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Statement

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Slovak Academy of Science support of NGT Regulation is not aligned with the science regarding this technology

The Slovak Academy of Science (SAS), in its statement supporting the new NGT Regulation of the European Union (EU), ascribes a series of benefits to New Genomic Techniques (NGTs), but does not provide any scientific evidence to support this. Furthermore, the SAS ignores the substantial risks of these techniques that have been reported in the scientific literature. These risks arise from the experimentally validated fact that NGT procedures as a whole are highly DNA-damaging and not as precise and predictable as is claimed, and neither are their outcomes. The existing scientific evidence provides no support for the NGT Regulation, but instead leads to the conclusion that it should be withdrawn and proper risk assessment and labelling should be put back in place.

NGTs are unquestionably artificial, laboratory-based genetic modification procedures, which by definition give rise to genetically modified organisms (GMOs), as ruled by the European Court of Justice in 2018.[i] Some NGTs (cisgenesis, intragenesis) are not "new", but have existed for many years and constitute a subtype of old-style gene addition transgenic procedures. Contrastingly, CRISPR-based gene editing NGTs are, comparatively, still in their infancy, with many unknowns regarding unintended effects that can arise from their application. All NGTs originally fell under Directive 2001/18/EC on the deliberate release into the environment of GMOs. However, the vast majority of NGT plants and their products (obtained by so-called NGT1 procedures) are now exempted from this directive by the recent EU Regulation 2026/1388. This NGT Regulation abolishes the provisions of Directive 2001/18/EC for risk assessment, traceability and monitoring of NGT1 plants, which are most types of NGT crops that are envisioned to be produced as well as NGT trees and wild plants. In addition, labelling of food and feed products derived from NGT1 plants is abandoned under the new NGT Regulation.

The SAS published a statement[ii] in support of the new NGT Regulation of the EU, claiming that NGTs have "*the potential to contribute to sustainable and ecological agriculture while respecting biodiversity conservation and the production of safe food and feed".* The statement also claims that NGTs *"make it possible to overcome the limitations of conventional breeding methods – such as multi-year cross-breeding and selection of plants with desired traits, random mutagenesis, or modern yet still demanding procedures such as marker-assisted selection*" and "*allow for more efficient development of varieties with traits such as increased resistance to plant diseases and abiotic stresses (high temperatures, drought, frost, salinity, soil contamination, etc.)".*

However, the SAS statement does not quote any scientific evidence to support these claims. This statement fails to acknowledge the fact that plants generated through NGTs, including those produced through CRISPR-mediated gene editing, also have long development timelines, running to years (15 years in the case of a tomato gene-edited to contain high levels of a blood pressure lowering substance[iii]).

The claim that NGTs can lead to "*development of varieties with traits such as increased resistance to plant diseases and abiotic stresses"* is at odds with the basic molecular genetic understanding that these are complex genetic traits, with the coordinated functioning of multiple gene families at their basis. As gene editing NGTs can, at best, only manipulate a few genes, it is beyond the capability of this approach to robustly achieve complex genetic trait outcomes of the type listed above, as well as the frequently claimed outcome of increased yields.

Furthermore, as genes do not work in isolation, but as part of a sophisticated, strictly balanced network, manipulation of just one gene through an NGT procedure could have repercussions on gene network function, which can have a major impact on plant performance in the field and on plant composition, with the latter including production of novel toxins and allergens or enhanced levels of them, and/or compromised nutritional value. In short, any attempts to robustly produce novel complex traits by gene editing are doomed to failure. Indeed, similar claims of future benefits have been made for first-generation genetically modified (GM) crops since the 1980s, but they remain unfulfilled promises and have never been supported by practical, independently and scientifically assessed results.[iv] That trajectory continues with the new generation of gene-edited GMOs: a gene-edited soybean was withdrawn from the market following poor farmer adoption as a result of disappointingly low yields.[v]

Overall, the NGT Regulation completely lacks a sound scientific basis. The notion on which the whole Regulation is built – that a NGT plant can and should be safe because of how similar it is to a conventional variety, judged exclusively by the intended DNA characteristics of the end product (trait) without any requirement for in-depth molecular analysis[vi] – is false. Yet the SAS uses this notion to make the assertion:

"The changes in the DNA that such plants acquire are indistinguishable in the laboratory from changes arising through natural crossing or conventional breeding. According to the available experimental data, the rate of unintended mutations in conventional breeding is even higher than when NGTs are used."

This statement ignores several fundamental innate aspects of NGT procedures and experimental evidence showing that some changes produced by gene-editing tools would be difficult or impossible to achieve by conventional breeding methods and even by random mutagenesis methods – and that the risks associated with such changes should be carefully assessed in a case-specific manner.[vii]

First, there is no experimental evidence to the claim that NGTs can give rise to exactly the same genetic modifications (intended and unintended) as can be achieved through conventional breeding. In other words, the DNA criteria by which NGT1 plants are defined in the Regulation are not scientific criteria but are entirely arbitrary and political. The fact is, that the mere number, size and character of DNA modifications cannot make a NGT plant equivalent to a conventional one.

Second, to our knowledge, only one study has compared DNA damage (mutation) rates between natural reproduction and CRISPR gene editing. Here, total DNA sequence analysis found that rice plants subjected to one round of CRISPR gene editing possessed several times more unintended sites of DNA mutation than plants that had gone through three rounds of natural reproduction. Crucially, most of the unintended mutations in the rice plants that had gone through the CRISPR gene editing procedure arose from the obligatory laboratory-based plant cell tissue culture and genetic transformation components of the process, and not the gene-editing tool itself.[viii] This means that no matter how accurately the gene edit may be targeted, large scale mutation, numbering in hundreds or thousands of sites of damage from the CRISPR gene editing process as a whole, is inevitable. Therefore the available experimental evidence shows that the SAS's statement "*the rate of unintended mutations in conventional breeding is even higher than when NGTs are used"* is incorrect or not generalisable to all crops. Plant cell tissue culture and plant cell transformation are also how cisgenesis and intragenesis NGT methods are executed, so these processes will also be prone to the large-scale unintended DNA mutation described above for the CRISPR procedure.

Third, CRISPR gene editing has been shown to produce unintended DNA mutations, even at the intended gene edit site, that will affect the functioning of many genes. This includes large insertions or deletions of DNA, large rearrangements of DNA, chromothripsis (chromosome shattering and random rejoining), and the creation of new gene sequences and the consequent production of mutant proteins.[ix] In addition, processes that form an obligatory part of the CRISPR gene editing procedure in plants – tissue culture and GM transformation – have been found to create thousands of mutations throughout the genome,[x] which generally are not adequately screened for by gene-edited product developers.[xi] In addition, the impact and adverse effects on non-target and unintentionally exposed organisms are as yet unknown.[xii] Such knowledge is only generated when risk assessments are required and in place and both the impact and the uncertainties are estimated and acknowledged.

As for food safety, it must be noted that no animal feeding trials have been carried out with CRISPR NGT gene-edited plants; nor are in-depth molecular analyses generally performed by developers. Therefore, claims of food safety, such as the SAS makes, are based on assumptions and not on experimental evidence. Further references pointing out risks and regulatory issues concerning NGTs, including review papers, are listed below this statement.[xiii]

Fourth, it is well established that the genetic variation that arises through rounds of natural reproduction is not random. Some regions of the genome of plants are protected from alteration, as they encode functions that are essential for basic life processes. In addition, where genetic variation is seen to occur after natural reproduction, it is now recognised as non-random and as part of a directed evolutionary adaptation response.[xiv] This is in stark contrast to NGT-mediated process mutation, where no part of the genome is spared from alteration and where the resulting product is not selected for over evolutionary timescales.

Taken together, the above scientific evidence argues that NGT processes for CRISPR gene editing, cisgenesis and intragenesis procedures, when considered as whole, are far more mutagenic than natural reproduction, with a greater risk of compromising crop performance and plant composition, including the production of novel toxins and allergens.

By focusing purely on the intended end traits and ignoring the process by which NGTs are conducted, the Regulation fails to consider the downstream consequences of the inevitable large scale DNA mutation that comes along with any intended cisgenic/intragenic/CRISPR gene edit in the targeted plants. This is tantamount to ignoring scientific method, the very foundation of science. Crucially, from a regulatory standpoint, the process of how a technology is applied not only provides information on how an intended outcome can be achieved, but also about any unintended outcomes that can arise and their possible consequences to health and the environment. In other words, the process of a technology informs appropriate regulation to better protect consumer health and the environment. By ignoring the process of NGTs and only considering intended end traits, the Regulation fails to put in place a policy that fully embraces the science that underpins this technology.

Based on the scientific evidence described above, the same approach as applied in the NGT Regulation was rejected by a US Federal Court at the end of 2024.[xv] Furthermore, based on such evidence, the national authorities of Austria, Germany, Italy, Poland and Switzerland concluded in 2023: "*a case-specific risk assessment approach is needed for genome-edited plants, based on the characteristics of the individual applications, taking into account their use* *and interaction with the receiving environment. Relevant for such an approach is the nature of the respective trait(s) developed in a particular genome-edited plant. A robust risk assessment approach is required in particular for genome-edited plants with novel and/or complex traits as well as traits with limited existing experience from practical use. Furthermore, a robust assessment of unintended modifications and possible adverse consequences of such modification needs to be maintained, based on an adequate molecular characterization of genome-edited plants and an appropriate comparative assessment*."[xvi]

Instead of ensuring such a risk assessment approach that considers both the intended end product and also any intended and unintended process-induced changes, the NGT Regulation has abolished the risk assessment that had been in place since 2001 for NGT plants and other GMOs.

Thus, the existing scientific evidence concerning NGTs provides no support for the NGT Regulation, but instead leads to the conclusion that it should be withdrawn. ENSSER has pointed this out many times for more than a decade.[xvii] We quote from our 2023 statement: "*The EU GMO regulations and directives have served a good purpose (environmental and public health safety) and have been successful in doing so for the past twenty years. There are no good reasons for weakening this system, let alone abolishing it for the majority of new NGT GM plants, in particular as these have no history of safe use.*" The European Commission has not only done people a great disservice in weakening GMO legislation by the NGT Regulation, but it also exposes citizens to unnecessary and unmonitored risks and thus contradicts its own treaty, which commits it to ensuring "a high level of protection, taking account in particular of any new development based on scientific facts".[xviii]

In summary, ENSSER strongly recommends that the government of the Slovak Republic oppose the EU NGT Regulation. In adopting such a position, the Slovak government should feel secure in the fact that it will be supported by solid scientific evidence.

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