EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

EXECUTIVE SUMMARY

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

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The Council of the European Union[1] asked the Commission to submit, by 30 April 2021, *a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of* ***new genomic techniques*** *under Union law.* It also asked the Commission to submit a proposal accompanied by an impact assessment, if appropriate in view of the outcomes of the study, or otherwise to inform it of other measures required as a follow-up to the study.

For this study, 'new genomic techniques' (NGTs) are defined as techniques that are capable of altering the genetic material of an organism and that have emerged or have been developed since 2001, when the current legislation on genetically modified organisms (GMOs) was adopted. Information and views on the status and use of new genomic techniques in plants, animals and micro-organisms for agri-food, industrial and pharmaceutical applications were gathered from Member States and EU-level stakeholders via a targeted consultation. The study was further supported by expert contributions[2] on specific aspects regarding safety, testing methods and technological and market developments.

The study makes it clear that organisms obtained through new genomic techniques are subject to the GMO legislation. However, developments in biotechnology, combined with a lack of definitions (or clarity as to the meaning) of key terms, are still giving rise to ambiguity in the interpretation of some concepts, potentially leading to regulatory uncertainty.

NGTs and their products have developed rapidly in the last two decades in many parts of the world, with some applications already on the market and more applications in different sectors expected in the coming years. This study confirms that there is considerable interest in research on new genomic techniques in the EU, but most of development is taking place outside the EU. Following the ruling of the Court of Justice of the European Union (CJEU), there have been reports of negative impacts on public and private research on new genomic techniques in the EU due to the current regulatory framework.

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. Examples include 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.

However, some stakeholders consider that these benefits are hypothetical and achievable by means other than biotechnology. In particular, the organic and GM-free premium market sector reported that they might face threats from coexistence with new genomic techniques and, therefore, any consideration of NGT products outside the scope of the current GMO regulatory framework would deal a severe blow to their value chain and risk damage consumer trust in their sector.

NGTs constitute a diverse group of techniques, each of which can be used in various ways to achieve different results and products. Therefore, safety considerations depend on the technique, how it is used and the characteristics of the resulting product and cannot be made on all techniques as a

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1 Council Decision (EU) 2019/1904.

2 From the European Food Safety Authority (EFSA), the Commission's Joint Research Centre (JRC) and the European Network of GMO Laboratories (ENGL).

whole. Some NGTs[3] in plant applications are widely addressed in expert opinions from the European Food Safety Authority (EFSA) and Member State authorities, and in Member States' and stakeholders' views on safety and risk assessment; less information is available on other NGTs and micro-organism or animal applications.

For certain NGTs[4], EFSA has not identified new hazards compared to both conventional breeding and established genomic techniques (EGTs). EFSA has also noted that random changes to the genome occur independently of the breeding methodology. Insertions, deletions or rearrangements of genetic material arise in conventional breeding, genome editing, cisgenesis, intragenesis and transgenesis. In addition, EFSA has concluded that off-target mutations potentially induced by site-directed nuclease (SDN) techniques are of the same type as, and fewer than, those mutations in conventional breeding. Therefore, in certain cases, targeted mutagenesis and cisgenesis carry the same level of risk as conventional breeding techniques.

Expert opinions at EU and national level have noted the need for flexibility and proportionality in risk assessment, although not all stakeholders share this view. Another aspect that has been raised is the need to develop risk assessment procedures that are specific to NGTs.

Respondents to the consultation expressed diverse, sometimes opposite views as regards the level of safety of NGTs and their products, and on the need and requirements for risk assessment. However, case-by-case assessment is widely recognised as the appropriate approach.

The study confirms that the current regulatory system involves implementation and enforcement challenges in the EU, relating in particular to the detection of NGT products that contain no foreign genetic material.

Although existing detection methods may be able to detect even small alterations in the genome, this does not necessarily confirm the presence of a regulated product; the same alteration could have been obtained by conventional breeding, which is not subject to the GMO legislation. This is a problem for enforcement authorities and operators. In addition, applicants seeking authorisation would find it difficult, and even impossible in certain cases, to comply with the legal requirement to submit a reliable detection method. Complementary traceability systems do not appear to offer a solution to this challenge and present a number of limitations.

In light of the different regulatory oversight for NGTs in other countries, the above difficulties could lead to trade limitations and disruptions, and put EU operators at a competitive disadvantage, with further negative consequences. This could also lead to the creation of technical barriers to trade, potentially leading to disputes between the EU and its trade partners.

Regulatory barriers would particularly affect small and medium-sized enterprises (SMEs) and small-scale operators seeking to gain market access with new genomic techniques, even though many Member States and stakeholders see opportunities for them in this sector.

The study acknowledges the benefits of patents and licensing in promoting innovation and the development of new genomic techniques and their products. However, these same aspects

[3] Site-directed nuclease (SDN) techniques, oligonucleotide-directed mutagenesis (ODM).

[4] Site-directed nuclease type 1 and type 2 (SDN-1, SDN-2), ODM, cisgenesis.

(together with high business concentration) can also act as a barrier to market entry for SMEs and can limit access to new technologies and to genetic material, e.g. for breeders and farmers.

The use of NGTs raises ethical concerns, but so does missing opportunities as a result of not using them. Based on the findings of the study, most of the ethical concerns raised relate to how these techniques are used, rather than the techniques themselves.

In Member States, there is interest in addressing NGT-related topics in dialogues and events carried out by various institutions, which can help to raise public awareness and understanding. Public perception of new biotechnologies is key to their market uptake.

Consumers' understanding and awareness enable them to make informed choices, so the provision of consumer information (e.g. via labelling) is key. However, stakeholders have opposing views, both on the need to continue labelling NGT products as GMOs and on the effectiveness of such labelling in informing consumers.

Overall, the study provides evidence confirming the conclusions of the past evaluations of the GMO legislation, which noted that some of the new techniques create new challenges for the regulatory system. These evaluations also concluded that, as the rate of innovation in the global biotechnology sector is unlikely to slow down, ensuring that legislation remains relevant is likely to be an ongoing challenge, especially if the focus is on the techniques used rather than the characteristics of the final products and the traits they express.

The key question, therefore, is whether legislation that raises implementation challenges and the application of which to new techniques and new applications requires contentious legal interpretation is still fit for purpose or needs updating in light of scientific and technological progress. However, reported views are split on whether the current legislation should be maintained and its implementation reinforced, or rather adapted to take account of scientific and technological progress, the level of risk of NGT products and the benefits to society. The specific characteristics of medicinal products should also be duly considered. The Commission has already announced this will be addressed as part of the pharmaceutical strategy[5].

The follow-up to this study should consider possible policy instruments to make the legislation more resilient, future-proof and uniformly applied. Any further policy action should be aimed at reaping benefits from innovation while addressing concerns. 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.

[5] COM(2020) 761 final.