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New Plant Genomic Techniques (NGT): an ongoing public consultation to modify European regulation.

By Catherine Regnault Roger - 18.07.2022



On July 25, 2018, a judgment of the European Court of Justice (EUCJ) indicates that all products resulting from new genome modification techniques (NGT) after 2001 fall under European regulations applied to GMOs. However, this legal decision, based on an administrative rationale and not on scientific analysis, places the EU at odds. Many countries of the American and Asian continents and of the Pacific zone have opened up, to different levels, to new genomic techniques (NGT) by adopting regulations adapted to their specificities.

European regulations on GMOs are based on Directive 2001/18. They are indeed very cumbersome. Furthermore, they have hindered the development of agricultural GMOs in the European Union (EU). The costs of the long files to be compiled to request marketing approval, – whether for cultivation in the field or import for processing for food and feed, and also for post-commercialization of authorized GMOs which must be carried out for the entire duration of the authorization granted (generally 10 years)-, have restricted the process to large international consortia (such as Syngenta-ChemChina, Bayer, Corteva), with sufficient financial strength.

In this context, can the European Union stand apart and place itself on the margins of the world market? As soon as the judgment of the EUCJ was published, several European institutions and bodies in the scientific and academic sphere, as well as citizens' movements, became concerned. They asked for a debate to be opened on this subject because the obstacles to technological progress but also development due to the infringement of the free movement of goods in a globalized market seemed obvious.

MANY CALLS TO CHANGE THE REGULATIONS

The Group of Principal Scientific Advisors to the European Commission (or Scientific Advice Mechanism SAM), a high-level committee of experts, created on June 9, 2015 to inform the European Commission on scientific subjects in complete independence and transparency so that it can enact Union policies in full knowledge, published a declaration in November 2018 in which it underlined that *“It becomes evident that new scientific knowledge and recent technical developments have made the GMO Directive no longer fit for purpose”*.

Then it was the turn of the European Union of Agricultural Academies (UEAA), supported by several Member States' Academies, to ask for *“new regulation frame adapted to most recent scientific advances”* in order to *“facilitate critical research in the European Union on Gene Editing”*.

Regarding Citizen movements, an European citizens' initiative named *Grow scientific progress: crops matter!* was initiated in the summer of 2019 by an eight different nationalities' group of students from Wageningen University (Netherlands) (1). It called for a change in current legislation *“To focus on the crop rather than the technique. In this way safety is ensured while the valuable benefits of new techniques are not lost to illogical regulatory hurdles.”*

Various statements and forums by French and German political actors expressing alarm at the consequences of the EUCJ's judgment were also noticed.

This context led the Council of the EU to invite the the European Commission to adopt a new approach in November 2019: this new approach consisted in a study and impact analysis in order to redefine the EU status of NTGs.

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THE EUROPEAN COMMISSION CONFIRMS THE NEED TO CHANGE THE REGULATION

The European Commission published the results of this study at the end of April 2021. It was documented by two reports from the European Commission Joint Research Center (EU-JRC). The first report focused on the state of the art of NGTs and the second one on Research and Development and their commercial applications (2).

This study confirmed that NGTs have developed in a dazzling way over the last decade on several continents. The flagship technique of NGTs is CRISPR, published just 10 years ago, in 2012 in the magazine *Science* by American-researcher Jennifer Doudna and European-researcher Emmanuelle Charpentier, who were awarded by 2020 Nobel Prize in Chemistry for this invention. More than 25,000 scientific publications have already been devoted to the applications of this technique. The European Commission points out " *that NGTs have developed rapidly in many parts of the world and are expected to continue to do so. There is significant interest both in the EU and globally for plant applications of NGTs, and some of their applications are already on the market outside the EU*". It noted " *that plants obtained by NGTs have the potential to contribute to the objectives of the European 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*".

A RESTRICTED PERIMETER

an initiative was therefore launched in Autumn 2021 to conduct a reflection on the European legal framework that could be applied to plants obtained by targeted mutagenesis and cisgenesis as well as to food and feed derived from such plants. The European Commission has restricted the scope of the forthcoming revision. Only the regulation to plant applications is concerned. This decision is based on the conclusions of the European Food Safety Authority (EFSA) that underlined " *that plants obtained by targeted mutagenesis and cisgenesis can have the same risk profile as plants produced with conventional breeding*"; but as " *EFSA has not yet assessed the safety of targeted mutagenesis and cisgenesis in microorganisms or animals, nor the safety of other techniques*" the EU Commission decided to delay the revision for these organisms (3).

STEPS STREWN WITH PITFALLS

This initiative, classified under the topic "food safety", intends to propose a new European regulation. It is carried out in three stages. It began in September 2021 with the definition of a "Roadmap". Then a public consultation is following, currently in progress until July 22, 2022. A third stage will take place in the 2nd quarter of 2023 and will lead to the adoption of plant NGTs' revised regulations by the Commission.

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The public was consulted on the Roadmap for one month, from September 24, 2021 to October 22, 2021 and 70,879 responses were received. A large majority of these responses came from citizens of the Union (more than 96% or 68,183 contributions), then university and research institutes (113 contributions), professional organizations and associations (190 contributions), and 93 contributions received from trade unions, NGOs, and environmental and consumer associations. Most responses came from German (46%) and French (36%) citizens, reaching together a total 92%, followed by Belgium, Dutch and Austrian (3%) and Italian (2%) citizens (other countries having contributed less than 1% each).

Because of the very high number of responses received, the European Commission was alerted on a possible trick. And in fact, this stage of the consultation gave rise to a campaign of manipulation by the political group the Greens/EFA (European Free Alliance) of the European Parliament which flooded it of more than 69,000 spam messages, with the help of a communications agency based in Estonia.


The German Federal Minister for Agriculture, Julia Klöckner, had qualified this action in November 2021 to be sabotage of legislative process (4). This manipulation was supported by a small handful of MEPs (seven of them) (5) who aimed to block the revision of the regulations as part of the campaign “*Let’s keep GMOs out of our fields and of our plates*” they led (6).

The purpose of the public consultation today is to carry out a survey to assess

1. the interest of the new regulations to be focused on risk assessment for products resulting from targeted mutagenesis or cisgenesis. This question is relevant because the products obtained by these techniques cannot be distinguished, in their majority, from a product harvested from the wild or obtained by conventional breeding techniques.
2. the consideration of the sustainability of these products.
3. the information to be communicated to operators and consumers in complete transparency
4. the technological access that this regulation would give to European SMEs.

On July, 17th, 1503 opinions were validated, three quarters of which were expressed by EU citizens. German respondents come first (31%), closely followed by the Italians (26%), and further behind the French and the Spaniards (12 and 9%), the other EU nationalities representing about 14%. There is one week left to speak.

I am hoping this process will lead to new European regulations facilitating the use of NGTs in all sectors where they can bring essential innovations for the competitiveness and sovereignty of European agriculture (7).

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(1) European Citizens' Initiative: sign the Green Biotech Petition, C.Regnault-Roger, European <https://www.europeanscientist.com/en/agriculture/european-citizens-initiative-sign-the-green-biotech-petition/>

(2) 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, Luxembourg ISBN 978-92-76-24696-1 doi:10.2760/710056 JRC121847; (2) Parisi C, Rodríguez-Cerezo E (2021) Current and future market applications of new genomic techniques EUR 30589 EN, Publications Office of the European Union, Luxembourg ISBN 978-92-76-30206-3 doi:10.2760/02472 JRC123830.

(3) Legislation for plants produced by certain new genomic techniques https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-applicable-aux-vegetaux-produits-a-laide-de-certaines-nouvelles-techniques-genomiques/F_en

(4) Un procédé scandaleux » À propos du Spamming de la consultation de la Commission européenne sur les « OGM » et « NGT » Schillipaepa <https://seppi.over-blog.com/2021/11/un-procede-scandaleux.html>

(5) Martin Häusling (🇩🇪), Benoit Biteau (🇫🇷), Eleonora Evi (🇮🇹), Tilly Metz (🇧🇪), Michèle Rivasi (🇫🇷), Thomas Waitz (🇩🇪), Sarah Wiener (🇩🇪) <https://act.greens-efa.eu/fr/gardons-les-ogm-hors-de-nos-assiettes>

(6) CheckNews. Le groupe des Verts au Parlement européen a-t-il organisé une campagne de «spams» contre une consultation sur les OGM ? https://www.liberation.fr/checknews/le-groupe-des-verts-au-parlement-europeen-a-t-il-organise-une-campagne-de-spams-contre-une-consultation-sur-les-ogm-20211103_J66AB4FP7BBVLPCJ3EA732B6NM/

(7) Enjeux Biotechnologiques des OGM à l'édition du génome , Catherine Regnault-Roger, préface Jean-Yves Le Déaut, collection Académie d'agriculture de France, 203 pages, 2021

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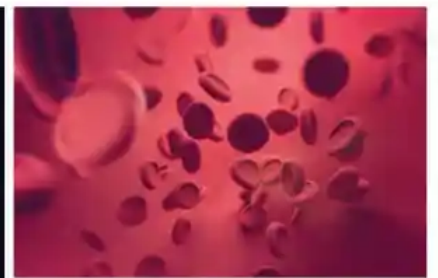
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Catherine Regnault-Roger

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Pr face de Jean-Yves Le D aut



Presses des Mines

Bayer Corteva CRISPR Directive 2001/18 EU-JCR EUCJ European Commission
GMO GMOs NGT NTG SAM Syngenta UEAA

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* Disclaimer, the opinions expressed by the author do not bind the institutions with which she collaborates.





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TOP ARTICLE THIS WEEK

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European Scientist was able to interview Jean-Pierre Jégou, President of the Académie Vétérinaire de France since the beginning of 2021, after five years as Secretary General, of this prestigious Academy

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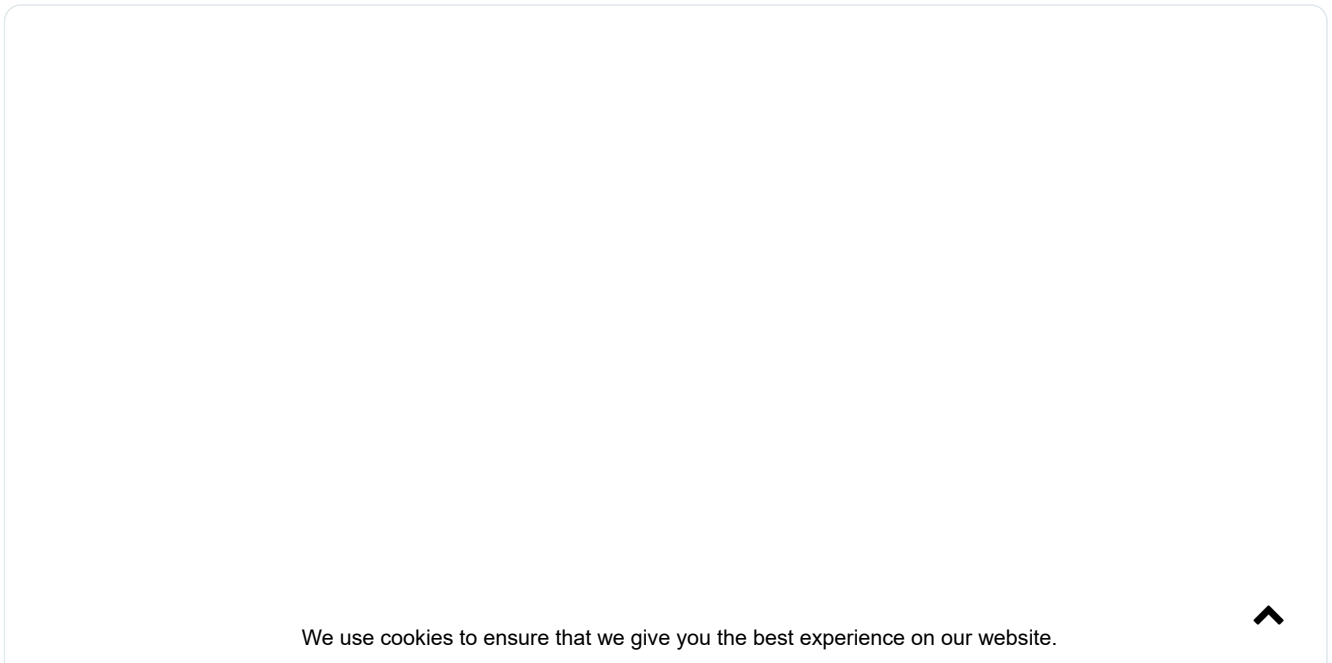
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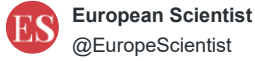
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Biodiversité et agriculture. Mythe et réalité. Le cas de l'Agriculture de Conservation des Sols (1ère partie) [dlvr.it/SV7K7](https://doi.org/10.1007/s11258-022-01000-0)

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