



50 years after Asilomar: Do not give up control over NGT plants!

Dear Commissioner Varhélyi,

In July 2023, the Commission made a proposal to deregulate plants issued from new genomic techniques (NGTs), which are currently regulated as GMOs. Negotiations on the file have proven thorny, with patents representing a particular bone of contention. We would like to stress that the future regulation of NGT plants is not only a debate about the EU's political and economic priorities, but also a question of science. Any new categories for NGT plants must be based on science, ensuring safety if released into the environment and introduced into the market. However, the proposal made by the Commission suffers from substantial flaws, since the criteria for speeding up market access are not science-based, but arbitrary:

Stop trying to sell us bad regulation!

The Commission proposed a 'category 1' to ease market access for NGT plants that are deemed to be equivalent to conventional plants. This category is closely related to perceived safety of NGT plants. Plants belonging to this category would not have to undergo any risk assessment before they are released in the environment or commercialised, and would be exempted from any post-market monitoring plan.

The basic concept is simple. In short, up to 20 genetic changes would be allowed, with each of them encompassing, for instance, up to 20 changes of nucleotides. However, there is no scientific rationale behind such a 'magic threshold', given there is no correlation between the number of mutations and the level of risks. What is clearly missing from the proposal of the Commission, is to take into account the site of the mutations, the function of the altered genes, the overall genetic combination and the resulting phenotype.¹

As proposed, the criteria for NGT category 1 plants completely ignore the fact that even small changes to the genetic material can lead to life forms with new characteristics that

¹ For more details, see: [Testbiotech, 10 questions and answers: Why the EU Commission should withdraw its proposal for the future regulation of NGT plants, 7 February 2025](#)

differ significantly from those resulting from conventional breeding or those found in natural populations. As the ECJ has rightly pointed out, the new techniques and methods alter the genetic material of an organism in a way that does not occur naturally.² Without taking this into account, the risks of NGTs for environment and health cannot be evaluated properly. Amongst others, possible negative consequences can concern crucial ecosystem functions such as the interaction between plants and pollinators, soil organisms and the food web above and below the ground.

The way how Parliament and Council are dealing with these criteria shows that they are arbitrary: The EU Parliament changed these criteria completely to assess changes in proteins. The Spanish Presidency simply multiplied the number of genetic changes that would be allowed under category 1. However, none of these versions took into account the critical points mentioned above, meaning all the versions of the proposal discussed so far are not scientifically valid and don't take properly into consideration the potential risks associated with NGTs.

The broader picture

In February 1975, scientists from all over the world gathered in Asilomar (California) for the "Conference on Recombinant DNA" to discuss the risks and regulation of genetic engineering, which had just been invented. The situation was similar to today: some of the experts called for a cautious approach to genetic engineering, while others were already registering the first patents and launching a competition for the commercial exploitation of genetically engineered organisms.

In the meantime, development has sped up. With new genetic engineering methods and tools such as the CRISPR/Cas gene scissors, the technical potential, but also potential damage, has grown rapidly. In crop plants and wild plants, vertebrates as well as insects, bacteria, fungi and viruses: these tools make it possible, for the first time, to genetically engineer every gene of every life form and to spread these genetic changes within the respective species.

According to many experts, greatest risks are currently posed by the convergence of genetic engineering and artificial intelligence (AI). AI can be used, for example, to create new gene variants and gene combinations and release many genetically engineered organisms within short periods of time. All applications of genetic engineering can be involved, from NGT plants and animals up to the creation of new pathogenic viruses. The risks, including cumulative effects, of these changes introduced by AI in NGT plants would escape risk assessment if the criteria as proposed by the Commission would be applied.

Against this background, the EU should not deregulate NGT plants, micro-organisms and animals. Instead, it is crucial to adapt the implementation of the current GMO regulation so that the pace and consequences of development do not get out of control.

² Judgement of the European Court of Justice, Case C-528/16, 25 July 2018

What we say is: Give good arguments and better solutions a chance! The EU must not compromise on safety for health and the environment. Instead, the EU should make use of the inbuilt flexibility of current GMO regulation and adapt risk assessment requirements to the level of risks, in cases where it can be demonstrated that the mutation reproduces a modification of the genome observed in nature or already obtained by traditional techniques, and for which no risk has been identified.

We demand that the European Commission withdraw its NGT proposal. Pseudoscience must not be an option for Europe.

Yours sincerely,

Aegilops, Greece

AgroCert s.r.o., Slovakia

Arbeitsgemeinschaft bäuerliche Landwirtschaft, Germany

Arche Noah, Austria

Arci APS, Italy

Associazione produttori biologici e biodinamici – AltragricolturaBio, Italy

Attac Italia, Italy

Biodynamic Federation Demeter International

Bund für Umwelt und Naturschutz Deutschland (BUND), Germany

BUND Naturschutz in Bayern, Germany

CEPTA – Centrum pre trvaloudržateľné alternatívy, Slovakia

Corporate Europe Observatory

Druživa, o.z., Slovakia

Égalité, Italy

EKOTREND Slovakia - Zväz ekologického poľnohospodárstva, Slovakia

Friends of the Earth Europe

Gen-ethisches Netzwerk e.V., Germany

GM Watch, United Kingdom

Nature & Progrès, Belgium

Občianska iniciatíva Slovensko bez GMO, Slovakia

OZ Vidiecky parlament na Slovensku - VIPA, Slovakia

Pollinis, France

Rete Semi Rurali ETS, Italy

SITO seeds, Greece

Testbiotech, Germany

Verdi Ambiente e Società – APS, Italy

Vidiecka platforma, Slovakia

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