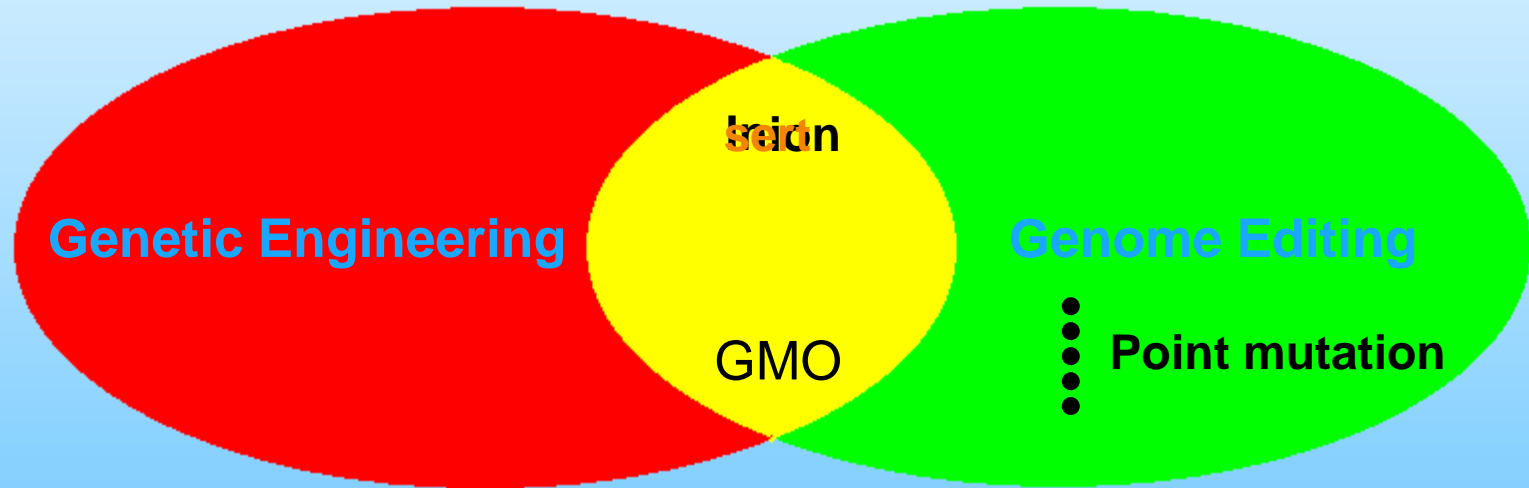


Legal classification of genome editing and its use in plants

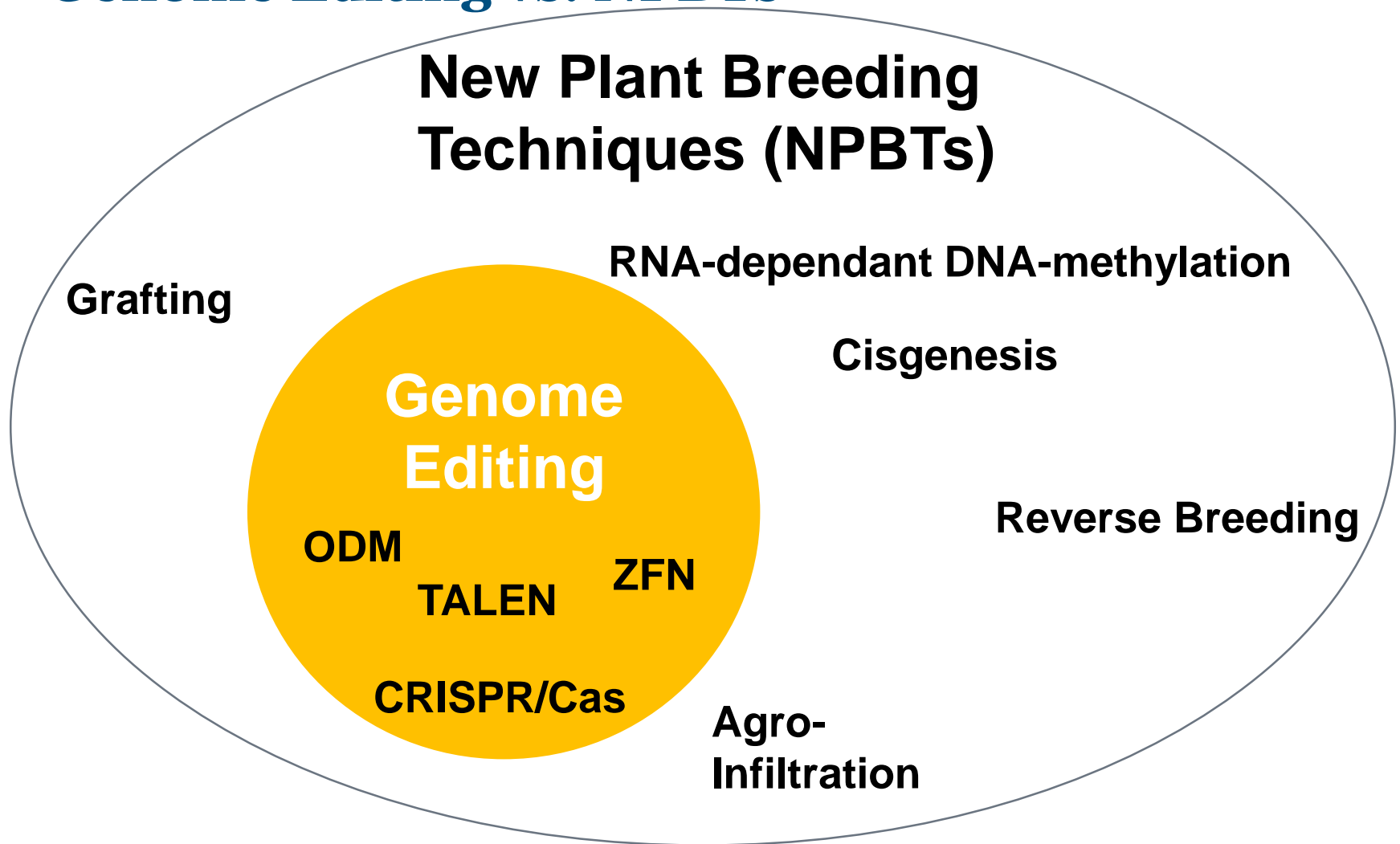
Trilateral Meeting of the Ethics Councils of Germany, France and Great Britain



Legal classification of genome editing and its use in plants

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Genome Editing vs. NPBTs



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



Picture: Nina, CC-BY-SA 3.0

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



Picture: Canada Hky, CC-BY-SA 3.0

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
→ 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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