Federal Agency for Nature Conservation

A nature conservation and risk assessment perspective

Dr. Margret Engelhard / Federal Agency for Nature Conservation

GMO – free Europe Event 2022, 17.11.2022

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German Federal Agency for Nature Conservation

The BfN is a higher federal authority providing scientific advice to the German Federal Ministry for the Environment

The BfN is involved as federal authority in the risk assessment of GMO on the national and EU level and provides expertise in this field since 2003

Transition in Biotechnology

- Biotechnology is undergoing profound transitions due to
  - Genome Editing tools ***and***
  - digitalisation,
  - artificial intelligence and
  - automatization.

- Dynamic field, Genome Editing tools change fast with **CRISPR/Cas** as a prime example

Genome Editing has numerous names

- New mutagenesis techniques (term used in the CJEU judgement)
- Novel genomic techniques (term used in the council decision for the EC study)
- New genomic techniques (term used in the EC study)
- New breeding techniques
- New gene technology
- ….

Genome Editing has numerous fields of applications

Genome Editing can:

- switch off genes
- activate genes
- inhibit genes

→ genetic engineering (targeted mutagenesis)

- Introduce new genes

→ genetic engineering (transgenesis)

- Introduce many new or synthetic genes

→ genetic engineering (synthetic biology)

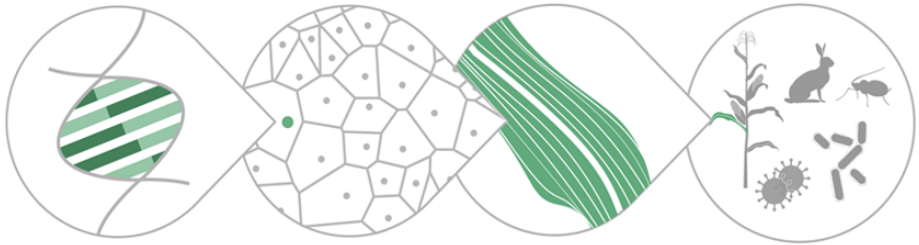
- While the old tools to transfer DNA into the cells are still the same (particle bombardment, *Agrobacterium* mediated transfer)

Transition in Biotechnology

- **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**.

- **The development of risk and technology assessment tools is not keeping pace** with these biotechnological developments



Familiarity does not exclude risks

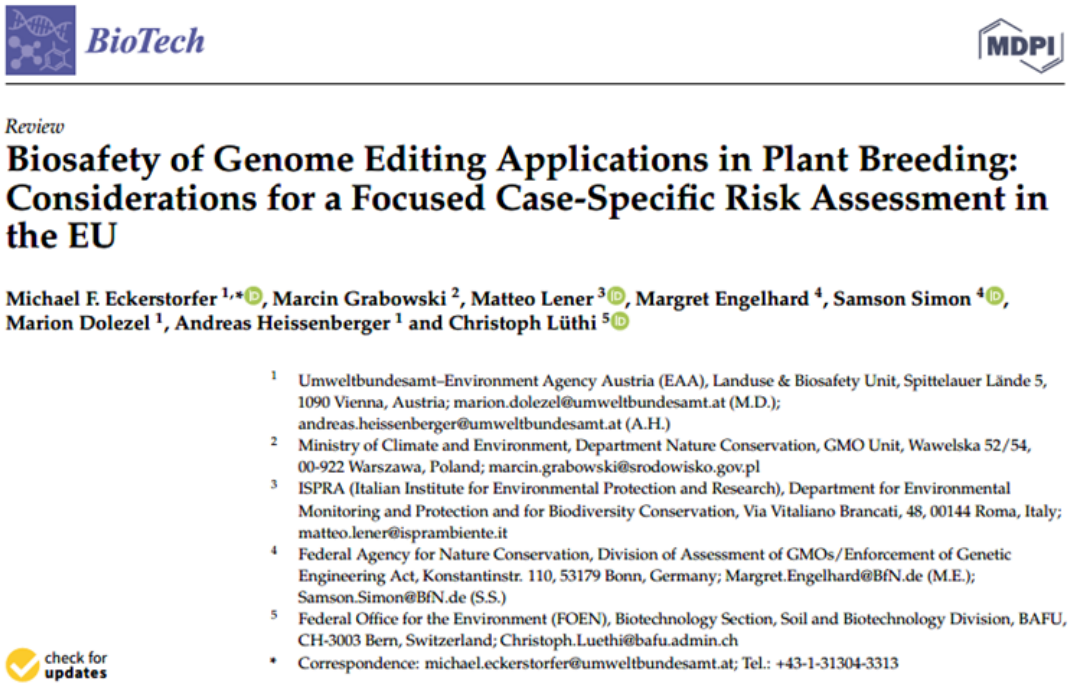
- Examples of specific risk areas **relevant for genome edited organism addressed in the environmental risk assessment under genetic engineering legislation in the European Union**

  - 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 by case instead of *per se* categorisation of risks

- Risk levels **are similar to classical GMO and can not be determined *per se* by the level of interference**

- No denominators exist to predict the risks (i.e. level of interference, history of save use, …)



BioTech

MDPI

Review

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

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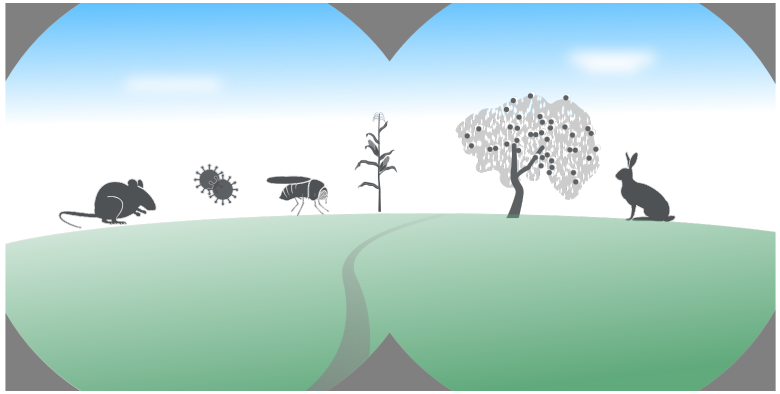
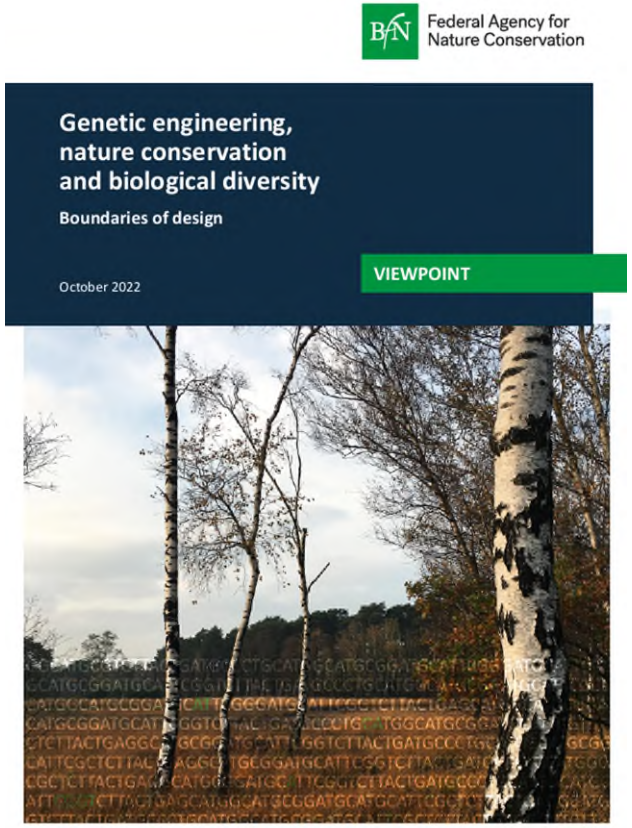
check for updates

Detection and Identification of Genome Edited GMOs

- **Detection** of small changes in the DNA sequence introduced by genome editing is possible.
- **Identification** of a GMO relies on additional information that has to be deduced from different sources.
- An **international database** containing sufficient information for detection and identification of GMOs would be very helpful.
- **Traceability** of goods that may contain GMOs is another important strategy to ensure that products are GMO free.

Horizon Scanning





https://www.bfn.de/en/latest-news/genetic-engineering-nature-conservation-and-biological-diversity-boundaries-design

https://www.bfn.de/aktuelle-meldungen/gentechnik-naturschutz-und-biologische-vielfalt-grenzen-der-gestaltung

Outlook, Future Actions

- Current regulation can be seen as an opportunity as it ensures the **precautionary principle**, **coexistence for agriculture** as well as **freedom of choice for the population** and the necessary trust in state action. It is resilient, flexible and future prove
- **Research efforts are needed:**
  - On Horizon Scanning
  - Developments of tool to evaluate impacts
  - Detection methods
  - Alternate path (i.e. resilience by humus formation)
- **International:** register for genome edited organisms

Questions