Keeping Europe Up to Date – a Fit-for-Purpose Regulatory Environment for New Genomic Techniques

Statement of the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation) and the German National Academy of Sciences Leopoldina regarding the proposal of the European Commission for an EU regulation on plants obtained by new genomic techniques

The German Research Foundation (DFG, German Research Foundation) and the German National Academy of Sciences Leopoldina welcome the proposal of the European Commission for a regulation on plants obtained with new genomic techniques (NGT), published on 5 July 2023. The proposed regulation will facilitate innovative plant research and help to realize the great potential these new breeding techniques offer for a more sustainable and more productive agriculture in Europe.

DFG and Leopoldina appreciate that the European Commission has developed a science-based regulation for the products of certain new breeding techniques. Plant varieties that have been bred by NGT and are indistinguishable from varieties that could have arisen naturally or could have been produced through conventional breeding are classified as NGT-1 plants. These plants will be regulated similarly to conventionally bred plants and will not require authorization to be grown in the field in EU member states. Importantly, the new regulation will provide easier access to field experiments with plants developed by these new technologies, and pave the way for more diverse and productive crops with a reduced ecological footprint.

Many of the world's largest agricultural producers and trading partners of the EU, including the USA, Canada, Argentina, Brazil, Australia, Japan, China and the UK, have already implemented science-based, innovation-driven regulatory frameworks for NGT plants. The EU, therefore, urgently needs an appropriate amendment of its legislation on genetically modified organisms (GMO) that reflects the state of the art in science and the environmental and geopolitical realities.

A well-balanced and science-based regulatory framework

The proposed regulation strikes a careful balance between scientific recommendations, the sustainability goals as outlined in the European Green Deal, and the interests of different stakeholders and sectors.

Regulating plants classified as NGT-1 (see above)[1] similar to conventional breeding products meets the long-standing need for a science-based approach that removes inconsistencies in the regulatory system that have been widely criticized following the judgement of the European Court of Justice (ECJ) on 25 July 2018 in Case C-528/16[2].

According to the ECJ's reasoning, both products of conventional mutagenesis methods (e.g., chemical or radiation mutagenesis) and products of NGTs are to be considered GMOs. However, up to now, only plants produced by conventional mutagenesis and their products have been completely exempted from GMO legislation. The new regulation stipulates that NGT-1 products will be exempt from GMO legislation as well. Given that in many cases a potential NGT origin of a new crop variety will be technically impossible to ascertain, any mandatory labelling would be nearly impossible to enforce. Transparency for breeders and farmers will be ensured via a public register that informs about all NGT varieties that have passed the verification procedure and obtained NGT-1 status. Consumers who wish to avoid NGT products can choose certified organic products.

As with any new plant variety, NGT plant varieties will not enter the European market in an uncontrolled manner. The European directives on seeds and other plant-propagating material, as well as national legislation implementing these directives, will continue to apply. Thus, prior to approval and listing in the national catalogue of plant varieties in Germany, new varieties, including those produced by NGTs, must undergo two or three years of thorough field testing. If there are reasonable grounds to assume that the plant variety may present risks to human health or the environment, the competent authority may deny the approval of the variety.

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[1] The definition of NGT-1 plants as "plants with up to 20 genetic modifications" that can be "substitution or insertion of no more than 20 nucleotides" is based on statistical considerations: A sequence of more than 20 nucleotides is most likely unique to a given plant genome, and therefore, is unlikely to occur by chance; see Lusser et al., New plant breeding techniques – State-of-the-art and prospects for commercial development, 2011, p. 165; Buhk, Synthetic biology and its regulation in the European Union, New Biotechnology 31 (2014), p. 529 (https://doi.org/10.1016/j.nbt.2014.02.007).

[2] European Court of Justice, Case C-528/16, Confédération paysanne and Others, ECLI:EU:C:2018:583.

Outlook and further options to improve the proposed regulation

We regret that the proposed regulation excludes the organic farming sector from the benefits of the new genomic technologies. While some organic farming organisations have requested this exemption, there is no scientific reason to deny organic breeders and farmers direct and unrestricted access to new plant varieties that fit their specific needs and bypass the requirement for agrochemicals, including the (few) chemicals that are currently allowed in organic farming. NGTs can provide new varieties that are resistant to pests and diseases such as mildew in viticulture, or are better suited for certain farming practices such as intercropping.

The European Commission's proposal currently lacks clarity concerning the question of whether EU member states are allowed to subject NGT-1 plants to national rules, which are similarly strict as, e.g., the rules for NGT-2 plants, thereby depriving the proposed deregulation of NGT-1 plants of any practical effect. The recitals of the proposed regulation provide that "NGT plants and related products should benefit from the free movement of goods". However, it would be preferable if the operative part of the regulation mirrored this recital through a clause that explicitly asserts that member states are not allowed to prohibit or restrict the deliberate release or placing on the market of NGT-1 plants and related products. Such prohibitions or restrictions would likely impede innovation in the agricultural sector and damage competitiveness of the affected countries at the European and global levels and, thus, compromise the regulation's objectives. Clearly, scientists, breeders and farmers in the EU need a reliable and consistent common regulatory framework.

The new proposal for the regulation of NGTs has reignited discussions about the role of patents in the European breeding sector. This issue, however, needs to be addressed in the context of European patent law, independent of how products of NGTs will be regulated in the EU.

Science and innovation for a safer and healthier global food supply

Advances in breeding and biotechnology are key to fight hunger and malnutrition, to sustainably produce healthier and more nutritious food and to adapt agriculture to a changing climate. The new breeding techniques offer two key advantages over conventional breeding methods: speed and precision. Thus, the new technologies can make a substantial contribution to the much-needed increase in agricultural productivity, and the breeding of new

varieties of crops that contribute to a healthier diet and are more resilient to climate change. Clearly, the new breeding techniques alone will not solve all of the many challenges that agriculture currently faces, but they provide a particularly powerful addition to the breeders' toolbox that would be irresponsible to not employ.

The freedom of research for the wellbeing of our society

A responsibly exercised freedom of science contributes to socially just, economically powerful, and ecologically sustainable societies in Europe. With this in mind, the potential of the new breeding techniques deserves to be explored without prejudice in the upcoming political discussion. The evaluation of the technologies should be conducted on the basis of scientific evidence and the societal and environmental benefits the NGTs offer. Any debate that is driven by ideology reinforces fear and promotes hostility towards science. Therefore, DFG and Leopoldina call on policy makers and stakeholders to solicit information from the scientific community about the state of the art in research, enter into a dialogue with experts to clarify any questions they may have about the NGTs and their products, and explore with an open mind what science has to offer for a more sustainable and climate-friendlier agriculture and a safer and healthier food supply.

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