European Economic and Social Committee

OPINION

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Plants produced by new genomic techniques

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 – 2023/0226 (COD)]

NAT/908

Rapporteur: **Arnaud SCHWARTZ**

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Referral	European Commission, 18/08/2023 European Council, 15/09/2023
Legal basis	Articles 43, 114, 168(4)(b) and 304 of the Treaty on the Functioning of the European Union
Section responsible	Section for Agriculture, Rural Development and the Environment
Adopted in section	02/10/2023
Adopted at plenary	26/10/2023
Plenary session No	582
Outcome of vote (for/against/abstentions)	168/48/15

1. Conclusions and recommendations

1.1 The EESC supports innovation, including innovation in varieties, and measures to safeguard the competitiveness of EU producers with a view to ensuring the EU's food security and sustainability. Therefore, the EESC welcomes the principle of an environmental and health risk assessment tailored to the type of modification applied, and believes that the European Commission must guarantee the transparency of plants obtained using certain new genomic techniques (NTG). Nevertheless, the EESC calls for surveillance to be stepped up by monitoring potential systemic effects on the environment and health, using a methodology to be developed in collaboration with the EFSA, the JRC and interested civil society players.

1.2 The EESC welcomes the Commission's intention to lay the groundwork for accelerating plant breeding processes and providing EU farmers with promising and resilient plant varieties. Meeting the ever-growing multifactorial challenges in this area will enable the sector to contribute more to food security and to the European Green Deal's various ambitious targets and to become more competitive on the global stage.

1.3 Moreover, the EESC calls on the Commission to ensure that the successful models of organic farming and the GM-free[1] sector can continue to flourish. Harmonised coexistence measures need to be defined at EU level to avoid different rules and distortion of competition between Member States. If such models decide to call for a ban, it would make more sense to include this in the organic legislation than in the NGT rules, which is not the appropriate legal area (as in the case of GMOs).

1.4 The EESC highlights the potential risk of a large number of patents linked to the use of NGTs, which could create dependencies for farmers and seed SMEs. The planned monitoring process will have to address this concern. The EESC therefore calls for a clarification of the intellectual property rules in relation to living organisms before this legislation enters into force.

1.5 The EESC also asks the Commission to address the issue of irreversibility and, therefore, responsibilities in this area. In particular, the EESC proposes the creation, in a public and decentralised way, of a European traditional seed bank which, through existing national seed banks or similar actions, would collect seeds from endemic plants in order to preserve them (prevent their potential extinction and cross-breeding with plants derived from NGTs) and make them available if needed in the future. This bank is important for the EU's food sovereignty and heritage, as well as for the EU's strategic autonomy. The EC should assess the possibilities for collaboration with the Global Seed Vault in Norway and build on national collections, as well as the European collection of genetic resources.

1.6 Furthermore, the EESC calls on the Commission to remedy the lack of legislation on the technologies themselves as soon as possible. Given their potential systemic impact from a One Health perspective, the EESC believes that it is necessary, for example, to make it impossible

[1] Genetically modified-free.

for non-NGT professionals to purchase on the internet and use kits for genetically modifying living beings using techniques such as CRISPR-Cas[2] without oversight.

1.7 The EESC could endorse the Commission's proposal if it takes into account the EESC's concerns effectively. Therefore, the Commission should specifically consider implementing an ex post systemic surveillance and labelling of NGTs category 1 for the consumer. This labelling could rely on administrative traceability and include information on the added value of the variety.

1.8 Until such measures are taken, the EESC remains open to helping improve the Commission's current proposal for a regulation on NGTs.

2. Legislative proposal of the European Commission

2.1 On 5 July the European Commission published a proposal[3] on plants obtained through certain NGTs falling under targeted mutagenesis and cisgenesis. It distinguishes between two categories of NGT usage:

- category 1 for plants with up to 20 genetic modifications through NGT. These plants are considered by the Commission to be comparable to plants obtained by conventional breeding methods;
- category 2 for plants requiring more than 20 genetic modifications. These are considered to be plants that cannot be obtained by conventional breeding methods.

For so-called NGT 1 varieties, the Commission stipulates that products must be traceable until they reach the farmer, no specific labelling is required for consumers and a standard assessment must be carried out when a product is registered in the catalogue (seed regulation). In addition, the Commission plans to create a public database listing all NGT plants.
For NGT 2 varieties, there would be mandatory traceability, specific labelling, including for consumers, and a GMO-type assessment.
The Commission proposes that NGT plants, including those in category 1, be banned in the organic sector.

2.2 The Commission intends to promote the development of NGT 1 plants and to facilitate placing on the EU market of plants, and food and feed derived from them, through a simplified authorisation procedure.

3. General comments

3.1 The EESC notes that the Commission proposal changes the framework the EU has followed since the Court of Justice ruling in 2018 interpreting Directive 2001/18/EC as meaning that organisms obtained through modern targeted mutagenesis techniques are GMOs subject to EU

2 Clustered regularly interspaced short palindromic repeats.

3 https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en?etrans=fr

legislation[4]. The Commission proposal takes account of the latest technological developments, particularly since the discovery of CRISPR-Cas almost 10 years ago, which has enabled advances in medicine in the area of immunotherapy.

3.2 Compared to the current situation[5], some farmers, seed producers, tradespeople, manufacturers and consumers who want to live without what they call "new GMOs" would feel deprived of some of their freedoms, as NGT 1 plants and products derived from them would be exempt from a thorough environmental and health risk assessment, traceability measures and labelling for the final consumer.

3.3 At the same time, the majority of farmers, who are members of the EESC, as well as seed producers, etc. want to be able to use NGTs as one of many tools to adapt to climate change and reduce their use of inputs. Like the Commission, they believe that category 1 NGT varieties are identical to varieties obtained through conventional breeding methods, which are used in different types of farming. They would like to point out that conventional selection methods include random mutagenesis, a GMO technique exempted from Directive 2001/18/EC, some varieties of which are used in organic farming.

3.4 The Commission proposal is based on scientific knowledge provided by the Joint Research Centre (JRC) and the European Food Safety Authority (EFSA). However, some civil society organisations believe that the knowledge provided ignores critical expertise and does not fully comply with the precautionary principle.

3.5 Although some organisations are in favour of the Commission's proposal regarding NGT 1 plants, others explain that the Commission is relying on a fictitious premise for this category: that NGT = conventional, because neither the method of breeding nor the results are the same, which goes against studies carried out by the EFSA and the JRC, and against a large majority of scientists using NGTs.

3.6 The EESC welcomes the fact that the Commission proposal provides for a programme to assess the regulation's impact on sustainability, organic farming and consumer acceptance of NGTs. However, the EESC calls for surveillance to include monitoring of potential systemic effects and a cost-benefit analysis.

3.7 A systemic or all-encompassing surveillance differs from a case-by-case assessment, as in the case of an analytical assessment. It requires indicators to be developed on the dynamics of the systems to which we belong (societies, ecosystems, etc.) to be developed in collaboration with the EFSA, the JRC and interested parties from civil society. The aim of such surveillance is to make possible practices that would otherwise be blocked by the precautionary principle.

3.8 The EESC acknowledges the existing legislation and notes that the Commission proposal calls for intellectual property issues to be addressed by 2026 by assessing the impact of patents on plant breeding. However, the issue of patents has not yet been addressed. It is difficult to assess

4 https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-07/cp180111en.pdf

5 Related EESC opinions on this subject.

the risk in relation to restricting the rights of farmers and other seed producers (other than patent holders) to use the plants to produce their own seeds, and the risk of imposing high usage costs on farmers.

3.9 The EESC therefore calls for consideration to be given to how to address the issue of patents, and how to find a solution that suitably respects the needs of farmers, seed producers and stakeholders in the food supply chain. The EESC supports the development of a regulation on NGT patents by the time the ad hoc regulation is implemented (two years after its ratification).

3.10 The EESC warns about the threat this poses to organic farming and the GM-free sector. Although GMOs are banned in this sector, and NGTs would be as well, because no method of detection, identification or traceability is required, buyers, Member States and the Commission would be unable to properly enforce the law. Introducing the proposed legislation would risk considerably increasing monitoring of the processes required for organic farming and other GM-free production models. It should therefore be ensured that the costs involved are covered fairly and that the burden is not borne solely by organic and GM-free production models.

3.11 Regarding whether or not to ban NGTs in organic farming, the EESC recommends referring to the opinions of professional organisations in the sector. If they decide to call for a ban, it would make more sense to include this in the organic legislation than in the NGT rules, which is not the appropriate legal area (as in the case of GMOs).

3.12 The EESC notes that an important segment of civil society wants a more secure framework for NGTs (citizens' petition, NGOs, certain agricultural organisations, numerous distributors and European supermarket chains). However, the regulatory framework proposed by the Commission already provides some safety guarantees. If consumers do not wish to consume NGT products, this could be reflected in their willingness to pay for "NGT-free" food products, with all the technical difficulties involved in ensuring the accuracy of such claims. As it stands, NGT 1 varieties are indistinguishable from varieties obtained through random mutagenesis, which are already widely sold and consumed in the EU.

3.13 However, the EESC supports the development of innovative technologies and seeds[6]. It therefore could endorse the Commission's proposal if it takes into account the EESC's concerns effectively.

3.14 Since NGTs are currently difficult to detect, controls involving biological analyses to ensure labelling for the consumer are impossible or extremely costly. Given the difficulty of carrying out these controls, labelling through to the consumer should only be done using administrative traceability, which is already provided for seeds through to the farmer. As NGTs are less expensive than transgenesis, the Commission should ensure, after a transparent debate with all stakeholders concerned, that the costs of this labelling are not borne by farmers and other smaller actors in the agri-food economic chain.

6 EESC exploratory opinion on Towards a Fair Food Supply Chain, OJ C 517, 22.12.2021, p. 38.

3.15 In the same spirit of sharing, the Commission could increase the opportunity that NGTs represent for EU SMEs by developing a public programme of systemic assessment of their creations.

3.16 Many agricultural and seed organisations are awaiting the new EU regulation, especially considering the competitive context, where various non-EU countries have made it easier to place products and seeds deriving from NGTs on the market. Until this regulation is comprehensive and effective as called for by the EESC, the Committee explicitly calls on the Commission to take all necessary measures in relation to non-EU countries to protect the EU from any distortions of competition and from exposure to risks.

3.17 The EESC supports the principle of proportionality (the measures proposed by the Commission must be appropriate and not unnecessarily restrictive), the precautionary principle (as there is scientific uncertainty as to the global impact of NGTs) and the principle of reversibility (to reverse or mitigate any damage if the operations regulated by the Commission were to have negative effects).

3.18 The EESC believes that the European Commission should take into account the impact of NGTs on different agricultural models. Small farmers are concerned that these new seeds will contaminate the organic, ecological, regenerative or traditional farming practices they already use. We therefore call on the Commission to carry out an impact study that takes into account the future viability and profitability of these forms of farming, as well as their social and cultural aspects. Furthermore, it is particularly necessary for the consumer to be able to identify the origin of the product, specifying the type of agriculture and seed, through correct labelling.

4. Specific comments

4.1 The EESC recommends a risk-benefit analysis applicable 10 years after the introduction of the new techniques

Given the need to adapt to climate change, the greater accuracy and reliability provided by NGTs compared to the methods used in transgenesis, and awareness of the environmental impact of GMOs over the last 30 years, a risk-benefit approach supports the conditional use of NGTs set out in the Commission proposal. Such an approach, particularly in relation to the environment, will make it possible to take into account the impact of biotechnology on an ecosystem.

We live in complex natural systems (ecosystems, societies, etc.). The organisation of these systems stems from the nature of the components and the links between them. In turn, this organisation comes back around to the components and their links, which all brings about a recursive emergence. The traditional assessment of technologies is mainly analytical: it is concerned with the predictable effects on a number of elements or phenomena that are considered relevant. This significant acceleration in the evolution of natural systems must be compared to the impacts of climate change. Climate change creates much more disruption in nature than the use of plants derived from biotechnologies. In fact, NGTs can provide resilience in the face of this disruption.

4.1.1 The artificial increase in the pace of evolution of the natural complex systems that concern us is a result of the exponential multiplication of technological products, but also, in the case of NGTs, the astronomical acceleration of the possibilities for obtaining the desired genetic modifications. For example, Limagrain[7] has obtained wheat resistant to mildew using NGTs with three mutations in specific places.

The likelihood of achieving such a result by selecting natural mutations means that the entire global production would have to have been observed for four million years.

For maize with 20 mutations, if natural mutations were selected, $1.25x10^{163}$ grains would have to be examined! The number of atoms in the universe is 10^{80}.

Such a rapid acceleration constitutes a drastic break with co-evolution and a major disruptive element in the organisation of ecosystems and societies.

4.2 The EESC highlights the need for improved ethics

4.2.1 Humans have always needed to come together in societies to survive. This means that their behaviour must be compatible with social life. This is the role of ethics.
Ethics were initially social, with nature implicitly seen as infinitely resilient. Currently, the technical power that has been developed is significantly disrupting natural systems and putting their stability in danger.

This implies a necessary change in ethics, which, while remaining social, must ensure that human behaviour is consistent with natural systems, which also entails a change in the hierarchy of values: since the stability of natural systems is necessary for the rest to exist, what is necessary to maintain this stability prevails over any other consideration, just as what is necessary to maintain societies prevails over individual interests. A study on systems as a whole cannot be carried out every time a new variety is introduced, considering the significant additional time and costs involved. The proposed systemic approach would therefore be limited to a single overall surveillance of techniques and not for each new variety.

4.2.2 To add another level to the ethical context, many Europeans want to be informed about the presence of GMOs in food. In this case it is necessary to respect personal beliefs. The EESC asks the Commission to do the same for plants and products from NGT.

4.3 General safety: The EESC stresses the complexity and technicality of this issue

4.3.1 Some schools teach how to use NGTs. Sometimes students happen to leave with their products. Kits for processing bacteria or plants with CRISPR-Cas9 can be found on the internet[8] for USD 85 and biology equipment for use at home for less than USD 3000. The sale of such kits cannot currently be regulated, as the regulation only concerns the release of final products and not reagents. The Commission proposal is on the right lines. It provides a framework for the use

7 OPECST, 7 April 2016, at 3 hrs 35 mins.

8 www.the-odin.com/diy-crispr-kit/

of NGTs. An outright ban would increase illegal use in order to obtain NGTs or the purchase of NGT varieties authorised outside the EU. Nevertheless, the EESC calls on the EC to put in place proper monitoring of online sales of these kits and points out that any unapproved products resulting from such sales would be considered fraudulent.

4.3.2 Monitoring of bioterrorism could be improved with the proposed regulation. The EESC believes that the Commission should tackle this issue and address security and safety concerns.

4.4 **The EESC warns of certain unrealistic simplifications**

4.4.1 The comparisons the Commission made between plants obtained through NGTs and conventional plants suggest that only the gene of interest is concerned.

4.4.1.1 Transgenesis, cisgenesis and intragenesis all involve techniques that include in vitro cultures that induce mutations and epimutations, not including unintentional foreign DNA insertions (Zang 2014). Under the Commission proposal, these unintentional modifications will be assessed either through the authorisation documentation for category 1 NGTs or through the specific assessment for category 2 NGTs. The EESC believes that authorities should have the means to verify the information provided in this regard, for example through independent bodies.

4.4.1.2 Cisgenesis corresponds to inserting genes from either the same species or a sexually compatible species into a variety of interest.

4.4.1.3 The reagents used by all NGTs (DNA, RNA, RNP) all leave traces of foreign DNA in modified genomes (Bertheau 2022; Kawall 2020; Norris 2019, 2020; Ono et al., 2015; Ono et al., 2019). There is therefore no equivalence between a GM plant and a natural plant.

4.4.1.4 Point mutations of a gene may have very different effects depending on the genetic basis and the environment when several genes are involved (Siegal 2017) and result in different functions (Copley 2014; Huberts 2010; Jeffery 2014). A synonym mutation may change the three-dimensional structure of a protein and its enzymatic activity without changing its sequence (Chamary and Hurst 2009; Kimchi-Sarfaty 2007).

4.4.2 Unintentional non-target changes are not eliminated through back-crossing (Bertheau 2019, 2022): in addition to non-target changes, NGTs allow chromothripsis and a very large number of epimutations. Non-target changes, epimutation and chromothripsis may occur in already authorised in vivo or in vitro random mutagenesis, what also raises questions about the GMOs derived from them, which for the moment are not subject to measures concerning other GMOs, or to simplified measures such as those proposed for NGT2. Varieties obtained by random mutagenesis have been on the market for over 30 years with no health or environmental consequences, despite potential off-target modifications or epimutations that could remain despite backcrossing.

Brussels, 26 October 2023.

Oliver Röpke
The president of the European Economic and Social Committee

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