

Project consortium new genomic techniques (bng) – Potthof, Peuker, Palme, INNRR

Evaluation of the COM study on new genomic technologies; Expert analysis commissioned by Federal Agency for Nature Conservation (BfN), Z 2-53202/2021/R/4

Analysis of the EU Commission study on NGTs - preliminary results (C. Potthof, bng)

Environmental risk of new genomic techniques - Closing conference on the 'Horizon Scanning' undertaken by the Project Genetic Engineering and the Environment

13 November 2022

Evaluation of the COM study on new genomic technologies

- **short summary of what you can expect today**
- **overview expert analysis – experts and subject areas**
- **(1) methodological approach of the COM study**
- **(2) legal issues**
- **(3) technical aspects and utilisation**
- **(4) risk assessment**

Evaluation of the COM study on new genomic technologies

– experts (lead) and subject areas –

- **(1) methodology of the COM study > Birgit Peuker (Berlin)**
- **(2) legal issues > Christoph Palme (Köln, Tübingen)**
- **(3+4) technical issues and utilisation > Christof Potthof (Berlin)**
- **(5) risk assessment > Christoph Palme & Christof Potthof**
- **(6) ethical aspects, socio-economic, societal issues – “Resterampe” > Birgit Peuker**
- **cross-cutting issue: nature conservation > Anke Schumacher/ Institut f Naturschutz und Naturschutzrecht (Institute for Nature Conservation and Nature Conservation Legislation, INNR, Tübingen)**

Evaluation of the COM study on new genomic technologies

- methodological approach of the COM study -

- **COM study, supplementary material (2 x JRC, EFSA, replies to the targeted consultation)**
- **Scientific Advice Mechanism High-Level Group (SAM HLG) of Scientific Advisors, European Network of GMO Laboratories (ENGL) and European Group on Ethics in Science and New Technologies (EGE)**
- **a set of 'own' analysis (implementation, legislation) of the European Commission**
- **different reference points (e.g. evaluations of EU regulation from 2010 and 2011 or Lusser et al./ JRC, 2011)**
- **(...)**

Evaluation of the COM study on new genomic technologies

- methodological approach of the COM study -

- **targeted consultation**

- selection of the Stakeholder does not meet the EU Commission's standards (Better Regulation)
- supporting voices (\pm for NGT, against strict or any regulation) overrepresented
- voices of consumer protection underrepresented

- **lack of transparency**

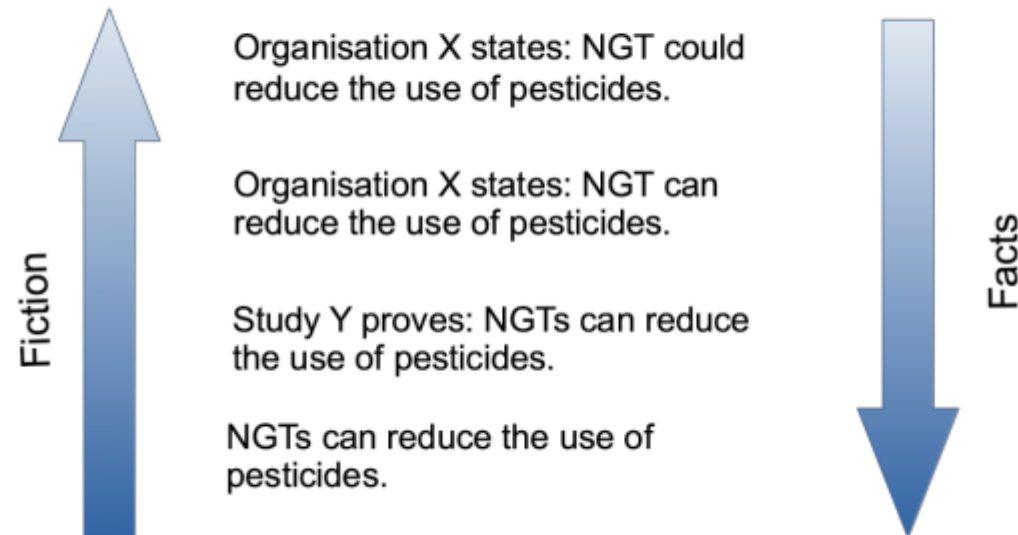
- difficult to reconstruct the results
- results of the targeted consultation are not assigned to the different sections of the COM study
- lack of consistency; COM study only summarises the material; no criteria or heuristics of the analysis are made transparent; COM study does not appear to have such criteria (and if so, they are not stated)

Evaluation of the COM study on new genomic technologies

- methodological approach of the COM study -

- **presentation of the arguments**
- arguments of proponents of NGTs appear to be closer to reality than the ones of the critics

Figure 2: Rhetorical strategy: Implicitly, some arguments are presented as more real than others. (see Latour 1987, p44 for this kind of analysis.)



Evaluation of the COM study on new genomic technologies

– methodological approach of the COM study –

- **conclusion of the critique**

- although the COM study systematically summarises the material, it lacks a systematic analysis
- although the document claims to be a "study", it is no more than a summary of arbitrarily selected material and a non-transparent stakeholder survey
- "Stakeholders have different and often opposing views on NGTs and their products." (COM study, conclusions, page 59)
- ... and we can extend this to the experts in the member states or EU organisations (EU Food Safety Authority - EFSA, Joint Research Center - JRC, Scientific Advisory Mechanism - SAM)
- The COM study fall short to weigh up or – at least – clearly contrast these different positions.

against this background, the COM study's conclusion

"Any further policy action should aim to reap the benefits of innovation while addressing concerns; efforts should be made to reconcile opposing views in order to find common ground to address the issues identified in this study" (COM study, conclusions, page 59)

is suprising, remarkable ... and a little desperate as well

Evaluation of the COM study on new genomic technologies

- legal issues -

- **“in light of the European Court of Justice (ECJ) ruling in Case C-528/16” (request of the European Council, 2018)**
 - **issues that were considered** (ECJ-references in the COM study; selection)
 - - interpretation of the exemption according to Art. 3 (1)/ Annex IB of 2001/18/EC
 - - interpretation of the term "altered"
 - - undefined legal terms
 - **issues that were not considered** (important issues in the ruling without ECJ-reference in the COM study; selection)
 - - precautionary principle
 - - history of safe use
- (both crucial for the decision of the ECJ)

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- legal issues -

- **list of legal issues not considered in the COM study (selection):**
 - **precautionary principle** (Art. 191 para 2 sentence 2 of the Treaty of the Functioning of the European Union, TFEU)
 - - a relaxed **risk assessment** of certain NGTs
 - - complete reduction of the **risk assessment/ mandatory application process** for certain NGTs
 - **polluter pays principle** (Art. 191 para 2 sentence 2 of the TFEU)
 - - abolishing of the rules regarding **identification and traceability**
- **other issues that were not considered:**
 - - planned rules of the Commission for **safeguarding biodiversity** (Proposal of a Nature Restoration Law)
 - - biodiversity of **nature 2000 sites** (EU Directives 2009/147/EC and 92/43/EEC)
 - - biodiversity of **national nature reserves** (national nature conservation laws)

Evaluation of the COM study on new genomic technologies – technical aspects and utilisation –

- **Detection and identification**

- the COM study states no conclusion with respect to detection and identification of plants and products obtained by NGT
- in the discussion chapter the COM study – with reference to an EURL/ ENGL report – writes for example:
 - “With the current state of knowledge, enforcement laboratories are **unlikely to be able** to detect the presence of **unauthorised genome-edited plant products** in food or feed entering the EU market **without prior information** on the altered DNA sequences” (COM study, page 56, discussion)
- ... leaves open how relevant this qualifications could be in the future
- ... does not discuss the developments over the last years

Evaluation of the COM study on new genomic technologies – risk assessment –

- **one of the most important conclusions of the COM study**
- "Furthermore, as concluded by EFSA, similar products with similar risk profiles can be obtained with conventional breeding techniques, certain genome editing techniques and cisgenesis. It may not be justified to apply different levels of regulatory oversight to similar products with similar levels of risk". (COM study, conclusions, page 59)
- "Darüber hinaus ist die EFSA zu dem Schluss gekommen, dass ähnliche Produkte mit ähnlichen Risikoprofilen durch konventionelle Züchtungstechniken, bestimmte Genome-Editing-Techniken und Cisgenese gewonnen werden können. Es ist möglicherweise nicht gerechtfertigt, für ähnliche Produkte mit ähnlichem Risikoniveau unterschiedliche Aufsichtsniveaus anzuwenden"

Evaluation of the COM study on new genomic technologies

- risk assessment -

- **similar products, similar risk profiles**

- unclear basis for similarity; "risk profiles" not defined

- case-by-case assessments

- no details, what might be necessary information, no discussion about

- ...

- **case-by-case assessments**

- - **"Embedding rigid risk-assessment guidance in legislation** limits case-by-case assessment and makes it difficult to adapt risk-assessment requirements to scientific progress; this appears to be very much the case for NGTs" (COM study, conclusions, page 59)

- - from the perspective of our evaluation this conclusion is not covered by the COM study

- - focus on the problems with case-by-case assessment in the COM study

Evaluation of the COM study on new genomic technologies

- risk assessment -

- **risk profiles**

- theoretically based on very specific examples (known plant varieties ...)
- practically most plant varieties obtained by NGTs
 - have not been studied in particular detail (especially on the ecological/ food safety level), or
 - the known information have not been published (especially on the molecular level)
- with the experiences of the 'old' genetically engineered plants and products
 - unspecified similarity ("similar risk profiles") is not enough

Evaluation of the COM study on new genomic technologies

- further information -

- project website at BfN: <https://www.bfn.de/projektsteckbriefe/auswertung-der-studie-der-eu-kommission-zu-neuen-gentechniken>
- bng preliminary results: https://www.bfn.de/sites/default/files/2022-07/Analysis-of-the-COM-study-on-NGT_summary_0.pdf
- evaluation of EU regulation
 - https://ec.europa.eu/food/sites/food/files/plant/docs/gmo_rep-stud_2010_report_eval-gm.pdf
 - https://ec.europa.eu/food/sites/food/files/plant/docs/gmo_rep-stud_2011_report_cultivation.pdf
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- Thank you/ Vielen Dank !