to a product-based regulatory system could enable its wider acceptance by taking into account	-
i. the development stage of the product,	-
ii. its benefits and risks, and	-
iii. its degree of certainty about its future properties.	-