



Federal Agency for
Nature Conservation

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

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10th GMO-Free Europe Conference, Brussels, 07.09.2023

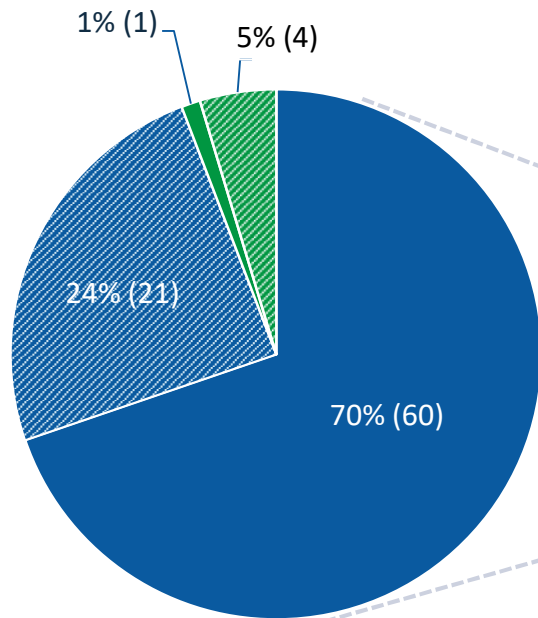


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94% of NGT plant applications fall into NGT category 1

■ NGT1 ■ Inferred NGT1 ■ NGT2 ■ Inferred NGT2

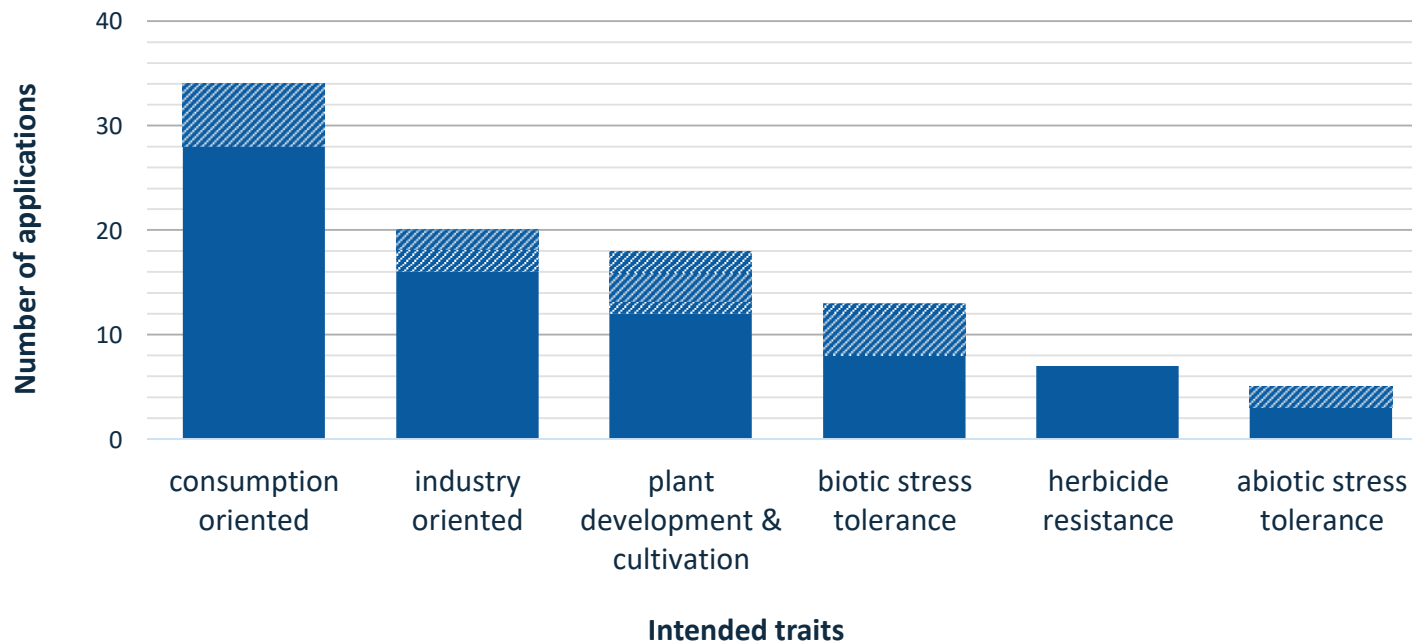


Category	Number of applications
NGT1	60
Inferred NGT1	21
NGT2	1
Inferred NGT2	4
Transgenic GMO	13
Not categorized	49
Total	148

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-studienberichte/endbericht-semnar-gelinsky.pdf.download.pdf/endbericht-semnar-gelinsky.pdf>

Many NGT plant applications* intend to confer consumption oriented traits

■ NGT1 ▨ Inferred NGT1

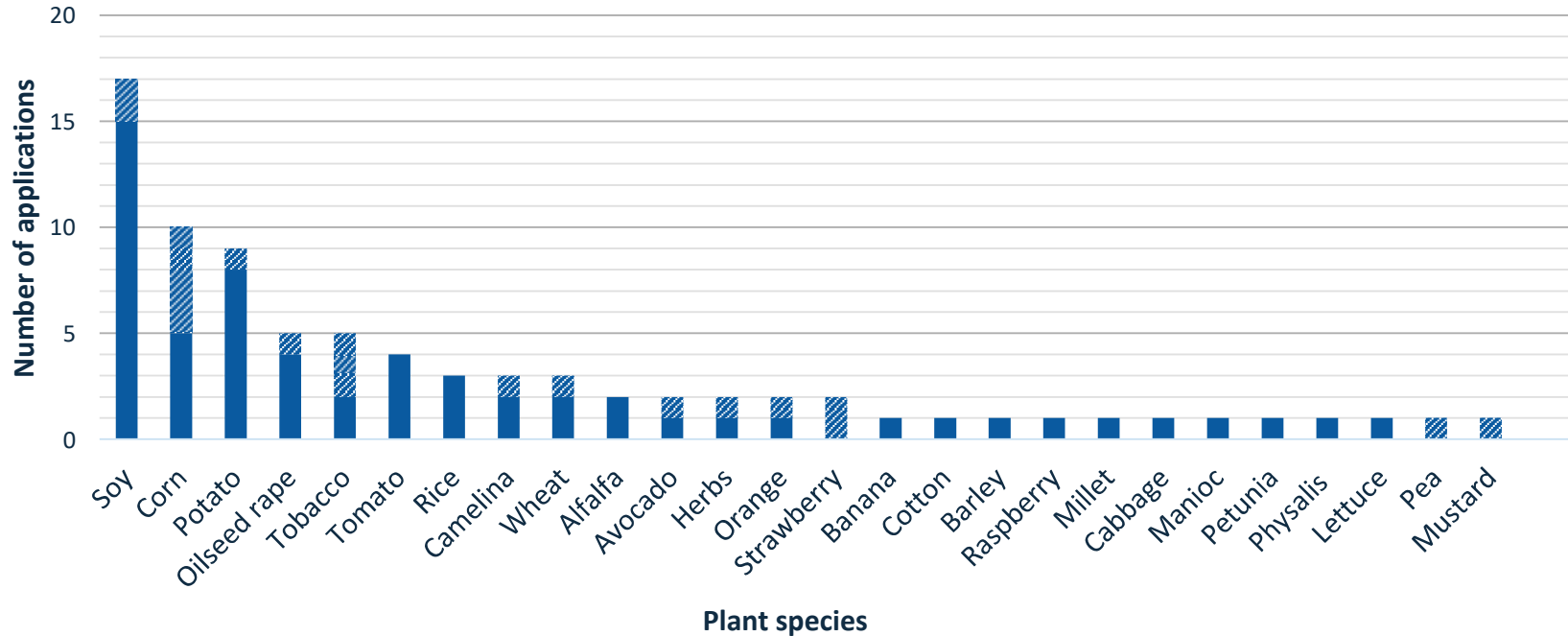


* 81 of BfN-analyzed case studies of NGT plant applications as listed in Gelinsky, 2022.

A broad spectrum of crops is affected by the de-regulation of NGT plants*



■ NGT1 ■ Inferred NGT1



* 81 of BfN-analyzed case studies of NGT plant applications as listed in Gelinsky, 2022.

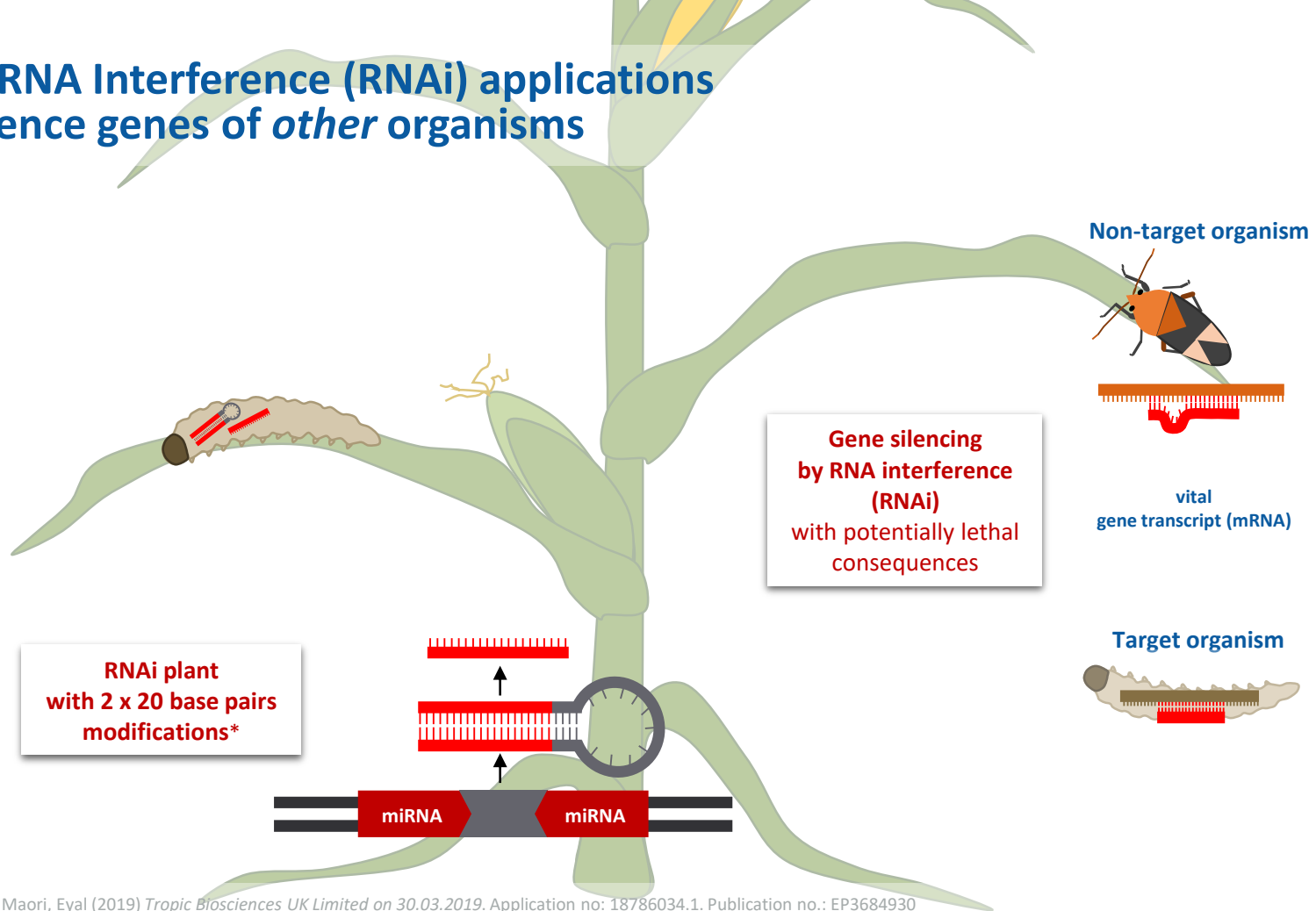
Case studies with high risk potential

- **Drought tolerant NGT tobacco shrub**
 - potentially invasive plant species
 - potentially *increased fitness and invasiveness* in dry locations
 - environmental risk

- **Herbicide resistente NGT plant applications**
 - usage of *complementary herbicides*
 - negative effects on biodiversity

- **NGT GABA-tomato**
 - Excessive accumulation of *GABA neurotransmitter* (reduced blood pressure)
 - potential effect on human health

NGT1-RNA Interference (RNAi) applications can silence genes of *other* organisms



*see patent of Maori, Eyal (2019) *Tropic Biosciences UK Limited on 30.03.2019*. Application no: 18786034.1. Publication no.: EP3684930

There exist no suitable denominators for *per se* risk assessment

Analysis from experts of five European environmental agencies

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

Category	Molecular equivalenz criteria
NGT1	<ul style="list-style-type: none"> Generated with NGT Max. 20 modifications: <ul style="list-style-type: none"> ➤ 20 bp insertion/substitution ➤ Deletions (unlimited) ➤ Cisgenesis („breeders’ gene pool“)
NGT2	<ul style="list-style-type: none"> Generated with NGT > 20 modifications (as NGT1)
Transgenic GMO	<ul style="list-style-type: none"> Conventional procedure Transgenesis <ul style="list-style-type: none"> ➤ Directive 2001/18



Review

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

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Citation: Eckerstorfer, M.F.; Grabowski, M.; Lener, M.; Engelhard, M.; Simon, S.; Dolezel, M.; Heissenberger, A.; Lüthi, C. Biosafety of Genome Editing Applications in Plant Breeding: Considerations for a Focused Case-Specific Risk Assessment in the EU. *BioTech* **2021**, *10*, 10. <https://doi.org/10.3390/biotech10030010>

Academic Editor: Vasiliki Mollaki

Received: 14 May 2021
Accepted: 15 June 2021
Published: 22 June 2021

Publisher's Note: MDPI stays neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Abstract: An intensely debated question is whether or how a mandatory environmental risk assessment (ERA) should be conducted for plants obtained through novel genomic techniques, including genome editing (GE). Some countries have already exempted certain types of GE applications from their regulations addressing genetically modified organisms (GMOs). In the European Union, the European Court of Justice confirmed in 2018 that plants developed by novel genomic techniques for directed mutagenesis are regulated as GMOs. Thus, they have to undergo an ERA prior to deliberate release or being placed on the market. Recently, the European Food Safety Authority (EFSA) published two opinions on the relevance of the current EU ERA framework for GM plants obtained through novel genomic techniques (NGTs). Regarding GE plants, the opinions confirmed that the existing ERA framework is suitable in general and that the current ERA requirements need to be applied in a case specific manner. Since EFSA did not provide further guidance, this review addresses a couple of issues relevant for the case-specific assessment of GE plants. We discuss the suitability of general denominators of risk/safety and address characteristics of GE plants which require particular assessment approaches. We suggest integrating the following two sets of considerations into the ERA: considerations related to the traits developed by GE and considerations addressing the assessment of method-related unintended effects, e.g., due to off-target modifications. In conclusion, we recommend that further specific guidance for the ERA and monitoring should be developed to facilitate a focused assessment approach for GE plants.

The path forward

- Maintaining the **precautionary principle**: Maintain individual case-specific risk assessment before approval of NGT products (naturalness is not a criterion for safety), seed law is not sufficient
- Ensuring (real) **labeling requirements and freedom of choice** for consumers and farmers
- Ensuring **coexistence** for a GMO-free (agricultural) economy
- **Genetic engineering legislation** retained in the **ordinary procedure** (no delegated acts)
- Strengthening **ecological risk and security research**
- Strengthening **agroecological and small structured farming**

Further reading



- **Eckerstorfer, M.F. et al. (2023):** Recommendations for the Assessment of Potential Environmental Effects of Genome-Editing Applications in Plants in the EU. *Plants* 12 (9), p. 1764. <https://doi.org/10.3390/plants12091764>
- **Federal Agency for Nature Conservation (ed.) (2021):** New developments and regulatory issues in plant genetic engineering. Viewpoint. Bonn. https://www.bfn.de/sites/default/files/2021-10/Viewpoint-plant-genetic-engineering_1.pdf
- **Federal Agency for Nature Conservation (ed.) (2022):** Genetic engineering, nature conservation and biological diversity: The boundaries of design. Viewpoint. Bonn. <https://www.bfn.de/sites/default/files/2022-10/2022-genetic-engineering-nature-conservation-biological-diversity-bfn.pdf>
- **Federal Agency for Nature Conservation (ed.) (2023):** FAQs on NGTs (in German). <https://www.bfn.de/haeufig-gefragt-gentechnik>
- **Potthof, C. et al. (2023):** Expert Opinion: Evaluation of the European Commission's study on new genomic techniques. https://www.bfn.de/sites/default/files/2023-03/bng_finalreport_COMstudy_Feb2023.pdf
- **Ribarits, A. et al. (2021):** Genome-Edited Plants: Opportunities and Challenges for an Anticipatory Detection and Identification Framework. *Foods* 10(2). <https://doi.org/10.3390/foods10020430>
- **Spranger, T.M. (2017):** In-depth analysis of various European directives and regulations with regard to their potential to regulate environmental effects of New Technologies besides Genetic Engineering Law Summary. https://www.bfn.de/sites/default/files/2021-10/NT_Auffangrechte_RGutachten_Spranger_en.pdf
- **Spranger, T.M. (2023):** Ad hoc-Stellungnahme zum Urteil des EuGH in der Rechtssache C-688/21. https://www.bfn.de/sites/default/files/2023-03/adhoc_Urteil_C_688_21_0.pdf

**Thank you
for your attention!**

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