# Parlamentul României
# Senat

*Bucharest, November 17, 2023* *Courtesy translation*

## OPINION
## of the SENATE of ROMANIA

**on the Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625**
**COM(2023) 411 final**

The Romanian Senate examined the Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 - COM (2023) 411 final – according to the provisions of the Treaty of Lisbon, Protocol (no. 2).

Taking into account the report of the Committee on European Affairs, the Plenary of the Senate, during its session of November 13, 2023,

(1) Notes that the Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 - COM (2023) 411 final – respects the subsidiary principles, but does not comply with the proportionality principles, art. 5 of the Treaty on the European Union.

(2) Considers that:
   i. the requirements of transparency and complete, correct and precise information of the consumers on the essential characteristics of the products are not met, so that they make informed decisions.

In this regard, the Court of Justice of the European Union decided in Case C-528/16 (Decision of 25th of July 2018) that organisms obtained by mutagenesis are GMOs within the meaning of Directive 2001/18/EC to the extent that mutagenesis techniques and methods alter the genetic material of an organism in a way that does not occur naturally, and that these organisms fall within the scope of Directive 2001/18/EC and are subject to the obligations provided by this normative act - traceability, labeling i.e. the obligations from which NTG1 plants, food and feed containing such plants are excluded by the proposed regulation, consisting of such plants or produced from such plants, as well as products, other than food or feed, containing such plants or consisting of such plants.

Only organisms obtained by means of mutagenesis techniques that have been conventionally used in a number of applications and that have a long safety record are excluded from the application of the provisions laid down in Directive 2001/18/EC, the CJEU considers. The CJEU considers that the risks associated with the use of new mutagenesis techniques that have emerged since the adoption of Directive 2001/18/EC may prove to be similar to those resulting from the production and release of a GMO by transgenesis because the direct modification of the genetic material of an organism by mutagenesis makes it possible to achieve the same effects as the introduction of a foreign gene into the body (transgenesis) and these new techniques make it possible to produce genetically modified varieties at a level that is not proportional to that resulting from the application of conventional methods of mutagenesis.

ii. The exclusion of organisms obtained by means of new mutagenesis techniques - as provided by this Regulation - from the scope of Directive 2001/18/EC would compromise its objective of avoiding negative effects on human health, health and well-being animals, the environment and the interests of consumers and would not respect the precautionary principle applied by Directive 2001/18/EC and by Regulation (EC) no. 178/2002 of the European Parliament and of the Council of January 28, 2002 establishing the principles and general requirements of food law, establishing the European Food Safety Authority and establishing procedures in the field of food safety.

(3) Outlines:

i. The importance of protecting Romanian exporters/producers of conventional products on third-party markets, in order to maintain commercial exchanges (Romania ranks first in the production and export of cereals on third-party markets);
ii. The need to include coexistence conditions for NTG1 products with conventional ones, otherwise conventional crops will disappear and NTG1 exports could be rejected by third markets as similar to GMOs.

(4) Raises attention that:

i. Since the creation of new plant varieties with certain characteristics obtained through genomic operations is aimed at, the evaluation of the modifications should be carried out at the level of the Member States in terms of agricultural, technological value and distinctiveness, stability and uniformity, in order to take into account the specificity of each Member State. It is important that the new varieties can be re-evaluated by the specialized of the Member States in the market of which they are intended to be marketed and used;
ii. Financial support by the EU of the Member States is necessary for the establishment of official specialized public laboratories, European accredited, for NTG specific testing, which will carry out the evaluation based on specific, identical procedures within all Member State authorities;
iii. It is appropriate to pay more attention to the aspects aimed at: requesting the tests and reports of the European Food Safety Authority (EFSA) regarding the risk analysis, respectively food safety for humans and animals, the safety of the environmental impact for each authorized product, ensuring the information by labeling new NGT products;

iv. Ensuring NGT's control methods, traceability and labeling, to respect consumers' rights to be informed and to choose;

v. It is necessary to exclude from patenting plants obtained through processes that could take place in the natural environment (NGT1), as well as plants that are already in the public domain and genes of interest that are the object of biodiversity heritage;

vi. The Senate does not support the licensing of transformation processes that would have taken place, with some probability, also "in vivo";

vii. The patenting of biotechnologies applied to plants should not limit breeders' access to genetic material and techniques;

viii. The establishment of a compulsory licensing system must be avoided, which could affect the availability of seeds and the economic value of the investments in production that farmers will make;

ix. The patenting of biotechnologies applied to plants must not have a negative impact on the competitiveness of the biotechnological industry in the EU.

(5) Asks the EU Commission:

i. To provide the scientific basis for the decision to differentiate the two categories through the limit of 20 genomic changes;

ii. To carry out steps to ensure the consultation of third countries on the equivalence of NGT1 with conventional ones, so that they can be accepted by the EU's trading partners;

iii. Clarifications regarding the international commercial consequences, namely the access of the new category of NGT1 products to third markets (equalization of the categories of NGT1 products on these markets and the protection of conventional crops) - considering Romania's interest in preserving the traditional grain export markets in the Eastern area Middle, Turkey etc.