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ON THE LIABILITY OF FOOD BUSINESSES FOR NEW GENETIC ENGINEERING IN THE EVENT OF DEREGULATION

Legal opinion[1]

on behalf of the VLOG Verband Lebensmittel ohne Gentechnik e.V.

Rechtsanwalt Dr Georg Buchholz

Berlin, 12.12.2024

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[1] The opinion was originally prepared in German. This translation is a revised version of a machine translation. Please note that it may contain translation errors. We apologise and ask for your understanding.

CONTENTS

A. Brief summary

The deregulation of category 1 NGT products by the planned EU Regulation on plants obtained by certain new genomic techniques (NGT) and their food and feed (NGT Regulation), will lead to a transfer of the implementation of risk assessments from genetic engineering law to novel food law and thus to the food businesses. Or that genetically modified foods are placed on the market as category 1 NGT products without any risk assessment.

Consumers and food businesses will have to bear the associated risks. This is because the food businesses are liable for the safety of their products. They bear the burden of proof for unrecognisable development risks.

It is doubtful whether food businesses can, in the event of liability, obtain compensation from the developers of unsafe NGT products. The enforceability of a claim for compensation depends on whether the developers are available and capable. It may be a small biotech business, e.g. in Asia, which has developed an unsafe NGT product. The developers of NGT products are only in a few EU countries liable for unrecognisable development risks. Insurance policies only cover damage caused by conventional foods; payments for damage caused by GMOs, including category 1 NGT products, are excluded in the insurance terms and conditions.

It should therefore be ensured for food businesses that

- all NGT products may only be placed on the market once their safety and usability as food or feed have been comprehensively assessed and officially authorised,
- all NGT products throughout the whole food chain have to be labelled as such,
- all developers of NGT plants that are placed on the market are fully liable for the development risks of their products,
- NGT products may only be placed on the market if compensation for damage in all Member States is covered by adequate financial security, i.e. sufficient liability insurance or a liability fund.

B. Summary

1. According to the planned EU Regulation on plants obtained by certain new genomic techniques (NGT) and their food and feed (NGT Regulation or NGTR), so-called category 1 NGT plants and products derived from them will no longer be subject to official risk assessment and authorisation under genetic engineering law. They should also no longer have to be labelled with a reference to genetically modified organisms (GMOs), even though NGT plants are GMOs.

2. The planned deregulation of category 1 NGT products burdens food businesses that do not exclude the use of such NGT products with considerable additional testing and authorisation costs, particularly with regard to classification of such NGT products as novel foods and liability for potential damage to health and property caused by such products.

3. The NGTR will mean that the authorisation burden for category 1 NGT products will no longer apply to the developers of the NGT plants, but will be shifted to the food businesses to an as yet uncertain extent. Food businesses throughout the EU will have to verify for each food that contains or is produced from category 1 NGT products whether it is a novel food within the meaning of EU Regulation 2015/2283 on novel foods (EU Novel Food Regulation, EU NFR). If in doubt, they have to seek clarification through a consultation procedure before the competent national authority. Food that is classified as novel food may only be placed on the market after authorisation by the EU Commission and inclusion in the Union list of novel foods. Food may have to be classified as novel food requiring authorisation simply because of the intentional modification of the molecular structure through the use of NGT. Authorisation is required in any case if the use of the NGT leads to significant changes in the food properties.

4. Even if foods containing NGT products are not classified as novel foods requiring authorisation, food businesses in the EU remain responsible for the safety of the food. In this respect, it will remain unclear for some time whether and, if so, which due diligence requirements must be met in the case of the use of category 1 NGT products.

5. German genetic engineering liability law and EU-wide product liability law applies above all to damage to health and property that may be caused by genetically modified properties of NGT products.

6. Even if food businesses are not legally obliged to label food with or produced from category 1 NGT products as such, voluntary labelling can be useful in order to reduce the associated liability risks.

7. Liability for the mere presence of category 1 NGT products may arise from contractual agreements, possibly from German genetic engineering law and possibly from tort product liability under tort law, in particular if the presence of such products means that a food can no longer be labelled as food "without genetic engineering".

8. Product liability under the EU-wide Directive on liability for defective products (Product Liability Directive) and the German Product Liability Law (ProdHaftG) does not extend to liability for development risks of category 1 NGT plants that were, at the time of placing the product on the market, not recognisable according to the state of scientific and technical knowledge. However, the food business bears the burden of proof for this. According to German genetic engineering law, food businesses are also liable for damage caused by unrecognisable development risks if they have placed on the market a category 1 NGT plant or product containing the GMO in question in Germany for the first time.

9. Damage caused by GMOs, including category 1 NGT products, is generally not insured. Unlike damage caused by conventionally produced organisms, damage caused by GMOs is generally excluded in general liability insurance conditions.

10. If a food produced with category 1 NGT products is not classified as a novel food, it will remain unclear for some time whether, and if so, in which cases and to what extent food businesses must ask their suppliers for information about the presence of category 1 NGT products in food ingredients and any risk assessments carried out for these NGT products and their results in order to fulfil their responsibility for food safety and minimise liability risks. The same applies to any obligation to inform the purchasers of their own products about the existence and any risk assessments for such products. It will also remain unclear for the near future whether and to what extent a food business's own liability can be minimised by passing on such information. In this regard, for each new NGT plant developed and placed on the market standards will have to be developed and experience gathered and taken into account. These standards will then have to prove themselves in court in the event of any damage claims.

11. The safest strategy for food businesses to avoid liability risks for category 1 NGT products is probably to only use ingredients that are not category 1 NGT products in the production of food, and to have this confirmed by their suppliers. This means that more effort is required to exclude the use of such products. However, the additional effort required to fulfil possible due diligence requirements for the use of NGT products can be avoided. In particular the examination of the classification as a novel food and any necessary safety precautions, for example in the form of information obligations regarding the distribution and use of category 1 NGT products and their potential risks or product monitoring obligations in this regard can be avoided. Liability risks can also be avoided in this way. This applies regardless of whether the food is labelled as food "without genetic engineering".

12. The main reasons for the special liability risks for category 1 NGT products are:

    12.1 The lack of official risk assessment under EU GMO legislation. If category 1 NGT products are no longer subject to official risk assessment, i.e. in particular not to the assessment of novel foods within the framework of the EU NFR, companies can no longer rely on corresponding official risk assessment results. According to the German Gentechnikgesetz (GenTG), those who place such GMOs on the market in Germany for the first time are also liable for development risks that are not recognisable according to the state of scientific and technical knowledge.

    12.2 The possible classification as a novel food. It is not yet clear whether foods containing category 1 NGT products must be classified, assessed and authorised by the EU Commission before being placed on the market for the first time simply because of the intentional modification of the molecular structure of the DNA by using NGT or only in the case of significant modifications of the food. Food businesses in the EU will have to verify this on a case-by-case basis and secure the permissibility of placing on the market through the consultation procedure provided for this purpose before the competent national authority.

    12.3 The lack of detectability of category 1 NGT products. The presence of category 1 NGT products will often not initially be detectable by analyses. In contrast to previous GMOs, no detection methods will have to be specified and no reference material will have to be deposited. The

extent to which NGT products will be subject to labelling is currently unclear. NGT products can therefore spread unnoticed to a considerable extent in food and food products. If a health risk of an NGT product or its presence in food labelled "without genetic engineering" or organic products only becomes apparent after broad market penetration, and analytical methods for NGT products are only developed subsequently, considerable damage may be unavoidable.

12.4 The lack of insurance for NGT products. Liability insurance policies generally exclude liability for damage caused by GMOs. This also excludes insurance cover for damage caused by NGT products and their unintentional presence.

12.5 Possible difficulties in recourse against the developers of the NGT plants. Food businesses in Germany and the EU that are held liable for damages will regularly have a right of recourse against the developers of the NGT plants as part of the joint and several debtor compensation. The food businesses must therefore compensate the injured party for the damage, but can assert an internal compensation claim against the developer of the NGT plants as the party responsible. However, this claim can often come to nothing in practice, particularly if the developer is not economically viable and/or it is difficult or impossible to enforce a claim against a developer abroad.

13. The liability risk also increases for the marketing of foods "without genetic engineering" as well as organic products. The companies involved must ensure that the established system of supplier declarations also covers category 1 NGT products, even if their use no longer has to be labelled with a reference to GMOs in future. They must fear additional and, due to a lack of suitable analytical methods, initially unrecognisable entries. If foods containing category 1 NGT products are no longer required to be labelled as GMOs, the labelling of foods "without genetic engineering" is the only legally permissible way to indicate the absence of category 1 NGT products, apart from the labelling of organic products.

14. If the NGTR is adopted as planned and category 1 NGT products are exempted from the risk assessment and authorisation requirement, the following provisions should be included in the NGTR to ensure uniform and binding coverage of the liability risks of food businesses throughout the EU:

14.1 For category 1 NGT products, which themselves or their processing products may be novel foods due to genetic modification, it should be regulated in the NGTR that their placing on the market is only permitted if the corresponding novel foods are also authorised. Otherwise, seeds can be placed on the market even though the products obtained from them may not be used as food. As a result, there is a risk of multiple violations of the requirements of the EU NFR due to mere unawareness, for which the food businesses are liable.

14.2 Labelling requirements should be included in the NGTR for all category 1 NGT products and the entire food chain. All food businesses must know whether the foods and ingredients they use are NGT products in order to be able to verify compliance with the requirements of the EU NFR with legal certainty.

14.3 Developers and importers of category 1 NGT plants should also be liable for damage arising from development risks within the framework of product liability throughout the EU and not just in individual Member States, as is the case in Germany.

14.4 Category 1 NGT products should only be allowed to be placed on the market if compensation for damage caused by such NGTs is covered by a specified, sufficient coverage, e.g. by liability insurance covering damage caused by GMOs or, if no liability insurance covers such damage, by a state-regulated liability fund.

14.5 In connection with liability for damage caused by NGT products the right to disclosure of evidence against liable parties and authorities provided for in the EU Product Liability Directive 2024 should also apply outside of court proceedings (cf. the corresponding right to information in the German genetic engineering code: Section 35 GenTG).

C. Initial situation and question

On 5 July 2023, the EU Commission published a proposal for a Regulation of the European Parliament and of the Council on plants obtainend by certain new genomic techniques and their food and feed (hereinafter referred to as NGTR or NGTR COM).[2] On 24 April 2024, the European Parliament adopted its position on the proposal (hereinafter referred to as: NGTR or NGTR EP).[3] The Council has not yet been able to agree on a common position.

It therefore remains to be seen whether the legislative bodies, i.e. the European Parliament and the Council, will agree on an NGT Regulation and, if so, with what detailed content. Based on the Commission proposal and the position of the European Parliament, we assume for the purposes of this study that the EU legislator will adopt an NGT Regulation with the following content:

- The NGTR defines NGT plants and category 1 NGT products on the basis of the type and number of genetic modifications caused by NGT.[4] NGT products include food containing or consisting of or produced from NGT plants.[5]
- Category 1 NGT plants are genetically modified organisms (GMOs) within the meaning of Directive 2001/18/EC on the deliberate release of GMOs and Regulation 1829/2003 on genetically modified food and feed.[6]
- NGT plants and category 1 NGT products are only subject to a status verification. This only determines whether the type and number of genetic modifications fulfil the requirements for classification in category 1. A risk assessment does not take place.[7] The relevant requirements of Directive 2001/18/EC on the deliberate release of GMOs and Regulation 1829/2003 on genetically modified food and feed and the requirement for risk assessment and authorisation prior to each release and first placing on the market regulated therein do not apply.[8]
- Whether and, if so, which NGT products must be labelled with which indication of the use of NGTs or GMOs is an open question. The Commission proposed that only plant reproductive material containing or consisting of category 1

[2] COM (2023) 411 final.
[3] P9_TA(2024)0325).
[4] See the definitions in Art. 3 in conjunction with. Annex I NGTR.
[5] Art. 3 No. 12 NGTR.
[6] Cf. the definition of NGT plants in Art. 1 No. 2 NGTR, according to which an NGT plant is a genetically modified plant, and the definitions of GMO and organism in Art. 3 No. 3 and No. 1 NGTR.
[7] Art. 6 and Art. 7 NGTR. In the Parliament's position, the application documents for the classification of a release for a purpose other than placing on the market also require verification that one of the sustainability criteria in Annex III Part 1 and no exclusion criterion in accordance with Annex III Part 2 of the NGTR applies (Art. 6 (1) of the Parliament's position). However, this requirement is not consistently anchored there. Nor does it constitute a risk assessment.
[8] Art. 5 para. 1 NGTR.

NGT plants, i.e. mainly seeds, should be labelled with the indication "cat 1 NGT" (Art. 10 NGTR COM). According to the Parliament's position, all category 1 NGT plants as well as products containing or consisting of category 1 NGT plants should be labelled with the indication "Novel Genomic Techniques" (Art. 10 para. 1 NGTR EP). Neither of the two proposals provides for the labelling of processed category 1 NGT products that are "produced from category 1 NGT plants" but do not contain organisms capable of reproduction. According to the current EU regulations for genetically modified food, food "produced from" GMOs must also be labelled with a reference to this.[9]

- The NGTR does not contain any requirements regarding the safety of NGT plants or category 1 NGT products, nor does it contain any requirements regarding liability for risks of NGT plants and NGT products and the coverage to be provided for cases of damage.

This opinion examines the impact that the adoption of the planned NGTR would have on the liability of food businesses, i.e. manufacturers, processors and distributors of food. The analysis focuses on category 1 NGT products, for which the risk assessment is to be cancelled and replaced by a status verification. For category 2 NGT products, on the other hand, genetic engineering law would continue to apply, albeit with various simplifications.

In the following, the risks associated with the placing on the market of category 1 NGT products are presented first (C.). The principles of liability and the effects of the NGTR on the liability risks (D.) and further risks due to the difficulty of recognisability and enforceability, in particular due to the lack of insurability of damage, are then explained (E.). Finally, we identify the need for a harmonised European liability regime for category 1 NGT products (F.).

D. Relevant risks

Relevant risks are risks to health and possible property damage (I.) as well as marketing risks (II.).

[9] Article 12(1)(b) in conjunction with the definition in Article 2(10) of Regulation 1829/2003 on genetically modified food and feed. The recitals of the Parliament's position state that the labelling requirements for food produced with NGTs should be "similar" to those for genetically modified food (recital 47b NGTR EP). However, the Parliament's regulatory proposal is explicitly formulated in such a way that the labelling requirement should only apply to products that contain or consist of category 1 NGT plants (Art. 10 para. 1 of the NGTR EP). This is despite the fact that the exemption from the requirements of genetic engineering law also explicitly extends to category 1 NGT products "produced from" category 1 NGT plants (cf. the definitions of NGT products in Art. 3 No. 12 to 14 of the NGTR).

I. Risks to health and damage to property

Health risks may arise if a category 1 NGT product is genetically modified in such a way that this modification leads to adverse health effects when the NGT product itself or a food produced with an NGT product as an ingredient is consumed.

This risk for category 1 NGT products is comparable to the corresponding risk for other products with or produced from GMOs.[10] To date, there is a lack of both practical experience and scientific findings to the effect that category 1 NGT products would only be associated with lower or generally negligible risks compared to other GMO products.

Classification as category 1 NGT plants is essentially based on the finding that the type and number of genetic modifications defined in Annex I NGTR also occur in conventional propagation. Only for this reason, such NGT plants are to be classified as equivalent to plants produced by conventional propagation. However, these criteria, which are therefore sometimes referred to as "equivalence criteria", do not imply a risk classification.[11] According to the minority opinion of Dr Elisabeth Bücking, a member of the German Central Commission for Biological Safety (ZKBS), such a limit value for the number of permitted genotypic deviations cannot be scientifically justified in principle. There is no law according to which a few deviations in the genotype cause minor changes in the phenotype and more deviations cause major changes in the phenotype. The effects on the phenotype - the characteristics of the plant - and the associated ecological risk depend on the location and context of the genotypic deviations.[12] The alleged "equivalence criteria" in Annex I of the NGTR therefore do not rule out the possibility that the use of NGT may also alter the DNA and thus the characteristics of a plant in category 1 NGT plants in a way that would not be possible with conventional propagation. For example, there may be natural barriers in particularly protected areas of the DNA that can be overcome by NGT. This

10 According to recital 12 of the NGTR, the potential risks of NGT plants vary, ranging from risk profiles similar to those of conventionally bred plants to different types and degrees of hazards and risks that could be similar to those of transgenesis-derived plants.

11 So explicitly EFSA, Scientific opinion on the ANSES analysis of Annex I of the EC proposal COM (2023) 411 (EFSA-Q-2024-00178), No. 3.3 page 5: "These equivalence criteria are not meant to define levels of risk but to allow certain NGT plants to be classified as equivalent to conventionally bred plants (Recital 14, European Commission Proposal)." (https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2024.8894).

12 This is the minority vote by Dr Elisabeth Bücking in the ZKBS statement on the European Commission's proposal for the new regulation of plants bred using "new genomic techniques (NGT)", October 2023, published in German and English at https://www.zkbs-online.de/ZKBS/DE/Kommentare/03_Kommissionsentwurf Neuregulierung NGT/Kommissionsentwurf Neuregulierung NGT_basepage.html.

can lead to NGT plants developing characteristics that do not occur with conventional propagation.

It is then questionable whether and in which cases such an NGT plant would be categorised as "equivalent" to a conventional plant. However, this would not play a role in the application of the NGTR and the categorisation of an NGT plant in category 1. This is because "equivalence" in the sense of equivalence of properties is not a classification criterion of the NGTR. Rather, equivalence in the legal sense should exist automatically if the type and number of changes to the DNA are within the framework specified by the NGTR. This would also apply if experts or layperson do not consider such an NGT plant equivalent to the corresponding conventional plant due to its modified properties.

In the case of food ingredients from conventionally produced plants, there is experience from thousands of years of breeding traditions as to which characteristics of an organism can be expected in the case of natural propagation. No such experience is available for products from category 1 NGT plants, which have only been being developed for a few years.

It is therefore possible that the genetic modification results in previously unknown changes to the properties of the products used. These altered properties can lead to health risks. However, altered properties could also have an impact on the processing of products and lead to material damage, e.g. to machinery or processed foods. For example, it is conceivable that altered properties of an NGT plant could lead to an altered viscosity of the products manufactured from it, for which a processing plant is not designed, resulting in malfunctions or even damage. Or an altered property of an NGT plant could mean that the food produced from it no longer has the desired properties, e.g. that it no longer fulfils requirements for consistency, taste or shelf life in the same way as the conventional product.

It may also take a very long time before it is recognised that certain damage to health or property can be attributed to certain NGT products and their properties.

In the case of conventional GMOs and category 2 NGT products, such risks are minimised by the official risk assessment required under genetic engineering law in an authorisation procedure prior to release and first placing on the market.

For NGT plants and category 1 NGT products, such an official risk assessment should no longer be required under genetic engineering law.

Food businesses will therefore have to verify whether a food containing or made from category 1 NGT products requires authorisation as a novel food within the meaning of the EU NFR (1.) and whether any risks to the health or property of third parties exist independently of this (2.).

1. Novel foods

First, food businesses wishing to place food containing category 1 NGT products on the market must clarify whether the use of such category 1 NGT products means that the food is a novel food within the meaning of Regulation (EU) 2015/2283 on novel foods (EU NFR). Additionally, they have to determine whether its placing on the market requires official authorisation in accordance with the EU NFR.

According to the EU NFR, all food business operators shall verify whether or not their food falls within the scope of the EU NFR (Art. 4 para. 1 EU NFR). Obligated food businesses are all undertakings, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food (Art. 3 Para. 1 EU NFR in conjunction with Art. 3 No. 2 EU Basic Food Regulation 178/2002). In addition to manufacturers and distributors of foods, food retailers and farmers are also obliged to fulfil the requirements of the EU NFR[13]. Food business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods satisfy the requirements of food law which are relevant to their activities and shall verify that these requirements are met (Art. 17 Para. 1 of the EU Basic Food Regulation 178/2002).[14]

If food businesses are unsure about the requirements of the EU NFR, they consult the Member State in which they first wish to place the food on the market (Art. 4 para. 2 EU NFR). In order to determine

[13] See also Rathke, in: Sosnitza/Meisterernst (formerly Zipfel/Rathke), Lebensmittelrecht, 189th EL 2024, EG-Lebensmittel-Basisverordnung Art. 3 Rn. 12 with reference to VG Düsseldorf, LMRR 2009, 66.

[14] See only Rathke, in Sosnitza/Meisterernst (formerly Zipfel/Rathke), Lebensmittelrecht, 189th EL 2024, EG-Lebensmittel-Basisverordnung Art. 17 para. 5 to 14 with further evidence on the scope of the responsibility of the various companies in the food chain, which is sometimes referred to as tiered responsibility and sometimes as chain responsibility.

whether a food is novel within the meaning of the EU NFR, the Member States can consult other Member States and the Commission (Art. 4 para. 3 EU NFR).

Similar to the NGTR, the EU NFR therefore enables a status verification to determine whether or to what extent a product falls within the scope of the regulation.

The Commission Implementing Regulation (EU) 2018/456 on the procedural steps of the consultation process for determination of novel food status contains rules on this consultation procedure and the required documents, including sample documents. In Germany, the Federal Office of Consumer Protection and Food Safety (BVL; Section 1 No. 1 of the German Novel Food Regulation) is responsible for the procedure.[15]

The competent authority of the Member State must then first decide on the validity of the consultation request (Art. 5 para. 4 of Implementing Regulation 2018/456) and conclude on the novel food status of a food within four months from the date of validation (Art. 6 para. 1 of Implementing Regulation 2018/456). The deadline can be extended by a maximum of four months (Art. 6 para. 4 of Implementing Regulation 2018/456). The competent authority shall notify the Commission of the decision and provide justification (Art. 6 para. 5 of Implementing Regulation 2018/456). The Commission publishes a declaration on the status of the food and the justification immediately in the EU Novel Food Catalogue[16] on its website (see Art. 7 para. 2 of Implementing Regulation 2018/456).

If it is a novel food, it may only be placed on the market if it is authorised, included in the Union list of novel foods[17] and placed on the market in accordance with the conditions of use and labelling requirements laid down therein (Art. 6 para. 2 EU NFR).

Novel foods within the meaning of the EU NFR are foods that were not used for human consumption to any significant extent in the EU before 15 May 1997 and fall into at least one of the categories of the

[15] See the website of the online consultation procedure at https://verwaltung.bund.de/leistungsverzeichnis/DE/leistung/99118033058000/herausgeber/LeiKa-102889162/region/00.
[16] https://ec.europa.eu/food/food-feed-portal/screen/novel-food-catalogue.
[17] Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods pursuant to Regulation (EU) 2015/2223 on novel foods.

EU NFR (Art. 3 para. 2 lit. a EU NFR). The categories include, for example:

- food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997 (Art. 3 para. 2 lit. a. point i. EU NFR) or
- food derived from plants obtained by non-traditional propagation practices which have not been used for food production in the EU before 15 May 1997, where those practices give rise to significant changes in the composition or structure of a food affecting its nutritional value, metabolism or level of undesirable substances (Art. 3 para. 2 lit. a. point (iv) indent 2 EU NFR),
- food resulting from a production process not used for food production before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances (Art. 3 para. 2 lit. a. vii. EU NFR).

In this respect, the first requirement of first placing on the market after 15 May 1997 is fulfilled for all category 1 NGT products. This is because, as far as can be seen, no such products have been placed on the market to date. As GMOs, they would have required a marketing authorisation in accordance with Regulation (EC) 1829/2003 on genetically modified food and feed.

In any case, the food is to be considered a novel food if it has a significant change in composition or structure due to the use of the category 1 NGT product, that affects the nutritional value, metabolism or level of undesirable substances in the food. The Commission expressly referred to this in recital 22 of its proposal for the NGTR.[18] This must be verified in each case.

The reference for assessing the existence of a significant modification is comparable food produced from conventionally produced plants instead of the respective NGT plant. The EU NFR does not specify when a modification must be categorised as significant with regard to the aspects mentioned. The commentary literature does not provide any practical guidance on this.[19] In case of doubt, a food business must

[18] COM(2023) 411 final.
[19] Cf. only Ballke, in: Sosnitza/Meisterernst (formerly Zipfel/Rathke), Lebensmittelrecht, 189th EL 2024, Regulation (EU) 2015/2283 Art. 3 para. 125 et seq.

clarify this with the help of the consultation procedure mentioned above.

In addition, foods are also to be classified as novel foods if the DNA modified with the aid of NGT intentionally modifies the molecular structure of a food and this structure was not used as, or in a food within the Union before 15 May 1997. This follows from the corresponding category in Article 3(2)(a)(i) EU NFR. The Commission did not mention this category in the recitals of the NGTR. However, this does not alter its validity.

This category explicitly applies alongside and independently of the other categories, which are based on a significant change in certain properties of the food. According to the clear wording of the regulation, it is sufficient for a food to fall into (at least) one of the categories regulated in the EU NFR (Art. 3 para. 2 lit. a EU NFR).

In case of doubt, it must also be clarified in a consultation procedure whether a food produced with the aid of category 1 NGT products has an intentionally modified molecular structure and may therefore only be placed on the market after inclusion in the Union list of novel foods.

This raises the question of whether foods that contain or are produced from category 1 NGT products must be classified as novel foods within the meaning of the EU NFR only if a molecular structure of the DNA that has been intentionally modified as part of the application of the NGT is still present in the final product.

It is true that conventional breeding also leads to a change in DNA. However, this is unlikely an intentional modification, but rather an accidental modification of the molecular structure of the DNA. Furthermore, conventional breeding does not preclude from classification as a novel food if one of the categories of the EU NFR for classification as a novel food applies (cf. only the explicit mention of conventional propagation methods for foods from plants that have no history of use as a safe food in Art. 3 para. 2 lit. a point (iv) indent 1 EU NFR).

The fact that the ECJ has interpreted the scope of this category broadly in other contexts speaks in favour of a rather far-reaching classification of foods with category 1 NGT products as novel foods. The aim of the regulation is to ensure effective protection of public health from the potential risks of novel foods. The harmonised safety

assessment of the EU NFR shall be required every time it is intended to use a substance for human consumption that has not previously served as food for humans.[20]

It could be argued against such a classification that, due to the aim of the NGTR to dispense with risk assessment and authorisation under genetic engineering law if the "equivalence criteria" in Annex I of the NGTR are met, category 1 NGT products should not generally be subject to any further safety assessment under food law either. However, this aspect of food law is not addressed in the proposed regulation. Furthermore, the NGTR does not affect the requirements of the EU NFR, as evidenced by the example of significant changes to food mentioned in recital 22. Finally, exemptions such as those in the NGTR are generally to be interpreted narrowly according to the case law of the ECJ.

As a result, a wide range of foods from NGT plants are likely to be categorised as novel foods within the meaning of the EU NFR. The food businesses will have to clarify whether this is the case in each individual case by means of the consultation procedure described above.

If a food from a category 1 NGT product is to be classified as a novel food but has not yet been included in the Union list, it may only be placed on the market after the authorisation procedure in accordance with Art. 10 et seq. EU NFR with the Commission and after inclusion in the Union list. This applies not only to the first placing on the market, but also to any further supply of the food to third parties.

The authorisation procedure and the updating of the Union list is initiated either by the Commission itself or at the request of an applicant (Art. 10 para. 1 sentence 1 EU NFR). Applicants can be Member States, third countries or interested parties (Art. 3 para. 2 lit. d EU NFR). The term "interested party" includes any natural or legal person or association of persons that submits an application.[21]

[20] ECJ, judgement of 9 November 2016, C-448/14, ECLI:EU:C:2016:839, Davitas, para. 33, on the classification of clinoptilolite, a mineral of volcanic origin, as a novel food. The ECJ categorised the substance as a novel food because it had not previously been used as a food and its molecular structure therefore differed from previously used foods, although the molecular structure of the substance as such was neither new nor changed by the manufacturer.

[21] Ballke, in: Sosnitza/Meisterernst (formerly Zipfel/Rathke), Lebensmittelrecht, 189th EL 2024, Regulation (EU) 2015/2283 Art. 3 para. 186.

The application for authorisation must contain, among other things (Art. 10 para. 2 EU NFR)

- the description of the production process(es),
- the detailed composition of the novel food,
- scientific evidence demonstrating that the novel food does not pose a safety risk to human health,
- where appropriate, the analysis method(s),
- a proposal for the conditions of intended use and for specific labelling requirements which do not mislead the consumer, or a verifiable justification why those elements are not necessary.

The Commission Implementing Regulation (EU) 2017/2469 contains administrative and scientific requirements for applications. Applications must be submitted electronically on a Commission application platform.[22]

The Commission may consult the EFSA to examine the applications. The EFSA submits an opinion to the Commission within 30 working days on whether the application fulfils the requirements of the EU NFR (Art. 6 para. 2 of Implementing Regulation 2017/2469). The required content of this opinion includes nutritional information, toxicological information, allergenicity information, an overall risk assessment and conclusions (Art. 7 para. 1 of Implementing Regulation 2017/2469). The authorisation procedures are largely determined by EFSA's scientific review and regularly require a great deal of time and money with an uncertain outcome.[23]

In this respect, the previously required authorisation procedure under GMO law for the first placing on the market of the category 1 NGT plant as a GMO may have to be replaced by a large number of authorisation procedures in accordance with the EU NFR for the respective foods in which the respective category 1 NGT product is used. This shifts the authorisation burden from the developer of the NGT plants to the food businesses.

If category 1 NGT plants were still authorised as GMOs, this would not be necessary. This is because the EU NFR does not apply to genetically

[22] https://food.ec.europa.eu/food-safety/novel-food/e-submission-accordance-new-novel-foods-regulation_en.
[23] Thus Teufer, in: Foerste/Graf von Westphalen, Produkthaftungshandbuch, 4th ed. 2024, § 69 para. 100 with reference to Gerstberger, ZLR 2008, 175.

modified food in accordance with Regulation (EC) No. 1829/2003 on genetically modified food and feed (Art. 2 (2) (a) EU NFR).

When a food is included in the Union list of novel foods, the entry in the Union list shall also include

- the conditions under which the novel food may be used,
- additional special labelling requirements and
- post-market surveillance requirements,

insofar as this is appropriate in each case (Art. 9 para. 3 EU NFR).

However, such labelling does not necessarily have to indicate that the food contains or has been produced from category 1 NGT products.[24]

As a result, the planned regulatory system of the NGTR must always be assessed in conjunction with the EU NFR from the perspective of food businesses. This system has two decisive liability-related disadvantages compared to the regulatory system of EU genetic engineering law:

On the one hand, category 1 NGT plants and corresponding seeds would be allowed to be placed on the market after the status verification has been carried out, even if foods produced from them require authorisation as novel foods but have not yet been authorised.

In order to comply with the requirements of the EU food safety regulations, food businesses must therefore always pay attention to this when selecting their primary products and foods and, if necessary, carry out verifications,

- whether the products are category 1 NGT products,
- whether an intermediate product, a food used or intended for sale or a food to be produced therefrom could therefore be classified as a novel food,
- whether the respective foods are already authorised as novel foods and included in the Union list or, if this is not the case, whether their classification has already been clarified in the context of a consultation procedure.

[24] See the respective labelling requirements in Table 1 of the Annex to the Union List Implementing Regulation 2017/2470. They often, but not always, contain a reference to the novel food contained in each case, without, however, having to refer to the novelty as such.

On the other hand, this verification presupposes that the food business knows that a product it uses is a category 1 NGT product. If, as proposed by the Commission, a final version of the NGTR does not contain a labelling requirement for category 1 NGT products, food businesses will therefore have to take their own measures to find out from their suppliers with sufficient certainty

- whether the products supplied are category 1 NGT products,
- whether the foods supplied or to be manufactured are therefore already classified as novel foods
- and, if so, whether they are included in the Union list of novel foods.

Only with such information can they verify whether the requirements of the EU NFR are applicable and complied with.

2. Health and property damage risks

Even if a food is not to be categorised as a novel food, food businesses in the EU must take the necessary measures to take precautions against any health risks of category 1 NGT products. In this respect, it will remain unclear for some time whether and, if so, what measures will be necessary.

The exemption of category 1 NGT products from the legal requirements for GMOs by the NGTR does not mean that food businesses are exempt from all due diligence obligations in this regard. The waiver of a state risk assessment does not guarantee the absence of risks or release from responsibility for such risks. Rather, the general principle of food law applies that the primary responsibility for the safety of a food lies with the food business operator (Art. 1 para. 1 lit. a EU Food Hygiene Regulation 852/2004).

Seed law offers no remedy in this respect. There is no specific examination of risks due to genetic modification. In variety authorisation procedures, the distinctness, stability, uniformity and cultural value of the seed are tested. The examination of the cultural value requires an overarching assessment of various characteristics for the cultivation or utilisation of the harvested material or the products obtained from

it.[25] The proposal for an EU regulation on plant reproductive material, which is currently in the legislative process, aims to replace the assessment of the cultural value with an assessment of the value for sustainable cultivation and utilisation, which also includes an overarching assessment of various characteristics.[26] No specific assessment of the effects of genetic modification on the plants and their products is envisaged for category 1 NGT products.[27]

In the event of deregulation of category 1 NGT products, food businesses in the EU that do not exclude the use of category 1 NGT products would have to verify the following as part of the legally required hazard analysis and critical control points based on the HACCP principles (HACCP, Hazard Analysis and Critical Control Points, Art. 5 para. 2 lit. a EU Food Hygiene Regulation 852/004) in order to fulfil their due diligence obligations:

- To what extent must the company obtain information from manufacturers and suppliers of intermediate or finished products about the use and presence of category 1 NGT products?
- To what extent must the company obtain information from manufacturers and suppliers of intermediate or end products about their risk prevention measures, e.g. whether and to what extent the developer of the NGT plant and/or subsequent users of the NGT plant or NGT products have carried out risk tests and what the results of these tests were?
- To what extent must the company inform its corporate customers about the use and presence of category 1 NGT products and about any risk prevention measures that have been implemented and their results (cf. the information obligations pursuant to Art. 8 (6) and (8) of the EU Food Information Regulation 1169/2011)?
- To what extent do the type and scope of the aforementioned information and testing obligations depend on specific characteristics of the respective NGT product, for example on the type and number of genetic modifications, on the characteristics caused by them or on the respective plant species?

[25] Art. 4 para. 1 and Art. 5 para. 4 of Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species.
[26] Art. 47 et seq., Art. 52 of the proposal for a Regulation on the production and marketing of plant reproductive material, COM (2023) 414 final.
[27] See Art. 47(1)(e) of the proposal for a Regulation on the production and marketing of plant reproductive material, COM (2023) 414 final. It only requires the existence of a declaration of status as a category 1 NGT plant.

- To what extent do the type and scope of the aforementioned information and testing obligations depend on the respective end consumer groups (e.g. in the case of infant formula)?
- Regardless of the specific products purchased and sold, to what extent must the company generally inform itself about any new developments of category 1 NGT products and any available experience or knowledge about possible risks in order to be able to take appropriate measures in good time if necessary?
- To what extent can the company avoid its own liability for any associated risks by informing its customers about the presence of category 1 NGT products?

In the event of deregulation of category 1 NGT products, standards will have to be developed for this purpose, particularly within the framework of the existing hygiene guidelines. These will continue to evolve depending on experience with and any risks actually identified for category 1 NGT products and, if necessary, in accordance with official requirements or court decisions. Until such standards are established and confirmed by the courts, the associated risk can only be assessed to a very limited extent.

II. Marketing risks

Food businesses that exclude the use of category 1 NGT products can largely eliminate the associated health and property damage risks. They can also save themselves the associated effort for the fulfilment of due diligence requirements, particularly for the testing of novel foods.

However, there is a risk to the economic value of their products if they accidentally and unintentionally contain parts of category 1 NGT products. The value-determining factors of food and feed, but also of other plant products, can also include the absence of GMOs, including NGT products. This applies in particular to foods labelled "without genetic engineering" (1.) and to organic products (2.). There are no such labelling risks for conventional foods, but they are threatened with a loss of trust and market share (3.).

1. Food "without genetic engineering"

In some EU countries, special national legislation applies to the labelling of food produced without the use of genetic engineering. In Germany, the Act on the Implementation of EU Regulations in the Field

of Genetic Engineering (Gesetz zur Durchführung der EU-Verordnungen auf dem Gebiet der Gentechnik - EGGenTDurchfG)[28] conclusively regulates the requirements for the labelling of food produced without genetic engineering.

According to the EGGenTDurchfG, a food may only be placed on the market or advertised with a claim that indicates that the food was produced without the use of genetic engineering if the requirements of the EGGenTDurchfG have been met (Section 3a (1) EGGenTDurchfG).

Most of the labelling requirements contained therein are directly linked to the provisions of EU Regulation 1829/2003 on genetically modified food and feed (Section 3a (2) to (4) EGGenTDurchfG). Category 1 NGT products are to be excluded from the scope of EU Regulation 1829/2003 on genetically modified food and feed in future in accordance with the NGTR. Therefore it would become unclear with the entry into force of the NGTR whether foodst may be placed on the market with the "without genetic engineering" labelling if they contain category 1 NGT products.

If the reference in the EGGenTDurchfG to EU law is interpreted as a dynamic reference, the use of category 1 NGT products would not prevent the labelling "without genetic engineering". This is because category 1 NGT products would then no longer fall within the scope of EU Regulation 1829/2003 and therefore no longer be subject to the labelling requirements of Section 3a (2) to (4) EGGenTDurchfG.

If, however, the reference in the EGGenTDurchfG to EU law is interpreted as a static reference to the version of EU Regulation 1829/2003 in force at the time the EGGenTDurchfG came into force, the use of category 1 NGT products in foods "without genetic engineering" continues to be prohibited, as category 1 NGT products are genetically modified foods.

The special requirements for foods, food ingredients and other substances "produced by" GMOs in Section 3a (5) EGGenTDurchfG are not based on the provisions of EU Regulation 1829/2003 on genetically modified food and feed, but on the provisions of the former EC

[28] See the English translation of an abridged version on the website of the German Federal Ministry of Food and Agriculture, https://www.bmel.de/SharedDocs/Downloads/EN/_Food-and-Nutrition/EG-Gentechnik-Durchfuehrungsgesetz.html (for the German version see https://www.gesetze-im-internet.de/eggentdurchfg/index.html).

Organic Regulation 834/2007. The exemption of the NGTR would not apply here. Therefore, substances "produced by GMOs" in foods "without genetic engineering" would continue to be inadmissible as substances "produced by" category 1 NGT plants. This applies regardless of whether the reference to the former EC Organic Regulation 834/2007 is interpreted as a static reference to it or as a dynamic reference to the current EU Organic Regulation 2018/848, which is now in force, because nothing has changed in this respect.[29]

The reference to the EC Organic Basic Regulation clearly indicates that the reference to EU law in Section 3a EGGenTDurchfG must be interpreted as a static reference. This is because if it were interpreted as a dynamic reference, the NGTR would mean that the presence of category 1 NGT products would not prevent the labelling "without genetic engineering". Foods without genetic engineering could then also contain category 1 NGT products. However, due to the reference to the EC Organic Regulation, they would still not be allowed to contain any substances that have been "produced by" NGT products. However, it would be an obvious contradiction in judgement if, on the one hand, substances produced by category 1 NGT products were not permitted in foods without genetic engineering, but, on the other hand, the direct use of category 1 NGT products were permitted. This contradiction in judgement is avoided if the reference to EU Regulation 1829/2003 is interpreted as a static reference and category 1 NGT products remain prohibited in foods without genetic engineering. This also corresponds to the clear regulatory purpose of the "without genetic engineering" labelling to inform consumers about the presence and use of GMOs in food, even beyond the mandatory labelling under GMO law.

The use of category 1 NGT products should therefore generally be just as impermissible in foods "without genetic engineering" as the use of other GMOs.

Irrespective of this, the Verband Lebensmittel ohne Gentechnik (VLOG e.V.) and many other players in the food industry have already clearly stated that they do not want to accept the use and presence of category 1 NGT products in foods "without genetic engineering". For

[29] See the definition of 'produced by GMOs' in Art. 2 lit. v EC Organic Regulation 834/2007 and Art. 3 No. 60 EU Organic Regulation 2018/848.

this reason, the corresponding VLOG standards and company requirements would probably also make it clear that the use of category 1 NGT products is not permitted.

However, due to the changes introduced by the NGTR, the supplier declarations required to prove the absence of GMOs would have to be adapted (see Section 3b sentence 2 no. 1 EGGenTDurchfG). Suppliers would also have to ensure that they do not use any category 1 NGT products. They would therefore have to inform themselves about which NGT products can be on the market as category 1 NGT products on the basis of the NGTR. In particular, the chain of supplier declarations would have to ensure that the farmers from whose original production the products used for food without genetic engineering originate do not use seed labelled as a category 1 NGT product.

In this respect, it remains to be seen whether farmers and other stakeholders in the "without genetic engineering" supply chains will be prepared to do so. However, the additional effort required for this is likely to be limited.

However, if there were to be any entries of NGT products, for example during cultivation on neighbouring fields or during food production through the use of food ingredients or other substances that are NGT products, or through contamination with such NGT products, the food would no longer be allowed to be labelled as "without genetic engineering".

If unintentional entries are made, this can result in economic damage, e.g. due to the loss of the possibility of labelling, but possibly also due to a complete loss of marketability due to a lack of alternative distribution channels. Furthermore, additional costs may arise for the fulfilment of existing supply contracts, for recalls or for the fulfilment of claims for damages for incorrectly labelled and already delivered foods.

In this respect, much depends on how many NGT plants and NGT products food businesses have to deal with, whether there will be many status tests for category 1 NGT products, whether and if so how many category 1 NGT products are grown here or enter the EU via imports, and whether and, if so, through the means of which coexistence

regulations unintentional presence of category 1 NGT plants in conventional plants can be excluded. In particular, it will be questionable whether the requirements of national genetic engineering law regarding the site register (Section 16a GenTG) and precautions against the unintentional presence of GMOs (Section 16b GenTG, Genetic Engineering Plant Production Ordinance) will continue to apply to category 1 NGT products.

2. Organic products

One of the general principles of organic production is not to use GMOs or products produced from or by GMOs, with the exception of veterinary medicinal products (Art. 5 lit. f iii of the EU Organic Regulation 2018/848). The use of GMOs and products produced from or by GMOs is prohibited (Art. 11 EU Organic Regulation 2018/848). Operators must take precautionary measures to avoid the presence of unauthorised products and substances (Art. 28 f. EU Organic Basic Regulation 2018/848). Products may not be labelled as organic if, in accordance with EU legislation, the labelling or advertising must include a statement indicating that the product contains GMOs, consists of GMOs or was produced from GMOs (Art. 30 para. 4 EU Organic Regulation 2018/848).

According to the current status of the legislative proposals, these bans should also apply to category 1 NGT products (recital 23 and Art. 5 para. 2 NGTR). However, the Parliament has proposed an additional provision according to which the accidental or technically unavoidable presence of category 1 NGT products should not constitute a violation of the EU Organic Regulation 2018/848 (Art. 5 para. 3a NGTR EP).

Irrespective of which provision the NGTR will adopt in this regard, the market participants remain free to agree on stricter requirements for organic products under private law, in particular on the basis of manufacturer standards under private law. The unintentional presence of NGTs in organic products can therefore also lead to economic damage if labelling as an organic product would still be permissible under the NGTR, but the respective contractual partners no longer accept products contaminated with NGTs as organic products.

The resulting cost risks correspond to those associated with the labelling of foods "without genetic engineering" (see 1. above).

3. Other foods

The aforementioned labelling risks do not exist for manufacturers and traders of other foods, i.e. those for which no specific statements are made regarding the absence of GMOs or NGTs.

However, they run the risk of losing the confidence of market participants and of losing market shares. Food businesses that do not exclude the use of category 1 NGT products must expect to lose business as well as end customers. This is because the possible presence of category 1 NGT products in conventional, non-separately labelled foods can lead to business and end customers increasingly opting for food "without genetic engineering" or organic foods in order to rule out all kinds of risks from NGT products from the outset.

The associated economic risks ultimately depend on the extent to which end consumers are able and willing to inform themselves about the presence or absence of category 1 NGT products and the importance they will attach to this. Complementary to this, there are additional marketing opportunities for foods "without genetic engineering" and organic products, as business and end customers can only rely on the non-use of category 1 NGT products for such products.

E. Liability in Germany and the EU

Liability for damage caused by the use of category 1 NGT products is governed by the respective contractual agreements (I.), the special provisions of national genetic engineering law (II.) and the EU and national regulations on product liability (III.). Liability in the EU is governed by the Product Liability Directive, the requirements of which are implemented by the German Product Liability Act (Produkthaftungsgesetz); liability in cases involving foreign countries is governed by private international law (IV.). Liability for environmental damage could also be of some significance (V.).

I. Contractual liability

Contractual liability is determined by the agreed upon or applicable national or international contract law in each case, by the agreements reached on

the quality of the products to be manufactured or delivered[30] and by the suitability for the use assumed under the contract.[31] In this respect, it is up to the respective contracting parties to determine whether and to what extent the use or the accidental presence of category 1 NGT products is permissible or is to be considered a defect that can trigger claims for damages. If the parties have agreed that the delivered products must be suitable for the production of food "without genetic engineering" or organic food, the quality requirements shall be based on the standards agreed for this purpose (see D.II.1. and 2. above).[32]

If a food product does not fulfil these requirements, the seller or manufacturer is liable in accordance with the respective warranty law. The purchaser can demand subsequent fulfilment and/or compensation (Sections 280 ff. BGB). The obligation to pay compensation shall not apply if the respective seller is not responsible for the defect. The seller is responsible for the defect if they are the manufacturer[33] or the manufacturer is their vicarious agent or if they knew or should have known of the defect.[34] Warranty claims for material defects also exist if food is suspected of being harmful to health due to its origin, this suspicion is based on concrete facts, this suspicion cannot be eliminated by reasonable measures and therefore the usability of the goods presumed under the contract no longer applies.[35]

A retailer is generally not obliged to inspect the goods for defects that are not readily recognisable.[36] However, under food law, every business in the food chain must ensure that the relevant food safety requirements are met at all distribution stages under its control in accordance with the principles of hazard analysis and critical control points (HACCP) (Art. 3 and 5 EU Foodstuffs Hygiene Regulation 852/2004).[37] This obligation under public law also leads to a corresponding extension of liability under civil law. Of course, it

[30] Section 434 para. 2 no. 1 Bürgerliches Gesetzbuch (BGB) (German Civil Code) for purchase agreements, Section 633 para. 2 sentence 1 BGB for contracts to produce a work.

[31] Section 434 para. 2 no. 2 BGB for purchase agreements, Section 633 para. 2 sentence 2 no. 1 BGB for contracts to produce a work.

[32] Cf. on the contractual liability of the seller for defective maize seed containing traces of unauthorised genetically modified maize, OLG Munich, judgment of 28 August 2014, 24 U 2956/12, NJW-RR 2015, 435.

[33] Cf. on manufacturer obligations Roffael/Wallau, in: Sosnitza/Meisterernst, Lebensmittelrecht, 189th EL 2024, LFGB (Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch), before § 58 para. 375 ff., para. 384 ff. on the testing of supplied raw materials.

[34] Cf. Grüneberg, in: Grüneberg, BGB, 83rd ed. 2024, Section 280 para. 19 with further references.

[35] BGH, judgement of 22 October 2014, VIII ZR 195/13, NJW 2015, 544, para. 43 with further evidence on liability for animal feed with suspected dioxin contamination.

[36] Cf. only Grüneberg, in: Grüneberg, BGB, 83rd ed. 2024, Section 280 para. 19 with further references.

[37] See Becker/Oettinger, in: Foerste/Graf von Westphalen, Produkthaftungshandbuch, 4th ed. 2024, Section 67 para. 27 et seq. with further references.

must be determined in each individual case whether and to what extent a case of damage is based on a breach of duty by the respective company.[38] In the absence of sufficient experience with regard to any risks posed by category 1 NGT products, considerable uncertainties are to be expected here.

This liability only applies in the respective contractual relationship.

A food business is therefore generally only contractually liable for damages suffered by its customers. However, the food business might also be liable to the customer for damages suffered by third parties if the customer is liable to pay compensation to third parties or if the damage occurs by chance not to the customer but to a third party (so-called "third-party damage liquidation").

Conversely, each food business is generally only entitled to contractual recourse claims against its contractual partners in the food production and distribution chain. Each business at a downstream level must therefore verify on the basis of the respective contractual relationship whether and to what extent it can take recourse against the respective upstream business for any damages it has to pay.

In the case of deliveries from other countries, the applicable law is determined by the contractual agreements made [Art. 3 para. 1 of the Rome I Regulation (EC) No. 593/2008].[39] If nothing has been agreed, the law of the country in which the seller has his habitual residence applies to sale contracts and contracts for work and materials [Art. 4 para. 1 lit. a) of the Rome I Regulation (EC) No. 593/2008].

II. Liability under genetic engineering law in Germany

EU genetic engineering law does not contain any specific liability provisions. Therefore, liability under genetic engineering law is governed exclusively by national law.

[38] Cf. on the affirmed breach of duty and liability of an intermediary trader of frozen cherries for foreign bodies that got into the products at the manufacturer based in Serbia OLG Munich, judgement of 18 November 2015, 7 U 1430/15, LMuR 2016.2015, 7 U 1430/15, LMuR 2016, 26. General information on the obligations of distributors Roffael/Wallau, in: Sosnitza/Meisterernst, Lebensmittelrecht, 189th EL 2024, LFGB, before Section 58 para. 395 et seq. on the obligations of wholesalers, para. 407 et seq. on the obligations of retailers.

[39] Regulation (EC) 593/2008 on the law applicable to contractual obligations (Rome I); on contracts for work and materials Thorn, in: Grüneberg, BGB, 83rd ed. 2024, Rome I Art. 4 para. 6 with further references.

The German Genetic Engineering Act (GenTG)[40] contains strict liability for damage resulting from genetically modified properties (1.) and specific regulations on claims for impairment of use (2.).

1. Strict liability for genetically modified properties

According to the German Genetic Engineering Act, an operator is obliged to pay compensation for damage to health and property resulting from the characteristics of an organism based on genetic engineering work (cf. Section 32 para. 1 GenTG).

An operator is anyone who places products containing or consisting of GMOs on the market for the first time, unless a marketing authorisation has already been granted under genetic engineering law (cf. Section 3 No. 7 GenTG). Placing on the market is the supply of products to third parties and the introduction into the area of application of the GenTG (cf. Section 3 No. 6 GenTG). The first placing on the market in Germany is therefore decisive.[41] This means that the first-time importer of a GMO already placed on the market in another EU Member State is also liable as an operator under the GenTG.

In this sense, a food business is also an operator if it places a product containing or consisting of NGT plants on the market in Germany for the first time. If a third party supplies the NGT plant to a food business in Germany, only the supplier can be the operator, not the receiving food business. Furthermore, the operator is only the person who places the GMO on the market for the first time. GMOs can only be organisms, i.e. biological entities that are capable of reproducing or transferring genetic material.[42] If an NGT product is produced from an NGT plant but no longer contains any material capable of reproduction, the manufacturer of the processed product is not an operator within the meaning of the GenTG even if he places the processed product on the market in Germany for the first time.

Therefore, food businesses that do not develop or produce NGT plants themselves are only liable under Section 32 GenTG if they bring

[40] Unfortunately, there is no English translation on the website of the German Federal Ministry of Justice. For the German version, see: https://www.gesetze-im-internet.de/gentg/index.html.

[41] See also OLG Frankfurt, judgement of 6 February 2009, 2 U 128/07, BeckRS 2009, 5548; Kohler, in: Staudinger, BGB, Umwelthaftungsrecht, 2017, §§ 32-37 GenTG para. 22.

[42] Section 3 No. 1 and 3 GenTG, Art. 2 No. 1 and 2 of Directive 2001/18/EC on the deliberate release into the environment of GMOs.

category 1 NGT products, that contain or consist of NGT plants, to Germany for the first time.

Liability under genetic engineering law also extends to damage caused by risks that were not recognisable according to the state of scientific and technical knowledge at the time the product was placed on the market.[43] Unlike the German Product Liability Act (ProdHaftG), the German Genetic Engineering Act (GenTG) does not contain an exclusion of liability for such risks [see D.III.1.b) below on the ProdHaftG].

The compensation obligation does not apply if products that contain or consist of GMOs are placed on the market on the basis of a marketing authorisation under genetic engineering law. This is also the case if placing on the market of such a product is based on an authorisation or approval that is at least equivalent with regard to risk assessment, risk management, labelling, monitoring and informing the public (cf. Section 37 para. 2 sentence 1 in conjunction with Section 14 para. 2 GenTG). An authorisation as a novel food is unlikely to be classified as an equivalent authorisation in this respect because less stringent requirements apply, particularly with regard to labelling and monitoring.

Category 1 NGT products are products containing or produced from GMOs (cf. C. above). According to the NGTR, no marketing authorisation should be required for them. Therefore, in addition to product liability law, the strict liability under the German GenTG would also apply to category 1 NGT products. In contrast, liability under the GenTG is excluded for category 2 NGT products and other GMOs with a corresponding marketing authorisation. Only other liability regulations apply to these, such as those of product liability law.

This strict liability for category 1 NGT products according to the German GenTG is justified by the fact that the official risk assessment and authorisation is not required.[44] It is, so to speak, the liability protection of the operator's responsibility.

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[43] See Kohler, in: Staudinger/Kohler, Umwelthaftungsrecht, 2017, §§ 32-37 GenTG para. 38 and 49. See also the special regulation for product liability after a marketing authorisation has been granted in Section 37 para. 2 sentence 2 GenTG, see below D.III.1.b).

[44] Cf. OLG Frankfurt, judgement of 06.02.2009, 2 U 128/07, BeckRS 2009, 5548: The OLG Frankfurt affirmed the applicability of the liability provisions of § 32 ff GenTG despite the existence of a marketing authorisation for

If the damage was caused by GMOs, it is presumed that it was caused by properties of these organisms that are based on genetic engineering (cf. Section 34 para. 1 GenTG). The presumption is rebutted if it is likely that the damage is due to other properties of these organisms (cf. Section 34 para. 2 GenTG). If there are facts that justify the assumption that personal injury or damage to property is due to genetic engineering work carried out by an operator, the operator and the competent supervisory authorities must provide the information required to establish the claim (cf. Section 35 GenTG).

According to the wording of the law, liability under genetic engineering law applies to damage resulting from characteristics of an organism that are based on genetic engineering work (Section 32 para. 1 GenTG). In this respect, the question arises as to whether reductions in the value of products resulting solely from the presence of a NGT product as such, e.g. in the case of foods "without genetic engineering" or organic products, can constitute compensable damage within the meaning of Section 32 GenTG.

This depends on whether the fact of the genetic modification as such is sufficient as a property relevant to the damage if the intended usability of the good is not only slightly impaired,[45] or whether the damage must be caused by specific properties caused by the genetic modification. [46]

The operator's obligation to pay compensation is also relevant for food businesses if they themselves can assert claims for damages against operators. This is possible if they themselves have suffered damages, or if their business customers or end consumers assert claims for damages against them and both the food business itself (e.g. on a contractual basis) and the operator within the meaning of Section 32 GenTG are liable for the damages. In this case, both are liable as joint and several debtors; the injured party can demand payment in full or in part from each of the debtors at their discretion (cf.

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the GM maize Bt 176 because the competent authority had already ordered the partial suspension of this authorisation at the time of the alleged case of damage and this order was enforceable.

[45] Hartmannsberger, Gentechnik in der Landwirtschaft: Die Entwicklung der Haftung für den Einsatz gentechnisch veränderter Pflanzen, Diss., 2007, pp. 87 to 92 and 190 to 194 with further references. Hartmannsberger, however, poses the question differently than here; he focuses primarily on general tort law requirements for damage to property and the protective purpose of the GenTG. In any case, this should be the decisive factor in tort law product liability, cf. below D.III.2.a).

[46] In this sense, Kohler, in: Staudinger, BGB, Umwelthaftungsrecht, 2017, §§ 32-37 GenTG para. 17.

Section 421 BGB; cf. also Section 32 para. 2 GenTG for several operators liable under Section 32 GenTG). The joint and several debtors are then obliged to compensate each other (cf. Section 426 BGB). Due to the developer's typically overriding share of causation, the operator who developed the NGT plant must regularly settle the full claim (cf. Section 32 para. 2 sentence 2 GenTG).

As a result, strict liability under genetic engineering law can give rise to liability for food businesses that supply category 1 NGT products, that contain or consist of NGT plants, to third parties for the first time in Germany. It can also give rise to claims for compensation by food businesses against third parties if the food businesses have suffered damage as a result of genetically modified properties. Finally, such claims for damages may be relevant for internal joint and several debtor compensation. However, all these claims for damages only apply to damage caused by genetically modified properties, not to the loss of the possibility of labelling food "without genetic engineering" or organic products due to the mere presence of category 1 NGT products in food.

2. Claims for impairment of use

The German Genetic Engineering Act also contains a special regulation on claims in the event of utilisation impairments (cf. Section 36a GenTG).

This regulation is intended as a concretisation of the general definition of the content of ownership of land in Section 906 BGB. Accordingly, a property owner must tolerate insignificant impairments emanating from another property (Section 906 (1) BGB). Insofar as significant impairments must also be tolerated, there is a claim for compensation under neighbouring law (cf. Section 906 (2) BGB).

In this respect, the Genetic Engineering Act (GenTG) clarifies that a significant impairment in this sense exists if, contrary to the intention of the authorised user, products are affected by the entries of GMOs and may therefore not be placed on the market at all or only under the following restrictions (cf. Section 36a para. 1 GenTG)

- only with a reference to GMOs or

- no longer labelled as food "without genetic engineering" or as an organic product.

These provisions therefore apply primarily to claims in the relationship between neighbours, i.e. farmers in primary production.

It may be indirectly relevant for food businesses. Section 36a para. 1 GenTG, contains the reasoning, that the effects of the introduction of GMOs on labelling obligations and labelling options lead to a significant impairment of property. This reasoning is also relevant for the finding that an infringement of property rights exists in other contexts, in particular in connection with claims arising from product liability (see III. below).[47]

III. Product liability in Germany

In Germany, product liability, if the requirements are met, applies in addition to liability under the Genetic Engineering Act (GenTG). It is governed by the German Product Liability Act (ProdHaftG) (1.) and the tort law liability provisions (2.).

1. German Product Liability Act

The German Product Liability Act (ProdHaftG)[48] transposes the EU Product Liability Directive, which applies throughout the EU, into national law (see IV. below).

According to the Product Liability Act, the manufacturer of a product is obliged to pay compensation for damage to health and property caused to an injured party by a defect in the product (Section 1 para. 1 ProdHaftG).

A broad definition of manufacturer applies within the meaning of the Product Liability Act [a)]. Although the liability of food businesses for category 1 NGT products should not extend to liability for development risks of such NGT plants, in the event of damage the companies bear the burden of proof that the damage was not recognisable at the time of placing on the market according to the state of scientific and

[47] Kohler, in: Staudinger/Kohler, Umwelthaftungsrecht, 2017, § 36a GenTG para. 62 with further reference to the opposing view.

[48] See the English translation on the official website of the German Federal Ministry of Justice, https://www.gesetze-im-internet.de/englisch_prodhaftg/index.html.

technical knowledge [b)]. Damage resulting from product defects [c)] and damage to property suffered by end users [d)] must be compensated. If several parties are liable to pay compensation, there are also internal compensation claims [e)].

a) Broad manufacturer term

A manufacturer[49] within the meaning of the Product Liability Act is anyone who has manufactured the end product, a basic material or a partial product (actual manufacturer, Section 4 para. 1 sentence 1 ProdHaftG). Anyone who claims to be the manufacturer by affixing their name, trade mark or other distinctive sign (quasi-manufacturer, Section 4 para. 1)sentence 2 ProdHaftG) is also deemed to be the manufacturer. Furthermore, anyone who imports or brings a product into the European Economic Area (EEA) for the purpose of selling it as part of their business activities (importer, Section 4 para. 2 ProdHaftG) is deemed to be a manufacturer.

According to the broad definition of a manufacturer under the ProdHaftG, a manufacturer is anyone in whose organisational area a movable object has been created, whereby it is relevant that its safety-relevant properties have been influenced.[50]

Food businesses are therefore responsible manufacturers within the meaning of the ProdHaftG if they produce food or food ingredients as preliminary, intermediate or end products, place them on the market under their name as quasi-manufacturers or merely import them into the EEA as distributors. Only traders who market products that are recognisably manufactured by other food businesses are exempt from liability.

Any food business that is the manufacturer under product liability law of a food that contains or is produced from NGT products is liable for any damage to health or property caused by NGT products. This applies regardless of whether the respective

[49] The term "manufacturer" is used in the same way as the term "producer". The term "manufacturer" seems to be more modern, since it is used by the new Product Liability Directive (EU) 2024/2853, whereas the former Product Liability Directive 85/374/EEC used the term "producer".

[50] Wagner, in: Münchener Kommentar zum BGB, 9th edition 2024, ProdHaftG § 4 para. 11 with reference to ECJ, BeckRS 2022,35689, para. 45 et seq.; BGHZ 200,242 para. 16 = NJW 2014,2106 (Strom).

manufacturer knows that the food contains or is produced from NGT products. This is because product liability is a strict liability.

b) Liability for development risks?

According to the Product Liability Act, the manufacturer's obligation to pay compensation is generally excluded if the defect could not have been recognised according to the state of scientific and technical knowledge at the time the product was placed on the market (so-called development risks Section 1 Para. 2 No. 5 ProdHaftG).

However, the German GenTG contains a special provision for product defects resulting from genetic engineering work. According to this, the person who has been granted a marketing authorisation for a GMO under genetic engineering law is also liable for development risks (Section 37 para. 2 sentence 2 GenTG).

According to the explanatory memorandum to the law, liability for damage caused by GMOs must in principle also apply if the damage is based on the realisation of a development risk, because the development risk is the actual and primary risk of genetic engineering.[51]

However, this extension of product liability does not apply to all manufacturers liable for compensation within the meaning of the ProdHaftG, but only to those manufacturers who have been granted marketing authorisation.[52]

For category 1 NGT products, the question arises as to whether and, if so, for whom product liability also includes liability for development risks.

The wording of the law initially speaks against the extension of product liability. This is because, according to the wording of the law, the extension of product liability only applies in the

[51] According to the explanatory memorandum to the Federal Government's draft bill, Bundestag printed matter 11/5622, p. 36 on Section 31 para. 2 GenTGE. Cf. on liability for development risks Sprau, in: Grüneberg, BGB, 83rd ed. 2024, ProdHaftG § 1 para. 21 with reference to BGH NJW 2013, 1302, para. 9.

[52] Section 37 para. 2 sentence 2 GenTG, see Kohler, in: Staudinger/Kohler, Umwelthaftungsrecht, 2017, §§ 32-37 GenTG para. 50.

event that a marketing authorisation under genetic engineering law has been granted (Section 37 para. 2 sentence 2 GenTG). Furthermore, only the holder of this marketing authorisation is liable for development risks. However, such an authorisation should no longer exist for category 1 NGT products. The regulation is therefore not applicable.

This could be countered with the argument that there is no reason for the distributors of category 1 NGT products to be placed in a better position under liability law. One could therefore consider a corresponding application of extended product liability for the applicant for the status verification.

However, the lack of a regulatory gap speaks against such a corresponding application of extended product liability. This is because, in addition to product liability, liability under genetic engineering law also applies to damage caused by category 1 NGT products (see II. above). This also extends to the development risk, as genetic engineering law, unlike product liability law, does not provide for an exclusion of liability for development risks.

Therefore, according to our assessment, the liability of food manufacturers under the ProdHaftG does not extend to development risks. However, this assessment is naturally not backed up by case law either.

In addition, the manufacturer bears the burden of proof that damage was not recognisable at the time of placing on the market according to the state of scientific and technical knowledge (cf. Section 1 para. 4 ProdHaftG). This is likely to be difficult for a food business that has only used, but not developed, a category 1 NGT product (see also E.I. below).

c) Damage due to product defects

Liability under the Product Liability Act only extends to damage to health and property caused by the defect of a product (cf. Section 1 para. 1 sentence 1 ProdHaftG). A product is defective if it does not offer the safety that can reasonably be expected

taking into account all circumstances, in particular its presentation, the use that can reasonably be expected and the time at which it was placed on the market (cf. Section 3 para. 1 ProdHaftG).

First of all, this means that liability under the ProdHaftG is unlikely to be considered if the damage is merely due to the fact that a food contains category 1 NGT products and therefore cannot be labelled as a food "without genetic engineering" or as an organic product, for example. This is because the loss of the labelling option is not a safety defect.[53] The general basic risk associated with GMOs and thus also with category 1 NGT products should not be sufficient as a (potential) safety defect.

However, damage based on specific properties of the NGT products, i.e. damage that would not have occurred with comparable conventional products, should generally be eligible for compensation. In any case, if the labelling of a food does not indicate that it contains or is produced from NGT products, the respective user can legitimately expect that the food is just as safe as a food made from conventional products.

It is unclear to what extent a product defect also exists if the manufacturer indicates in the presentation of a food that it contains or is produced from category 1 NGT products. Such a reference could modify the relevant legitimate safety expectations to the effect that the purchaser of such a product accepts any safety risks associated with such NGT products. In this respect, the manufacturer of food containing or produced from category 1 NGT products could possibly exclude or reduce his liability by informing the purchasers.[54]

Due to the general principle of food law that the primary responsibility for the safety of a food lies with the food business operator (Art. 1 para. 1 lit. a EU Food Hygiene Regulation

[53] See Wagner, in: Münchener Kommentar zum BGB, 9th edition 2024, ProdHaftG § 3 para. 2 on the limitation of the concept of defect to safety-relevant properties.

[54] Cf. on the limitation of safety expectations through the presentation of the product Graf von Westphalen, in: Foerste/Graf von Westphalen, Produkthaftungshandbuch, 4th ed. 2024, § 48 para. 52 et seq. with further evidence

852/2004), such risk minimisation through information is likely only possible to a limited extent.[55]

There is a high degree of legal uncertainty here. In the absence of sufficient experience with category 1 NGT products, it is unclear whether and to what extent manufacturers or users of category 1 NGT products are obliged to assess the safety of these products on their own responsibility at their respective production stages.

The practical relevance of this question also depends on the interpretation of the EU NFR: If an official authorisation procedure is to be carried out in accordance with the EU NFR, the requirements for safety testing are derived from this (see D.I. above). The narrower the scope of application of the EU NFR is interpreted, the less it can be assumed that foods that are not subject to the EU NFR are safe on the basis of this categorisation alone. If, on the other hand, the scope of application of the EU NFR is interpreted broadly in accordance with the precautionary principle, special independent risk assessments may only be necessary if there are specific indications of possible risks.

It is equally unclear whether and to what extent the respective manufacturers at the respective production stages are obliged to obtain information from their suppliers about the tests carried out by them or their upstream suppliers in order to avoid such safety risks. In the same way, it is unclear whether and to what extent the respective manufacturers at the respective production stages must inform their respective customers of their own accord about the presence of category 1 NGT products and any risk assessments carried out by themselves or by their upstream suppliers (see D.I.2. above).

Points of reference for such information obligations may arise from European and national genetic engineering legislation. For example, developers who carry out genetic engineering work in genetic engineering facilities are obliged under genetic

[55] See Graf von Westphalen, in: Foerste/Graf von Westphalen, Produkthaftungshandbuch, 4th ed. 2024, § 48 para. 54 with further evidence on the justified expectation of basic safety

engineering law to categorise their work into one of four safety levels depending on the organisms used.[56] In contrast to the classification as a category 1 NGT plant, this classification is not only based on the type and number of genetic modifications. The classification also has to take account of the function and stability of the genetic modification, the location of the inserted genetic material, the toxic or allergenic effects, product risks in general and environmental considerations such as factors that influence the survival, reproduction and spread of the GMO in the environment.[57]

It is therefore quite possible that food businesses that use category 1 NGT products for the production of food must obtain information - possibly via their supply chain - from the developers of these NGT products about the key results of this risk assessment and the aspects examined therein in order to fulfil their responsibility for food safety (cf. Art. 1 para. 1 lit. a EU Food Hygiene Regulation 852/2004). Conversely, the developers of category 1 NGT products could in any case be obliged to pass on information to their customers if they have found indications of relevant risks in the context of the categorisation of their activity in one of the safety levels under genetic engineering law.

As a result, food manufacturers are liable under the ProdHaftG for the safety of the food, but not for the absence of NGT products in products. It is unclear whether and to what extent food manufacturers can and must avoid or minimise their product liability for category 1 NGT products by providing information about the presence of such NGT products and, if available, risk assessments carried out. Even if food businesses are not legally obliged to label food with or made from category 1 NGT products as such, voluntary labelling can be useful in order to reduce the associated liability risks.

[56] Section 7 GenTG, Sections 2 and 5 GenTSV, Art. 4 para. 2 to 6 of Directive 2009/41/EC on the contained use of genetically modified micro-organisms.

[57] Cf. Section 5 in conjunction with Annex 1 No. 2.1 lit. lit. d., g. and j., No. 2.2 lit. lit. a. and b. and No. 2.3 lit. lit. a. GenTSV; Annex III of the Systems Directive 2009/41/EC.

d) Material damage

Liability under the ProdHaftG also covers damage to property. However, it is limited to damage to items which, by their nature, are normally intended for private use or consumption and have been used primarily for this purpose by the injured party (cf. Section 1 sentence 2 ProdHaftG).

Liability under the ProdHaftG does not extend to property damage caused by the fact that a category 1 NGT product leads to property damage in the production process of a food manufacturer due to its altered properties (cf. D.I. above).

e) Several liable parties

If several manufacturers are liable to pay compensation for the same damage, they are liable as joint and several debtors [see above E.III.1.a) on the broad definition of manufacturer in the context of the ProdHaftG]. In the relationship between the parties liable to pay compensation, the obligation to pay compensation and the scope of the compensation payment depend on the circumstances, in particular on the extent to which the damage was primarily caused by one party or the other, unless otherwise specified (cf. Section 5 ProdHaftG).

A food manufacturer who uses category 1 NGT products, who is however not the developer of them, may be liable as a manufacturer to injured parties for full compensation due to product defects. However, if the damage is due to a product defect in the NGT product, the manufacturer can take recourse against the developer of the NGT product or, if applicable, the manufacturer of preliminary products containing the NGT product.

f) Conclusion

As a result, all food businesses that use category 1 NGT products for the production of food or import such food into the EEA are liable, within the scope of their area of responsibility, for damage to the health and property of consumers caused by specific properties of category 1 NGT products. However, liability under

the ProdHaftG does not apply to damage caused by development risks that are not recognisable according to the state of scientific and technical knowledge; in this respect, a food business is liable at most under the GenTG.

Liability under the ProdHaftG also does not apply to damage caused by the fact that food may no longer be labelled as "without genetic engineering" due to the presence of category 1 NGT products.

It is unclear whether and to what extent food manufacturers can exclude or reduce their liability for the safety of their food by informing the users of the food of the presence of category 1 NGT products. It is also unclear to what extent food manufacturers must verify the safety of category 1 NGT products or obtain information from their suppliers about the safety and any risk assessments carried out.

According to the ProdHaftG, food manufacturers are liable to third parties, but they can take internal recourse against the developers of category 1 NGT products if the damage is due to safety defects in these NGT products.

2. Product liability in tort law

The German Genetic Engineering Act (GenTG) and the German Product Liability Act (ProdHaftG) do not affect liability under other legal provisions. [58]

In German law, other legal provisions include general liability for damages arising from tort. This includes general liability for damage to health and property [a)] and liability for the violation of protective laws [b)].

a) Liability for damage to health and property

According to the general tort law of the German Civil Code (BGB)[59], anyone who intentionally or negligently injures the life,

[58] Section 37 para. 3 GenTG, Section 15 para. 2 ProdHaftG, furthermore Art. 13 Product Liability Directive 1985, Art. 2 no. 4 b) and c) as well as Art. 6 para. 3 Product Liability Directive 2024.

[59] See the English translation on the official website of the German Federal Ministry of Justice, https://www.gesetze-im-internet.de/englisch_bgb/index.html.

body, health, property or any other right of another person is obliged to compensate the other person for the resulting damage (cf. Section 823 para. 1 BGB).

From this, case law has developed liability for a breach of legal duty to maintain safety. According to this, anyone who creates or allows to persist a hazardous situation of any kind for third parties in their area of responsibility, which is associated with risks to the legal interests of third parties, must take this risk into account. They therefore have a general legal obligation to take the necessary and reasonable precautions to prevent damage to third parties as far as possible.[60] The person who is responsible for the area of a source of hazard and is in a position to take the necessary measures to avert the hazard is obliged to do so.[61]

One form of this liability in tort law for breaches of the duty to maintain safety is product and manufacturer´s liability in tort, which was developed independently of the Product Liability Act and applies in parallel to it.[62] Its content differs in part from the content of product liability under the ProdHaftG:[63]

The fundamental difference is that product liability in tort developed by German case law is not strict liability, but requires fault. What is required, therefore, is at least a negligent breach of safety obligations.[64] The scope of these legal duties to maintain safety can result from special statutory requirements, but also from requirements that case law has developed from general liability principles. Product-related legal duties to maintain safety are manifold; they extend to organisation, design, production, instruction, product monitoring and risk avoidance, e.g. through warnings or recalls.[65]

[60] On this in general Sprau, in: Grüneberg, BGB, 83rd ed. 2024, § 823 para. 46 with further references.
[61] Sprau, in: Grüneberg, BGB, 83rd ed. 2024, § 823 para. 48 with further references.
[62] In general, Sprau, in: Grüneberg, BGB, 83rd ed. 2024, § 823 para. 169 et seq.; Wagner, in: Münchener Kommentar zum BGB, 9th ed. 2024, § 823 para. 1033 et seq.
[63] For deviations, see Sprau, in: Grüneberg, BGB, 83rd ed. 2024, Section 823 para. 173 et seq.; Förster, in: Hau/Poseck, BeckOK BGB, 71st ed. 2024, Section 823 para. 685 et seq.
[64] Sprau, in: Grüneberg, BGB, 83rd ed. 2024, § 823 para. 175.
[65] Sprau, in: Grüneberg, BGB, 83rd ed. 2024, § 823 para. 176 ff. with further references.

Unlike the German Genetic Engineering Act (GenTG), German tort law product liability does not generally apply to development risks, as there is typically no breach of duty or fault in such cases.[66] In this respect, however, legal uncertainties remain because the reasonableness of gaining knowledge must be taken into account in the case of uncertain risks from novel products.[67]

In contrast to the ProdHaftG, manufactorer´s liability under tort law does not by definition extend to quasi-manufacturers and importers. Rather, it must be examined on a case-by-case basis whether and to what extent they can be accused of a breach of legal duty to maintain safety that caused the damage. However, this may also be the case for quasi-manufacturers or importers, particularly in the event of a breach of instruction and product monitoring duties to maintain safety.[68]

In contrast to the ProdHaftG, product liability under tort law also allows compensation for property damage to commercially used items.[69]

In contrast to the ProdHaftG, liability for the loss of the opportunity to label a food as "without genetic engineering" or organic is also possible under German tort law product liability. This is recognised in case law. The Higher Regional Court of Rostock, for example, has recognised the loss of the possibility of labelling an organic product as such due to the unauthorised introduction of pesticides as an infringement of property rights.[70] According to the case law of the Bundesgerichtshof (BGH), Germany's highest court of civil jurisdiction, contaminated fish feed constitutes an infringement of property rights

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[66] Sprau, in: Grüneberg, BGB, 83rd ed. 2024, § 823 para. 176 with reference to BGH, NJW 2009, 2952, para. 27.

[67] Sprau, in: Grüneberg, BGB, 83rd ed. 2024, § 823 para. 176 ff. with reference to Meyer VersR 2010, 869 for nanoproducts.

[68] Sprau, in: Grüneberg, BGB, 83rd ed. 2024, § 823 para. 184 with further references.

[69] Sprau, in: Grüneberg, BGB, 83rd ed. 2024, § 823 para. 180. In this regard, Foerste, in: Foerste/Graf von Westphalen, Produkthaftungshandbuch, 4th ed. 2024, § 21 para. 90 et seq. with many references from case law, which recognises the compensability of such damages.

[70] OLG Rostock, judgement of 20.07.2006, 7 U 117/04, NJW 2006, 3650, with reference to product liability case law of the BGH on an infringement of property in the case of a ban on the sale of fish due to contaminated fish feed (BGHZ 105, 346 = NJW 1989, 707) or in the case of wine that is still edible but has become unsaleable due to defective corks (BGH NJW 1990, 908. Foerste, in: Foerste/Graf von Westphalen, Produkthaftungshandbuch, 4th ed. 2024, § 21 para. 15 with further references.

relevant under product liability law if this leads to a ban on the sale of fish that have not been fed the feed.

It is true that case law assumes that the concept of defect developed in tortious product liability corresponds to that of the ProdHaftG.[71] However, product liability under tort law is not limited to damage caused by product defects within the meaning of Section 3 ProdHaftG.[72] An infringement of property rights can also lie in a significant impairment of the intended use of the item, which is practically equivalent to a deprivation of property.[73] This is confirmed by the statutory regulation of a significant impairment of property through the loss of labelling options pursuant to Section 36a GenTG in conjunction with Section 906 BGB (see E.II.2. above). Liability in German tort law is also not limited to damages resulting from the properties of an organism that are based on genetic engineering works (cf. Section 32 para. 1 GenTG, see E.II.1. above).

This means that there may be compensable damage if a food business supplies a manufacturer of food "without genetic engineering" with a preliminary product that contains unrecognised category 1 NGT products. If the manufacturer of the food "without genetic engineering" uses this preliminary product and thereby loses the opportunity to label its end product as a food "without genetic engineering", this can be economically equivalent to significant damage or even destruction of the end product.

The decisive factor for product liability under tort law in such cases is likely to be whether and to what extent the respective supplier can be accused of a breach of legal duty to maintain safety. Such a breach of duty is likely because the labelling of food "without genetic engineering" generally requires that the food manufacturer has binding declarations from the upstream supplier that the requirements for labelling have been met (Section 3b sentence 1 no. 1 EGGenTDurchfG). If a supplier makes

[71] Thus Wagner, in: Münchener Kommentar zum BGB, 9th edition 2024, ProdHaftG § 3 para. 3 with reference to BGH, judgement of 16 June 2009, VI ZR 107/08, BGHZ 181, 253 (airbag), para. 12.
[72] See Wagner, in: Münchener Kommentar zum BGB, 9th edition 2024, ProdHaftG § 3 para. 3 and BGB § 823 para. 1068.
[73] Sprau, in: Grüneberg, BGB, 83rd ed. 2024, § 823 para. 7 with further references.

such a declaration untruthfully, it is likely to be either a breach of their own legal duty to maintain safetyor a breach of the legal duty to maintain safety of one of the supplier's upstream suppliers.

Product liability under tort law could therefore allow a food business that is no longer able to label food produced from NGT products as "without genetic engineering" due to the unrecognised supply of NGT products to directly claim against the business in the food chain that is responsible for the incorrect labelling of a preliminary product due to its own breach of legal duty to maintain safety.

Whether and in which cases such liability can actually exist has not yet been clarified by the courts.

Here too, several liable parties are considered joint and several debtors. A party liable for compensation can therefore take recourse against other parties liable for compensation in the internal joint and several debtor compensation in accordance with the respective shares of responsibility.

b) Liability for violation of protective laws

Furthermore, anyone who wilfully or negligently violates a law intended to protect another person is obliged to pay compensation (cf. Section 823 para. 2 BGB). This may also give rise to claims under product liability law.[74]

Food law regulations, in particular the general requirements for food safety in accordance with Art. 14 Para. 1 and Para. 2 No. 1 of the Basic Food Regulation 178/2002, are recognised as protective laws with regard to consumer protection.[75] They are concretised by the requirements for food hygiene, including the HACCP principles (see D.I.2. above).

[74] See Wagner, in: Münchener Kommentar zum BGB, 9th ed. 2024, § 823 para. 1147 et seq.

[75] BGH, judgement of 19 November 1991, VI ZR 171/91, BGHZ 116, 104 (Hochzeitsessen) on the protective character of the former Section 8 No. 1 LMBG (old version), according to which it was prohibited to produce food that was harmful to health. This regulation was replaced by Art. 14 para. 1 and para. 2 no. 1 of the Basic Food Regulation 178/2002 and § 5 para. 1 of the Food and Feed Code. See Teufer, in: Foerste/Graf von Westphalen, Produkthaftungshandbuch, 4th ed. 2024, § 48 para. 15 with further evidence; Sprau, in: Grüneberg, BGB, 83rd ed. 2024, § 823 para. 68; Wagner, in: Münchener Kommentar zum BGB, 9th ed. 2024, § 823 para. 1158 et seq.

The protective character of labelling regulations under food law is also recognised.[76]

Insofar as they serve to protect health, liability should, according to a view expressed in the commentary literature, only extend to damage to health, but not to financial losses, such as those that may occur as a result of a marketing stop due to contamination.[77] Whether the traceability requirements have the character of protective legislation is disputed.[78] The scope of the obligation to protect is therefore partially unclear in this respect.

With regard to food containing category 1 NGT products, liability for violation of protective legislation may be considered in particular if a food business places such food on the market without fulfilling the requirements of the EU NFR for novel foods. The requirements of the EU NFR are likely to be categorised as protective legislation because they serve to protect health and consumers.

In addition, under German law, liability for damage to health and property also applies in accordance with Section 823 para. 1 BGB. As a rule, the violation of a protective law should also be categorised as a violation of a legal duty to maintain safety. Legal duties to maintain safety can, however, go further than obligations under food law if and to the extent that the respective courts consider further measures to prevent damage to be necessary and reasonable.

IV. Liability in the EU and third countries

As the provisions of the ProdHaftG are based on the Product Liability Directive 85/374/EEC (Product Liability Directive 1985), key principles of German product liability law apply throughout the EU. This will not change with the new Product Liability Directive 2024/2835 (Product Liability Directive

[76] OLG Frankfurt, judgement of 20.03.1997, 1 U 162/95 (Kindertee) on the protective character of the former Section 3 LMKV old version with requirements for the labelling of foodstuffs in pre-packaging. See Sprau, in: Grüneberg, BGB, 83rd ed. 2024, § 823 para. 68; Wagner, in: Münchener Kommentar zum BGB, 9th ed. 2024, § 823 para. 1159.

[77] Thus Wagner, in: Münchener Kommentar zum BGB, 9th ed. 2024, § 823 para. 1158 et seq. with reference to Stollhof, Zivilrechtliche Haftung bei Lebensmittelskandalen, 2018, 313.

[78] See Wagner, in: Münchener Kommentar zum BGB, 9th edition 2024, § 823 para. 1161 with further references.

2024)[79]. This directive obliges the member states to transpose further regulations on the burden of proof and the disclosure of evidence into national law by 09.12.2026 (see Art. 9, 10 and 22 of the Product Liability Directive 2024, see E.I. below).

The principles laid down by EU law include, in particular, the broad concept of manufacturer,[80] liability for product defects and the relevance of the expectation of safety,[81] limited liability for property damage[82] and joint and several liability.[83]

A significant difference between national and EU law is that the liability of manufacturers under EU law for development risks not recognisable according to the state of scientific and technical knowledge at the time of placing on the market is generally excluded.[84] It is left to the Member States to decide whether and to what extent they extend product liability to such development risks.[85] According to information provided by the Commission in 2018, liability for development risks is provided for to varying degrees in five Member States; in three of them (Finland, Luxembourg and Spain), the extended liability applies to food (and therefore probably also to genetically modified food).[86] Liability for development risks therefore depends on the applicable national law.

The national law applicable to the individual case is governed by the private international law of the Rome II Regulation. [87]

Accordingly, the applicable law in cases in which both the injured party and the business against which a claim is made have their habitual residence in the same country at the time the damage occurs is the law of that country (Art. 4 para. 2 Rome II Regulation).

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[79] Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC.
[80] Art. 3 Product Liability Directive 1985, Art. 4 No. 10 and Art. 8 Product Liability Directive 2024.
[81] Art. 6 Product Liability Directive 1985, Art. 7 Product Liability Directive 2024.
[82] Art. 9 sentence 1 lit. b Product Liability Directive 1985, Art. 6 para. 1 b) iii) Product Liability Directive 2024.
[83] Art. 5 Product Liability Directive 1985, Art. 12 and Art. 14 Product Liability Directive 2024.
[84] Art. 7(e) of the Product Liability Directive 1985, Art. 11(1)(e) of the Product Liability Directive 2024.
[85] Art. 15 Product Liability Directive 1985, Art. 18 Product Liability Directive 2024.
[86] Commission report on the application of the Product Liability Directive of 7 May 2018, COM(2018) 246 final, p. 4, and (slightly deviating) the associated working document SWD(2018) 157 final, p. 10, according to which liability for development risks applies to all sectors in Luxembourg and Finland. In Hungary and Spain, it applies to medicinal products; according to the Commission's working document, it also applies to food in Spain and to products of the human body in France. The German special regulation for GMOs is not even mentioned in the documents.
[87] Regulation (EC) 864/2007 on the law applicable to non-contractual obligations.

If this is not the case, product liability cases are generally governed by the law of the country in which the injured party had their habitual residence when the damage occurred, provided that the product was placed on the market in that country (Art. 5 para. 1 lit. a of the Rome II Regulation).[88] This applies to all cases of product liability regardless of the type of liability and legal source. It therefore applies not only to strict liability under the German Product Liability Act and the Product Liability Directive, but also to product liability in tort.[89] It should therefore also apply to special product liability under the German Genetic Engineering Act (GenTG).

German law therefore also applies to cases of damage caused to an injured party residing in Germany by a business based in Germany or a food product placed on the market in Germany, even if the category 1 NGT product causing the damage was produced in another country. The food business is then also liable for damage caused by category 1 NGT products under German genetic engineering law and therefore also for unrecognisable development risks if it is the operator within the meaning of the Genetic Engineering Act (GenTG), i.e. if it developed the NGT plant or placed it on the market in Germany for the first time.

Conversely, in the event of damage caused to an injured party domiciled in another country by a company based there or by a food placed on the market there, the law applicable there also applies if the food was produced in Germany.

For example, under Spanish, Luxembourg and Finnish product liability law[90], a food business is also liable for damage caused to an injured party based there due to a business based there or a product placed on the market there with category 1 NGT products for unrecognisable development risks.

The Rome II Regulation also stipulates that, in the event of recourse by one party liable to pay compensation to another party liable to pay compensation in another country, liability is governed by the law applicable to the original obligation to pay compensation (Art. 20 Rome II Regulation). In product liability cases, the law applicable to the injured party also applies to recourse against other parties liable to pay compensation.

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[88] For the applicable law in other constellations, see Art. 5 para. 1 sentence 1 lit. b) and c) of the Rome II Regulation.

[89] Sprau, in: Grüneberg, BGB, 83rd ed. 2024, Rome II Art. 5 para. 3 with further references.

[90] In accordance with the above-mentioned Commission reports; otherwise, the existence and scope of product liability claims in the above-mentioned Member States has not been examined here.

This means that German law also applies if a food manufacturer liable to pay compensation for a claim in Germany wishes to take recourse against a manufacturer of a category 1 NGT product based in another country who is also liable to pay compensation within the framework of joint and several liability. The same applies to Spanish, Luxembourg or Finnish law. The scope of liability for development risks therefore also depends on the law of the Member State in which the product was placed on the market and the damage occurred in the case of recourse claims.

V. Liability for environmental damage

Special liability for environmental damage can generally be considered under the German Environmental Liability Act (UmweltHG) and the German Environmental Damage Act (USchadG).

Liability under the German Environmental Liability Act (UmweltHG) is liability for damage caused by the environmental impact of certain industrial plants (see Section 1 UmweltHG). With regard to plants in the food industry, only mills and plants for extracting vegetable fats or oils are affected (Annex 1 No. 66 and 67 UmweltHG). Liability is limited to damage caused by environmental impacts emanating from a plant that have spread to soil, air or water (cf. Section 3 para.1 UmweltHG). The placing on the market of NGT products in food is not covered by this. Liability under the UmweltHG is therefore only likely to be considered in very specific cases, for example if category 1 NGT products are released into the environment from one of the aforementioned facilities and damage is caused as a result.

Furthermore, hazard prevention and remediation obligations may arise under the German Environmental Damage Act (USchadG). This is based on the EU requirements of the Environmental Liability Directive 2004/35/EC. In this respect, the different designations of the three sets of regulations as environmental damage or environmental liability regulations are unfortunate.

The German Environmental Damage Act (USchadG) and the Environmental Liability Directive require remedial measures if the placing on the market of a GMO causes damage to species and natural habitats that has a significant impact on the achievement or maintenance of the favourable conservation status of these habitats or species.[91] Qualified damage to water bodies or

[91] Section 3 para. 1 no. 1 in conjunction with. Annex 1 No. 11 and Section 6 USchadG as well as Section 19 BNatSchG, Art. 6 in conjunction with Art. 2 No. 1 and Annex I Environmental Liability Directive 2004/35/EC. Art. 2 No. 1 and Annex I Environmental Liability Directive 2004/35/EC.

soil can also constitute compensable environmental damage (see Section 2 No. 1 USchadG).

Responsibility under the USchadG and the Environmental Liability Directive is therefore not a civil liability, but an obligation to act under public law, which is primarily aimed at compensating for ecological damage. It is most likely also only to be considered in very specific cases.

F. Recognisability, enforceability and lack of insurance cover

In addition to the question of liability, the recognisability of category 1 NGT products (I.) and the question of the enforceability of any claims for damages or recourse (II.) are of practical importance.

I. Recognisability and provability

The recognisability of category 1 NGT products plays an important role both for damage to health and property due to specific properties of the NGT products and for labelling damage due to the mere presence of category 1 NGT products.

A fundamental problem is that, unlike for authorised GMOs, developers of category 1 NGT plants will not have to submit any identification and detection methods or reference material to the authorities in accordance with the NGTR.[92] It is therefore possible that category 1 NGT products will initially not be analytically detectable at all. Until reliable detection methods have been developed, NGT plants may have mixed unrecognised with others and thus led to unrecognised entries into food "without genetic engineering". As a result, damages may accumulate unrecognised.

Furthermore, it may take a long time to establish and prove that certain damage to health or property is due to specific properties of category 1 NGT products. Furthermore, it can be difficult to prove.

Injured parties regularly have no insight into product development and the associated specific risks. They are therefore often unable to prove that dam-

[92] See the corresponding requirement in Article 5(3)(i) and (j) of Regulation (EC) No 1829/2003 on genetically modified food and feed in conjunction with Article 3(1)(e), Article 4(1), second sentence, and Annexes I and II of Implementing Regulation (EC) No 641/2004; also Annex III A, points III.C.2. f) and g), Annex III B No. I.B. 5. and No. II.B.5, and Annex IV A.7. of Directive 2001/18/EC on the deliberate release into the environment of GMOs.

age is attributable to a genetic modification. For this reason, German genetic engineering law as well as European and national product liability law contain special simplified or facilitated rules of evidence for the enforcement of claims for compensation.

According to German genetic engineering law, if damage has been caused by GMOs, it is presumed that it was caused by properties of these GMOs that are based on genetic engineering work (cf. Section 34 para. 1 GenTG). The party liable for compensation can rebut this presumption if it is likely that the damage is due to other properties of these organisms (cf. Section 34 para. 2 GenTG).[93]

Furthermore, the operator and the authority responsible for monitoring a genetic engineering facility must, at the request of the injured party, provide information on the nature and course of the genetic engineering work carried out in the genetic engineering facility or underlying a release. They must do this insofar as this is necessary to determine whether a claim exists, if facts exist that give rise to the assumption that personal injury or damage to property is due to genetic engineering work carried out by an operator (cf. Section 35 para. 1 GenTG).[94]

Product liability law also makes it easier to provide evidence. In principle, the injured party bears the burden of proof for the defect, the damage and the causal connection between the defect and the damage.[95] However, the manufacturer bears the burden of proof for the existence of liability exclusions. [96]

The manufacturer must therefore prove that the conditions for a development risk that was not recognisable at the time the product was placed on the market are met. This is likely to be difficult for a food business that has only used but not developed a category 1 NGT product. In this respect, support from the developer of the respective NGT plant is likely to be indispensable.

According to the current revision of the Product Liability Directive, injured parties must also be granted claims against manufacturers for the disclosure

[93] See Kohler, in: Staudinger/Kohler, Umwelthaftungsrecht, 2017, Sections 32-37 GenTG para. 21.
[94] Kohler, in: Staudinger/Kohler, Umwelthaftungsrecht, 2017, §§ 32-37 GenTG para. 38 ff. on this and on similarities with and differences to comparable claims for information under Sections 8 to 10 UmweltHG.
[95] Section 1 (4) sentence 1 ProdHaftG, Art. 4 Product Liability Directive 1985, Art. 10 (1) Product Liability Directive 2024.
[96] Section 1 para. 4 sentence 2 in conjunction with Para. 2 and 3 ProdHaftG, Art. 7 Product Liability Directive 1985, Art. 11 Product Liability Directive 2024.

of evidence (Art. 9 of the Product Liability Directive 2024). If the manufacturer does not disclose such evidence, the defectiveness of the product will be presumed [Art. 10 para. 2 lit. (a) of the Product Liability Directive 2024]. Further facilitation of evidence is also provided for (Art. 10 para. 2 to 5 of the Product Liability Directive 2024). In future, a national court is to assume the defectiveness of a product or the causal link between defectiveness and damage if it is excessively difficult for the plaintiff to prove this despite the disclosure of evidence, in particular due to the technical or scientific complexity, and the plaintiff proves the probability of a defect or a causal link (Art. 10 para. 4 of the Product Liability Directive 2024). The member states must transpose these regulations into national law by 09.12.2026 (Art. 22 Product Liability Directive 2024).

According to the distribution of the burden of proof developed by case law in product liability under tort law, the injured party bears the burden of proof with regard to the product defect and its causality for the breach of legal interests that has occurred, while the manufacturer must exonerate itself with regard to the breach of the duty of care.[97]

As a result, the lack of recognisability of category 1 NGT products can lead to damage to health and property as well as labelling damage only being recognised when the damage has reached a significant level.

Conversely, the legislator and the courts have developed simplified rules of evidence and obligations to provide information for operators of genetic engineering work in order to take account of the asymmetry of knowledge between developers of GMOs and injured parties and to facilitate the enforcement of claims for compensation.

II. Enforceability and lack of insurance cover

The enforceability of any claims for damages and recourse depends on the capacity and tangibility of the respective liable party and the existence of insurance cover.

The scope of the insurance cover of any parties liable to pay compensation depends on the individual insurance contract concluded. There is no legal obligation to take out liability insurance.

[97] See only Wagner, in: Münchener Kommentar zum BGB, 9th ed. 2024, § 823 para. 1138 with further references.

Since 1990, the German Genetic Engineering Act has required the Federal Government to oblige those who carry out releases or operate genetic engineering facilities in which genetic engineering work of safety levels 2 to 4 is to be carried out to take precautionary measures to cover claims for damages, e.g. through liability insurance (Section 36 GenTG). However, this obligation does not exist because the Federal Government has never issued a corresponding ordinance.[98]

The content of insurance contracts in Germany is usually based on the standard terms and conditions of the German Insurance Association (GdV). According to their General Insurance Conditions for Business and Professional Liability Insurance (AVB BHV) of March 2024[99], claims and obligations due to damage attributable to GMOs or products containing components from GMOs or produced from GMOs or with the help of GMOs are generally excluded. This applies both to the insurance of the general public and professional liability risk and to the insurance of the environmental liability and product liability risk.[100]

These insurance exclusions are comprehensive. They apply to damage to health and property, including damage caused by contamination with GMOs. The exclusions also apply to category 1 NGT products, as NGT products are GMOs by definition (see C. above). Finally, they apply both to original claims for damages and to recourse claims in the context of joint and several debtor compensation between several liable parties.

Food businesses must expect to be held liable for any damage to health or property caused by category 1 NGT products. However, they will generally not be insured against these risks and will not be able to insure themselves against them.

In the event of damage, they will have a right of recourse against the developer of category 1 NGT products and, where applicable, the suppliers of preliminary products. However, due to a lack of insurability and if the developer is based in a country in which such claims cannot be enforced, food businesses must expect to have to bear the damages themselves.

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[98] See Kohler, in: Staudinger, BGB, Umwelthaftungsrecht, 2017, Sections 32-37 GenTG para. 17, although not explicitly referring to labelling risks.

[99] Published under https://www.gdv.de/gdv/neu-strukturierte-haftpflichtbedingungen-ab-2014--5962.

[100] Sections A1-7.8 AVB BHV for the general public and professional liability risk, A2-8.8.1 for the environmental liability risk and sections A3-8.8 AVB BHV for the product liability risk.

G. Regulatory requirements

Against this background, it is highly recommended to refrain from deregulating category 1 NGT products in order to protect food businesses.

Should the EU legislator nevertheless adhere to the deregulation of category 1 NGT products, it should supplement the Regulation with standardised liability rules throughout the European Union. These rules should include:

- For category 1 NGT products, which themselves or their processing products may be novel foods due to genetic modification, it should be regulated in the NGTR that their placing on the market is only permitted if the corresponding novel foods are also authorised. Otherwise, seeds can be placed on the market even though the products obtained from them may not be used as food. As a result, there is a risk of multiple violations of the requirements of the EU NFR due to mere unawareness, for which the food businesses are liable.
- Labelling requirements should be included in the NGTR for all category 1 NGT products and the entire food chain. All food businesses must know whether the foods and ingredients they use are NGT products in order to be able to verify compliance with the requirements of the EU NFR with legal certainty.
- An EU-wide standardised obligation for developers and importers of category 1 NGT plants to compensate for damage caused by NGT products, which also includes compensation claims for development risks. If the official assessment is cancelled without replacement, the originator's responsibility must remain enforceable via liability law regardless of the EEA state in which the injured party is based and the state in which the product was placed on the market.
- Category 1 NGT products should only be allowed to be placed on the market if compensation for damage caused by such NGTs is covered by a specified, sufficient coverage, e.g. by liability insurance covering damage caused by GMOs or, if no liability insurance covers such damage, by a state-regulated liability fund.
- In connection with liability for damage caused by NGT products the right to disclosure of evidence against liable parties and authorities provided for in the Product Liability Directive 2024 should also apply outside of court proceedings (cf. the corresponding right to information in German genetic engineering code: Section 35 GenTG).