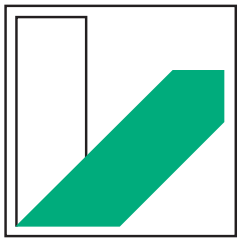

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and their Possible Economic Implications for the EU and Beyond

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EU REGULATION OF NEW PLANT BREEDING TECHNOLOGIES AND THEIR POSSIBLE ECONOMIC IMPLICATIONS FOR THE EU AND BEYOND

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31 August 2020

Abstract

New plant breeding technologies (NPBTs), including CRISPR gene editing, are being used widely, and they are driving the development of new crops. They are nevertheless a subject of criticism and discussion. According to a summer 2018 interpretation by the Court of Justice of the European Union (CJEU), European Union (EU) law makes most NPBTS subject to regulations governing the use of genetically modified organisms (GMOs) in the EU. The implications of this decision have been widely discussed in the literature, thereby stressing the importance of the decision for plant breeding and international trade within and beyond the EU.

This contribution summarizes the status of the debate and highlights issues that have thus far not been considered—particularly with regard to the implications of EU regulations for NPBTs for countries outside the EU.

We conclude that the practical implications of the CJEU decision reduce the EU's comparative advantage and increase the cost of achieving the objectives of the European Green Deal. Our findings reveal an almost complete lack of possibilities for changing the current situation. China and countries oriented towards China are the most likely economic beneficiaries of the current situation.

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I Introduction

New plant breeding technologies (NPBTs) include a range of technologies aimed at helping plant breeders to develop crops with desired traits more precisely and much more rapidly than would be possible with technologies based on chemical or radiation-induced mutations. In many cases, the new technologies induce only very precise desired point mutations, while other breeding tools (e.g., mutations induced by chemicals or radiation) are less precise, altering much larger parts of a plant's genome. Although the use of NPBTs cannot eliminate off-target effects (i.e., changes to other parts of a plant's genome), it does make such effects less common. In addition, the potential off-target effects of NPBTs are better understood than are those of other plant-breeding technologies, particularly with regard to techniques involving the application of chemical and radiation-induced mutations. For this reason, many scientists consider NPBTs safer than many of the alternative tools (Nationale Akademie der Wissenschaften Leopoldina, Deutsche Forschungsgemeinschaft und Union der deutschen Akademien der Wissenschaften. 2019). Despite considerable consensus among experts in the areas of molecular biology and plant-breeding with respect to the safety of the technologies, many policymakers and lobby groups are less convinced. In this contribution, we apply the language and syntax of European Union (EU) legislation—especially the definitions stipulated therein, as well as in those documents used by the Court. In addition, we summarize as NPBTs those discussed by Sprink et al. (2017).

The diverse views on safety and related regulatory policies have led to considerable controversy, particularly within the EU. Experts in the areas of molecular biology and plant breeding call for regulating plants derived from NPBTs, depending on the method applied, in a manner similar to the regulation of plants derived from chemical and radiation-induced mutations. In contrast, many others view almost all plants derived from NPBTs as genetically modified organisms (GMOs), thus claiming that they are regulated as such (Sprink et al. 2017). In the longer term, many argue the need for revising the GMO regulations to reflect an approach based more on products than on processes (Eriksson et al. 2019; Purnhagen et al. 2018b; Seitz, 2018; Wanner et al. 2019).

Most scholars agree that the current legal status in the EU is that plants produced by NPBTs fall under the regulations for GMOs. This has wide-ranging implications for plant breeding within and beyond the EU. The implications are much broader than has previously been discussed in the literature, which has tended to overlook a number of links between EU-level regulations and their implications for investments in plant breeding and trade in agricultural products.

In this contribution, we summarize the regulations that apply to GMOs in the EU, along with the case decided by the Court of Justice of the European Union (CJEU). Based on this summary, we discuss the implications of the regulations and their interpretation for plant breeding within and beyond the EU, particularly with regard to international trade. We further consider these implications in terms of possibilities for changing the situation within the EU. As we note, however, such possibilities are limited, and those that are available are likely to be time-consuming.

Overall, our analysis of the political and legal situation leads to the conclusion that the application of NPBTs to crops intended for the European market and for countries that produce for the European market are extremely limited. First, this reduces the comparative advantage for the agricultural sector in the EU and the opportunities for the United States for exporting to the EU. Second, this provides stronger incentives for countries to adopt NPBTs that do not export substantial volumes of agricultural and food products to the EU than otherwise.

II The Legal Situation in the European Union

A Regulation of GMOs in the European Union

In the broadest terms, the approval of GMOs in the EU follows a two-step risk-analysis procedure. In this section, we summarize the basic steps. The approval process is discussed in greater detail by Wesseler and Kalaitzandonakes (2019). For a comparison between the approval processes of the EU and the United States, see e.g. Smart, Blum, and Wesseler (2017).

Risk assessment is the first step in the approval process. This assessment is, as a matter of principle, conducted by the European Food Safety Authority (EFSA). The second step consists of the risk management, which is performed by the European Commission (EC) and EU Member States.

In Article 2 of Directive 2001/18 on the deliberate release of GMOs into the environment (EC, 2001, hereinafter "Directive" or "Directive 2001/18"), the EU defines a GMO as follows: "…an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination." As specified in Article 3, the Directive does not apply to techniques listed in Annex I B of the Directive. Without further specification, these exemptions include mutagenesis, which is conventionally understood in non-legal terms as the process of altering the genetic information of an organism either spontaneously or deliberately (e.g., by using chemicals, radiation, or NPBTs).

Directive 2001/18 is relevant to the approval of GMOs for deliberative release into the environment (i.e., "cultivation") or for placement on the market within the EU. The Directive does not directly apply to approvals for the import and processing of genetically modified food and feed, which are covered under Regulation 1829/2003 (EC, 2003a) on genetically modified food and feed (hereinafter "Regulation" or "Regulation 1829/2003"). This Regulation defines genetically modified food and feed as "containing, consisting of or produced from GMOs" (Article 2, Regulation 1829/2003), with GMOs understood as defined in Directive 2001/18. All food and feed covered under Regulation 1829/2003 are further subject to requirements concerning labeling and traceability. These requirements are further detailed in Regulation 1830/2003 on the labeling and traceability of GM food and feed (EC, 2003b). Labeling exemptions apply to the adventitious or technically unavoidable presence of traces of GMOs, as long as they do not exceed the threshold level of 0.9%, as defined under Regulation 1829/2003. This threshold applies to the labeling of GMOs that have been authorized for import and processing. For GMOs that have not been approved but that have received a positive risk assessment by the EFSA, a threshold level of 0% applies for food, with a threshold of 0.1% for feed (EC 2011). Regulation 1830/2003 also states that GMOs require unique identifiers prior to authorization.

B GMO Risk Analysis in the EU

Applications for the approval of GMOs for cultivation and/or import and processing must be submitted to the competent authority in one of the Member States, which assesses the application and submits it to EFSA. The EFSA then assesses the application and presents a recommendation to the EC, which sends a proposal, based on the recommendation by the EFSA, to the relevant EC Standing Committee, which includes representatives of all EU Member States. The Committee members discuss the EC proposal and arrive at a deci-

sion by qualified majority voting (see Box 1). If no qualified majority is reached in favor or against the proposal, the EC may revise the proposal and resubmit it to the Committee, or it may submit the original proposal to the Appeal Committee. The Appeal Committee also includes representatives from all EU Member States and decides by qualified majority voting. If it fails to reach a qualified majority in favor or against the EC's proposal, the EC will make the final decision (Wesseler and Kalaitzandonakes 2019). Experience has shown that, since 2001, neither the Standing Committee nor the Appeal Committee has ever reached a qualified majority, and the EC has made the final decision in all cases (Smart, Blum, and Wesseler 2015). Even if crops are approved, each EU Member State has the possibility of opting out of approval for cultivation with effect to their territory (EC, 2015).

If a new crop does not fall under the approval process for GMOs, this does not imply that it is "unregulated," as claimed by some authors. For example, in cross-border cases, the new crop would still be subject to general EU requirements (e.g., those applying to the free movement of goods and possibly the General Food Law), and it would need to comply with the registration requirements of EU Member States (Purnhagen et al, 2018b). Furthermore, such new crops are not exempt from the various liability regimes for environmental and food safety that apply at the level of the EU or that of its Member States (Dries et al. 2019).

C The Decision of the Court of Justice of the European Union

The widely discussed regulations on NPBTs originated with a court case in France in 2015, where the cultivation of herbicide-tolerant crops developed by non-GMO plant-breeding techniques (e.g., oilseed, rape, and sunflowers) has increased in the past 20 years. Nine French agriculture and environmental associations had asked the French Prime Minister to impose a moratorium on the sale and cultivation of herbicide-resistant oilseed rape and sunflower in France in December 2014. They argued, if herbicide resistance had been introduced by mutagenesis, those crops should be considered GMOs, but would be exempted according to Annex I B of the Directive 2001/18. According to their reasoning, if directed mutagenesis had been applied, cultivation should be stopped until approval, as the exemption applied only to methods of mutagenesis that had been in use before 2001. The Prime Minister did not respond to the request—under French law, this is regarded as a rejection of the request. On March 12, 2015, therefore, the associations submitted an application to the Conseil d'État (Council of State, France) to ask the Prime Minister to impose the moratorium (Liberation, 2015). On October 3, 2016, the Conseil d'État referred this case to the Court of Justice of the European Union (CJEU) by asking four specific questions, which can be summarized as follows (for additional details, see e.g., Bobek, 2018; Purnhagen, 2019; Seitz, 2018): are plants produced by using mutagenesis to be considered GMOs, and are those produced by us-

ing directed mutagenesis exempted from Directive 2001/18, as they would also be covered by the mutagenesis exemption in Annex I B of the Directive?

Not surprisingly (Purnhagen et al. 2018a), the CJEU (2018) decided that plants developed by mutagenesis are regarded as GMOs, but that plants developed by directed mutagenesis do not fall under the mutagenesis exemption. The latter decision came as a surprise, as the Opinion of the Advocate General (Bobek 2018)—which the CJEU follows in a majority of the cases (Purnhagen 2018b)— had proposed a different kind of interpretation.

Many biologists and other scientists criticized the judgement, and particularly the CJEU's argument that only "*organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are excluded from the scope of that directive*" (CJEU 2018, para 54). They regard plants developed by directed mutagenesis—which often results in point mutations only —as being at least as safe as those developed by traditional methods of mutagenesis. Furthermore, they pointed to the long safety record of plants developed by transgenesis (e.g., Eriksson et al. 2019; Group of Chief Scientific Advisors 2018; Nationale Akademie der Wissenschaften Leopoldina, Deutsche Forschungsgemeinschaft und Union der deutschen Akademien der Wissenschaften 2019).

As a result of the judgment, plants developed by methods of directed mutagenesis are regarded as GMOs, and they must therefore be approved for cultivation. The judgment could also be interpreted as covering the placing of food and feed on the EU market, including import and processing (Purnhagen, 2019), thus making them subject to requirements concerning labelling and traceability along the supply chain (Eriksson et al. 2019).

D Application of the Precautionary Principle

The precautionary principle has been an important argument for placing techniques of directed mutagenesis under the EU regulations for GMOs. In its decision, the CJEU states, "*It follows that an interpretation of the exemption in Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B thereto, which excludes organisms obtained by means of techniques/methods of mutagenesis from the scope of that directive, without any distinctions, would compromise the objective of protection pursued by the directive and would fail to respect the precautionary principle which it seeks to implement.*" As specified in Article 4 of Directive 2001/18, "*Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs. GMOs may only be deliberately released or placed on the market in conformity with part B or part C respectively.*" In line with its case law, the CJEU based its decision on a specific understanding of the precautionary principle that is tailored to the risks legally associated with GMOs. This understanding reflects the wording and spirit of

the applicable EU regulations. As such, this understanding can be understood as an absolute interpretation of the precautionary principle.

III Implications of the CJEU Judgment

If the CJEU judgment is interpreted to cover food and feed, it has direct implications for investments in plant breeding. In general, a firm's investments in new technologies can be viewed as a portfolio of call options (Berk et al. 1999). The value of a specific investment depends on the investments to be made, the expected returns to be generated, and market risks related to the investment. The value chain for plant breeding can be divided into four important phases: R&D, approval, market, and ex-post liability. The R&D and approval phases generate costs, while the market phase generates the benefits from investment. The ex-post liability phase entails the potential costs of legal issues related to the introduction of the product. The duration of each phase and the costs and benefits associated with them are uncertain from an ex-ante perspective. Treating NPBTs as GMOs substantially increases the cost of approval, as it affects both the time required for a new product to reach the market and the costs involved in bringing it to the market. Moreover, differences in approval requirements across jurisdictions generate asynchronicity in market access, thereby disrupting international trade.

The marginal effects of an increase in approval costs on the investment hurdle have been estimated as amounting to a factor of between seven and fourteen. In other words, one unit of additional costs requires between seven and fourteen additional units of benefits. Similar results have been derived for the marginal effects of changes in R&D costs (Purnhagen and Wesseler 2019). Later in this article, the implications of the ruling are discussed in the light of the framework discussed above by explicitly considering the legal environment.

A Implications for Plant Breeding in the European Union

The results of the CJEU judgment have a direct effect on the costs of applying techniques of directed mutagenesis within the context of plant breeding. For illustration, to date, only three agricultural crops—two corn events and one potato event—have received approval for cultivation in the EU. Only one of these crops is currently being cultivated on a commercial scale. Of the other two crops, one has not been commercialized due to poor performance, and the other has been withdrawn due to high public resistance and regulatory problems. The two corn events received approval prior to the change in the GMO regulation, while the potato event received approval after more than 15 years (Wesseler and Kalaitzandonakes 2019).

Crops developed by NPBTs for cultivation in the EU must go through the approval process for GMOs—a long, costly, and uncertain process. Fur-

ther, the opt-out possibility mentioned above may reduce the number of farmers that can cultivate the plant. Depending on the trait in question, this could reduce the potential market for the crops and overall incentives to invest in the application of NPBTs for the EU market (Nationale Akademie der Wissenschaften Leopoldina, Deutsche Forschungsgemeinschaft und Union der deutschen Akademien der Wissenschaften 2019; Smyth and Lassoued 2019; Wesseler, Politiek, and Zilberman 2019). The implications for plant breeders in the EU are mixed, depending on their position in the market. The CJEU judgment protects plant-breeding companies developing products only for the European market from outside competition. At the same time, it increases the likelihood that international plant breeders will relocate their research from Europe to other places. Plant-breeding companies that do not develop crops only for the EU market now have even stronger incentives to relocate their research to other regions, like the Americas (Wesseler, Politiek, and Zilberman 2019) or China. The risks associated with importing food and feed into the EU are likely to be distributed along the food and feed supply chain increasing the price. As a consequence, new innovations in plant breeding might not reach farmers in the EU or, if they do reach the EU, it will be at a substantial delay. Seed and feed prices are also expected to increase. Overall this will reduce the comparative advantage of European agriculture (e.g. Gocht et al. 2020).

The CJEU decision could potentially strengthen the development of organic agriculture in the EU, as it could potentially lead more farmers to move into that sector after losing their comparative advantage in non-organic agriculture. The CJEU decision also comes at a cost, as it reduces the use of NPBTs for the organic sector. Such developments will depend on the development of the organic sector outside the EU. The possibility that NPBTs might be allowed in organic agriculture outside the EU (e.g., in the United States) could also cause the EU organic sector to lose its comparative advantages. Although the overall effect is largely an empirical question, the negative implications of such a situation for innovations in plant breeding and related environmental and health benefits are obvious. Table 1 provides an overview of NPBT applications in plant breeding, as mentioned in the literature, as an illustration of the expected benefits that might be foregone by an increase in approval costs and smaller markets.

The implications of the CJEU judgment are also affecting the development of the EU bioeconomy. Many technological developments that produce high-value products depend on achieving improvements in biomass for processing. This is now more difficult, given the expected increases in development costs that are dependent on crop improvement through NPBTs. Moreover, many of the bioreactors that process biomass use genetically modified bacteria-producing enzymes to increase the efficiency of the conversion process (Wesseler and von Braun, 2017). Their approval is also to be expected by the Courts ruling as further discussed below.

B Challenges for Labeling and Identity Preservation

GMOs entering the market in the EU are required to be labeled. An overview of the labeling requirements for GMOs in the EU is provided in Table 2. Final products that are not intended as food or feed (e.g., biofuels) are likely not to be affected by labeling and identify preservation requirements. Nevertheless, the labeling and identify preservation requirements induced by the CJEU decision go beyond the traditional food and feed sector. The strategy of the bioeconomy (Wesseler and von Braun 2017), however, is to produce products that can be used as food and feed additives in order to increase value. Such products would require approval in the EU, in addition to being subject to requirements concerning labeling and tracking, particularly if they are derived from genetically modified bacteria developed through directed mutagenesis. The following example of a transgenic crop to produce a biolpolymer serves to illustrate the implications of the CJEU judgment.

The EU-funded sustainable co-production project (https://www.cobiotech.eu/funded-projects/sustainable-co-production) aims to extract and process cyanophycin from transgenic tobacco. The tobacco will be grown in Argentina, as cultivation in Europe is subject to a lengthy, costly, and uncertain approval process. Cyanophycin is an amino acid polymer that can be used as feed additive, for the coating of medical tablets, and for the development of food-packaging material. The current legal interpretation is that the use of cyanophycin as a feed additive and coating for medical tablets requires labeling for the European market. It is not yet clear whether the food-packaging material would require labeling as well. The labeling requirements specify that products have unique identifiers to allow the identification and tracing of the cyanophycin (EC, 2003a).

The CJEU judgment results in similar labeling requirements on NPBTs, thereby posing difficulties for minor alterations, which could also result from spontaneous mutations. This increases the difficulty to differentiate and is likely to constitute a challenge in terms of labeling, traceability, and liability for food business operators in the supply chain. The resulting products would be similar to credence goods, for which identity preservation (IP) is arranged through contracting along the supply chain, combined with a monitoring system, as is common for food products labeled as organic or GM-free (Castellari et al. 2018; Venus, Drabic, Wesseler 2018). These processes increase costs (Bovay and Alston 2018; Kalaitzandonakes, Lusk, and Magnier 2018), however, thus having further implications for international trade, as discussed in greater detail below.

C Implications for International Trade

The practice resulting from the CJEU decision has substantial implications for international trade. For example, the judgment would require GMOs devel-

oped by NPBTs and cultivated in the United States, Canada, China, Brazil, Argentina, or other countries outside the EU to obtain approval for import into the EU (see above). As mentioned before, the approval process would require the submission of a unique identifier method, which is likely to be difficult to develop. One solution might be to add a genetic marker gene or enzyme, but this would result in additional changes in the genome. Other solutions might include using a unique identification code that can be linked to a specific change in a plant. The potential precision of each of these approaches is still to be tested in practice, however, as is the question of whether it would satisfy the legal requirements for approval (Grohmann et al. 2019).

Plant breeders outside the EU do not necessarily have to apply for approval for import to the EU, particularly if the EU is not among the targeted export markets. The problem is that, if a GMO has not been approved for import into the EU, it will be subject to a threshold level of 0% for food or 0.1% for feed as discussed above. This opens up the possibility of an import ban from countries cultivating plant developed by NPBTs (e.g., corn or soybeans), as has happened in the past. In practical terms, the current situation imposes an implicit ban on the import of commodities derived from GMOs and non-GMOs from countries where GMOs developed using NPBTs have been approved and are cultivated. The implementation of a reliable system of tracking and tracing will cause economic difficulties along the supply chain and such systems are vulnerable to the threat of a potential import ban (Punt and Wesseler 2016). Countries that export significant volumes and numbers of agricultural and food commodities to the EU may consider whether to approve the cultivation of GMOs derived through NPBT. Liability is particularly likely to become an important issue for plant breeders active in the United States. Under the Lanham Act, companies can be held liable if their policies threaten export opportunities for US products. In the past, this occurred in the case of corn, where Syngenta had received approval for the cultivation of GM corn in the US, which had not yet obtained approval for import into China (Redick 2019). Although China ultimately did approve the GM corn, it was at a substantial delay. In the meantime, it rejected corn imports from the US, as a zero-tolerance level could not be ensured. Syngenta was sued by farmers and corn traders, and it was forced to pay several millions of dollars in compensation. Similar situations are likely to occur with the approval of NPBT-derived GMOs that are destined for the European market. The decision of the CJEU could thus have important international spill-over effects, resulting in what is known as the "Brussels effect" (Bradford 2012; Sinopoli and Purnhagen 2016).

Although the Americas might be reluctant to adopt NPBTs for crop production, other regions might be less concerned. China is a world leader with regard to investments in such technology (Martin-Laffon, Kuntz, and Ricroch 2019), and it is much less dependent on agriculture and food exports to the EU. China is able to use the technology widely, in addition to disseminating its technology to neighboring countries, which are more tightly connected

to China than they are to the EU. Examples include African countries, whose Chinese foreign strategies in the past decade have increased their collaboration with China (Brautigam 2015). In the end, Africa may not be as disadvantaged as many fear, as China could potentially fill the technology gap (Castell 2019).

D Implications for the Environment

The absolute interpretation of the precautionary principle (see above), as exercised by the CJEU in the case of GMO regulations, is questionable. It blurs the line between the precautionary principle and the principle that preventive action should be taken. Adverse effects can never be excluded with certainty (Bobek 2018, Van den Belt 2003). Moreover, an absolute application of the precautionary principle could be counter-productive, as it could delay or even prevent the use of new technologies that can reduce harm to human health and the environment. Herbicide-resistant crops (e.g., in combination with glyphosate) result in the release of less-toxic active ingredients (AI) into the environment by substituting them for more-toxic herbicides. They also support the adoption of reduced and zero-tillage systems, and they have the potential to reduce the overall use of herbicides in crop rotations (Wesseler, Scatasta, and Fall 2011). Almost all of herbicide resistant crops would be banned for cultivation in the EU. Other applications of directed mutagenesis for agricultural crops include increasing the shelf-life of food products (e.g., non-browning mushrooms and apples), thereby reducing food waste. Researchers are working to develop a variety of crop improvements, including wheat that is resistant to powdery mildew (thereby reducing fungicide use) and insect-resistant corn. More examples are listed in Table 1. Empirical evidence concerning the cultivation of GMOs indicates that they have made substantial contributions to reducing the use of insecticides, to promoting the shift to more environmentally-friendly herbicides, and to decreasing the emission of greenhouse gases (e.g., Brookes and Barfoot 2020; Brookes, Taheripour, and Tyner 2017; Smyth et al. 2011a,b). For example, Wesseler et al. (2017) provide a detailed discussion of four transgenic crops that provide nutritional benefits for malnourished children in Africa, while Qaim (2020) discusses the wider implications for food security and sustainable agriculture. These developments will also make it more difficult (i.e., more expensive) for the EU to achieve the objectives of the EU Green Deal, which include zero net emissions of greenhouse gases by 2050, with no person and no place left behind (EC 2019).

IV A Way Out?

Thus far, the discussion has highlighted several real and potential implications of the CJEU decision, which initiated a debate about possibilities for changing the current situation. Initiatives have been instigated in order to adjust EU legislation and policy concerning GMOs (Eriksson et al 2020a, Eriksson et al

2020b; Eriksson et al 2020c). The EU Council has requested the EC to conduct a study on the legal status of "novel genomic techniques" and, depending on the results of the study, to develop a proposal for change (Council of the European Union 2019).

One crucial difficulty in changing the current situation has to do with the qualified majority of Member States needed in order to adopt such changes. If a proposal is submitted by the EC, it requires a qualified majority of 55% of the EU Member States to vote in favor (16 out of 28 before Brexit, and currently 15 out of 27), representing at least 65% of the total EU population (about 334 million before Brexit, and currently 290 million). If these conditions are not met, the requirements for a qualified majority increase. Furthermore, no more than three countries may vote against the proposal (see Box 1).

As evidenced by the voting behavior of Member States with regard to the approval of GMOs for import and processing since 2001, a qualified majority for or against approval has never been reached. In an analysis of voting behavior concerning approval between 2001 and 2014, Smart, Blum, and Wesseler (2015) identify patterns in which some Member States voted for and some voted against, while others switched. Since 2015, the pendulum has swung in the direction of the "against" faction. The voting behavior of 2019 clearly reflects an increase in the number of countries voting "against" or abstaining (Figure 1). The situation is likely to become even more difficult in the wake of Brexit, as the UK has always been a strong supporter of transgenic crops, in addition to having a relatively large population.

Figure 1 provides an illustration of the voting behavior of the Standing Committee and the Appeal Committee since 2013. The maximum number of Member States voting in favor of a proposal was 14 in 2014. In 2019, the highest number in favor was 12. The greatest share of the population was slightly more than 46%—almost 20% shy of reaching the qualified majority-population threshold. If a qualified majority in favor of a change to Directive 2001/18 cannot be reached in either the Standing Committee or the Appeal Committee, the EC decides.

The legislative procedure for changing Directive 2001/18 or any other EU legislative act concerning GMOs also requires a qualified majority among the representatives of the Member States in the Council. Not being able to reach consensus on the approval of a GMO in the comitology procedure is hence a strong indication that any proposed change to Directive 2001/18 is likewise unlikely to receive a positive qualified majority, even ignoring the difficulty of reaching agreement on the type of changes that would be required in the first place. As experience shows, the more supportive the legislative proposal is toward reducing regulatory hurdles for the approval for NPBTs (i.e., by reducing the costs of approval), the stronger the opposition is likely to be. While "lighter" proposals, which involve only marginal reductions in approval costs, might not receive strong opposition, they might not resolve the potentially negative implications for R&D and international trade. Independent of

the details of proposed changes, changes to Directive 2001/18 can be expected to take many years, as such proposals would need to be developed by the EC voted on by the representatives of the Member States in Council and the European Parliament.

The procedures, hence, for changing the Directive concerning the release of GMOs into the environment question the feasibility of proposals calling for an extension of the mutagenesis exemption to include additional technologies (e.g., CRISPR-Cas TALEN or OMG), as proposed by such institutions as the Nationale Akademie der Wissenschaften Leopoldina, Deutsche Forschungsgemeinschaft und Union der deutschen Akademien der Wissenschaften (2019). Such proposals are unlikely to be implemented soon, if at all.

Another possibility for challenging the decision by the CJEU and calling for action by the EC could be through a "citizens' initiative." One such initiative has been initiated (https://ec.europa.eu/citizens-initiative/public/initiatives/open/details/2019/000012) and, if supported, it would call on the EC to respond and act. This might be an alternative way to seek action if the EC concludes (as a result of Council Decision 2019/1904) that no further action is needed. In this case as well, however, any changes would require a qualified majority in the Council and a supporting vote by the European Parliament.

At this point, there does not seem to be any quick way out of the current deadlock.

As proposed by Purnhagen (2019), another alternative could involve filing another court case in a Member State different than France. In this case the local court expresses an opinion different from the one issued by the French court based on French law, and approves cultivation of a crop developed by using a NPBT. Such a case could potentially be transferred to the CJEU, which would once again need to decide. In such a case, however, it would be possible to submit facts other than those presented to the court in the French case, possibly resulting in a different outcome.

An alternative route could also be to initiate another case triggering a different procedure from the one initiated by the Conseil d'État. A member state such as the Netherlands or Sweden allows farmers to grow herbicide resistant oilseed rape developed by NPBTs, the same herbicide resistant oilseed rape triggering the court case in France. The Member State would not implement EU law and the EC initiate a legal procedure, similar to the case initiated by the EC against Germany in the case nitrate emissions (EC 2017). In such procedures the role of the CJEU is a different one. It would not be tied to help local courts deciding their case according to the questions referred, but is rather tied to solve the case brought before it including own fact finding. This may result in a different outcome.

Each of the solutions would also require the representatives presenting the facts to be extremely well prepared. Depending on the outcome of such a case, it may, however, well be that the representatives of the EC would still need

to demonstrate a willingness to adopt a change. The ultimate success of such an effort could be questioned, given that EC representatives have applauded the current judgment as a great decision providing clarity.

Further, as long as the CJEU maintains its interpretation of GMO legislation, and particularly its absolute interpretation of the precautionary principle, future court cases aimed at changing the implications of the current case should stress both the relative safety of NPBTs (as mentioned in the Opinion by the General Advocate) and the potential risks to the environment and human health associated with restricting access to NPBTs.

V Conclusions

In this contribution, we assess and discuss the implications of the decision reached by the CJEU on July 2018. Our assessment is arguably speculative, as we are not able to provide any quantitative calculation of the effects of this decision. It is nevertheless based on legal facts, and the economic implications derived from the assessment are based on economic theory.

The CJEU decision of July 2018 has far-reaching economic implications, given that products derived through the application of NPBTs are currently regarded as GMOs, such that they are not covered by the mutagenesis exemption. This reduces the possibilities available to EU farmers to take advantage of NPBTs, thereby reducing their comparative advantage. As a consequence, it will be more costly to achieve the objectives of the European Green Deal.

The decision increases the costs of plant breeding both within and beyond the EU. The "Brussels effect" may result in substantially fewer applications of NPBTs—not only from within the EU, but also from countries that export to the EU. This is particularly likely to affect the United States, as plant-breeding companies that release crops in the US that are regarded as GMOs in the EU could potentially be held liable under the Lanham Act. Even if this is not the case, any crops derived from NPBTs would need approval for import and processing in the EU, thereby increasing costs.

Many scientists and other stakeholder groups have requested a revision of the EU policies on GMOs. The EU Council of Ministers has recently started exploring the possibilities for a change. In addition, there is a legal possibility for clarifying the legal uncertainty resulting from the CJEU decision. Nevertheless, any change in policy—if possible at all—would take several years, given the highly controversial nature of the topic. As new developments continue to emerge in the area in plant breeding and biotechnology in general, the EU and its major trading partners will be affected. This offers opportunities for countries like China and those supported by China, which do not depend on exports to the EU. These countries are able to adopt NPBTs and enjoy a relatively higher rate of growth in their agricultural sectors, in addition to possessing the knowledge of new technologies, as well as improvements in human health and environmental protection.

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VII Appendix

Table 1 Applications and Potential Applications of NPBTs in Agriculture (Examples).

Plant	Trait
Improved food and feed quality	
Alfalfa	Reduced lignin content[1]
Camelina	Improved fatty acid composition[1]
Lettuce	Increased vitamin C content[1]
Potato	Reduced arcylamide formation[1]
Oilseed rape	Improved fatty acid composition[2]
Soybean	Improved fatty acid composition[1]
Wheat	Low gluten content[1]
	Improved fiber content[1]
Improved agronomic properties	
Banana	Fungus resistance[1]
Cassava	Virus resistance[1]
Cherry	Virus resistance[4]
Cocoa	Fungus resistance[1]
Flax	Herbicide tolerance[3]
Corn	Drought tolerance[1]
	Fungus resistance[1]

Plant	Trait
Oilseed Rape	Disease tolerance[2]
	Herbicide tolerance[2]
	Shatter tolerance[3]
Rice	Fungus resistances[1,4]
	Herbicide tolerance[3]
	Salt tolerance[1]
Soybean	Drought tolerance[1]
Tomato	Bacterial resistance[1]
Wheat	Fungus resistance[1]

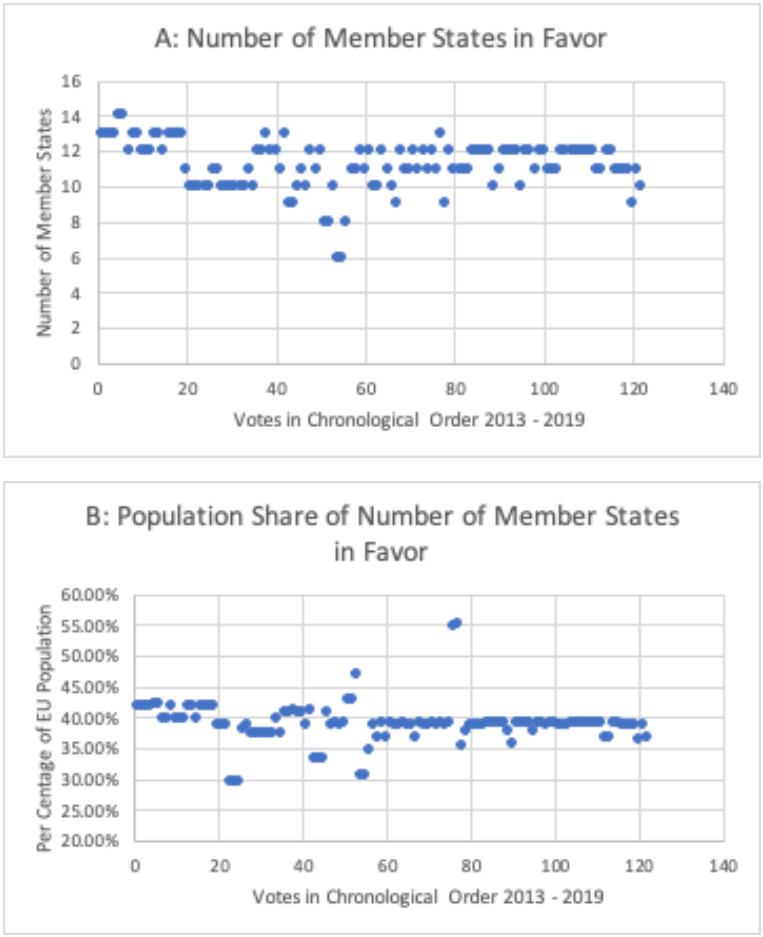
Source: Nationale Akademie der Wissenschaften Leopoldina, Deutsche Forschungsgemeinschaft und Union der deutschen Akademien der Wissenschaften (2019) note by superscript (1) along with a few additional examples: 2) European GMO Initiative for a Unified Database System (2019); 3) APHIS (2019); 4) Schaart et al. (2016).

Table 2 Labeling Requirements for GMOs in the European Union

GM product	**Example**	**Labeling requirement**
GM plants, seeds, and food	Corn, corn seed, cotton seed, soybean sprouts, tomato	Yes
Food produced from GMOs	Corn flour, soybean oil, rape seed oil	Yes
Food additives/flavorings produced from GMOs	Highly filtered lecithin extracted from GM soybeans	Yes
GM feed	Corn	Yes
Feed produced from a GMO	Corn gluten feed, soybean meal	Yes
Feed additive produced from a GMO	Vitamin B2	Yes
Food from animals fed on GM feed	Eggs, meat, milk	No
Food produced using a GM enzyme	Bakery products produced using amylase	No

Source: EC (2003c).

Figure 1 Voting Behavior by EU Member States with regard to the Approval of GMOs, 2013 to 2019.



Source: Authors, based on reports by Agrafacts, several years. Note: Panel A shows the number of Member States that have voted in favor of approval, and Panel B shows the percentage of EU population reached by Member States voting in favor. Votes include decisions in the Standing Committee and the Appeal Committee. The results are presented in chronological order from 2013 to 2019.

Box 1 Qualified Majority Voting in the EU

A qualified majority requires two threshold levels:

1. 55% of Member States must vote in favor: prior to Brexit, this translated to 16 out of 28, and it currently means 15 out of 27.

2. The proposal must be supported by members representing at least 65% of the total EU population.

Blocking minority: at least four Council members representing more than 35% of the EU population. This has been implemented to avoid a situation in which three large countries (e.g., France, Germany, and Italy) could block a decision.

Special cases

When not all Member States participate in the vote (e.g., due to an opt-out in certain policy areas):

1. 55% of the participating Council members must vote in favor.

2. The proposal must be supported by members representing at least 65% of the total EU population.

For proposals not coming from the Commission or the High Representative:

1. 72% of all Council members (currently 21 Council members) must vote in favor.

2. The proposal must be supported by members representing at least 65% of the total EU population.

Abstentions

An abstention under qualified majority voting counts as a vote against the proposal. Abstention is not the same as not participating in the vote. Any member can abstain at any time.

Source: https://www.consilium.europa.eu/en/council-eu/voting-system/qualified-majority/