Summary of findings
of the expert opinion on 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

submitted by
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August 2023

A. Mandate for investigation and methodological approach

With Council Decision of 8 November 2019[1], the European Commission was requested to carry out a study on the status of new genomic techniques in light of the CJEU ruling in Case C-528/16 and – if appropriate in view of the outcomes of the study – to submit a proposal. The outcomes of this study were published on 29 April 2021 in the form of the Commission Staff Working Document "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" (hereinafter referred to as Commission study).

This expert opinion provides a legal analysis of the outcomes of the Commission study and comprehensively assesses their potential legal implications before it goes on to evaluate them from the perspective of the required consideration of environmental protection and nature conservation.

It places a special focus on questions regarding methods and detectability, incorporating the particular challenges of import constellations.

[1] Council Decision (EU) 2019/1904 of 8 November 2019, OJ. No L 293, p. 103 et seq.

B. Summary of findings

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” (hereinafter referred to as Commission study) in many respects falls short of the mandate formulated in Council Decision (EU) 2019/1904 of 8 November 2019. In particular the CJEU ruling in Case C-528/16, which provided the initial impetus for the study, and the legal considerations that are the basis for this ruling are almost completely disregarded. The study therefore fails to address the aspect of “study….in light of the ruling” as called for by the Council.

Although the Commission study’s consultation procedure was very comprehensive, its methodology was anything but transparent. The study contains no explanation of which deliberations led to what input from which stakeholders in the Commission’s comments. This has a negative impact on the study’s value as a whole.

With regard to identifying and assessing environmental risks, the Commission study develops the holistic approach. Placing the discourse about new genomic techniques in a more comprehensive legal and political landscape occurs both vertically and horizontally. Vertically, it is a question of existing or assumed interfaces of the genomic techniques discourse with non-genetic-specific concepts, ideas, programmes and policies of EU and international law. The study specifically refers to the European Green Deal, the Farm to Fork Strategy, the goals of the Biodiversity Strategy and the UN Sustainable Development Goals. Horizontally, there is a clear mixing of different criteria specific to genetic engineering, for example when the categories of environmental impact, risk assessment and general safety concerns are mixed.

The inclusion of other contexts and levels of reference not connected to genetic engineering law in the strict sense may make it possible to break

up ingrained patterns and may help reinvigorate the discourse. However, the key challenge lies in ensuring the absolutely essential objectivity of observations and strict transparency of all procedures and processes. Additionally, it is important to address the fundamental issue of the necessary prioritisation of different categories of documents and perspectives to be included in considerations.

The Commission's selection of documents deemed relevant does not satisfy these requirements. Instead, the concepts referred to – for the most part policy strategies – have no relevant overlaps with genetic engineering issues and are also very influenced by the problem of self-referentiality. Where known narratives of genetic engineering discussions are drawn on (e.g. the alleged potential of reduced pesticide use), these narratives need to be founded on sound scientific evidence rather than mere promises.

The Commission proposals regarding greater flexibility of risk assessment ultimately react to a typical challenge of all regulation (of engineering and technology): highly dynamic technological developments are regulated on the merits of basically static standards. The legislator has a number of instruments at its disposal to enable sufficient dynamism. The possibility to obtain a broad basis of knowledge and findings in this way – as the foundation of any risk assessment – is undoubtedly welcome. In this context, it would be essential to also incorporate possible off-target effects of scientific methods into risk assessment.

In contrast, the concrete flexibility options proposed by the Commission are not convincing. Both with regard to the call for data requirement reduction and in light of an only partial implementation of risk assessment, the specific prerequisites required as far as the Commission is concerned remain unclear, as do the criteria for identifying suitable case constellations.

The Commission deliberations on reviewing unforeseen risks to human health and the environment ultimately result in the assumption that the rules governing risk assessments for SDN-1, SDN-2 and cisgenesis techniques can be relaxed and that these techniques can be subject to a relatively simplified procedure. Irrespective of the fact that this perspective clashes with the established CJEU case law regarding Cases C-528/16 and C-688/21, there is also incompatibility with the requirements of “history of safe use”, which is standardised by secondary law and established in primary law.

Regarding the precautionary principle, the Commission study aims for uniformity of the case-by-case practice that calls for a harmonisation of the precautionary principle with the principle of proportionality. In this context, there are also indications that the Commission considers the precautionary principle to be an “ethical guideline”. However, the requirement of measure-based application of the precautionary principle is already established legal practice. The same applies to reconciling the precautionary principle and the proportionality principle. In this context, the precautionary principle is “hard law” that must be respected and complied with. Similarly, in its established case law, the CJEU assumes an unlimited legal quality of Article 191 (2), second sentence, of the Treaty on the Functioning of the European Union (TFEU).

Consumer interests are addressed in detail in the study. The Commission sees cause to state that the organic sector itself uses seeds that may also result from conventional mutagenesis and therefore qualify as GMOs but at the same time are not subject to the obligations of the Directive. Irrespective of the fact that this political narrative developed following the CJEU ruling in Case C-528/16 is irrelevant for the assessment of new genomic techniques as such, the Commission presents its legal interpretation as irrefutable – an opinion that may not be singular but certainly does not represent the prevailing opinion.

Regarding risk assessment for new types of challenges, the Commission gives more room to the EFSA and other institutions and bodies than in other sections of the summarising evaluative discussion, although these opinions are always designed as a counterpoint to specific objections. The unbalanced emphasis on a small number of opinions therefore already contradicts the postulate of a “holistic approach” as developed by the Commission itself. From a regulatory perspective, the various deductions contradict the established case law of the CJEU, and also the applicable primary law framework.

The assumptions of the Commission regarding regulatory uncertainties and a lack of enforceability refer to different, legally non-defined terms and criteria in Directive 2001/18/EC, from which a possible need for revision is apparently deduced. Irrespective of the fact that the CJEU was not called on to define these terms, there is no indication of such a need for revision, also with a view to the legislator. Every modern state based on the rule of law has to draw on undefined legal terms and general clauses to be able to guarantee the functionality of its legal system. The views expressed by the Commission ultimately envisage a legal system in which every relevant term is legally defined. This, however, is impossible because the constitutive elements of those legal definitions would themselves give rise to further interpretation.

The Commission study therefore contains numerous shortcomings and blind spots from a methodological, empirical and logical perspective. These undermine the general validity of the document.

These deficiencies are also found in the special focal areas of the Commission study. Regarding the discussion on detectability, this applies for example to the rather selective presentation of member state

adaptation of monitoring systems, but also regarding the construction of an – actually unnecessary – multilayer detection method.

The brief reference in the Commission study only mentioned on the margins without being addressed in detail – that the alleged inability of enforcement laboratories regarding detection is primarily due to a lack of prior information on altered DNA sequences – also falls into this category. This leads to a legally unacceptable shift of existing legal obligations in the interests of relevant companies. As a result, the corporate obligation to submit or develop viable detection methods is in fact disregarded.

The inaccuracy of the narrative popular with some stakeholders of an “enforcement deficit” is also reflected in this context. Real enforcement deficits have existed in European environmental law for decades. These are the subject not only of rulings by the Court of Justice of the European Union, but also of detailed legal analyses found in the legal literature. However, the discussion on detectability does not address aspects of a lack of or inadequate enforcement by authorities. It instead addresses a very different element – the unwillingness of companies to comply with the legal obligation to develop detection methods.

This is a case of non-compliance with environmental law obligations which to date – and rightly so – has never been responded to with deregulation and instead exclusively with corresponding penalties. The expansion of environmental criminal law registered also at EU level is compelling proof of this. Any other approach – notably the deregulation of applicable genetic engineering law to “cushion” corporate legal obligations – would ultimately lead to an erosion of rule of law principles.

The Commission study in no way addresses possibilities to close the alleged “deficiency gap”. In fact, the analysis is found to intentionally create blind spots.

It is true that the usability of the knowledge incorporated into patent law databases is limited for various reasons. However, according to the Commission study, in particular document-based traceability systems like those already established in genetic engineering law or in the seed variety certification system also have the power to “overcome the analytical limitations”.

The argument of additional costs that is put forward is not sustainable. In fact, the financial accountability of companies distributing the technology corresponds with the polluter pays principle laid down in primary law in Article 191 (2) TFEU, but also with the key principles of public administration: whoever seeks authorisation or requests a review from an authority has to bear the costs incurred.

The detection method to be submitted does not have to be in a position to detect the specific process used to manufacture a GMO.

Genetic engineering law obligates companies both within the scope of the Deliberate Release Directive and in application of the Contained Use Directive. The Contained Use Directive designates corresponding obligations exclusively to the “user”.

The – inaccurate – claim of the impossibility of submitting a reliable detection method can, from a legal perspective, be understood as a reference to an objective impossibility (for example within the meaning of Section 44 (2) No 4 of the Administrative Procedure Act (VwVfG)). However, this narrowly interpreted standard is not pertinent for several reasons.

Firstly, there are an increasing number of scientifically founded indications of the existence or feasibility of suitable detection methods. Secondly, the

European legislator has clearly assigned the obligation to companies to develop suitable detection methods if necessary. In other words, the law classifies the time, personnel and financing required to comply with this obligation as reasonable. Ultimately, it can be ruled out as a matter of logic that companies will develop, use and market a technology without also having the possibility to prove unauthorised use of this technology by a third party. Every company must be in a position to prove unauthorised use of its technology in a way that withstands legal scrutiny in order to ensure return on investment. The prerequisite for this is a detection method.

The mere unwillingness to meet legal obligations in order to save time, personnel and money in no way represents objective impossibility. In fact, it amounts to a legally irrelevant subjective failure.

European genetic engineering law also covers import constellations. The new Official Controls Regulation (EU) 2017/625 that entered into force at the end of 2019 explicitly extended the control regime to genetic engineering. The main goal of the regulation is to prevent risks to human health, animals, plants and the environment resulting from divergent law enforcement.

The Official Controls Regulation (EU) 2017/625 in no way modifies the requirements of genetic engineering law. It fact, it makes them a prerequisite and aims at uniform implementation in compliance with the law. This also applies to the detectability of GMOs in import constellations.

The Official Controls Regulation (EU) 2017/625 confirms the provisions on providing proof under genetic engineering law as far as import constellations are concerned. In Article 67, it also explicitly clarifies that the costs of the corresponding controls are applied at the expense of the operator responsible for the consignment.

The question of potential liability of the authorities involved is answered by applicable state liability law. In this context, the constellations of European state liability law are not pertinent; in fact, national state liability law applies.

According to the most recent legal rulings, the claim regarding official liability in Section 839 of the German Civil Code (BGB) in conjunction with Article 34 of Germany's Basic Law (GG) can fundamentally also be applied to cases with an international element and thus to import constellations. However, the call to submit a detection method is supported by current genetic engineering law, which means that there is no relevant breach of official duty. There is also no culpable action on the part of the officials concerned as a cause of liability.

Other liability instruments (under judge-made law) are also not pertinent because there is not even any relevant violation of property rights. Liability under international trade law is also ruled out, as is satisfaction pursuant to Article 41 of the European Convention on Human Rights (ECHR) as the potential countries for import constellations are not members of the Council of Europe.

It is possible to differentiate between a number of different case groups with regard to special constellations under liability law where it is subsequently ascertained that a product was not actually GMO-free. The initial measures required to determine the state of matters are regulated in Article 137 of the Official Controls Regulation (EU) 2017/625. The measures then to be taken when non-compliance is ascertained are the subject of the provisions in Article 138 of the Official Controls Regulation.

Culpable action by the responsible company is covered by the penalties regulated in Article 139 of the Official Controls Regulation.

Where a product is subsequently proven not to be GMO-free, authorities must in particular restrict or prohibit continued placing on the market pursuant to Article 138 (2) (d) of the Official Controls Regulation.

European genetic engineering law also applies to the submission of reference material/detection methods for imports from non-EU countries. This already applies with a view to the principle of territoriality under international law, but is also comprehensively reaffirmed by the Official Controls Regulation.

Unwillingness on the part of exporting companies to meet the requirements of European genetic engineering law is in no way an enforcement deficit meriting further attention – it is simply a matter of non-compliance with applicable law.

A number of generally accessible sources are already available to assess organisms and products. In addition to individual public databases from non-EU countries, a range of scientific databases and the supplementary use of patent databases, particular mention should be made of the Biosafety Clearing House mechanism, more precisely the category of project-related reference records.

A structured and comprehensive examination of scientific literature is likely to lead to additional, extensive findings in future. This could also be the case with regard to supply chain initiatives.