European Commission

INCEPTION IMPACT ASSESSMENT

Inception Impact Assessments aim to inform citizens and stakeholders about the Commission's plans in order to allow them to provide feedback on the intended initiative and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have, including on possible impacts of the different options.

TITLE OF THE INITIATIVE	*Legislation for plants produced by certain new genomic techniques*
LEAD DG (RESPONSIBLE UNIT)	DG SANTE (Unit E3 – Biotechnology)
LIKELY TYPE OF INITIATIVE	*Legislative proposal*
INDICATIVE PLANNING	*Q2 2023*
ADDITIONAL INFORMATION	*https://ec.europa.eu/food/plant/gmo/modern_biotech_en* *https://ec.europa.eu/food/plant/gmo/modern_biotech/new-genomic-techniques_en*

The Inception Impact Assessment is provided for information purposes only. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the Inception impact assessment, including its timing, are subject to change.

A. Context, Problem definition and Subsidiarity Check

Context

In the last decades, advances in biotechnology have led to the development of new genomic techniques (NGTs). These are techniques capable of altering the genetic material of an organism that have emerged or have been developed since 2001, when the current legislation on genetically modified organisms (GMOs) was adopted. The Court of Justice of the EU in 2018 clarified that organisms produced by targeted mutagenesis[1] are GMOs, therefore subject to the requirements of the EU GMO legislation. Based on the reasoning followed by the Court, the GMO legislation also applies to organisms produced by other NGTs, including cisgenesis[1].

In November 2019, the Council requested[2] the Commission to prepare a study on the status of NGTs under EU law. The study, published in April 2021, has confirmed that NGTs have developed rapidly in many parts of the world and are expected to continue to do so on a global scale. There is significant interest both in the EU and globally for plant applications of NGTs. Some of their applications are already on the market outside the EU and this trend is likely to continue, across different sectors and countries.

The study has also concluded that plants obtained from NGTs have the potential to contribute to the objectives of the European Green Deal and in particular to the Farm to Fork and Biodiversity Strategies and the United Nations' Sustainable Development Goals (SDGs) for a more resilient and sustainable agri-food system. Examples of potential benefits include plants more resistant to pests, diseases and environmental conditions or to the effects of climate change (e.g. droughts), or requiring less natural resources and fertilisers. NGTs could also improve the nutrient content of plants for healthier diets, or reduce content of harmful substances such as toxins and allergens. At the same time, the study reported concerns linked to the use of these technologies, e.g. on their potential safety and environmental impacts, including on biodiversity, the coexistence with organic and GM-free agriculture as well as concerns on labelling and consumers' right to information and freedom of choice.

Among NGTs, targeted mutagenesis and cisgenesis can be used to produce alterations of the genetic material that can also be obtained by natural mutations or conventional breeding techniques. The European Food Safety Authority (EFSA) concluded that plants obtained by targeted mutagenesis and cisgenesis can have the same risk profile as plants produced with conventional breeding. EFSA has not yet assessed the safety of targeted mutagenesis and cisgenesis in microorganisms or animals, nor the safety of other techniques.

The Council also requested[1] the Commission to submit, if appropriate in view of the outcomes of the study, a proposal accompanied by an impact assessment, or otherwise to inform the Council of other measures required. Based on the outcome of the study, **the Commission will prepare a policy initiative on plants obtained by**

[1] In targeted mutagenesis, mutation(s) are induced in selected target locations of the genome without insertion of genetic material. In cisgenesis, genetic material (e.g. a gene) is inserted into a recipient organism from a donor organism with which the recipient is sexually compatible (crossable) in nature, e.g. a gene from a wild potato indo a domesticated potato.

[2] https://eur-lex.europa.eu/eli/dec/2019/1904/oj

targeted mutagenesis and cisgenesis, accompanied by an impact assessment. It will also cover food and feed derived from such plants (hereinafter, references to plants obtained by targeted mutagenesis and cisgenesis will refer as well to their food and feed products). Such an action follows from the study conclusions and is particularly timely in view of the potential contribution of plants obtained by targeted mutagenesis and cisgenesis to the sustainable agri-food system objectives of the European Green Deal and its related strategies, as mentioned above. The initiative shall maintain the objectives of the current legislation as regards a high level of protection of human and animal health and the environment.

Animals and microorganisms, and other NGTs, are outside the scope of this initiative; in these areas, the Commission intends to continue to build up the required scientific knowledge at this stage. Considerations related to the use of NGTs in medicinal products will be addressed in the context of the Commission's Pharmaceutical Strategy.

Problem the initiative aims to tackle

NGTs are regulated under the GMO legislation. The Commission study, however, has indicated that the current legislation is no longer fit for purpose and is in need of adaptation to scientific and technological progress for some NGTs and their products. This confirms the conclusions of the 2010-2011 evaluations of the GMO legislation as regards NGTs, which showed that ensuring the relevance of the existing legislation is likely to be an ongoing challenge. This is mainly due to:

- Legal uncertainties in Directive 2001/18/EC (and other legislation based on it) that have been intensified by developments in biotechnology. Certain terms and notions in the legislation, relevant to but not concerning only plants obtained by targeted mutagenesis and cisgenesis, are unclear or undefined (e.g. "mutagenesis", "conventional use in a number of applications", "long safety record").
- These techniques can be used to produce alterations of the genetic material that can also be obtained by natural mutations and conventional breeding techniques, or can be used to produce alterations that are more complex. Current regulatory oversight and requirements, however, are not adapted to the resulting diverse risk profiles, and in some cases can be disproportionate or inadequate. EFSA has concluded that plants produced by targeted mutagenesis and cisgenesis generally pose lower risks than plants obtained with conventional genetic modification techniques (transgenesis)[3]. However, they are subject to the same requirements. In addition, EFSA also concluded that, in some cases, plants produced by targeted mutagenesis and cisgenesis do not pose new hazards compared to plants produced with classical mutagenesis or conventional breeding techniques.
- The GMO legislation includes authorisation, traceability and labelling requirements that, for certain plants obtained by targeted mutagenesis or cisgenesis, raise implementation and enforcement challenges, as it will be difficult or impossible to differentiate them from plants from conventional breeding. In such cases, applicants might not be able to provide a specific detection method required for a marketing authorisation under the GMO legislation. The above issues impact applicants, agri-food system operators and enforcement authorities, and may also negatively affect innovation and trade.
- The current legislative framework does not take into account whether products have the potential to contribute to societal challenges, notably sustainability. It therefore lacks mechanisms to incentivise the development and placing on the market of products that contribute to the sustainability objectives of the European Green Deal and Farm to Fork and Biodiversity strategies, provided they are safe.

The main driver behind these problems is that the current framework is based on defined techniques/methods of biotechnology as understood in the late 1990s. This leads to difficulties to keep up with the rapidly evolving field of NGTs, where new techniques/methods are rapidly discovered and applied, and where the procedures currently embedded in the legislation make it difficult to adapt to the specificities of the products or to scientific advances. In addition, the current authorisation procedure was not designed to promote sustainability in the agri-food sector.

The issue is of EU magnitude; these problems could negatively affect numerous operators across the agri-food system, including in agricultural biotechnology innovation and research, non-food/feed bio-based and biotechnology industries, operators in EU trade partners, organic and GM-free operators, EU and national authorities (e.g. Member States competent authorities and evaluation bodies, especially those responsible for enforcement/detection controls, EFSA), and EU citizens and consumer organisations. The issues are of interest to a broad spectrum of stakeholders, including NGOs active in the environmental protection, agri-food system, biotechnology and consumer protection areas.

Over time, and in case of no action, the problems identified above will persist and even exacerbate, as described in the baseline scenario under section B.

[3] https://www.efsa.europa.eu/en/efsajournal/pub/2561, https://www.efsa.europa.eu/en/efsajournal/pub/2943, https://www.efsa.europa.eu/en/efsajournal/pub/6299.

Basis for EU intervention (legal basis and subsidiarity check)

The legal basis of this initiative would be Articles 43, 114 and 168(4)(b) TFEU. Organisms produced by NGTs are already regulated as GMOs by a harmonised EU-level framework based on Articles 114 TFEU (Directive 2001/18, Regulations 1829/2003 and 1830/2003) as well as Articles 43 and 168(4)(b) TFEU (Regulation 1829/2003). Any action in this area should continue to be at EU level to ensure the smooth functioning of the internal market of plants obtained by targeted mutagenesis or cisgenesis, and a high level of protection of health, environment and consumers, in accordance with Article 114 TFEU. Action at EU level would also prevent fragmentation of the internal market in case Member States decided to take their own initiatives. The action is also linked to the achievement of the objectives of EU-level strategies (notably the European Green Deal and the Farm to Fork and Biodiversity Strategies).

B. Objectives and Policy options

The envisaged policy action on plants obtained from targeted mutagenesis and cisgenesis will aim at an appropriate regulatory oversight for the concerned plant products, ensuring a high level of protection of human and animal health and the environment, and enabling innovation and the contribution of safe NGTs to the objectives of the European Green Deal and the Farm to Fork Strategy. In particular, the objectives of this initiative are to:

- Maintain a high level of protection of human and animal health and of the environment; more specifically, to ensure the placing on the market of plants produced by targeted mutagenesis or cisgenesis provided they are safe for health and for the environment.
- Enable safe plants to provide benefits and contribute to the innovation and sustainability objectives of the European Green Deal and of the Farm to Fork and Biodiversity strategies; more specifically, to ensure that the legislation takes into account whether the plants and their products contribute to sustainability, ensuring coherence with the ongoing work on a proposal establishing a framework for a Union sustainable food system.
- Enhance the competitiveness of the EU agri-food sector, and possibly beyond, and ensure a level-playing field for its operators; more specifically, to promote a future-proof legislation that is able to keep up with scientific developments, and which is proportionate to the risk involved.
- Ensure the effective functioning of the internal market; more specifically, to ensure that the legislation provides legal clarity and certainty, is enforceable and uniformly applied and sets out proportionate requirements and efficient and transparent procedures.

In the baseline scenario (status quo is maintained), plants obtained by targeted mutagenesis and cisgenesis will continue to be regulated under the current GMO framework, maintaining the current risk assessment, traceability and labelling requirements and not including a sustainability analysis. Based on the findings of the study, the cultivation and market uptake of these products is expected to be limited in the EU. In some cases, applicants might not be able to meet the traceability requirements as they stand today. Research, development and commercialisation of these products are likely to increase in most major EU trade partners that have a more enabling regulatory oversight; some of them already regulate them differently than GMOs, or do not regulate them at all, while others are now in the process of changing their legislation. With the existing difficulties in detection, the above developments are expected to further jeopardise the enforcement of the legislation, and potentially negatively impact trade and the competitiveness of EU researchers, agri-food system business operators and SMEs. Obstacles would remain for innovative plant biotechnology to contribute to the objectives of the European Green Deal and Farm to Fork Strategy, e.g. for a sustainable food system. Different interpretations of the GMO legislation at national level may further affect the correct functioning of the EU single market in the products concerned.

Different policy elements will be considered in the subsequent development of the policy options, including:

- Risk assessment and approval requirements proportionate to the risk involved, e.g. in terms of data and studies, in line with risk profiles and on a case-by-case basis, taking into account elements such as the specific technique used, the type of modification or the novelty of the trait. In this context, mechanisms to enable the applicant to identify the regulatory requirements applying to a specific product may be considered. Meeting the safety requirements would remain a prerequisite for the deliberate release or placing on the market.
- A sustainability analysis to examine whether, and in which way, these products contribute to sustainability, taking into account the criteria developed under the policy action on a sustainable food systems framework. Specific regulatory mechanisms may be considered to introduce sustainability-related requirements or incentives.
- Appropriate traceability and labelling provisions that are implementable and enforceable and take into account the capacity of plants obtained by targeted mutagenesis and cisgenesis to contribute to a sustainable food system and ensure consumers' right to make informed choices.
- Mechanisms to be able to rapidly adjust elements of the legislation and its implementation over time, as warranted by scientific and technological progress, for a future-proof regulatory framework.

The policy options will be developed on the basis of the above elements, together with other elements that might

emerge from the feedback from the public to this document and from the consultation activities. They will be assessed against the baseline scenario and compared in the Impact Assessment.

C. Preliminary Assessment of Expected Impacts

Likely economic impacts

The initiative is expected to incentivise and facilitate the development and placing on the market of safe plants obtained by targeted mutagenesis and cisgenesis and avoid potential negative consequences outlined in the baseline scenario on innovation, competitiveness, trade and missed opportunities for the agri-food system and other sectors. Concerns regarding the potential negative impact on other areas of the agri-food system (such as organic agriculture) will also need to be considered. The policy options will explore how to maximise the benefits from the positive impacts and minimise any negative ones identified.

The following potential economic impacts, and others yet to be identified (e.g. during the consultation) will be assessed during the impact assessment:

- Primary agricultural production and its capacity to address specific needs across the EU. In particular the initiative will look at levels and cost of agricultural inputs (e.g. plant protection products, fertilisers), use of natural resources, development of more resilient varieties (e.g. to environmental or specific geographical conditions and plant diseases and pests), capacity to support local agricultural solutions and reduce costs and time in plant breeding. Aspects that may impact product prices will also be explored.
- Innovation and research in the EU in agri-food system, as well as in bio-based and biotechnology industries, which may benefit from a framework providing legal clarity and a more adapted regulatory environment for plants produced by targeted mutagenesis and cisgenesis.
- Potential negative impacts for organic and GM-free agriculture and their premium retail sector (e.g. due to compliance, certification and segregation costs).
- The engagement of SMEs in the agri-food sector, which could increase due to faster product development and lower market access costs (including regulatory costs of the current authorisation procedures).
- The impact assessment will also consider issues related to the contribution of intellectual property to innovation, as well as issues concerning access to these technologies and to genetic material by economic operators.

Likely social impacts

The impact assessment should provide evidence to better understand, identify and qualify social effects. The planned initiative is intended to ensure high levels of safety and the protection of consumer health. The introduction of a sustainability analysis, to ensure products placed on the market bring a clear added value to society, will also be analysed; benefits for consumers could occur due to reduced toxin or allergen content or by improved nutritional profiles in certain products, contributing to healthy diets. Impacts affecting the variety of products meeting consumers' demand for sustainable food production will also be examined. Impacts on sustainability and biodiversity on a local level (including rural areas, supply chains and minor, niche or orphan crops that address local needs) will be assessed, taking into account the objectives of the European Green Deal and Farm to Fork and Biodiversity strategies and the 'Long term vision for rural areas' Communication.

Likely environmental impacts

The planned initiative aims to maintain a high level of environmental protection. It shall aim at facilitating the development and uptake of innovative plants that could provide direct and indirect benefits to the environment. Several of the plant products obtained from targeted mutagenesis and cisgenesis have the potential to contribute to the objectives of the European Green Deal and Farm to Fork and Biodiversity strategies and the United Nations' Sustainable Development Goals for a more resilient and sustainable agri-food system. Examples include plants more resistant to diseases and environmental conditions or climate change effects in general, improved agronomic or nutritional traits, reduced use of natural resources (e.g. water) and agricultural inputs.

At the same time, concerns exist on potential negative impacts of plants obtained by NGT on the environment and on biodiversity, e.g. due to potential displacement of traditional varieties and loss of agricultural diversity, concerns for increased use of pesticides. These possible impacts will also be assessed. Application of NGTs in the agri-food system must not undermine other aspects of sustainable food production, e.g. as regards organic agriculture, or biodiversity.

Likely impacts on fundamental rights

The initiative has the potential to contribute to a number of objectives contained in the Charter of Fundamental Rights of the EU, including the principle of sustainable development. It should ensure a high level of human health protection (Article 35), a high level of environmental protection and improvement of the quality of the environment (Article 37), and a high level of consumer protection (Article 38). The impacts on health, environment and consumers' right to information will be assessed. Adapting legal requirements for plants obtained by targeted mutagenesis and cisgenesis in accordance with their risk levels may bring new opportunities for agri-food system

and biotechnology operators, as well as researchers, and SMEs, enhancing their freedom to conduct their business.

Organic and GM-free operators have expressed concerns that their freedom to conduct business might be negatively affected. The impact assessment will identify and assess any limiting factors, with the goal of minimising them. It will also tackle potential ethical concerns related to environmental, economic and social impacts.

Likely impacts on simplification and/or administrative burden

This initiative aims at exploring options to introduce a streamlined framework, including, if and where appropriate, proportionate risk assessment, traceability and labelling requirements and approval procedures. In addition, it is expected to increase legal certainty by clarifying certain aspects, in the new legislation. It is thus expected to reduce current costs and administrative burden incurred by researchers, applicants, control and enforcement authorities, risk assessors and risk managers and other actors and which act as entry barriers for the internal market. The policy action might, introduce new requirements, which could have an administrative burden on the economic actors involved in placing these products on the EU market.

The impact assessment will quantify, to the extent possible, these positive and negative contributions to the administrative burden, with the goal of an overall net burden reduction.

D. Evidence Base, Data collection and Better Regulation Instruments

Impact assessment

An impact assessment will underpin this initiative and assess the policy options and their likely impacts. The impact assessment will take into account the evidence base and data collection outlined below, and the feedback received during the consultation process.

Evidence base and data collection

The evidence base will be built on and complement existing information gathered from past work on the topic, including the Commission study on the status of new genomic techniques, past evaluations of the GMO legislation, and work from the European Food Safety Authority[4], the European Network of GMO Laboratories, the Joint Research Centre[5], the Scientific Advice Mechanism High-Level Group and the European Group on Ethics in Science and New Technologies. In addition, a study supporting the impact assessment will be carried out.

Consultation of citizens and stakeholders

The Commission will carry out a series of consultation activities to gather data and opinions on this initiative and give any interested party the possibility to contribute. A 12-week public consultation will be carried out (indicative timing Q2 2022). To this end, a questionnaire will be available in all EU languages and replies can be made in any official EU language; it will be accessed via the Commission's 'Have Your Say' portal. A factual summary of the contributions to the public consultation will be published after its closure. The activities above will build on and take into account the information received during the comprehensive targeted consultation with Member State competent authorities and EU-level stakeholder associations that are impacted by or have expressed interest in NGTs in the context of the NGT study. The latter group encompassed agri-food business operators (including organic and GM-free sectors), the biotechnology industry, environmental and agri-food non-governmental organisations and academia/research organisations.

Will an Implementation plan be established?

The need for an implementation plan will be assessed in the Impact Assessment and will depend on further analysis of the policy options and measures; should one be needed, it will include necessary support actions for the Commission and Member States.

[4] https://www.efsa.europa.eu/en/efsajournal/pub/2561, https://www.efsa.europa.eu/en/efsajournal/pub/2943, https://www.efsa.europa.eu/en/efsajournal/pub/6299, https://www.efsa.europa.eu/en/efsajournal/pub/6314

[5] https://op.europa.eu/en/publication-detail/-/publication/5a661f2b-a180-11eb-b85c-01aa75ed71a1/language-en, https://publications.jrc.ec.europa.eu/repository/handle/JRC123830