



Bundesamt für  
Naturschutz

# New GMOs/NGTs: What is on markets and in development pipelines?

Dr. Samson Simon, Dr. Finja Bohle

Federal Agency for Nature Conservation (BfN), Germany

Non-GMO Summit 8.10.2024



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[www.bfn.de](http://www.bfn.de)

- Introduction to genetic engineering, Transgenesis and New Genomic Techniques (NGT)
- The development pipeline and the market situation for NGT plants
- Environmental Risk Assessment of NGT plants in relation to the EU regulatory situation

- Biotechnology is undergoing profound transitions due to
  - Genome Editing tools *and*
  - digitalisation,
  - artificial intelligence and
  - automatization.
- **Genomes of organisms can now be shaped, redesigned and even shuffled to a revolutionary new extend**, no matter if foreign genes are introduced or not
- On the other hand, **knowledge about the effects** of these genetic changes in the organisms and the ecosystem **is limited**.

# Categorisation of Genetically Modified Plants using New Genomic Techniques (NGT)



The COM proposal for regulating plants modified with NGTs

Category	Molecular equivalence criteria
Transgenic GM-plants	<ul style="list-style-type: none"><li>• Conventional procedure or NGT</li><li>• Transgenesis<ul style="list-style-type: none"><li>➤ Directive 2001/18</li></ul></li></ul>
NGT 2	<ul style="list-style-type: none"><li>• Generated with NGT</li><li>• More than 20 modifications</li><li>• Type of modifications like NGT-1</li></ul>
NGT 1 (no risk assessment)	<ul style="list-style-type: none"><li>• Generated with NGT</li><li>• Max. 20 modifications:<ul style="list-style-type: none"><li>➤ 20 bp insertion/substitution</li><li>➤ Deletions (unlimited)</li><li>➤ Cisgenesis („breeders' gene pool“)</li><li>➤ Inversion of any size</li></ul></li></ul>

### Gelinsky 2024

→ A (continuous) study commissioned by the Swiss Federal Office of the Environment (FOEN) on NGT applications in the development pipeline

### USA

→ Regulatory status of NGT plants by the Animal and Plant Health Inspection Service (APHIS), which is an agency of the United States Department of Agriculture (USDA)

### Bohle *et al.* 2024

→ a BfN publication analyzing the impact of the COM proposal on the NGT plant development pipeline by Gelinsky 2022.

# Which NGT plants (non-transgenic) are on the Market?



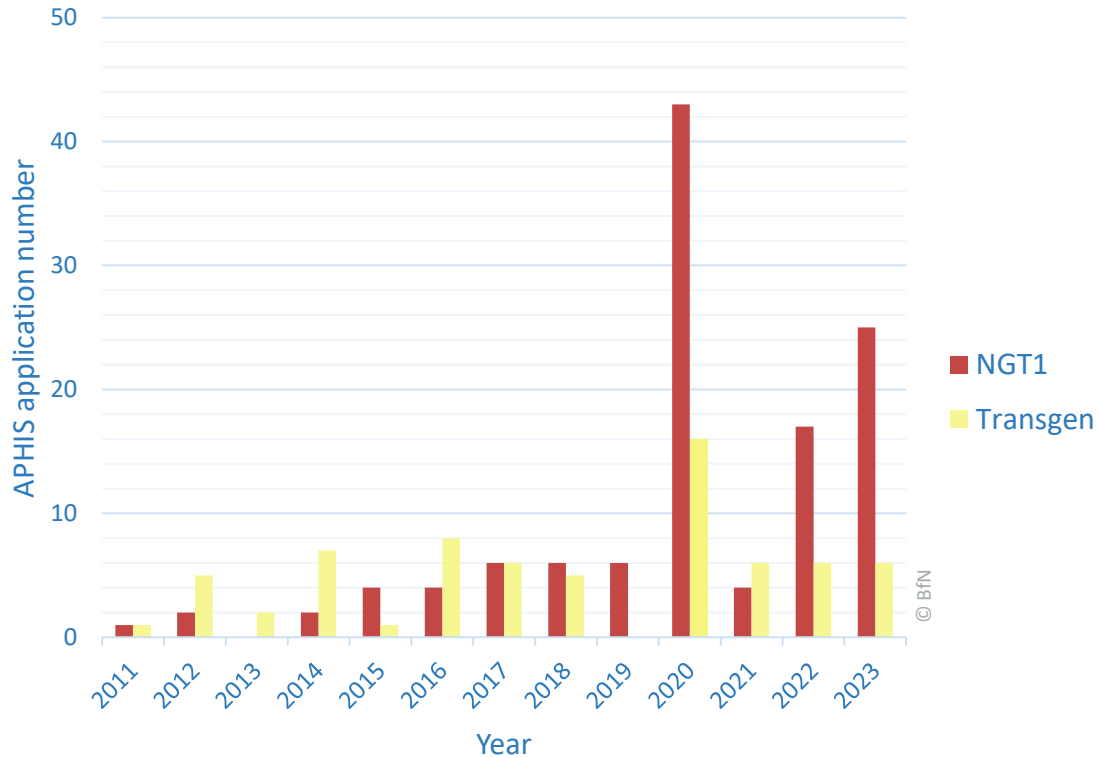
## On the market in the EU?

-> No application on cultivation or import for NGT GM-plants (non-transgenic) pending or granted

# Which NGT plants have an approval outside the EU?



## USA – NGT plants

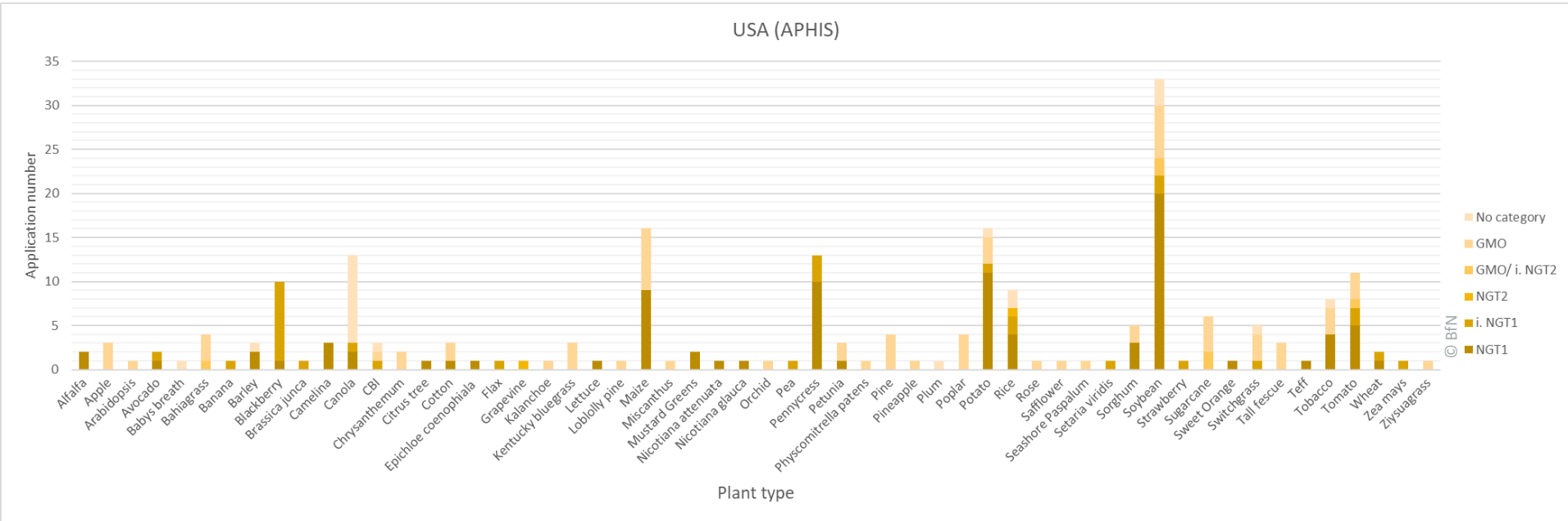


Animal and Plant Health Inspection Service (APHIS) is an agency of the United States Department of Agriculture (USDA)

# Which NGT plants have an approval outside the EU?



## USA (APHIS) – NGT applications sorted by plant species



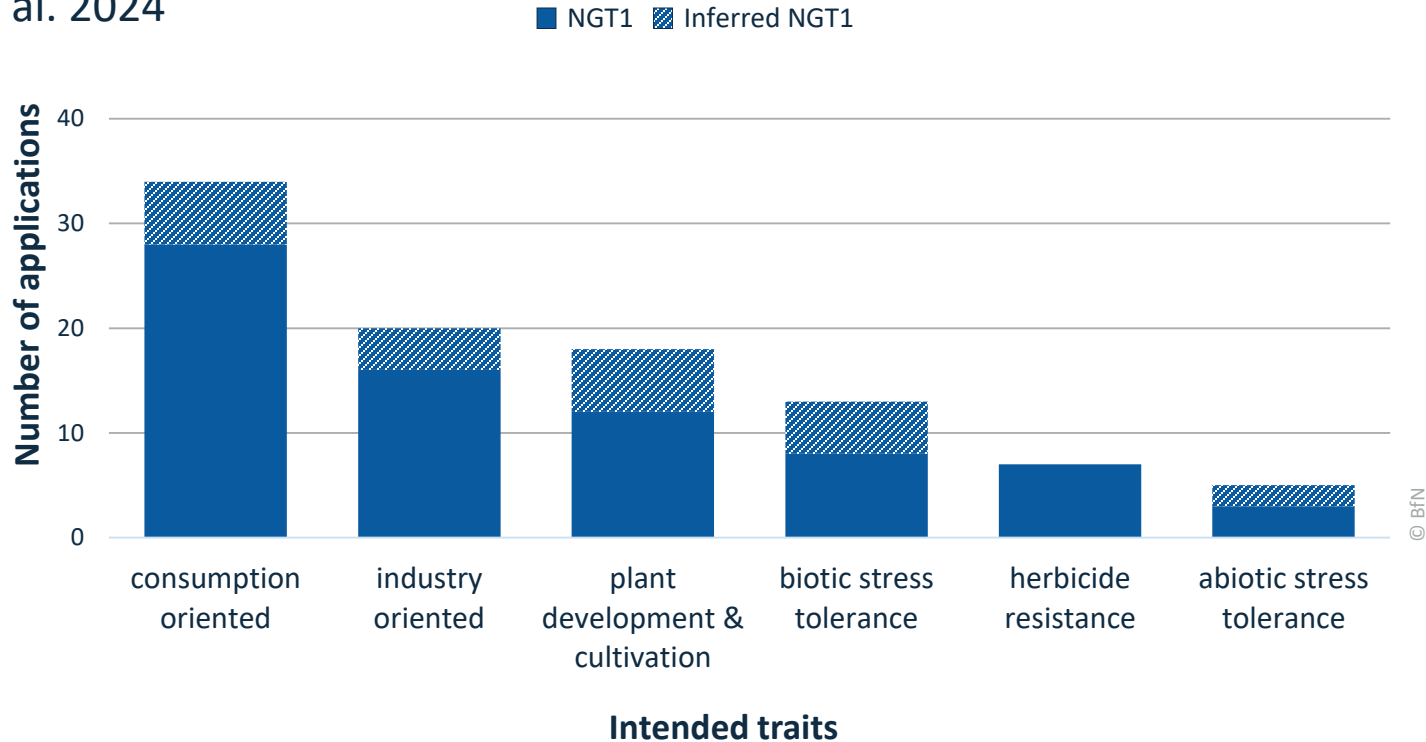
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# Many NGT plant applications intend to confer consumption oriented traits



Bohle et al. 2024



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<https://www.frontiersin.org/articles/10.3389/fgeed.2024.1377117/abstract>

BfN analyzed all 148 case studies of NGT plant applications in plant breeding commercialization pipeline and licensing agreements, as listed in Gelinsky, Eva (2022): On behalf of the Swiss Federal Office for the Environment (FOEN). <https://www.bafu.admin.ch/dam/bafu/de/dokumente/biotechnologie/externe-studien-berichte/endbericht-semnar-gelinsky.pdf.download.pdf/endbericht-semnar-gelinsky.pdf>

# Which NGT plants (non-transgenic) are on the market?



## On the market in the EU?

→ No application on cultivation or import for NGT GM-plants (non-transgenic) pending or granted

## On the market outside the EU? (Source Gelinsky 2024<sup>1</sup>)

→ More difficult to evaluate, no warranties

Crop	Trait	Country
Tomato	Increased GABA content (medicinal purpose)	Japan
Salad	Shelf-life /non-browning	USA
Mustard greens	Reduced pungency	Canada
Maize	"waxy corn" modified starch composition	USA, Canada, Brazil, Argentina, Chile, Japan

## Close to the market outside the EU (Source Gelinsky 2024<sup>1</sup>)?

→ ~12 (e.g. Soy, potato, canola, rice)

<sup>1</sup><https://www.nutzpflanzenvielfalt.de/welche-produkte-der-neuen-gentechniken-ngt-sind-zu-erwarten>

# The impact of the COM proposal on Environmental Risk Assessment of NGT plants



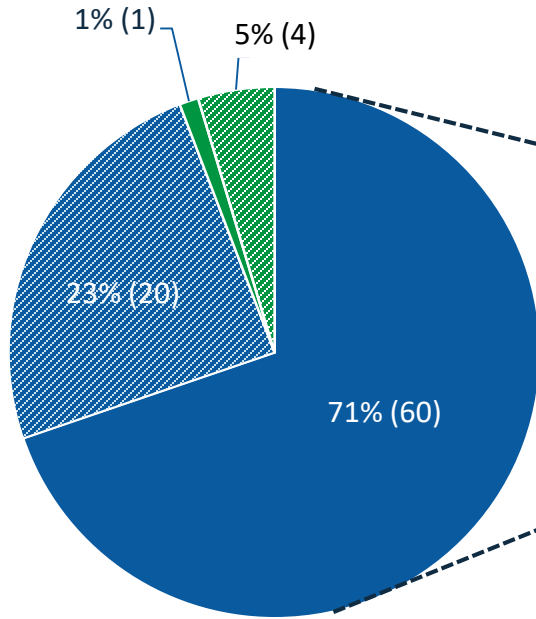
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# 94% of NGT plant applications fall into NGT category 1



■ NGT1 ■ Inferred NGT1 ■ NGT2 ■ Inferred NGT2



94%

6%

Category	Number of applications
NGT1	60
Inferred NGT1	20
NGT2	1
Inferred NGT2	4
Transgenic GMO	15
Not categorized	48
Total	148

Link to the study  
<https://www.frontiersin.org/articles/10.3389/fgee.d.2024.1377117/abstract>

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# Study by eight European environmental agencies: Differences to breeding



Table: Comparison of techniques ("not applicable": there is no specific target site)

	Conventional breeding techniques		Established techniques of genetic modification	New genomic techniques					
	Cross-breeding	Random mutagenesis	Transgenesis	Cisgenesis	Intragenesis	(SDN3)	Genome Editing		
							Targeted mutagenesis (SDN2)	Targeted mutagenesis (ODM, SDN1)	
Intended modifications	Gene insertions (large insertions)	No	No	Yes (untargeted)	Yes	Yes	Yes	No	No
	Deletions and/or small insertions	No	Yes (untargeted)	No	No	No	No	Yes (targeted)	Yes (targeted)
	Point mutations	No	Yes (untargeted)	No	No	No	No	Yes (targeted)	Yes (targeted)
	Targeted multiplexing (multiple genomic changes)	No	No	No	No	No	Yes	Yes	Yes
	Site specific modification	No	No	No	No	No	Yes	Yes	Yes
	Modification of RNA	No	No	No	No	No	No	No	Yes
	Modification of gene expression	No	Yes (untargeted)	Yes	No	Yes	Yes	Yes	Yes
	Modification of epigenome	No	No	Yes (untargeted)	No	No	No	No	Yes
	General unintended modifications	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Unintended on-target modifications	Not applicable	Not applicable	Not applicable	Yes	Yes	Yes	Yes	Yes
Presence of exogenous DNA in product	No	No	Yes	Yes	Yes	Yes	Yes	No	
Selection marker	No	No	Yes	Yes	Yes	No	No	No	
Delivery method needed	No	No	Yes	Yes	Yes	Yes	Yes	Yes	
Regeneration via tissue culture	No	No (in vivo) Yes (in vitro)	Yes	Yes	Yes	Yes	Yes	Yes	

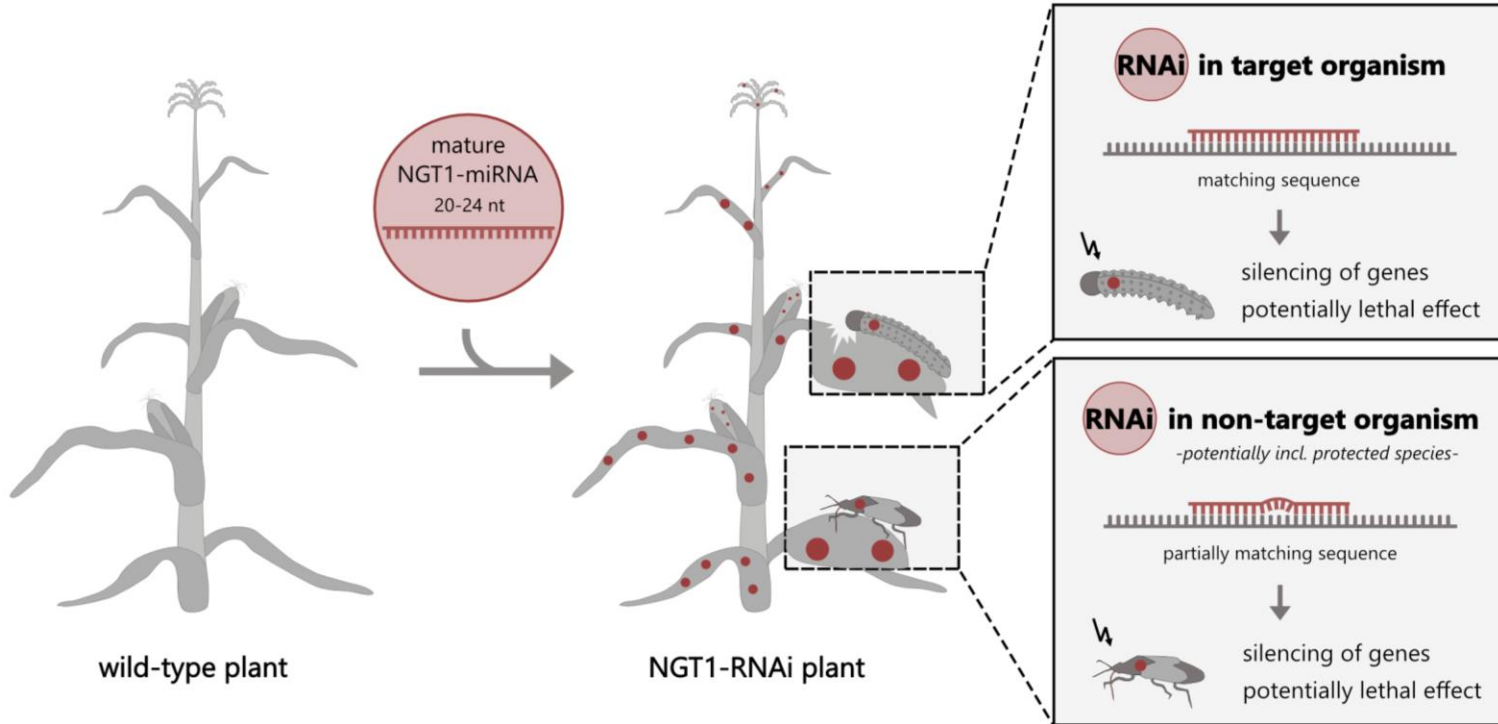
Source: <https://www.bafu.admin.ch/bafu/en/home/topics/biotechnology/info-specialists/ig-gmo.html>



Examples of specific risk areas **relevant for genome edited organism addressed in the environmental risk assessment under genetic engineering legislation in the European Union**

- Persistence and invasiveness
- Interactions with target organisms and non-target organisms
- Impacts of the specific cultivation, management and harvesting techniques
- Effects on biogeochemical processes
- Effects on human and animal health

# Case studies with high risk potential: NGT1 plants can kill insects



BfN study with detailed description:

<https://www.frontiersin.org/articles/10.3389/fgeed.2024.1377117/abstract>

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BioTech



Review

## Biosafety of Genome Editing Applications in Plant Breeding: Considerations for a Focused Case-Specific Risk Assessment in the EU

Michael F. Eckerstorfer <sup>1,\*</sup>, Marcin Grabowski <sup>2</sup>, Matteo Lener <sup>3</sup>, Margret Engelhard <sup>4</sup>, Samson Simon <sup>4</sup>, Marion Dolezel <sup>1</sup>, Andreas Heissenberger <sup>1</sup> and Christoph Lüthi <sup>5</sup>

Analysis from experts of five European environmental agencies

<https://doi.org/10.3390/biotech10030010>

Naturalness is not a criterion for safety

Maintaining an individual **case-specific risk assessment** before approval of NGT products is crucial



Federal Agency for  
Nature Conservation

## For a science-based regulation of plants from new genetic techniques

Deregulation of NGT plants  
contradicts the precautionary  
principle.



POLICY BRIEF #02/2024



<https://doi.org/10.19217/pol241en>

Many different NGTs plants are in the development pipeline.

**In the EU** no (non-transgenic) NGT plant is on the market.

**Outside the EU** many NGT plants have market approval; only a handful of NGT plants are in cultivation in third countries.

**No equivalence of NGT** to plant breeding and **naturalness** is not a criterion for safety.

There are NGT plants in **category 1 with a clear risk profile** (i.e. RNAi).

**Thank you  
for your attention!**

