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Integrating societal concern into an EU regulatory proposal for new genomic techniques in food crops using association rules

Iuri Peri¹, Federica Consentino^{1*}, Alessandro Grasso¹ and Gabriella Vindigni¹

Abstract

Ensuring global food security is an increasingly complex challenge, prompting researchers and the agri-food industry to explore biotechnological solutions. Over the past decade, New Genomic Techniques (NGTs) have transformed plant breeding by enhancing yields, disease resistance, and climate adaptability. Despite these innovations, NGTs remain regulated under the same framework as Genetically Modified Organisms (GMOs), while the European Union (EU) seeks to establish an alternative regulatory approach. Advances in agricultural biotechnology present complex challenges, involving a wide range of stakeholders, conflicting opinions, and vast amounts of information. As part of the regulatory review process for NGTs, the European Commission (EC) launched a public consultation in 2022 to support the revision of existing regulations. This study applies Association Rule Mining (ARM) to analyze the consultation's key concerns and policy preferences. Stakeholders—including industry representatives, environmental organizations, scientists, and citizens—have voiced differing opinions. ARM enables the identification of recurring patterns in their responses, highlighting three key themes: sustainability, risk assessment, and transparency. Some consider sustainability an inherent advantage of NGTs, while others view it as irrelevant or as a justification for stricter regulations. Risk assessment and transparency are widely recognized as essential but approached differently—some downplay their importance, while others advocate for more stringent oversight. Additionally, a strategic neutral stance emerges, with certain stakeholders prioritizing risk assessment and transparency without expressing a position on sustainability. The new sustainability-driven regulatory framework may face resistance from those demanding more in-depth evaluations before recognizing NGTs as a sustainable solution. Finally, this paper discusses critical issues related to public consultation processes, highlighting challenges and opportunities in shaping an inclusive and effective regulatory framework.

Keywords New genomic techniques, NGTs, EU genomic regulation, Data mining, Association rules, EU public consultation process

Introduction

Ensuring a sustainable food system requires a multi-strategic approach that encompasses various aspects, such as reducing food waste, lowering greenhouse gas emissions

(GHGs), and promoting healthier diets [6]. These efforts aim to optimize resource use, enhance food security, and mitigate the impacts of climate change [14]. Within this broader framework, improving crop genetics represents a crucial strategy to enhance agricultural resilience and productivity. Developing plants that are more resistant to environmental stresses—such as extreme droughts, pests, and soil degradation—can help secure food production in the face of climate change. Among the most recent

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scientific advancements in this field, New Genomic Techniques (NGTs) offer an innovative and precise approach to modifying plant genomes, accelerating breeding processes, and introducing desirable traits that contribute to a more resilient and sustainable food system [7].

NGTs are ground-breaking methods for precisely and effectively introducing genetic alterations defining desirable characteristics into the plant genome, speeding up the breeding process [8, 45]. They follow a path of scientific advancement that began with the introduction of genetically modified organisms (GMOs). The matching or non-matching of GMOs and NGTs is at the root of stakeholders' disputes and policymakers' difficulties in finding an appropriate regulation [29]. As technology has evolved, many countries have updated their regulations [17, 37]. Instead, the European Union (EU) has long maintained an ambiguous approach. On one hand, the precautionary principle¹ has limited the application of NGTs, while on the other hand, the impending needs in agriculture have led to questions as to why their application is still so restrictive.

Recent discussions highlight this tension, emphasizing both the potential benefits of NGTs for sustainable agriculture and the need for stringent oversight to address environmental risks, such as the possible invasiveness of certain NGT plants [2].

For this reason, the legislation governing the application of NGTs remains that of GMOs (Directive 2001/18), which has been in effect for over 20 years. However, during this time, research has made significant strides forward. Considering this, politicians and international organizations are considering new policies to ensure equitable access to food in the context of climate change, and resource scarcity.

On 5 July 2023, the European Commission presented a proposal for a new regulation and voted by the EU Parliament on 7 February 2024. This process, however, involved the stakeholders, who were asked to voice their different opinions. The issue of the application of genetic techniques has always been a controversial topic, where personal interests, ethical values, and incomplete or contradictory knowledge come into play. Mampuy [30] discussed the NGTs application in a frame of wickedness, highlighting the complexity of the issue. Indeed, according to Rittel and Webber [44] and Kolko [26], a wicked problem can be described as resulting from a conflict of facts and values, a lack of shared definition of the problem, and is extremely difficult to solve.

In this framework, the EU puts in place a consultation strategy to increase transparency, inclusivity, and citizen engagement and thus enhances the legitimacy and effectiveness of democratic decision-making. Through mechanisms such as public consultations, stakeholder dialogues, and expert forums, the European Union seeks to gather input from a diverse range of actors, including citizens, civil society organizations, industry representatives, and academics. These consultations provide opportunities for stakeholders to express their views, concerns, and preferences on proposed policies and initiatives. In any case, it is crucial to ensure that the demands raised by stakeholder involvement are meant in the legislation [9, 32].

This article examines the findings of a public consultation held by the EU Commission in 2022 according to the Better Regulation agenda to solicit feedback from interested parties on possible new standards for NGTs. The aim is to understand the areas of greatest interest and concern that have emerged and the extent to which the consultation responses have been incorporated into the new draft regulation.

The European Union has published a Public Consultation Factual Summary Report [16] presenting the initial analysis of the findings from the consultations.

However, we used the Apriori algorithm [1] to find important correlations between respondents' preferences and trends in stakeholders' opinions, expanding on the primary analyses conducted by the EU. Apriori algorithm is, indeed, a useful data mining tool to handle huge datasets, based on association rules and machine learning techniques. WEKA System software was applied to facilitate the application of the Apriori algorithm.

The article is organized as follows: in Sect. [EU Policy in New Genomic Techniques](#) we present the state of the art of the current regulation in force, the EU consultation strategy applied for NGTs, and the new proposal. In Sect. [Materials and Methods](#), we introduce the basic concepts of the association rule technique, providing a detailed description of the Apriori algorithm and its implementation in the WEKA System software. We present the results in Sect. [Results](#) and discussion in Sect. [Discussion](#). Conclusion and future research suggestions are provided.

EU Policy in new genomic techniques

State-of-the-art of regulatory framework

The application of genetic knowledge and techniques in food production and the related regulatory approach has developed over time, as highlighted in the timeline in Fig. 1. While genetic engineering research dates back to the early 1970 s, the first commercial genetically modified (GM) crops were introduced in the mid-1990 s. Since

¹ The precautionary principle was introduced in 1992, after the United Nations Conference on Environment and Development (UNCED) held at Rio de Janeiro. It underscores the importance of taking preventative action when uncertain about potential risks to public health or the environment.

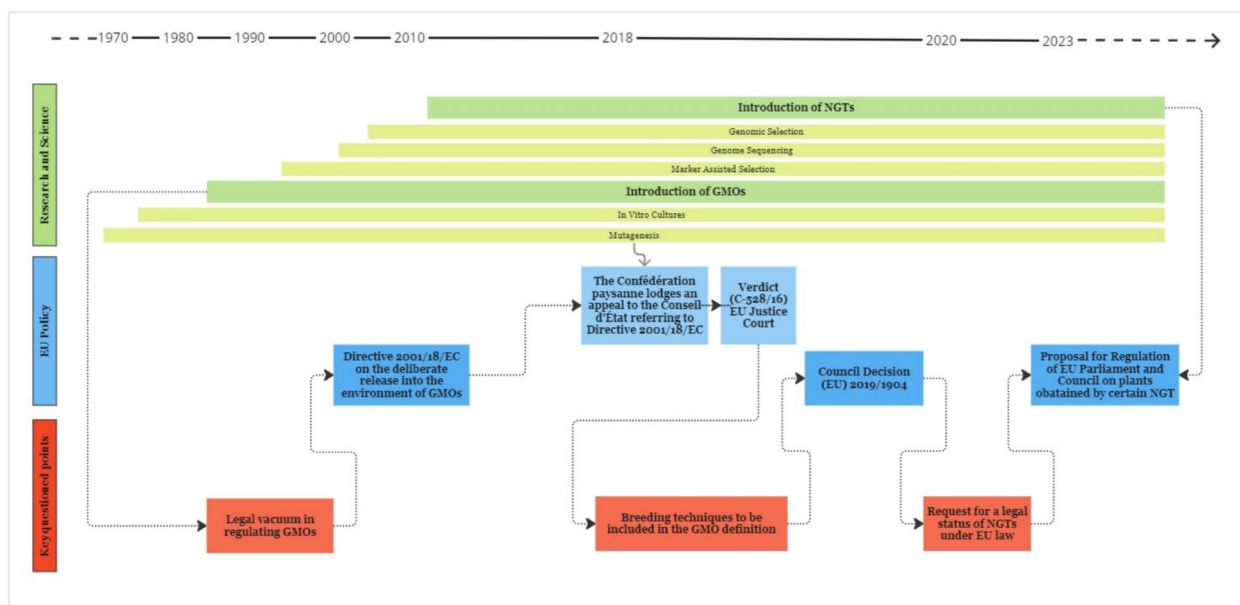


Fig. 1 Timeline of the EU legislation process on NGTs. Source: our elaboration

then, regulations governing GMOs and, more recently, New Genomic Techniques (NGTs) have developed in response to scientific advancements and public debates. Since its introduction, the term GMO has encompassed a wide range of techniques that include, among others, the insertion of foreign genes from other species [42, 43]. The increasing variety and sophistication of genetic modification techniques.

The advancement of technical variety leads toward the need for a unified definition that finds a place in Directive 2001/18.² Still in force, the Directive defines GMOs as organisms other than a human person, in which the genetic material (DNA) has been transformed in a manner that differs from what happens in nature, via natural genetic reproduction and recombination. Following this and according to the precautionary principle, Appendix I of the Directive defined certain genetic modification procedures that must be regulated as GMOs. It is important to note that traditional mutagenesis techniques—such as radiation- and chemical-induced mutagenesis—were explicitly excluded from this regulation, despite generating multiple, often unpredictable genetic changes [11]. This exemption has led to a long-standing regulatory discrepancy that has played a key role in shaping the ongoing debate on genetic modification policy.

In 2016, the emblematic case was *Confédération paysanne*³'s request to the French *Conseil d'État* to clarify the scope of GMO Directive particularly regarding the exclusion of mutagenesis from Appendix I. The case focused on targeted mutagenesis techniques, such as site-directed mutagenesis and genome editing, which modify the DNA sequence in a precise manner without introducing foreign genes. The debate centered on whether these newer mutagenesis-derived products should be classified as GMOs. The applicants argued that modern mutagenesis techniques enable the creation of herbicide-resistant crops, which pose similar risks to the environment and human health as transgenic GMOs [12, 52]. Conversely, proponents of targeted mutagenesis maintained that these methods merely accelerate natural mutations and are consistent with conventional breeding practices [46]. The European Court of Justice (ECJ) addressed this issue in Case C-528/16, ruling in July 2018 that organisms obtained through targeted mutagenesis techniques are subject to Directive 2001/18/EC and must comply with the associated regulatory requirements. The Court's interpretation was based on the use of in vitro nucleic acid modification techniques, rather than the final genetic composition of the modified organism. In other words, the ECJ ruled that the process used to modify the genome, rather than the nature of the final

² 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 – Commission Declaration.

³ farmers' union or organization in France that advocates for the interests of small-scale and family farmers, promoting sustainable agriculture, fair trade practices, and rural development.

product, determines whether an organism falls under GMO regulations. This was controversial because mutations introduced through genome editing can be indistinguishable from those occurring naturally or through traditional mutagenesis ([19]). However, the inconsistencies within the annexes of Directive 2001/18 have been central to the legal debate. Annex IA, Part 1 lists genetic modification techniques that result in genetic alterations, but this list is not exhaustive, creating uncertainty about emerging techniques. Annex IB specifically exempts conventional mutagenesis (techniques used before 2001) from regulatory oversight but does not extend this exemption to modern targeted mutagenesis techniques. Article 2(2) defines GMOs based on genetic modifications occurring outside of natural mating or recombination but do not clearly differentiate between conventional and modern mutagenesis. This regulatory incoherence led the Court to a strict interpretation of the Directive, concluding that modern mutagenesis techniques must be regulated as GMOs unless explicitly exempted. The Court emphasized that even though mutagenesis does not involve the introduction of foreign DNA, it still results in genetic alterations beyond natural processes and therefore falls within the definition of a GMO under Article 2(2). The contradiction between Annex IB and Annex IA—where one exempts conventional mutagenesis, while the other does not exhaustively define modern genetic techniques—created legal uncertainty. This has led to differing interpretations among Member States and within the scientific community regarding whether modern mutagenesis techniques should be subject to GMO regulations.

To address the controversy and regulatory uncertainty, the EU Council requested the European Commission, through Decision (EU) 2019/1904, to submit a study and legislative proposal on the status of NGTs under EU law by April 30, 2021. The Commission's consultation strategy concluded that the existing GMO regulatory framework is not aligned with recent technological advancements, and it recognized divided opinions among stakeholders regarding the necessity of regulatory reform [15]. While some stakeholders argue that the current framework is too restrictive and hinders innovation, others maintain that strict regulation is essential to ensure environmental and consumer safety. As a first step toward reform, the European Commission emphasized the importance of stakeholder involvement, stating that "collecting technical information, practical experiences, and diverse perspectives from Member States and EU-level stakeholders through targeted consultations" is crucial for future policymaking. This process has paved the way

for ongoing discussions on how NGTs should be regulated within the EU.

Dealing with multiple viewpoints

Policymakers face a significant challenge when trying to translate genome editing standards into regulations that are balanced and effective for all stakeholders. They must consider diverse perspectives, including those of individuals, industry sectors, the scientific community, and consumers. However, these collected opinions are often contradictory and fragmented, making the regulatory process particularly complex. Rittel and Webber [44] were among the first to analyze decision-making in highly complex contexts, while Kolko [26] further explored how certain societal and cultural challenges remain difficult to solve due to multiple factors. These include incomplete or conflicting knowledge, diverse perspectives, substantial economic implications, and interconnected regulatory issues with broader socio-economic and environmental challenges.

Thus, the complexity of the multivariate, multi-stakeholder environment arises from clashing interests and the absence of a comprehensive dataset capable of capturing all relevant dimensions of the problem ([32, 38]).

In the NGTs debate, nowadays, some stakeholders still argue that the current regulatory framework is overly restrictive and could stifle innovation in the agriculture sector [39, 40]. Others instead still consider NGTs to pose potential risks to the environment and human health, and that strict regulation is necessary to ensure their safe use [27]. For instance, farmers may be interested in increasing crop yields, improving product quality, and reducing production costs through the adoption of NGT. At the same time, not all farmers could agree on the adoption of NTGs. Small-scale farmers may worry about being marginalized or economically disadvantaged because of the dependency on large agribusiness corporations for seeds and inputs associated with genetically modified crops [24, 25]. EU breeders and seed producers could argue that NGTs help develop more sustainable and resilient crops, with immediate benefits for consumers, such as improved nutritional value [47]. Consumers, on one hand, may welcome the potential benefits of NGTs. On the other hand, they may have reservations or outright objections to NGT-derived products, linked to fears that food is not safe [49]. Using stakeholder knowledge and values on policy simulation may increase policy efficacy by considering the key features of complex problems [31, 32]. Moreover, it is essential to democratize the new regulation [35]. From September to October 2021, citizens and stakeholders were asked to provide feedback on the planned initiative by concretely participating in consultation activities. Thus, the EU Commission's suggestion

was translated into a Consultation Strategy ([15]), structured into participatory ventures. The first was carried out from April 2022 to July 2022. Later, from June 2022 to September 2022, interviews, surveys, and focus groups were conducted to provide technical feedback on specific aspects of policy initiatives.

The new EU Regulation in the context of international approaches

On 5 July 2023, the European Commission presented its proposal to regulate NGTs, aiming to facilitate their market introduction. This proposal diverges from the 2018 ruling of the European Court of Justice, which classified NGTs as equivalent to GMOs in all respects. Instead, it adopts a proportional and flexible approach, prioritizing the characteristics of the final product rather than the technology used to develop it. The proposal divides NGTs into two categories: Category 1 includes NGT plants that are substantially equivalent to those obtained through conventional breeding methods and follows the same approval procedures for cultivation. Category 2 covers plants produced using other specific NGT techniques and requires a step-by-step risk assessment approach; however, the approval process is expected to be less complex and burdensome than that applied to GMOs [25]. For Category 1, the regulation (see Chapter II, Articles 5–11) does not require formal authorization but introduces a “verification procedure.” Additionally, Category 1 plants are exempt from the traceability and labeling requirements imposed on GMOs but must be registered in a publicly accessible database (see Article 9). In contrast, Category 2 plants remain subject to authorization, traceability, and labeling requirements under GMO regulations (see Chapter III, Articles 12–25), even in cases of minor modifications. The proposed rule also introduces a revised risk assessment framework that is less stringent for small and medium-sized enterprises (SMEs), with the European Food Safety Authority (EFSA) providing applicants with detailed guidance before submission of an application. Furthermore, food products derived from NGTs may be voluntarily labeled as GMOs by food operators, allowing consumers to understand the purpose and nature of the genetic modifications (see Article 23). Regarding organic farming, Member States must implement specific measures to prevent the presence of NGTs in both organic and conventional crops (see Article 24). Indeed, the definition of “organic production” in Regulation (EU) 2018/848 explicitly excludes GMOs and other artificial genetic modification techniques, including NGTs. This exclusion is not necessarily based on scientific risk assessment but rather on the fundamental principles of organic farming, which prioritize natural breeding methods and ecological processes. Organic

agriculture favors traditional selection and crossbreeding over biotechnological interventions, aligning with consumer expectations and the established standards of organic farming. Consequently, plants developed using NGTs cannot be incorporated into organic farming (see Article 5), regardless of whether they fall into Category 1 or Category 2. The overarching goal of the regulation is to create a supportive framework for the adoption and development of NGTs in agriculture, promoting sustainability, resilience, and the sector’s ability to address future environmental challenges. At the same time, preserving a clear distinction between conventional and organic agriculture ensures that consumers can make informed choices about the products they purchase.

On 7 February 2024, the European Parliament adopted its position on the European Commission’s proposal, endorsing the new rules and agreeing that NGT plants should be exempt from the strict GMO legislation.

The EU’s regulatory approach reflects a broader international debate on NGT regulation. While the EU distinguishes between NGT categories, many other countries adopt product-based rather than process-based regulations, prioritizing the characteristics of the final product rather than the technology used to create it. For example, the United States does not impose additional regulatory scrutiny when foreign DNA is not introduced [13]. Canada follows a trait-based assessment, focusing on the novelty of plant traits rather than the modification process [10]. Argentina, the first country to introduce a genome editing-specific framework, exempts genome-edited crops from GMO regulations if they do not contain transgenic sequences [50]. Similarly, Japan and Australia differentiate between conventional genetic engineering and site-directed mutagenesis, which does not introduce foreign DNA [20]. These international approaches highlight a global trend toward more flexible, outcome-based regulations, which can better accommodate scientific advancements. The EU partially aligns with this approach by exempting Category 1 NGTs from strict GMO rules, signaling a shift toward proportional regulation. However, Category 2 NGTs remain under stricter oversight, indicating a more cautious stance compared to other jurisdictions. This regulatory divergence could have significant implications for global trade, innovation, and market competitiveness, emphasizing the need for continued dialogue and regulatory harmonization efforts.

Materials and methods

Stakeholder consultations on NGTs have generated extensive qualitative data reflecting diverse concerns and regulatory preferences. Association rule mining, a data-driven approach widely used in pattern recognition, can uncover significant relationships between

stakeholders’ concerns and their corresponding policy positions. This method enables policymakers to identify frequent co-occurrences in stakeholder responses, providing empirical insights into regulatory debates. Stakeholder consultations on new NGTs encompass diverse perspectives, reflecting varying concerns and regulatory preferences. Applying association rule mining to these consultations enables the identification of recurring patterns in stakeholder responses, providing insights into the dominant themes influencing policy discourse.

Dataset

The dataset used in this study was obtained from an EU public consultation, which ran from 29 April to 22 July 2022, on the laws relating to plants generated by specific NGTs, i.e., targeted mutagenesis and cisgenesis, as well as food and feed products derived from them. A total of 2300 responses were submitted but, out of them, 2196 individual contributions were considered relevant and were evaluated. As shown in Fig. 2, respondents consist mainly of EU citizens (66.8%), followed by smaller percentages of academic and research institutions (8.4%), companies and enterprises (7.7%), business associations (5%), non-governmental organizations or NGOs (4%), and non-EU citizens (2.3%). The group “others” is composed of public authorities, environmental organizations, trade unions, and consumer organizations. They were

grouped under “others” because they received less than 2% of the responses.

Association rules

Association Rules Mining (ARM) is one of the most used tools of data mining. Data mining techniques are well-known tools for extracting useful information [18] from raw data [5]. The extracted knowledge can be used to investigate hidden relationships in a large database and helps provide useful insights to data owners [48]. Additionally, as noted by Hearst [21], such techniques are used to analyze vast data set—often for decision-making purposes.

The study applies rules in the form of *if-then*, following the Apriori technique. The Apriori technique was first conceived by Agrawal and Srikant [1] and several algorithms were proposed and expanded after that [51]. Despite this, the Apriori algorithm is still being considered a pioneering and approved method in ARM [4, 34].

The association rule can be equational explained as follows:

Let $I = \{i_1, i_2 \dots i_m\}$ be a set of literals, called items. Let D be a set of transactions (database), where each transaction T is a set of items such that $T \subset I$. TID indicates a unique transaction identifier. An association rule is an implication of the form $X \rightarrow Y$, $X \subset I$ and $Y \subset I$ and $X \cap$

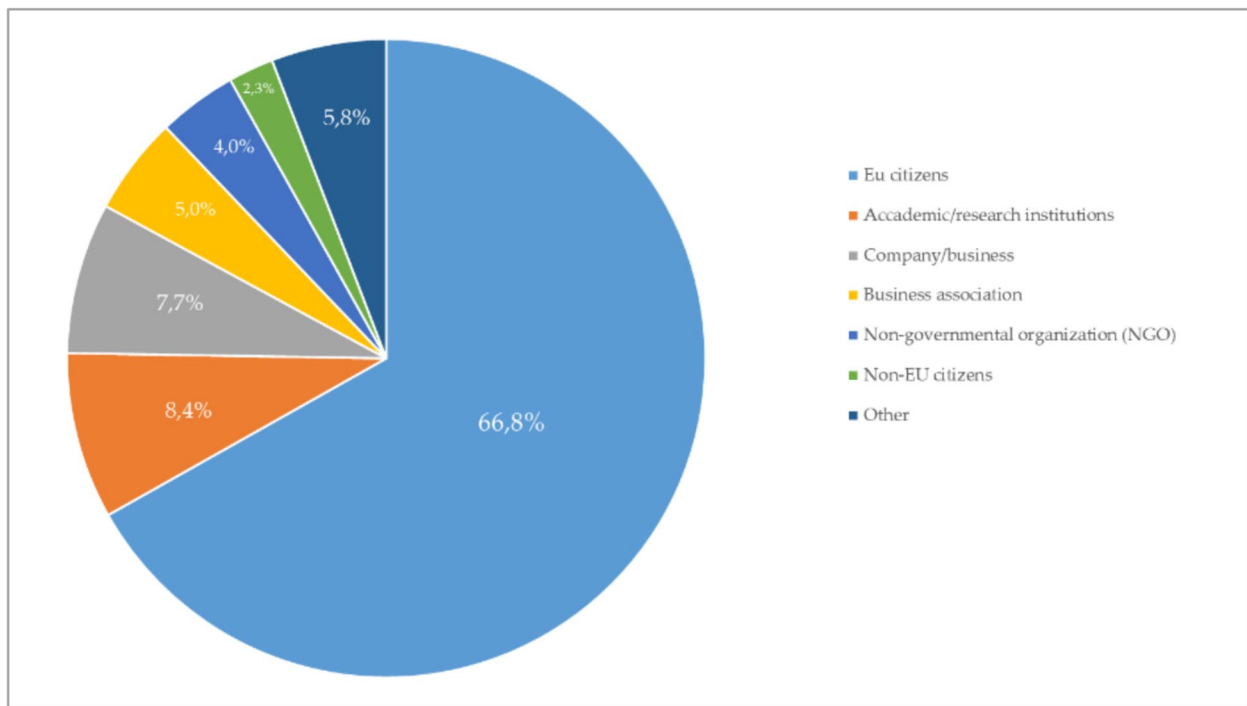


Fig. 2 Responses submitted for public consultation from EU [16]

$Y = \Phi$, with X called antecedent while Y called the consequence of the rule [1].

The equation can be made explicit with the “If–then” statements that are fundamental constructs used to represent conditional relationships. These statements consist of two parts: the antecedent (the “if” part) and the consequent (the “then” part). The antecedent is the condition or criteria that must be met for the consequent to be executed. The consequent is the action or outcome that follows if the antecedent condition is satisfied [34].

Two useful measures can be applied to understand the validity of the model: *lift* and *confidence* [36].

Lift measures the strength of association between two items (or sets of items) in a dataset.

A lift > 1 indicates that the antecedent and consequent appear more often together than expected, this means that the occurrence of the rule body has a positive effect on the occurrence of the rule head.

A lift < 1 indicates that the rule body and the rule head appear less often together than expected, this means that the occurrence of the rule body has a negative effect on the occurrence of the rule head.

A lift value near 1 indicates that the rule body and the rule head appear almost as often together as expected, this means that the occurrence of the rule body has almost no effect on the occurrence of the rule head.

Confidence is the ratio of the number of transactions that include all items in the association rule to the number of transactions that include all items on the left-hand side of the rule. It thus measures the reliability of the association rule.

This paper use *lift* and *confidence* to determine the relationship between item sets and the specific algorithm employed to address this shortcoming. To obtain strong rules we set the Minimum lift at 0.1 and Minimum confidence at 0.9. In this way, it will be possible to identify the type of correlation between antecedent and consequent in the association rules [22].

Data were cleaned and prepared before using association rule mining algorithms. Specifically, the data’s consistency and quality were examined, and any noisy, missing, or unnecessary values were eliminated.

Later, WEKA (Waikato Environment for Knowledge Analysis) software was used for association rule mining once the raw data were pre-processed by employing the software. WEKA is a machine learning software, which is built in Java and incorporates a wide range of machine learning algorithms from different learning paradigms [28].

Applying the Apriori algorithm on WEKA, we scan the database and identify relevant item sets. After that, we identified the associations.

Table 1 Stakeholder opinions on potential factors affecting new EU Regulation on NGTs

Attribute	Values	Count	%
View on the existing regulation	Adequate	456	19.83
	Not adequate	1754	76.26
	No opinion	90	3.91
View on legal clarity	Necessary	1862	80.96
	Not necessary	275	11.96
	No opinion	163	7.09
View on risk assessment	Rigorous	547	23.78
	Case specific	1368	59.48
	Not necessary	289	12.57
View on sustainability contribution	Agree	1319	57.35
	Disagree	737	32.04
	No opinion	244	10.61
View on transparency	Trough label	2013	87.52
	Not necessary	216	9.39
	No opinion	71	3.09
View on the need to adapt regulation to scientific progress	Agree	1609	69.96
	Disagree	530	23.04
	No opinion	161	7.00

Source: Our elaboration

Results

Six attributes were identified from the EU original dataset based on the most pertinent ones for the proposed new NGT regulation. The attributes are shown in Table 1, where the respective number of responses and percentage of responses are listed for each attribute.

In line with the results of the report of the EU consultation [15], the majority of consultation participants (76%) concluded that the GMO laws currently in place are insufficient for plants created by NGTs and ask for legal clarity (82%). Awareness of the need to adapt regulation to scientific advancement is in fact spread among respondents (70%).

Importantly, dissatisfaction with current regulation does not necessarily equate to a call for complete deregulation. Instead, many stakeholders advocate for regulatory revisions that provide greater legal clarity while maintaining structured risk assessment protocols. This is reflected in the fact that 59% of respondents favor a case-specific approach to risk assessment, which suggests a desire for a nuanced regulatory framework rather than a one-size-fits-all policy. Additionally, 23% support maintaining rigorous risk assessment standards similar to existing GMO regulations, reinforcing the notion that dissatisfaction with the current framework does not imply a preference for deregulation but rather for improved regulatory design.

More than half of the respondents (57%) agreed that NGT regulations should incorporate sustainability provisions. However, there remains a notable dissenting minority (32%) regarding the necessity of such provisions in legislation, with another segment (10%) not expressing an opinion. There are differing views on ensuring product traceability from NGTs. However, most respondents (87%) believe labeling the finished product is the best option. Regarding the view on the need to adapt regulation to scientific progress, the responses highlight differing perspectives. The 70% who agree reflect broad acknowledgment that regulatory frameworks should evolve in response to scientific advancements. However, the 23% who disagree may not necessarily reject scientific progress but may believe that existing regulations already sufficiently accommodate advancements or that frequent regulatory changes could introduce instability or uncertainty. This distinction clarifies why this category is not entirely overlapping with “View on the existing regulation” but instead provides insight into attitudes toward the general principle of regulatory adaptability.

To identify interesting relationships among attributes in the dataset, the association rules method was applied. A total of 20 rules (see Annex 1) emerged with a lift > 1, while rules with a lift < 1 were not included. By not including the items that do not often appear together, i.e., those that generate a rule with a lift < 1, an evaluation of the relevant attribute was carried out. Four of the six attributes detected were found relevant to the associations (Table 2). They are “View on the existing regulation,” “View on risk assessment,” “View on sustainability contribution,” and “View on transparency.”

Although all the selected rules reported in Annex 1 are statistically strong, some of them exhibit redundancy. Thus, we focused on rules 1, 10, 13, and 17, which exhibit confidence values ranging from 96 to 98%, signifying that they represent highly reliable patterns. Furthermore, the

interpretability and relevance to policy of these rules provide essential insights into regulatory perspectives, which are pivotal for effective policymaking. They reveal divergent opinions regarding the governance of NGT, illustrating a divide between stringent oversight and deregulation advocates.

Rule 1 (Deregulation Preference with Sustainability) highlights a stakeholder perspective supporting sustainability provisions while rejecting the need for extensive risk assessments and transparency measures. Despite advocating for sustainability, these stakeholders consider the current EU GMO regulation (Directive 2001/18/EC) inadequate for governing New Genomic Techniques (NGTs). This suggests that they perceive NGT-derived plants as inherently low-risk and do not see a need for stringent oversight, particularly if these modifications mimic natural mutations or conventional breeding processes. Their stance aligns with the EU’s Green Deal and Farm to Fork Strategy, which emphasizes the role of biotechnological innovation in promoting sustainable agriculture by reducing pesticide and fertilizer use, enhancing crop resilience to climate change, and improving food security.

The rejection of transparency measures, including mandatory labeling and traceability, could suggest an underlying assumption that NGT products should be treated like conventionally bred plants, without additional regulatory burdens. This perspective stands in contrast to groups advocating for consumer awareness and traceability mechanisms, reflecting broader tensions in the regulatory landscape. Additionally, the dissatisfaction with existing GMO regulations may reflect a perception that Directive 2001/18/EC is outdated and overly restrictive. Our analysis of the data suggests that many respondents associate the current framework does not adequately reflect scientific advancements and imposes unnecessary barriers to innovation, leading to strong support for a

Table 2 Strong rules selected

N. rule	Antecedent (IF)	Consequent (THEN)	Lift	Confidence
1	View on risk assessment = Not necessary Sustainability contribution = Agree View on transparency = Not necessary	View on the existing regulation = Not Adequate	lift:(1.86)	conf:(0.98)
10	View on risk assessment = Case-specific Sustainability contribution = Agree View on transparency = Trough label	View on the existing regulation = Not Adequate	lift:(1.28)	conf:(0.96)
13	View on risk assessment = Rigorous Sustainability contribution = Disagree View on Transparency = Trough label	View on the existing regulation = Adequate	lift:(4.09)	conf:(0.97)
17	View on risk assessment = Rigorous Sustainability contribution = No opinion View on Transparency = Trough label	View on the existing regulation = No opinion	lift:(1.85)	conf:(0.96)

Source: Our elaboration

more flexible, science-driven regulatory approach that facilitates NGT adoption.

The statistical strength of this rule, with a lift value of 1.86 and a confidence level of 98%, confirms that these views frequently co-occur, indicating a strong and reliable association within the dataset. Overall, Rule 1 represents a pro-NGT stance that sees these technologies as naturally contributing to sustainability and therefore not requiring the same level of regulatory scrutiny as traditional GMOs. This aligns with the EU's efforts to introduce a more differentiated regulatory framework, while also highlighting the ongoing divide between stakeholders who push for innovation and those who demand stricter governance. *Rule 10 (Case-by-Case Regulation)* suggests that proponents of adaptive risk assessment and labeling also regard existing regulations as inadequate. This underscores the demand for reforming the regulatory framework to enhance its efficacy and flexibility.

It highlights that respondents who support a case-specific approach to risk assessment, favor the inclusion of sustainability provisions, and advocate for transparency through labeling tend to view the current regulation as inadequate. This perspective acknowledges that while NGTs offer sustainability benefits, they also require a more tailored risk assessment framework rather than a blanket approach. The emphasis on case-specific evaluations suggests a recognition that some NGTs may carry higher risks than others, requiring a more flexible and science-based regulatory framework.

The strong support for transparency through labeling reflects the belief that consumer choice and public trust are essential components of NGT regulation. While these respondents advocate for regulatory adaptation, they do not necessarily seek deregulation; rather, they push for a system that ensures sustainability advantages are achieved without unintended consequences. Their dissatisfaction with existing regulations likely stems from the perception that current GMO laws impose a rigid, one-size-fits-all approach that does not adequately support sustainability-driven innovation.

This rule suggests that while NGTs are broadly supported, their governance should incorporate both adaptability and oversight, ensuring that sustainability goals are met while addressing potential risks. The policy implication is that regulatory reform should not simply ease restrictions but rather develop a more nuanced, case-dependent framework that balances innovation, safety, and transparency.

Rule 13 (Strict Risk Assessment = Regulation is Adequate). The strongest predictor (high lift value) (Lift 4.09) suggests that rigorous risk assessment and transparency are associated with satisfaction with existing regulations. Rejection of sustainability provisions implies skepticism

toward the idea that NGTs inherently contribute to sustainability, possibly viewing it as a justification for regulatory weakening. The preference for transparency through labeling indicates a desire for public accountability and traceability, even if they do not see sustainability as a necessary regulatory criterion. This stance is likely held by stakeholders favoring strict GMO-like oversight, such as organic farming groups, environmental NGOs, and some consumer advocacy organizations, who may see NGT deregulation as a risk rather than a benefit.

Rule 17 (Uncertainty in Regulation): Stakeholders who support rigorous risk assessment and transparency but have no opinion on sustainability or the adequacy of regulation. This indicates a segment of undecided or strategically neutral stakeholders. These respondents strongly support risk assessment and labeling, suggesting they value regulatory control and consumer awareness. No opinion on sustainability could indicate that they either lack a clear stance on whether NGTs contribute to sustainability or do not see it as a relevant factor for regulatory decisions. The lack of a clear position on regulatory adequacy suggests uncertainty or strategic neutrality, possibly from stakeholders who wish to influence specific aspects (e.g., risk assessment) without committing to a broader stance on NGT regulation. This group could include scientific institutions, regulatory agencies, or industry players who acknowledge the need for oversight but remain cautious about defining sustainability as a regulatory goal.

From rules emerged, several general insights and policy implications can be observed. Firstly, there exist varying perspectives regarding sustainability as a regulatory criterion. Some stakeholders see NGTs as inherently sustainable (Rule 1), whereas others oppose the incorporation of sustainability provisions within regulatory frameworks (Rule 13).

This reflects broader debates on whether sustainability should be an explicit regulatory requirement or an expected innovation outcome. While sustainability is strongly promoted, it is not a strict regulatory condition for NGT approvals. However, it plays a decisive role in shaping the regulatory framework, influencing risk assessment, market access, and public acceptance of NGTs.

Secondly, there is agreement on the importance of risk assessment and transparency, though the reasons vary. Stakeholders supporting deregulation (Rule 1) dismiss risk assessment and transparency, believing that sustainability advantages are obvious. In contrast, proponents of a case-specific approach (Rule 10) endorse transparency and tailored risk assessment, striking a balance between innovation and responsibility safeguards. Supporters of current regulations (Rule 13) advocate for rigorous

oversight and clear labeling while viewing sustainability as a regulatory priority of less importance. Third, there emerged a strategic neutrality among certain respondents. Rule 17 indicates a group of stakeholders that selectively engage with regulatory matters, prioritizing risk and transparency but remaining neutral on sustainability and the general sufficiency of regulations.

The results indicate a division among stakeholders concerning the integration of sustainability into NGT regulation. Some advocate for relaxing regulations based on sustainability, while others deem it irrelevant or a justification for stricter scrutiny. As the new regulation champions sustainability-driven innovation, it may face resistance from groups that insist on thorough assessments and transparency before recognizing NGTs as sustainable solutions.

Discussion

The use of Association Rule Mining (ARM) in analyzing stakeholder responses to the EU public consultation on NGTs provides valuable insights into the relationships between key concerns such as sustainability, transparency, and risk assessment. As a data-driven method, ARM minimizes interpretative bias, offering a structured perspective on stakeholder preferences based on the evidence presented in the dataset. However, the reliability and representativeness of the data collected through public consultations face several limitations that must be considered when interpreting the results.

One of the main concerns in public consultations is self-selection bias. Participation in the EU consultation was voluntary, which likely attracted stakeholders with a pre-existing interest in NGT regulation, including industry representatives, advocacy groups, and researchers. Consequently, the dataset may not adequately reflect the diversity of societal opinions, particularly those from less engaged individuals, such as the general public or small-scale farmers. This imbalance risks overrepresenting the views of well-organized interest groups while underrepresenting those with fewer resources or less direct involvement in policy discussions [29, 30]. This divergence highlights the risk of overrepresenting the most engaged groups in public consultations.

The *Public Consultation Factual Report—Legislation for plants produced by certain new genomic techniques* [15] confirms this issue, showing that responses were largely dominated by academia, industry, and advocacy organizations, while the general public was underrepresented and exhibited high uncertainty about NGTs. The prevalence of self-selection bias in voluntary consultations means that findings may not fully reflect broader societal attitudes.

Several studies have documented the general public's limited engagement with GMO-related issues and, by extension, with genome editing techniques. This lack of interest has often been emphasized by pro-biotechnology organizations such as the ISAAA [23], which argue that most Europeans show minimal concern for issues related to food safety and genetic editing, with opposition coming from a smaller, more vocal subset of stakeholders. Consequently, the feedback gathered in the public consultation—although useful in identifying key stakeholder concerns—may not fully capture the diversity of opinions present across EU citizens [33].

To mitigate this limitation, future consultations should employ structured sampling techniques to ensure a more representative distribution of viewpoints. Additional methods such as public opinion surveys, citizen assemblies, and deliberate discussions could help capture a wider and more balanced range of societal perspectives.

Another concern is that the reliability of the associations identified through ARM is inherently linked to data quality and representativeness. If the consultation responses are skewed or unbalanced, the patterns that emerge may not be entirely generalizable to the broader EU population. Moreover, since consultations do not follow a randomized sampling approach, the insights generated may reflect the most vocal and engaged stakeholders rather than the full spectrum of public opinion. This limitation is acknowledged in the European Commission's Better Regulation guidelines, which explicitly state that public consultations do not provide a representative view of the EU population due to their self-selecting nature. Policymakers must therefore interpret the findings with caution, recognizing that while consultations offer valuable qualitative insights, they do not provide a statistically representative basis for decision-making. Another challenge in stakeholder consultations is the sheer volume and diversity of responses, which can create informational overload for policymakers. With multiple competing viewpoints and technical details, distilling actionable insights from stakeholder contributions can be complex. Policymakers must navigate informational noise, where conflicting perspectives may obscure clear policy directions [41].

Furthermore, while consultations serve as tools for gathering stakeholder input, their impact on actual policy decisions remains uncertain. Critics argue that well-organized interest groups often dominate consultations, possibly influencing regulatory outcomes more than the broader public sentiment. Ensuring that stakeholder insights genuinely shape policy decisions—rather than merely serving as a procedural step—remains a critical challenge for the European Commission [3].

Given these limitations, future research on NGT regulation should adopt a mixed-method approach that combines (i) quantitative methods (e.g., large-scale surveys) to capture public opinion trends beyond highly engaged stakeholders, (ii) qualitative methods (e.g., in-depth interviews, expert policy analysis) to contextualize stakeholder concerns and understand regulatory expectations, and (iii) comparative case studies to examine how different jurisdictions regulate NGTs and how public attitudes evolve in response.

By integrating multiple sources of evidence, policymakers can develop a more holistic and inclusive understanding of societal attitudes toward NGTs. This will be crucial in ensuring that regulatory decisions balance scientific advancements with public trust, consumer preferences, and long-term sustainability goals.

Conclusion

This study has analyzed the evolving regulatory landscape of NGTs within the European Union, highlighting the complexities and challenges policymakers face in addressing the diverse perspectives of stakeholders. The intersection of technological progress, legislative frameworks, and social values has generated an intricate debate on the most effective regulation of genome editing in agriculture. While NGTs represent a significant opportunity to enhance crop resilience, sustainability, and food security, their regulation remains a controversial issue, requiring a balance between scientific advancement and precautionary control measures.

One of the key findings of this research underscores the persistent ambiguity in the European Union's approach to regulating NGTs. Although recent legislative proposals attempt to introduce a differentiated regulatory framework—distinguishing between Category 1 and Category 2 NGTs—disagreements persist regarding the adequacy of risk assessments, sustainability considerations, and the necessity of transparency measures. The ARM analysis applied to public consultation data further confirms these divisions, demonstrating that respondents hold divergent positions based on their perceived benefits and risks of NGTs.

Although most participants acknowledge the need for regulatory adaptation in line with scientific advancements, they are divided on the level of oversight required. Some advocate for a more permissive approach aimed at fostering innovation and accelerating the adoption of NGTs, arguing that these technologies promote sustainability and should not be excessively regulated. Others insist on rigorous risk assessments and mandatory transparency measures, emphasizing potential environmental and health risks.

This divergence of opinions highlights the broader challenge of regulating complex issues, where conflicting values, incomplete knowledge, and scientific advancements complicate the decision-making process.

Despite the European Commission's consultation process reflecting efforts to enhance transparency and inclusivity, concerns persist regarding the representativeness of such consultations. The findings highlight the risk of self-selection bias, where well-organized interest groups dominate the debate, potentially influencing regulatory outcomes. This calls for a more comprehensive approach to public engagement, integrating structured surveys, deliberative democracy mechanisms, and awareness campaigns to ensure a balanced representation of societal opinions.

Ultimately, this study emphasizes the need for a regulatory framework that is not only scientifically robust and adaptable to future advancements in genetic technology but also socially acceptable. As NGTs continue to shape the future of sustainable agriculture, policymakers must navigate an ever-evolving landscape, ensuring that regulations are evidence-based, inclusive, and capable of fostering responsible innovation. Future research should continue to explore interdisciplinary approaches that integrate scientific, legal, and social perspectives, thereby refining regulatory models that support both technological progress and democratic legitimacy in policymaking.

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s40066-025-00539-y>.

Additional file 1.

Author contributions

Conception G.V. design of the work I.P. and G.V.; the acquisition and analysis A.G. and F.C.; interpretation of data I.P. and G.V.; writing I.P., G.V., F.C., A.G. All authors reviewed the manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

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