Project:

Expert Opinion:

Evaluation of the COM study on new genetic technologies

Analysis of the content and methods of the COM study on NGTs – *summary of preliminary results*[1]

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Project consortium new genomic techniques
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Abstract:
Here preliminary results of a detailed analysis of the "Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16" (COM Study) are presented. The COM study was published by the European Commission in April 2021. Legal, technical, societal and - last but not least - methodological aspects are taken into account in this analysis. We conclude that the COM Study systematically summarizes the material, but it lacks a systematic analysis. Although the document claims to be a "study," it is nothing more than a summary of arbitrarily selected material and a non-transparent stakeholder survey. As far as the legal dimensions are concerned, the central conclusions in the COM study ignore various principles of European environmental law, for example the precautionary principle and the polluter pays principle. Considerations of the technical-scientific issues of the New Genetic Technologies are not convincingly substantiated. This is especially true for the view expressed in the COM study that plants and products produced with New Genetic Technologies could support goals or strategies of the European Union like the farm to fork strategy or the Green Deal. The research within the scope of the COM study was - at least partially - limited by a lack of transparency and access to information. In addition, some of the results could only be presented in very aggregated form, which makes comprehensibility and understanding considerably more difficult.

1 On behalf of the Federal Agency for Nature Conservation (Bundesamt für Naturschutz, BfN, Bonn, Germany), Z 2-53202/2021/R/4.

A. Objective and methods of the expert opinion

In the European Union, genetically modified organisms are regulated by the EU genetic engineering law, building on the Deliberate Release Directive 2001/18/EC. When this Directive came into effect in 2001, only transgenic modification of organisms were known, which today is often referred to as classical transgenesis. Since then, various techniques, grouped under the term "New Genomic Techniques / New Genetic Technologies" (NGTs), has been developed. On 25 July 2018, the European Court of Justice (ECJ) ruled in case C-528/16 that plants produced by targeted mutagenesis are covered by the provisions of the EU Deliberate Release Directive and thus by the whole European genetic engineering law.

Thus by its Decision (EU) 2019/1904 of 8 November 2019, the Council summoned the EU Commission to prepare a study on the legal state of NGTs in the light of this ECJ decision and within the framework of Union law and – if necessary – to make proposals for action. This study (in the following called "COM study") was published on 29 April 2021 as a commission staff working document.[2] Claiming to address NGTs in plants, animals and microorganisms, respectively for agriculture, industry and pharmaceuticals (cf., for example, p. 6 of the COM study), the study itself focuses on issues of plants and plant-based products. The COM study deals – more or less extensively – with the following topics:

- Implementation and enforcement of GMO legislation with regard to new genetic technologies,
- current and future technical developments of NGTs,
- state of the utilisation of new genomic techniques for agriculture, industry, and pharmacy,
- risk assessment, and
- ethical and socio-economic implications of new genetic techniques.

The COM study was mainly based on reports conducted on special request of the European Commission, a targeted consultation of EU Member States and stakeholders and some elder reports and expert opinions (see chapter C.).

One of the conclusions drawn by the European Commission from the results of the study is that the current legislation may not be appropriate for some NGTs and their products and needs to be adapted to scientific and technological progress. The reason given by the Commission is that it cannot be justified to regulate similar products with similar risks differently. This is – according to the Commission – the case for conventionally bred plants and plants derived from certain NGTs (SDN-1, SDN-2 and cisgenesis).

Against this background, the aim of the expert opinion "Evaluation of the COM study on new genetic technologies" is to evaluate the Commission study and the documents on which it is based and to assess the consistency of its arguments. A strong focus is laid on environmental protection and nature conservation.

For the evaluation of the COM study, the arguments presented therein are compared with additional materials as well as with the public debate. Moreover, results of the expert opinion are validated by interviews of selected experts. The expert opinion furthermore examines the extent to which the challenges identified, in particular the maintenance of a high level of protection for the environment and human health as well as the freedom of choice of consumers, are addressed in the COM study.

2 European Commission Staff Working Document "Study on the status of the new genomic techniques under Union law and in light of the Court of Justice Ruling in Case C528/ 16", SWD(2021) 92 final. https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques_en.

Based on the results of the above-mentioned analysis, options for action for the further discussion on NGTs are presented.

The preparation of the present expert opinion is organised into three work packages (WPs I to III).

- In WP I, the COM study and its supplementary material is evaluated and assessed according to the consistency of their arguments. This evaluation is carried out both by comparing the arguments in the COM study with the additional materials and by comparing them with the public debate and a survey of selected experts.
- In WP II, the circulating reform proposals, in particular those of the authors of the COM study, are examined to determine whether they address the challenges identified in WP 1. The guiding principle for this expert opinion is a high level of protection for the environment and human health as well as freedom of choice for consumers in the EU.
- Within the framework in WP III, possible options for action by Federal Agency for Nature Conservation (Bundesamt für Naturschutz, BfN) will be discussed and a one-day workshop organised.

B. Preliminary Results

I. General Criticism of the methodological approach of the COM study

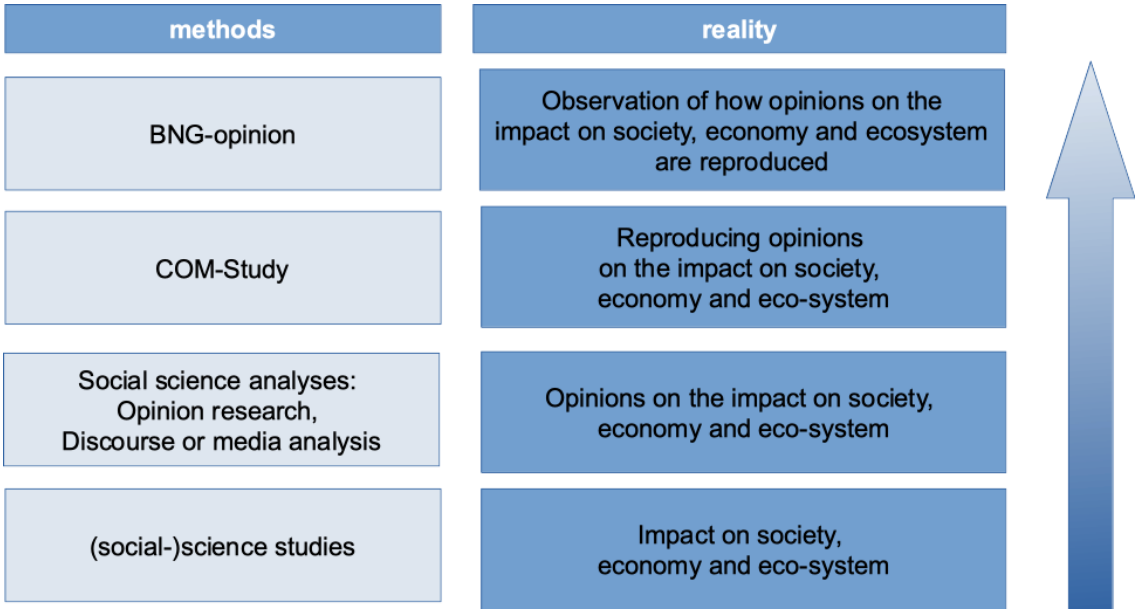
The COM study describes its methodological approach in chapter 3 "Methodology of the study" (cf. European Commission, 2021a, p. 7ff.). Accordingly, the study relies on two different sources. On the one hand, it is based on expert opinions and studies, which are described and evaluated; for example two papers of the Joint Research Center (JRC) on market applications and the state of technology development of NGT (see chapter C.).

Another main source of the COM study are two surveys ("targeted consultations"). First a survey of the Member States and then a survey of stakeholders. These surveys were carried out using questionnaires. Most of these questionnaires contained open questions that Member States and stakeholders were free to answer. The completed questionnaires are published on the European Union website for the COM study (https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques/stakeholders-consultation_en).

Most of the topic-specific sections of the COM study present the outcomes of the two targeted consultation surveys. The research question of the study, what are the consequences of NGTs for the economy, the society and the ecosystem, for example, can however not be answered by this approach. By simply reproducing the answers of the two questionnaires, the study does not answer the scientific question of what the consequences will be. Quite the opposite: only opinions on the consequences are presented.

Figure 2 shows which realities exist in relation to NGT. The lowest level in the figure illustrates reality as we perceive it with our senses and by means of scientific methods. However, there is a second reality above this: the reality of how this reality is spoken about in society. It is the opinions about this reality, which are not scientifically validated, but can very well be investigated by the social sciences through the application of social science methods. The next level is when this level of social discourse is perceived and reproduced from the perspective of a social actor. Furthermore, it can be further investigated how this discourse is reproduced from an actor's point of view. Each time one moves further away from the reality in which we practically solve problems with NGT.

Figure 1: Levels of perceived reality – Impact of NGTs



1. Criticism of the methodological approach

In the following, the methodological approach of the COM study is criticised. Four points of criticism are highlighted: The focus of the study, the selection of stakeholders for the targeted consultation, the lack of transparency, the way the opinions from the targeted consultations are reproduced.

1.1. Focus of the COM study

The COM study was prepared at the request of the European Council. This request was made on 8 November 2019 (OJ L 293, 14.11.2019, p. 103-104). According to the description in the COM study, the reason for the request was the practical problems arising from the ECJ judgment, but in the focus of the study , more general issues were addressed. This broad focus of the COM study was criticised by some NGOs, due to the fact that the expansion of the scope of the COM study has not led to a discussion on the implementation of the current GMO regulation respectively the ruling of the European Court of Justice from July 2018 (ECJ, 2018a).

1.2. Selection of Stakeholder

The selection of stakeholders who participated in the stakeholder survey does not meet the EU Commission's standards for such consultations as presented in the Better Regulations (cf. European Commission, 2009, p. 20ff.[3]). It states that stakeholders will be carefully selected to ensure that all interested parties have their say and their views are heard. In contrast, an analysis of the expert opinion shows that voices in support of NGT are overrepresented. Voices from consumer protection are underrepresented. Organisations from the agricultural and food industries make up the majority. Pharmaceutical and cosmetic organisations are marginal. The analysis of the expert opinion is based firstly on a list of the organisations that took part in the stakeholder survey and secondly on the questionnaires completed by the stakeholders. It is also worth noting that the guidelines of the Better Regulations still do not specify a specific method for obtaining a balanced selection. A basic strategy is to "consult all relevant target groups" comprehensively and transparently (cf. European Commission, 2009, p. 20).

1.3. Lack of transparency

One of the most important aspects of the Better Regulation is transparency (European Commission, 2021c, p. 9). Transparency is also a quality criterion of scientific examinations which claim to be a "study". The COM study lacks transparency in several aspects. This makes it difficult to reconstruct its results. In the following, some of these points responsible for this lack of transparency are specified and suggestions for improvement are made.

- **Publications of the results:** An important quality criterion in the context of the Better Regulations of stakeholder surveys involves the presentation of the results. It is in line with the transparency criteria that the completed questionnaires are provided online. This has been done in the COM study. The questionnaires are made available on the website of the European Commission and can be easily opened and downloaded. However, this does not apply to the supporting documents that stakeholders and Member States were able to attach in the course of the survey as evidence for their views. The supporting documents often

3 This document was updated in November 2021 after the publication of the COM study. See European Commission 2021c, d.

consists of entire studies and expert reports. However, these documents are not j documented and there is no information on the website that additional documents were attached to the questionnaires. It would have been for example desirable to provide a list of the supporting documents with links to the respective documents. It is also not clear, whether the supporting documents were evaluated within the COM study at all.

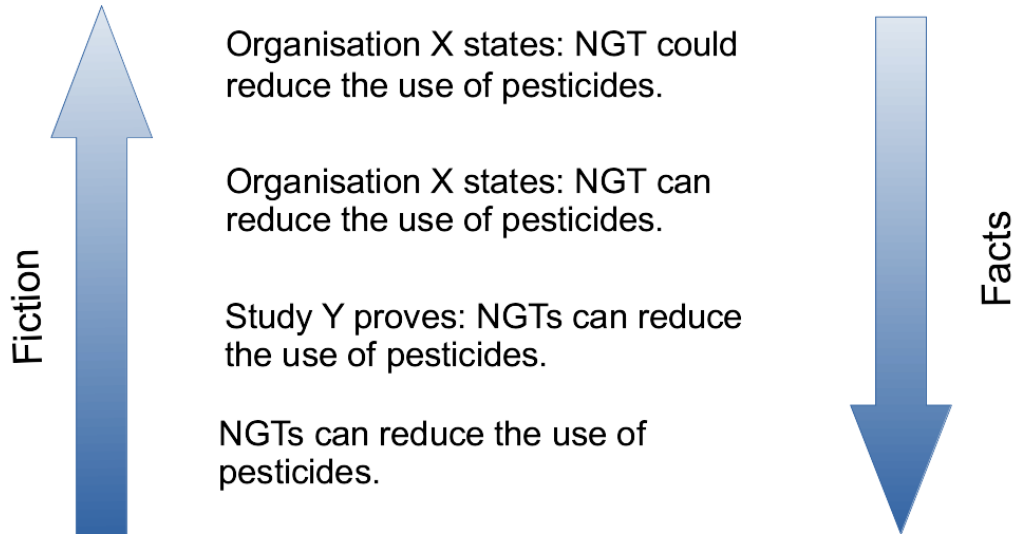
- **Presentation of the results of the targeted consultations:** The COM study does not indicate in the different sections to which questions in the questionnaire the specific analyses refer. This expert opinion reconstructed which material was summarised in which section of the COM study. The reconstruction was based on a thematic comparison of the content sections of the COM study and the questions in the questionnaire. Thus, although the questionnaires are referred to as a source, it is not stated to which questions in the questionnaire the analyses refer. Similarly, the appendix to the COM study should document not only the questionnaire, but also at which point in the COM study the corresponding questions are analysed. The COM study seems to proceed systematically here and it would also have been advantageous for the COM study itself to make this procedure transparent.
- **Lack of consistency**: As already indicated, the COM study only summarises the material on which it is based. For scientific studies of documents and questionnaires, it is essential that the criteria or heuristics used to evaluate the material are made transparent. The COM study does not appear to have such criteria, and if it does, they are not stated. It is therefore not clear how the COM study arrives at the results and conclusions it highlights in the concluding chapters. Similarly, the lack of an analytical approach means that important issues related to the COM study's objectives are presented only in very general terms. Thus, the COM study's conclusions seem arbitrary and not based on a systematic analysis.

1.4. Arguments of the proponents are presented in a way, that they appear to be closer to reality than that of the critiques

As indicated above, the selection of stakeholders is biased to organisations who favoured NGT in their completed questionnaires. Moreover, from the viewpoint of this expert opinion, it is not ultimately decisive how many stakeholders from each interest group were involved – representativeness cannot be achieved through such a procedure – but to what extent the arguments from the completed questionnaires were taken into account in the COM study and in the final discussion.

- The expert opinion has taken a close look at the arguments put forward in the COM study. First of all, it can be stated that the levels of reality of the arguments – that is, to "distinguish evidence from opinion" (cf. European Commission, 2009, p. 20) – are not clearly separated. Statements and opinions by stakeholders and Member States are placed on an equal footing with findings from empirical studies on these facts. But the validity of the arguments presented in the COM study is different. Nevertheless, the COM study treats some arguments as if they describe reality, while others are treated as if they were only hypotheses or speculations of a few. For example, statements about the benefits of NGTs are presented as if the benefits expectations have already materialised. Concerns, on the other hand, are treated as mere opinions and invalidated by means of counterarguments.

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



2. Conclusion

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.

II. Important legal issues not considered in the COM study

According to Art. 2 Section 2 of the Council Decision 2019/1904/EU requesting the COM study the Council wants the COM study to be accompanied by an impact assessment.[4] This means that also an impact assessment regarding legal principles of the European environmental law was requested. To be more precise, and with the knowledge of today where the proposals of the Commission take more shape: With its decision of 8 November 2019, the Council of the European Union requests the European Commission to examine the legal consequences in case of an exemption of certain NGTs from the European genetic engineering law. In the following is examined whether this had been done.

1. Precautionary Principle

1.1. Constitutional principle for European genetic engineering law

One of the most important legal principles of the European environmental law and specifically of the European genetic engineering law is the precautionary principle (Art. 191 para 2, sentence 2 TFEU). It requires precautionary measures when scientific evidence about an environmental or human health hazard is uncertain and the stakes are high. This is the very reason why the current EU legislation on genetic engineering requires in a compulsory way a thorough risk assessment for every plant and organism modified by genetic engineering, irrespectively of the kind of the modification (Annex II Dir. 2001/18/EC). This risk assessment is required by the precautionary principle which is a legal principle of the European Constitution (primary law). This means that the European legislator when adopting legal acts like directives or regulations (secondary law) has to abide by that. Whilst the Commission – together with the European Parliament and the Council – is free to change secondary law, it has not the power to change primary law.

1.2. Nearly complete ignoring of the precautionary principle

The COM study mentions this principle, but only in a few places and very superficially. The all-important question of whether it is compatible at all with the precautionary principle to exempt certain classes of NGTs from the European genetic engineering law or release the respective organisms into the environment without any risk assessment or only with a very superficial one is nowhere even only addressed. On the contrary, there are strong indications that the Commission intends to undermine the risk assessment in a way that NGTs, which (allegedly) have benefits do not need to be analysed as thoroughly as usually prescribed by the European genetic engineering law. This approach is completely out of character in environmental law.

1.3. Exemption of certain NGTs from the European genetic engineering law as infringement of this principle

According to the results of the present expert opinion at the time being two scenarios are possible. In the first scenario certain NGTs would be completely exempted from the European genetic engineering law. In the second scenario NGTs would not be exempted but the requirements for the risk assessment would be relaxed like for instance the requirements for the data to be submitted lowered. In the first scenario this definitely would mean an infringement of the precautionary principle,

4 Document 32019D1904. Council Decision (EU) 2019/1904 of 8 November 2019 requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study. ST/12781/2019/INIT. OJ L 293, 14.11.2019, p. 103–104. Online: http://data.europa.eu/eli/dec/2019/1904/oj.

because releasing genetically engineered organisms in the environment without any scientific evidence for their safety is the opposite of precaution. But also in the second scenario a relaxed risk assessment probably would not be compatible with this principle.

2. Polluter pays principle

2.1. Meaning of this principle

Another important principle of the European environmental law is the polluter pays principle. It stipulates that polluters of the environment bear the costs of their pollution including the cost of measures taken to prevent, control and remedy pollution and the costs it imposes on society. The rationale behind this principle is to give an incentive for potential polluters to avoid such damage in the first place (European Commission, 2022). Applied on genetic engineering this means that for each damage on human beings, animals and the environment, the operator of NGTs causing this damage is to be held responsible for that.

2.2 Infringement of this principle by abolishing identification rules

This very principle would be turned upside-down in case deregulation, be it in form of a complete exemption or in form only of an abolishment of the rules regarding identifiability and traceability.Those are the current obligations of the operator to ensure that the NGT-organisms it has developed can always be unambiguously detected. This would lead to a situation where NGTs could damage humans, animals and biodiversity without any chance of being held responsible. This pivotal principle of environmental law, also enshrined as primary law in the European constitution (Art. 191 para 2, sentence 2 TFEU), is not addressed at all in the COM study.

3. Principle of Coexistence

3.1. NGT-free cultivation as fundamental right

Safeguarding coexistence also is an important collateral issue in the regulation of genetic engineering. It means that the release of genetically modified organisms may not lead to a situation of ubiquitous spread of GMOs which makes it impossible for conventional and especially organic farmers to produce GMO-free. The possibility of a proprietor of real estate to produce GMO-free on his own soil, is guaranteed by the fundamental right of property (German Constitutional Court, 2010). So, Member States constitutionally are obliged to safeguard this kind of cultivation, irrespectively of the fact whether classical GMOs or NGTs are involved. And as all fundamental rights of the EU are derived from the fundamental rights of the Member States the same is true for the European legislator.

3.2. Undermining of this right by exemption of certain NGTs from the European genetic engineering law or by lowering of labelling standards

In case NGTs would be exempted from the status as GMOs or the standards of labelling in certain individual cases would be lowered within the European genetic engineering law, the rules safeguarding GMO-free agriculture would cease to exist for the following reasons:

Free Movement of goods is one of the legal pillars of the European domestic market. As NGTs also are goods this means that national provisions like rules on coexistence, which impair the free trade of NGTs, need an authorization for that to be compatible with European law (ECJ, 1988). Art. 26a section 1 of the current Deliberate Release Directive 2001/18/EC clearly confers this right to implement coexistence rules to the Member States. But the prerequisite for this empowerment of the

Member States is that the organisms against which conventional and organic agriculture are protected are classified as GMOs within the European genetic engineering law.

If NGTs would be exempted from this status, this authorization for the Member States would no longer apply to NGTs. The safeguard clause for national coexistence regulations under European law could no longer apply, because there would be a risk that such measures would then be regarded as inadmissible interference in the free movement of goods.

Apart from those trade-related aspects, the national regulations on coexistence itself would be thwarted. For example, the German regulations on coexistence protection, i.e. the rules on the federal location register, on good professional practice, and the special neighbour defence and liability claims are all based on the concept of GMO i.e. they only protect against organisms legally classified as GMO (Federal Office of Consumer Protection and Food Safety, 2022). And this GMO concept must be interpreted in conformity with European law. So, if the EU were to exclude certain NGTs from the GMO concept of the Deliberate Release Directive, these coexistence rules could no longer be applied and operators using NGTs could challenge such coexistence rules before the courts.

The COM study does not address those legal consequences of exempting certain NGTs at all. This poses a lethal risk for GMO-free agriculture.

4. Undermining of European nature protection law

4.1. NGTs and protected areas under current legislation

One of the most discussed risks of genetic engineering are adverse effects on biodiversity. Areas particularly sensitive in their biodiversity are legally protected on European level by the Natura 2000 network, which covers 18.5 percent of the land area of all Member States (Federal Agency for Nature Conservation, 2022). The European law requires a strict protection of those areas against all harmful impacts which include impacts by NGTs like displacing and impoverishing endangered species, creating negative ecosystem changes, toxic effects on non-target organisms or increased use of herbicides. In order to rule out such damages a special (location-based) impact assessment – additionally to the one being part of the approval process of a certain GMO event generally– is required, before potentially damaging activities in such areas could take place. According to the current legislation this impact assessment also has to be done before NGT-products are used in protected areas (ECJ, 2018b).

4.2. Consequence of the exemption from the European genetic engineering law certain NGT for protected areas

It is very likely that an exemption from the European genetic engineering law of certain NGTs or the lowering of certain risk assessment and labelling standards in individual cases would thwart the current protection of ecologically sensitive areas vis-à-vis NGTs. As only the status of a GMO – and not certain newly added traits – currently triggers the obligation of an impact assessment according to nature protection law, the exemption of certain NGTs from this status could lead to the situation that the use of such plants would be considered as conventional agriculture. The consequence would be that if those NGT-products were used on soils were agriculture already has been conducted before the rules for the Natura 2000 network came into effect in 1992, this would not trigger any more impact assessment (ECJ, 2016).

5. Infringement of Cartagena Protocol

The European Union and the Member States of the European Union are parties to the Cartagena Protocol (CP). Since there is no exemption in the Cartagena Protocol for certain types of genetic engineering such as NGTs, the Protocol also applies on organisms developed through NGTs.

According to Art. 15 para 1 CP, risk assessments must be carried out in a "scientifically sound manner" and be "based on available scientific evidence". Thus, the Cartagena Protocol sets a strict standard for risk assessment. This means for example for the risk assessment of NGTs that not only those areas of the genome should be looked at, where modifications occurred, but that a more detailed and comprehensive approach must be taken. The best approach for assessment based on available scientific evidence would be to sequence the whole genome. The practice of EFSA, which only looks at the modified areas selectively, is not compatible with Art. 15 para 1 CP.

6. Contempt of court

The classic definition of contempt of court is an offence of being disobedient to or disrespectful toward a court of law and its officers. Although this is not the case here, a certain form of at least political contempt of the European Court of Justice as outlined further down should also be part of the political discussion because this might be a sign of not conducting good governance by the Commission.

6.1. Contempt of mutagenesis 1 decision

The pressing ahead of the Commission for the exemption from the European genetic engineering law of certain NGTs or other moves for loosening the rules (i.a. the lowering of certain risk assessment and labelling standards in individual cases) can be considered as contempt of court, in form of contempt of the European Court of Justice (ECJ). In 2018 the ECJ has ruled in its mutagenesis 1 decision (ECJ, 2018a), that directed mutagenesis does fall under the EU genetic engineering law. In doing so the ECJ explicitly took a position against at least the complete exemption of directed mutagenesis from the European genetic engineering law. The reason for this was the absence of a history of safe use. This also applies for the other NGTs. So, at least the plans of the Commission to exempt certain NGTs or the lowering of certain risk assessment and labelling standards in individual cases would ignore the legal requirements of the ECJ for such exemptions.

By the same token the position of the Commission that the legal concept of mutagenesis in European genetic engineering law is not clear which would need a clarification by the Commission (European Commission, 2021a, p. 54) is false. The ECJ ruled that directed mutagenesis does fall under the European genetic engineering law and so has clarified the concept of mutagenesis (ECJ, 2018a).

6.2. Contempt of mutagenesis 2 procedure

This disrespect of the Court since November 2021 has been intensified. On 17 November 2021, the French Conseil d'Etat requested the ECJ to clarify follow-up questions regarding the mutagenesis 1 judgment of 2018 in a further referral procedure (ECJ, 2021). In this mutagenesis 2 proceedings, the European Court of Justice will comment on key aspects on which the Commission bases its reform proposals.

On the one hand, it is the question of when exactly a history of safe use exists. More precisely, the ECJ will clarify whether only the method by which the genetic material is modified should be considered in this assessment or whether all changes to the organism caused by the method used are to be taken into account. In other words, the ECJ will clarify in these proceedings whether it is permissible to relax the safety standards for certain groups of genetic modifications solely because

a certain GE-technique was used. Since this is exactly what the Commission intends with certain NGTs (European Commission, 2021b), the Commission deliberately disregards the ECJ a second time if it keeps on moving forward without waiting for the ECJ's position on the matter.

The same applies to the second point that the ECJ now has to clarify, namely the question of whether the experience of field cultivation is a prerequisite for establishing a history of safe use, because the Commission intends to classify certain NGT as safe without having any experience with field cultivation with those plants.

The impact assessment for the proposals that the COM study paves the way for is one-sided. It emphasises the alleged advantages for climate protection, sustainable agriculture and Sustainable Development Goals if certain NGTs are exempted from the European genetic engineering law. On the other hand, the highly problematic consequences for the environmental law in case of the exemption from the European genetic engineering law of certain NGTs or the lowering of certain risk assessment and labelling standards in individual cases are not discussed.

III. Technical aspects and utilisation of plants and products obtained with New Genomic Techniques

As mentioned before, the European Commission had requested a set of supplementary materials. With respect to the technical aspects and utilisation of plants and products obtained with New Genomic Techniques, these materials were published in particular by the European Commissions Joint Research Center (JRC) (Broothaerts et al., 2021; Parisi & Rodríguez-Cerezo, 2021). Other sources find their way into the COM study, for example an explanatory note of the scientific advisors of the European Commission (SAM HLG, 2017).

1. Technical aspects

The COM study regularly compares NGT-plants and products with plants produced by conventional breeding methods. NGT-plants and products are also compared with plants that are modified due to 'natural' mutations. As a consequence, the COM study states: "EFSA concluded, on the basis of recent experimental evidence, that the off-target mutations potentially induced by SDNs are of the same type as, and fewer than, those in conventional breeding, including spontaneous mutations and those produced by physical and chemical mutagenesis" (European Commission, 2021a, p. 53).

However, there is no strong or convincing experimental evidence for this conclusion. EFSA 'proves' this – alleged – evidence with three publications in which only CRISPR techniques were used (Lee, 2019; Li, 2019; Tang, 2018). Moreover, only maize, rice and cotton were investigated. In this respect, the results can at best be taken as indications that need to be tested by further studies. Therefore, the EFSA conclusion in this generalized and - prospective - form lacks evidence. And hence, a case-by-case evaluation is indispensable.

The fact that the COM study only very weakly substantiates its claim is all the more astonishing since the COM study makes the similarity of the changes an essential, if not the most important pillar in EFSA's non-case-specific risk assessment (see chapter IV.2.).

2. Utilisation of plants and products obtained with NGT

All in all, the COM study paints an extremely positive picture of the expected developments of NGT-plants and -products. However, it fails to provide evidence, because so far only very few of these products have made its way to the market – regardless of the country in the world in which approvals are being sought. What is particularly striking in this context is that the information presented in the report is in large parts not comprehensible. Parisi and Rodríguez-Cerezo (2021, p. 9) write, that "much of the data was obtained under conditions of confidentiality, the report shows data aggregated into species groups and trait/disease categories. The detailed content of the database will not be made public". Limited information with respect to genome editing had been an issue for other reports as well (SAM HLG 2017) and is a major problem within risk assessment of genetically engineered organisms since at least 15 years (cf. Pollack, 2009; Waltz, 2009).

The conclusion that NGT-crops and products can help achieve current European Union goals is not tenable. This is all the more true as the EU Commission has made a small but subtle (and important) shift in its communication following the publication of the COM study in April 2021: Whereas the COM study itself states "NGT products and their applications could provide benefits for EU society and address major challenges [...]" (European Commission, 2021a, p. 59). A little later, the Commission no longer speaks in the subjunctive: "[...] can contribute to Green Deal and Farm to

Fork objectives" (presentation commissioner Stella Kyriakides at EU Council meeting in May 2021, underlining by authors).

3. Potential contribution of NGTs to sustainability

One of the main arguments of the COM study to think about changing the legal requirements for NGTs is the potential contribution of some NGTs for a more sustainable agriculture and food production. The COM study emphasises that "several of the plant products obtained from NGTs have the potential to contribute to the objectives of the EU's Green Deal and in particular to the 'farm to fork' and biodiversity strategies and the United Nations' sustainable development goals (SDGs) for a more resilient and sustainable agri-food system" (European Commission, 2021a, p. 2). The European Commission further states that "a purely safety-based risk assessment may not be enough to promote sustainability and contribute to the objectives of the European Green Deal and in particular the 'farm to fork' and biodiversity strategies; benefits contributing to sustainability would also need to be evaluated, so an appropriate mechanism to accompany risk assessment may be required" (European Commission, 2021a, p. 4).

Mentioned examples are "plants more resistant to diseases and environmental conditions or climate change effects in general, improved agronomic or nutritional traits, reduced use of agricultural inputs (including plant protection products) and faster plant breeding" (European Commission, 2021a, p. 2). According to the COM study, the development of a few plants with herbicide tolerance or fungal resistance is in the pre-commercial stage, while the development of plants tolerant to abiotic stress factors (such as drought, salinity, and heat) is expected in the medium term (by 2030). It is unclear whether these examples of single traits could lead to more sustainable agriculture that takes systemic effects into account.

In its study, the European Commission seems to assume uncritically that these NGT-plants can either have no negative effects on the environment and health or that certain risks are to be accepted due to possible benefits. Thus, the Commission ignores the results of numerous studies that have found, for example, negative effects of herbicide-tolerant plants on the environment. With regard to the potential development of plants that are more resistant to certain effects of climate change, it can be assumed that this will require complex changes in the plant genome. Experience with "conventional GMOs" shows that multiple modifications can be associated with unintended effects (e.g. on the plant's metabolism). In addition, plants that have some tolerance to drought, heat or soil salinity also run the risk of being altered regarding their invasiveness due to their competitive nature. They could then for example invade biotopes with high conservation value, displace the wild plants adapted to these locations and increase their extinction risk.

IV. Risk assessment

An overview of EFSA and European national authorities' scientific opinions on the risk assessment of plants developed through New Genomic Techniques had been published as part of the supplementary material of the COM study. (EFSA, Paraskevopoulos & Federici, 2021) For the COM study, this work is crucial. Other EFSA papers are used as well (see list of selected EFSA papers in chapter D.). Generally, the COM study refers often to EFSA papers. Sometimes it is not clear, whether the COM study actually adopts the arguments as their own, or not. In other cases, similarly to what is shown above for the COM study (see B.I.2.), it remains open how EFSA's own position is weighed against other voices. For example, the mentioned paper by EFSA, Paraskevopoulos & Federici (2021) presents the results of several older opinions issued by Member States and EFSA itself. The different opinions do not always come to the same conclusions and it is – at least partly – not clear how on the one hand EFSA, but also the COM study, weighs the results against each other. What is missing is a set of criteria against which the arguments can be measured.

1. Similar levels of risk

The following paragraph from the COM study is most important, when it comes to conclusions with respect to technical and risk assessment aspects: "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" (European Commission, 2021a, p. 59). First of all, the quote shows an implicit demand, to change a – in the sense of the COM study – unjustified regulatory oversight. The demand is based on the conclusion of the EFSA, that "similar products with similar risk profiles can be obtained with conventional breeding techniques, certain genome editing techniques and cisgenesis". This demand is not trivial, but far reaching. To make it clear: The European Commission is thus calling the entire structure of risk assessment of genetically modified organisms in the EU into question. Until now, the genetic modification of a certain organism is the "trigger" that leads to its comprehensive assessment regarding risks for environment and human health. This assessment proceeds on a case-by-case basis, meaning that each genetic event (a particular genetic modification in a particular plant species) is examined individually. This would no longer be the case if this idea becomes reality. Maybe it is the first time, that one can read it from the Commission: To "apply different levels of regulatory oversight to similar products with similar levels of risk" – what means the actual EU regulation of genetic engineering – "may not be justified". Even if this statement is formulated in a somewhat complicated way, the authors refrain from making relativising restrictions. This is new in contrast to previous statements of the Commission on this issue.[5] This is significantly more far-reaching than any other finding of the COM study. Consequently it is the most important outcome with respect to risk assessment, and it is the core of the discussion in the EU with technical aspects.

5 The Commission has been struggling for years to meet the demands of the EU Member States for a clear statement on the regulation of NGTs, respectively on the interpretation of existing European law. See for example Commissions letter to Competent authorities of the Member States (European Commission, 2015). Later, after the European Court of Justice had announced case C-528/16, a statement of the Commissions would no longer have been appropriate.

2. Case-by-case assessment

Several parts and terms of the COM study remain unclear. For example the term "risk profiles" is neither explained in the COM study nor in the supplementary material. What is clear is that risk profiles – despite the lack of explanation – play a central role in the context of a possible new regulation of NGTs.

As proposed by the EU Commission in the aftermath of the publication of the COM study in April 2021, NGT-plants and -products (made with SDN-1 and SDN-2 techniques or cisgenesis) that would have been assigned to the same risk profile as unregulated plants and products and on this basis could then in turn be left out of the regulation of genetic engineering. As a consequence, the principle of case-by-case risk assessment could not remain as it currently is. In its conclusions the COM study problematises the case-by-case approach for the risk assessment as follows: "The GMO legislation sets out stringent safety requirements and procedures. 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" (European Commission, 2021a, p. 59).

The emphasis here is on the problems caused by the valuation that the "rigid risk assessment guidance" is part of the EU genetic engineering regulation. At the same time, the COM study do not refer to a specific part, a specific formulation of the genetic engineering regulation. The section on case-by-case assessment in the discussion of the COM study reads quite differently: "Case-by-case assessment is widely recognised as the appropriate approach. EFSA and the Member State opinions agree on the need for flexibility and proportionality in risk assessment methodologies and data requirements, to take account of available knowledge on the history of use of the modification(s) and the trait(s) introduced. On these points, not all stakeholders share the expert body opinions. Several Member States, agencies and stakeholders see a need to develop specific case by case risk-assessment procedures for NGTs. Some stakeholders called for research on safety and environmental risks linked to unintended adverse effects and NGT-products' interaction with the environment" (European Commission, 2021a, p. 53).

Case-by-case assessments are applied at the level of individual GMO events in order to make fit-for-purpose environmental impact assessments without collecting superfluous information. But the case-by-case assessments are the implementation of an abstract principle. They are part of risk management and are intended to ensure that the diversity of genetically modified or genome-edited plants is taken into account. In this context – and in this sense – the case-by-case assessments are primarily intended to ensure that - sufficient data are collected as a result of general, non-specific examination and assessment regimes.

C. Supplementary material to European Commission (2021) and further references in the COM study

Supplementary material:

Member States and stakeholders replies to the targeted consultation
https://ec.europa.eu/food/plant/gmo/modern_biotech/stakeholder-consultation_en

Overview of EFSA and national authorities' scientific opinions on the risk assessment of plants developed through New Genomic Techniques
https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.631
[see below: EFSA (European Food Safety Authority), Paraskevopoulos & Federici, 2021]

JRC Science for Policy Report – Current and future market applications of New Genomic Techniques
https://doi.org/10.2760/02472
[see below: Parisi, C. & Rodríguez-Cerezo, E. (2021)]
link to web dashboard:
https://datam.jrc.ec.europa.eu/datam/mashup/NEW_GENOMIC_TECHNIQUES

JRC Technical Report – New Genomic Techniques: State-of-the-art Review
https://data.europa.eu/doi/10.2760/710056
[see below: Broothaerts, W., Jacchia, S., Angers, A., Petrillo, M., Querci, M., Savini, C., Van den Eede, G., & Emons, H. (2021)]

Further references mentioned in the COM study (European Commission, 2021) beneath others:

EGE (European Group on Ethics on Science and New Technologies, 2021): Opinion on Ethics of Genome Editing. Opinion no. 32, 19 March 2021. European Commission.

EURL/ ENGL (2019). Detection of food and feed plant products obtained by new mutagenesis techniques. European Network of GMO Laboratories (ENGL). https://gmo-crl.jrc.ec.europa.eu/doc/JRC116289-GE-report-ENGL.pdf.

SAM HLG (2017). New techniques in Agricultural Biotechnology. Explanatory Note 02/2017. Formerly known as the Scientific Advise Mechanism High-Level Group (SAM HLG) of Scientific Advisors, now Group of Chief Scientific Advisors. *[cpo: in Paraskevopoulos and Federici/ EFSA (2021) zitiert als "European Commission (EC-SAM), 2017. New techniques in agricultural biotechnology. Scientific Advice Mechanism (SAM), Directorate-General for Research and Innovation. EU publication, https://doi.org/10.2777/574498"]*

Different papers published by EFSA (selection):

EFSA (European Food Safety Authority), Paraskevopoulos, K., & Federici, S. (2021). Overview of EFSA and European national authorities' scientific opinions on the risk assessment of plants developed through New Genomic Techniques. EFSA Journal 2021, 19(4):6314, 43 pp. https://doi.org/10.2903/j.efsa.2021.6314.

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli, H., Bresson, J.-L., Dalmay, T., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Mullins, E., Nogué, F., Sanchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Casacuberta, J., Gennaro, A., Paraskevopoulos, K., Raffaello, T., & Rostoks, N. (2020). Scientific opinion. Applicability of the EFSA Opinion on site-directed nucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis. EFSA Journal 2020, 18(11):6299, 14 pp. https://doi.org/10.2903/j.efsa.2020.6299.

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms) (2012). Scientific opinion addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function. EFSA Journal 2012, 10(10):2943, 31 pp. https://doi.org/10.2903/j.efsa.2012.2943.

Vlugt, C. J. B. van der (2021). Overview of sixteen scientific opinions on genetically modified plants obtained by new genomic techniques. EFSA supporting publication 2021:EN-1973. 39 pp. https://doi.org/10.2903/sp.efsa.2021.EN-1973.

D. Literature

Broothaerts, W., Jacchia, S., Angers, A., Petrillo, M., Querci, M., Savini, C., Van den Eede, G., & Emons, H. (2021). New Genomic Techniques: State-of-the-Art Review, EUR 30430 EN, Publications Office of the European Union. https://doi.org/10.2760/710056.

ECJ (1988): Judgment of the Court of 20 September 1988 – Commission of the European Communities v Kingdom of Denmark – Free movement of goods – Containers for beer and soft drinks - Case 302/86.

ECJ (2016): Judgment of the Court (Fourth C–hamber) of 10 November 2016 – European Commission v Hellenic Republic – Case C-504/14.

ECJ (2018a): Judgment of the Court (Grand Chamber) of 25 July 2018 - Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt – Request for a preliminary ruling from the Conseil d'État – Case C-528/16.

ECJ (2018b): Judgment of the Court (Second Chamber) of 7 November 2018 -Coöperatie Mobilisation for the Environment UA and Vereniging Leefmilieu v College van gedeputeerde staten van Limburg and College van gedeputeerde staten van Gelderland - Requests for a preliminary ruling from the Raad van State – Joined Cases C-293/17 and C-294/17.

ECJ (2021): Request for a preliminary ruling from the Conseil d'État (France) lodged on 17 November 2021 – Confédération paysanne and Others v Premier minister, Ministre de l'Agriculture et de l'Alimentation – Case C-688/21.

European Commission (2009). Impact Assessment Guideline. SEC(2009) 92. https://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/iag_2009_en.pdf (accessed 25 June 2022).

European Commission (2015). Letter to Competent authorities of the Member States. Subject: Herbicide tolerant oilseed produced using oligonucleotide directed mutagenis. Ref. Ares(2015)2495644 – 15/06/2015.

European Commission (2021a). Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16. COMMISSION STAFF WORKING DOCUMENT SWD(2021) 92 final. https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques_en (accessed 25 June 2022).

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European Commission (2021c). Better Regulation. Toolbox. November 2021. https://ec.europa.eu/info/sites/default/files/br_toolbox-nov_2021_en.pdf (accessed 25 June 2022).

European Commission (2021d). Better Regulation Guideline, November 2021, Commission Staff Working Document. https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox_en

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Federal Office of Consumer Protection and Food Safety (2022). Koexistenz. https://www.bvl.bund.de/DE/Arbeitsbereiche/06_Gentechnik/02_Verbraucher/04_GVO_nach_Genehmigung/04_Koexistenz/gentechnik_koexistenz_node.html (accessed 25 June 2022).

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