



Ethical aspects of GMO regulation in the EU

Regulating new plant breeding techniques as GM has negative effects on sustainability, diversity and inclusion

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In April 2021, the European Commission issued a study on the status of new genomic techniques under EU law, which concluded that the existing GMO regulations were not sufficient to cover new scientific developments. This has started a reconsideration of the regulation of plant breeding techniques in the EU. These considerations take place while the EU tries to position itself as a leader in research and innovation to bolster climate resilience and sustainable food systems. In this paper, we consider the ethical implications of regulating New Breeding Technologies (NBTs) as GMOs by analysing the impact on European values and commitments, safety and precaution, and inclusion and diversity. We argue that NBTs should not fall under the GMO regulations and instead advocate for a regulatory framework that addresses the ethics problems of the current situation; is more coherent with EU goals around leadership in innovation and sustainability; that recognises the varying risk/benefit profiles of products and regulates them proportionally; and that promotes inclusion, diversity and choice in food markets.

The EU regulates genetically modified organisms under directives and regulations mostly dating from the early 2000s (Box 1), the most relevant of which in regard to NBTs is Directive 2001/18/EC. It requires for any proposed GMO a case-by-case environmental risk assessment prior to release or marketing and lays out the principles and methodology for said assessment. Further stipulations include field testing of GMOs in ecosystems that would be affected by their

use; measures for post-release monitoring; labelling and traceability of products consisting of or containing GMOs; and independent research on the potential risks of deliberate release or marketing to be conducted by EU Member States and the Commission (European Parliament and the Council of the European Union, 2001).

Box 1. EU Directive and Regulations governing GMOs.

- Directive 2001/18/EC on the deliberate release of GMOs into the environment.
- Regulation (EC) 1829/2003 on genetically modified food and feed.
- Regulation (EC) 1830/2003 concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs.
- Directive 2009/41/EC on contained use of genetically modified micro-organisms.
- Regulation (EC) 1946/2003 on trans-boundary movement of GMOs.

Not fit for purpose

While the GMO Directive is meant to protect human health and the environment, many have argued that it is no longer fit for purpose as it does not adequately consider new technologies that were developed since when it was drafted. These NBTs range from full transgenesis to gene editing whereby no alien DNA is introduced and no change to an organism's genetic sequences takes place: the resultant organisms are indistinguishable from those that could be produced by

random mutation or conventional breeding (Grohmann *et al*, 2019). NBTs offer the potential for a wide array of innovations with prospective benefits for agriculture, consumers and the environment.

There is an urgent need for such innovations. Adaptation to, and mitigation of, ongoing climate change will require major changes in agriculture, which itself is both a driver of climate change and distinctly vulnerable to its effects (IPCC, 2019). Agricultural practices must become more sustainable and more resilient, for example, through the use of crop varieties that require fewer inputs, with greater tolerance to extreme weather, or greater resistance to pests which may be expanding with changing climatic conditions.

However, the regulation of NBTs under the current GMO Directive may result in unwarranted restrictions and delay the development and introduction of new crop varieties. Here, we discuss ethical concerns for policymakers with regard to both producer's and consumer's interests and to the EU's commitments to science and sustainability. Given the ethics issues surrounding the EU's stated values and commitments, safety and precaution, and diversity and inclusivity in agri-food markets, we argue that NBTs should not be regulated under the existing GMO directive.

European values and commitments

Among the core values of the EU, as described in foundational documents, are sustainable development, free and fair trade, security and the elimination of poverty

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(European Union, 2007). Major EU programmes, policy initiatives and political commitments have reaffirmed and built upon these. Globally, the EU is committed to the Sustainable Development Goals (SDGs) set out by the United Nations. The latest EU Commission put forward a set of interrelated programmes and policies, which are, in part, motivated by achieving the SDGs. Chief among these is the €95.5 billion scientific research initiative *Horizon Europe* and the *European Green Deal* policy initiative, as well as the supporting *Farm-to-Fork Action Plan* and *Biodiversity Strategy for 2030*. Taken together, these will play a key role in instantiating the goals and values of the EU over the next decade. The European Commission's study on the Status of New Genomic Techniques identified the potential of NBTs to significantly contribute to achieving the objectives of the EU's Green Deal, the Farm-to-fork strategy, the 2030 Biodiversity Strategy and the SDGs (European Commission, 2021).

For the purposes of this paper, we focused on those expressed values, foundational principles and political commitments that relate to plant breeding (Fig 1).

Environmental sustainability

The EU is committed to promoting and implementing ambitious environment and energy policies both internationally through commitments to the SDGs and internally under the EU green deal. Specifically, the EU aims to achieve net-neutral greenhouse gas emissions by 2050 and prepares for adapting to, mitigating the effects of and scaling up solutions to climate change (European Commission and Directorate-General for Health and Food Safety, 2020).

Leadership in research and innovation

Horizon Europe is the EU's tool to achieve technological and scientific excellence and affirm it as a global leader in research and innovation. The initiative aims to foster innovation and mobilise research to help achieve SDGs and other targets in EU programmes and policies (European Commission and Directorate-General for Research and Innovation, 2021).

Sustainable food systems

The EU is committed to ending hunger and improving food security, and ensuring access

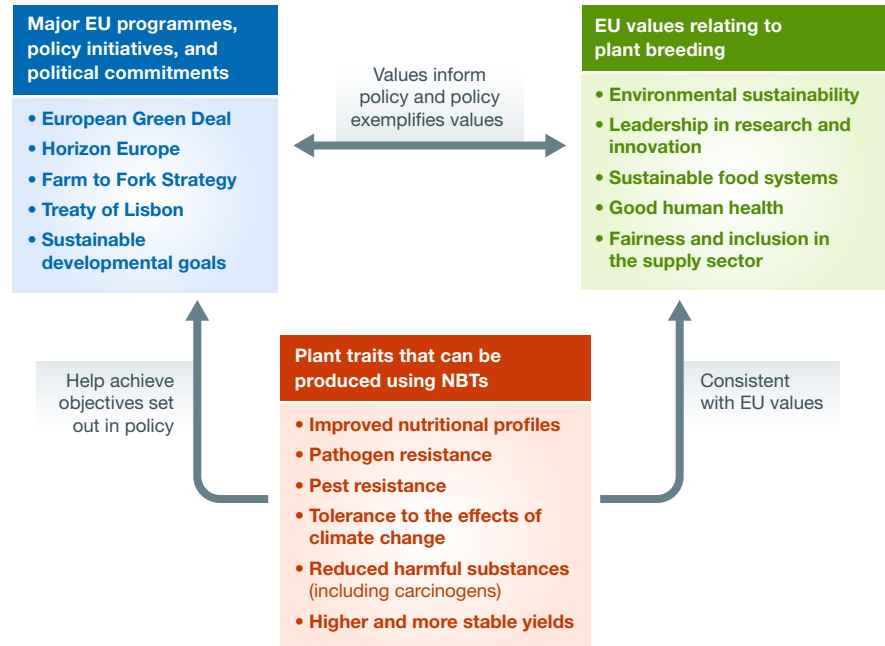


Figure 1. Relationship between EU policy, EU values and traits that can be produced using new plant breeding techniques.

to nutritious, sustainable food for all by 2030 (UN General Assembly, 2015). The Farm-to-Fork strategy identifies measures to achieve this, including increasing access to quality varieties adapted to the pressures of climate change, emerging pests and diseases; halving food waste at the retail and consumer levels; reducing reliance on agricultural inputs; and engaging food system actors and member states to deliver innovative solutions (European Commission and Directorate-General for Health and Food Safety, 2020).

Good human health

Through Horizon Europe, the EU looks to improve and protect the health and well-being of its citizens by generating new knowledge and developing novel solutions to prevent, diagnose, monitor, treat and cure diseases (European Commission and Directorate-General for Research and Innovation, 2021).

Fairness and inclusion in the supply sector

The EU aims to foster a competitive and inclusive supply sector by creating new business opportunities and supporting small and medium-sized enterprises (SMEs) (European Commission and Directorate-General for Health and Food Safety, 2020).

Despite alignment with EU values and their potential to contribute to major EU objectives, NBTs have been met with significant resistance from special interest groups. This culminated in 2018 at the ruling by the European Court of Justice (Case C-528/16), which determined that NBTs would have to be treated as GMOs under the GMO Directive, extending what has amounted to a *de facto* ban of these new techniques. However, the European Commission's newly initiated policy action on the regulation of plants produced with targeted mutagenesis and cisgenesis presents an opportunity to exempt some NBTs from current regulations.

Safety and precaution

Blanket opposition to NBTs in the EU fails to acknowledge that they can be used to design products with a wide variety of risk profiles. Instead, precaution and consumer safety have been applied haphazardly and without regard for proportionality. This failure has been instantiated by the application of the precautionary principle (PP) in the ECJ ruling which ruled that all plants bred using NBTs should be regulated as GMOs regardless of the technique, the presence of foreign genetic materials or the possibility of similar

changes occurring through random mutagenesis or traditional breeding techniques.

While the PP is important for protecting the well-being of Europeans and the environment, it can be applied inappropriately. *The Communication from the Commission on the Precautionary Principle* sets out six conditions for actions taken based on the principle. According to this guidance document, such actions should be proportional, non-discriminatory, consistent, subject to review, capable of assigning the burden of proof and should examine potential benefits and costs (European Commission, 2000).

Examination of the guidance concerning the application of the principle calls into question whether its application is appropriate in the case of NBTs.

Are measures proportionate?

A one-size-fits-all regulation is not a proportionate approach to deal with the wide variety of possible alterations and varying risk profiles. Instead, NBT varieties may require more detailed and deliberate risk assessments for complex changes involving many new genes or off-target changes (European Commission et al 2019). In contrast, if changes occur in a well-characterised area of the genome and render that portion of the genome similar or identical to closely related organisms, proportionality calls for more light-handed regulation (European Commission et al, 2019).

Is the application of the principle discriminatory?

Plant varieties bred using NBTs can be indistinguishable from those attained through traditional breeding techniques or established genomic techniques; in these cases, we have comparable things being treated differently. Meanwhile, NBTs are different from first-generation GMOs, yet they are treated the same. Both situations constitute discrimination.

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Has the scientific information been updated and reviewed?

The GMO directive uses a definition for GMO from 1990, 22 years before NBTs were first described. When the decision to include NBTs under the GMO Directive was made, no review of scientific information was conducted. Since the European Food Safety Authority (EFSA) has found that many NBTs—site-directed nucleases type 1 and 2, oligo-directed mutagenesis and cisgenesis—create no new hazards compared with both conventional breeding or other established genomic techniques (European Commission, 2021).

Are both potential costs and potential benefits considered?

Some products of NBTs present minimal risk to the environment or human health but could be instrumental for achieving EU goals and objectives. Yet, despite varying risk/benefit profiles, all plants bred with NBTs face the same heavy regulatory burden under the GMO directive.

According to this analysis, invocation of the PP as justification to include NBTs under the GMO directive is inconsistent with EU guidance on the application of the principle. Considerations around proportionality, discrimination, up-to-date scientific review and potential benefits indicate the need for more nuanced regulation.

Diversity and inclusion in agri-food markets

Some concerns around GMOs are driven by beliefs that multinational companies use biotechnologies to gain competitive advantages and control the food supply by controlling the seeds available to farmers (Qaim, 2020). According to this view, the prohibitive cost associated with developing biotech crops makes SMEs less able to compete and the consequent narrowing of varieties available to farmers limits the choice of crops available to consumers. In this way, some see biotechnology in the agricultural sector as incongruent with values of fairness, inclusion and competition.

It was estimated that an application to import a GMO crop into the EU in 2015 would cost between 11 and 16.7 million euros and take six years from submission to

final approval (Schulman et al, 2020). These costs, long timelines and uncertainties disincentivize SMEs and other groups interested in using NBTs to pursue plant breeding; it excludes new breeders and favours consolidation within the sector (Schmidt et al, 2020). Accordingly, a *de facto* ban on NBTs is likely to deprive SMEs of tools that would enable them to compete with multinational companies. A more nuanced and proportional regulation of NBTs could, therefore, increase the range of companies and other actors involved in developing new crop varieties.

If small-scale breeders are systematically excluded from the market, this may also limit the variety of goods on offer, with particular constraints on more local and niche produce, and undercut the ability of consumers and producers to choose the products they consider most desirable. This will come at the expense of farmers’ livelihoods and the viability of European SMEs, thereby widening existing inequities, while stifling EU competitiveness and innovation. A *de facto* ban on NBTs is, therefore, incongruous with the EU’s stated commitment to the SDGs, particularly goals related to innovation, elimination of poverty and reduction of inequalities. Instead, the EU should seek to capitalise on the benefits of NBTs to support its research sector and ensure NBTs are leveraged to benefit both farmers and consumers. In jurisdictions which have set up different regulations for gene editing in plants, smaller businesses or public research institutions are now playing a key role in the development of crop varieties (Schmidt et al, 2020).

Divergence in EU regulation of NBTs with the rest of the world has implications for the competitiveness of EU researchers, companies and farmers. In addition to putting SMEs at a disadvantage, treating NBTs as GMOs puts all European agricultural businesses at a disadvantage relative to non-EU competitors. Even larger EU businesses, which may have the wherewithal to clear the regulatory hurdles in the EU, will incur extra costs and wait times compared to those working within less onerous governance frameworks. This process disincentivizes investment in agricultural research and development in the EU, causing funding and talent to move elsewhere, and undermines the EU’s commitment to fostering innovation. Indeed, companies are already

cutting funding to research projects in the EU or moving them overseas (Schmidt *et al.*, 2020). This chilling effect may not be limited to the private sector but could impede academic and public sector research as well, which typically have fewer resources to direct towards long and uncertain regulatory processes.

“Current regulation discourages investment and leaves only groups with larger budgets and greater ability to absorb risk to seek approval for their products.”

Opponents of NBTs have attempted to justify their inclusion under strict GMO regulations through appeal to EU values such as fairness, inclusion and non-monopolistic competition. The trouble with this line of argument is that NBTs are not the same as GMOs. Rather, NBTs have a wide variety of risk profiles, are much more accessible and far less costly than GMOs and can contribute to diversity and inclusion in the agri-food industry.

Discussion

In the light of our analysis of EU values and commitments, guidance for the application of the precautionary principle and the impact of existing regulation on SMEs and the market and in anticipation of the European Commission’s forthcoming policy initiative and impact assessment, we put forward the following recommendations to consider in the crafting of a new regulatory framework for NBTs (Box 2).

First, products generated by new breeding techniques should not be regulated under the current EU GMO directive. Examining the track record of the existing regulation shows that it has in effect banned genetically modified organisms from the EU. An approach that breaks with this track record would signal to EU researchers, scientists, innovators, investors, consumers and others that the EU is willing to ensure coherence between its avowed goal to be a centre of scientific and technological innovation in support of sustainability and its regulatory system.

Next, the notion of proportionality should be at the centre of regulatory approaches. A new regulatory framework should include

Box 2. Recommendations.

- Products issued from NBTs should not be regulated under the existing EU GMO directive.
- New regulations should recognise the differences between the products of NBTs and those of first-generation GMOs and regulate them accordingly.
- A new regulatory framework should weigh both risks and benefits of innovation as well as consider the cost of inaction.
- Regulation of products resulting from NBTs should be right-sized to their risk/benefit profiles as to not arbitrarily exclude SMEs, non-profits, publicly funded research, and NGOs from the market due to their relative inability to bear the risk and cost of compliance.
- A new regulatory approach should recognise that technological development could yield yet-unknown techniques in the future and thus be flexible to accommodate different approaches without requiring changes or new regulations each time.

an interpretation of the precautionary principle that is open to weighing risks and benefits of innovation and that considers the cost of inaction. Rather than a blanket assumption of high risk, the EU should balance the regulatory burden with the probable risks and benefits of products. Some approaches, because of the type of changes they result in, do not require the heavy-handed approach under the EU’s GMO regulation.

It is also critical to recognise that the more complex and cumbersome it is to comply with regulations, the more it excludes smaller companies, innovators and not-for-profit groups. This is another reason why the regulation of products resulting from NBTs should be right-sized to their risk/benefit profiles. Current regulation discourages investment and leaves only groups with larger budgets and greater ability to absorb risk to seek approval for their products. This systematic exclusion is detrimental to researchers, farmers and consumers and creates conditions that exacerbate existing social and economic inequalities.

Finally, a new regulatory approach should recognise the diversity of techniques that fall under the umbrella of NBTs and recognise that technological development could yield novel and unknown techniques in the future. The regulation should thus

be flexible to accommodate different approaches without requiring changes or new regulations each time.

With the current review of plant breeding regulation, the EU has an opportunity to align its regulatory system to its stated goals, values and commitments. This is also an opportunity to ensure the normative values embodied in the precautionary principle are applied in a way that is justifiable and consistent with how it was meant to be used. Finally, in keeping with the EU’s stated desire to contribute to the SDGs—including those concerning innovation, elimination of poverty and reduction of inequality—ensuring the inclusion of SMEs in the agri-food industry should tip the balance towards implementing a more equitable, flexible, adapted and proportional approach to regulating NBTs. Such an approach would weigh their risks, benefits and the social and economic costs of inaction without tying them to the regulatory legacy of GMOs.

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The authors declare that they have no conflict of interest.

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