

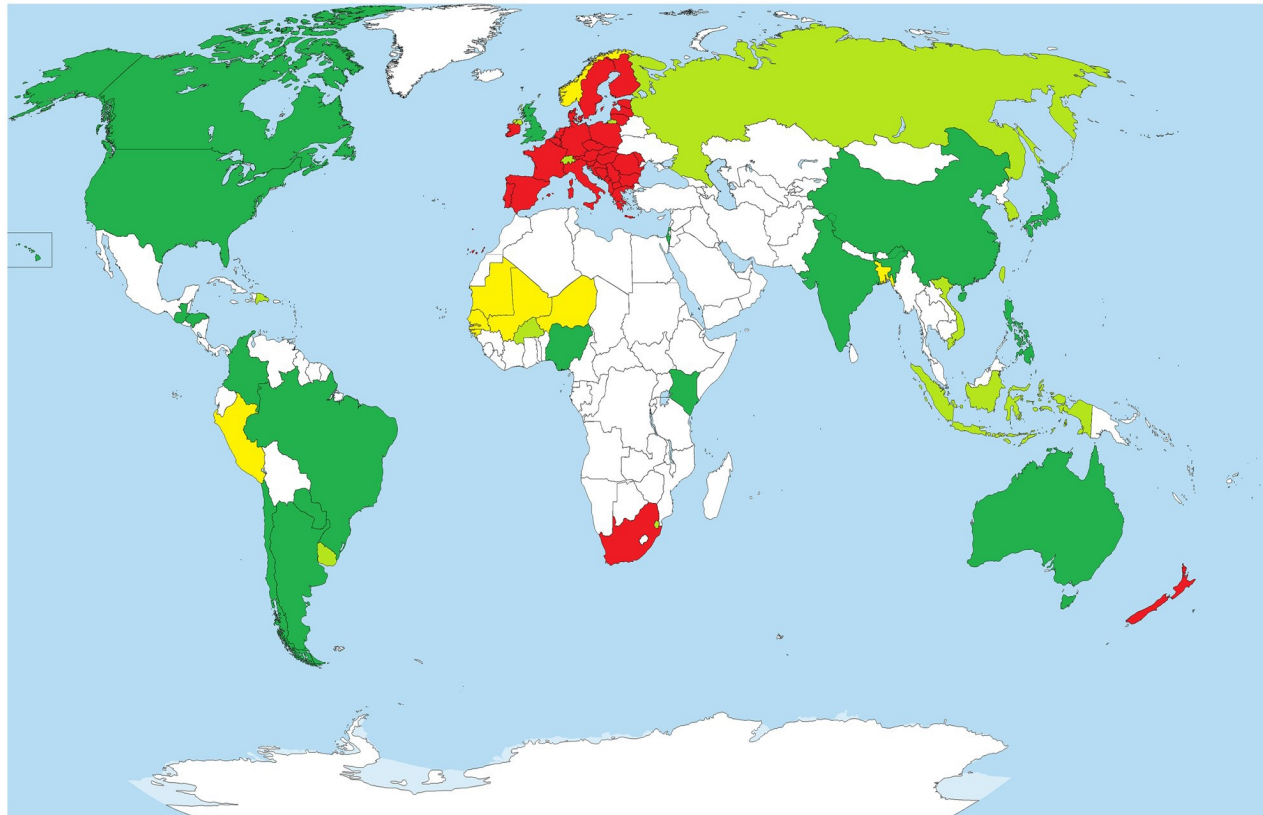
Gene Editing Regulation – Acknowledging Uncertainty

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The regulatory landscape on a global schema

Color code: Dark green: legislation open toward GEd, light green: open legislation or positive statement being prepared, yellow: discussion ongoing with no decision yet. Red: strict GMO regulation for GEd products. White: no discussion on GEd or no information available



Plant Physiol, Volume 190, Issue 3, November 2022, Pages 1579–1587, <https://doi.org/10.1093/plphys/kiac359>

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Regulatory processes – a diversity of approaches

- New animal and plant breeding techniques as CRISPR change how we do breeding (faster, cheaper and more diverse approaches)
- Are present frameworks for regulation adequate?
- Different approaches and different levels:
 - 1. *Not regulated as GMOs?***

Organisms without novel genetic material is not considered as GMOs in some countries and termed as NPBT or NGT and process for precision breeding
 - 2. *Plants versus animals***

Several genome edited plants are approved around in the world and are not regulated as GMOs and not labelled.

Argentina and Japan has approved genome edited fishes. Japan requires the fish to be labelled as genome edited in a given period.

USA, a country without a GMO legislation, may label the AquAdvantage as bioengineered.



UK, EU and Norway processes

Genetic Technology Act key tool for UK food security

New legislation unlocks key technologies to improve UK food security, reduce pesticide use, and enhance climate-resilience in our crops

Country	GM commercial cultivation	Legislation on release of GM crops	Links to GM legislation	Gene editing legislation
European Union	Only Spain and Portugal	Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed 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	https://tinyurl.com/y9yn2p8x https://tinyurl.com/y82dhdrk	Decision of the ECJ, but report and proposal requested from EU Commission (due 30 April 2021)
Norway	None	Gene Technology Act of 2 April 1993 No. 38 relating to the production and use of genetically modified organisms, etc	https://www.regjeringen.no/en/dokumenter/gene-technology-act/id173031/	None, but proposal submitted

NOU Norges offentlige utredninger **2023: 18**

Genteknologi i en bærekraftig fremtid

EU–regulatory process and expert committees

EC study on new genomic techniques (on plants)



Brussels, 29.4.2021
SWD(2021) 92 final

COMMISSION STAFF WORKING DOCUMENT

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

There are strong indications that the applicable legislation is not fit for purpose for some NGTs and their products, and that it needs to be adapted to scientific and technological progress. It may not be justified to apply different levels of regulatory oversight to similar products with similar levels of risk, as is the case for plants conventionally bred and obtained from certain NGTs.

• Background

- Supported by scientific reports as EFSA
- Took into account reports as from European Group on Ethics, European Network of GMO laboratories etc.
- Targeted consultations (online questionnaire)

SCIENTIFIC REPORT



APPROVED: 30 October 2020

doi: 10.2903/j.efsa.2021.6314

Overview of EFSA and European national authorities' scientific opinions on the risk assessment of plants developed through New Genomic Techniques

European Food Safety Authority (EFSA),
Konstantinos Paraskevopoulos and Silvia Federici

EC- regulatory process and expert committees

- Ongoing on plants (targeted mutagenesis and cisgenic)
- Hearing
 - Ca 70 000 input to the Roadmap
- Hearing more detailed including sustainability cases and questions
- Next step: commission adoption (3Q in 2023)

- What may be left out by the main focus on plants?

In preparation

Roadmap

Feedback period
24 September 2021 - 22 October 2021

FEEDBACK: CLOSED

Public consultation

Consultation period
29 April 2022 - 22 July 2022

FEEDBACK: CLOSED

UPCOMING

Commission adoption

Planned for
Second quarter 2023

FEEDBACK: UPCOMING

About this initiative

Summary

This initiative will propose a legal framework for plants obtained by targeted mutagenesis and cisgenesis and for their food and feed products. It is based on the findings of a Commission study on [new genomic techniques](#).

The aim is to maintain a high level of protection for human and animal health and the environment, enable innovation in the agri-food system and contribute to the goals of the European Green Deal and the 'Farm to Fork' strategy.

Topic

Food safety

Type of act

Proposal for a regulation

Roadmap

FEEDBACK: CLOSED

Feedback period

24 September 2021 - 22 October 2021 (midnight Brussels time)

[View feedback received >](#)



Inception impact assessment - Ares(2021)5835503
English (265 KB - PDF - 5 pages)

Download

Feedback (70894)

Norway–regulatory process and expert committees



Genteknologiutvalget

Et offentlig utvalg som skal utrede spørsmål knyttet til genteknologi, nye teknikker og reguleringen av genmodifiserte organismer (GMO)

[Aktuelt](#) [Mandat](#) [Medlemmer](#) [Sekretariatet](#) [Innspill](#) [Kontakt](#)

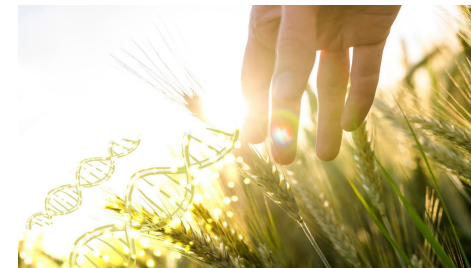
Genteknologiutvalget

Genteknologiutvalget skal utrede spørsmål og komme med råd om genteknologi, nye teknikker og genmodifiserte organismer (GMO).

Committee with 12 members appointed by the government with a broad mandate. The report published on the 6 June 2023

27 reports submitted to the hearing about the mandate one year after start up. After published a new round of hearing.

VKM
Vitenskapstoeiteen for mat og miljo
Norwegian Scientific Committee for Food and Environment



Genome editing in food and feed production – implications for risk assessment

Opinion of the Steering Committee of the Norwegian Scientific Committee for Food and Environment

EFSA guidance on risk assessment of genetically modified organisms provides a functional framework for risk assessment of genome-edited organisms (plants, animals and microorganism)

Norwegian GeneTechnology Report , all expert members agree that:
All living organisms, i.e. plants, animals and microorganisms shall be included in regulation

Regulation should promote sustainable products, include assessment of the properties of the product or the organism, take into account consumer interests and transparency.

Ethical justifiability is an overarching concept that is assessed according to four central principles; utility, sustainability, fair distribution and transparency (only GMOs)

• Majority

- The risk primarily depends on the product's characteristics, and that the risk of a product produced with gene technology does not differ from the risk of a corresponding conventional product if the genetic changes can be considered to be similar or identical.
- A significant restructuring of current regulation and administration
- The majority proposes four levels of regulation, two for PB and two for GMOs.

• Minority

- There is not a linear relationship between the technique used, the magnitude of a genetic modification, and the potential corresponding change in the organism's risk profile. This means that even small genotypic changes can have phenotypic or environmental consequences.
- A modernization of current regulations and practice to better facilitate research and innovation that can contribute to sustainable products.

2018

The Gene Technology Act – Invitation to Public Debate



	Matters of Concern for Regulation	Perception of the Current GTA
Business and industry (umbrella) organizations (8)	Competitive abilities; Communication of gene technology's benefits;	GTA strict and outdated; not rigged for the future
	Competitive abilities; Environmental challenges; Maintaining a precautionary approach	GTA neutral framework
Agricultural and environmental organizations (9)	Maintaining a precautionary approach; Consumer confidence; Democratic processes; UN sustainability goals	GTA robust and flexible, gives unique freedom of action
	Maintaining a precautionary approach; Consumer confidence; Democratic processes; Protection of ecosystems	GTA well-functioning and flexible
	Maintaining a precautionary approach; Democratic processes; Knowledge gaps; Increasing pressures on ecosystems	GTA well-functioning and flexible
Scientific institutions and environments (17)	Competitive abilities; Sustainability; Animal welfare; Patent rights; Trust	GTA outdated (or neutral); lacks clear definitions; not rigged for the future
	Hinders sustainable development	GTA strict and old;
	Knowledge gaps; Complexities; Transparency; RRI; Environmental challenges; Competitive ability	GTA well-functioning
	Change towards product-based regulation; Maintaining a precautionary approach; Environmental protection; Search for alternatives; Trust	GTA strict and unpredictable; discriminatory GTA well-functioning

Kjeldaas et al. (2021) Sustainability

The role of uncertainty in the debate

- How and what to regulate
- Definition of the process and the product
- Reason for exclusion and inclusion
- Animals, plants and microorganisms
- Medical applications
- Other uses as gene drives and in synthetic biology
- Biodiversity and the environment
- Socio-economics
- Sustainability

Are there uncertainties?

Are there many stakeholders?

Do the stakeholders hold conflicting interests?

Is the research likely relevant for policy or decision making process

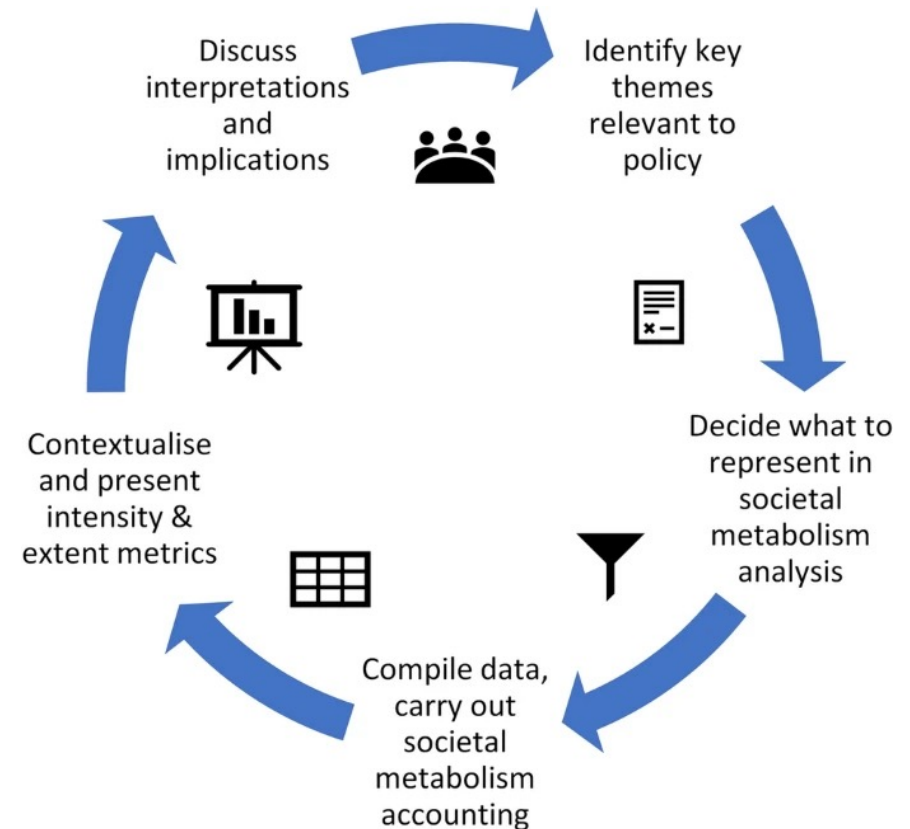
Is there a need for urgency

Post-normal approach may be relevant

Dealing with uncertainty

- **Process:** stakeholder inclusion and engagement
- **Dealing with multiple knowledge**
- What knowledge is pertinent to this context and how / with whom is it held?
- How will different knowledge claims be validated?
- What differences in understanding might exist, and how will these be dealt with?
- **Managing uncertainty**
- What level of technical and epistemic uncertainty exist? And how are these types of uncertainty addressed within the process?
- How can uncertainty and trade-offs be made transparent to all involved?

Ainscough et al (2018) Ecosystem Services



Blackstock et al (2023) Sustainability science

Citizen engagement for a responsible governance of GM and genome editing

- Need to develop a broad knowledge base for responsible governance in the agricultural and aquaculture sectors.
- Citizens' opinions about science and its applications are expressions of value systems (vs. the knowledge-deficit model).
- People's contribution is a necessary complement to the approaches represented by experts (scientists, technologists, ethicists).
- Goal: To create a public discourse on how relevant public values should function as a guide for the development and regulation of GM and GE.

