Joint statement of scientists on the future EU regulation of NGT plants from the perspective of the protection goals

This statement addresses serious scientific concerns in regard to the proposal on the future regulation of plants obtained from new genetic engineering methods, also known as new genomic techniques (NGTs).[1] We want to support the EU in order to avoid decisions that could endanger health, the environment and biodiversity.

Who we are
Numerous scientists are currently engaged in the development and application of new genomic techniques in plants. Many scientists working in this field are also in favour of deregulating plants obtained from NGTs, because they have an interest in speeding up developments and facilitating the marketing of NGT plants. Very often, they are also involved in filing patents on the technology as well as on plants derived thereof.

Our joint statement has been drawn up by experts and scientists working on the future EU regulation of NGT plants from the perspective of the protection goals of health, the environment and biodiversity. All of the scientists involved in drawing up our statement are bound by common scientific standards in natural sciences, but have no financial or career interests in the development, release or marketing of NGT plants. We are scientists with expertise in the field of agroecology, agronomy, biology, developmental biology, ecology, environmental biosafety, environmental science, molecular biology, molecular genetics and toxicology, plant physiology, plant populations genetics, soil microbiology, technology assessment, and veterinary medicine and see one of our roles as supporting independent risk assessment as enshrined in Directive 2001/18/EC[2] (Recital 21). This requests that "systematic and independent research on the potential risks involved in the deliberate release or the placing on the market of GMOs is conducted."

Many of us work with civil society organisations. Within Europe, we represent a major group of those experts that are working on NGTs from the perspective of the protection goals. ***Our work is carried out independently of any interests in the development or marketing of NGT plants*.**

Our joint conclusions on the risk assessment of NGT plants
A strong consensus was reached by the signatory scientists and experts who have been working on genetically engineered plants from the perspective of the protection goals (such as health, the environment and biodiversity): ***In short, the proposal made by the Commission cannot ensure health or environmental safety if NGT plants or products derived thereof are released into the environment or placed on the EU market. Therefore, the proposal as it stands should be rejected or extensively revised.***

[1] COM (2023) 411 final 2023/0226 (COD) 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, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX%3A52023PC0411.

[2] The Commission's proposal constitutes lex specialis with regard to the Union GMO legislation.

We are concerned that CRISPR/Cas, and other gene editing methods covered by the proposal, are mostly referred to as tools which can be used to imitate mutations that occur naturally, or can be introduced using conventional breeding. However, there is no doubt that tools such as CRISPR/Cas gene scissors have the potential and capacity to alter gene sequences (genotype), and thus gene function and plant characteristics (phenotype) in a way that is unlikely to occur in conventional breeding, regardless of whether these are intended or unintended changes. Earlier genetic engineering methods involve the transfer of genes across individual plant or species boundaries to achieve new traits (transgenic plants). Now, however, NGTs make it possible to change the characteristics of a species to an extent that would be impossible, or at the very least unlikely, using conventional breeding, even without the insertion of additional genes.

The Commission appears to be aware of this technical potential as they divide NGT plants into two categories: one that needs risk assessment and one that may only require registration. However, the proposed criteria to distinguish between these two categories, i. e. 20 genetic changes, are not based on science.

It is scientifically incorrect to assume that the risks to health or the environment from NGT plants are generally lower compared to transgenic plants. Therefore, in both cases (transgenic plants and NGT plants), the risks to health, the environment and biodiversity need to be assessed on a case-by-case basis.

As highlighted by the EU Court of Justice (CJEU), EU regulation of genetically engineered organisms is based on the precautionary principle (PP), as laid down in Directive 2001/18/EC.[3] According to the Commission, this will remain the basis of NGT plant regulation. However, in order to uphold the precautionary principle and to ensure that no substantial harm is caused, a core element of current regulation must be retained and not simply abandoned, i. e. the requirement for mandatory risk assessment of NGT plants which may be released into the environment, including all products derived thereof prior to marketing.

Given the differences in processes and outcomes of NGT compared to conventional breeding, we disagree with the EU Commission proposal. Instead, we conclude that all NGT plants must continue to be subject to a mandatory risk assessment, carried out on a case-by-case and step-by-step basis, before any reasoned assumption can be made on their safety:

In accordance with the precautionary principle, all NGT plants must be examined in detail on a case-by-case basis to determine which intended or unintended genetic changes (genotypes), or biological traits (phenotypes), are present in the plants that are unlikely to be achieved using conventional breeding methods, and, importantly, including an assessment of any associated risks, as currently laid down in Directive 2001/18/EC.

The Commission states that it wants to adapt current legislation to take recent technical developments into account, and secondly to introduce more flexibility. In our opinion, the existing GMO legislation has sufficient clarity and flexibility to deal with applications for the release or marketing of NGT plants and products. Indeed - and as pointed out by the CJEU - NGT plants are

[3] Judgment of the Court (Grand Chamber) of 25 July 2018, Case C-528/16, *Confédération paysanne*, paras 50 and 52.

genetically engineered organisms as defined in Directive 2001/18/EC, and their regulation under this Directive is necessary as they have similar risk profiles to transgenic plants.[4]

As already stated, this legal framework already encompasses flexibility: the amount of data needed for risk assessment may vary from case to case, depending on the specific NGT plant ('event'). Therefore, we cannot see why it is necessary to introduce additional legislation. Our position is backed by the CJEU court ruling stating that current rules applying to NGT plants are appropriate in light of their risk profile. As the court states, they have not "conventionally been used in a number of applications" and do not have a "long safety record" as foreseen in Recital 17 of Directive 2001/18/EC in relation to plants obtained from random mutagenesis.[5]

If the institutions of the EU nevertheless believe it is necessary to introduce specific legislation regarding NGT plants, this would require a substantial overhaul of the current proposal on several different levels. This must include deleting Category 1 from the proposed regulatory framework, as it would exempt a large group of NGT plants from mandatory risk assessment and only require their registration. Risk assessment must remain mandatory for all NGT plants. As far as Category 2 is concerned, it would require the introduction of some specific requirements and steps within the risk assessment process in order to ensure that safety is not compromised. As it stands, the legislative proposal for Category 2 would, for example, allow risk assessment to be reduced to the intended traits only.

In addition, a broad range of species, e. g. crops, wild plants, forest trees, grasses, as well as traits, e. g. enhanced fitness, drastic modifications in plant physiology or changes in environmental interactions, could in future be engineered with NGTs at fast pace. It would, therefore, be imperative to introduce measures to control and limit the overall scale of releases in terms of the number of organisms and traits. As has already been discussed in other fields of nature protection, any potentially disrupting interference with the environment must be limited and avoided as far as possible.

If releases of several NGT plants with different traits into a shared environment were to be considered, this would necessitate the establishment of clear criteria and methodologies to assess potential interactions and cumulative effects to avoid a disruption of ecosystem function and processes by organisms which have not adapted through evolutionary processes. NGT plants that have the potential to persist, reproduce or spread in the open environment need to be evaluated with the greatest possible scrutiny in respect to their impact on nature and the environment. In case of remaining uncertainty, their release into the environment must be prohibited.

Furthermore, in regard to food safety, it also has to be taken into account that NGT processes can cause unintended DNA changes and unintended effects at (off-)target genomic sites which are unlikely to occur in conventionally bred plants. Without detailed molecular analysis and risk assessment, it can not be excluded that the resulting alterations in gene functions and biochemistry may impact human or animal health at the stage of consumption.

4 see above, *Confédération paysanne*, para 48.
5 see above, *Confédération paysanne*, para 51.

Additional comments linked to the future regulation of NGT plants
There is a need to launch research programs and establish guidelines for technology assessment so that the supposed benefits of NGT plants can be realistically evaluated. This must include a comparison to lower-risk alternatives.

Patents on NGT seeds must be strictly limited to the technical processes in order to avoid these being extended into conventional breeding: many of these patents claim genetic resources and gene variants that are also needed in conventional breeding. The patents can block access to biodiversity in such a way that traditional breeding carried out by small or medium-sized breeding companies would become impossible in the future.

NGT plants must be subject to mandatory traceability and labelling all the way through up to the consumers in order to enable intervention and retrieval if damage to health, the environment or biodiversity occurs. These cornerstones of the precautionary principle must not be called into question by the new regulation. Furthermore, consumers, food producers, farmers and breeders should be provided with full transparency about NGT plants and their usage at different stages of food and feed production. We should not abandon the above-mentioned advantages provided in current GMO regulation.

Signed in alphabetical order

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