

Dear President of the European Commission Ursula von der Leyen,
Dear Vice-President Frans Timmermans,
Dear Commissioner Stella Kyriakides,
Dear Commissioner Janusz Wojciechowski,
Dear Commissioner Virginijus Sinkevičius,

By electronic mail

Cc : Ion Codescu; Margaret Bateson-missen; Kamil Kiljanski; Carlo Pettinato; Flavio Coturni;
Madelaine Tuininga

Subject : Questions and concerns about draft proposal to deregulate New GMOs

By this letter, Nature & Progrès en Velt, NGOs promoting organic farming, as well as Canopea, environmental federation of NGOs from Wallonia wish to let you know why they oppose this far-reaching deregulation proposal. **We emphasize the need to keep the European law that regulates all GMO's (also the new gmo's).**

First of all, the risk assessment proposed is completely unscientific. It assumes that any plant in which less than 20 nucleotides have been altered, or an unlimited number of nucleotides deleted, is "equivalent" to a conventional plant (category 1). However, the number of 20 nucleotides is random and has no scientific basis. A change in even a single nucleotide could result in the GM plant posing risks to health (unexpected toxins or allergens, alteration of metabolic pathways, lower nutritional quality, interferences on gene regulations, ...) or the environment. The risk assessment categories based on cutt of criteria is arbitrary and there is no scientific justification for them. Each GM plant must be assessed individually, no matter how small the intended change. In addition, the entire spectrum of unintended changes, identified using adequate screening methods (long-read whole genome sequencing), must be taken into account. The Commission's proposal completely disregard unintended effects

The text will create more biosafety risks for health and environment because there is no risk assessment for Category 1 plants, and only a weakened risk assessment for Category 2. For effective protection, health risks that must be assessed include unexpected toxins or allergens or altered composition, including nutrient levels. Environmental risks that must be assessed include unintended on-site/off-site effects, environmental fate, contamination of wild species, and unpredicted adaptation of ecosystems.

It represents a move away from process-based to product-based evaluation, for both categories. This enables GMO developers and regulators to ignore the processes by which the organism was produced, even though the very nature of those processes and their intended and unintended effects, taken together, could make the difference between safety and danger. The evaluation has to be based both on the process and on a case by case analysis. For gene edited processes, the first phase is transgenic. As the intentional transgene step is removed, there is no impact check of this transgene on the rest of the genome. The unintentional effects depends also on the genomic site of the targeted intentional mutagenesis. It is rather ignored that not all mutations occure with the same likelihood and that some areas of the genome are protected. Consequently, targeted mutagenesis in these protected area could generate additionanl unintended effects.

It is underpinned by unsubstantiated claims about sustainability and we oppose any sustainable label. An isolated trait does not confer sustainability. Sustainability arises out of the entire system within which the GMO is produced, grown, and used. If sustainability is to be considered, the sustainability test must be a separate and independent procedure and must not be linked to GM approval.

The precautionary principle is undermined.

The Commission's proposal keeps GMO-free producers and consumers in the dark. GM plants deemed to be equivalent to conventional plants will be treated like non-GM plants, but are banned in organic farming and will still be viewed as GMOs. Farmers and breeders will be informed that they are GMOs through a label, "new genomic technique Category 1", as well as an EU database and national seed catalogues. But food and feed producers and retailers as well as consumers will not be informed. Also, there is no provision for food producers and sellers who do not want to use GMOs to avoid contamination throughout the production chain. Deregulation would effectively end GMO-free production in the EU - conventional and organic farming!

Member States' views are sidelined. The Commission can decide that any GMO is equivalent to a conventional plant, and thus exempt it from risk assessment, traceability and labelling, without the approval of a majority of Member States. Member States' opinions are not binding on the Commission. GM gene-edited plants that are not deemed to be equivalent to conventional plants and will still need to undergo an EU authorisation. EU Member States will not be able to ban the cultivation of these GM plants.

The Commission leaves it to Member States to take coexistence measures. But for a large proportion of New GM crops, the Commission will remove the necessary traceability, obligatory labelling, provision of detection methods, and site register. These are minimum requirements for coexistence measures, including liability provisions and monitoring, which the Commission does not mention. **The Commission's proposal therefore endangers the very existence of all GMO-free supply chains, be it conventional, Non-GMO or organic.**

For the above reasons, we urge you to ensure that all NGTs crops continue to be regulated under existing EU GMO legislation.

Please, stop the draft regulation on NGTs

Keeping GMO regulations in place in no way restricts research and development; it simply makes the release of these NGTs plants into the environment subject to the precautionary principle and to a proportionate health/environmental assessment as well as to labelling, which will guarantee the free choice of whether or not to plant or consume plants modified by these new techniques.

Yours sincerely,



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