

# New techniques in plant biotechnology - old deficiencies in risk assessment

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# The **Federal Ethics Committee on Non-Human Biotechnology** (ECNH)

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Our mandate includes:

- to observe and evaluate the developments and applications of non-human biotechnology from an ethical point of view
- to advice the Federal Council and the Federal Administration on ethical issues in the preparation of legislation
- to advice the authorities on the enforcement of federal regulations
- to provide information and advance public debate on the risks of biotechnology



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**Federal Ethics Committee on Non-Human Biotechnology ECNH**

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A typical procedure:

1. Arising of a new technology and arising awareness of new ethical issues coming up

→ sources of information: scientific publications and media, other federal expert committees and federal administration

2. Phase of collecting information: What exactly is at stake?

→ expert hearings, research, what arguments are brought forward by stakeholders?

3. Creating an “ethical landscape”: What are the objectives of the technology resp. its application? What ethical values are at stake? What are the risks/consequences of the technology?

→ internal and external ethical expert opinions, debate

4. Writing an advisory opinion

→ Publication, Press Conference

New plant breeding Techniques



Risks Associated with their Application

**New Plant Breeding  
Techniques and Risks  
Associated with their  
Application** by Michael  
Eckerstorfer, Marianne Miklau,  
Helmut Gaugitsch,  
Environment Agency Austria,  
Vienna, commissioned by  
ECNH, March 2014

<http://www.ekah.admin.ch>

## New techniques in Plant Biotechnology – old deficiencies in risk assessment

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- New techniques in Plant Biotechnology: too technical, too complicated?
- Are the new GM plants **safe** or are they **risky**?
- Old deficiencies in risk assessment: Just read the statements of the proponents thoroughly.

## Again: “Old” GM plants are safe

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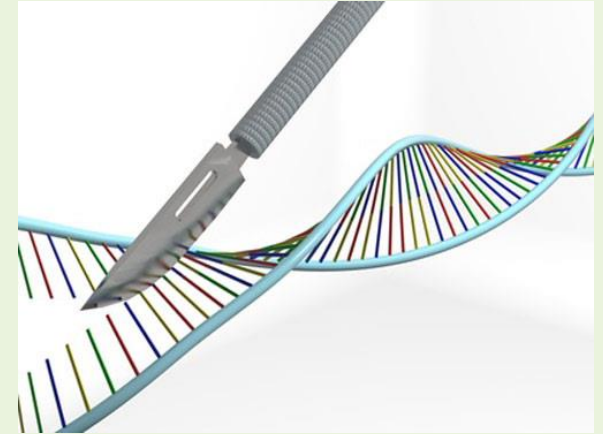
“There is no evidence that GM technologies are any riskier than conventional breeding technologies and this has been confirmed by thousands of research projects.”

Anne Glover, Interview on ‘Planting the future’, report of the European Academies of Science Advisory Council (EASAC) at <http://www.euractiv.com>

# New GM plants are even safer

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“Using these [new] techniques, potential adverse effects are even less likely than in conventional transgenic plants or plants resulting from conventional breeding. The combination of various new techniques will allow precise genetic modification, resulting in plants that harbour as little recombinant DNA as possible or none at all.”



Hartung, F., Schiemann, J. 2014: Precise plant breeding using new genome editing techniques: opportunities, safety and regulation in the EU. In: The Plant Journal (2014) 78, 750

# Adequate regulation

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In view of the “promising novel plant breeding technologies, post- GM, (...) we shouldn't make the mistake of regulating them to death as we have done with GM.”



Anne Glover, Interview on ‘Planting the future’, report of the European Academies of Science Advisory Council (EASAC) at <http://www.euractiv.com>



# No regulation?

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“[T]here is no scientific reason to classify a plant as a transgenic organism, (...) if there is no foreign recombinant DNA in its genome.”

“NPBTs or other future techniques, should be evaluated according to the new trait and the resulting end product rather than the technique used to create the new plant variety.”

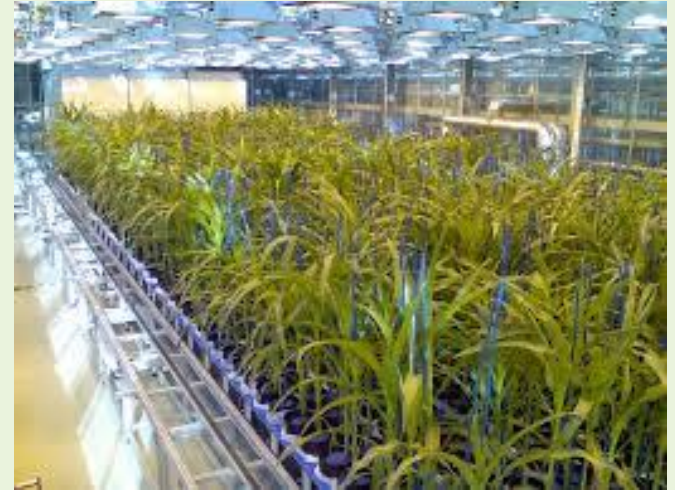


Hartung, F., Schiemann, J. 2014: Precise plant breeding using new genome editing techniques: opportunities, safety and regulation in the EU. In: The Plant Journal (2014) 78, 742/750

# Beware of Europe's competitiveness

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If the new techniques fall under the scope of GM legislation in Europe “there is the risk that scientists and companies will move elsewhere, accelerating the negative impact on the science base and on Europe's competitiveness.”



Heap, B. (2013) Europe should rethink its stance on GM crops. *Nature*, 498, 409, cited by Hartung, F., Schiemann, J. 2014: Precise plant breeding using new genome editing techniques: opportunities, safety and regulation in the EU. In: *The Plant Journal* (2014) 78, 750

# Old arguments...

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1. It is asserted that GM plants are safe.
2. New GM plants are even safer, because the techniques are more precise.
3. Change the whole GM regulation to a product-based assessment (versus process-based) and/or:
4. Don't regulate at all.



Why? Because there's scientific evidence and we have to be aware of future competitiveness of the European plant breeding sector.

# First explanatory model

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**GMP = Plant of origin + additional properties inserted by gene technology**

Essentially based on concept of Substantial Equivalence

- Biochemical and toxicological properties in comparison to the original product substantially unaltered.
- Inserted properties are neither toxic nor allergenic.



Concept used to assess food safety with regard to human health  
Influences the evaluation of the impact of GM plants onto the environment

## Second explanatory model

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GMP is *more* than plant of origin and additional properties inserted by gene technology  
→ possible unexpected effects



Evaluation restricted to certain effects of the transgene considered insufficient

Typical risk situation:

→ Evaluation of GM plants = risk evaluation

# Recommendations

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1. Apply the risk model

*New GM: Assess the **process** and the **product***

2. Apply the precautionary principle

3. Step-by-step approach

4. Independent risk research

*New GM: Urgent, no data!*

5. Monitoring

6. Freedom of choice and protection of GM-free (seed) production

*New GM: Don't create precedents*

*New GM: Genetic engineering in the process and/or in the product:  
regulate as GMOs*

*If not/not clear: moratorium (my suggestion)*

# Thank you!

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