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Challenges and opportunities of genome edited crops: An analysis of experts' views in Italy through a Delphi survey

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Abstract

New breeding techniques (NBTs) in agriculture have generated significant interest due to their potential to address many sustainability challenges related to food production. However, this potential is hindered by existing regulations and negative societal attitudes. The debate is wide open internationally. In this study, a Delphi technique was applied to assess the potential challenges and opportunities associated with genome editing applied to Italian agriculture. To this extent, a panel ranging from 22 to 27 experts from different professions, including academics, staff scientists, policymakers and farmer associations has been interviewed. The Delphi process included two rounds of expert inputs to reach a reasonable consensus and, in some cases, a potential dissensus. Results revealed that experts reached a strong consensus on the potential benefits of NBTs in agriculture, such as greater agronomic performance and enhanced quality for consumers. Nevertheless, experts did not reach a consensus on excluding some potential risks, like possible toxicity or allergy generation. They also shared concerns about some socio-economic risks like limited seed access, traceability, or negative consumers' attitudes.

Keywords: New Breeding techniques, innovation, risk, regulation, Delphi technique

JEL codes: Q16, O13, O33

Highlights

- Experts (in Italy) agree on the potential benefits of NBTs as greater agronomic performance and enhanced quality for consumers.
- Experts do not reach a consensus on excluding some potential risks, like possible toxicity or allergy generation.
- Experts have shown concerns about some socio-economic risks like limited seed access, traceability or negative consumers' attitudes.
- Experts are still divided on regulatory aspects such as risk assessment procedures and labelling.

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1. Introduction

New Breeding Techniques (NBTs) based on genome editing (GE) have progressed rapidly in recent years, leading to the creation of plants with novel traits. NBTs, like CRISPR/Cas or cisgenesis, are instrumental to the selective modification of DNA at specific genomic loci. These techniques encompass several methodologies, such as point mutations, excision, or the incorporation of new sequences. They differ from the “first generation” of genetically modified organisms (GMOs) which include foreign genetic material from different organisms (Wolt *et al.*, 2016; Lowder *et al.*, 2015; Fiaz *et al.*, 2022).

This section provides a short literature review on NBTs and the current debate around them. NBTs development in agriculture is applied to a wide variety of crops and possible results include the development of new varieties resistant to abiotic or biotic stressors (Mishra, Zhao, 2018; Jaganathan *et al.*, 2018; Gao, 2021). These encompass challenges related to climate change, such as rising temperatures and increasing drought exposure (Shinwari *et al.*, 2020). Furthermore, NBTs could facilitate sustainable intensification i.e. reducing the use of chemical pesticides by developing resistance to pests and other diseases (Bisht *et al.*, 2019). CRISPR/Cas9 genome editing has been successfully demonstrated in a large number of plants, including maize (Svitashev *et al.*, 2016), wheat (Liang *et al.*, 2017), rice (Toda *et al.*, 2019), tomato and wheat (Aliaga-Franco *et al.*, 2019; Okada *et al.*, 2019). Currently, many disease-resistant crops against non-viral pathogens have even been developed for rice, wheat, tomato and citrus (Yin, Qiu, 2018). NBTs have also been developed to create new products as

functional food or food with other desired attributes such as seedless vegetables (Lusser *et al.*, 2012; Sedeeck *et al.*, 2019).

The European Academies Science Advisory Council (EASAC) – based on scientific results published in the previous 20 years on the risks and benefits of crop NBTs – highlighted that “policy-makers must ensure that the regulation of applications is evidence-based, takes into account likely benefits as well as hypothetical risks, and is proportionate and sufficiently flexible to cope with future advances in the science” (EASAC, 2017). However, the regulatory landscape governing NBTs remains highly heterogeneous across different countries. Some nations, like the US, Japan, Argentina and recently India have adopted a liberalizing approach (Sprink *et al.*, 2022) where NBTs do not need to adopt the same risk assessment procedures as those used for GMOs. Other countries, most notably the European Union (EU), have upheld strict regulations (Sprink *et al.*, 2016) that do not authorize any GMOs.

Nowadays, many scientists and other stakeholders are calling for the liberalization of NBTs claiming that it is not possible to distinguish new varieties from those obtained through other more consolidated genetic methods like mutagenesis or from mutations that occurred in nature (Broll *et al.*, 2019; Callaway, 2018; Dederer *et al.*, 2019; Zimny *et al.*, 2019). There is a call for the European Union to shift its position on plant biotechnology if agriculture has to meet the challenges of the coming decades (Halford, 2019). In 2018 the EU Court of Justice concluded that, according to the EU’s regulatory framework for GMOs, targeted, genome-editing mutagenic technologies are GMOs, regardless of whether any foreign DNA is present in the final variety (Purnhagen, Wesseler, 2020). In 2021, the European Commission published a new study, at the request of the Council of the EU, according to which NBTs could contribute to a more sustainable food system, but the EU GMOs regulatory framework is currently challenging the development of innovative genetic technologies¹. A legislative process has since then started and on July 5, 2023, the European Commission (EC) adopted a new proposal² to regulate plants obtained by certain new genomic techniques (NGTs) and their use for food and feed. The genome editing proposal was presented as part of the adopted package of measures for the sustainable use of key natural resources, and it will now be evaluated by the European Parliament and Council of the EU.

In the context of Italy, studies have been conducted to assess the feasibility and potential benefits of NBTs applications in Italian agriculture, particularly addressing the challenges related to climate change and crop sustainability (Nerva *et al.*, 2023). Many authors have investigated public perception regarding NBTs and how the information may provide a substantial impact on public acceptance (Marangon *et al.*, 2021; Demaria, Zezza, 2022).

The aim of this study is to contribute to the existing literature to shed some light on the following two issues: 1) the opportunities and challenges of agricultural products obtained through genome editing techniques; 2) the governance questions including risk assessment, varietal approval procedures and labelling.

¹ https://food.ec.europa.eu/system/files/2021-04/gmo_mod-bio_ngt_eu-study.pdf

² https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en

To achieve these objectives, a Delphi survey has been conducted (Avella, 2016; Okoli, Pawlowski, 2004) to anonymously analyse the level of consensus among a panel of Italian experts coming from different backgrounds.

2. Materials and methods

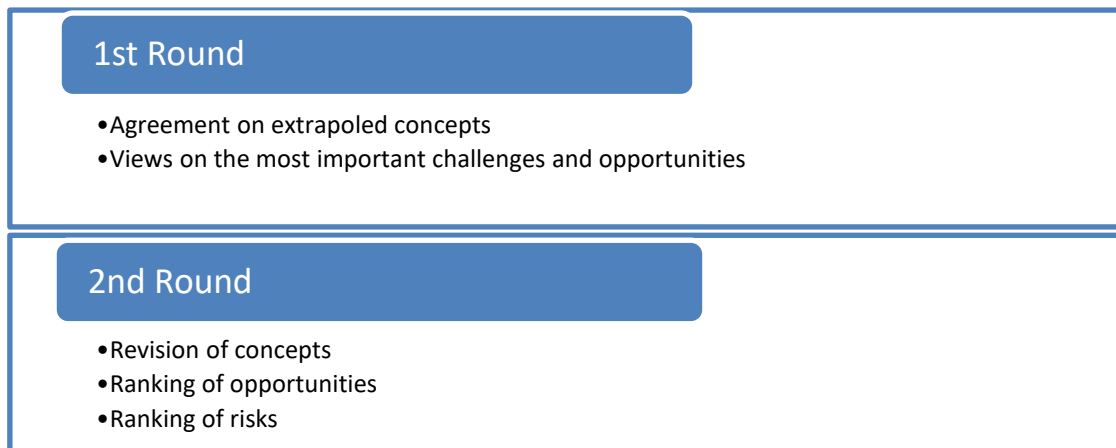
The Delphi approach, first described by Dalkey and Helmer (1963), is a well-established and widely used forecasting process based on the results of multiple rounds of *ad hoc* questionnaires sent to a panel of experts. The Delphi consensus technique has been employed by the research community for a broad range of problems, utilizing experts' viewpoints and knowledge, although it has not frequently been applied in the context of agriculture (Frewer *et al.*, 2011; Rikkonen *et al.*, 2019) even to transgenic agricultural products (Badghan *et al.*, 2020).

In this paper, the experts' judgment concerning concepts, risks and opportunities in new breeding techniques has been analysed. According to the report of Okoli and Pawlowski (2004) among others, the Delphi methodology presents several advantages such as:

- no need for a physical meeting of experts;
- no requirement for a large number of experts, as long as participating ones are specialized in the subject;
- an appropriate method to rank opinions;
- it's a flexible method for follow-up interviews;
- it's a suitable method for complex questions that require deep knowledge;
- it's a compatible method with regard to specific issues that need experts' deep understanding of several dimensions (economic, environmental, agronomical, social and political).

The methodology adopted in the present study involves two distinct stages (Figure 1). In the first stage, the questionnaire was divided into three sections. The first section introduced the subject and the research purposes along with a description of the Delphi methodology. The second section directly inquired about participants' level of agreement/ disagreement with the issues that are more frequently reported in the debate on NBTs, such as the role of public vs private research, labelling and risk analysis. The third section investigated participants' general views on the most important opportunities and challenges of NBTs. To assess the level of agreement with each concept a five-point Likert-type bipolar scale including a neutral midpoint was adopted.

Figure 1. Delphi strategy



Based on the results of the first round, a second round was conducted. In the second-round participants were informed of the result of the first round, including an overview of the levels of consensus achieved. This allowed participants to compare their responses with the others, and eventually to change, or revise, their views.

Next, the questions where consensus had not been reached were reformulated by considering the inputs provided by the panellists in the first round. For this part, a four-point Likert-type unipolar scale omitting the “neutral” option to encourage experts to express straighter opinions was used. Finally, the survey on the challenges and opportunities proposed in the first round was proposed again in a modified “ranking-type” version to assess the level of consensus.

Due to the results of the two Delphi rounds along with the complexity and sensitivity of the topic it was decided not to continue with a potential third round, essentially because it was evaluated that the panellists had had enough opportunity to explain their viewpoints and thus preserve some dissensus. For this reason, forcing a third round would have caused a potential risk of increasing both the time required to provide further answers and the drop-out rate. This situation is not new in Delphi literature (Rowe, Wright, 2001; Toma, Picioreanu, 2016) and it is especially true in the so-called “policy Delphis” where views on policy alternatives (Cuhls, 2015; De Loë *et al.*, 2016; Franklin, Hart, 2007) are required.

The classical Delphi method aims to reach expert consensus, assuming that experts behave rationally and that, after sharing and discussing arguments, will tend to converge on a reasonable agreement. However, in the context of policy questions, this approach is no longer considered realistic or desirable: experts often disagree, and decision-making may require considering pluralistic alternatives. Indeed, when concerning policy decisions, a combination of the “consensus and dissensus” Delphi is needed (Rikkonen *et al.*, 2019). In this context, the data analysis of consensus was based on the measures of central tendency (modes, medians, percentages of agreements that take into account variations in responses and thus potential dissensus). The main limitations of a Delphi survey consist of selecting different experts who can provide different views (Marbach, 1991: 97). Furthermore, generalizing Delphi survey results is always very critical when the selection of the participants is not randomly based (Belton *et al.*, 2019). On the other hand, authors (Anney, 2014; Kuper *et al.*, 2008) underline the importance of transferability of the Delphi results rather than their generalizability. In other words, what really matters is whether, or not, the results have described the phenomenon under

analysis in a sufficient manner to transfer the conclusions to the current times, contexts and people (Polit, Beck, 2010).

The study starts with the definition of the research problem and the characteristics of participants for the Delphi process based on the nature of the specific issues under investigation. Then, the panel was identified and invited to complete the questionnaire. According to the recent Belton *et al.* (2019) review a Delphi panel should consist of a range from 5 to 60 experts, depending on the issue. Furthermore, a heterogeneous sample of panellists seems to be always preferable to better represent the variety of perspectives on a particular topic and to obtain more accurate and reasonable judgments (Bolger, Wright, 2011; Spickermann *et al.*, 2014).

The panel used in this research included heterogeneous experts engaged in agriculture policy and research (academics, staff scientists, policymakers and farmer associations) as reported in Table 1. The first-round questionnaire was distributed to 50 experts, with 27 responses received. The second-round questionnaire was distributed to all 27 respondents of the first round and responses from 22 experts out of 27 were received. Each round was open for a month and several reminders were sent to ensure timely participation³.

Table 1. Characteristics of the expert panellists for the Delphi survey.

Row Labels	1 st round	2 nd round
Consumers Association	1	1
Farmers association	3	2
Green Chemistry Association	1	1
Ministry	1	1
Organic Association	2	2
Producers Association	1	1
Public Research	5	4
Region	2	2
University	11	8
Total	27	22

3. Results

3.1. First Round

The Delphi exercise started by consulting the experts on some concepts extracted from the literature review in the form of a close-ended questionnaire. The intention was to examine the extent to which experts agreed with each concept, by converting them into questions with a five-point Likert-type scale (1: totally agree to 5: totally disagree).

Upon receiving responses, the percentage of agreement (by summing up the 1 and 2 scores - totally agree and agree) and the statistics of centrality median and mode to evaluate a consensus among Delphi experts were calculated. According to Hsu and Sandford (2007), a range between 70-80% of the percentage of agreement allows a reasonable consensus to be achieved with the possible support of median and mode (Table 2).

³ The survey was conducted between September and November 2022.

Table 2. Percentage of agreement, median and mode of the concept items in the first round (ordered by the highest percentage of agreement).

Items	Percentage of agreement	Median	Mode
1. Increased communication between researchers and society can enhance social acceptance of NBTS.	88%	1	1
2. Assessing the risks deriving from the introduction into the environment of organisms engineered with NBTs should be based on the nature of the organism and of the environment in which it will be introduced, rather than the modification method.	74%	2	1
3. The label should clearly indicate that the product was obtained by NTBs.	62%	2	1
4. The fact that genetic technologies are covered by patents held by the private sector poses a challenge to social acceptance.	60%	2	2 - 1
5. A gap exists between risks as perceived by the public and those considered by the experts.	59%	2	2
6. There is no evidence of specific dangers arising from the use of new genome editing biotechnologies.	59%	2	1
7. Consumers might have a more favourable view of foods obtained through new genetic technologies if they were developed by public research centres rather than by private industry.	59%	2	1
8. Consumer acceptance of foods produced through NBTs could increase if the products contain traits directly beneficial to consumers rather than just agronomic traits such as pest resistance, herbicide tolerance and yield increase.	52%	2	3
9. The risks associated with organisms engineered with NBTs are comparable to those associated with the introduction into the environment of unmodified organisms and organisms modified by other genetic techniques.	48%	3	3

1 - *Increased communication between researchers and society can enhance social acceptance of NBTs.* This was one of the two concepts where the agreement was reached in the first round, with an 88% percentage of agreement and no neutral (score=3) position. Two experts expressed their views, one stating that: “*Researchers have a favourable bias and therefore act in terms of reassurance rather than objective framing*” and the other affirming that: “*Favourable researchers have never told the truth on GMOs and NBTs*”.

2 - *Assessing the risks deriving from the introduction into the environment of organisms engineered with NBTs should be based on the nature of the organism and of the environment in which it will be introduced rather than the modification method.* This statement, although

- similar to the previous one, achieved a partial consensus (74%). Two experts expressed their views on what should be considered in the risk assessment process: *“The risks assessment must cover all relevant aspects, including the genetic modification technique”* and *“Risks are not limited to the effects on the environment and health but also extend to food quality”*.
- 3 - *The label should clearly indicate that the product was obtained by NTBs.* Consensus on this statement reached 62%. Respondents motivated their disagreement by pointing out that: *“The indication on the label is not justified given the absence of risks”* and that, in the same vein, *“Labelling would suggest that there may be risks associated with consumption of such products”*. Others suggested that there should be no distinction i.e. with products obtained by mutagenesis stating that *“It is not indicated on the flour that the grain used was obtained thanks to a mutation”*.
 - 4 - *The fact that genetic technologies are covered by patents held by the private sector poses a challenge to social acceptance.* Based on the responses to this statement, a consensus was not reached as the percentage of agreement was 60%. There were some opinions to support this statement such as: *“If it were true, the same should also apply to medicals”* or *“In the absence of patents, research in the private sector is discouraged”*. In the same vein, others affirmed that: *“There are also public sector patents”*, *“Few know what a patent is”* and finally *“Most new technologies are protected by patents”*. Interestingly, one expert underscored that: *“Only a specific segment of society, primarily concerned about the capitalization of GMOs, is concerned about this aspect while others prioritize environmental and health risks”*.
 - 5 - *A gap exists between risks as perceived by the public and those considered by the experts.* Although the median and mode were indicative of agreement, the percentage of agreement of 59% showed that consensus was not satisfactorily reached. Some experts expressed their views in this regard. One expert pointed out that: *“Very often the attention is placed on the short-term effects, neglecting or attributing less weight to the long-term ones”*. On the contrary, another expert affirmed that: *“The experts are aware of the existence or the absence of objective risks”*.
 - 6 - *There is no concrete evidence of specific dangers arising from the use of new genome editing biotechnologies.* On this issue, a partial consensus with 59% percentage of agreement was reached. Seven out of 27 experts remained neutral. Among the experts who expressed their views, there were different opinions such as: *“There is scientific literature that highlights unexpected effects of genome editing”* and *“There is no evidence that there are any dangers arising specifically from the use of new genome editing biotechnologies”* on the one side and *“There is no third-party research on the matter and risks are not only about health”* on the other. One expert affirmed that *“These assessments should be carried out on a case-by-case basis”*.
 - 7 - *Consumers might have a more favourable view of foods obtained through new genetic technologies if they were developed by public research centres rather than by private industry.* This statement showed a percentage of agreement of 59% indicating a lack of consensus among experts. They also shared some interesting contrasting opinions such as: *“Consumers have no interest in knowing where the research is done”*, and *“The private*

sector provides many goods that the consumers accept” on the one side, and “Consumer information is dominated by commercial and non-informative interests” or “This statement applies to everything related to health and the environment” on the other.

- 8 - Consumer acceptance of foods made with NBTs could increase if the products contain traits directly beneficial to consumers rather than just agronomic traits such as pest resistance, herbicide tolerance and yield increase. This concept did not achieve consensus as the percentage of agreement was only 52%. The number of people with no opinion on this matter was quite high (9 out of 27). Some interesting opinions on how communication should be addressed were expressed such as: “The principle of food and environmental safety should be central to the marketing of such foods” or “Effective communication to the public should emphasize that even agronomic traits (less perceived by the consumer) are actually “direct” benefits for the consumer/citizen”. However, there were also critical viewpoints, such as: “Even if they contain “wonders”, the fundamental issue still remains: they are GMOs”.
- 9 - The risks associated with organisms engineered with NBTs are comparable to those associated with the introduction into the environment of unmodified organisms or organisms modified using other genetic techniques. This statement showed the lowest level of agreement with only 48% of consensus. Many experts (11) were on the neutral side, showing a lack of opinion in this regard. Two opinions showed interesting different perspectives: “I don’t think there is evidence in this sense and therefore the precautionary principle always applies” on the one side, and “The organisms obtained with NGT are indistinguishable from those obtained with classical mutagenesis, indeed the process is much more precise” on the other.

The second part of the questionnaire consisted of items related to opportunities and challenges assessed by using a four-point Likert unipolar scale of importance (1=not all important; 4=very important). Responses were processed reporting the percentage of consensus (adding very and moderately important) and the usual statistics of centrality, median and mode (see Tables 3 and 4).

Table 3. Opportunities extracted for gene-edited products: first round statistics (ordered by the highest percentage of agreement).

Opportunities – Items	Percentage of agreement	Median	Mode
1. Drought resistance	100%	4	4
2. Reduction of water consumption	100%	4	4
3. Reduction of use of chemical products	100%	4	4
4. Weed control	96%	4	4
5. Reduction of chemical residues	96%	4	4
6. Contribution to the Sustainable Development Goals	93%	4	4
7. Reduction of production costs	89%	4	4
8. Increased productivity	85%	3	3

9. Defence of biodiversity	85%	3	4
10. Technological innovation of agriculture	85%	3	4
11. Higher nutritional value	81%	4	4
12. Product shelf-life improvement	81%	4	4
13. Food safety	81%	4	4
14. Development of innovative products	78%	3	4
15. Improved competitiveness	74%	3	4
16. Export growth	67%	3	4

Table 4. Challenges extracted for gene-edited products: first round statistics (ordered by the highest percentage of agreement).

Challenges – Items	Percentage of agreement	Median	Mode
17. Possible toxicity	78%	3	4
18. Negative consumer attitude	78%	3	4
19. Possibility of causing allergic diseases	74%	3	4
20. Limited access to seeds	74%	3	3
21. Traceability issues	70%	3	4
22. Resistance to antibiotics	67%	3	4
23. Involuntary transfer of genes	67%	3	3
24. New viruses and toxins	67%	3	4
25. Direct or indirect effects on the ecosystem	67%	3	3
26. Threat to biodiversity	63%	3	4
27. Absence of labelling systems	63%	3	4
28. Pesticides resistance	59%	3	4
29. Fear of unknown effects	56%	3	4
30. Low product quality	52%	3	3
31. Lack of expert consensus on impact	52%	3	4
32. Risks of loss of traditional production systems	52%	3	1
33. Incompatibility of organic farming	44%	2	1
34. Negative impact on imports	33%	2	1
35. Absence of commercial and specific agreements	30%	2	2
36. Religious issues	19%	1	1

Among the opportunities, “Drought resistance”, “Reduction of water consumption” and “Reduction of use of chemical products” ranked the highest and obtained complete consensus. On the other hand, the potential opportunity of “Export growth” ranked the lowest, showing no agreement among experts. Interestingly, the results concerning the challenges were highly heterogeneous. “Possible toxicity” and “Negative consumer attitude” reached a good level of agreement in the importance, followed by “Possibility of causing allergic disease” and “Limited access to seeds”. Additionally, “Religious issues” and “Adherence to commercial and specific agreements” obtained high and good levels of low importance and thus a substantial disagreement.

3.2. Second Round

In the second round, the first round of questions on which consensus had not been reached were reformulated. Since consensus was reached on 2 out of 9 concepts, 7 concepts were redeveloped. This process had considered also the opinions expressed by the panellists in the first round. The new concepts are reported in Table 5. At the end of the second round, 22 experts out of 27 replied to this new concepts’ evaluation.

Table 5. Concepts extracted for gene-edited products: second round statistics (ordered by the highest percentage of agreement).

New Concepts	Percentage of agreement	Median	Mode
1. Consumers are more interested in product innovations rather than process innovations (e.g., seedless varieties, higher content of microelements, etc.).	73%	2	2 - 1
2. Scientists can comprehensively evaluate all the potential risks associated with the introduction of edited varieties.	68%	2	2
3. Enhanced social acceptance of foods obtained through new genetic technologies would result if they were developed by public research centres rather than by private industry.	59%	2	3
4. Specific labelling is necessary for products obtained through NBTs.	55%	1,5	1
5. The fact that genetic technologies are protected by patents owned by the private sector hinders social acceptance.	55%	2	1
6. Risk assessment of the introduction of new modified varieties should follow the protocols used for non-genetically modified varieties rather than those required for transgenic organisms.	45%	3	5 - 2 - 3
7. There is no evidence supporting the existence of specific dangers arising from the use of new genome editing biotechnologies.	41%	3	3

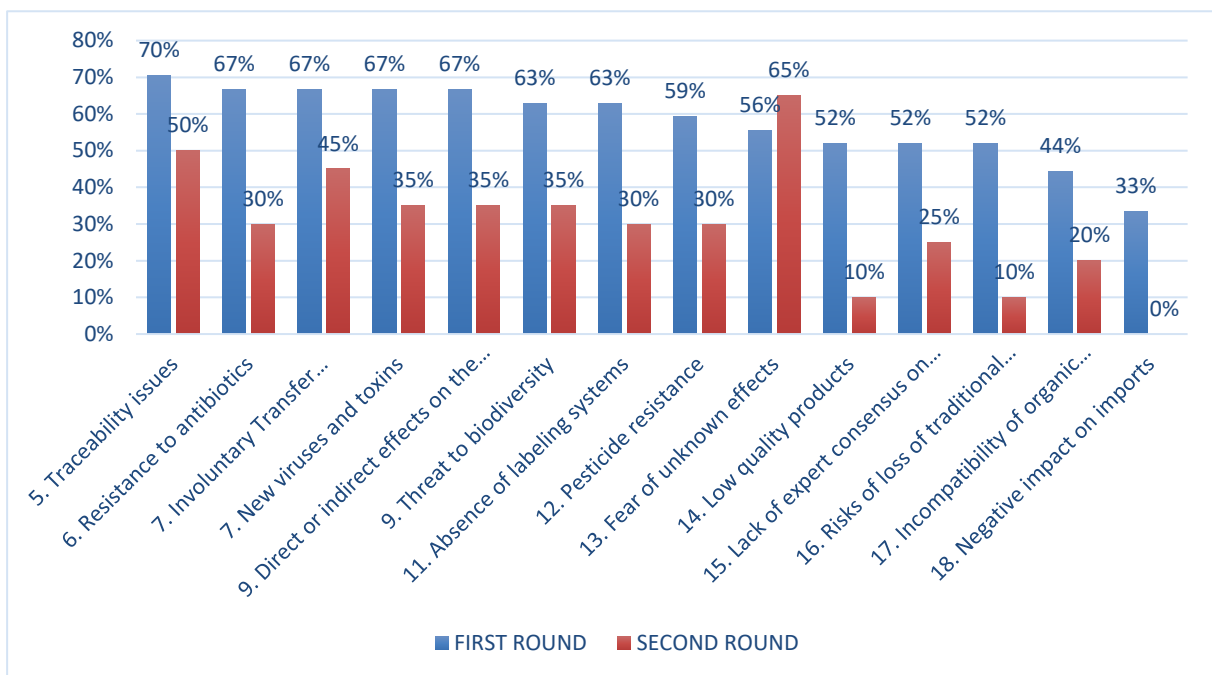
Reformulating the questions produced different results in 6 out of 7 cases. For two questions the level of agreement increased with concept n. 1, reaching a good level of consensus (above 70%); whereas the experts agreed that consumers would be more interested in product innovations rather than process innovations. Partial consensus (68%) was reached on concept n. 2: “Scientists are able to consider all the potential risks deriving from the introduction of edited varieties”. All other issues remained highly controversial, even showing a lower percentage of consensus. Particularly opinions on the evidence of the existence of specific dangers arising from the use of new genome editing biotechnologies and labelling were revisited with fewer experts agreeing on the absence of risk and at the same time, fewer advocating for specific labelling.

Respondent behaviour becomes clearer when opinions on perceived benefits and risks are analysed. In this regard, the survey on the challenges and opportunities proposed in the first stage was reformulated in a modified “ranking-type” version to assess the level of consensus. Concerning the benefits, the experts were asked to confirm, or not, the ranking gained in the first round. The majority of experts confirmed the ranking, whereas just 3 out of 22 expressed their doubts on the general presence of such benefits, claiming that the same was announced but not realized in the case of first-generation GMOs.

The ranking regarding the risks or challenges, gained in the first round, with regard to the cases where consensus had not been reached (i.e., from item number 5 to number 18; see Table

4) was presented to the experts. They were then invited to indicate which of these were effectively risks to be considered as such. Figure 4 reports a comparison of the two rounds. The “traceability issues” that reached a 70% consensus in the first round were not confirmed in the second since only 50% of the experts declared that it was an effective challenge. All the other issues were confirmed not to be alarming except for “fear of unknown effects” where consensus grew with respect to the first round.

Figure 2. First-round percentages of agreement (very + moderately) related to the challenges and percentages of experts who confirmed those challenges in the second round.



4. Discussion

To analyse the results, given the high number of insights from the two Delphi rounds, it is useful to organize the discussion under four main questions:

- 4.1. What are the potential NBTs benefits?
- 4.2. What are the foremost concerns in terms of NBTs safety?
- 4.3. Which factors influence public opinion about NBTs?
- 4.4. How should NBTs be regulated?

4.1. What are the potential NBTs benefits?

This area is notably the least controversial both among the panel and within the existing literature.

Abiotic stress factors, such as drought, heat and salinity currently stand as major causes of yield losses in crops, posing a significant threat to food security. Adapting to climate change

requires the development of improved crops with higher tolerance against abiotic stress factors. Conventional and transgenic breeding approaches have primarily focused on developing drought-tolerant crop varieties. Nevertheless, these methods are – for different reasons – both very time-consuming. In addition, GMOs face significant regulatory hurdles. Considering that drought and salinity stress tolerance are polygenic traits influenced by genome-environment interactions, CRISPR/Cas9-based transgene-free genome editing is considered a very promising approach, enabling many genes to be manipulated concurrently, thus working on very complex metabolic pathways (Raza *et al.*, 2023; Joshi *et al.*, 2020; Shelake *et al.*, 2021).

Biotic stresses, caused by pathogens, represent another significant factor contributing to reduced crop yields, thereby compromising food security and farmers' income. At the same time, addressing crop diseases often relies on chemical pesticides, which can be harmful both to humans, to water quality and, more generally, to the natural environment. Reducing the dependence of food production on chemical pesticides is a key objective reflected in many Sustainable Development Goals (SDGs). Conventional breeding techniques and GMOs have proved to be successful in creating resistant crop varieties but with several limitations that can hinder their ability to address the challenges posed by increasing food demand in the context of global climate change. As remarked on in the introductory literature review, genome editing holds great potential for overcoming these limitations.

The panel reached a unanimous consensus on three issues: drought resistance, reduction of water consumption and decrease in the use of chemical products. Almost total consensus was also observed for potential benefits related to weed control and the reduction of chemical residuals. This consensus is in line with Lassoued *et al.* (2019a), whose study reveals that experts largely agree on the potential benefits of genome-edited crops in terms of agronomic performance (disease resistance, drought tolerance, and climate change resilience). Similar results were reported by Ruder and Kanlikar (2023) for Canada.

4.2. What are the foremost concerns in terms of NBTs safety?

Qaim (2020) distinguishes two different types of risk that need to be considered: risks associated with the breeding process and those related to the developed traits. As a matter of fact, while off-target effects can occur, they are generally detectable and can be eliminated or mitigated during the testing phase. Research evidence suggests that GMOs do not pose more risks than conventionally bred crops (EASAC, 2013; NAS, 2016; German National Academy of Sciences Leopoldina, 2019), although there are diffused concerns about possible negative health and environmental consequences. The second type of risk, associated with the new trait itself, cannot be generally assessed, as each new trait can have different effects. Therefore, trait-specific risks need to be assessed case by case, calling for a product-based regulatory approach akin to the regulatory framework applied for the new varieties obtained through conventional breeding methods.

Concerning this domain, achieving a consensus proved to be challenging. Broadly, the lack of agreement is clearly reflected in the different approaches to risk assessment at world level, with safety regulations being much stricter for GMOs than for any other agricultural

technology (Qaim, 2016). This absence of consensus is not only evident in the existing literature (Lassoued *et al.*, 2019b) but also in this study panel.

The concept of risk was analysed from various points of view. Initially, the questions aimed to understand if panellists perceived a risk perception gap between the general public and experts. There was no consensus in this regard, with someone asserting that scientists paid more attention to short-term time effects than to the long-term consequences. It was also mentioned that third-party research in this domain is lacking. No agreement was found on the concept that: the risks associated with NBTs do not differ significantly from those related to conventional breeding methods. This view is in line with the current EU legislation based on the application of the precautionary principle.

While investigating specific risks associated with NBTs, a partial consensus was reached on the fact that an obstacle is raised by the fear of unknown effects. On the other hand, there was also agreement on other potential obstacles, such as resistance to antibiotics, release of new viruses and toxins and direct and indirect effects on the ecosystem.

4.3. What factors influence public opinion about NBTs?

In their extensive survey of existing studies on consumers' attitudes about NBTs-based food, Beghin and Gustafson (2022) highlighted the limited familiarity of the general public with these issues but also existing consumers' concerns about food's naturalness. They also found that higher levels of trust can be achieved when consumers perceive tangible benefits, such as increased nutritional value or more sustainable production processes, including reduced pesticides usage (Lusk *et al.*, 2015; Gaskell *et al.*, 2003) as well as other environmental benefits (Delwaide *et al.*, 2015; Lusk *et al.*, 2004; Gaskell *et al.*, 2003). Additionally, consumers' acceptance is influenced by several factors such as trust in technology developers (Lucht, 2015; Siegrist *et al.*, 2012, Vindigni *et al.*, 2022), ethical and cultural values, and health concerns (Lusk, Coble, 2005; Costa-Font *et al.*, 2008).

Within the panel, consensus was reached on the notion that improved communication between researchers and society could have a positive impact on the acceptance of NBTs. However, there was no agreement regarding whether distrust in the private sector plays a role in limiting social acceptance. Furthermore, the panel did not agree on the concept that traits directly linked to food quality, rather than to the production process would be accepted more readily by consumers. This result was confirmed when panellists were asked to rank opportunities related to NBTs. In this case, 100% consensus was reached for traits such as drought resistance, reduction in water consumption and the use of chemicals.

4.4. How should NBTs be regulated?

The debate surrounding the regulation of NBTs has gained further attention contextually to the development of such techniques, leading many countries worldwide to reconsider their legislative frameworks, distinguishing between NBTs from traditional GMOs regulations. In the EU, this issue has been central in the political agenda ever since the Court of Justice of the European Union determined in 2018 that genome-editing mutagenic technologies are

considered GMOs, under the EU's regulatory framework for genetically modified organisms (GMOs), regardless of the presence of any foreign DNA in the final variety. Many scholars including Halford (2019) and Dederer *et al.* (2019) have highlighted the urgent need for a shift in the European Union's position on plant biotechnology in agriculture to address the challenges of coming decades.

Throughout the literature, some authors distinguish between process-triggered, where the regulatory framework and risk assessment solely depend on the product characteristics, and process-triggered regulation, where the regulation framework depends on the method used for creating the innovation (Hartung, Schiemann, 2014; Hamburger, 2019; Ishii, Araki, 2017; Medvedieva, Blume, 2018; Qaim, 2020; Smyth, 2020; Tagliabue, Ammann, 2018). Lemarie and Marette (2022) note that the Canadian regulation represents one extreme of product-based while the EU stands at the opposite extreme of process-triggered regulation. Other countries such as the US, Argentina and Australia, adopt a mixed approach, where legislation is process-triggered on some aspects and product-based on others. According to Lusk *et al.* (2018), consumers support the idea that genetically modified (GM) food products should be regulated based on a risk analysis of their impact on health and the environment rather than on the specific process used to create new varieties. In the panel, the assumption that "*The assessment of the risks deriving from the introduction into the environment of organisms engineered with NBTs should be based on the nature of the organism and of the environment in which it will be introduced rather than on the method by which it was modified*" reached a partial consensus in the first round (74%), but only 45% in the second round when the question was reformulated.

Another aspect of concern pertains to the labelling of products derived from NBTs. In the EU, GM products approved for import must comply with EU regulations that require labelling and traceability of food and feed containing GMOs. However, the panel did not achieve any agreement consensus on the need to specify labelling either in the first or second round.

Both of these results underline the very controversial issue of how to regulate NBTs also in Italy.

5. Concluding remarks

The development of NBTs in agriculture is considered a potential answer to the many challenges associated with the growth of food demand: food security, climate change mitigation and adaptation, and environmental sustainability. NBTs innovative varieties have not yet been widely diffused and, in many countries, experimentation remains confined to laboratories. In Italy, the law that allows field trials of NBTs is also very recent. Therefore, it is very difficult to objectively assess the potential benefits for farmers, the agricultural industry and consumers. The same is true for the assessment of the risks, whether related to the environment or food safety.

Regulations governing NBTs are currently subject to a protracted and articulate debate worldwide, primarily due to the uncertainty surrounding market approval procedures for new varieties and the approach to GMOs risk assessment. Ethical and socio-economic

considerations are also intensively debated in this context. Moreover, beyond market approval, another contentious argument under discussion is whether and how the products obtained through NBTs have to be labelled.

In this work, given the absence of objective data to analyse opportunities and risks associated with NBTs innovation, experts' opinions was examined through a Delphi study to identify where a consensus can be reached among experts and which concepts remain the object of dissensus. In the light of these findings, this research may contribute to the ongoing debate, in Italy and the EU, on the urgent need to revise the present legislation on NBTs, also to avoid the shift of R&D investment to countries that have already adopted a product-based approach.

Results have indeed shown that, among experts, there is a very high consensus on the potential benefits of NBTs in agriculture. They agree on many aspects such as improved agronomic performance (e.g., drought resistance, pest resistance, increased productivity) and better-quality products for consumers (e.g., improved nutritional value, shelf life). Nevertheless, experts do not reach a consensus on excluding some potential risks, like possible toxicity or generation of allergies. They also express certain concerns about some socio-economic risks like limited seed access, traceability or negative consumers' attitudes. In discussing regulatory issues, the experts have not reached an agreement on the approach to be adopted (process or product-based) about labelling.

Understanding the future of new breeding technologies and their ability to contribute to solving the many challenges of food systems worldwide still requires a lot of research. In this context, regulatory issues are central in shaping how the benefits will be distributed across the whole supply chain. Controversies upon regulatory issues may be strongly related to the perception of the different impacts of the innovation on the various actors involved. For these reasons, an open-minded and informed dialogue between all the stakeholders is very much required and demanded.

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Author Contributions

A.Z.: Conceptualization, Writing – Original draft preparation, Methodology, Data Curation, Supervision, Writing – Reviewing and Editing. M.V.: Methodology, Writing Methodology, Data Analysis, Validation, Writing- Reviewing and Editing.

Declaration of Competing Interest

The authors declare no conflict of interest in this manuscript.

Data Availability

Data will be made available by the corresponding author upon request.

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