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ENGA summary of the implications for the food sector of the European Commission's deregulation proposal of New Genomic Techniques

A political précis of new legal opinion

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ENGA summarises for key EU audiences a new legal opinion, 'On the liability of food businesses for new genetic engineering in the event of deregulation' by lawyer Dr Buchholz, commissioned by VLOG (The German Association of Food without Genetic Engineering), which lays out the legal responsibilities of the food industry should New Genomic Techniques be deregulated as per the European Commission's proposal.

ENGA's overall conclusion:

The EU Commission's deregulation proposal shifts responsibility for the safety assessment of New Genomic Techniques (NGTs) and liability risks from biotech companies to food companies. All the burden will be at the expense of the EU food sector.

According to the EU Commission, the entire agricultural and food sector in the EU should benefit from its deregulation proposal in terms of competitiveness within and outside the EU, and a level playing field should prevail for entrepreneurs. However, the Commission's proposal does not fulfil this objective, as the legal opinion shows.

In its proposal for a *Regulation of the European Parliament and of the Council on plants derived from certain new genomic techniques and the food and feed derived from them and amending Regulation (EU) 2017/625*, the EU Commission names under 'general objectives':

- *ensure the effective functioning of the internal market in NGT plants and products and food and feed containing, consisting or produced from NGT plants,*
- *enhance the competitiveness of the Union agri-food sector at the Union and global levels, including a level-playing field for operators.*

Quite the contrary, **the proposal creates winners and losers**. If the proposed legislation is passed without any significant changes, the winners in the agri-food sector would be biotech and seed companies that develop and market NGTs. The losers would be EU food companies, i.e. farmers, manufacturers, processors and food retailers.

Safety checks under the Novel Food Regulation are the responsibility of food companies.

The EU Commission's proposal exempts biotech and seed companies from the obligation to carry out a risk assessment for category 1 NGTs. Instead, a so-called verification procedure is used to check whether NGT plants fall under category 1. It is of a technical nature and does not involve any risk assessment or risk management considerations.

According to the Commission, this will save biotech companies costs of up to 11.2 million euros per authorisation.[1] A study by the German Federal Agency for Nature Conservation (BfN) shows that around 94 per cent of all NGTs in the development pipelines fall under category 1.[2]

According to the EU Commission, safety tests for category 1 NGTs could have to be carried out in accordance with the Novel Food Regulation and will be the responsibility of EU food companies. If they place food on the market that contains or is made from category 1 NGT products, they must check whether:

- It is a Novel Food within the meaning of EU Regulation 2015/2283 on Novel Foods;
- Its placing on the market requires official authorisation in accordance with the EU Novel Food Regulation;
- And whether it is already included in the Union list of authorised Novel Foods.

If they are not sure whether a food is novel, they must consult the Member State in which they first want to place the food on the market**. If it is a Novel Food, they may only place it on the market once a safety assessment has been carried out in accordance with the Novel Food Regulation** and the food has been included in the Union list of authorised Novel Foods.

The legal opinion summarises: **"This shifts the authorisation burden from the developer of the NGT plants to food companies.** If category 1 NGT plants were still authorised as GMOs, this would not be necessary. This is because the EU Novel Food Regulation does not apply to genetically modified food in accordance with Regulation (EC) No. 1829/2003 on genetically modified food and feed (Art. 2 para. 2 letter a EU Novel Food Regulation)."

Lack of labelling for NGT 1 food and feed puts food companies at risk of breach of the law.

Food businesses often may not even be aware that they are placing an NGT1 food on the market. This is because the Commission's proposal only provides for a labelling obligation for seeds and plant propagating material, not for food and feed. According to the Commission's proposal, transparency rules would only apply to seed companies, but not to all other economic operators. Furthermore, NGT1 seeds would be allowed to be placed on the market even if the foodstuffs produced from them were not authorised under the Novel Food Regulation and therefore are not allowed to be sold. This means that food companies along the entire food chain, from farmers to retailers, could unknowingly violate the Novel Food Regulation. One way to protect themselves from this breach of the law is to obtain assurances from their suppliers that food does not contain NGT1 products.

The Commission's proposal does not include a calculation of the costs imposed on EU food companies because of having to carry out safety tests for NGT1 products in accordance with the Novel Food Regulation. Consequently, the Commission does not differentiate between

[1] *The savings for breeders per verification procedure are estimated to range from EUR 9.95 million to EUR 11.2 million. For administrations, the total savings for verification procedures are estimated to be up to EUR 1.4 million per year.*

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

multinational corporations and small and medium-sized food businesses, for which the administrative and financial burdens are likely to be much more significant.

Liability under the Food Hygiene Regulation and Product Liability lies with the food companies.

EU GMO law does not contain any specific GMO liability provisions. According to EU GMO law, biotech and seed companies are not obliged to pay for the risks of genetically modified plants and genetically modified products or any damage caused by them.

Liability under GMO law is governed exclusively by national law. Germany, for example, has enacted specific regulations, where strict liability applies for damage caused by genetically modified properties and claims can be asserted for impairment of use, i.e. for GMO contamination. Otherwise, the general civil liability regulations that apply throughout Europe based on the national civil codes also apply to GMOs and the damage they can cause.

EU food businesses are always liable for the products they place on the market, firstly under EU food law and secondly under EU product liability law.

The legal opinion quotes from the EU Food Hygiene Regulation: "The general principle of food law that the primary responsibility for the safety of a foodstuff lies with the food business operator applies (...) (Art. 1 para. 1 letter a EU Food Hygiene Regulation 852/2004)."

According to the EU Product Liability Directive, the manufacturer of a product is liable for damage to health and property caused to an injured party by a defect in the product. A manufacturer is deemed to be anyone "who, by affixing his name, trademark or other distinctive sign, holds himself out as the manufacturer (...). Furthermore, anyone who imports or brings a product into the European Economic Area (EEA) for the purpose of selling it in the course of their business activities (importer) is deemed to be a manufacturer."

According to the legal opinion, food businesses are liable for certain damage caused by NGT products even if they do not know that a food they have placed on the market contains NGTs.

This is a very likely scenario, as the Commission's legislative proposal for category 1 NGTs only provides for labelling for seeds, but not for food and feed: "Any food business that is a producer in the product liability sense of a food containing or produced from NGT products shall be liable for any injury to health or property caused by NGT products. This applies regardless of whether the respective manufacturer knows that the food contains or is made from NGT products. This is because product liability is a strict liability."

The legal opinion summarises: "As a result, (...) all food businesses that use NGT products of category 1 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 NGT products of category 1."

Liability under the Product Liability Act does not apply to damage caused by unrecognisable development risks, i.e. risks that were not recognisable according to the current state in science and technology at the time the product was placed on the market. However, this only partially relieves food companies, as in the event of damage they bear the burden of proof that the damage was not recognisable at the time of placing on the market according to the current state in science and

technology. In the EU, developers of NGT products are only liable in a few countries[3] for risks that were not recognisable at the time the product was placed on the market.

Under the Product Liability Act, food companies can take recourse against the developers of category 1 NGT products if the damage is due to safety defects in these products. However, whether and to what extent they will be reimbursed for the costs they have incurred depends largely on whether the biotech companies responsible are available and solvent. As many NGT products are developed in Asia and by small biotech companies, this seems doubtful.

No insurance covers genetic engineering damage.

Whilst it is common practice for food companies to end up being liable for their products, they generally are covered by insurance for damage caused. This is not the case for GMOs: no insurance company covers damage caused by genetic engineering. Damage caused by genetic engineering is explicitly excluded from general liability insurance; and special insurance does not exist. **In the event of damage, food companies are left without insurance cover for damage caused by food containing NGTs.**

Conclusion

With its legislative proposal on NGTs, the EU Commission is making policy, which is in favour of biotech companies, and which is to the detriment of food companies. As far as safety tests for category 1 NGTs are concerned, they will either be carried out by food companies in accordance with Novel Food legislation or not at all; in this case, completely untested NGT1 products will be placed on the market and on consumers' plates.

Possible cases of damage affect consumers first, then the food industry. The latter is liable for the safety of its products. It also bears the burden of proof for unrecognisable development risks, i.e. it must prove that any damage caused was not recognisable at the time the product was placed on the market according to the current state in science and technology.

Whether food companies can rely on compensation from developers of NGT1 products in the event of liability is more than questionable. This is because, on the one hand, they must have the necessary resources for such legal action (a problem especially for small and medium-sized companies) and, on the other hand, biotech companies must be accessible and solvent. This depends on where they are based and how financially strong they are - this criterion is unlikely to apply to start-ups. Insurance companies will not pay compensation instead of biotech companies: No insurance covers damage caused by genetic engineering.

Food companies that do not accept the less favourable legal position assigned to them in the Commission's proposal are urgently recommended to lobby the EU institutions to maintain the current EU legislation. In any case, an NGT regulation should include the following:

[3] In Finland, Luxembourg and Spain

ENGA's Demands:

- All NGT products may only be placed on the EU market if their safety has been adequately tested.
- Confirmation of the NGT1 status of an NGT1 product is not sufficient for placement on the market. For seeds that are used for food production, it must be clarified before they are placed on the market whether the food is subject to the Novel Food Regulation. If this is the case, the corresponding safety assessment must be completed, and the food must be included in the Union list of authorised Novel Foods. Without these measures, food businesses throughout the food chain run the risk of unknowingly violating the Novel Food Regulation.
- Food businesses must know that they are placing an NGT food on the market. This is the only way they can fulfil their obligations under the Novel Food Regulation. To this end, the labelling obligation for category 1 NGTs must be extended to the entire food chain. In addition, manufacturers and marketers of NGT1 plants must be obliged to submit detection measures, reference material and information on the genetic modifications and their location in the genome as part of the status verification procedure (or an actual authorisation procedure with safety testing). This will give food companies (and authorities) the opportunity to check whether the labelling obligation has been complied with.
- All developers of genetically modified plants placed on the EU market must be fully liable for development risks of their products, i.e. for damage caused by genetic engineering, regardless of whether these were recognisable according to the current state in science and technology.
- NGT products may only be placed on the EU market if compensation for damage is covered by adequate insurance in all Member States. A state-regulated liability fund into which biotech companies that place NGTs on the EU market must pay could be considered. Theoretically, damage could also be covered by adequate liability insurance. However, there are no signs that insurance companies will cover genetic engineering risks.

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