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ARTICLE

Regulatory Requirements for the Identification, Detection and Quantification of Gene-Edited Products in Light of the (R)evolution of New Genomic Techniques: State of the Art and Prospects for Changes

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Abstract

The key requirement for GMO authorisation is the submission of analytical methods for the detection, identification and quantification (DIQ), which has proven challenging in the case of New Genomic Techniques (NGTs). Currently available non-analytical approaches, such as blockchain traceability and probabilistic analysis, while potentially useful for monitoring, are insufficient for authorisation purposes. The lack of reliable DIQ methods hinders the authorisation of NGT products and raises concerns for both organic and conventional agriculture, where the presence of NGT products goes undetected. Therefore, the existing GMO regulatory framework requires reevaluation to address the challenges posed by NGTs while ensuring compliance with the broader EU food law framework.

Keywords: detection; genetically modified organisms; identification; new genomic techniques

I. Introduction

In response to numerous food safety crises, the European Union (EU) has established one of the most stringent regulatory frameworks for the food chain globally.[1] This is particularly relevant to the EU's regulation of products derived from genetically modified organisms (GMOs).[2] These regulations affect consumers and food business operators (FBOs) both within and outside the EU, with significant implications for international trade and innovation.[3,4] In order to remain compliant with international trade law the EU legislator must adapt legal solutions to (scientific) reality.[5]

[1] See H Schebesta and K Purnhagen, *EU Food Law* (Oxford, New York, Oxford University Press 2024) 7–34.

[2] MA Pollack and GC Shaffer, "Risk Regulation, GMOs and the Limits of Deliberation" in D Naurin and H Wallace (eds), *Unveiling the Council of the European Union* (London, Palgrave Macmillan UK 2008) 144 and MA Pollack, "International Trade and Risk Regulation: Whatever Happened to the Transatlantic Gmo Conflict?" APSA 2013 Annual Meeting Paper, American Political Science Association 2013 Annual Meeting, 1.

[3] J Martínez-Fortún and Others, "Natural and Artificial Sources of Genetic Variation Used in Crop Breeding: A Baseline Comparator for Genome Editing" (2022) 4 Frontiers in Genome Editing 13.

[4] G Brookes and SJ Smyth, "Risk-Appropriate Regulations for Gene-Editing Technologies" (2024) 15 GM Crops & Food 1, 2–4.

[5] Art 5 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

Under EU GMO law, the detection, identification and quantification (DIQ) methods are an indispensable requirement for the placing on the market and cultivation of GMO products. These methods are mandatory components of the dossier submitted to the competent authority of the Member State during the authorisation process.[6] They are also essential for ensuring compliance with labelling requirements,[7] and are facilitating international trade, serving as tools for control authorities tasked with implementation and enforcement of sectoral food legislation.[8]

Without valid DIQ methods, it remains challenging, if not impossible, to effectively implement and enforce the current legal framework governing GMOs and non-GMOs.[9] This has significant implications, including for organic production, which prohibits a substantial proportion of GMO products.[10] It also impacts the ability of Member States to enforce restrictions of or bans on GMOs cultivation under Directive (EU) 2015/412.[11] Furthermore, it affects international trade with third countries, where not all GMOs are subject to labelling, authorisation or registration requirements. This issue is gaining increasing prominence with the emergence of New Genomic Techniques (NGTs).

"NGTs" are not defined in EU Law. For the purposes of this analysis we will use the definition proposed by the Commission in Recital 2 of its recent proposal for a regulation on plant reproductive material (Proposal)[12]: "NGTs constitute a diverse group of genomic techniques, and each of them can be used in various ways to achieve different results and products. They can result in organisms with modifications equivalent to what can be obtained by conventional breeding methods or in organisms with more complex modifications. Among NGTs, targeted mutagenesis and cisgenesis (including intragenesis) introduce genetic modifications without inserting genetic material from non-crossable species (transgenesis)." As NGTs may hence cover many different modification events, this

[6] Art 5(3)(i) and Art 17(3)(i) of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (GMO Regulation), Annex III Part 3.D of Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 (GMO Food Authorisation Regulation).

[7] Art 12(2) and Art 24(2) of the GMO Regulation.

[8] In particular Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation), Commission Regulation (EU) No 619/2011 of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired.

[9] A Saltykova and Others, "Detection and Identification of Authorized and Unauthorized GMOs Using High-Throughput Sequencing with the Support of a Sequence-Based GMO Database" (2022) 4 Food Chemistry: Molecular Sciences 100096, 1.

[10] Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (Organic Regulation).

[11] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC.

[12] Proposal for a Regulation of the European Parliament and the Council on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031, 2017/625 and 2018/848 of the European Parliament and of the Council, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC (Regulation on plant reproductive material) Brussels, 5.7.2023, COM(2023) 414 final, 2023/0227(COD).

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article is mainly addressing mutagenesis that creates mutation(s) without the insertion of foreign genetic material,[13] as the most challenging type of genetic intervention in the context of DIQ methods.

The objectives of this article are to: (1) provide a legal perspective on DIQ methods; (2) examine the available methods for NGTs; (3) evaluate whether these methods align with the current regulatory framework; and (4) outline the legal limitations to amending GMO legislation. While the focus is on NGTs, the article also demonstrates that the discussion is equally pertinent to classical, transgenic GMOs.

II. Regulatory landscape

As a result of the *Confédération Paysanne*[14] judgment, most NGT foods, plants and organisms (except human beings) are considered GMOs and are not exempted from the GMO legislation and therefore require authorisation before being placed on the market or cultivated.[15,16] A key requirement for authorisation is the inclusion of methods for the detection, identification and quantification of NGT products within the dossier submitted as part of the application process.[17]

EFSA, as a risk assessor, is tasked with frequent reconsideration of its GMO outputs due to the fact that new data often invalidates previous conclusions.[18] EFSA has therefore assessed the safety of NGTs, concluding that a significant proportion of NGTs can be considered equivalent to conventionally bred plants and does not identify "any additional hazards and risks associated with the use of NGTs compared to conventional breeding techniques".[19] This opinion, however, does not change the legal status of the NGTs, therefore the DIQ methods that are embedded in the regulatory landscape allowing for robust enforcement in the EU[20] and their applicability to NGTs is discussed below.

1. What is detection, identification and quantification?

EU law mandates that the submitted methods must be capable of detecting, identifying and quantifying a specific genetic modification.[21] Detection enables the determination of whether certain modifications are present or absent in a genome (or at the phenotypic level)[22] and serves as the first step toward identification.[23] Identification involves associating a specific

[13] Commission Working document, Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16, Brussels, 29.4.202, SWD(2021) 92 final, 63.

[14] Case C-528/16 *Confédération paysanne and Others* [2018] EU:C:2018:583.

[15] S Sowa and Others, "Legal and Practical Challenges to Authorization of Gene Edited Plants in the EU" (2021) 60 New Biotechnology 183, 1–2.

[16] K Purnhagen, "How to Manage the Union's Diversity: The Regulation of New Plant Breeding Technologies in Confédération Paysanne and Others" (2019) 56 Common Market Law Review 1379.

[17] Art 5(3)(a) to (h) and Art 17(3)(a) to (h) of the GMO Regulation.

[18] S Poli, "Scientific Advice in the GMO Area" in S Gabbi and A Alemanno (eds), *Foundations of EU Food Law and Policy* (London, Routledge 2014) chapter 7.

[19] E Mullins and Others, "Scientific Opinion on the ANSES Analysis of Annex I of the EC Proposal COM (2023) 411 (EFSA-Q-2024-00178)" (2024) 22 EFSA Journal e8894.

[20] C Bruetschy, "The EU Regulatory Framework on Genetically Modified Organisms (GMOs)" (2019) 28 Transgenic Research 169, 170, 172.

[21] Art 5(3)(i), Art 17(3)(i) of the GMO Regulation, Annex III A, part II.C.2. (f) and (g) of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (GMO Directive).

[22] "New Techniques in Agricultural Biotechnology – Scientific Advice Mechanism" <https://scientificadvice.eu/advice/new-techniques-in-agricultural-biotechnology/> (last accessed 12 November 2024).

[23] A Ribarits and Others, "Genome-Edited Plants: Opportunities and Challenges for an Anticipatory Detection and Identification Framework" (2021) 10 Foods 430, 3.

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modification with a modification event, determining whether the changes resulted from spontaneous mutation or technical intervention, and if the latter, identifying the technique used.[24] Quantification refers to the process of generating measured values for a specific GM event,[25] enabling assessment of compliance with legal labelling thresholds – 0.9% of GM material per ingredient[26] in food and 0.1% in mass fractions of feed.[27,28] However, even with validated methods for detection and quantification, the identification of NGTs is becoming increasingly challenging.[29,30] This difficulty arises because the genomic changes in most NGT plants are most of the times identical to, or at least very similar to, transformations that could occur naturally or through classical breeding techniques.[31,32]

While the issue has gained prominence in the context of NGTs, the adequacy and reliability[33,34] of DIQ methods remains a significant challenge for classical transgenic events, which involve foreign genetic material. The concern of reliable DIQ methods has been emphasised in the literature since the early stages of the implementation of the current GMO framework.[35,36] Although the uniqueness of DNA insertions in transgenic plants often makes detection alone sufficient for identification,[37,38] this is not universally true. For example, the P35S promoter derived from the Cauliflower Mosaic Virus (CaMV) is present in 65.7% of commercialised genetically modified (GM) crops but can also occur

[24] L Grohmann and Others, "Detection and Identification of Genome Editing in Plants: Challenges and Opportunities" (2019) 10 Frontiers in Plant Science 4, 5.

[25] European Commission, Joint Research Centre, and European Network of GMO Laboratories, *Detection of Food and Feed Plant Products Obtained by Targeted Mutagenesis and Cisgenesis.* (Publications Office 2023) 6.

[26] Art 12(2) of the GMO Regulation.

[27] Explanatory notes to ANNEX III of Commission Implementing Regulation (EU) No 503/2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 (Authorisation Explanatory Notes).

[28] European Commission, Joint Research Centre, *Guidance Document on Measurement Uncertainty for GMO Testing Laboratories: 3rd Edition* (Publications Office 2020) 6, 17.

[29] KP Purnhagen and Others, "EU Court Casts New Plant Breeding Techniques into Regulatory Limbo" (2018) 36 Nature Biotechnology 799.

[30] cf Commission (n 25) 14.

[31] cf Ribarits and others (n 23) 2.

[32] P Guertler and Others, "Detection of Commercialized Plant Products Derived from New Genomic Techniques (NGT) – Practical Examples and Current Perspectives" (2023) 152 Food Control 109869, 2.

[33] "Adequacy" and "reliability" are not defined further in EU law. At the very least, it covers the minimum requirements stipulated by the European Court of Justice, which we subsequently describe in greater detail. "Adequacy" and "reliability" is hence determined by the application of the latest scientific methods. Legal authorities then test if there has been no "manifest error" made in the selection and application of the scientific methods, according to the circumstances. In our case, the latest scientific methods are in particular determined by the minimum performance criteria for the analytical methods, laid down in *Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing, Part 1, European Network of GMO Laboratories: European Union Reference Laboratory for Genetically Modified Food and Feed* and *Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing. Part 2, European Network of GMO Laboratories: European Union Reference Laboratory for Genetically Modified Food and Feed.*

[34] For the purposes of this article reliable method means a method that meets all the legal requirements.

[35] M Miraglia and Others, "Detection and Traceability of Genetically Modified Organisms in the Food Production Chain" (2004) 42 Food and Chemical Toxicology 1157.

[36] HJ Aarts and Others, "Traceability of Genetically Modified Organisms" (2002) 2 Expert Review of Molecular Diagnostics 69, 69–76.

[37] cf Ribarits and others (n 23) 3.

[38] European Commission, Joint Research Centre, *Explanatory Note Challenges for the Detection of Genetically Modified Food or Feed Originating from Genome Editing* (Publications Office 2018) 7–10.

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naturally in non-GM plants infected with CaMV.[39] To address this, a specific method has been developed to distinguish between the two.[40]

This issue is becoming increasingly significant in the context of unauthorised classical GMOs, whose prevalence is steadily growing in terms of cultivation area as well as taxonomic and genetic diversity.[41,42] Legally valid DIQ methods are available only for products that have been authorised or for which authorisation applications have been submitted. For unauthorised GMOs, DIQ methods can only be developed based on publicly available information. In recent years, there has been a notable rise in the number of transgenic GMOs evading the control systems.[43] This potentially affects conventional and organic farming systems, thereby calling into question the legal framework in place.

2. *Solutions for distinguishing NGTs from other plants and products*[44]

Considering the technical challenges associated with existing methods, there are three approaches which we consider to reflect the main methods discussed in relation to distinguishing specific NGT events from conventional and GMO events: (1) Probabilistic analysis, (2) Implementation of a chain of custody (COC) system, and (3) Utilisation of the common variety catalogue.[45]

a. Probabilistic analysis

Because modifications identical to those induced by NGTs can also occur naturally or through classical breeding, one method of identifying genomic changes is to assess the likelihood that a particular event was induced by NGT intervention. Naturally occurring DNA mutations arise from processes such as DNA repair, cell division, and errors in DNA replication. The frequency of these mutations depends on factors such as cell type, genomic locus, species, and DNA repair pathways.[46] Coupled with the inherent diversity of genomic sequences, predicting the characteristics of a mutation presents a significant challenge.

One approach to distinguish naturally occurring events from those induced by NGTs involves the inclusion of stable markers[47] or identifying mutations specific to the genetic

[39] A Bak and JB Emerson, "Multiplex Quantitative PCR for Single-Reaction Genetically Modified (GM) Plant Detection and Identification of False-Positive GM Plants Linked to Cauliflower Mosaic Virus (CaMV) Infection" (2019) 19 BMC Biotechnology 73, 1–12.

[40] A Bak and JB Emerson, "Cauliflower Mosaic Virus (CaMV) Biology, Management, and Relevance to GM Plant Detection for Sustainable Organic Agriculture" (2020) 4 Frontiers in Sustainable Food Systems, Article 21, 1–5.

[41] European Commission, Joint Research Centre, Institute for Health and Consumer Protection, *Guidance Document from the European Network of GMO Laboratories (ENGL): Detection, Interpretation and Reporting on the Presence of Unauthorised Genetically Modified Materials* (Publications Office 2011) 9–10.

[42] cf Saltykova and others (n 9) 2, 6, 11.

[43] J Teufel and Others, "Strategies for Traceability to Prevent Unauthorised GMOs (Including NGTs) in the EU: State of the Art and Possible Alternative Approaches" (2024) 13 Foods 369, 2.

[44] Since NGT products are not identifiable, they are considered credence goods, meaning that consumers are unable to distinguish between NGT and non-NGT products without supplementary information. Therefore, if they are to be distinguished by the consumers, the implementation of specific identity preservation systems would be necessary, see D Eriksson and Others, "A Comparison of the EU Regulatory Approach to Directed Mutagenesis with That of Other Jurisdictions, Consequences for International Trade and Potential Steps Forward" (2019) 222 New Phytologist 1673 and E Castellari and Others, "Food Processor and Retailer Non-GMO Standards in the US and EU and the Driving Role of Regulations" (2018) 78 Food Policy 26.

[45] Our consideration is based on the outcome of discussions conducted within the framework of the European Horizon DETECTIVE Project.

[46] cf Guertler and others (n 32) 7.

[47] Ibid.

modification, known as off-target changes.[48] These markers must be located near the detected genomic change, remain detectable across generations, and be described by the NGT developer. A recent report from the German Federal Office for Agriculture and Food detailed the development and testing of DIQ methods for NGT rapeseed and barley. While no neighbouring mutations suitable for this purpose were identified in barley, a method for rapeseed was developed that detects the induced change alongside an adjacent one. However, the distance between these mutations was too large to exclude the possibility that they could occur independently.[49]

Increasing emphasis is being placed on the use of Artificial Neural Networks, particularly Convolutional Neural Networks (CNNs), a machine learning solution to assist in determining whether a product was produced by NGT. CNNs have become a standard in genome analysis,[50] offering a wide range of applications. These deep learning frameworks are modelled on the visual perception processes of living organisms[51] and feature neurons that adapt and improve through learning.[52] CNNs consist of various layers that process input data, such as convolutional layers that analyse small fragments (or features) of the object and classify them, merging layers that aggregate results from localised processing, and layers that reduce irrelevant features to enhance the classifier's effectiveness.

In the context of gene editing, these algorithms typically rely on training datasets designed to teach CNNs to perform specific tasks, such as predicting phenotypes,[53] assessing CRISPR off-target activity,[54] quantifying natural selection,[55] predicting cancer types,[56] or estimating mRNA abundance.[57] This technology also holds potential for aiding in the identification of NGT plants and animals.

The primary limitation of using CNNs is that the quality of their output is directly dependent on the quality of the input datasets used during the algorithm's training and evaluation. Moreover, the algorithm's results are derived solely from the explicit knowledge contained within the data it has been exposed to. In contrast, researchers depend not only on explicit data but also on tacit knowledge accumulated through years of practice and experience.[58]

b. Implementation of a chain of custody (COC) system

Another method of distinguishing GMOs from products of classical breeding is by tracking information about specific products throughout their production journey to the end

[48] Ibid.

[49] J Kumlehn and Others, *Machbarkeitsstudie zu Nachweis- und Identifizierungsverfahren für Genom-editierte Pflanzen und pflanzliche Produkte* (Berlin, Bundesministerium für Ernährung und Landwirtschaft 2023).

[50] Z Zhang and Others, "An Automated Framework for Efficiently Designing Deep Convolutional Neural Networks in Genomics" (2021) 3 Nature Machine Intelligence 392.

[51] J Gu and Others, "Recent Advances in Convolutional Neural Networks" (2018) 77 Pattern Recognition 354.

[52] A Saxena, "An Introduction to Convolutional Neural Networks" (2022) 10 International Journal for Research in Applied Science and Engineering Technology 943.

[53] Y Liu and Others, "Phenotype Prediction and Genome-Wide Association Study Using Deep Convolutional Neural Network of Soybean" (2019) 10 Frontiers in Genetics 1091.

[54] J Lin, X Chen and K-C Wong, "An Artificial Intelligence Approach for Gene Editing Off-Target Quantification: Convolutional Self-Attention Neural Network Designs and Considerations" (2023) 15 Statistics in Biosciences 657.

[55] L Torada and Others, "ImaGene: A Convolutional Neural Network to Quantify Natural Selection from Genomic Data" (2019) 20 BMC Bioinformatics 337.

[56] M Mostavi and Others, "Convolutional Neural Network Models for Cancer Type Prediction Based on Gene Expression" (2020) 13 BMC Medical Genomics 44.

[57] V Agarwal and J Shendure, "Predicting mRNA Abundance Directly from Genomic Sequence Using Deep Convolutional Neural Networks" (2020) 31 Cell 1.

[58] M Krajewski, "On Crosswords and Jigsaw Puzzles: The Epistemic Limits of the EU Courts and a Board of Appeal in Handling Empirical Uncertainty" (2023) 2 European Law Open 784.

consumer, a process known as Chain of Custody (COC). This approach involves monitoring the movement of evidence through its lifecycle – collection, safeguarding, and analysis – while documenting every individual who handled the evidence, the date and time of collection or transfer, and the purpose of each transfer.[59]

Various methods exist for managing COCs, with blockchain technology taking a leading role. It enables the creation of a computerised chain of sequential transactions, storing data about the parties involved (eg, farmers, producers) and the traced products. This approach allows information about a product's lifecycle to be readily accessible without requiring all participants to be online. Each piece of information is stored as a "block," which is cryptographically linked to other data in the chain, ensuring that the records cannot be altered retrospectively.[60]

Blockchain has the potential to revolutionise the food supply chain by transforming it from a slow, error-prone, and complex system of information flow to one that is real-time, accurate, and highly transparent, thereby improving food quality and safety.[61] A case study conducted by Walmart and IBM demonstrated this potential by comparing the time required to trace a commodity using traditional paper trails versus blockchain. The paper trail took nearly seven days, while the blockchain achieved the same result in just 2.2 seconds.[62] However, some researchers emphasise challenges such as data protection, privacy concerns, and the risk of over-engineered technology that could reduce transparency and exacerbate power imbalances within food value chains.[63] A significant issue is the need for a stable internet connection, which is not always available in rural areas – particularly at the "first mile," the most vulnerable part of the food chain.[64]

Although the idea could indeed be implemented, the number of commodities subject to such obligations is very limited, and such an approach would also add to the already high level of bureaucracy in the food trade. Furthermore, due diligence measures are based on an obligation of reasonable care or means, with no obligation of the result. This approach does not appear to provide a suitable solution for the case at hand.

Regardless of the technology employed, COC approaches are gaining importance across various markets. They are commonly used for products or materials that are scarce or associated with child labor or other human rights abuses. Recent EU initiatives, such as the Conflict Minerals Regulation[65] and the Deforestation Regulation,[66] aim to ensure the sustainable and ethical sourcing of specific commodities. Some researchers propose leveraging existing due diligence systems used to meet other regulatory requirements for tracing GMOs, including NGTs.[67] While this idea could be implemented, its applicability is limited by to the small number of commodities currently subject to

[59] 'Chain of custody' (*National Institute of Standards and Technology, Information Technology Laboratory Glossary*) <https://csrc.nist.gov/glossary/term/chain_of_custody> (last accessed 29 October 2024).

[60] "Blockchain for Agri-Food Traceability" (*UNDP*) available at <www.undp.org/publications/blockchain-agri-food-traceability> (last accessed 12 November 2024) 3.

[61] V Sri Vigna Hema and A Manickavasagan, "Blockchain Implementation for Food Safety in Supply Chain: A Review" (2024) 23 Comprehensive Reviews in Food Science and Food Safety e70002, 20–1.

[62] R Kamath, "Food Traceability on Blockchain: Walmart's Pork and Mango Pilots with IBM" (2018) 1 The Journal of the British Blockchain Association 1, 49.

[63] Y Commandré and Others, "Implications for Agricultural Producers of Using Blockchain for Food Transparency, Study of 4 Food Chains by Cumulative Approach" (2021) 13 Sustainability 9843, 16–17.

[64] cf UNDP (n 60) 5, 29, 33.

[65] Regulation (EU) 2017/821 of the European Parliament and of the Council of 17 May 2017 laying down supply chain due diligence obligations for Union importers of tin, tantalum and tungsten, their ores, and gold originating from conflict-affected and high-risk areas.

[66] Regulation (EU) 2023/1115 of the European Parliament and of the Council of 31 May 2023 on the making available on the Union market and the export from the Union of certain commodities and products associated with deforestation and forest degradation and repealing Regulation (EU) No 995/2010.

[67] cf Teufel and others (n 43) 13–18.

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such obligations. Furthermore, it is being questioned whether the commodities subject to these regulations sufficiently represents the supply chains subject to these kinds of abuses.[68] Additionally, this approach would increase the already substantial bureaucratic burden on the food trade, risking the implementation of a "tick-box" mentality rather than taking actions with real impact.[69] Due diligence measures typically impose an obligation of reasonable care or means rather than guaranteeing specific outcomes.[70]

c. Utilisation of the common variety catalogue

Another potential approach is to register NGT organisms in a comprehensive catalogue, providing detailed information on their breeding history accessible to both operators and consumers. This could be implemented through national variety catalogues, which are subsequently integrated into the common EU catalogue. Typically, a variety cannot be marketed in the EU without being listed in the common catalogue, making this an effective tool for ensuring traceability and transparency.

To be included in the catalogue, a variety must undergo the DUS test, which evaluates its distinctness, uniformity and stability. For agricultural crops, an additional assessment of value for cultivation and use is conducted, considering factors such as yield, resistance to harmful organisms, adaptability to environmental conditions, and quality traits.[71] Under the European Commission's Proposal for a regulation on plant reproductive material, this requirement would be revised to assess the variety's value for sustainable cultivation and use.[72]

Using the catalogue could enhance the recognition of NGTs on two levels. First, specific varieties could be verified against the entries in the catalogue. Second, the distinct traits assessed during the DUS test could serve as a potential distinguishing factor for identifying NGT varieties.

Although most plant species are subject to this obligation, some marketed varieties are not listed in EU or national catalogues. To address this gap and ensure comprehensive tracking of NGTs, a dedicated catalogue specifically for NGT registration could be established. Such a system would ensure that all relevant species are thoroughly documented and effectively monitored.

3. Analytical and enforcement nature of DIQ methods

The EU's GMO authorisation process operates on two levels.[73] First, authorisation for the deliberate release of GMOs into the environment and for placing genetically modified

[68] R Muradian and Others, "Will the EU Deforestation-Free Products Regulation (EUDR) Reduce Tropical Forest Loss? Insights from Three Producer Countries" (2025) 227 Ecological Economics 108389, 1.

[69] CA Adams and S Abhayawansa, "Connecting the COVID-19 Pandemic, Environmental, Social and Governance (ESG) Investing and Calls for 'Harmonisation' of Sustainability Reporting" (2022) 82 Critical Perspectives on Accounting 102309, 1.

[70] cf Teufel and others (n 43) 11.

[71] Annex III of Commission Directive 2003/90/EC of 6 October 2003 setting out implementing measures for the purposes of Article 7 of Council Directive 2002/53/EC as regards the characteristics to be covered as a minimum by the examination and the minimum conditions for examining certain varieties of agricultural plant species.

[72] Proposal for a Regulation of the European Parliament and the Council on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031, 2017/625 and 2018/848 of the European Parliament and of the Council, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC (Regulation on plant reproductive material) Brussels, 5.7.2023, COM(2023) 414 final, 2023/0227(COD).

[73] For a more detailed account on the EU GMO legal framework see cf Schebesta and Purnhagen (n 1) 174–191 and J Wesseler and N Kalaitzandonakes, "Present and Future EU GMO Policy" in L Dries and Others (eds), *EU Bioeconomy Economics and Policies: Volume II* (Cham, Springer International Publishing 2019) 245.

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organisms as or in products on the market is governed by Directive 2001/18/EC (the GMO Directive). Second, authorisation for placing on the market of GMO-derived food and feed products is governed by Regulation (EC) No 1829/2003 and Commission Implementing Regulation (EU) No 503/2013, while authorisation for GMO-derived animals and micro-organisms is governed by Regulation (EC) No 1829/2003 and Commission Regulation (EC) No 641/2004. Because authorisation of one GMO product often falls under the first two regulatory regimes, the Commission introduced the "one door, one key" principle, which allows applicants to seek both authorisations simultaneously.[74,75] Consequently, although authorisation requirements differ for the cultivation and placing on the market of non-food and non-feed products, as well as for placing food and feed products on the market, in practice these requirements must typically be considered together.

This practical requirement is also exemplified by case-law, where food and feed authorised for cultivation resulted in liability risks as, without intervention of the authorisation holder, the GMO products were detected in food. A notable example is the *Bablok* case, where traces of genetically modified corn, authorised solely for cultivation, were detected in honey.[76,77] The authorisation granted for cultivation cannot be extended to food and feed purposes, and vice versa, as the potential risks to human health and the environment vary depending on the scope of the authorisation.[78] Consequently, the presence of pollen in the honey was deemed illegal. Another example is the genetically modified maize StarLink®, which was engineered to express the Cry9C protein for resistance to various insect pests. Approved in the United States in 1998 solely for feed and industrial purposes, StarLink® maize was found in taco shells in 2000, leading to a significant disruption in the food market.[79] However, the majority of applications submitted by companies pertain to food and feed, meaning that the GMO Regulation exerts a more significant impact on businesses operating within the EU market.[80]

DIQ methods must comply with specific requirements established under EU law. The primary legal framework governing these methods in food and feed are Commission Implementing Regulation (EU) No 503/2013[81] (the GMO Food Authorisation Regulation) and Commission Regulation (EC) No 641/2004.[82] For cultivation and placing on the market, the primary relevant legal framework is the GMO Directive, in connection with national implementing legislation. Both regimes are connected by the "one door, one key principle."

The authorisation procedure outlined in the GMO Directive concerning cultivation and placing on the market of non-food and non-feed requires the submission of DI(Q) methods.

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[74] Question and Answers on the regulation of GMOs in the EU <https://ec.europa.eu/commission/presscorner/detail/en/memo_04_102> (last accessed 10 December 2024).

[75] B Meulen van der (ed), *EU Food Law Handbook* (Wageningen, Wageningen Academic Publishers 2020) 215–27.

[76] Case C-442/09 *Bablok* [2011] EU:C:2011:541.

[77] For analysis of the case see K Purnhagen and J Wesseler, "The 'Honey' Judgment of Bablok and Others Versus Freistaat Bayern in the Court of Justice of the European Union: Implications for Co-Existence" in N Kalaitzandonakes and Others (eds), *The Coexistence of Genetically Modified, Organic and Conventional Foods: Government Policies and Market Practices* (New York, Springer 2016) 149–65.

[78] cf Case C-442/09 (n 76) paras 101–2.

[79] T Zimny and S Sowa, "Potential Effects of Asymmetric Legal Classification of Gene Edited Plant Products in International Trade, from the Perspective of the EU" (2021) 1 EFB Bioeconomy Journal 100016, 6.

[80] cf Poli (n 18).

[81] Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006.

[82] Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.

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For GMOs other than higher plants, this includes a description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector; sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques are needed.[83] For GM higher plants, the GMO Directive requires a description of the detection and identification techniques.[84]

In addition, Article 25 of the GMO Directive states that the sequences used for detecting, identifying, and quantifying the transformation event must not be considered confidential. This means that detailed DNA sequence information is essential for these processes, which in turn requires the use of analytical methods.

The nature of the Directive as a legal instrument delegates its implementation and enforcement to Member States, leaving the specifics of requirements – such as those for DIQ methods – open to national interpretation. While the Directive does not provide a detailed description of these specific requirements, its provisions imply the necessity of employing analytical methods to fulfill its objectives.

This paper, though not centered on a comparative analysis of national legislation, has examined the approaches adopted by Poland and Germany in this context. Both legal frameworks align in their conclusion that these methods must be analytical in nature to ensure compliance with the GMO Directive's overarching principles.[85] While Member States retain the discretion to implement Directives in ways that reflect their national contexts, they are nonetheless bound to legal and factual requirements when doing so. That means, their implementation is bound to the realisation of the objectives of the Directive and, ultimately, in the case of the GMO Directive, to the provisions of the free movement of goods. Analytical methods, as indicated by both Polish and German requirements, provide a standardised approach to achieving both, the GMO Directive's objectives and the free movement of goods, reinforcing the need for scientific rigour and uniformity across Member States and realization of the "one door, one key principle."

The authorisation procedure outlined in the GMO Regulation concerning food and feed likewise requires the submission of methods. It is noteworthy that the GMO Food Authorisation Regulation stipulates a conditional science-based paradigm for most parts of the GMO authorisation dossier. According to Article 5 of the GMO Food Authorisation Regulation most parts of the authorisation procedure must meet the scientific requirements for GM food and feed risk assessment, but derogations are allowed if valid justifications are provided. DIQ methods are not within the scope of these requirements but are regulated separately in Article 8 of the GMO Food Authorisation Regulation. Unlike in its Article 5, the legal requirements for DIQ methods are strict, as no derogation from them is foreseen in the GMO Food Authorisation Regulation. Furthermore, as DIQ methods are explicitly excluded from the application of Article 5 of the GMO Food Authorisation Regulation, they do not have to meet the risk assessment requirement. This is aligned with practice, as DIQ methods are validated outside of EFSA's operations, namely by the EU Reference Laboratory for Genetically Modified Food and Feed.[86]

In the GMO Regulation concerning food and feed DIQ methods need to be submitted in the authorisation dossier to enable authorities and FBOs to trace GMO products. FBOs have to be in the position to control their labelling obligations, and enforcement authorities need to have the possibility to exercise official control procedures. DIQ methods are hence a part of the enforcement regime, they are not part of the scientific evaluation of safety.

[83] Annex III A.2.C.2 (f) and (g) of the GMO Directive.

[84] Annex III B.I.B.5. and Annex III B.II.B.5. of the GMO Directive.

[85] See Ustawa z dnia 22 czerwca 2001 r. o mikroorganizmach i organizmach genetycznie zmodyfikowanych and Rozporządzenie Ministra Klimatu i Środowiska z dnia 19 października 2021 r. w sprawie wzoru wniosku o wydanie zezwolenia na zamierzone uwolnienie organizmu genetycznie zmodyfikowanego do środowiska.

[86] Annex point 3(d) of the GMO Regulation.

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Accordingly, they also have different objectives than assessing risks and hazards. It is therefore sensible to have them excluded from Article 5 of the GMO authorisation procedure and place them into a separate, strict regime, following the rationale of the law of enforcement and not the one of risk analysis. DIQ methods, hence, are not part of risk assessment and do not have to comply with risk analysis standards, but are governed, by analogy, by rules of enforcement such as, for example, in Article 17 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (hereinafter General Food Law). In this sense, they need to be "effective, proportionate and dissuasive."

Article 8 of the GMO Food Authorisation Regulation stipulates requirements for the methods used to detect and identify transformation events, so does Commission Regulation (EC) No 641/2004. The wording of these provisions pertains exclusively to analytical methods deemed sufficient to satisfy authorisation requirements,[87] with a particular focus on the use of polymerase chain reaction (PCR) modules.[88] All EU reference methods for GMO analysis include analytical methods (the PCR modules).[89] Next Generation Sequencing (NGS) has recently gained more recognition as a possible solution for reliable DIQ methods for NGTs, but due to the technical and financial aspects this is still in the distant future.[90] However, unlike for other parts of the dossier, the EU lawmaker did not provide for any exemptions concerning the regulation of DIQ methods in the GMO Food Authorisation Regulation. Unlike in its Article 5, Article 8 of the GMO Food Authorisation Regulation does not provide for an exemption. The legislator hence deliberatively refrained from providing any possibility for deviation from the analytical methods requirement.

Legally limiting the available methods for detection and identification for both regimes to analytical methods is supported by the practical requirements applicants and laboratories face when validating the methods in the authorisation procedure. Applicants are required to submit event-specific DIQ methods that are only functional with the GM organism or GM-based product under consideration.[91] "[A]n event-specific method targets the unique insert-to host organism junction originated in the transformation event."[92] Laboratories must have suitably qualified staff with appropriate training in the analytical methods used for the detection and identification of GMOs and GM food and feed,[93] and must test the methods against the minimum performance requirements for analytical methods as part of the full validation process.[94]

This interpretation of legal provisions is also shared by the European Network of GMO Laboratories (ENGL). In its evaluation,[95] ENGL states that prior knowledge of the mutation (ie, paper trail) does not allow the identification of mutations generated by genome editing

[87] cf Ribarits and Others (n 23) 1.

[88] See Annex III of the GMO Food Authorisation Regulation, and Explanatory note to Commission Regulation (EC) No 641/2004: explanatory notes to applicants.

[89] See GMOMETHODS tool available under <https://gmo-crl.jrc.ec.europa.eu/gmomethods/> (last accessed 12 November 2024).

[90] cf Commission (n 38) 7.

[91] Annex III part 3.1.C.1 of the GMO Food Authorisation Regulation.

[92] Authorisation Explanatory Notes.

[93] Annex I part (a) of Commission Regulation (EC) No 1981/2006 of 22 December 2006 on detailed rules for the implementation of Art 32 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms (Commission Regulation 1981/2006).

[94] Art 2(a)(i) of Commission Regulation 1981/2006.

[95] Evaluation of the scientific publication "A Real-Time Quantitative PCR Method Specific for Detection and Quantification of the First Commercialized Genome-Edited Plant" P Chhalliyil et al. in: Foods (2020) 9, 1245 by the European Network of GMO Laboratories (ENGL).

within the meaning of GMO Food Authorisation Regulation. Therefore, it precludes the use of non-analytical traceability tools as valid methods for the purposes of applying for authorisation in the current regulatory framework.

Therefore, non-analytical traceability tools described under point 3 are not the answer to the problems associated with DIQ methods in relation to NGT authorisation. Although the analytical methods are not error-free,[96] the tools under point 3 are prone to errors and, conscious or not, information distortion. Furthermore, in some jurisdictions outside the EU, NGTs are not legally classified as GMOs and thus such information may not be available for a specific product. The same applies to any system that increases the likelihood of guessing whether a product is NGT or not.

Non-analytical, reliable traceability information could help to distinguish between authorised and unauthorised GMOs and other, conventional products, reducing the requirement of resources, such as time and money, required for the identification process.[97] It should also be noted that without it, there is a high possibility that NGT plants could enter the EU market unnoticed.[98,99] Given the difficulties in developing reliable analytical methods, more emphasis is also placed on the non-analytical approaches in the political discourse.[100] However, they can only be implemented and used by the control authorities, ie, specific national bodies that are responsible for verifying if food products are marketed legally and are meeting the requirements of EU law. From a legal point of view, reliable, analytical DIQ methods are still required for the purposes of authorisation.

III. The boundaries of changing the GMO legislation

The legal requirement for the use of analytical methods and likewise the lack thereof in reality may prompt a desire for legal change. However, such a legal change is subject to legal limitations from procedural and substantive points in law. The main interlocking elements are (1) the committee procedure,[101] (2) the legislation pertinent to enforcement, ie, official controls and labelling, (3) conventional and organic production rules, and (4) the case-law of the CJEU with regard to the use of scientific evidence. This list is non-exhaustive and does not cover several topics, such as data protection, unfair commercial practices and others. However, we decided to narrow down the list to the three most important regulatory regimes in the context of the scope of this paper.

1. Committee procedure

The Commission is granted a wide margin of discretion in its implementing powers, so Member States are afforded a procedure that allows them to control the Commission's actions – the committee procedure.[102] Implementing acts drafted by the Commission must pass the consultation or examination procedure before specialised committees composed

[96] cf Saltykova and Others (n 9) 1.

[97] cf Commission (n 41) 10.

[98] cf Commission (n 38) 2, 4.

[99] Position Statement No. 2016/01: Guideline for Monitoring Genetic Modifications in Food available at <https://www.bvl.bund.de/SharedDocs/Downloads/06_Gentechnik/nachweis_kontrollen/Guideline-GMO%20monitoring%20in%20food.pdf?__blob=publicationFile&v=1> (last accessed 29 October 2024) 16–17.

[100] Non-paper by the Presidency on the work of the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) in relation to the Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625, 11820/24.

[101] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (Committee Procedure Regulation).

[102] Art 291 of the Treaty on the Functioning of the European Union.

of representatives of the Member States. Delegated representatives are usually coming from national ministries, and national food, health and environment authorities.[103,104]

Most implementing acts (including GMOs) must be approved by the committees under the latter, more rigorous procedure.[105] If the committee's opinion is favourable, the Commission adopts the act; if it is unfavourable, it cannot. If no opinion is delivered in cases of acts concerning the protection of the health or safety of humans, animals or plants, again the Commission shall not adopt it. However, in cases where the act is deemed necessary and the committee did not adopt an opinion or when it was negative, the amended act can be filed once more before the committee or, in a non-amended version, can be submitted to the appeal committee. If the opinion is positive, the Commission shall adopt the act, if negative it shall not, and if no opinion is delivered the Commission can adopt it.[106]

However, if an act needs to be adopted without a delay in order to avoid creating a significant disruption of the markets in the area of agriculture or a risk for the financial interests of the Union, the Commission is placed to adopt it, immediately submitting it to the appeal committee. The act shall only be repealed if the appeal body delivers a negative opinion. It is still subject to debate if in the area of food, when adopting this decision, the Commission is bound by the principle of risk analysis as stipulated in Article 6 of General Food Law. Consequently, the Commission may always have to vote along the lines of risk assessor's (EFSA's) recommendation. If Article 6 of General Food Law were applicable, the Commission would only have to take into account EFSA's assessment but may also consider "other factors legitimate to the matter."[107] In its decision, however, the Commission is, bound to the achievement of the general objectives of food law as stipulated in Article 5 of General Food Law.

In the case of GMOs, particularly those derived from NGTs, it appears highly likely that EU Member States will not be in a political position to reach a positive decision, given the manner in which the Commission's NGT Regulation proposal[108] is being addressed by the Council.[109] Therefore, although mostly technical, the probability of not passing the committee procedure must be taken into account when drafting new GMO legislation.

2. *Legislation pertinent to enforcement*

The EU legal framework governing GMOs is based on a presumption that the GMOs are potentially hazardous, and creates principles embedded in the precaution when handling them, such as prior authorisation before being placed on the market or the shift of burden of proof to the applicant.[110] Although this approach is being contested in case of NGTs,[111,112]

[103] Participants list can be found here: available at <https://ec.europa.eu/transparency/comitology-register/screen/documents?lang=en> (last accessed 29 October 2024).

[104] More on the committee procedure in the GMO sector see S Poli, "The Reform of the EU Legislation on GMOs: A Journey to an Unknown Destination?" (2015) 6 European Journal of Risk Regulation 559.

[105] Art 2(2) of the Committee Procedure Regulation.

[106] Art 6(3) of the Committee Procedure Regulation.

[107] Art 6 (3) of the General Food Law.

[108] Proposal for the Regulation of the European Parliament and the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625, Brussels, 5.7.2023, COM(2023) 411 final, 2023/0226 (COD).

[109] K Purnhagen and J Wesseler, "EU Regulation of New Plant Breeding Technologies and Their Possible Economic Implications for the EU and Beyond" (2021) 43 Applied Economic Perspectives and Policy 1621.

[110] M Weimer, "Applying Precaution in EU Authorisation of Genetically Modified Products – Challenges and Suggestions for Reform" (2010) 16 European Law Journal 624, 638.

[111] J Davison and K Ammann, "New GMO Regulations for Old: Determining a New Future for EU Crop Biotechnology" (2017) 8 GM Crops & Food 13, 15.

[112] D Eriksson, "The Evolving EU Regulatory Framework for Precision Breeding" (2019) 132 Theoretical and Applied Genetics 569, 571.

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enforcement mechanisms that facilitate control over the market have been created – both from the perspective of consumers and Member States or relevant institutions and authorities. Their primary pillars are labelling obligation and official controls. The development of DIQ methods is crucial in this regard,[113] requiring any framework changes to align with relevant labelling and controls requirements. As a principle GMO food and feed shall be labelled as such,[114] with the exception of products containing GMO material in a proportion no higher than 0.9% of the ingredient, provided that this presence is adventitious or technically unavoidable.[115] In accordance with Article 17(1) of the General Food Law the FBOs are responsible for satisfying the requirements of food law. FBOs failing to comply with these provisions are at risk of law enforcement against them as well as reputational damage, as consumers are hesitant to choose GMO products.[116] Without the ability to identify, one cannot decently quantify and therefore label in accordance with the applicable rules.

In the EU the responsibility to enforce food regulatory framework falls primarily on FBOs, and, subsequently, on the Member States.[117] The main legislative act governing the shape of controls system is the Official Control Regulation (OCR), with certain rules outlined specifically for the GMOs. The aim of the activities under the OCR is to verify: (a) compliance by the operators with applicable laws, and (b) that animals or goods meet the requirements laid down in the applicable laws.[118] The national authorities responsible for the activities under this framework need be able to distinguish GMOs from non-GMO products for the purposes of compliance checks.

Article 14 of the OCR outlines methods for verifying compliance with GMO legislation, including equipment inspections, traceability records, sampling, analysis, diagnostics, and audits. These methods must be applied appropriately, allowing for some interpretation. Therefore, if the legislation with regard to methods is to be changed, its main purpose has to be taken into account – enforcement and labelling.

3. Conventional and organic agriculture rules

Finally, there is the question of organic farming and its ban on the use of a large proportion of GMOs.[119] This ban is motivated by the notion that use of GMOs, as well as products produced from or by GMOs, is incompatible with the concept of organic production and consumers' perception of organic products.[120] However, prohibition does not mean that no GMO is present in organic agriculture.

First of all, products that are modified using methods listed in the Annex I B the GMO Directive, are exempted from application of the GMO legal framework, and therefore can be found in organic and conventional agriculture. Interestingly, in accordance with Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC)

[113] T Ruttink and Others, "Molecular Toolbox for the Identification of Unknown Genetically Modified Organisms" (2010) 396 Analytical and Bioanalytical Chemistry 2073, 1.

[114] Art 4B of Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

[115] Art 12(2) and 24(2) of GMO Regulation.

[116] C Bain and T Selfa, "Non-GMO vs Organic Labels: Purity or Process Guarantees in a GMO Contaminated Landscape" (2017) 34 Agriculture and Human Values 805–6.

[117] KP Purnhagen and A Molitorisová, "Public and Private Enforcement in European Union Food Law" (2022) 13 European Journal of Risk Regulation 464.

[118] Art 2(1)(a) and (b) of the Official Controls Regulation.

[119] Art 11 of the Organic Regulation.

[120] Recital 23 of the Organic Regulation.

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No 834/2007 these products are not included in the GMO definition's scope[121] and are therefore not perceived as GMOs in this specific sector. Apart from being incoherent, this inconsistency in definitions might be qualified as misleading the consumers.

Furthermore, since organic operators can rely on GMO labelling (or the lack of it) when deciding which products to use,[122] the issue of the lack of reliable DIQ methods *de facto* leaves room for the introduction of GMOs (i.e. NGTs and other non-identifiable transgenic products) into organic farming. Although no breach of a food law provisions can be spotted here, these considerations question the existence of organic framework in the current form.

In conventional agriculture, FBOs cannot rely on labelling only to determine the GMO-feature of a product (unlike in organic farming). As a consequence, they are required to consistently control the products they introduce to the market for traces of GMOs. Without reliable DIQ methods, this is not feasible. Additionally, recent increases in FBO liability are placing disproportionate responsibility on them. The New Product Liability Directive requires courts to presume product defectiveness and a causal link to damage if the claimant can only provide evidence of its likelihood in cases when scientific or technical complexity makes proving the defect or causality difficult.[123] The only feasible way of changing the legislation in this regards would be to either add the same no label, no GMO presumption as in the Organic Regulation or exclude the NGTs (or part of NGTs) from the application of the GMO legal framework, similarly to the mutagenesis techniques with the history of safe use.[124]

4. Scientific evidence in CJEU case-law

Even if the type of evidence required for the recognition of NGTs would be adjusted in the legislation pertaining to DIQ methods (i.e. moving away from evidence obtained through analytical methods to non-analytical), there are also boundaries of using scientific evidence as a basis for interpretation of enacting EU law. The CJEU's reasoning on the legal prerequisites for the use of scientific evidence in EU law was developed in cases where the CJEU reviewed the Commission's discretion of implementing scientific evidence into EU law. As a change of requirements in the law would require the Commission to take the initiative (and hence exercise its discretion), the case-law is also applicable to the case of changing DIQ methods.

The Commission has broad discretion when it comes to scientific and technical assessment. "The [CJEU] must verify [. . .] whether the facts accepted by the Commission have been accurately stated and whether there has been a manifest error in the appraisal of those facts or a misuse of powers."[125] In order to avoid being accused of committing manifest error of assessment, the Commission shall examine, "carefully and impartially, all the relevant facts of the individual case on which that assessment" is based, and lastly "evidence relied on is factually accurate, reliable and consistent and also whether that evidence contains all the information which must be taken into account in order to assess a complex situation and whether it is capable of substantiating the conclusions drawn from it."[126] This also means that there has to be a causal relationship between the problem and the solution where scientific evidence then establishes causality between the two. In the case of DIQ methods, this means causality between the mutation and the cause.

[121] Art 3(58) of the Organic Regulation.

[122] Art 11(2) and (3) of the Organic Regulation.

[123] Recital 48 of 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, not yet in force.

[124] Annex I B of the GMO Directive.

[125] Case T-279/20 *CWS Powder Coatings v Commission* [2011] EU:T:2022:725, para 41.

[126] Ibid, paras 42–3.

However, when establishing causation in EU law, the European Court of Justice has established some general criteria. Among them, causal relationships cannot be established if they are conditional upon a series of external factors which, apart from not being verifiable, cannot be attributed.[127]

The scientific evidence provided by applicants in the authorisation procedure shall enable FBOs and control authorities to establish causal links between the mutation and the cause in order to determine their respective legal obligations to intervene. DIQ methods are hence evidence for causation, which need to be verifiable and attributable to the respective event. In addition, such a standard of verifiability via scientific evidence ensures that decisions are based on sound knowledge and not on arbitrariness, and therefore the evidence such as studies, data, etc. should pass such a test in any type of scientific assessment, irrespective of the body carrying it out (EFSA, EC, food business operator).

IV. Non-scientific evidence in risk management

As a final remark, it is important to emphasise that science is not the only element in the puzzle of the authorisation of food products.[128] This can be seen, for example, in the Commission's decision-making process. The outcome of the risk assessment is the scientific opinion on safety, which forms the basis for the risk management decision. However, the Commission has to take into account other legitimate factors and the precautionary principle when making a decision. EFSA was created to separate science from politics, primarily to allow for unbiased scientific assessment,[129] but also to provide room for political considerations in the food authorisation process, such as social, ethical or cultural aspects.

Furthermore, the precautionary principle should not be viewed as an endless repository that can accommodate any and all arguments. Instead, it should be regarded as a tool for decision-makers, facilitating a more comprehensive evaluation of the circumstances. This approach acknowledges that, in situations involving risks, traditional risk assessment may not always provide sufficient guidance and grounds for decision-making.[130] It provides a possibility to introduce non-discriminatory and objective restrictive measures in case of uncertainty to "the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted,"[131] however the approach towards risk cannot be purely hypothetical. [132] Furthermore aiming at a zero risk situation is not possible since such circumstances never exist.[133] Thus "[t]here should be reasonable grounds for concern that an unacceptable level of risk to health exists, the available supporting information and data are not sufficiently complete to enable a comprehensive risk assessment to be made, and measures taken may only be temporary".[134]

Undeniably, the question on the demarcation line between what is scientific and political remains. The latter can be stretched, responsibility can be transferred in both

[127] Joined cases 197 to 200, 243, 245 and 247/80 *Ludwigshafener Walzmühle v Council and Commission* [1981] EU:C:1981:311, para 52.

[128] Art 6 (2) and Art (3) of the General Food Law.

[129] MLP Groenleer, "The Actual Practice of Agency Autonomy: Tracing the Developmental Trajectories of the European Medicines Agency and the European Food Safety Authority" (2011) The Minda de Gunzburg Center for European Studies at Harvard University 7.

[130] cf M Weimer (n 110) 653.

[131] Case T-719/17 *FMC Corporation v Commission* [2021] EU:T:2021:143, para 72.

[132] Ibid, para 69.

[133] Communication from the Commission on the precautionary principle, Brussels, 2.2.2000 COM(2000) 1 final, point 6.3.1.

[134] cf Schebesta and Purnhagen (n 1) 120.

directions – political questions addressed as scientific and vice versa.[135] However one has to bear in mind that although scientists "have scientific legitimacy, [they] have neither democratic legitimacy nor political responsibilities. Scientific legitimacy is not a sufficient basis for the exercise of public authority."[136] This gives the Commission a wide margin of discretion when drafting implementing legislation or authorisation decisions, allowing it not to fully reflect or follow EFSA's scientific opinion.[137]

The decision of which products are under the scrutiny of GMO legislation is also a political decision. This opens the door for changes in the regulatory framework that go beyond switching from analytical to non-analytical DIQ and traceability methods.

V. Conclusions

Maintaining the current legal framework, in which NGTs are classified as GMOs and subject to the same (or slightly relaxed) regulations as classical transgenic organisms, presents several challenges. The legal requirement to submit analytical DIQ methods for authorisation creates a cascade of issues. Firstly, this makes it impossible to grant NGT authorisation under the existing regulatory system, as no reliable analytical DIQ methods are currently available. Additionally, if the legal requirements for market authorisation of NGTs cannot be met, companies are unlikely to invest in the EU sector, which would have broader implications for innovation both within the EU and globally. The current methods available for differentiating between NGT and conventional products are not feasible for implementation, as they are non-analytical in nature. For instance, systems such as blockchain-based traceability through the food chain, algorithms assessing the likelihood of specific changes being caused by NGTs, or the creation of a comprehensive catalogue of NGT plant varieties do not align with the legal framework in place. While these approaches may be valuable for monitoring by control authorities within Member States, they are of no use in the GMO authorisation procedure.

Finally, any changes to legislation must be carefully considered within the context of the broader legal framework. If NGTs remain prohibited in organic farming but labelling requirements for such products are not mandated, how can consumers be assured that the products they purchase are free from NGTs? Given the extensive international trade, including with countries where NGTs are not subject to additional regulatory requirements, it is crucial that the rules governing FBOs are structured in a manner that ensures they are feasible for compliance and provide legal certainty.

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[135] MBA Van Asselt and E Vos, "Science, Uncertainty and GMOs" in R Dehousse and L Boussaguet (eds), *The transformation of EU policies: EU governance at work* (Mannheim, HAL 2008) 65–98.

[136] Case T-13/99 *Pfizer Animal Health SA v Council* [2002] EU:T:2002:209, para 201.

[137] MBA Van Asselt and E Vos, "EU Risk Regulation and the Uncertainty Challenge" in S Roeser and Others (eds), *Handbook of Risk Theory* (Dordrecht, Springer Netherlands 2012) 117–33.

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