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Precaution and the Precautionary Principle: A View on the EU – The Example of Modern Biotechnology

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Synonyms

GMOs; Novel Foods; Prevention

Definition

The precautionary principle is a general principle of Union law and part of the Treaty on the Functioning of the European Union. The precautionary principle holds a prominent position in EU secondary regulations related to GMOs. However, when it comes to interpretation of this principle, it is often observed that it is construed in a manner that blurs the delicate distinction between the precautionary principle and the principle that preventive action will be taken. This tendency puts the integrity of the precautionary approach, which serves as the foundational basis of the precautionary principle, at risk. This entry highlights the differences between a precautionary approach and the precautionary principle in EU law and the implications this has for the debates on GMOs. The economic rationale for a precautionary approach underpinning the precautionary principle will be presented and the misunderstandings and misuses discussed.

Introduction

Market interventions involving the precautionary principle can take many forms such as requiring additional information or banning specific activities. The precautionary principle plays an important role in EU law governing the use of "genetically modified organisms" (GMOs) and has been gaining prominence recently in the debate surrounding the regulation of new plant breeding technologies. The regulation of plant breeding technologies developed through modern biotechnologies varies across different regions of the world. This variance hinges on the specific alterations and methodologies employed. For instance, in the United States, an agency-based model is being employed, where several agencies such as the United States Department of Agriculture are involved (U.S. Department of Agriculture 2023). Within the EU, the regulatory framework encompasses both process-based and product-based components. The regulatory trigger predominantly considers the process aspect, while

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the authorization employs a product-based approach. Some processes, especially those involving radiation or chemically induced mutations, are exempt from GMO authorization. If these processes concern seeds, they require varietal authorization, and if they qualify as "food," they might undergo assessment under the Novel Food regime.

Within the European Union (EU), the precautionary principle stands as one of the fundamental principles guiding GMO and other regulations. The driving force behind its adoption lies, inter alia, in the recognition of the potential for irreversible risks associated with the application of modern breeding technologies. By incorporating the precautionary principle, legislators are empowered to enact laws that govern and regulate these specific technologies.

The precautionary principle is explicitly articulated in the legal framework addressing the use of modern biotechnology. In contrast, this explicit mention is absent from the regulatory texts in Canada and the United States. Nevertheless, both countries have established regulatory frameworks that mandate compliance for plants, animals, and food products resulting from the application of modern biotechnology before they can be released into the market. Similar regulatory regimes are also prevalent in numerous other jurisdictions worldwide (Eriksson et al. 2019).

The interpretation of the explicit mention of the precautionary principle in various EU laws, including some soft laws and court rulings, by scientists and other stakeholders has frequently been overly broad and simplistic. Consequently, this has led to misunderstandings and confusion in the discourse.

Many scholars have tended to perceive the EU as excessively protective, a viewpoint that, while potentially well-founded, oversimplifies the matter and neglects the intricate political-economic dynamics at play in regulatory policies. These dynamics stem from the competition among diverse interest groups, a phenomenon not unique to the EU but observed in other jurisdictions as well (Smith et al. 2021; Smart et al. 2015).

Given the widespread existence of this competition among interest groups across most jurisdictions, the question arises: why does the EU often seem to be characterized by stricter authorization policies? Is this perception accurate, or could it be influenced by a biased viewpoint held by stakeholders such as scientists and business operators?

In this entry, we will argue that both perspectives hold some truth. The political-economic landscape has indeed contributed to the formulation of more stringent regulations for modern plant breeding in the EU. Additionally, certain stakeholders may harbor biases that favor stricter GMO regulations.

The Economics of a Precautionary Approach

The economic rationale behind adopting a precautionary approach is rooted in scenarios characterized by decision-making under uncertainty, irreversibility, and flexibility. In this context, uncertainty refers to situations where individuals or entities possess some understanding of potential future states of nature and assign subjective probabilities to these outcomes. Moreover, this approach takes into account the presence of irreversible costs: "*Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation*." (Principle 15, Rio Declaration). Furthermore, as time progresses, new information emerges regarding future states and their respective probabilities. In such instances, it can be prudent to delay a decision and await the acquisition of additional information (Wesseler and Zhao 2019). This concept is elucidated in greater detail in the section below.

Box: Precaution, Uncertainty, and Irreversibility (Wesseler and Zhao 2019)

A policy decision necessitates choosing between two options: either implementing an immediate policy change or deferring

(continued)

the decision to a future date. The social cost of the policy is $I > 0$. If implemented now, the current period's social benefit is $B_0 > I$ and is known with certainty. However, the social benefit in period t_1 can take two possible values, at $B_{1h} > B_0 > I$ with probability $q \in [0, 1]$ and at $B_{1l} < I < B_0$ with probability $1 - q$. Let $\beta \in (0, 1)$ be the discount factor. Assume the payoffs and probabilities are such that the expected net present value of implementing the policy now is positive, $E[NPV_i] = -I + B_0 + \beta(qB_{1h} + (1 - q)B_{1l}) > 0$, so that the traditional NPV model would recommend implementing the policy now. But consider the possibility of postponing the policy for one period, after observing the realized value of B_1. If the realized value is $B_{1h} > I$, the policy should be implemented, resulting in a net social benefit of $B_{1h} - I$. If, however, the realized value is $B_{1l} < I$, the policy should not be implemented, to avoid the net loss of $B_{1l} - I < 0$. The NPV of the expected net benefit of delay is $E[\text{NPV}_\text{P}] = \beta q(B_{1h} - I)$. Postponing the decision until more information is available is desirable, i.e., $E[\text{NPV}_\text{p}] > E[\text{NPV}_\text{i}]$, if the loss that is avoided by waiting is sufficiently high, i.e., if B_{1l} is sufficiently low:

$$B_{1l} < \frac{I(1 - q\beta) - B_0}{(1 - q)\beta}. \qquad (1)$$

In this case, postponing the decision to the beginning of t_1 generates a higher expected NPV from today's perspective. The lower B_{1l} is the higher the chances that postponing the decision will be economical. It is noteworthy that the delay condition depends only on the downside risk of B_{1l} being too low, but not the upside benefit B_{1h}. This is known as the "bad news principle:" the investment decision is driven by the desire to avoid bad consequences.

Further, one can easily see that for one unit of benefits B_{1l}, less than one unit of irreversible costs is needed for delaying immediate investment. This creates a stronger incentive to delay immediate introduction of a GMO in comparison to the "standard" model, where it would be optimal to introduce immediately if the benefit just exceeds the cost. This observation has been called the irreversibility effect in the literature (Henry 1974) and is similar to the quasi-option effect introduced by Arrow and Fisher in 1974 (Fisher 2000).

In conclusion, opting to delay a decision and awaiting additional information can be economically justified. However, this approach entails a trade-off, as it involves forgoing potential benefits. Those can be in several million Euros per year as mentioned in more detail below. It is essential to recognize that this trade-off does not invariably warrant delays. In the context of GMOs, concrete reports of irreversible costs linked to their release have not surfaced; they remain speculative. In contrast, irreversible benefits, such as a reduction in pesticide use (Kluemper and Qaim 2017) (e.g., of more than 242 million kg in active ingredients for the case of herbicide tolerant maize) (Brookes and Barfoot 2020), in greenhouse gas emissions (Brookes and Barfoot 2020; Smyth et al. 2011; Barrows et al. 2014), e.g., of more than 2.5 billion tons of carbon dioxide in 2018 (Brookes and Barfoot 2020), in land use, e.g., 13 million hectare for the year 2010 (Barrows et al. 2014), in mycotoxins in food crops (Wu 2006), and an increase in micronutrients (HarvestPlus 2018), and in food security (Wesseler et al. 2017a) have been identified. Certain studies have suggested potential impacts on nontarget organisms, although these findings have not been confirmed (Wesseler et al. 2011; FAO 2022).

Countries have adopted varying policies in response to the potential impact on the environment and food safety (Eriksson et al. 2019). Some nations have chosen to implement robust ex post

liability regulations, which create incentives for companies to voluntarily ensure the safety of their developed seeds. In contrast, others place greater emphasis on ex ante safety standards that companies must adhere to before their products enter the market. Research has revealed that ex ante safety standards tend to be considerably more costly than ex post liability rules, which can diminish incentives for immediate investments (Wesseler et al. 2023).

However, it is noteworthy that the plant breeding sector's response to stricter regulations is not uniform and depends on their market position (Wesseler et al. 2019).

Studies have highlighted the significant foregone benefits associated with certain cases, such as vitamin A-enriched rice in India resulting in foregone benefits of over 700 million USD over a 10-year period (Wesseler and Zilberman 2014), transgenic field crops in Africa with over one billion USD over a 10-year period for selected countries (Wesseler et al. 2017b), Bt-maize and herbicide-resistant maize with forgone benefits of more than 200 million Euro per year (Wesseler et al. 2017b), and sugar beets in Europe with over 170 million Euros per year (Demont et al. 2004). A recurring concern raised is that the environmental risks posed by GMOs remain uncertain and potentially indefinite. A similar argument can be made for the potential benefits, which could justify immediate release (Van den Belt 2003). However, one may contend that we lack knowledge about the probabilities of future outcomes.

In the context of deciding whether to approve GMOs now or later, this concern is somewhat mitigated from a methodological perspective. Contingent claim analysis suggests that quasi risk-neutral probabilities should be applied when future states can be identified (Wesseler and Zhao 2019). The current distribution of future states can be deduced by extrapolating our current behavior and continually adjusting results as new information becomes available. Such modeling can offer crucial insights for policymaking (Wesseler et al. 2019). Early findings related to GMOs indicate substantial economic benefits (Van den Belt 2003) that could be realized. Wesseler et al. (2007) have proposed a method to determine the maximum incremental social tolerable irreversible costs (MISTICs) associated with the introduction of GMO technology. Their approach relies on a model grounded in contingent claim analysis. According to their framework, a decision to postpone the release of GMOs should only be considered if there are indications that these threshold levels could be exceeded. Importantly, these threshold levels explicitly factor in uncertainties regarding future benefits and costs. They are set lower than the expected value of future benefits and costs, as exemplified by the value of B_{1L} in the accompanying box.

When applied to various instances, such as herbicide-resistant maize, sugar beets, Bt-maize, and bacterial wilt-resistant banana, these threshold levels appear to be significantly distant from being reached based on the existing knowledge. This suggests that immediate introduction aligns with the precautionary principle.

Furthermore, the explicit modeling of decisions under conditions of irreversibility and temporal uncertainty highlights another crucial aspect. Postponing a decision due to the irreversibility effect becomes more likely. Renowned psychologist Daniel Kahneman (2011), a Nobel Laureate, utilizing research conducted in collaboration with his late colleague Amos Tversky, introduced the concept of loss aversion into economics. This concept underscores that individuals tend to weigh losses more heavily than gains, emphasizing the greater significance of potential losses. The model presented in the box furnishes the economic rationale for such behavior and aids policymakers in recognizing the importance of economic losses, as people typically prioritize avoiding losses over achieving gains. These observations lead to an important insight: given that losses have a greater impact than gains, accentuating and perhaps exaggerating the potential irreversible costs associated with a technology —achieved through carefully crafted narratives— can significantly influence people's concerns about these potential losses. Consequently, individuals may express disapproval toward the introduction of that technology. Employing such a narrative and leveraging the effect of loss aversion can prove to be a potent strategy in campaigns

advocating for the delay or cessation of an immediate technology introduction.

In this context, policymakers "captured" in their current approach (Stigler 1971; Dal Bó 2006) are likely to be particularly responsive to these types of campaign arguments. Their primary focus is often to maintain their position, attain promotion, or secure reelection. To counterbalance one unit of irreversible costs, more than one unit of reversible benefits is typically required. This creates an asymmetry favoring opponents over proponents in public debates surrounding technologies like GMOs. Notably, research by Wesseler and Zhao (2019) and Wesseler et al. (2017b) sheds light on this phenomenon, particularly through a case study on Vitamin A-enriched rice, showcasing how this imbalance can potentially lead to an abuse of the precautionary principle.

The Precautionary Principle in EU Law on Genetically Modified Organisms

The precautionary principle has drawn considerable attention, particularly in the realms of law and politics. Its legal significance is traced back to the 1970s German *Vorsorgeprinzip*, which encapsulated environmental conservation aspirations (Boehmer-Christiansen 1994; Rehbinder 1994; Purnhagen 2014). This principle manifests in diverse forms, rendering it context-specific, but it has not been without its critics, who contend that it is overly vague, excessively restrictive, and irrational (Sunstein 2005; Majone 2002). (p 89).

The interpretation of the precautionary principle varies depending on its specific application field (Fisher 2007). In an effort to bring more clarity to this principle, the European Commission has issued a Communication outlining practical guidelines for its implementation (European Commission 2000). Additionally, the EU judiciary has affirmed the precautionary principle as a general principle of EU law (Artegodan GmbH and Others v Commission of the European Communities 2002), granting it legal standing equal to that of human rights. The principle is defined as follows:

> [W]here there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent. (Case C-157/96 of 5 the Court of May 1998)

The explicit reference to irreversibility, as articulated in the Rio Declaration, has been omitted or overlooked.

Within the EU Treaties, the precautionary principle is referenced only once, specifically in relation to the environmental protection (Article 191 TFEU) and is not subjected to further elaboration or definition. In several pieces of secondary legislation, the precautionary principle is mentioned (See especially Art. 1 Directive 2001/18), with food-related legislations being the exception as they provide a definition. Notably, Article 7 of the General Food Law (GFL) incorporates a version of the precautionary principle as a broadly applicable principle of food law:

> In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

Despite its general nature, the precautionary principle, as defined by Article 7 of the GFL, is not universally applicable to all food products in the same way. Instead, it requires interpretation "in the light of the procedural operation of those provisions" (Case C-111/16, Fidenato 2017) which outline how the precautionary principle is to be applied. When the precautionary principle is applied to products that have previously undergone an authorization procedure, its application should be less stringent in comparison to products that have not received prior authorization. The operationalization of the food-related precautionary principle has been clarified by the Court in the *Queisser Pharma* case (Case C-282/15, Queisser Pharma GMBH, and co. KG v Bundesrepublik Deutschland 2017). This entails two key steps:

1. Identification of the potential adverse health effects associated with the substances or foods in question.
2. Conducting a comprehensive health risk assessment based on the most reliable scientific data available and the latest findings from international research.

Restrictive measures can be instituted where "it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm persists should the risk materialise, (. . .) provided [. . . the measures] are non-discriminatory and objective." (Case T 719/17, FMC Corporation v Commission 2021).

In the domain of GMOs, the precautionary principle applies to two distinct regulatory frameworks: those related to food and those pertaining to the market placement and environmental release. Both frameworks have implications for internal-market matters, particularly concerning the free movement of goods. It is important to note that EU GMO regulations are not based on the Treaties' specific environmental protection competence norms. Therefore, the application of the precautionary principle primarily revolves around trade law considerations.

Within this context, EU law differentiates between GMO foods, governed by Article 7 of the GFL, and GMOs intended for environmental release and market placement, which are subject to the general interpretations provided by the Court concerning the precautionary principle within the GMO regime.

In the sphere of foods, the Court of Justice of the European Union (CJEU) jurisprudence has applied Article 7 of the GFL as a provision supporting the precautionary principle as a general principle of EU law, resulting in a situation where the precautionary principle cannot undermine, modify, or relax existing EU GMO regulations (Case C-111/06, Giorgio Fidenato and Others 2017). This judicial approach has effectively diminished the regulatory impact of Article 7 of the GFL (Purnhagen 2021), thereby harmonizing its application between the food sector and the environmental release/market introduction sector.

In a general sense, the Court has adopted a broad interpretation of the precautionary principle (Case C-157/96, National Farmers' Union and Others 1998). However, this expansive interpretation carries the risk of blurring the distinction between the precautionary principle and the principle that preventive action needs to be taken (This separation is explicitly recognised in Art. 192 (2) TFEU concerning environmental policy), where only the latter principle may warrant the implementation of permanent measures. This expansive interpretation aligns with international agreements like Article 5 (Fisher 2000) of the SPS Agreement and the Rio Convention (This separation is explicitly recognised in Art. 192 (2) TFEU concerning environmental policy). It is also reflected in the definition of Article 7 of the GFL, even though the latter's function has been rendered inactive within EU law by the CJEU.

Consequently, due to the Court's broad interpretation and the deactivation of Article 7 of the GFL in the context of GMO regulations, the precautionary principle can, through legislation, support and justify permanent measures and such not linked to irreversability (Purnhagen 2021). This extends the application of the precautionary principle to cover measures governed by the principle that necessitates preventive action, potentially jeopardizing the integrity of the precautionary approach as its foundational basis.

Links with EU GMO Policy

In compliance with the requirements of SPS law, the EU's version of the precautionary principle has been a guiding force behind EU policies related to GMOs. It forms an integral component of the EU's regulatory framework for GMOs, especially in terms of selecting regulatory tools and making decisions within the authorization procedure.

Precautionary considerations have also played a significant role in shaping EU food safety policies, as noted in the EU Environmental Council's actions in 1999. In the context of risk analysis, decision-making in both GMOs and food safety is

bifurcated, dividing responsibilities between scientific risk assessment and political risk management. In the realm of food safety, this bifurcation means that the European Food Safety Authority (EFSA) is responsible for risk analysis, while the European Commission handles risk management, with varying degrees of involvement from Member States.

This bifurcation has resulted in a two-step procedure within the EU regulatory regime. For GMOs, applicants submit dossiers for authorization of GMOs for environmental release, market placement (including imports), and processing through national competent authorities to EFSA. In summary, as described in greater detail by Smart et al. (2015), the authorization process operates as follows: EFSA conducts an assessment of the dossier and provides an opinion to the European Commission. The European Commission then prepares a recommendation based on this opinion, which is subject to a decision by the standing committee, taken by qualified majority. If a qualified majority cannot be reached, the proposal proceeds to the Appeal Committee for qualified majority voting. If, once again, no qualified majority is reached, the European Commission retains the authority to make the final decision on authorization.

Up to the present, no GMO proposal submitted has garnered a qualified majority either in favor or against it (Purnhagen and Wesseler 2021). Some Member States consistently vote against these proposals or abstain, with abstentions essentially functioning as votes against under the voting systems employed in the two committees. In each case, the European Commission has followed the recommendations of EFSA and its own recommendations, ultimately authorizing the applications. Since 2003, applications have been predominantly submitted for import and processing. Applications for environmental release were primarily submitted before 2001 when GMOs still required authorization under the EU's Novel Food regulation.

The current decision-making framework also has implications for potential changes in the regulatory policies governing GMO approvals. Since the committee procedure closely resembles legislative decision-making, the experiences gained from this process may influence potential modifications in the regulatory policies concerning GMO authorizations (Purnhagen et al. 2021). In response to requests from Member States, the European Commission has been tasked with developing a proposal to adapt the existing regulation to more effectively accommodate changes in plant breeding techniques that have emerged after 2001. In a preliminary ruling, the CJEU determined that crops created using new plant breeding technologies are classified as GMOs, necessitating authorization for environmental release if intended for cultivation within the EU or for import and processing. However, as demonstrated by the experiences with GMOs, the authorization process has proven to be burdensome, time-consuming, and costly.

The European Commission has put forth a proposal that offers the possibility for certain plants developed through SDN-1 technologies to enter the market without requiring authorization. Additionally, it outlines a less rigorous authorization process that would be less time-consuming and expensive for other plants (European Commission 2023). This proposal has received favorable feedback from the scientific community, plant breeders, and pro-biotechnology advocacy groups. However, many environmental organizations and anti-biotechnology advocacy groups have expressed concerns about these potential changes.

It is important to note that not all Member States are likely to support a proposal that streamlines the authorization process for some GMOs. This raises uncertainty about whether any European Commission proposal aimed at reforming GMO legislation will garner the necessary support in the Council of the European Union. In the Council, legislative proposals by the EC require a positive vote by a qualified majority, making consensus challenging to achieve.

Discussion and Conclusions

The economic theory of decision-making under uncertainty and irreversibility offers justification for delaying the introduction of GMOs when

irreversible costs are sufficiently high. The application of the precautionary principle, as outlined in the Rio Declaration, underscores the significance of irreversible costs. This is missing from the interpretation of the precautionary principle in EU law. The EU deviates from the original meaning of the precautionary principle resulting in a misuse with substantial consequence for the EU economy and environment.

The precautionary approach, as established in the Rio Declaration, finds economic support in the context of decision-making under uncertainty and irreversibility. These principles give rise to additional costs that must be taken into account, analogous to the benefits derived from loss aversion. It is important to note that this economic rationale does not necessarily advocate for the outright prohibition of activities but rather underscores the need for safety policies governing the authorization of GMOs for introduction into the market or release into the environment. Such safety policies are observed in various forms around the world, and they can impose varying degrees of costs on private sector companies involved in GMO investment, resulting in regional disparities in investment levels.

From a policy campaign perspective, the economics of precaution provide incentives for stakeholders who oppose GMOs. Mounting opposition to GMOs is generally less costly than supporting them. Among these, the EU stands out for having some of the most stringent policies governing GMO authorizations. However, it is worth noting that EU policies have faced criticism for potentially misusing the precautionary approach and the precautionary principle in their original sense. Both of these approaches hinge on the presence of irreversible costs, which, up to this point, have remained speculative, while irreversible benefits have been realized.

Cross-References

- ▶ Court of Justice of the European Union
- ▶ Environmental Damage
- ▶ European Community Law
- ▶ European Integration
- ▶ Food Safety

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