A future task in good hands

The need for proper risk assessment

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About

- COM study intends to regulate *some NGT plants* differently
- Indicates lowering of risk assessment requirements
- Genome editing by SDN-1, SDN-2 and cisgenesis
- Is this presently justified?

NGT = new genetic techniques
SDN = site directed nucleases, e.g CRISPR, TALEN, ZFN
Some important points of the COM study

- Full body of scientific evidence considered
- Several approaches developed to improve method specificity
- Precaution and proportionality could be applied unison
- Some NGT plants have same safety profile as conventionally bred plants
CRISPR is new and powerful

- Jinek et al. (2012) CRISPR/Cas application
- Tool constantly and rapidly evolving
- Yet no CRISPR edited GMO on the market
- Alter not just one, but multiple DNA-sequences (multiplexing)
- Access *all* genes of a genome
- Alter genetically linked genes
Range of unintended molecular effects

- Occurrence of off-target effects
  - Their extent depends on the experiment
    - Design, concentration, duration, ...
    - Trade-off specificity vs efficiency observed
- Occurrence of on-target effects
  - Range of outcomes
  - Observed, but not well studied
- On-target effects at off-target sites!
Full body of evidence considered?

- CRISPR’s power for SDN-1 alterations not considered
- Full range of unintended changes not appreciated
- CRISPR’s mechanisms fully understood?
Methods developed to improve specificity

- Technology is constantly evolving: specificity and potential (cf. Court ruling)
- Each method not fully tested for possible other effects at molecular level
- No standards yet for their applications
- Indication to method developments alone is a poor advice to introduce pre-classification
Study: Policy measures should address how to interpret both principles; they could be applied in unison.

The first is a legal principle binding for all Union action; only limited by the second when applied arbitrarily.

Their relation also clear from the ECJ’s case law C-528/16 and communications.

No question of applying both in unison.
General considerations

- ECJ’s statement as to the impact and power of targeted mutagenesis not questioned (para 48)
- EFSA’s opinion less based on data and evidence
- No database with field trial results from GE plants
- No CRISPR edited plant on the market yet; no practical experience, no history of safe use
- 2001/18: Initial and renewal applications
- Strong R&D imbalance: potential versus impacts
- Different regulation of some NGT plants not justified
Some Risk Assessment Considerations

- Molecular outcomes vary; data need to be checked and fully assessed.
- Impacts at higher levels are hardly predictable, but need to be investigated.
- Unintended effects can light up under certain conditions only.
- Therefore a range of conditions (controlled and in the field) need to be applied and tested.
Way forward

- List and discuss a range of policy measures
- Including Directive 2001/18/EC as status quo
- No other adequate law for regulating GE*
- Status quo does not mean being passive
  - develop detection methods
  - collect data and evidence
  - establish an EU wide and global register

* [https://www.bfn.dea/fileadmin/BfN/agrogentechnik/Dokumente/NT_Auffangrecht_e_RGutachten_Spranger_en.pdf](https://www.bfn.dea/fileadmin/BfN/agrogentechnik/Dokumente/NT_Auffangrecht_e_RGutachten_Spranger_en.pdf)
Some points for discussion

Comparing conventional plants and NGT plants

- What is conventional breeding and what is genome editing? (aim and approach)
- How to compare “off-target effects”?
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Thank you for your attention!