ARRIGE

Association for Responsible Research and Innovation in Genome Editing

STATEMENT ABOUT EC PROPOSAL ON NEW GENOMIC TECHNIQUES REGULATION IN PLANTS

July 2023

SCIENTIFIC COMMITTEE

ARRIGE
Association for Responsible Research and Innovation in Genome Editing

EC 2023 PROPOSAL

Recently, on May 8th 2023 during the ARRIGE annual meeting, "Genome Editing in Plants (and Animals) in the European Union versus other countries in the world" was discussed. The EU position regarding regulation of new genomic techniques (NGTs) was questioned in relationship to US, Africa or South America. On July 5th 2023 the European Commission published a proposal for the regulation of plants obtained by certain NGTs, including gene editing and modifications of genes obtained from the same organism.

NGTs describes a variety of techniques that alter the genetic material of an organism. These techniques did not yet exist in 2001, when the EU legislation on genetically modified organisms (GMOs) was adopted. Currently, plants obtained by NGTs are subject to the same rules as GMOs. To better reflect the different risk profiles of NGT plants, the published proposal creates two distinct pathways for NGT plants to be commercialised. Five different criteria (defined in the Annex 1 of the proposal) related to the breadth and the nature of the genetic modification will be considered. On one side, NGT plants that can occur naturally or by conventional breeding will be subject to a verification procedure. if they meet the criteria, these will be treated like conventional plants and therefore exempted from the requirements of the GMO legislation. Thus, no risk assessment has to be performed and they can be labelled similarly to conventional plants. Conversely, NGT plants that do not meet the criteria will meet the requirements of the current GMO legislation, will be subjected to risk assessments, and they can only be commercialised following an authorisation procedure. Nevertheless, for these plants there will be adapted detection methods and tailored monitoring requirements. It would require a complete molecular characterization of the genetic modification in all cases but any further analysis of potential environment or food and feed risk should be triggered by a plausible risk hypothesis. In the absence of such a hypothesis the molecular characterization would be sufficient.

This proposal will now be discussed in parallel by the EU Council and the EU Parliament. There will be many sectorial meetings starting on July 25th, with different official and informal meetings of the Agricultural Ministries. At the Parliamentary level, the process will probably be slow. In any case, the following months will be crucial as this will be actively discussed among the EU Member States and the different countries will need to raise and justify their position. Therefore, a good communication with the public is particularly important at this moment.

ARRIGE

Association for Responsible Research and Innovation in Genome Editing

STATEMENT

The proposed regulation would be an important change in the way GMOs (which include gene edited plants and animals) are regulated in the EU. On one hand because it focuses more on the characteristics of the final product rather than on the technique used, establishing different categories of NGT plants to be regulated differently. More importantly, it adjusts the risk assessment to the expected risks. It actually requires a plausible hypothesis of risk to require the assessment of environmental or food/feed risks. This introduces flexibility in the system and allows for a proportionate risk assessment, which is exactly what the scientific community asked for during all these years.

The limits of the maximum number of genetic modifications (20) or the number of nucleotide changes/introduced in each modification (also 20) can be criticised as they are completely arbitrary and lack scientific support. Also the difference tolerance between insertions and deletions does not seem to be scientifically justified. However, if the analysis of the Category 2 NGT plants is done as it is proposed, many plants still subjected to the GMO regulation will follow a risk assessment proportionate to the potential risks, which will translate, in most cases, to a cheaper and faster process while ensuring a high degree of food and environment security. The consideration of GMO of Category 1 NGT Plants (plants excluded from the regulation) for their use in organic agriculture is also not justified scientifically. If these plants are considered as equivalent to plants that could also have been obtained naturally or by conventional breeding techniques, they should also be considered as such for their use in organic agriculture.

In any case, the Scientific Committee of ARRIGE embraces this initiave that aproaches the EU to the rest of the world and that will potentiate research and innovation in the field of plant genome editing within the EU, helping the European agrifood industry and the farmers in their efforts to develop a more sustainable agriculture.

USEFUL LINKS

https://food.ec.europa.eu/system/files/2023-07/gmo_biotech_ngt_proposal.pdf

https://www.science.org/content/article/european-commission-proposes-loosening-rules-gene-edited-plants?utm_source=sfmc&utm_medium=email&utm_campaign=WeeklyLatestNews&utm_content=alert&et_rid=17035139&et_cid=4805948

EU seeks to relax gene-edited crop restrictions

The European Commission proposed revising its rules on genetically modified organisms (GMOs) on