GMO-free seed production under threat!

Practical consequences of a possible deregulation of new genetic engineering in the EU

Summary

In July 2023, the European Commission (COM) presented a *lex specialis* (specific law) to regulate plants produced using certain new genetic engineering techniques (NGTs) differently from conventional GMOs. The planned deregulation for Category 1 NGT plants (which the draft regulation defines as equivalent to conventionally bred or naturally mutated plants) is particularly far-reaching. In future, these plants will not be subject to labelling or to the current authorisation procedure for genetically modified organisms (GMOs), which includes risk assessment, location registration, mandatory submission of detection/identification methods, and monitoring.

GMO-free seeds form the basis of a GMO-free agricultural and food sector. The potential impact of the European Commission's planned deregulation of NGTs on GMO-free seed production has hardly been discussed so far. This position paper summarises the challenges that the GMO-free seed production sector could face.

Detection methods: Under current EU genetic engineering legislation (Directive 2001/18/EC), those applying for authorisation for a GMO must also provide the information necessary to develop a detection method, including reference materials (seeds or other plant material from the GMO that provide laboratories with the information to check for the presence of that GMO). Under the planned deregulation of Category 1 NGT plants, these requirement would disappear.

Without detection methods that can be applied at the genetic level, it will not be possible to check for GMO contamination in seeds. Rapid detection is particularly important in the seed sector as seeds are reproduced on a large scale and traded globally. If companies are no longer required to provide detection methods, other actors will have to assume the responsibility and the cost of developing these tests.

Zero tolerance: The current zero tolerance policy for seeds is based on two articles of the EU Release Directive (Art. 4, para. 1, sentence 2 and Art. 21, para. 2, sentence 1 of Directive 2001/18/EC). These stipulate that unauthorised GMOs must not be released, meaning that they must not be present in seeds intended for sowing. With regard to authorised GMOs, the following applies: Since no threshold values have been set for seeds, contamination with authorised GM constructs must be labelled. We currently assume that the zero tolerance policy for seeds will remain in place for unauthorised or unregistered NGT.

However, verification is not possible without comprehensive transparency – on which NGT plants are being grown, and where – and without detection methods that can reliably detect or distinguish

between NGT1 and NGT2 modifications (that is NGT plants that do not meet the criteria for Category 1 plants and would therefore be subject to the current GMO legislation). Added to this is the problem that NGT plants are already being grown in the USA, for example, without labelling or traceability.

Cultivation register and other 'coexistence' measures: Current EU genetic engineering legislation stipulates that both GMO-free and GM cultivation should exist in parallel. Yet the deregulation plans for NGT1 do not yet include any coexistence rules. This means that the existing location register for GMOs will not apply to NGTs. As a result, it will no longer be transparent whether and, if so, where NGT1 plants are being cultivated in one's own neighbourhood. These uncertainties not only hinder the exchange of breeding material, which affects breeding progress; they also mean it will no longer be possible to take appropriate precautionary measures, such as protecting one's own crops or not growing crops that could be affected by potential cross-pollination.

Polluter pays principle and collective liability: Current genetic engineering legislation does not stipulate that those who develop and patent GMOs are also liable for contamination. Instead, farmers who grow GMOs are collectively liable. The draft deregulation bill does not anticipate or provide for any cases of damage. However, organic farming will suffer damage. The proposed new law stipulates that the cultivation of NGT plants (NGT1 and NGT2) will remain prohibited in organic farming. This is consistent with the GMO regulations, as NGTs are genetic engineering techniques, as the European Court of Justice clarified in July 2018.[1] However, without full transparency, it remains unclear how the organic sector is to implement this legal ban in practice. It is also unclear how GMO-free agriculture is to protect itself from unwanted contamination with NGT plants and who will bear the costs in the event of contamination.

Labelling: Current EU GMO rules require labelling throughout the entire value chain. While Parliament is calling for full value-chain labelling, the Commission's proposal, supported by the Council, would limit labelling to NGT seeds only. If the Commission's position prevails, it would be impossible for farmers, food businesses, or consumers to know whether products contain genetically modified organisms.

Patent law and the actual scandal: European law is clear: NGTS are GMOs. The Commission's presumption of equivalence, which is political rather than scientific, is therefore, untenable. The Commissions position is further undermined by the fact developers are applying for patents on NGT processes and products. Deregulation is likely to accelerate this trend. Patents will intensify the contamination problem, as accidental presence of patented traits could expose breeders, propagators and farmers to patent claims. Even now, companies use references to CRISPR/Cas in patent applications to circumvent the proposed prohibition in Article 53(b).[2] While solving NGT

1 https://curia.europa.eu/juris/document/document.jsf?mode=DOC&pageIndex=0&docid=204387&part=1&doclang=EN&text=&dir=&occ=first&cid=12334367

2 https://www.epo.org/en/legal/epc/2016/a53.html

patent issues will be challenging, there are existing options to challenge unlawfully granted patents on conventionally bred plants.

In light of the challenges mentioned above, we have developed a series of specific demands.

Conclusion: In its current form, the European Commission's proposal to deregulate NGTs will pose enormous challenges for GMO-free seed production and incur high costs. This will also have serious consequences for the entire downstream sector. IG Saatgut is convinced that without GMO-free seeds, there can be no independent seed production and breeding by farmers, nor can the urgently needed restructuring of agriculture take place. Therefore, new genetic engineering must remain regulated as genetic engineering. Only in this way can we secure our food and seed sovereignty.

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1 Introduction

GMO-free seeds form the basis of a GMO-free agricultural and food system.[3] However, GMO-free seed activities (conservation, propagation, breeding) are highly vulnerable to contamination. This risk arises from release trials, the global cultivation of genetically modified plants, international trade in seeds and the transport of seeds intended for food and feed (including soya, maize and cereals).

The potential impact of the European Commission's planned deregulation of new genetic engineering techniques (NGT)[4] on GMO-free seed production has so far received little attention.

With this paper, we therefore aim to demonstrate to policymakers, the wider public and civil society organisations the critical challenges the GMO-free seed production sector could face.

2 What is at stake?

In July 2023, the European Commission (COM) presented a *lex specialis* (specific law) to regulate plants produced using certain new genetic engineering techniques (NGTs) differently from conventional GMOs. According to the proposal, plants produced using NGTs are to be assigned to two different categories:

- Category 1 NGT plants (NGT1) are considered equivalent to conventionally bred plants because their genetic modifications *could also occur naturally or through conventional breeding*, including random mutagenesis.
- Category 2 NGT plants (NGT2) are those that do not meet the criteria for Category 1 plants and would therefore be subject to the current GMO legislation.

All other GM plants are to remain regulated under (Release) Directive 2001/18/EC.

For 'NGT plants of category 2' (NGT2), an adapted, possibly reduced risk assessment on a case-by-case basis is proposed.

For 'NGT plants of category 1' (NGT1) the proposal goes much further: These plants would granted market access through a simplified, purely technical procedure, without risk assessment. The Commission argues that the presumed equivalence with conventionally bred plants renders the mandatory risk assessment of the Release Directive obsolete. However, the claimed 'equivalence' is

3 The majority of European agriculture operates without genetic engineering. This represents an important competitive advantage internationally.

4 NGT = New Genetic Techniques.

scientifically untenable[5] and not in alignment with current EU law (Directive 2001/18/EC). Despite this, the Commission and proponents of deregulation continue to adhere to it unreservedly.

Currently (as of November 2025), the draft regulation is being negotiated between Parliament, Council and Commission in what is known as a trilogue.

It can be assumed that the vast majority (about 94%) of future NGTs will fall under the NGT1 category.[6] In future, for these plants, there will be no labelling or approval procedure with risk assessment, location register, mandatory submission of verification procedures, and monitoring.

This paper therefore focuses primarily on the consequences of deregulating of NGT1 plants. It, nevertheless, recognises that the cultivation and trade of seeds and plant materials that have been modified using first-generation genetic engineering (which remains regulated under Directive 2001/18/EC)[7] or which fall under NGT2 category are also crucial for GMO-free seed work.

3 Contamination and cross-breeding possibilities

The vulnerability of seed production and the associated legal framework

Variety preservation, seed propagation and a large part of breeding take place in the open air or in open greenhouses, not in strictly controlled laboratories. Seed work is, therefore, inherently subject to environmental influences. Good professional practice aims to exclude or minimise undesirable cross-pollination or contamination as far as possible. Seed legislation recognises this by requiring varietal purity while accepting varying proportions of deviating types, depending on the species. With regard to genetic contamination from GMOs, however, it is all the more important for people working with GMO-free seeds to avoid cross-pollination or mixing completely.

The more genetically modified plants and first- or second-generation seeds there are in the fields and in circulation, the more frequently incidents occur that can sometimes result in widespread contamination. This is particularly true when these incidents are only detected after sowing. The list of examples is already long.[8] In the EU, relatively strict genetic engineering legislation came into

5 Mundorf, J., Simon, S. & Engelhard, M. The European Commission's regulatory proposal on new genomic techniques in plants: a focus on equivalence, complexity, and artificial intelligence. Environ Sci Eur 37, 143 (2025). https://doi.org/10.1186/s12302-025-01199-2

6 https://www.frontiersin.org/journals/genome-editing/articles/10.3389/fgeed.2024.1377117/full

7 This refers to genetically modified (transgenic) plants of the first generation of genetic engineering (developed from the 1990s onwards). The dominant characteristics of these plants are resistance to various herbicide active ingredients, often combined with the production of insecticidal substances (Bt toxins) targeting various insect pests. Figures on the global cultivation of GM plants can be found, for example, at transgen. https://www.transgen.de/anbau/flaechen_international.html

8 https://www.testbiotech.org/en/resource/transgene-escape/

force with the first generation of genetic engineering. According to EU law, approved GMOs – including seeds – must be labelled as genetically modified (Article 21(1) of EU Directive 2001/18/EC). In addition, zero tolerance is mandatory: seeds contaminated with GMOs not approved in the EU may not be placed on the market. If contamination is discovered, the seeds must be withdrawn from the market (Article 4(1) of EU Directive 2001/18/EC).

In 2003, labelling thresholds for 'adventitious or technically unavoidable traces of authorised GMOs' in food and feed were set at 0.9% for authorised GMOs (Article 21(2) of EU Directive 2001/18/EC). Thresholds for seeds (0.3 – 0.7%), proposed at the same time, were never adopted – an important success for contamination prevention.

The following illustration shows the potential impact of 0.3% contamination in 100 g of rapeseed:

Rapeseed contaminated at 0.3% means:

- 1,500 to 2,100 modified rapeseed plants per hectare
- Approximately 500 genetically modified seeds per plant
- Cross-pollination up to 26 km away
- Seeds carried by wind etc. to neighbouring fields
- 10 to 15 years of viable seeds in the soil
- Genetically modified seeds/plants along transport routes
- Cross-pollination with related wild plants (e.g. field mustard, black mustard, turnip, wild mustard), including possible backcrossing.

Once genetically modified plants are released and cultivated, contamination with GMOs is possible at all stages of plant breeding and seed production:

- **Cross-pollination:** If genetically modified plants capable of cross-pollination grow in the wider vicinity of a breeding garden or propagation area, pollen from the GM plants can be spread by wind or insects, leading to cross-pollination. Wild populations into which genetically modified plants have cross-pollinated can also lead to (back) cross-pollination with GMOs.
- **Volunteer plants:** In most cultivated plant species, many seeds or other plant parts remain in the field after harvesting. In subsequent years, these 'volunteers' can germinate and contaminate the harvest in the same field or other fields via pollen dispersal. The seeds of some plant species can remain viable in the soil for a very long time and represent a significant source of contamination over the years. This problem is increasing as the Earth

warms: for example, 'volunteer maize' already survives mild winters in the soil and can germinate the following year.

- **Multi location trials and transport:** Even during the breeding phase, varieties are often grown and tested at different locations. Later, the seeds must be transported to the propagation companies and then from the propagation companies to the trade. During the transport of seeds, as well as during their storage, contaminated trailers, containers or silos pose a risk. In addition, genetically contaminated seeds may be lost during transport, resulting in genetically modified plants growing and flowering along motorways and near ports or railway tracks.[9] These can then cross-pollinate with seed production crops, including via other plants.
- **Imported seed material:** Another risk of contamination comes from the seed stock used for breeding new varieties. This often comes not only from the breeder's own breeding garden, but also from other breeders or gene banks used to maintain a diverse gene pool. Breeders must carry out[10] complex tests, especially for high-risk crops, to determine whether their variety development has been exposed to genetic contamination – partly because information on the location of genetically modified cultivation areas in other countries is lacking or because the results of seed inspections are not published or are published too late.[11]

In order to survive in the long term, GMO-free seed production must be 100% free of GMOs. To achieve this, methods that are currently only used in seed production in certain circumstances[12] could increasingly become a constant necessity: for example, isolating flowers with crop protection nets (e.g. for cruciferous plants) or hand pollination for maize. Both are possible for small stocks, but extremely costly or impossible for larger ones. Related wind-pollinated and therefore interbreedable crops, such as chard, beetroot, sugar beet and fodder beet, can only be protected from cross-pollination by bolters in GM sugar beet stocks at great expense. In order to safeguard breeders' own work, initial varieties for breeding projects or sales batches of at-risk crops are currently being tested for GM contamination using PCR analysis. The costs incurred are borne by

9 https://www.frontiersin.org/journals/genome-editing/articles/10.3389/fgeed.2023.1176290/full

10 High-risk crops such as rapeseed and (sugar) beet place particularly high demands on GMO-free seed production in terms of cross-pollination with related cultivated and wild plants, volunteer growth, and seed persistence in the soil.

11 Securing seeds – preventing thresholds. Effects of genetic engineering contamination in seeds on organic and conventional seed production. Summary of a study by IG Saatgut (author: Siegrid Herbst), updated by Stefanie Hundsdorfer, 2016, pp. 4 – 5. https://www.dreschflegel-verein.de/_pdf/2016-zusammenfassung-schwellenwerte-studie.pdf

12 Good professional practice in conservation, breeding and propagation takes precautionary measures to rule out unwanted cross-breeding and contamination as far as possible. This ensures varietal purity. However, it is recognised – including in seed legislation – that 100% varietal purity is not possible. https://www.gesetze-im-internet.de/gentpflev/index.html

those who want to work without genetic engineering. Some farms (in the EU, the USA) are already paying six-figure sums for precautionary measures against GM contamination.[13]

It is questionable whether, and if so, at what point cross-breeding or contamination can be detected phenotypically. Herbicide tolerance, insect or disease resistance, and modified ingredients – common traits of NGT plants[14] – are difficult or impossible to detect based on appearance alone. Deviations in other characteristics can be detected externally, but the question is: at what point in time? Already in the year of seed production (possible in some cases with maize), or before or after flowering?

In the latter case, with cross-pollinators, this may mean that older seed, harvested before cross-pollination must be used.[15] In the event of deregulation of NGT, two developments with unforeseeable consequences are emerging, which will make it even more difficult to maintain GMO-free seed production, as described below.

1. Genetically modified wild plants

The European Commission's proposal to deregulate new genetic engineering techniques for plants applies to *all* plant species – not just agricultural plants. This could mean that in future, genetically modified wild plants could also be released without comprehensive risk assessment, liability regulations and labelling. NGTs could be used to introduce traits that, for example, promote the invasive spread of wild plants or have other unintended consequences. This could have negative effects on biodiversity and the environment. At the same time, it can be assumed that NGT wild plants could crossbreed with related cultivated species, thereby creating further sources of contamination for GMO-free breeding and seed production.[16]

2. Altered fitness of NGT plants

It can be assumed that interventions using NGT, e.g. in plant metabolism, can alter fitness. For example, increased seed formation, prolonged seed life, altered germination behaviour, and altered pollen quality and quantity can be expected.[17] Whether and how this could exacerbate the

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13 https://www.organicseurope.bio/content/uploads/2020/06/ifoameu_policy_gmos_dossier_201412.pdf?dd, https://foodandwaterwatch.org/wp-content/uploads/2021/03/GMO-Contamination-Farmers-IB-March-2014_0.pdf

14 https://www.enga.org/fileadmin/user_upload/New_GMOs_Market_Report.pdf

15 One part of breeding work involves consciously continuing to work with different types within a variety. This is unlikely to be possible in the future if the risk of crossbreeding increases significantly.

16 https://cogem.net/en/publication/introgression-from-cultivated-plants-into-their-wild-relatives/

17 Koller, Cieslak and Bauer-Panskus (2024) state the following for NGT Brassicaceae: 'Regarding fitness-related traits, other risks were identified, i.e. an increased spread and persistence of NGT plants.' The

contamination problem is currently unclear. To date, there has been little research into the environmental impacts of NGT plants. In addition, the effects of global warming must also be taken into account; NGT plants could, for example, develop unexpected characteristics during cultivation as a result of heat waves.[18]

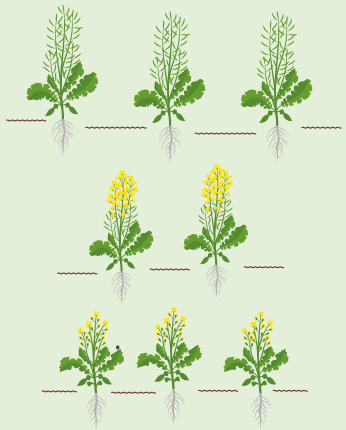
appendix to the publication lists desired/undesired characteristics that may influence fitness. Source: https://enveurope.springeropen.com/articles/10.1186/s12302-024-01009-1

18 In the case of MON810 maize (genetically modified to produce its own insecticide), it has been found that various stress factors such as heat/drought or cold and humidity can cause the content of the insecticide to change/increase significantly. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0123011

Non-GMO Seed Production at Risk

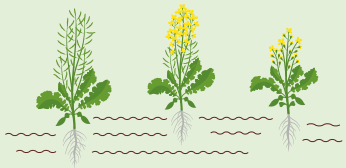
GMO-free Seed Work

Multiplication Of Seeds



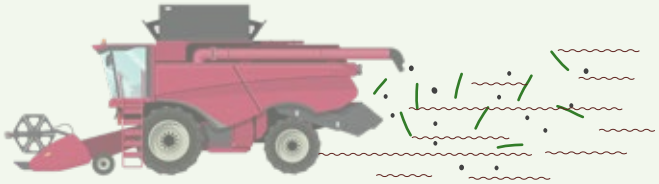
Field

Breeding



Plant Breeding Nursery

How Seeds Can Become Contaminated With GMO

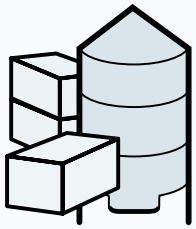


Contaminated Machinery

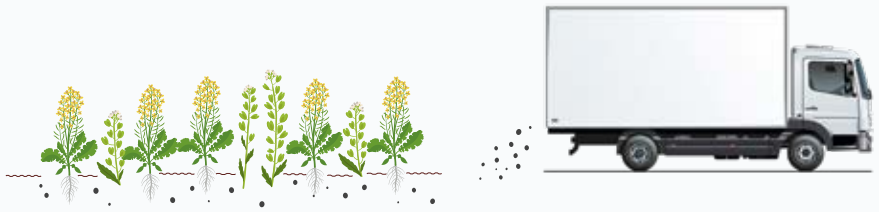
Fields with (GM-) Plants

Wildlife Population

Unintented Cross-Pollination: Regrowth From Previous Plants



Contaminated Trailers, Containers or Silos



Contamination From Seed Loss Along Transport Routes

Risks of Seed Contamination Across the Supply Chain

4 Consequences of deregulating NGT plants: A comparison with existing genetic engineering legislation

Detection methods

Under current EU genetic engineering legislation, those applying for approval of a genetic engineering construct must also provide the information necessary to develop a detection method (Annex III A, 2. f) of EU Directive 2001/18/EC). Under the planned deregulation of Category 1 NGT plants, the mandatory submission of the relevant genomic data and the development of detection methods is no longer required. Companies would also not be required to provide the reference material that enables detection of NGTs.

Two research projects currently underway, initiated and funded by the EU, aim to develop detection methods that can reliably identify the use of new genetic engineering techniques in plants, with – and in some cases even without – information about the type and location of genetic modifications in the plant genome. The DARWIN and DETECTIVE projects will run until 2027.[19]

The results of the projects are of particular importance for the GMO-free seed sector. However, important questions remain unanswered:

- If the projects are successful in developing detection methods for NGTs, who will have access to them?
- Will there be conditions attached to their use?
- Who will bear the costs, for example, for the relevant tests and the additional administrative burden?
- Who will be liable in the event of contaminated seeds or contaminated breeding lines?

If detection methods for NGT plants are not required to be provided, this would have significant consequences for the GMO-free sector. Important elements of the proposal for deregulation currently being discussed – such as labelling of NGT-contaminated seed – could not be implemented in practice.

19 https://darwin-ngt.eu/news-and-events/, https://detective-ngt.eu/. At the beginning of August 2025, the first scientific paper from the DARWIN project was published, showing that it may be possible to detect even 'small' NGT changes. Source: https://www.sciencedirect.com/science/article/pii/S096399692501556X?via%3Dihub#bb0235

Zero tolerance

The current zero tolerance policy for seeds is based on two articles of the EU Release Directive:

- "GMOs may only be deliberately released or placed on the market in accordance with Part B or Part C",[20] i.e. if they are authorised in accordance with the procedure laid down in the Release Directive. This in turn means that unauthorised GMOs may not be released, i.e., they may not be present in seeds intended for sowing.
- "For products where accidental or technically unavoidable traces of authorised GMOs cannot be excluded, a threshold value may be set below which these products do not have to be labeled."[21] No threshold values have been set for seeds, so the following applies here: Contamination with authorised GM traits must be labeled.

However, the draft regulation is intended to remove NGT1 plants from the scope of the Release Directive (Articles 1 and 4). Parallel to the Release Directive, the draft regulation also stipulates in §4 that NGT plants may only be released into the environment if they are either registered in accordance with the procedure laid down in this regulation (NGT1), are progeny of registered NGT1 plants, or are approved (in the case of NGT2 plants). We therefore currently assume that zero tolerance for non-authorised or non-registered GMOs in seeds would remain in place.

However, without comprehensive transparency on which NGT plants are grown where – and without verification procedures that can reliably detect or distinguish between NGT1 and NGT2 modifications – this cannot be verified. When we look at approved or registered GMOs, the following problem arises: In the US, for example, NGT plants are already being cultivated without labelling or traceability.[22] Two corn plants have been approved for import into the EU (as food and feed).[23]

Location registers and other "coexistence" measures

Current EU genetic engineering legislation stipulates that both GMO-free and GM crops should exist in parallel. The foundation for the so-called coexistence rules was laid by the then Agriculture Commissioner Franz Fischler. Distance rules are intended to ensure that labelling thresholds are not exceeded for feed and food. In Germany, a location register enables GMO-free farms to track whether GM crops are planned to be grown in their neighbourhood. Since there is currently hardly

20 Article 4, paragraph 1, sentence 2.

21 Article 21, paragraph 2, sentence 1.

22 Since the end of 2023, for example, CRISPR-modified field pennycress has been cultivated on a trial basis in various states.

23 These are the two maize plants DP910521 and DP915635 from Corteva. As transgenesis and CRISPR were used here, the plants are subject to the EU Release Directive.

any cultivation of GM crops in the EU,[24] the GMO-free sector in plant production has hardly had to deal with cross-pollination problems in recent years.

However, no coexistence or distance rules were established for the seed sector at that time that could guarantee zero tolerance.[25] Seed legislation stipulates minimum distances from fields of the same species in order to maintain varietal purity. These distances are already significantly greater than the GMO-coexistence distances for food and feed. However, the minimum distances cannot guarantee that cross-pollination will not occur.

The deregulation plans for NGT1[26] do not yet include any coexistence rules. Accordingly, the existing location register is not to be used for this purpose. This means that in future it would no longer be transparent whether and, if so, where NGT1 plants are being cultivated in one's own neighbourhood. These uncertainties not only hinder the exchange of breeding material, which affects breeding progress, but also mean that it would no longer be possible to take appropriate precautionary measures, such as protecting one's own crops or not growing crops that are susceptible to potential cross-pollination. This raises the question: If contamination were later discovered – perhaps after detection methods become available – who would be liable?

In the event of deregulation, it is precisely those businesses working on concrete solutions for agricultural reform that would face enormous challenges.

'Polluter pays' principle and collective liability

Current genetic engineering legislation does not hold developers or patent holders liable for contamination. Instead, farmers who may unintentionally grow GMOs are jointly and severally liable: in the event of contamination, they would bear the financial loss, regardless of whose field the pollen came from.

The draft deregulation does not assume that damage will occur. However, in addition to the aforementioned issue of zero tolerance for NGT plants in organic seeds, it is envisaged that the cultivation of NGT plants (NGT1 and NGT2) will remain prohibited for organic farming. This is also consistent, as NGT is a genetic engineering process, as the European Court of Justice clarified in July 2018.[27] However, it remains unclear how the organic sector can implement this legal ban in practice.

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24 https://www.transgen.de/anbau/653.anbau-gentechnisch-veraenderter-pflanzen.html

25 Statement by the then head of department Köhler at the Federal Ministry of Agriculture in a discussion with representatives of IG Saatgut on 18 May 2006.

26 For NGT2, the draft regulation would delegate the introduction of coexistence measures to the Member States (Art. 24).

27 https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-07/cp180111de.pdf

Labelling

Existing EU genetic engineering legislation requires GMOs to be labelled throughout the entire value chain. Processed food and feed produced from GMOs must also be labelled.

The Commission and the Council both support labelling only for seeds and the recording of registered NGT constructs (the engineered DNA sequences used to introduce new genetic material into an organism's cells) in a database. The Parliament, on the other hand, is calling for labelling throughout the entire value chain. If the Commission and the Council have their way, it would no longer be possible to tell whether a product contains genetically modified organisms, anywhere in the value chain from the field onwards.

It is crucial for breeding and seed production that seeds are clearly labelled. Transparency in food and feed is essential to ensure freedom of choice for consumers and producers.

In addition, food and feed can also be capable of reproduction or can contain viable seeds, e. g. potatoes, unground grain, tomatoes, and pumpkins. If, for example, an NGT1 tomato were placed on the market as a foodstuff without being labelled, its seeds could be sown and thus (unwittingly) release GMOs. Clearly understandable labelling right through to the end product is therefore essential.[28]

Patent law and the actual scandal

Patents on life represent a private appropriation of our basic resources. We therefore reject them on principle.

The development of the first generation of GMOs led to an opening up and expansion of patent law, first in the USA and then in Europe. In order for the patentability requirement for plants and animals in the EU Biopatent Directive (Directive 98/44/EC) to take effect, the corresponding prohibition in the European Patent Convention (EPC) of 1973 had to be amended, as this is the basis for European patents.

Individual plant varieties and 'essentially biological processes' for breeding plants (Art. 53 (b)) are still not patentable. These processes are 'entirely' based on natural phenomena such as crossing or selection. However, since this article came into existence, its exact interpretation has been the subject of debate. Despite various decisions and clarifications by the Administrative Council of the European Patent Office,[29] adjustments to national patent laws[30] and appeals by the EU Commission

28 The Commission proposes the label 'cat 1 NGT' for NGT1 plants, along with the identification number of the NGT plant. The European Parliament calls for the label 'New Genomic Techniques'; in the case of propagable material, the identification number should also be included in the label. https://data.consilium.europa.eu/doc/document/ST-7448-2025-INIT/en/pdf, p. 145 -146

29 https://www.no-patents-on-seeds.org/en/background/legal-framework

30 https://www.no-patents-on-seeds.org/en/news/law-austria

and Parliament, companies have found ways to circumvent the ban. As a result, the number of patent applications in the field of conventional breeding is steadily increasing: there are already over 1,500 applications and more than 200 granted patents in Europe.[31]

Regardless of the fact that the draft regulation is based on the scientifically untenable assumption of the equivalence of NGT1 plants with conventionally bred plants, companies using NGTs are advocating and applying for patents. New genomic techniques, as they are genetic engineering techniques, are patentable. Under current patent law, the resulting products can also be protected by patents. The planned deregulation of new genetic engineering will therefore lead to a sharp increase in patents in Europe in general. Since the market-dominating corporations in particular have already secured central patents (or, in some cases, exclusive licences),[32] the use of NGT processes and the products developed with them will, for the time being, only be possible if licence fees are paid to patent holders. In addition, patents also influence the problem of contamination: as in the case of Percy Schmeiser from Canada,[33] breeders, propagators and farmers must expect that, in the event of NGT contamination, they will unwittingly also incur patent claims.

For this reason, the issue of patents plays a decisive role in the ongoing trilogue negotiations. Both the European Parliament and the Council have submitted amendments proposing ways to deal with the problem. At the end of 2024, Bündnis90/Die Grünen had these proposals reviewed in a legal opinion.[34] In its assessment of the opinion, the No Patents on Seeds coalition concludes[35] that the proposals submitted by the Parliament and the Council are insufficient. In order to effectively restrict patents in the field of new genetic engineering, an amendment to the European Patent Convention (EPC) would be necessary. Not only would this be a time-consuming process that could take at least 10 years, but also, it is unlikely at present that the necessary unanimity for a ban or restriction on patents on NGTs could be achieved if the EPC were opened up. In addition, many EU politicians regard NGTs as an important tool for ensuring the competitiveness of European agriculture while at the same time making it more 'sustainable'. As long as this assessment prevails, it is unlikely that patent protection in this area will be restricted. Seed companies will therefore continue to have the opportunity to apply for patents on their processes and products. In the case of first-generation genetic engineering, industrial policy considerations and investor protection were also the main arguments used to push through the Biopatent Directive (against strong opposition from civil society organisations).

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31 https://www.no-patents-on-seeds.org/en/background/problem

32 https://www.ige.ch/en/, CRISPR technology: Patent & License landscapes, p. 37

33 https://rightlivelihood.org/the-change-makers/find-a-laureate/percy-and-louise-schmeiser/

34 https://www.gruene-bundestag.de/fileadmin/dateien/downloads/Weitere_Dokumente/Rechtsgutachten_Biopatentrechtsreform_Gruene_Bundestag.pdf

35 https://www.no-patents-on-seeds.org/sites/default/files/2024-12/Kurzkommentar_C_Then_zum%20Gutachten%20Biopatente__1.pdf

Even before deregulation, NGT patents are influencing conventional breeding. The No Patents on Seeds coalition regularly documents in its reports how companies use NGTs to circumvent the prohibition in Article 53(b): patent applications often include wording that is intended to suggest the use of genetic engineering techniques. However, a closer look at the patents shows that in most cases these technical processes were not used and are not necessary for the development of the desired plants.[36] The result is that conventionally bred plants end up being covered by the patent.

Such patents can make future breeding considerably more difficult.[37] Breeders who own varieties in which the claimed plant material has already been used in earlier breeding processes may also encounter difficulties. Licence agreements with the patent holders would be the only way out of this problem – but this would generally create new dependencies and additional costs and restrict breeders' freedom of operation.

While the problems with patents in the field of NGTs cannot be solved in the foreseeable future, there are solutions to the problem of (unlawfully granted) patents on conventionally bred plants and, in principle, to the problem of the extension of GMO and NGT patents to conventional plant breeding that could be implemented within the existing legal framework. This real-life and ongoing scandal is repeatedly neglected in the current political discussion.

We therefore endorse the demands of ARCHE NOAH:[38]

- **Limiting the scope of patents:** The European Patent Office may not grant patents with 'absolute substance protection' in the field of animal and plant breeding. 'Absolute substance protection' stipulates that patents on characteristics of genetically modified plants or animals also apply to all plants and animals with these characteristics from conventional breeding.
- **Precise definition of 'essentially biological processes':** It must be clarified that the term 'essentially biological processes' covers all conventional breeding processes, as well as all individual steps in the breeding process, such as selection and/or propagation. With regard to conventional breeding, any use of genetic resources that occur in nature or have been produced using these methods must be excluded from patent law.

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36 One of these patents is EP3380618, granted to KWS in 2022. The maize claimed in the patent was produced using existing maize plants. The genome of these plants was analysed and so-called marker genes (gene variants) were identified that can be used for screening and selecting the desired traits. Interestingly, tools such as CRISPR/Cas are also mentioned in the description of the patent. However, new genetic engineering techniques were not used and are not necessary to obtain the desired plants, as these already exist in nature.

37 https://infogm.org/en/a-dutch-seed-company-faces-up-to-kws-patents/

38 https://www.arche-noah.at/media/briefing_on_patents_on_ngt_plants_and_processes_october_2025.pdf, see also: https://www.no-patents-on-seeds.org/sites/default/files/2025-11/How%20to%20rectify%20the%20interpretation%20of%20European%20Patent%20law.pdf

- **Definition of 'products' used or produced in breeding processes:** It must be made clear that all 'products' used or produced in essentially biological breeding processes are excluded from patenting, including all parts of plants and animals, their cells and genetic material.

When we reject patents on plants and on life, we are not pursuing the goal of obtaining licence-free access to NGT plants ourselves. Nor do we believe that these plants represent a breeding advance that must be made available free of charge to the entire plant breeding industry. Rather, our demand is that the existing ban on patents in the field of conventional breeding be consistently enforced. It is also crucial for us that patents on GMO and NGT plants do not affect the gene pool of conventional plant breeding.

5 Our demands for the preservation of GMO-free seed production

- All old and new genetic engineering techniques must be legally defined and regulated as genetic engineering. This means that NGT plants must continue to be subject to comprehensive risk assessment and approval procedures in the future.
- Labelling and traceability must be ensured throughout the entire value chain.
- Zero tolerance for NGT events in seeds must be maintained (for both approved/registered and unregistered NGTs).
- Before plants in NGT categories 1 and 2 are placed on the market, binding and strict coexistence rules must be established to help prevent contamination. Possible changes in the fitness of NGT plants (increased seed and pollen production, etc.) must be taken into account.
- A location register for NGT1 plants must be established and continuous monitoring of released plants must be implemented.
- There must be mandatory disclosure of all relevant genomic data and submission of reliable and practical detection methods by companies using NGT.
- Risk research projects (with regard to the threat to GMO-free seed production) and research and development in the field of detection methods (specific to certain modifications and methods) must be promoted.
- Compliance with freedom of choice and the precautionary principle must be ensured by mandating clear labelling throughout the value chain.
- Patent holders of NGTs must be liable for contamination and other consequences of the release of NGTs and finance all precautionary and corrective measures.

- Effective protection mechanisms against the negative effects of patents must be implemented to preserve breeding freedom and access to genetic diversity.

6 Conclusion

A decisive factor for the quality of varieties is their diversity. The security of our food supply depends on the adaptability of plants to and within a rapidly changing environment. In breeding, it is therefore common practice to cross different varieties and origins in order to diversify the gene pool. Without fundamental control mechanisms, such as mandatory verification procedures and the maintenance of zero tolerance in seeds, the purchase of seeds could become increasingly risky for the GMO-free seed sector in the future. The availability and quality assurance of GMO-free seeds is therefore at risk. The decoupling of NGT products from genetic engineering legislation undermines fundamental principles of freedom of choice, precaution and transparency. This would have far-reaching consequences for GMO-free seed production and GMO-free organic and conventional agriculture: they would be unable to identify or exclude GMOs and would therefore no longer be structurally capable of maintaining their quality standards.

Whether we protect GMO-free seed production has an impact on the organisation of our plant breeding, seed production and agriculture. IG Saatgut is convinced that without GMO-free seeds, there can be no independent seed production and breeding by farmers, nor the urgently needed restructuring and reorganisation of agriculture. Ultimately, it is about securing our food and seed sovereignty.

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published: November 2025