How BASF adapts to evolving NGT legislation

Maarten Stuiver, Gent, 26 March 2024

BASF’s segments

Chemicals

Petrochemicals

Intermediates

Materials

Performance Materials

Monomers

Industrial Solutions

Dispersions & Resins

Performance Chemicals

Surface Technologies

Catalysts

Coatings

Nutrition & Care

Care Chemicals

Nutrition & Health

Agricultural Solutions

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Agricultural Solutions Offering

Seeds & traits

- Field crop seeds
- Vegetable seeds

Solutions beyond crop protection

- Seed solutions
- Soil management
- Biologicals
- Pest control solutions
- Public health

Crop protection

- Herbicides
- Fungicides
- Insecticides

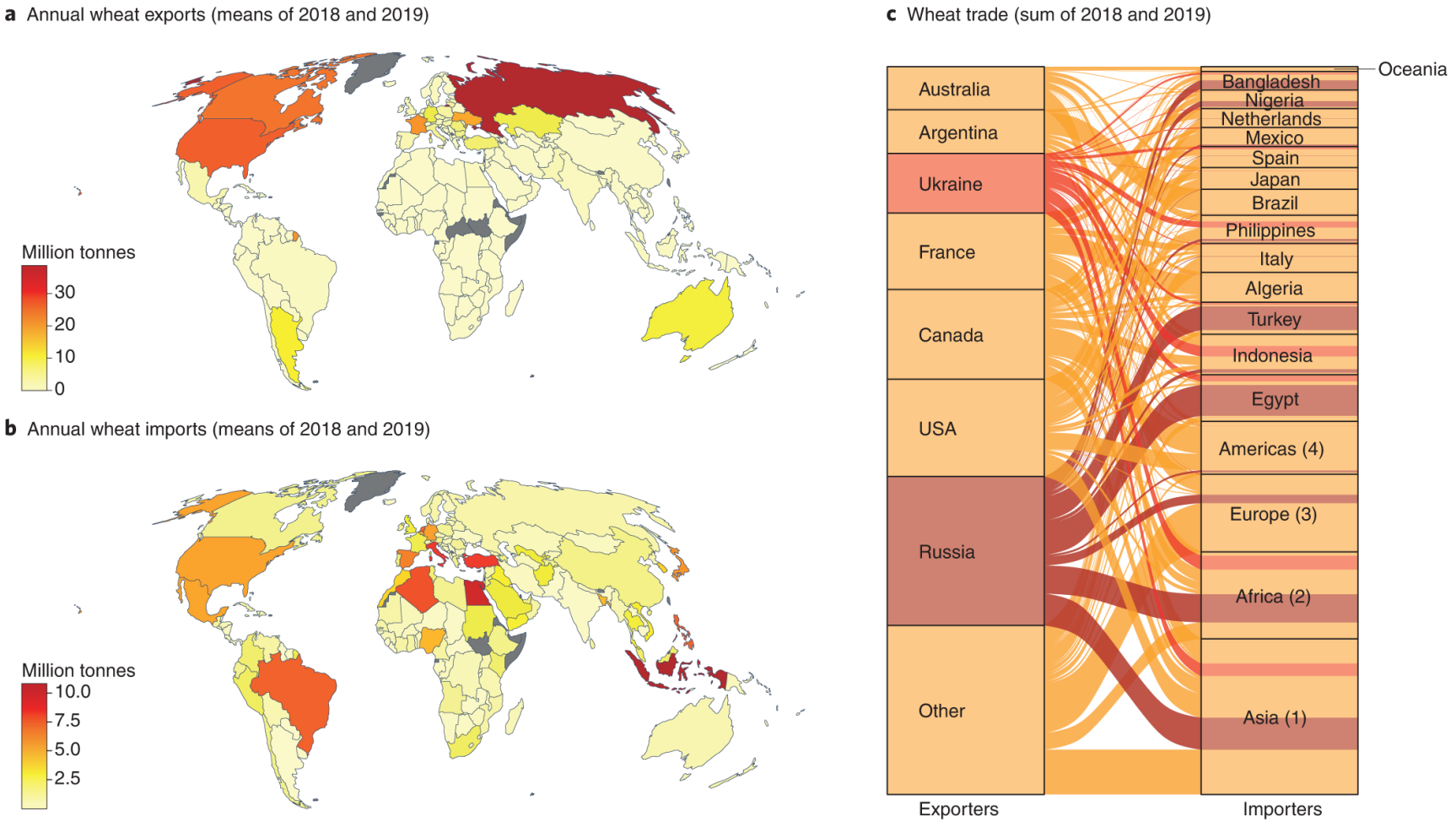
Digital farming

- Digital farming solutions
- Sales and marketing excellence

BASF Trait Research

- Trait research creates **gene-based solutions** to improve food, feed, and fiber crops that benefit farmers and society
- Conducts research projects in a prioritized portfolio to discover, validate and optimize genes from multiple origins (bacteria, plants, fungi).
- Indications: Crop Efficiency, Weed Control, Pest Control, Disease Control.
- Multiple Crops

Wheat import/export streams exemplify global movements of commodity crops

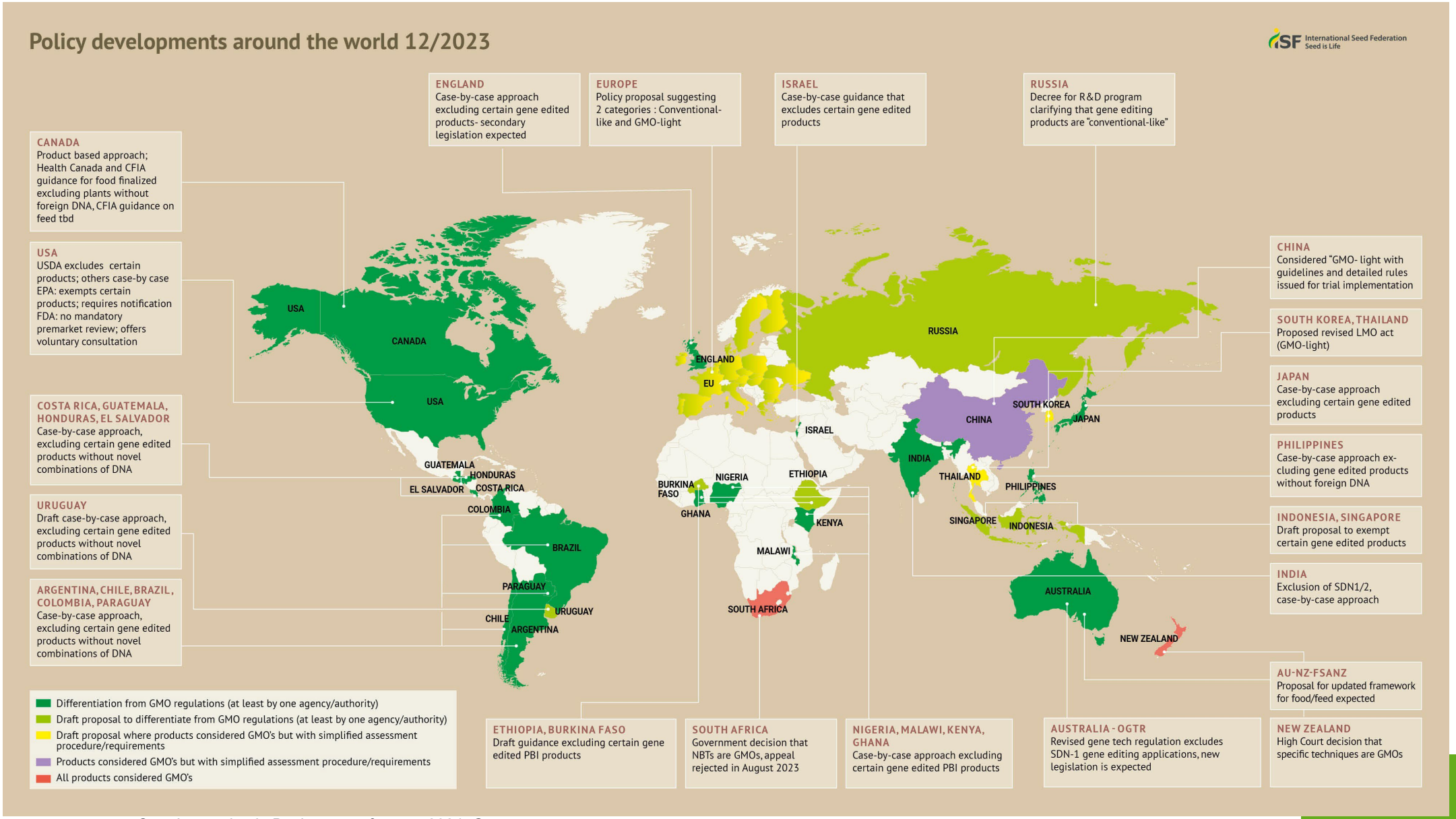


From: Bentley, A.R., Donovan, J., Sonder, K. *et al.* Near- to long-term measures to stabilize global wheat supplies and food security. *Nat Food* **3**, 483–486 (2022). https://doi.org/10.1038/s43016-022-00559-y

Moving carefully with NGTs in a globalized world

- Commercialized (field) crops absolutely need global deregulation, to avoid
  - Trade disruptions
  - Litigations
- Large competitors share same carefulness
  - Corteva‘s waxy corn (GE; 100% amylopectin starch)) still not marketed, though announced market launch was 2020
- Crops on the market locally produced without much risk of flow to other regions
  - Sanatech‘s high GABA tomato- hobby farmers and controlled production
  - Pairwise‘s Conscious Greens – controlled production

The global regulatory landscape continues to be diverse & complex



Exemptions from regulation are different by country

	Regulatory Policy	Type of genome edit			
		Targeted deletion	Targeted edit	Targeted insertion	Targeted allele replacement
USA[1] (USDA)	Self-determination; can request case-by-case consultation	Not regulated	Not regulated [2]	Not regulated [3]	Not regulated [3]
Canada	Case-by-case consultation	'Novelty trigger' [4]			
Argentina, Brazil, Colombia	Case-by-case consultation	Not regulated	Not regulated	Regulated	Not regulated
Japan	Case-by-case consultation	Not regulated	Not regulated	Regulated	Unclear
Philippines	Case-by-case consultation	Not regulated	Not regulated	Unclear	Not regulated
Australia (OGTR)	Self-determination (SDN-1 only)	Not regulated	Not regulated [5]	Regulated	Regulated
EU (proposed)	Case-by-case consultation	Not regulated	Not regulated [6]	Not regulated [3]	Not regulated [3]

1) US-EPA: Plant-incorporated protectants (PIPs) trigger – Exemption criteria for certain PIPs, includes a notification requirement
2) Single nucleotide
3) Known to occur in the gene pool. (EU: On the condition that the genetic modification does not interrupt an endogenous gene.)
4) If a product is classified as 'non-novel' and doesn't contain foreign DNA it is exempt from regulation. HT traits are generally considered novel.
5) SDN-1 only, any other GE technique regulated as GMO
6) Substitution or insertion of no more than 20 nucleotides. Any other targeted modification of any size, on the condition that the resulting DNA sequences already occur in a species from the breeders' gene pool.

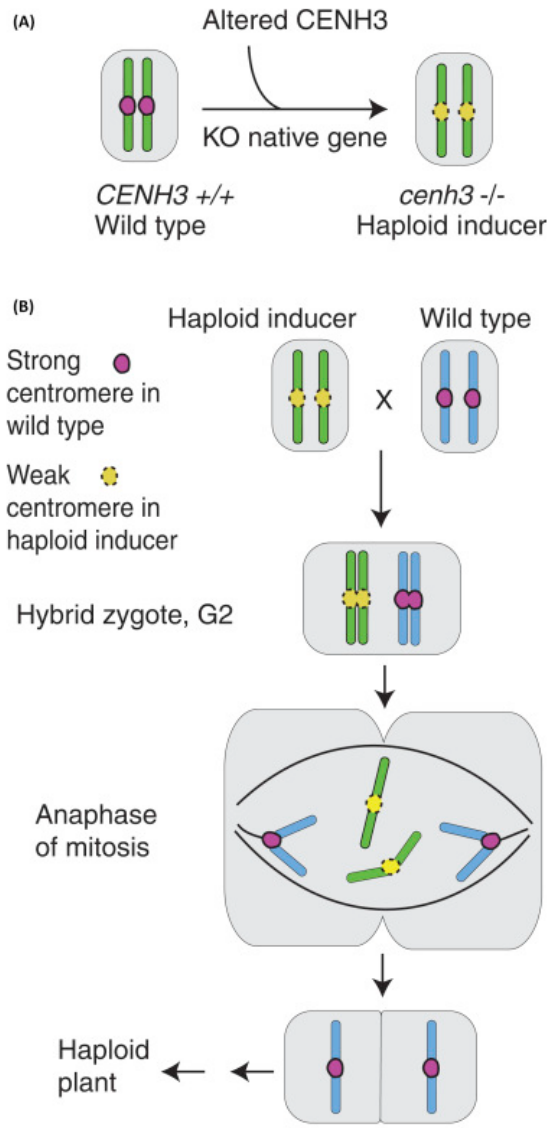
What can we likely do with NGTs without global deregulation?

- Develop technology portfolio to be ready for a harmonized regulatory situation
  - Cas12a-base editors

Gaillochet et al, Genome Biology (2023) 24:6
https://doi.org/10.1186/s13059-022-02836-2

  - Cas12a nickases
  - Efficient delivery, regeneration and selection procedures for all our crops

- Support breeding and gene discovery
  - QTL fine mapping
  - Gene discovery
  - Haploid Inducer Lines



From: Comai & Tan (2019)
Trends in Genetics 35(11), 791
https://doi.org/10.1016/j.tig.2019.07.005

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Steps in a lengthy EU process towards new proposal legislation

2018 EU Council request

EU Member states requested the Commission to complete a study on the status of NGTs under Union Law & to submit a proposal for **new legislation**.

2019 EU Court of Justice ruling

Crops developed using NGTs fall under the EU GMO legislation.

2021 NGTs study published

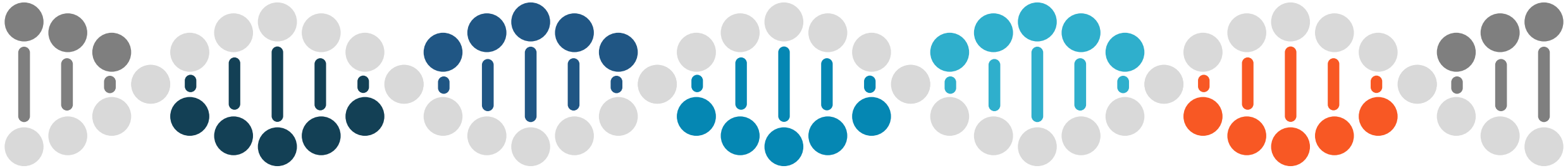
- EU Commission published a **comprehensive study** in April.
- Inception impact assessment concluded in October.

2022 Consultations

- 12-Week public consultation
- Targeted consultation with private sector.
- EFSA assessment of possible risk assessment.

2023 Draft NGTs legislation proposal

- **Impact assessment** in April.
- NGT **legislation proposal** in July.



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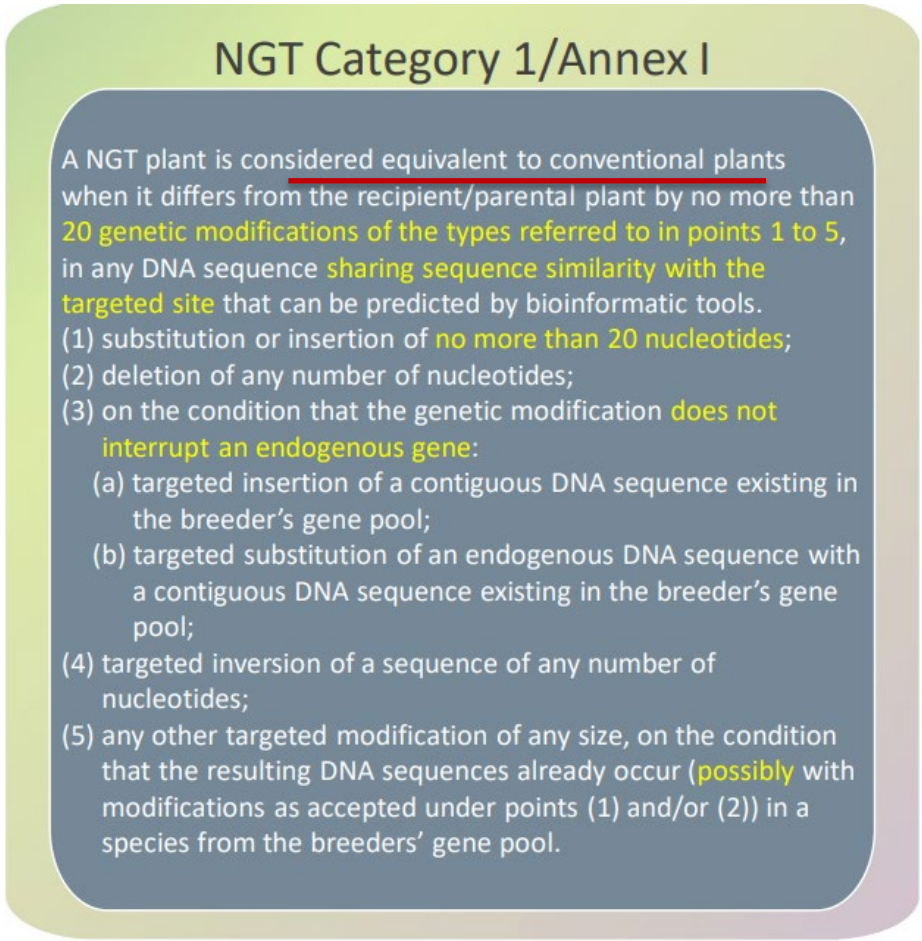
EU timelines on NGTs going forward

- EU Commission proposal July 2023
- EU Parliament amendments and positive vote Feb 2024
- EU Council
  - Before or after elections June 2024?
- Trilateral alignments
- EU Commission implementing acts and guidelines (12-18 months)
- Influence of the presidency country of the council?

EU Commission proposal



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Ability to patent plants made with NGTs

- EU parliament amended the EU commission proposal
  - Broader freedom in the amount of genome edits per genome/gene
  - Ban on patentability of plants made with NGTs
- Development costs plants with NGTs
- Impact on Innovation
- Commodities versus locally-produced and –consumed goods.
  - Farmer saved seed
  - Competitors breeding with other‘s NGT traits

- Very thorough assessment and recommendations around patentability of NGTs in Kim et al, 2024 GRUR International https://doi.org/10.1093/grurint/ikae017

What other traits can we expect?

When globally it is allowed to do simpler genome editing and cis-genics with limited or no regulatory burden?

- Disease resistance
- Plant architecture (example short stature corn)
- Nitrogen- and water-use efficiency
- Submergence tolerance
- Drought tolerance
- .....

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