The EU Regulation on plants obtained by NGT's

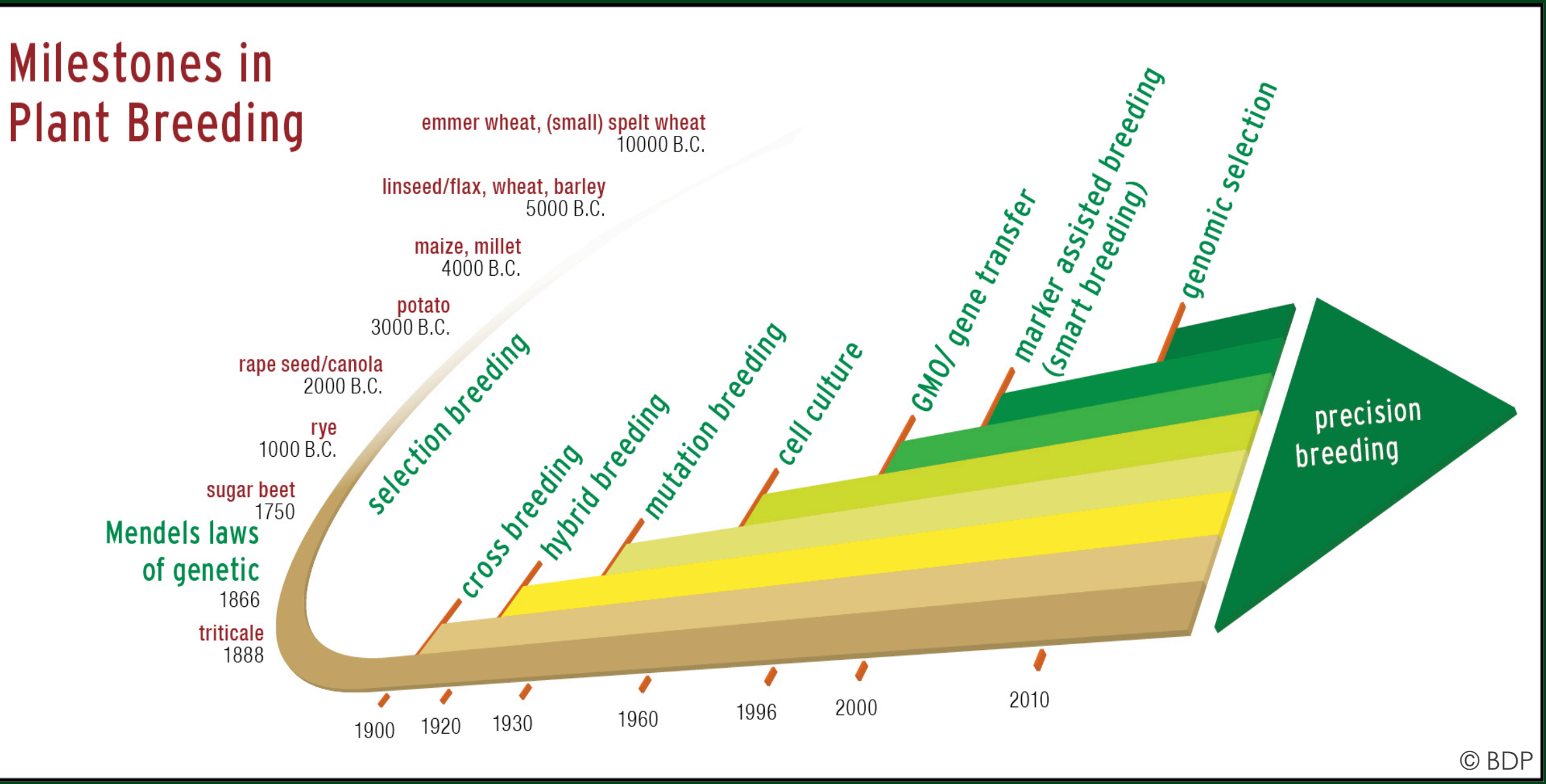
An extension of the breeders toolbox

2 july 2026

Arend Streng

RIJK ZWAAN

Development of plant breeding



Legal framework EU

- Classical – transgenic – GMO's are subjected to the EU Directive 2001/18 for experimental introduction and commercialisation purposes
- Plants obtained from random mutagenesis and cell fusion (of crossable species) are exempted from scope ('shall not apply')
- GMO's in vegetables are rare (3 known examples worldwide) and economically not very interesting.

Definition of a GMO in 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;
- Art. 3 Exemptions:
  This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B.

Definition of a GMO in Directive 2001/18/EC

- genetic modification occurs through the use of the techniques of
  (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.

Definition of a GMO in Directive 2001/18/EC

- the following techniques are not considered to result in genetic modification;
  (1) in vitro fertilisation,
  (2) natural processes such as: conjugation, transduction, transformation,
  (3) polyploidy induction.

Definition of a GMO in Directive 2001/18/EC

Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:

(1) mutagenesis,

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

‘Intermediate’ clarity

- In 2018, the Court of Justice of the European Union (in C528/16) ruled that “only organisms obtained by means of techniques/methods of mutagenesis which have been conventionally used in a number of applications and have a long safety record are excluded from the scope of that Directive”.
- So: plants obtained by gene and genome editing are considered GMO’s

Start of a long process

Studies by:

- SAM (2017)
- JRC (2021)

Consultation activities:

- Inception impact assessment
- Public consultation
- Targeted consulation

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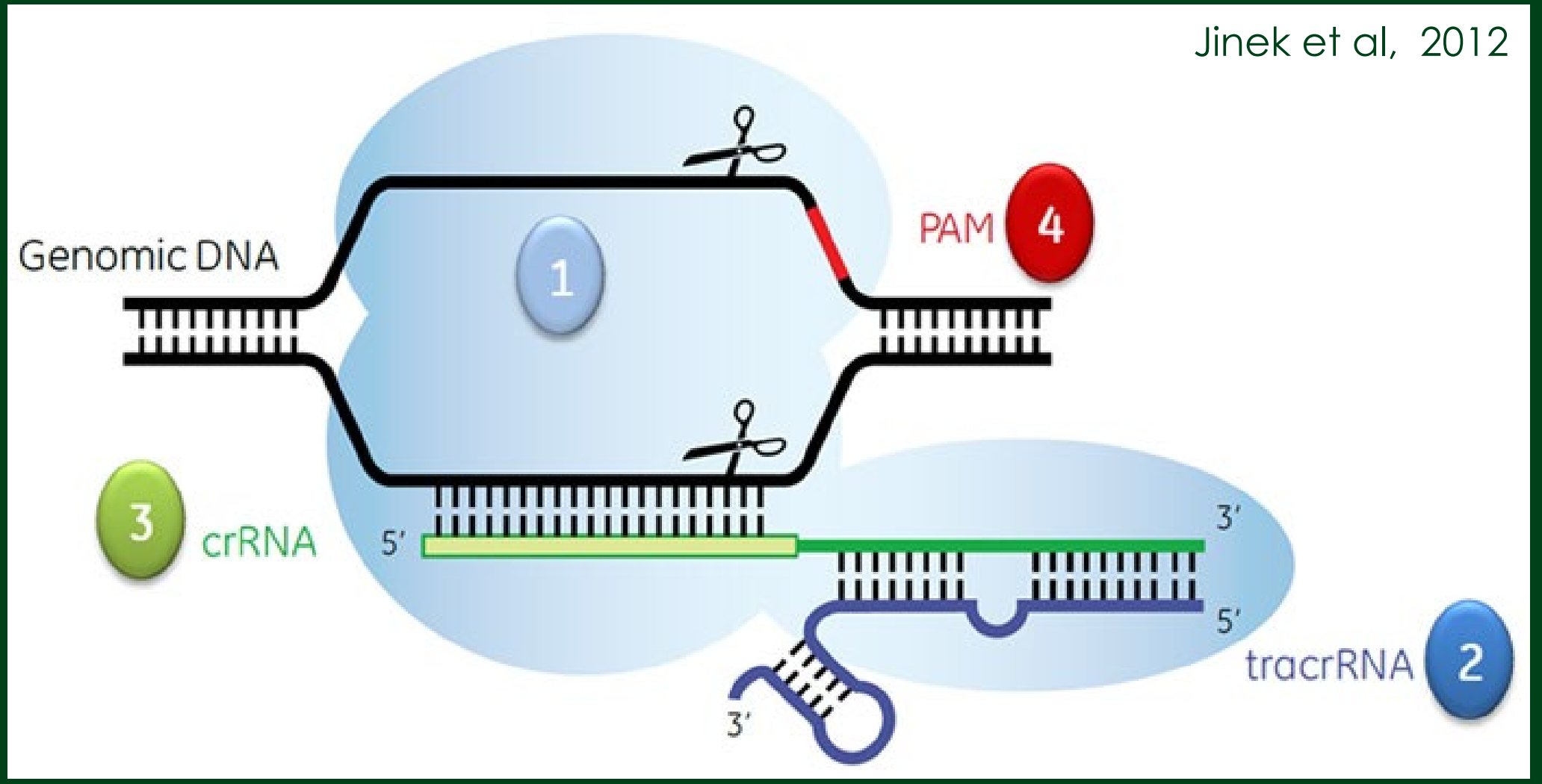
Proposal by European Commision in july 2023

- Additional piece of law: regulation (besides the known GMO Directive 2001/18
- Focused on ‘certain new genomic techniques’:
  - Targeted mutagenesis
  - Cisgenesis
- Published on the same day as the plant reproductive material (PRM) regulation

Targeted mutagenesis and cisgenesis



Decision making process in the European Union

European Union – how are decisions made?

Three **institutions**:

European Parliament

European Commission

European Council

New Laws start at the Commission…

The Commission has the ‘right of initiative’

… and continue with Parliament and Council

… and continue with Parliament and Council

European Parliament

Elected directly – elections June ‘24
720 Members

Composed of Member States ministers – elected nationally

… and continue with Parliament and Council

European Parliament writes changes to proposals.

These are voted on in committees & adopted in a plenary session.

End product is an amended version of the original proposal.

… and continue with Parliament and Council

European Council experts negotiate the proposal article-by-article

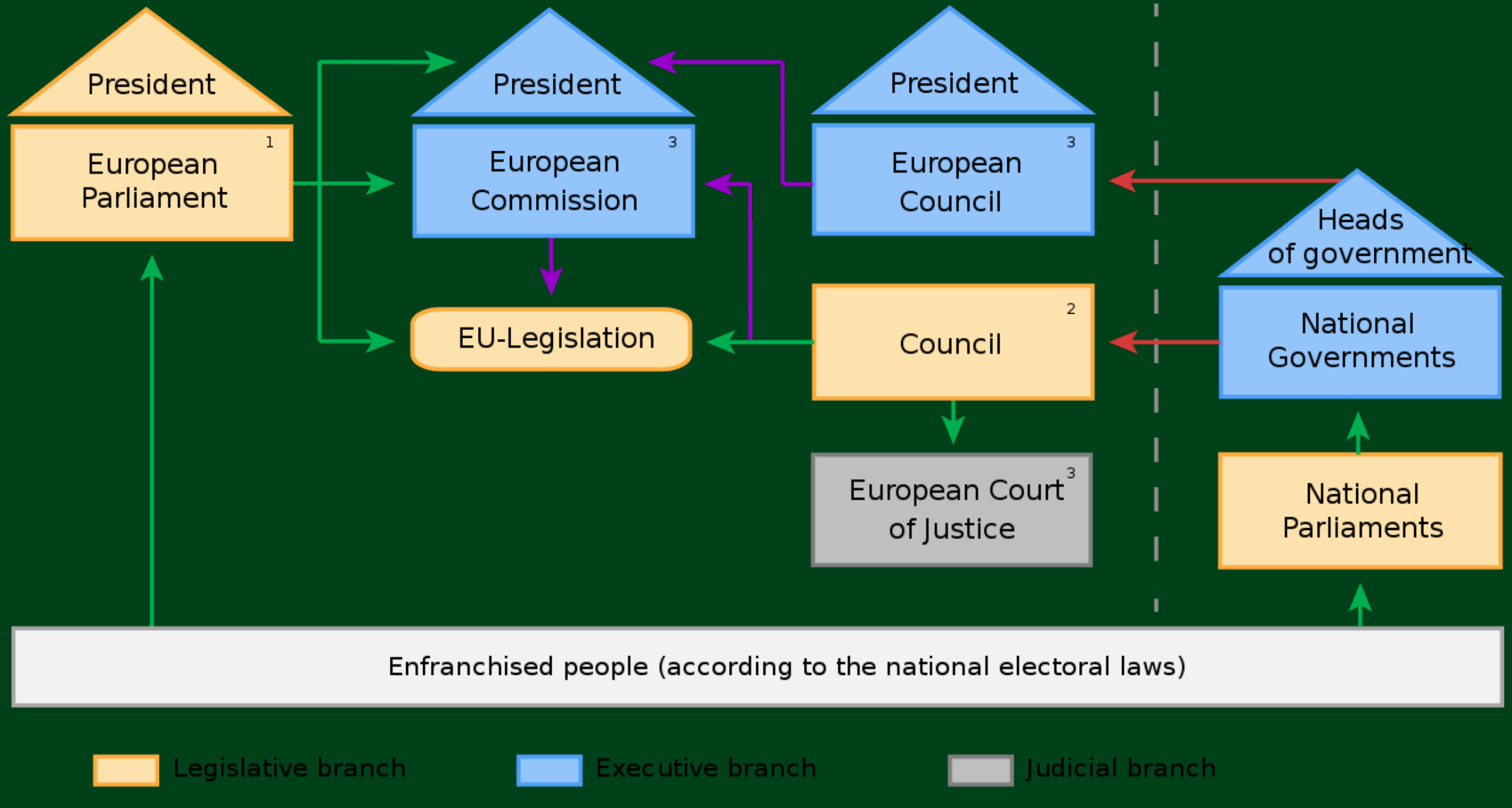
End product is a ‘Compromise Text’

This text needs approval from a Qualified Majority of Member States

Now all three institutions have their version

If negotiations fail – back for round 2!

If negotiations succeed


President
European Parliament
1
President
European Commission
3
President
European Council
3
Heads of government
National Governments
EU-Legislation
Council
2
European Court of Justice
3
National Parliaments
Enfranchised people (according to the national electoral laws)
Legislative branch
Executive branch
Judicial branch
member
proposes
elects / appoints / decides

New genomic techniques

- Proposal accepted by European Parliament (in amended form) in February and April ‘24
- European Council endorsed a negotiating mandate in March ‘25
- So called ‘trilogue’ expected to start in April ‘25

New genomic techniques

Amendments Parliament

Annex 1 amended

Labelling throughout the chain

NGT1 plant should also comprise one sustainable trait

- Herbicide tolerance cannot be NGT1

Prohibition for organic market remains

Limitation of patentability

- Plants obtained with NGTs
- Plants obtained with classical mutagenesis
- Genetic information

NGTs and sustainability

- yield
- tolerance/resistance to biotic stresses
- tolerance/resistance to abiotic stresses
- more efficient use of resources
- characteristics that enhance the sustainability of storage, processing etc.
- improved quality or nutritional characteristics
- reduced need for external inputs

NGT1 plant cannot be a herbicide tolerant plant

- Fear of creating weeds that are resistant to herbices, therefore requiring higher dosages of herbicides.
- Political and societal pressure from France
- Multiple court cases before le Conseil d'Etat filed by French NGO's on herbicide plants obtained by traditional mutagenesis.

New genomic techniques
Amendments Council

Annex I is amended
For NGT1 plants, patent information needs to be disclosed

- Optionally, willingness to license can be declared
- This will be publicly available in database

Herbicide tolerance cannot be a NGT1 trait

New genomic techniques Amendments Council

- **For NGT2 plants, GMO like restrictions are proposed**
- Opt-out possibility for cultivation
- Optional co-existence measures to avoid unintended presence
- Labelling also for plants

Patenting expert group and study

Gene and genome edting: regulatory considerations

- Trilogue started in May 2025, which is a negotiation process between Council, Commission and Parliament.
- In December 2025, a provisional agreement was reached between the European Council and the European Parliament, paving the way for future EU legislation.
- In June 2026, an ENVI commission and plenary vote in the European Parliament confirmed this (with no amendments accepted to the text agreed to in December 2025)
- A transition period is triggered which might result in the first GE products/plants entering the verification procedure in the middle of 2028, and subsequentially the market 3-6 months later.
- The regulation “shall apply from 17 July 2028. However, Articles 29, 30 and 31 shall apply from 16 July 2026.

Voting procedure

- In total 37 amendments were tabled, mainly on traceability, labeling and IP
- Members of the ENVI commission have rejected all amendments
  - Rejection of the proposal: 69 against, 21 in favor, 0 abstentions
  - Council position at first reading: 31 against, 58 in favor, 0 abstentions

- Wednesday 17 June, the plenary meeting of the EP parliament will vote.
- Same amendments were tabled, also others
  - Rejection of the compromise text: 341 against, 201 in favor, 29 abstentions
  - No amendments were accepted
- Any change by EP would have re-opened the entire file. That was not the case.

Going into detail: what is it all about?

- This concerns a new piece of additional law: a regulation.
- It introduces verification procedures for NGT1 and NGT2 plants.
- Labelling is required for seeds and other plant reproductive material, but not for the NGT1 plants and their products as such.
- A list of intended traits that shall be excluded from the NGT1 category is agreed on.
- When applying to register a NGT1 plant, information on patent applications should be provided and will be published in a public database.
- An intention to license the use of a patented NGT1 plants might be provided.
- A patenting expert group will be created, focusing on the effect of patents.
- A study on the impact of patenting shall be published by the Commission.

Definitions

- ‘NGT plant’

means a genetically modified plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, and not containing any genetic material originating from outside the gene pool for conventional breeding purposes that might have been temporarily inserted during the development of that plant;

- ‘Category 1 NGT plant’

fulfils the criteria of equivalence to conventional plants set out in Annex I and does not include any trait listed in Annex II among the traits intended to be conveyed by the genetic modifications; **or**

is the progeny of NGT plants as referred to in point (a), including progeny obtained by crossing of such plants, and contains no further modifications obtained through targeted mutagenesis, cisgenesis or other techniques that would make it subject to Directive 2001/18/EC or Regulation (EC) No 1829/2003;

Definitions

- ‘Category 2 NGT plant’

means an NGT plant other than a category 1 NGT plant;

- ‘produced from NGT plants’

means derived, in whole or in part, from NGT plants, but not containing or consisting of NGT plants;

- ‘NGT product’

means food and feed containing, consisting of or produced from NGT plants, and products, other than food and feed, containing or consisting of such plants;

Verification processes

- Two different verification processes are provided for NGT1 plants:
  - Art. 6: for requests submitted prior to the deliberate release for any other purpose than placing on the market
  - Art. 7: for requests submitted prior to the placing on the market of NGT products
- Art. 6 procedure is done with a competent authority in a member state; reasoned objections may be filed by Commission or other member states; turnaround time: 12 to 19 weeks.
- Art. 7 procedure is done with EFSA; no reasoned objections possible; turnaround time: 12 weeks, with possibly additional time.
- Verification process for NGT2 plants will take 6 months at the fastest.

What should be submitted with verification?

(a) the name and the address of the requester;

(b) the designation and specification of the NGT plant;

(c) a description of the trait(s) or traits and characteristics which have been introduced or modified;

(d) a copy of the studies, including relevant DNA sequence information, and any other available material to demonstrate that:

(i) the plant is a NGT plant, including information on the technique or techniques used to obtain it, and information that it does not contain any genetic material originating from outside the gene pool for conventional breeding purposes where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the delegated act adopted in accordance with Article 25a(a)

What should be submitted with verification?

(ii) the NGT plant meets the criteria set out in Annex I;

(e) in the cases referred to in paragraph 2, an indication of the Member States in which the requester intends to undertake the deliberate release;

(f) an identification of the parts of the verification request and any other supplementary information that the requester demands to be treated as confidential, accompanied by verifiable justification, pursuant to Article 11 of this Regulation and Article 39 of Regulation (EC) No 178/2002.

Labeling, Annex 2 and organics

- Labeling requires indication of ‘cat 1 NGT’, followed by the identification number of the NGT plant(s) it has been derived from for ‘plant reproductive material, including for breeding and scientific purposes’.
- Traits (…) that exclude NGT plants from category 1 status

  (1) tolerance to herbicides

  (2) production of a known insecticidal substance
- NGT1 and NGT2 plants are not allowed in organic production. (Art. 5)

Patents – part of verification process

- Art. 6/7 :
  "Together with the verification request, the requester shall submit information, to the best of its knowledge, on patents or published patent applications including one or more claims on the biological material of the NGT plant, or declare the absence of such patents or published patent applications."
- "Together with the verification request and the patent information referred to in paragraph 5, the requester may submit a written declaration of the holder of a patent identified under paragraph 5 confirming the patent holder's willingness to license the protected subject matter under fair and reasonable conditions in all Member States where the patent holder is entitled to grant such a licence."

Patents – part of verification process

- Art. 6/7:
- "If the requester is the patent holder, it shall submit a written declaration clarifying whether:
  (a) it is willing to license the protected subject matter under fair and reasonable conditions in all Member States where it is entitled to grant such a licence; and
  (b) it is, or intends to become, a member of relevant and appropriate licensing platforms.
- The patent information referred to in paragraph 5 and the licence declarations referred to in paragraph 6 shall not be subject to verification and shall have only declaratory value.
- NB: no patent information requirement for NGT2 plants.

NGT1 vs NGT2

- The provisional agreement on the regulation defines a ‘category NGT1 plant’ as

  (a) fulfils the criteria of equivalence to conventional plants, set out in **Annex I**, and does not include any trait listed in **Annex II** among the intended traits to be conveyed by the genetic modifications, or

  (b) is the progeny of NGT plants referred to in point (a), including progeny obtained by crossing of such plants, and contains no further modifications obtained through targeted mutagenesis, cisgenesis or other techniques that would make it subject to Directive 2001/18/EC or Regulation (EC) No 1829/2003;

- A ‘category 2 NGT plant’ means a NGT plant other than a category 1 NGT plant;
- A NGT1 plant/variety can – after a verification procedure – be marketed as a plant/variety obtained by conventional breeding, except for the organic market.
- A NGT2 plant/variety will – after a verification procedure – marketed as a GMO plant/variety and is therefore also not available for the organic market.

Annex 1: defines the boundaries of NGT1

Criteria of equivalence of NGT plants to conventional plants

A NGT plant is considered equivalent to conventional plants (and thus NGT1) if the genetic modifications introduced by the new genomic technique(s) meet the following conditions:

1. In the case of plants obtained by targeted mutagenesis, the number of the following genetic modifications, does not exceed **3 per each protein-coding sequence** taking into account that **genetic modifications in introns and regulatory sequences are excluded** from this limit:

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

   (b) deletion of any number of nucleotides;

Annex 1: defines the boundaries of NGT1

2. In the case of plants obtained by cisgenesis, the genetic modifications:
   (a) consist of any of the following types:
      (i) insertion of continuous DNA sequences existing in the gene pool for conventional breeding purposes;
      (ii) substitution of endogenous DNA sequences with continuous DNA sequences existing in the gene pool for conventional breeding purposes;
      (iii) inversion or translocation of continuous endogenous DNA sequences ;
   (b) and fulfil one or both of the following conditions:
      (i) they result in a combination of DNA sequences that occurs in the gene pool for conventional breeding purposes; or
      (ii) they do not lead to interruptions of endogenous genes, including those interruptions that create chimeric proteins.
3. The genetic modifications referred to in points 1 and 2 in any combination do not exceed the number of 20 per monoploid genome.

Annex 2 exlusions from NGT1

- Traits referred to in article 3 (13)(a) that exclude NGT plants from category 1 status:

  (1) Tolerance to herbicides
  (2) Production of a known insecticidal substance

Art. 29: Guidance

1. By 17 July 2028, the Authority shall publish detailed guidance to assist requesters, notifiers and applicants in the preparation and the presentation of the verification requests, the notifications and the applications referred to in Chapters II and III and for the implementation of Annex III.

2. By 17 July 2028, the EURL, assisted by the ENGL, shall publish detailed guidance to assist the notifier or the applicant for the application of Article 14(1), point (l), and Article 20(2).

3. By 17 July 2028, the Commission shall publish, and thereafter review and update if needed, guidance for the purpose of assisting operators, in particular breeders and farmers, on matters relating to plant intellectual property. The Commission shall consult the competent intellectual property offices of the Member States when drafting the guidance. The guidance

- shall include information on:

- (a) plant licensing platforms;

Art. 29: Guidance

The guidance shall include information on:

- (a) plant licensing platforms;
- (b) public organisations that have the purpose of assisting plant breeders with intellectual-property-related questions;
- (c) databases allowing operators to identify the intellectual property rights which apply to a given plant;
- (d) basic information on intellectual property rights relevant to plants, including on conditions for obtaining protection, rights conferred and their limitations, as well as compulsory cross-licensing.

4. By 17 July 2028, the Commission shall publish information for operators, with particular emphasis on breeders, about the opportunities to benefit from the various programmes, financial mechanisms and policies designed to support research and development in the area of new genomic techniques.

Art. 30: Code of conduct

1. The Commission, in cooperation with the Member States, shall oversee the drawing-up of a code of conduct at Union level to enhance the transparency of information relating to patents on plant biological material, to facilitate breeders' access to such material and to enhance legal certainty for breeders and farmers ('code of conduct').
2. The Commission shall invite the owners of patents relating to NGT plants, representatives of voluntary platforms for the licensing of patents on plant biological material, plant breeder and farmer organisations as well as other civil society organisations and other interested parties, as appropriate, to participate on a voluntary basis in the drawing-up of the code of conduct.

Art. 30: Code of conduct

3. The Commission shall aim that the code of conduct include the following commitments by patent owners:

(a) the provision of clear, comprehensive and publicly accessible information on patents and patent applications covering biological material incorporated in plant varieties placed on the market in the Union;

(b) arrangements for the licensing of patents under fair and reasonable conditions, including through the voluntary platforms referred to in paragraph 2;

(c) the amicable settlement of patent disputes involving breeders which are SMEs, or involving farmers in the case of unintentional minor presence of patented biological material in their fields.

Art. 30: Code of conduct

6. The Commission shall monitor the rate of participation in, and the functioning of, the code of conduct and the achievement of its aims, as referred to in paragraphs 1 to 5.

7. By 17 July 2033 and every five years thereafter, the Commission shall publish a report on the evaluation of the functioning of the code of conduct. In its evaluation, the Commission shall examine the results of the drawing-up of the code of conduct referred to in paragraphs 1 to 5 and of the monitoring referred to in paragraph 6. In this context, the Commission shall also assess if and to what extent provisions covered in the code of conduct have been infringed and if the code of conduct has ensured fair and reasonable access to patented NGT plant biological material. The report shall be accompanied, where appropriate, by legislative proposals to safeguard the good functioning of the sector, in particular access to patented NGT plant biological material for primary users, including farmers.

8. The code of conduct shall be ready by 17 January 2028.

Art. 30: Code of conduct

4. The Commission shall aim that the code of conduct include the following commitments by voluntary platforms for the licensing of plant biological material:

(a) cost-attractive fees for participation in the platforms to facilitate participation in the platforms by breeders which are SMEs.

(b) standard license agreements.

(c) fair and impartial mechanisms for settling disagreements on licensing fees.

5. The Commission shall aim that the code of conduct set out its objectives, contains indicators to measure the achievement of those objectives, takes due account of the needs and interests of all interested parties at Union level, including plant breeders and farmers, and provides a reporting framework to ensure that participants annually report to the Commission on any measures taken to implement the code of conduct and their outcomes, including aggregated information on licenses granted on patents referred to in point b) of paragraph 3. (…)

Art. 30: Code of conduct

(…) The Commission may provide recommendations to operators in the drawing up of the code of conduct.

8. The code of conduct shall be ready by 17 January 2028.

NGT plant patent expert group and assessment

1. The Commission shall establish an expert group on the effect of the patenting of NGT plants (the ‘expert group’).

2. The expert group shall assist the Commission and exchange information on a regular basis as regards the assessment conducted by the Commission in accordance with paragraph 4 on the effect of patent law and the implementation practice on access to modified genetic resources, transparency of the patent landscape and innovation in the field of NGT plants.
The expert group shall, in particular, assist the Commission on surveying the patent licensing practices for the breeding and marketing of NGT plants protected by a patent, ongoing patent application procedures concerning NGT plants and patent enforcement practices vis-à-vis farmers and, if available, examples of cases thereof.

NGT plant patent expert group and assessment

3. The expert group shall be constituted in accordance with the horizontal rules on the creation and operation of Commission expert groups. Each Member State may appoint a delegation of maximum two experts to the expert group. That delegation shall have knowledge and experience in the areas covered by this Regulation and in the area of intellectual property rights, including their impact on the market. The European Patent Office and the Community Plant Variety Office may each appoint one expert to the expert group.

4. The Commission shall regularly assess the impact that the patenting of NGT plants, traits and techniques, as well as related licensing and transparency practices, have in the Union on:
(a) innovation in plant breeding;
(b) breeders' access to patented plant biological material, traits and techniques, and breeders' ability to conduct experimentation;
(…)

NGT plant patent expert group and assessment

- (c) farmers' access to plant reproductive material, including the price of available products and other commercially available propagating material, as well as their rights to use farm-saved seeds and propagating materials;
- (d) the risk of litigation involving farmers or breeders in situations where patented plant biological material may appear in their crops or products due to accidental presence or similarity, without intentional use of the patented plant biological material;
- (e)competition in the plant-breeding sector, in particular from the perspective of small and medium-sized breeders, while considering the potential risks of market concentration; and
- (f) transparency and legal certainty regarding patented plant biological material.

NGT plant patent expert group and assessment

5. The first of the assessments referred to in paragraph 4 shall be conducted one year after NGT products have become available on the Union market.

6. The assessment referred to in paragraph 4 shall also include an evaluation of the necessary conditions to ensure that the Union breeding sector using new genomic techniques has a fair and reasonable access to patented plant biological material, exploring the possibility of granting access for free to such material.

7. When carrying out the assessment referred to in paragraph 4 and when considering the appropriate follow-up actions, the Commission shall take into account the findings of the expert group as well as the reporting from the Union breeding sector. To this end, the Commission shall invite the Union breeding sector to report on its experience with commercial access to patented plant biological material.

NGT plant patent expert group and assessment

- (…)

9. If the assessment referred to in paragraph 4 reveals significant barriers to access to patented plant biological material, undue restrictions on experimentation, negative effects on breeders and farmers, increased market concentration, reduced diversity in seed supply, insufficient transparency, or other evidence that the system is not functioning smoothly, the Commission shall, where appropriate, submit legislative proposals to set up mandatory conditions or safeguards.

10. If the Commission considers that, on the basis of the assessment referred to in paragraph 4, no follow-up measures are necessary, it shall inform the European Parliament and the Council thereof and shall repeat the assessment as defined in paragraph 4 no sooner than four years and no later than six years after the publication of the first assessment.

Implementation phase

- A delegated act will specify the information required from operators to demonstrate that a plant is an NGT plant and the information required for the verification of category 1 NGT status.
- An implementing act will specify the information required for applications for the authorisation of category 2 NGT plants, including on adapted risk assessment, post-market environmental monitoring and detection methods requirements tailored to the characteristics of these plants.
- EFSA will prepare **guidance** for the preparation and presentation of the verification requests for category 1 NGT plants and for applications for authorisation of category 2 NGT plants, as well as for the adapted risk assessment for category 2 NGT plants.
- In the meantime, current GMO rules continue to apply to NGT plants and products.

Implementation phase

- All these acts and guidance should be ready before the application of the Regulation two years after its entry into force.
- During the preparatory work, Member States will be directly involved, and stakeholders and the public will have opportunities to contribute through consultations.
- Further details of the how the Regulation will be implemented will be published shortly by the Commission in the form of an implementation strategy

Policy developments around the world – May 2026

International Seed Federation
Seed is Life

CANADA
Product based approach; **HEALTH CANADA** and **CFIA** guidance for food, feed and environmental release finalized excluding plants without foreign DNA

US
USDA: excludes plants where there is no plant pest sequence
EPA: exempts certain genome edited plants that are conventional-like products; requires notification
FDA: voluntary pre-market meeting

ARGENTINA, CHILE, COSTA RICA, GUATEMALA, HONDURAS, PARAGUAY, URUGUAY
Case by case approach excluding certain genome edited products without a novel combination of DNA

COLOMBIA, ECUADOR
Case by case approach excluding certain genome edited products without foreign DNA

BRAZIL
Case by case approach excluding certain genome edited products without recombinant DNA/RNA

PERU
Case-by-case approach excluding genome edited products without exogenous DNA and depending on type of modification/edit.

EL SALVADOR
Trade agreement between HN, GT, and SV that covers GM and Genome editing with national implementation guidelines under development

ENGLAND
Case by case approach excluding gene edited plants where the genetic changes made could have occurred through traditional processes ('precision bred'). Separate precision bred food and feed marketing authorisation by FSA.

EU27
Policy proposal suggesting 2 categories: Conventional- like and GMO-light

SWITZERLAND
Policy proposal excluding certain genome edited products without foreign DNA and based on their added value for agriculture, the environment or consumers

ISRAEL
Case-by-case guidance that excludes certain genome edited products

RUSSIA
Decree for R&D program clarifying that gene editing products are "conventional-like"

CHINA
GMO- light with guidelines and detailed rules issued for trial implementation

SOUTH KOREA
Proposed revised LMO act (GMO-light)

INDONESIA (FDA), JAPAN, SINGAPORE, THAILAND
Case by case approach excluding certain genome edited products without foreign DNA

VIETNAM
Excludes genome edited products without foreign DNA

PHILIPPINES
Case by case approach excluding certain genome edited products without a novel combination of DNA

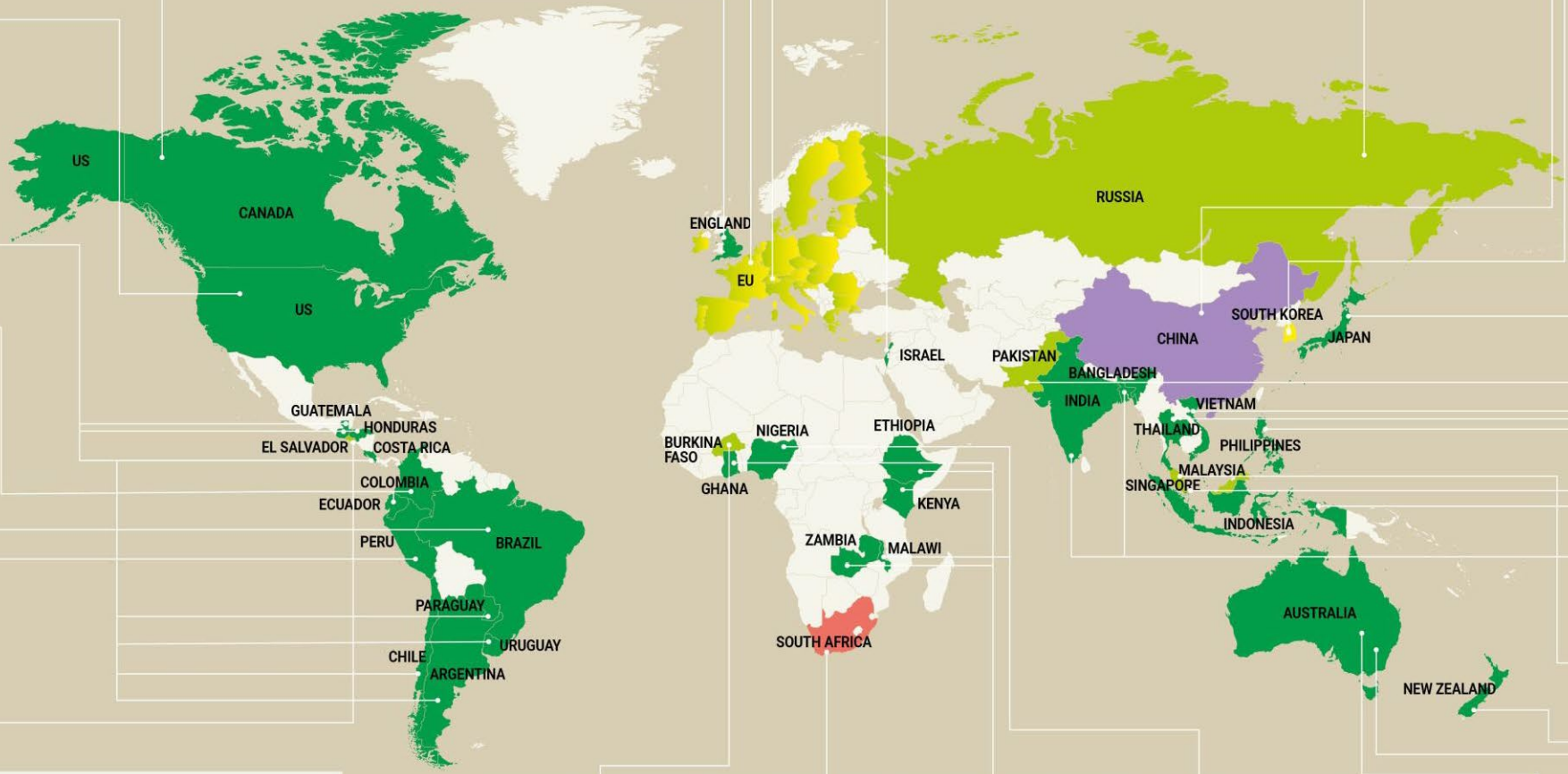
PAKISTAN
Draft proposal to exclude certain genome edited products that are SDN1/2 or that are without exogenous DNA

INDIA, BANGLADESH
Case-by-case approach excluding SDN1, SDN2 products without foreign DNA

MALAYSIA
Draft proposal to exclude certain genome edited products for research purposes

AU-NZ FSANZ
Excludes food from genome edited organisms where there is no novel DNA present

NEW ZEALAND EPA
Proposal for a differentiated regulation of genome edited products



- Differentiation from GMO regulations (at least by one agency/authority)
- Products considered GMOs but with simplified assessment procedure/requirements
- All products considered GMOs
- Draft proposal to differentiate from GMO regulations (at least by one agency/authority)
- Draft proposal where products considered GMOs but with simplified assessment procedure/requirements

BURKINA FASO
Draft case-by-case policy approach excluding certain genome edited products without novel combinations of DNA

SOUTH AFRICA
Government decision that genome editing are GMOs, appeal rejected in August 2023

GHANA, ETHIOPIA, KENYA, MALAWI, ZAMBIA
Case by case approach excluding certain genome edited products without foreign DNA

NIGERIA
Case by case approach excluding certain genome edited products without a novel combination of DNA

AUSTRALIA OGTR
Exclusion of SDN-1 products; new legislation proposed

Comparison with other jurisdictions

- USA

USDA: Case-by-case exclusion process through Am I regulated process.
  - Since December 2024, the exemption system (2020 rule) is vacated by a court judgement.
  - ‘Legacy framework’ restored.
  - ‘Requests for confirmation’ issued before December 2024 remain valid.

EPA: exempts certain products, requires notification.
FDA: voluntary pre-market meeting

- Japan

case-by-case approach certain genome-edited products.

Comparison with other jurisdictions

- South America:

Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, Guatemala, Honduras, Paraguay, Uruguay: case-by-case approach, but likely accepted. (Foreign/recombinant DNA is a trigger).

- Australia:

only exclusion of SDN-1 products. (Foreign DNA is a trigger). New legislation proposed

- China:

GMO light regulation: currently 10 gene-editing events are approved for cultivation/production in corn (2), wheat (2), soy (5) and rice (1).

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Thank you for your attention!

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