

Sicherheitsbewertung der neuen Pflanzenzüchtungstechnologien aus Sicht der Wissenschaft

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Breeding technologies portfolio

Coventional Breeding (CB)

Random undirected genome alterations through crossing or mutagenesis...

Selection based on phenotype or biochemical markers...

*Defined **low** level regulation, no risk assessment*

**Genetically altered
crops with superior chracteristics (traits),**
e.g. higher yield, pest resistance, drought tolerance,
nutrient use efficiency, nutritional value

New Plant Breeding Techniques (NPBT)

***Specific directed** genome alterations with or
without DNA integration or site
specific mutagenesis...*

Selection by molecular markers...

*Regulatory requirements **not** decided,
low level recommended (as CB)*

Genetic Engineering (GE)

***Specific undirected** genome alterations by
cisgenic (same gene pool) or transgenic (different
gene pool – access to full biodiversity potential)
DNA integration...*

*Selection by molecular markers or phenotype...
Defined **high** level regulation including risk assessment*

- Anhang IA Teil 1 der Richtlinie 2001/18/EC:
Nicht erschöpfende Liste von Techniken, die zu einer genetischen Modifikation führen
- Anhang IA Teil 2: Techniken, die zu keiner genetischen Modifikation führen oder nicht berücksichtigt werden müssen
- Ausnahmen: Gelistet in Anhang IB:
 - Mutagenese (Radioaktivität, mutagene Chemikalien)
 - Zellfusionen von Pflanzenzellen, die auch durch natürliche Kreuzungen entstehen könnten

Gentechnisch veränderter Organismus (GVO) definiert als “ein Organismus mit Ausnahme des Menschen, dessen genetisches Material in einer Weise verändert worden ist, wie sie unter natürlichen Bedingungen durch Kreuzen oder natürliche Rekombination nicht vorkommt”

Neue Pflanzenzüchtungstechniken?

New techniques working group:

- Durch Mandat der EU-Kommission etabliert im Oktober 2007
 - Zwei Experten pro Mitgliedsstaat
 - Bewertung der neuen Techniken im Kontext zur GVO-Gesetzgebung
- + Joint Research Center Studie über die **Entwicklung und Anwendung** dieser Techniken durch die kommerzielle Züchtung (Lusser et al., 2011)

Neue Pflanzenzüchtungstechniken



Acht neue Techniken, die von der EU-Kommission in 2007 definiert wurden*

Zinc Finger Nuclease (ZFN) Technik	(Schneiden des Genoms an definierten Stellen ZFN / MN / TALEN / CRISPR/Cas)
Oligonucleotide Directed Mutagenesis	(Punktmutationen durch MMR) (ODM)
Cisgenesis/Intragenesis	(Klonieren von Sequenzen aus nahe Verwandten)
RNA-dependent DNA methylation	(miRNA, RNAi, hairpin RNA) (RdDM)
Grafting (on GM rootstock)	(Pfropfen auf eine transgene Unterlage)
Reverse Breeding	(Rückwärtzüchtung zum Inzucht-Elter)
Agro-Infiltration	(transiente / stabile Agrobakterien-Transformation)
Synthetic Genomics (Biology)	(Herstellung von Genen am Synthesizer, klonieren von neuen Stoffwechselwegen in Bakterien / Pflanzen)

* Lusser et al., 2011. JRC Scientific and technical report.

Techniken, die von der GVO-Regulierung ausgeschlossen werden sollten [Annex IB (2001/18/EC) and Annex II part A (2009/41/EC)]:

- Oligonukleotid-gesteuerte Mutagenese (ODM)
- Zink Finger Nukleasen (ZFN-1 und -2) (ohne Einführung rekombinanter DNA)
- Nachkommen und Produkte aus Pfropfungen mit nicht-GV Pfropfreis
- Nachkommen von Pflanzen erzeugt durch transiente Agro-Infiltration “sensu stricto”
- Durch RNA-abhängige DNA-Methylierung erzeugte Pflanzen ohne vererbare Veränderungen in der DNA
- Nachkommen aus dem Reverse Breeding

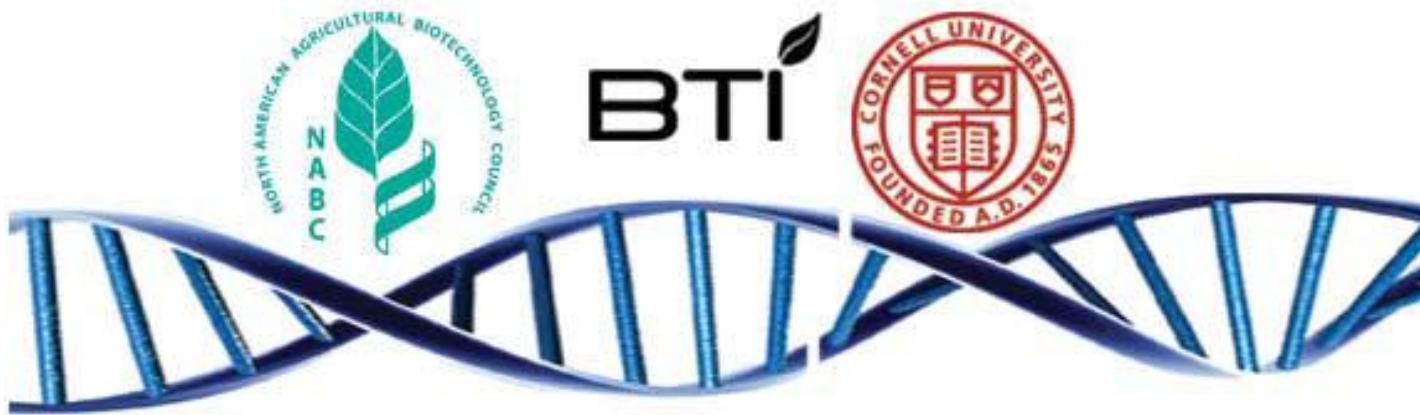
Null-Segreganten

Techniken, die im Regulierungsbereich der GVO-Regulierung liegen [Annex IA Part 1 (2001/18/EC)]:

- Zink Finger Nukleasen (ZFN-3) (mit Einführung rekombinanter DNA)
- Cis- und Intragenese
- Nachkommen und Produkte aus Pfropfungen mit GV Pfropfreis
- Durch Agro-Infiltration (floral dip) stabil transformierte Pflanzen und GV Agrobakterien enthaltende Pflanzen
- Durch RNA-abhängige DNA-Methylierung erzeugte Pflanzen mit integrierter rekombinanter DNA
- Alle intermediären Pflanzen, die rekombinante DNA enthalten

Die Techniken ZFN-3 und Cisgenese (und Kombinationen hieraus) könnten ausgeschlossen werden, wenn der entstehende Organismus auch durch „Selbstklonierung“ erzeugt werden könnte.

EU-Perspektiven zu NPBTs (1)



NABC 26

New DNA-Editing Approaches: Methods, Applications and Policy for Agriculture

October 8-9, 2014, Ithaca, New York

“EU perspectives on New Plant Breeding Techniques”

EU-Perspektiven zu NPBTs (2)

- Does the European Union have a position on NPBTs?
 - Does the European Commission have a position on NPBTs?
 - When will the European Commission touch the “hot potato”?
-
- Current rules on GM crops ‘create conflict’, says European Commissioner-designate
by Caroline Scott-Thomas, 03-Oct-2014, <http://www.foodnavigator.com/Legislation/Current-rules-on-GM-crops-create-conflict-says-European-Commissioner-designate>
The European Commissioner-elect for health and food safety has said he intends to review rules on GM crop cultivation and broker compromise on animal cloning, among other top-priority topics.
 - Vytenis Andriukaitis: “Right from the start, on November 1, I immediately have to take measures and look into the whole package of rules. The current rules create conflict because the opinions of the Member States are ignored. In my opinion, the sovereignty and subsidiarity of the Member States must be respected.”

EU-Perspektiven zu NPBTs (3)

- **Does the European Scientific Community has a position?**
 - New Techniques Working Group (2012) Final Report
 - Position statement (2012) of the ZKBS on new plant breeding techniques
http://www.bvl.bund.de/SharedDocs/Downloads/06_Gentechnik/ZKBS/02_Allgemeine_Stellungnahmen_englisch/05_plants/zkbs_plants_new_plant_breeding_techniques.pdf%3F__blob=publicationFile%26v=2
 - Report (2011/2012) of the Joint Research Center (JRC) working group
 - ETP “Plants for the Future” (2012) Position paper on New Breeding Techniques
<http://www.epsoweb.org/file/1096>
 - **EFSA-Opinions (2012) on safety assessment of Cisgenesis and ZFN-3**
 - **Report of the European Academies Science Advisory Council (2013)**
 - ETP ‘Plants for the Future’ & NBT platform information meeting (2014) ‘The Future of Plant Breeding Techniques in the European Union’
 - Biotechnology and Biological Sciences Research Council (BBSRC) Position Statement (2014) ‘New Techniques for Genetic Crop Improvement’
 - **EPSO Statement on Crop Genetic Improvement Technologies**

SCIENTIFIC OPINION

Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis

Mandate: Determine whether there is a need for new guidance or whether the existing guidance on risk assessment should to be updated or further elaborated, in anticipation of the placing of products on the market through the application of the listed techniques.

The EFSA GMO Panel considers that the Guidance for risk assessment of food and feed from genetically modified plants and the Guidance on the environmental risk assessment of genetically modified plants are applicable for the evaluation of food and feed products derived from cisgenic and intragenic plants and for performing an environmental risk assessment and do not need to be developed further. It can be envisaged that on a case-by-case basis lesser amounts of event-specific data are needed for the risk assessment.

EASAC Report “Planting the Future”



Planting the future: opportunities and challenges for using crop genetic improvement technologies for sustainable agriculture



EASAC policy report 21

June 2013

ISBN: 978-3-8047-3181-3

This report can be found at
www.easac.eu

building science into EU policy

European Academies Science
Advisory Council
Launch June 2013, Brussels

www.easac.eu

- Introduction
- International comparison of policy choices and GM experience
- The connections between the EU and Africa
- Connecting the evidence base and EU policy development
- Conclusions and recommendations

- The potential of crop genetic improvement technologies is very significant
- It is urgent for the EU to capture these benefits
- This requires better policy coherence to exploit the research and technologies that the EU was instrumental in generating: in common with other sectors, the aim should be to **regulate the trait and/or the product but not the technology** in agriculture
- We have collective responsibility to provide and utilise scientific solutions to improve agricultural productivity globally and reduce the adverse impact of agriculture on the environment
- All available approaches – traditional and novel – must be deployed

Unterstützung des Reports



*Anne Glover, former Chief Scientific
Adviser to the President of the European
Commission*

“The conclusions of the report are based on the best possible evidence and I endorse its conclusions whole-heartedly.”

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

“Finally, we shouldn't forget that there are also other promising novel plant breeding technologies, post-GM, and we shouldn't make the mistake of regulating them to death as we have done with GM.”

*Interview at
<http://www.euractiv.com>*

Zitate aus dem Abschlussbericht des NFP 59:

- Das Nationale Forschungsprogramm «Nutzen und Risiken der Freisetzung gentechnisch veränderter Pflanzen» (NFP 59) hat keine Gesundheits- oder Umweltrisiken der Grünen Gentechnik festgestellt.
- Aus den Studien des NFP 59 zu den Auswirkungen auf die Umwelt ergibt sich: Nicht das Züchtungsverfahren sollte für die Risikobewertung von Pflanzen ausschlaggebend sein, sondern die Eigenschaften der für den Anbau vorgesehenen Sorte.
- Somit erweist sich eine Sonderbehandlung gentechnisch veränderter Pflanzen aus wissenschaftlicher Sicht zunehmend als fragwürdig.



Photo: Kalenderbild.ch



Forderungen der Europäischen Pflanzenwissenschaften (1)



European Plant Science Organisation

www.epsoweb.org

Statement

Crop Genetic Improvement Technologies

Crop genetic improvement technologies for a sustainable and productive agriculture addressing food and nutritional security, climate change and human health

Forderungen der Europäischen Pflanzenwissenschaften (2)

- ❖ EPSOs request to the European Commission
- ❖ Contribution of the EU agriculture sector
- ❖ Crop genetic improvement technologies are progressing rapidly
- ❖ Current European legislation neither reflects the progress made in new crop genetic improvement approaches nor the positive economic, social or environmental impact of the resulting biological outcomes
- ❖ The European Commission should create favourable regulatory conditions for the European plant breeding sector
- ❖ The European plant science community calls upon policy makers to implement a science-based policy as a priority

Forderungen der Europäischen Pflanzenwissenschaften (3)

EPSOs request to the European Commission

- ❖ The European Plant Science Organisation welcomes the outcome of the majority opinion of the Member States expert working group (the “New Techniques Working Group”) report and asks the European Commission to provide a guideline document in the same sense to get timely legal certainty for science and industry concerning the application and exploration of New Plant Breeding Techniques.
- ❖ Since more and more new breeding techniques will be developed a more detailed and comprehensive discussion on a new approach for the regulation of new plants is required. This new approach might be based on new characteristics of a product/trait and should take the following into account:
 - ✓ A clear and reliable definition, based on scientific evidence, of what constitutes a novel plant trait, and thus needs to be assessed by an appropriate body (legal certainty);
 - ✓ The need to avoid overregulation whereby an unwarranted number of processes and products will have to undergo expensive and lengthy authorization procedures (disadvantage for SMEs and scientists);
 - ✓ The need to uncouple the question of environmental risk and safety assessment from the question of labeling (consumer acceptance).

Vielen Dank für Ihre Aufmerksamkeit

