

Where does the EU Commission's path lead to? Analysis of case studies

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Webinar: NGT plants - unresolved questions with relevance for future regulation, 19.01.2024



Key elements of the proposal



	NGT 1	NGT 2
Verification procedure	technical evaluation of the category	technical evaluation of the category
Approval procedure	X	Reduced
Risk assessment	X	Reduced
Provision of detection methods	X	Reduced
Labeling	„NGT1“ Only on seeds	„NGT2“ incl. proposed trait
Monitoring	X	Reduced
Organic farming	X	X
Procedural incentives	X	For many (proposed) traits
Opt-out	X	X

-> valid for all plants, including wild plants

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-> safety of agricultural products cannot be ensured

Key elements of the proposal

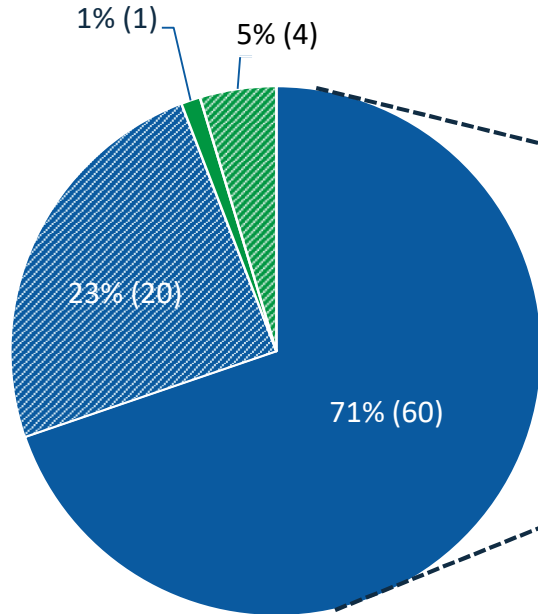


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-> freedom of choice for consumers cannot be ensured

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](#)

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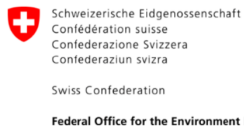


Definition of Genome Editing and Relevant Terminology

A technical report of the joint EPA / ENCA Interest Group on Genetically Modified Organisms

September 2023

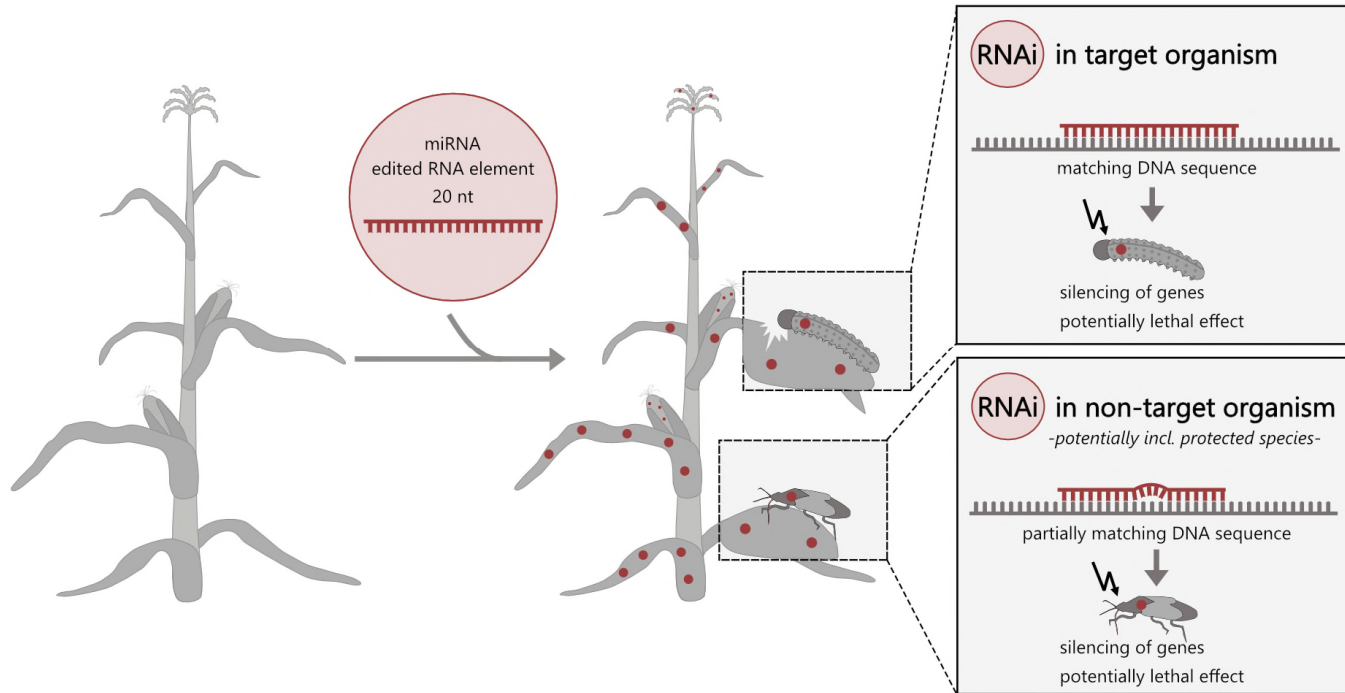
This technical report has been prepared as output form an expert Working Group mandated by EPA network and ENCA network. The following agencies support this technical report:



[Link to the study](#)
& more information



Case studies with high risk potential: NGT1 plants can carry insecticides



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[BfN study with detailed description](#)







Patent of Maori, Eyal (2019) WO2019058255 - Tropic Biosciences UK Limited,
<https://register.epo.org/espacenet/regviewer?AP=18786034&CY=EP&LG=en&DB=REG>



Review

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

Michael F. Eckerstorfer ^{1,*}, Marcin Grabowski ², Matteo Lener ³, Margret Engelhard ⁴, Samson Simon ⁴, Marion Dolezel ¹, Andreas Heissenberger ¹ and Christoph Lüthi ⁵



[Link to the analysis from experts of five European environmental agencies](#)

- Maintain individual case-specific risk assessment before approval of NGT products is crucial

- Naturalness is not a criterion for safety

- Two legal opinions by Prof. Dr. Tade Spranger commissioned by the BfN.
 - the "**equivalence criterion**" to conventional breeding and thus Annex I of the proposal are not in line with the necessary legal standard to properly apply the precautionary principle.
 - COM proposal not compatible with the **precautionary principle** enshrined in European primary law and the established case law of the European Court of Justice on genetic engineering law.

Summary



94 % of NGT plants in the analysed pipeline would be deregulated

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

Safety of agricultural products can only be ensured by individual case-specific risk assessment before approval

Freedom of choice for consumers, including the organic market, cannot be ensured

The proposal violates the precautionary principle enshrined in the european primary law.

**Thank you
for your attention!**

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