Legal classification of genome editing and its use in plants

Trilateral Meeting of the Ethics Councils of Germany, France and Great Britain
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Genome Editing vs. NPBTs

New Plant Breeding Techniques (NPBTs)

- Grafting
- RNA-depdendant DNA-methylation
- Cisgenesis
- Reverse Breeding

Genome Editing

- ODM
- TALEN
- ZFN
- CRISPR/Cas
- Agro-Infiltration
Use of genome editing in plants in Germany

- So far only used in laboratories (due to legal uncertainty)

- **CRISPR/Cas** used by Federal Research Centre for Cultivated Plants (Julius-Kühn-Institute, JKI)
  - e.g. in *Arabidopsis thaliana*
    - to silence/modify genes and analyze their effects
    - to evaluate the “off-target effects” of CRISPR/Cas
    - to proof usage of DNA-free CRISPR/Cas

- Some companies obviously work on modifying the color of petunias via genome editing techniques
Cibus case – herbicide resistant canola created by genome editing (ODM)

- **Jul 2014**: „Can field trials be done without obtaining an authorization by BVL?“
- **Jul 2014 – Feb 2015**: Administrative procedure
  - Comprehensive examination of the ODM-technique
  - Opinion by German Central Committee on Biological Safety (CCBS)
- **Feb 2015**: Administrative act (legally binding assessment): „No authorization required!“
- **Mar 2015 – Jun 2015**: Objection proceeding
- **Since Jul 2015**: Proceeding at the administrative court of Braunschweig
BVL legal opinion

• GMO definition in Article 2(2) the Directive 2001/18/EC is process AND product based
• An organism, which may occur naturally cannot be considered a GMO (like an organism with a pointmutation)
• On the other hand, an insertion of genes lead to GMO
  \( \rightarrow \) Each case needs an individual evaluation
• Point mutations are considered mutagenesis and therefore outside the scope of the Directive 2001/18/EC
Precautionary principle – commonly misunderstood

Common claim: *Precautionary principle demands to always „take the safest way“, but…*

- Precautionary principle **does not** demand „zero risk“! Regulator has to decide about the acceptable risk
- Precautionary principle **is more a tool, rather than a rule:** It authorises States to take measures, even if risks are uncertain
- By enacting Directive 2001/18/EC the precautionary principle has already been applied!
What is genetic engineering according to law?

• GMO = „Organism […], in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.“

• Wording ambiguous at first glance, but: If term „that does not occur naturally“ only referred to the process, the terms „by mating and/or natural recombination“ would be redundant – they do occur naturally!

• Other provisions also relate to the product, e.g. Annex I A Part 1(1): recombinant nucleic acid techniques involving the formation of new combinations of genetic material […] and their incorporation into a host organism in which they do not naturally occur […]
Systematic interpretation...

- GMO definition is used as transposition of the Cartagena Protocol on Biosafety
- The Cartagena Protocol regulates living modified organisms (LMO), that is „any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology“ → clearly product- and process-based
- Modern biotechnology refers to methods „that overcome natural physiological reproductive or recombination barriers“ Article 3(i) Cartagena Protocol)

...and teleological interpretation

- Using genome editing techniques to induce point mutations is undoubtedly more precise (less off-targets) than conventional mutagenesis-techniques
  → Exemption clause for mutagenesis (Annex IB(1) must *a fortiori* apply (Goal: Protection of Health and environment)
Problems of purely process based approach

If GMO definition was purely process based and Annex IB(1) was not applicable, the following would be regulated:

• Organisms with artificially induced point mutations (like Cibus canola)
  → Cause of pointmutation (identity) cannot be determined
  → Therefore organisms cannot be authorized for release or placing on the market (see Annex III A, II.C.2.(f) / Annex III B, D No. 12)
  → Basic principles such as „zero tolerance“ cannot be enforced

• Plants whose original genome has been restored via artificially induced point mutations
  → Identical organisms would be treated differently
A few closing remarks...

- Even if GMO-regulation would not apply to some genome-edited plants, there still would be rules that apply:
  - Food & Feed law
  - Novel Food-Regulation (under certain circumstances)
  - Seed legislation
  - Animal welfare act
  - Environmental acts
  - Provisions of civil law (e.g. on damages)

- Legal questions are not as easy to answer as some people claim
Thank you for your attention!

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