
The Regulation of New Genomic Techniques in the EU



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GMOs legislation

- It depends on each country.
 - The EU has its own regulation.
 - The definition of GMO is not the same all over the world.
 - Labelling of GMO products in the marketplace is required in many countries. In Canada and the US labelling of GM food is voluntary, while in Europe all food or feed which contains greater than 0.9% of approved GMOs must be labelled.
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The European Union has established a **legal framework** to ensure that the development of modern biotechnology, and more specifically of GMOs, takes place in safe conditions.



Food Safety

The legal framework aims to:

- **Protect human and animal health and the environment** by introducing a safety assessment of the highest possible standards at EU level before any GMO is placed on the market.
- Put in place **harmonised procedures** for risk assessment and authorisation of GMOs that are efficient, time-limited and transparent.
- Ensure **clear labelling** of GMOs placed on the market in order to enable consumers as well as professionals (e.g. farmers, and food feed chain operators) to make an informed choice.
- Ensure the **traceability** of GMOs placed on the market

The building blocks of the GMO legislation are:

- [Directive 2001/18/EC](#) on the deliberate release of GMOs into the environment
- [Regulation \(EC\) 1829/2003](#) on genetically modified food and feed
- [Directive \(EU\) 2015/412](#) amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory
- [Regulation \(EC\) 1830/2003](#) EN concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms
- [Directive 2009/41/EC](#) on contained use of genetically modified micro-organisms. [Regulation \(EC\) 1946/2003](#) on transboundary movements of GMOs

Definition of GMO in the Directive 2001/18/EC

„Genetically modified organism (GMO)“ means an organism, with the exception of human beings, in which the **genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination**;

Within the terms of this definition:

- (a) genetic modification occurs at least through the use of the techniques listed in [Annex I A, part 1](#);
- (b) the techniques listed in [Annex I A, part 2](#), are not considered to result in genetic modification;

GMO

- (1) **recombinant nucleic acid techniques** involving the formation of new combinations of genetic material by the **insertion of nucleic acid molecules** produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation **into a host organism in which they do not naturally occur but in which they are capable of continued propagation**;
 - (2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including **micro-injection, macro-injection and micro-encapsulation**;
 - (3) **cell fusion** (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.
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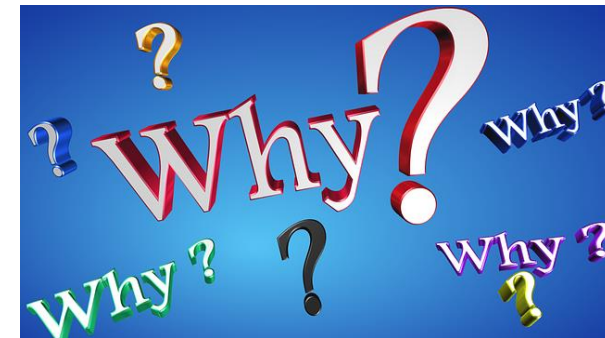
No
GMO

- (1) in vitro fertilisation,
- (2) natural processes such as: conjugation, transduction, transformation.
- (3) polyploidy induction.

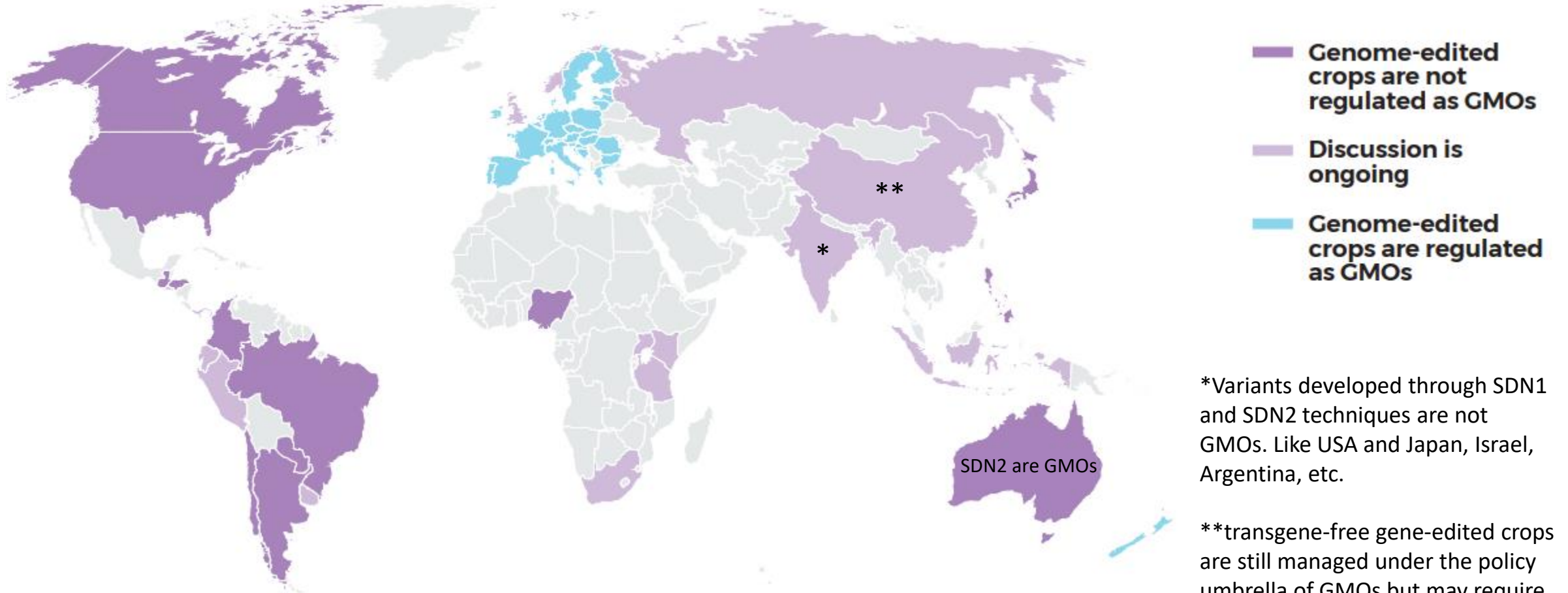
As an EXEMPTION this Directive shall not apply to organisms obtained through the techniques of genetic modification listed in [Annex I B](#).

GMO
but
exempted

- (1) mutagenesis,
- (2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.



AND WHAT ABOUT REGULATION OF GENE EDITING?



Organisms obtained by mutagenesis (including genome editing) are GMO



Press and Information

Court of Justice of the European Union

PRESS RELEASE No 111/18

Luxembourg, 25 July 2018

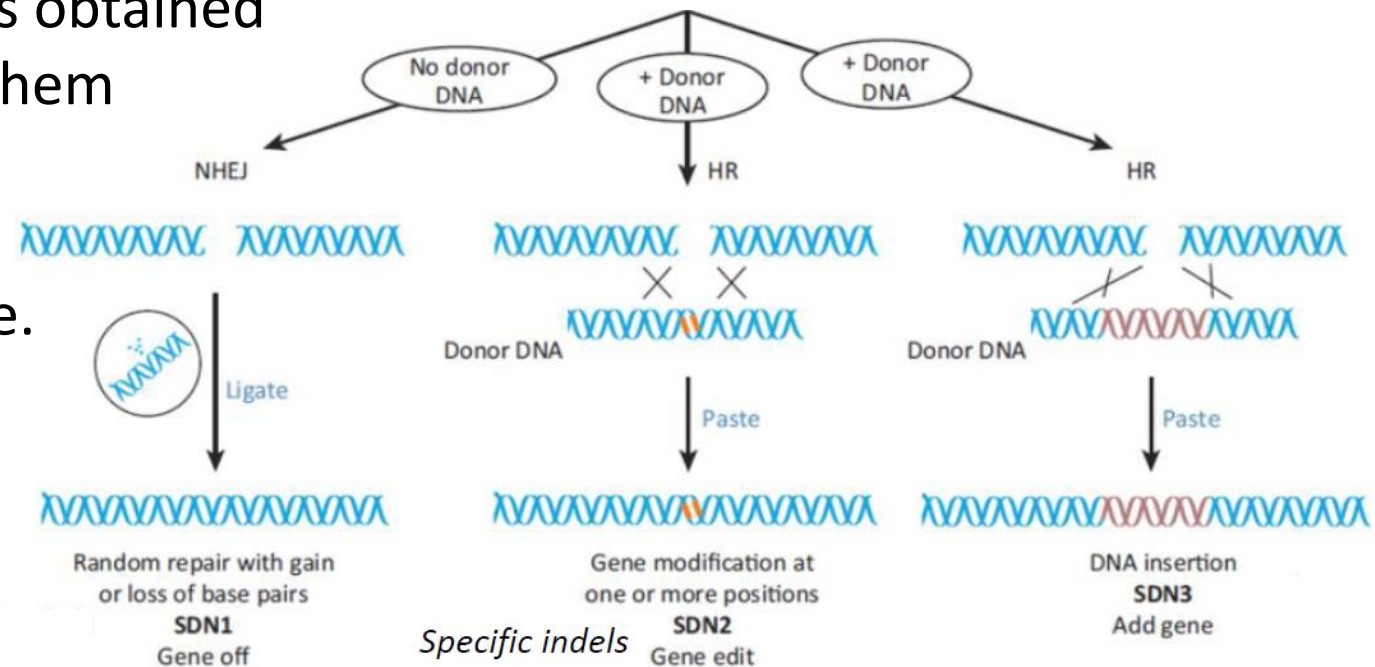
Judgment in Case C-528/16

Confédération paysanne and Others v Premier ministre and Ministre de
l'Agriculture, de l'Agroalimentaire et de la Forêt

Organisms obtained by mutagenesis are GMOs and are, in principle, subject to the obligations laid down by the GMO Directive

However, organisms obtained by mutagenesis techniques which have conventionally been used in a number of applications and have a long safety record are exempt from those obligations, on the understanding that the Member States are free to subject them, in compliance with EU law, to the obligations laid down by the directive or to other obligations

- The background on the case C-528/16 is the request by the French Conseil d'État after the Confédération Paysanne (agricultural union) together with eight other associations contested the French legislation concerning mutagenesis and genetic modifications.
- Many of the new breeding techniques including SDN1/2 (CRISPR or not) can be considered as a form of mutagenesis. The Court of Justice of the EU found that organisms obtained by the new mutagenesis techniques are subject to the GMO directive. Now the interpretation is that organisms obtained by mutagenesis are GMO, but some of them (conventional) are exempt from GMO legislation. The new mutagenesis techniques are subject to GMO Directive.



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- The scientific community and other stakeholders reacted against this ruling stating that it ignores scientific evidence and *de facto* blocks the introduction of crops obtained using New Genomic Techniques to the EU market.
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Brussels, 29.4.2021
SWD(2021) 92 final

EC STUDY ON NEW GENOMIC TECHNIQUES

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

The Council of the European Union asked for the study, regarding the status of new genomic techniques under Union Law, in light of the Court of Justice's judgment in Case C-528/16.

- For this study, NGTs are defined as techniques capable to change the genetic material of an organism and that have emerged or have been developed **since 2001, when the existing GMO legislation was adopted.**
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Some conclusions of the study:

- There are strong indications that the current GMO legislation is not fit for purpose for some NGTs and their products, and that it needs to be adapted to scientific and technological progress.
 - **The Commission also concludes that NGT products have the potential to contribute to sustainable agri-food systems in line with the objectives of the European Green Deal and the ‘farm to fork’ strategy.** Both of these seek to improve the sustainability of the agri-food system, while also highlighting climate change challenges and noting that biotechnology can play a role, for example, in **reducing dependency on pesticides, developing plants that are more resistant to climatic conditions, as well as contributing to food security and a more sustainable food chain.**
 - Drawing generalized conclusions about their safety is impossible. Case-by-case assessment, the study argues, is widely recognized as the appropriate approach.
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May to July 2022: public consultation of the EC

Questions related to:

- the potential contribution to **sustainability** of the modified trait. How should the information on the sustainability benefits of a modified trait to a plant be made available to the consumer?
- **Traceability**
- **Labelling**

October 2022:

Upon request from the European Commission, EFSA (European Food Safety Authority) proposed **criteria for the risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis.**

July 2023: European Commission's legal proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed

- The EC suggest a more relaxed regulation of NGT plants.
 - **category 1 NGT plants:** plants that could also occur naturally or be produced by conventional breeding techniques and their progeny obtained by conventional breeding techniques
 - **category 2 NGT plants:** the other ones. They remain subject to the requirements of the Union GMO legislation. Risk assessment will vary on a case-by-case basis.
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PROBLEMATIC:

A NGT plant is considered equivalent to conventional plants (NGT1) when it differs from the recipient/parental plant by **no more than 20 genetic modifications**. The substitution or insertion should be of **no more than 20 nucleotides**.

All NGT plants excluded from organic farming.

The verification procedure of NGT1 plant status prior to **field trials** should be conducted by national competent authorities, and a decision should be taken at the Union level only if there are comments to the verification report by other national competent authorities.

Negotiations among the member states and in European Parliament have introduced several possible amendments to the original legal proposal put forward by the European Commission.

Good change:

“ 20 modifications“ accounts for the genome size and structure regarding polyploid plants and such plants with large genomes.

Dangerous changes:

NGT1 should be labelled, go through a risk assessment, traceability all the time.

Important:

Text on Intellectual Property Rights (IPR) should not be included in the NGT legislation.



PLENARY VOTE OF THE EUROPEAN PARLAMENT (JANUARY 2024):

Parliament adopted its position for negotiations with member states on the [Commission proposal](#) on New Genomic Techniques (NGTs), which alter the genetic material of an organism, with 307 votes to 263 and 41 abstentions.

The objective is to make the food system more sustainable and resilient by developing improved plant varieties that are climate resilient, pest resistant, and give higher yields or that require fewer fertilisers and pesticides.

<https://www.europarl.europa.eu/news/en/press-room>

Council

Voting calculator

Countries participating	Votes
<input checked="" type="checkbox"/>  Austria 2.00% of population	<input checked="" type="radio"/> <input checked="" type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Belgium 2.60% of population	<input checked="" type="radio"/> <input type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Bulgaria 1.53% of population	<input checked="" type="radio"/> <input type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Croatia 0.86% of population	<input checked="" type="radio"/> <input checked="" type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Cyprus 0.20% of population	<input checked="" type="radio"/> <input checked="" type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Czech Republic 2.36% of population	<input checked="" type="radio"/> <input type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Denmark 1.31% of population	<input checked="" type="radio"/> <input type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Estonia 0.30% of population	<input checked="" type="radio"/> <input type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Finland 1.24% of population	<input checked="" type="radio"/> <input type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  France 15.16% of population	<input checked="" type="radio"/> <input type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Germany 18.59% of population	<input checked="" type="radio"/> <input type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Greece 2.37% of population	<input checked="" type="radio"/> <input type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Hungary 2.17% of population	<input checked="" type="radio"/> <input checked="" type="radio"/> <input type="radio"/>

Voting rule

Qualified majority


Final result
Rejected

27 member states
Minimum "Yes" required for adoption: (55%) 15



0% Population
Minimum "Yes" required for adoption: 65%



<input checked="" type="checkbox"/>  Éire/Ireland 1.13% of population	<input checked="" type="radio"/> <input type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Italy 13.32% of population	<input checked="" type="radio"/> <input type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Latvia 0.42% of population	<input checked="" type="radio"/> <input type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Lithuania 0.63% of population	<input checked="" type="radio"/> <input type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Luxembourg 0.14% of population	<input checked="" type="radio"/> <input checked="" type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Malta 0.12% of population	<input checked="" type="radio"/> <input type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Netherlands 3.96% of population	<input checked="" type="radio"/> <input type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Poland 8.41% of population	<input checked="" type="radio"/> <input checked="" type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Portugal 2.31% of population	<input checked="" type="radio"/> <input type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Romania 4.25% of population	<input checked="" type="radio"/> <input checked="" type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Slovakia 1.21% of population	<input checked="" type="radio"/> <input checked="" type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Slovenia 0.47% of population	<input checked="" type="radio"/> <input checked="" type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Spain 10.60% of population	<input checked="" type="radio"/> <input type="radio"/> <input type="radio"/>
<input checked="" type="checkbox"/>  Sweden 2.33% of population	<input checked="" type="radio"/> <input type="radio"/> <input type="radio"/>

I: Agreement before the elections

Council reaches
general
approach

Inter-
institutional
negotiations

Provisional
agreement

EP vote

Council
approves

Law adopted

II: Continuation after the elections

Council reaches
general
approach later
than February

Process paused

6-9 June 2024
Elections

New Parliament:
Continue with
the mandate or
start over

As outlined
above

III: The process stops in the Council

The Council does not reach a general approach

No law adopted

Slide prepared by Dr. Jarka Chloupková, ECR Policy Advisor



Iceland 
Liechtenstein
Norway grants

**THANK YOU FOR
LISTENING!**

EditGrass4Food

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