European Non-GMO Industry Association

ENGA AISBL
Rue du Trône 194
1050 Ixelles
+32 (0) 493 33 5491

Background paper on NGT traceability, NGT labelling and NGT detection methods

Traceability

Parliament's position

Only Parliament voted for the traceability of *all* NGTs, taking a different position from the Council and Commission. The text agreed by the Parliament on traceability, in article 10, reads: "Appropriate document-based traceability for NGTs shall be provided by the transmission and holding of information that products contain or consist of NGT plants and product, and the unique codes for those NGTs, at each stage of their placing on the market."

According to the Parliament, at each stage of their marketing, information must be transmitted and retained for any products that contain or consist of NGT plants and products. Each NGT must also have a unique code. The starting point for traceability will be seed labelling, which is the common stance for all three institutions.

However, seed labelling only applies to agricultural production in the EU, not to imports from outside the EU. **Clarification** should therefore be provided here: **As soon as a product enters the EU market, the NGT status and the unique code must be recorded via the traceability system.**

General EU food law

Traceability is a general standard in general EU food law. It is not specific to GMO products and will not be specific to NGT products. Traceability is legally binding and always feasible. Article 18 ("Traceability") of Regulation (EC) 178/2002 states that "Food or feed which is placed on the market or is likely to be placed on the market shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions."

Traceability in EU GMO law

Traceability is a long-established practice in EU GMO legislation. Thus, a traceability system for NGTs does not have to be reinvented, rather the existing system must be adapted to NGTs. Regulations (EC) 1829/2003 and (EC) 1830/2003 require GMOs to be identified through documentation systems when technical evidence is not possible. Traceability systems are used, for example, for oil from GMO soy and sugar from GMO sugar beet.

Costs for NGT traceability

According to general EU food law, every product is subject to a traceability system. **For products that contain or consist of NGTs it is merely a matter of transmitting two additional pieces of information to the traceability system: "NGT" and the unique code.**

What traceability means for authorities

Another argument in favour of setting up a traceability system for all NGTs is that traceability enables authorities to **monitor NGTs and intervene in the case of negative health or environmental effects** that may appear after a market authorization.

The Parliament voted in favour of the monitoring of environmental effects of NGT1 plants (article 7) as well as for three amendments called "withdrawal of the decision" (articles 11a, 17 and 21). "Withdrawal" means that marketing of the NGT plant or the product (NGT1 and NGT2) "may" be prohibited by the competent authority "if the monitoring results show that there is a risk to health or the environment" or if "new scientific data supports this hypothesis."

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In addition, the Commission has been obliged to establish a detailed monitoring program and to report on "intended and unintended effects and systematic effects on the environment, biodiversity and ecosystems" (article 30); 24 months after entry into force of the new legislation at the latest.

Labelling

Parliament's position

While the Commission and Council only want seed labelling for NGT1 plants, the Parliament has spoken out in favour of labelling for category 1 NGT plants, plant reproductive material and products containing or consisting of category 1 NGT plant(s) throughout the entire supply chain right up to the product on the supermarket shelf. The label should read 'New Genomic Techniques'. This decision is even more important because, according to a study by the Federal Agency for Nature Conservation, 94% of the NGTs currently in the companies' pipelines fall under category 1.[1]

Article 10 of the Parliament's position reads: "Category 1 NGT plants, products containing or consisting of category 1 NGT plant(s) and plant reproductive material, including for breeding and plant reproductive material, including for breeding and scientific purposes that contains or consists of category 1 NGT plant(s) and is made available to third parties, whether in return for payment or free of charge, shall bear a label indicating the words 'New Genomic Techniques'. In the case of plant reproductive material, it shall be followed by the identification number of the NGT plant(s) it has been derived from."

For category 2 NGTs GMO labelling is mandatory according to all three institutions.

Consumers' right to know

Consumers' right to know is an essential social and political achievement. Their right to information is enshrined in the Treaty of the European Union: "In order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests." (Article 169(1) Treaty of the European Union)

The EU General Food Law adds to Article 169(1) of the Treaty of the European Union: "Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume." (Article 8 (1) of Regulation (EC) 178/2002)

To abolish NGT labelling for category 1 plants and products would not only be an unjustifiable step backwards, but would also promote mistrust against NGTs: **If NGT products are as convincing as their proponents claim - why should they remain invisible in order to be a success on the market?**

EU Food Sector's need to know

Labelling and transparency for NGT1 plants and products is also a major topic for the EU food industry. **To preserve their entrepreneurial freedom, food business operators** throughout the value chain, i.e. breeders, farmers, beekeepers, feed and food processors and retailers, **must have the right to know what food they are producing and selling, regardless of whether they work organically or conventionally.**

[1] Federal Agency of Nature Conservation (2024): Where does the EU-path on new genomic techniques lead us? https://www.frontiersin.org/journals/genome-editing/articles/10.3389/fgeed.2024.1377117/full

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A legal opinion by the Berlin law firm GGSC[2] emphasises the importance of labelling throughout the whole value chain for food companies. According to recital 22 of the NGT legislative proposal food, companies must check whether an NGT1 plant requires authorisation under the Novel Food Regulation. If it does, food companies are responsible for safety tests. However, food companies cannot know that they are placing food on the market that contains category 1 plants and that they could have to fulfil the Novel Food Regulation requirements. That's because the Commission's proposal only provides for a labelling obligation for seeds and plant propagating material, but not for food and feed. Transparency rules would only apply to seed companies, but not to all other economic operators. Furthermore, according to the Commission's proposal, NGT1 seeds could 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**. **To avoid the fact that the entire EU food sector runs the risk of violating the obligations which the Commission's legislative proposal assigns to them, the labelling obligation for category 1 NGTs must be extended to the whole food chain.** 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. Regarding the EU food sector an extended labelling would be desirable: Is an NGT of category 1 a Novel Food and does it have a Novel Food authorisation?

As far as liability risks for the food sector are concerned, the legal opinion explains**: In the event of damage, claims would primarily be made against food manufacturers and retailers.** They are liable for defective food and the resulting damage. Even if they can take recourse against the developers of the NGT1 products, such claims will often not be enforceable, particularly in the case of biotechnology companies abroad or companies with limited assets. Food companies are usually insured against liability risks, such as damage to health. However, there is no insurance that covers GMO/NGT risks. **Due to these liability risks alone, the food sector should know - through labelling across the supply chain - whether it has NGT1 products in its supply chains.**

NGT on-package labelling

An **NGT label on-package,** as proposed by the Parliament, **serves as a quick way for consumers to know** whether NGTs are in the product when shopping. In addition, **this form of transparency is also best suited for business operators because it allows quick and reliable overview.** And it has proven its worth. GMO labelling in the form of a note in the list of ingredients on food or feed has been working for more than 20 years.

For the EU food sector, tedious searching for a possible NGT origin of a product or ingredient would be an additional, time-consuming activity that would put producers that want to avoid NGTs at a competitive disadvantage.

Traceability as basis for labelling

Traceability alone can - and does - serve as a basis for labelling. If category 1 NGT products cannot (or cannot yet) be detected by analytical methods and/or if it is currently not possible to distinguish them from similar plants, they are always traceable - and can thus be labelled as GMOs or NGTs, respectively: Their traceability is possible through appropriate documentation. The fact that traceability systems work, even if

2 https://www.enga.org/fileadmin/user_upload/GGSC_legal_opinion_on_liability_in_event_of_deregulation_of_NGT.pdf

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the information given on the label cannot be verified in the laboratory, is shown by long-term experience with an EU labelling system for regional specialities and organic food, for example.

Detection methods

Council's position

Of all three institutions, the Council is the only one that is in favour of detection methods for NGT1 plants. Even if "the introduced modifications of the genetic material are not specific to the NGT plant in question", and "they do not allow the differentiation of the NGT plant from conventional plants" (…) "an analytical method should still be provided by the notifier or applicant." This should apply with the following restriction: "if duly justified, the modalities to comply with analytical method performance requirements should be adapted." (recital 28)

Food sector's need for detection methods

If companies that want to bring category 1 plants onto the market were obliged to submit detection methods, reference material and data on genetic modification, that would be a major relief for the European food sector. If the genetic variation is specific for an NGT 1, they would have analytical methods at their disposal that would allow them to know whether NGT 1 plants are present in their supply chains. But even with unspecific tests, conventional and organic Non-GMO producers in particular would have another option in addition to traceability, to guarantee that their products are Non-GMO.

It can, though, be assumed that NGT 1 developers have detection methods - simply in order to be able to assert their intellectual property, which is protected by patents.

Conclusion

Increased/enhanced transparency is a major trend in the food sector. To almost completely abolish transparency and thus freedom of choice for consumers and food companies in one of the most controversial issues in the food sector would send a fatal signal and undermine trust in EU food and EU institutions.

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