

NEW GENOMIC TECHNIQUES, NEW RISKS

Strict risk, labelling and technology assessments for CRISPR/Cas and Co. are indispensable

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The European Commission has announced that it considers softening strict European rules on genetically modified organisms (GMOs) for new genomic techniques (NGTs) such as the "gene scissors" CRISPR/Cas. A legislative proposal is expected in 2023. The European Food Safety Authority (EFSA) suggests that no in-depth risk assessment should be required for NGTs in plants if no "new" genes are inserted. The Federation of German Consumer Organisations (vzbv) demands that NGTs must continue to be strictly regulated and labelled in order to protect consumers from risks, to guarantee freedom of choice and to prevent damage to ecosystems and biodiversity. Sustainability claims made by producers must not lead to lower safety and labelling standards.

NGTs can achieve genomic changes extending far beyond what is known to be possible with conventional breeding techniques and without having to insert additional genes. Natural evolutionary protective boundaries in cells, which determine what can and cannot be changed, can be overcome using NGTs.

Examples for applications of NGTs

The potential applications of NGTs go far beyond those of previous genomic techniques. They can be applied to a wide range of plants and animals, including non-domesticated species. Many of these genetically modified species have the potential to persist and spread in the environment.

Genetic modifications are often used to change the composition of plants, for example a change in fat composition. Other applications aim to promote higher yields in plants or meat, herbicide resistance or to improve shelf life. Better heat tolerance is also often a goal – in plants as well as in animals, for example by breeding cattle with thinner coats.

In Japan, a tomato has been approved, which, according to the manufacturer, can lower blood pressure. In the US, mushrooms whose surface browns slower than that of other mushrooms and are therefore considered to have a longer shelf life, could be marketed. In both cases, data on possible unintended side effects are not publicly available and have not been investigated by regulatory authorities.¹

¹ Then, Christoph: Testbiotech, New genomic techniques (NGTs): agriculture, food production and crucial regulatory issues, commissioned by and written for Verbraucherzentrale Bundesverband (vzbv), 2022, S. 38, https://www.vzbv.de/sites/default/files/2022-11/vzbv-report_final_final.pdf (04.11.2022)

Risks and opportunities of NGTs

The traits developed using NGTs are often extreme variations, or new biological properties, that are unlikely achievable by conventional breeding. This could lead to unintended and not fully controllable interactions with the environment and could impact the climate, animal welfare and food safety. These unintended effects can also emerge in cases where the intervention in the genetic material is considered targeted and precise.

For example, in the US, it only became apparent that after several years of breeding hornless cattle using NGTs, genes from bacteria had accidentally entered the genetic material of the animals. This included genes which could lead to antibiotic resistance.² If potentially hazardous unintended effects remain undetected, they can spread quickly within larger populations.

The intentional and unintentional genetic changes can also cause risks to humans and the environment that are difficult to predict. For example, if fats and proteins are altered in food crops, this can affect the potential for allergies as well as disrupt interactions with pollinators and soil organisms.

In addition, many genetically modified plants and animals have the potential to persist and to spread in the environment. Only the adequate control of these organisms could prevent this.

Producers and researchers often claim that plants and animals produced with NGTs contribute to more sustainable agriculture and nutrition. However, since agriculture, food production and nutrition are highly complex systems, such claims are not tenable without a comprehensive technology assessment. In addition to the risks and potentials of individual applications, a technology assessment should also consider the overarching ecological, socio-economic and health-related contexts as well as possible alternatives to NGTs. Sustainability claims should not, under any circumstances, be used as a justification to lower safety standards within the EU. This would contradict the precautionary principle, which is an essential pillar of European legislation.

THE VZBV DEMANDS

❖ Risk assessment and authorisation procedure

All animals and plants, as well as foods produced with NGTs, must undergo an authorisation procedure and a risk assessment. The risk assessment has to consider accumulated effects on the environment, animals and human health. Furthermore, it must analyse if foods produced using NGTs can be consumed in normal quantities without having critical side effects on human health. Publicly funded risk research must be significantly intensified.

² Then, Christoph: Testbiotech, New genomic techniques (NGTs): agriculture, food production and crucial regulatory issues, commissioned by and written for Verbraucherzentrale Bundesverband (vzbv), 2022, S. 41, https://www.vzbv.de/sites/default/files/2022-11/vzbv-report_final_final.pdf (04.11.2022)

❖ **Labelling and freedom of choice**

Foods produced using NGTs must continue to be labelled as GMOs so that consumers can decide whether they want to buy and eat these products. Labelling also allows consumers to decide which form of agriculture they want to support with their purchasing decisions. Organic and GMO-free food production must be effectively and reliably protected against contamination.

❖ **Technology assessment**

The existing GMO legislation should not allow for any exceptions and adaptations for NGTs. Should the European Commission nevertheless introduce new, separate authorisation requirements for NGTs, they should include a mandatory case by case risk assessment and a comprehensive and anticipatory technology assessment.

In accordance with the precautionary principle, the actual need for NGTs, and possible, less hazardous alternatives, should be examined in detail. The aim should be to limit the release of genetically modified organisms as much as possible. This is important to avoid passing potential tipping points, which can lead to irreversible damage to ecosystems or can have long-term effects on human health.

❖ **Comprehensive risk analysis by EFSA**

The European Commission should mandate the European Food Safety Authority (EFSA) to conduct a comprehensive risk analysis of NGTs where the unintended effects need to be systematically analysed. This is a crucial prerequisite to any potential legal adjustments.

Kontakt

*Verbraucherzentrale
Bundesverband e.V.*

*Team
Lebensmittel*

*Rudi-Dutschke-Straße 17
10969 Berlin*

lebensmittel@vzbv.de