New Genomic Techniques: European Commission's proposal for new legislation requires wholesale improvement!

WHAT HAS HAPPENED TO DATE?

In April 2021, the European Commission published a **study on the status of New Genomic Techniques (NGTs).** It argued that existing legislation was no longer fit to regulate state-of-the-art genomic techniques and was therefore in need of an update *(see also our White Paper published in September 2021).*

In September 2021, the European Commission published an **Inception Impact Assessment**, outlining the process of drafting a proposal and its envisaged content. Even this document, published at an early stage in the process, indicated the Commission's intention to weaken risk assessments and **water down labeling requirements.** For this reason, the Commission entertained the idea of emphasizing the sustainability aspects of NGTs.

The subsequent stage in the process, the **Impact Assessment**, was based in large part on several surveys with stakeholders, Member States and the public. The **questionnaire was one-sided and heavily suggestive**, with the possible answers influenced by preconceived opinions and assumptions. This led to vehement protests by NGOs and trade associations as well as several Member States, who refused to participate in the survey in its proposed form. Many of these organizations and institutions wrote to the Commission to express their criticisms and concerns regarding the proposal.

Following **complaints from numerous NGOs**, the Ombudsman opened a case on the issue in February 2023 and raised several questions with the Commission regarding the content, transparency and balance of the Impact Assessment. The Commission was set a deadline of the end of July 2023 to answer these questions.

Despite the ongoing Ombudsman process and massive criticism from numerous governmental and non-governmental organizations and business groups, **the European Commission published its proposal for a regulation on July 5, 2023.**

KEY CONTENT AND POTENTIAL CONSEQUENCES

On July 5, 2023, the European Commission published a Proposal for a regulation on plants obtained by certain New Genomic Techniques following lengthy discussions and a process of more than two years. This proposal involves complete deregulation of most NGT products and therefore presents a fundamental threat to successful GM-free food production across Europe. This white paper provides an overview of the proposal's key content and identifies its weaknesses, points of criticism and potential consequences for GM-free food.

THE EU COMMISSION'S PROPOSAL FOR A REGULATION ON NEW GENOMIC TECHNIQUES – AN OVERVIEW

The Commission's aim: Easier market access

By publishing this proposal, the European Commission is pursuing a **clear objective** that is also explicitly named in the reasons for the proposal: **"The cultivation of NGT plants in the Union should be facilitated."** This has been justified since the beginning of this discussion by the contributions these plants could make to objectives of the Green Deal.

Proponents argue that NGT plants contribute to sustainable agriculture and can make a significant contribution to food security. In order to achieve this overarching goal, the Commission's proposal – unlike the existing GMO legislation – lays the groundwork for significant measures that

- facilitate or consciously promote NGT products being placed on the market,
- significantly restrict some rights of Member States in relation to the authorization and assessment of NGT products,
- remove the **labeling requirements** for the majority of NGT products, and thereby
- make **consumers' freedom of choice when purchasing food** – a right anchored in the fundamental laws of the EU – **impossible**.

Entirely new categories for NGT products

The European Commission's proposal envisages dividing NGT products into two categories:

- **Category 1 NGT plants:** This category includes all NGT plants that, according to the Commission, are considered equivalent to conventionally bred plants. This not only includes NGT plants with small genetic modifications but also includes some with complex modifications – so long as the foreign DNA originates from the "breeders' gene pool". This categorization focuses solely on changes to genetic material and does not relate to new traits in the plants in any way.
- **Category 2 NGT plants:** This category covers other NGT plants, e.g. plants containing genetic material from non-related species.

A precondition of both categories is that the method used to effect the genetic modifications is "targeted" (i.e. genome editing).

For NGT 1 plants and the products produced using them, the developer is essentially required to demonstrate that their product falls into this category. Once this has been confirmed by the authorities, all such plants and products produced from them can be placed on the market like any other conventionally bred plant. This means that **risk assessments, labeling and traceability requirements are scrapped for NGT 1 plants.** Manufacturers are also **not required to provide detection methods.** Furthermore, processors, retailers and consumers will not receive any information about whether or not a plant is an NGT plant. NGT 2 plants and products will be subject to a similar authorization procedure as GMO plants and products under current legislation. However, the Commission may weaken risk assessment requirements without consultation with Member States. In addition, detection methods will not be required for all plants and products in this category.

Abolition of labeling requirements

Given that category 1 NGT plants are to be treated like conventional plants following a notification procedure, **no further labeling will be required to provide transparency for food processors, retailers or consumers.** One exception is seeds, which will still have to be labeled in order to – according to the Commission – provide transparency and thus freedom of choice to farmers and breeders.

After receiving authorization, category 2 NGT plants will be subject to the labeling requirements currently in place for GMOs. However, they may also be accompanied by a sustainability label, which has not yet been defined in detail.

Relaxation of requirements for NGT 2 plants

Similar to conventional GMOs, NGT 2 plants are "transgenic" organisms – the only difference being that they are produced using NGTs. The Commission's proposal includes **significant relaxations of authorization requirements** compared to the existing regulation. These include, for example, assistance with submitting applications for authorization and, potentially, less stringent risk assessments. Furthermore, exemptions may be granted to the detection method requirement – if the applicant can demonstrate that such analytical detection methods are not technically feasible. However, no criteria for such detection methods have been proposed. These plants are also set to be authorized in a simplified process compared to conventional GMOs.

Regulations for organic production

The Commission's proposal does refer to the EU Organic Products Regulation and includes a **general prohibition of the use of NGT plants in organic production.** However, it provides no details at all about how this ban can be enforced in the absence of labeling and traceability requirements.

No regulations on coexistence

The Member States must adopt coexistence-rules to ensure that NGT 2 plants can be used in agriculture alongside organic and GM-free products. However, the proposal does

not provide further details, criteria or requirements for a comparable or harmonized pan-European approach. National cultivation bans, as currently allowed for GMOs and implemented in 18 Member States, will be prohibited for NGT plants.

Regulatory powers for the Commission

The proposal includes empowering the Commission to take numerous regulatory actions. These include the ability to unilaterally amend the "equivalence" criteria for NGT1 plants and the requirements for detection methods for NGT plants. Member States will only be peripherally involved in such changes, if at all.

MAIN CRITICISMS OF THE EU COMMISSION'S PROPOSAL FOR NEW LEGISLATION

The Commission's goals

The Commission's fundamental goal – to promote NGT plants – **is based on a series of highly dubious assumptions and assertions.** The promise that NGT plants will contribute to sustainability and play an important role in ensuring food security cannot be substantiated according to current research. Around 3% of developed plants have traits such as tolerance of salinity stress or drought stress as a climate change adaptation, which are named as examples of sustainability. However, the Commission itself notes elsewhere that food security in the EU is not under threat. By expressing substantial support for a single method of breeding and producing plants while simultaneously failing to consider alternatives and removing transparency and traceability requirements, **the Commission is significantly restricting the opportunities available to GM-free and organic farmers** – which is highly questionable from a competition perspective.

The proposal, which explicitly aims to promote NGT plants, blatantly contradicts other objectives of the European Commission. It is entirely unclear how the prohibition on use in organic production, and therefore in GM-free production, will be implemented after the proposed regulation enters into force. In this context, the European Green Deal target of using 25% of agricultural land for organic farming appears unattainable. In addition, maintaining a high level of protection of human health and of the environment – a goal referenced in the proposal itself – cannot be achieved without risk assessments, which would be removed completely for NGT1 plants.

Categorization of NGT products

The categorization of NGT plants states that NGT 1 plants are considered equivalent to conventional plants; NGT 2 plants are to be treated like GMOs, subject to certain restrictions. This raises several points:

WHAT ARE THE PROPOSAL'S REQUIREMENTS FOR NGT PLANTS COMPARED TO ESTABLISHED GMOS?

	GMO	NGT1	NGT2
Authorization procedure	Assessment by EFSA and Member States Decision taken by Member States and/or European Commission	No authorization process Only a review of NGT1 status by a Member State and/or European Commission	Accelerated authorization procedure Responsible parties similar to GMOs
Risk assessment	Comprehensive assessment of risks to health and the environment	None	Limited risk assessment Assessment scope not yet defined
Labeling	Labeling required for all GMO products above 0.9% threshold	Only for seeds	Same as for GMOs, if detection method is provided. Procedure unclear if no detection method is provided. Sustainability label possible
Detection method	Mandatory; must be provided by applicant	None	Mandatory in principle Exemptions possible if applicants state that detection is not technically feasible
Traceability	Mandatory	None	Mandatory
Coexistence	Possible at national level; not mandatory	None	Mandatory regulations at national level
Cultivation bans	Possible	Although not set out in explicit terms, equivalence with conventional plants implies that this is not possible.	Not possible

- Some of the criteria for this supposed equivalence are **not scientifically or technically justified.**
- The criteria for equivalence are so broad that most of the products currently in development fall into this category.
- The limits specified in the proposal – of 20 modified or excised DNA building blocks, and 20 different modifications per product – **lack any scientific basis** and have not been justified by the Commission.
- The term "breeder's gene pool" has a very broad definition and also covers modern biotechnological methods.

This very broad definition of NGT 1 plants also permits extensi**ve, complex modifications to the genome.** This does not eliminate the risk of undesirable effects. Combined with the lack of a risk assessment for these products, this raises concerns about the Commission's commitment to a high level of protection of human health and the environment.

The proven, scientifically justified, stringent provisions for GMOs would be removed completely for NGT 1 plants and would be only apply to a limited extent to NGT 2 plants, even though both categories are clearly GMOs according to the definition used in previous GMO legislation. This was also confirmed in July 2018 by the European Court of Justice.

Abolition of labeling requirements

Removing labeling requirements for NGT 1 plants, with the exception of seeds, is also highly problematic, as is the proposed creation of a database for registration of NGT 1 plants. As a fundamental rule, NGT 1 plants should not be treated the same as conventionally bred plants. According to the Commission, seed labeling and the database should ensure that organic agriculture, consumer trust and freedom of choice are protected at the start of the production chain.

In reality, however, this aspect has several implications:

- Large parts of the production chain and retail **will not be subject to labeling requirements of any kind.**
- Monitoring and control of GM-free and organic production will involve considerably greater expenditures than to date.
- This additional work and the associated costs will fall on the user – i.e. the organic/GM-free producers and retailers. The developers and distributors of NGT 1 plants will not have contribute in any way – which therefore **abrogates the polluter pays principle.**

The European Commission has stated on numerous occasions that consumers' freedom of choice is a precious asset. It was one of the catalysts for regulations on mandatory labeling requirements for GMOs and food products made from them. **This freedom of choice would be made impossible in future, with consumers losing out** along with organic food production and GM-free food production, to the benefit of producers and users of NGT plants.

Relaxation of requirements for NGT 2 plants

The proposed relaxations of the authorization procedure for NGT 2 plants also cannot be justified. These relaxations would apply to products that possess one of the traits defined and described as "sustainable" by the Commission. These include higher yields, resistance to diseases and tolerance to drought and heat, as well as changes to nutritional characteristics and improved quality. Once again, the Commission fails to provide any scientific or objective justification for selecting these traits. Furthermore, these relaxations are to be granted without any form of assessment. Instead, the existence of one of the specific traits is sufficient, for example, for authorities to grant extensive assistance in the authorization procedure or conduct an accelerated procedure.

Nevertheless, the sustainability of a product is never dependent on any single trait: this can only be assessed in the overall context of the environment and the economic and social setting in which an NGT product is used. No in-depth sustainability analysis of this type is included in the proposal but it states that such products can be labeled as "sustainable".

It is also highly questionable that an **exemption from the requirement to develop and provide a detection method can**

be granted (and will almost certainly be granted in practice by the Commission) solely on the basis of justification provided by the applicant. The proposal does not give any further details of what this justification should look like or what data should be provided.

NGT 2 plants are very clearly GMOs – with the sole difference being that new techniques have been used to produce them. A **relaxed authorization process**, especially in relation to limited risk assessments and exemptions to the requirement to develop detection methods, **should be firmly rejected.**

Regulations for organic production

The proposal includes a prohibition of the use of NGT plants in organic production, and therefore also in GM-free production. Due to the lack of labeling requirements for such products, and given the lack of any information on the practical implementation of this ban, **countless questions remain as to how this prohibition could be implemented in practice.** Seed labeling and the creation of an – as yet entirely undefined – database are in no way sufficient to ensure GM-free practices throughout an entire production chain.

Establishing and monitoring traceability systems, and the fact that certain production chains may need to be closed, is likely to create additional costs. These increased costs mean that **market distortions cannot be ruled out.**

Regulations for coexistence

The European Commission also avoids all responsibility regarding the development of coexistence regulations for NGT 2 plants. Instead, this responsibility will lie solely with Member States. However, there are no guidelines as to how such regulations should be structured or how to bring about Europe-wide comparability. Many countries in the EU do not have any coexistence regulations for GMOs at present. Member States' policies on genetic modification range from widespread authorization of agricultural use (Spain) to a constitutional prohibition of GMOs (Hungary). Widely varying regulations on coexistence are therefore likely, which could in turn lead to varying competitive conditions. If these rules are to be made mandatory, this must take place at the European level with the integration of all Member States. In addition, the creation of breeder registers by the Member States based on information from distributors must be made mandatory.

The Commission's proposals regarding coexistence and organic production shift the responsibility to producers and Member States. This means that, once an application to place the product on the market has been authorized, the developers and distributors of NGT 1 products are not subject to any obligations or liability regulations.

Regulatory powers of the Commission

The proposal sets out numerous areas in which the European Commission would be empowered to adopt rules and regulations. First, it gives the Commission the power to update at any time the annexes to the proposed regulation – i.e. the equivalence criteria for NGT 1 plants, the list of "sustainable" traits in NGT 2 plants and the data requirements for the risk assessment of NGT 2 plants. While Member States will be involved through their experts, the decision ultimately lies with the Commission.

The Commission would be required to prepare a series of rules to implement the proposal. These include many of the points mentioned above, such as information requirements for demonstrating the equivalence of NGT 1 plants or the reason why a detection method cannot be developed. However, as these points are decisive to the proposal's implementation, they must be clarified before any vote on adoption of the proposal, and therefore in parallel with the ongoing institutional discussions.

The chosen approach of **"all power to the Commission", with no co-decision rights for the Member States,** represents a significant infringement on the rights of the national authorities and must therefore be firmly rejected.

General criticism

In addition to the above criticisms of specific elements of the proposal, there are a series of general aspects of importance to the overall picture.

One-sided, suggestive preparation

The process conducted by the European Commission to develop this proposal was highly one-sided and suggestive from the outset. It was solely designed to deregulate NGT plants and products as far as possible and thereby **significantly ease their market access.** The criticisms and concerns expressed by numerous stakeholders and trade associations, as well as skeptical scientists and Member States, have been disregarded entirely. When drawing up its proposal, the Commission exclusively considered voices advocating deregulation.

Precautionary principle ignored
The precautionary principle, which is anchored in the treaties of the European Union, is **criminally ignored** by this proposal. NGT plants are products created using relatively new techniques – so we have very little experience in how these plants behave in a natural environment and the potential undesirable traits they may develop. In the interests of precaution, it is essential that an authorization procedure be applied in line with existing GMO rules.

Entirely new form of product assessment
The proposal also represents a paradigm shift in product assessment. NGT 1 plants must correspond to certain criteria, such as their size, number of genetic modifications and the origin of newly introduced DNA. The new traits of NGT plants are completely ignored. However, given that NGT plants can also entail complex modifications of traits, such as modified composition and modified behavior in a natural environment, **the safety of NGT plants cannot be assured without a risk assessment.**

Polluter pays principle ignored
Another principle established in the treaties of the European Union is the costs-by-cause principle. This principle is also ignored by this proposal. While the proposal includes the abolition of authorization requirements for NGT 1 plants and relaxed authorizations for NGT 2, it remains **entirely unclear who will bear the costs** of producing and ensuring compliance with the coexistence rules or the increased monitoring work involved in organic and GM-free production. The proposal is also vague in relation to liability and only makes general references to environmental liability and applicable nature conservation legislation.

Patents? Entirely unclear …
Another point is the unresolved question of the patentability of NGT plants, because many countries are issuing patents for such plants. In the EU, the issue of patents on plants, including NGT plants, has not been conclusively resolved. However, major corporations have already patented many such products – with patent applications including not only the seeds but also the resulting crops and all products made from them. This means that all users throughout the entire production chain may be required to pay license fees.

The Commission itself has admitted that it has not engaged with the issue of patentability in its proposal. Instead, it plans to observe the effects of deregulation on the market and breeding innovation before reporting on this in 2026. The risk of growing dependence on major biotech and seed corporations is ignored in the proposal.

Liability? Unclear …
Legal issues that may arise in the event of improper use due to the lack of labeling have also not been clarified.

Fierce criticism even within the European Commission
Even the Scrutiny Board of the European Commission, which examines each proposal before publication, **identified numerous shortcomings** that have only been partially resolved by the Commission. Even after a second round of feedback, unanswered questions remained. Consequently, the Scrutiny Board only issued conditional approval.

WHAT'S NEXT?

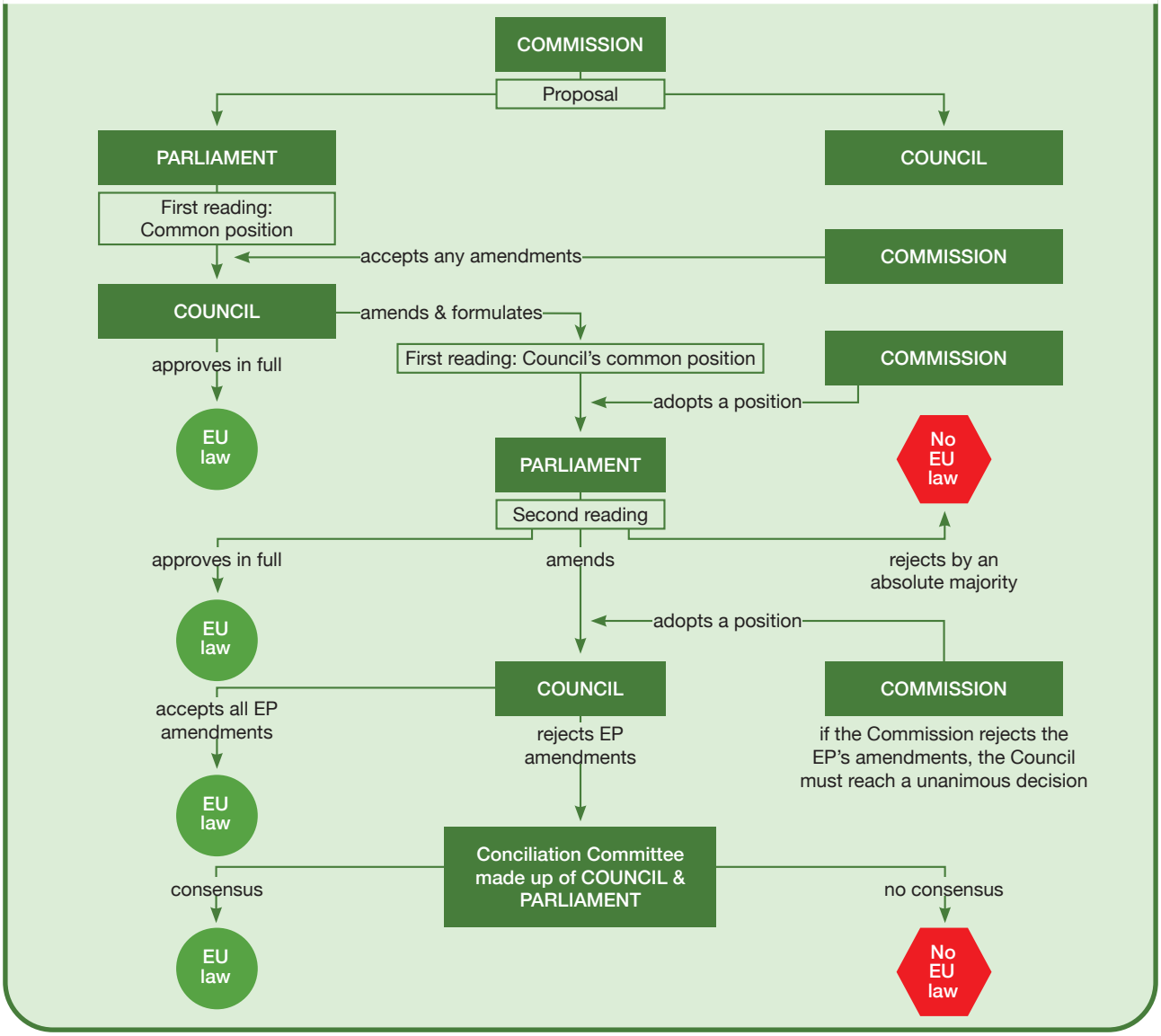
Now that the proposal has been published, it's the turn of the Council of the European Union (Council) and the European Parliament (EP). *(See diagram for the EU's ordinary legislative procedure)*

The EP discusses the proposal in parallel in the EP's Environment Committee and in the Agriculture Committee and finally must come to a formal consensus in the Plenary. In the next stage, a common position on the proposal must be agreed with the Council and the Commission. In most cases, the EP puts forward a number of amendments, which are then presented to the Council.

In practice, the Council's working parties – in this case the "Working Party on Genetic Resources and Innovation in Agriculture" – conducts negotiations in parallel with the discussions in the EP to develop a common position to be adopted by the Member States. The negotiations on the Commission proposal began in July 2023 and will progress on a tight schedule under the Spanish Presidency of the Council until the end of 2023.

So far, little is known about other Member States' official positions on the proposal. While some have been clear in their support for the proposal, such as the Netherlands, Spain and Denmark, only a handful have expressed clear opposition to date. Besides Austria, the proposal's main opponents include Hungary and Slovakia. However, as most Member States do not have a distinct national position on genetic engineering, their position will only become clear in the course of the negotiations.

HOW EU LAWS ARE MADE



WHAT DOES THIS MEAN FOR GM-FREE PRODUCTION?

If adopted in its present form, the Commission's proposal would have **massive repercussions for GM-free agriculture and food production, which has become a central quality standard in Austria.** As is the case in organic production, the use of NGTs in GM-free production is not open to debate and will remain prohibited. First and foremost, this raises the question of how commodity flows can be kept separate without labeling, traceability requirements or detection methods.

On the one hand, the Commission's proposal involves **passing the responsibility and costs on to GM-free producers and retailers.** On the other hand, there is no legal guidance or information of any kind about how separate production paths could be set up.

One aspect that must not be neglected is that placing NGT products on the market without the need for authorization or labeling could lead to a loss of trust in GM-free and organic production. If consumers have doubts about control methods and guarantees that products are actually GM-free, they may switch to cheaper, conventional products. This could have unforeseeable consequences for these market segments, which have been very successful to date.

It is therefore essential to **maintain the existing rules in relation to authorization requirements, risk assessments, labeling and traceability.**

AUSTRIAN FEDERAL GOVERNMENT: EU PROPOSAL ON NEW GENOMIC TECHNIQUES IS UNACCEPTABLE

The Austrian Federal Government has also expressed fierce criticism of the proposal:

- "In Austria, we have positioned ourselves as pioneers of organic and GM-free agriculture. The government's

position is that strict regulations are also required for so-called 'New Genomic Techniques'. The Commission's proposal is a **threat to the Austrian approach to agriculture and also takes freedom of choice away from consumers."**

- "We will not permit this and will therefore do our utmost in Brussels to ensure that **genetically modified plants and foods remain subject to strict regulations.** The EU Commission's attempt to force Member States to permit the uncontrolled cultivation of genetically modified plants is unacceptable."
- The Austrian position is clear: the **three basic pillars – the precautionary principle, scientific risk assessments and labeling requirements – must apply** to all categories of so-called "New Genomic Techniques". Austria will therefore insist to the European Commission that effective, strict rules must be maintained.

ARGE GENTECHNIK-FREI: PROPOSAL WOULD OBLITERATE SUSTAINABLE CORPORATE VALUES!

- "This is a **clear attack by the European Commission on the GM-free and organic sectors,** which generate around €4.5 billion per year in Austria alone," said ARGE Gentechnik-frei, the trade association for GM-free agriculture, food production and food retail in Austria, in response to the proposal. "The European Commission wants to scrap the established rules on risk assessments, authorization procedures and labeling requirements for the majority of plants produced by 'New Genomic Techniques'. That would be the **end of transparency and freedom of choice in the food sector."**
- "As representatives of the Austria GM-free sector, we demand that the **core values of existing EU legislation on genetic engineering – in which the precautionary principle, risk assessments and clear transparency requirements as key pillars – continue to apply to new GMOs in the future.** New GMOs must continue to be regulated just like old GMOs."
- You can find the detailed position paper issued by ARGE Gentechnik-frei on New Genomic Techniques here:

WHAT CAN COMPANIES IN THE GM-FREE SECTOR DO?

- **Take a clear position** – and express it to your consumers as well as to political and administrative stakeholders. Emphasize the vital significance of GM-free production for consumers, farmers and food processors in Austria; this sector will be subject to huge pressure without labeling, traceability and transparency requirements.
- **Research the wide-ranging benefits of GM-free foods:** No genetic modification at any stage of the value chain; intensive, regular monitoring and safe, natural products.
- **Engage proactively with politics** (at European, national and regional levels): Contact your representatives and call on them to support the most successful GM-free sector anywhere in Europe and uphold our freedom to conduct business.
- **Support the activities of leading associations and NGOs** – above all **ARGE Gentechnik-frei** (www.gentechnikfrei.at) and the **European Non-GMO Industry Association / ENGA** (www.enga.org). Both organizations provide extensive information on New Genomic Techniques.

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