

Perspective

New Plant Breeding Technologies: An Assessment of the Political Economy of the Regulatory Environment and Implications for Sustainability

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Abstract: This perspective discusses the impact of political economy on the regulation of modern biotechnology. Modern biotechnology has contributed to sustainable development, but its potential has been underexplored and underutilized. We highlight the importance of the impacts of regulations for investments in modern biotechnology and argue that improvements are possible via international harmonization of approval processes. This development is urgently needed for improving sustainable development. Policy makers in the European Union (EU) in particular are challenged to rethink their approach to regulating modern biotechnology as their decisions have far ranging consequences beyond the boundaries of the EU and they have the power to influence international policies.

Keywords: bioeconomy; biotechnology; international agreements; international trade; new plant breeding technologies; political economy; regulation; sustainable development



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1. Introduction

Growing and increasingly urgent concerns about climate change and food security have led decision makers and research organizations across the world to seek new policies and technologies that will contribute to globally sustainable development. In such a sustainable environment, the Greenhouse gas (GHG) challenge will be met, biodiversity preserved, economic development and social welfare improved, and the incidence of global hunger diminished. Developing new technologies as rapidly as possible is a fundamental requirement for achieving sustainable global and regional food production and distribution systems. Those technologies are needed for adaption to climate change and to mitigate agriculture's carbon footprint [1–3], and seen as a prerequisite for sustainable development of the bioeconomy [2].

However, the development of a sustainable bioeconomy requires the effective use of recent innovations in biotechnology tools for the rapid and precise development of new crop varieties, healthier and more productive livestock that require less forage, feed supplements and land [3,4]. Biorefineries are also needed that more efficiently convert biological resources into food, feed, and non-food-feed products, such as textiles, lubricants, detergents, packaging material and more [5]. Applications of the recent innovations in biotechnology tools that fall under the broad category of gene editing are not uncontroversial, in particular applications typically categorized as new plant breeding technologies (NPBTs) [6]. A substantial body of evidence has demonstrated that such technologies are at least as safe as traditional breeding technologies, and the innovations based on what so far have been heavily restricted applications of those new research techniques have provided substantial economic benefits and improved environmental conditions in critical ecosystems with overall important contributions towards sustainable development [4].

Nevertheless, the application of these tools has been constrained by complex and largely uncoordinated sets of regulations in many countries throughout much of the world [5]. As a result, their potential is currently being underutilized [6–8] at a time when, from a carbon footprint reduction and global sustainability perspective, it is essential to increase crop yields and food production while ideally reducing, and certainly not increasing the amount of land devoted to agriculture [3].

In this paper, therefore, we present an overview of the current status and potential productivity and other contributions of NPBTs, and the regulatory challenges innovators confront in applying them. We argue that political economy considerations have played a crucial role in limiting the utilization of NPBTs. Furthermore, we develop an expanded theory of the political economy of biotechnology by incorporating cross-country differences in political structures and economic incentives that provide insights about the current national and international regulatory environment. In particular, we incorporate the role of international trade and aid, and the impacts of international buyers and aid donors on the regulation of biotechnologies, especially in developing countries. The analysis permits an assessment of the implications of the current complex of country specific regulatory frameworks for the global bioeconomy. It also leads to the identification of reforms that would allow the modern research capabilities available to the life sciences to enable a transition to sustainable development, in particular, contributing by de-carbonization and food security.

The paper is organized as follows. In the next section, we provide an overview of plant biology and the different research technologies available to plant scientists for developing new crop varieties. We then discuss the evolution of biotechnology, the interaction between the public and private sectors in technology development, and the role of intellectual property. Section 4 provides a brief analysis of the impact of biotechnologies, followed by a description of how they are regulated in the United States (US), the European Union and other countries, and the economic impacts of those regulations. In Section 5, we examine how the political economies of different countries generate differences in their regulatory approaches to biotechnology innovations, where an important focus is on the roles of different domestic groups, as well as trade partners and donors, in affecting policy choices. The analysis suggests that there is an urgent need for increased emphasis on internationally harmonized science-based policies in the regulation of biotechnology innovations. In addition, developed nations should become more aware of and give more attention to some of the unintended consequences of their actions for developing countries that may limit attempts to control climate change and adversely affect food security.

2. The Nature and Evolution of Plant Breeding Technologies

Plant breeding and food production continue to be revolutionized through innovations in modern biotechnology. These advancements in biological knowledge include a wide range of new plant breeding technologies (NPBTs). NPBTs based on site directed mutations (SDM) allow targeted changes in double stranded plasmid DNA [9]. They include techniques such as CRISPR-Cas 9, TALEN or ODM and are being used to breed plants with desired traits and have the advantage of being more precise and faster to apply than other plant breeding technologies [6]. However, both in the scientific literature and in the regulatory processes adopted by countries, often a distinction is drawn between conventional techniques and NPBTs. Those conventional techniques are considered to be “safe” plant breeding methods by most countries’ regulators but in many countries NPBTs may not, while the scientific consensus is that the older techniques are not any safer [4].

The science that underpins modern biotechnology is available on a global basis. So too, increasingly, is the knowledge required to develop new plant varieties based on NPBTs. However, in different countries the rate at which researchers develop new biotechnology science and utilize that science to develop new products has changed substantially in response to the regulatory environments that affect incentives for public and private research institutions to develop those products [6]. As a result, as Martin Laffon et al [10],

report in their study of worldwide CRISPR patenting, there is a strong geographical bias in the utilization of NPBTs.

The legislative origins of the legal context that has influenced the recent history of biotechnology science in the United States lie in the provisions of the 1970 Plant Variety Protection Act that permitted plant breeders to obtain patent-based protections for new plant varieties developed using asexual methods. In the 1960s and 1970s, universities in the United States had begun to rely on third party organizations such as the University of Wisconsin Alumni Association to facilitate the use of patents by their research faculty. This shift was partly in response to the increasing importance of microbiology as a vehicle for developing health care therapies [11]. Through the 1980 Bayh-Dole Act (BDA), universities and other non-profit organizations were given the option of exclusively licensing patented products (or processes) developed with federal funds. Thus, the BDA created incentives for private companies to provide additional funding for university research supported by federal grants and contracts that could lead to patentable research results [11]. In addition, the 1980 BDA made the patent process much simpler and less costly for universities and other not-for-profit organizations, and substantially increased the potential for revenue generation from intellectual property.

Additionally, in 1980, the US Supreme Court rendered its verdict in *Diamond v Chakabarty*, a case in which the US patent office had previously denied a patent application by Anand Chakabarty, a researcher employed by General Electric, for a genetically modified bacterium capable of breaking down crude oil components. Critically, this decision established the precedent that genetically modified material could be patented, opening up the potential for new health care therapies and agricultural products to be developed on a commercial basis, including new plant varieties obtained using modern biotechnology. In response to these decisions, as reported by Link and van Hasselt [12], between 1980 and 2013, many US research-focused universities established offices of technology transfer which aimed to distribute university technologies to the private sector and generate revenues for the universities and their researchers.

When research leads to new products, the BDA requires universities to make those products available to researchers at other universities for non-commercial uses [13]. This has been important in facilitating the use of innovations that take the form of platform products that are used in biotechnology research [9]. For example, the BDA enabled organizations like Addgene (a non-profit entity located in Massachusetts) to establish “banks” for plasmids and other genetic materials [14]. Through such banks, those materials can be redistributed inexpensively to researchers at universities and other non-profit entities throughout the world, and more expensively to researchers at “for profit” companies, facilitating their research enterprises.

As in the United States, modern biotechnology was introduced in the EU in the early 1980s and applied to genetically modified microorganisms (GMMs) producing enzymes for the food and feed industry as well as the pharmaceutical sector. The first genetically modified organisms (GMOs) introduced for crop production were varieties of corn produced by Monsanto and Syngenta in the mid and late 1990s. From the outset, the initiative was controversial and opposed by some media savvy and relatively high profile interest groups [15,16]. Thus, in the late 1990s, the European Union implemented a temporary ban on approvals for cultivation as well as for imports of GMO commodities. The decision, notionally based on the precautionary principle and concerns about the credibility of scientific claims, was influenced by several events, including the “Mad Cow Disease” episode in the United Kingdom and the distribution of HIV/AIDS tainted blood in France [17].

The European Council asked for a revision of the approval process for GMOs which would include a risk assessment that explicitly considered environmental conditions in Europe, as well as the implementation of a labelling, tracking and tracing policies for GMOs. In response, EU regulators implemented revised and new directives and regulations. They included a new directive for the release of GMOs into the environment, new regulations laying down the principles for product labelling, tracking and tracing, and

recommendations for processes that permitted the co-existence of GM and non-GM crops. The policy documents were subsequently up-dated by allowing member states to opt-out from EU Commission approvals for cultivation. The up-dated documents also established a differentiated threshold level for unapproved varieties, contingent on whether such products are used for animal feed and other industrial uses (0.01%) or food (zero per cent). The adjustments were the Commission's response to country-specific concerns about the implications for imports as well as the decisions for approval [18].

Despite these changes to the approval process, EU decision-making bodies to which dossiers are submitted for approval, and on which they vote on the basis of a qualified majority, have never obtained a qualified majority either for or against a GMO proposal [18]. When a qualified majority is not obtained for either approval or rejection, the right to decide on an application reverts to the European Commission (EC). Not surprisingly, the EC, in common with many other countries, has adopted a case-by-case approach [19], and, in the end, all dossiers submitted have resulted in an approval for import and processing of the commodity. However, currently only one agricultural GMO crop variety, the MON810 event for corn, is cultivated on a commercial scale, mainly in Spain and Portugal and to a lesser extent in a few Eastern European EU member states [18]. In contrast, in the United States, between 2007 and 2018, the regulatory authorities approved 130 of 162 applications for non-regulated status to be given for plants developed using transgenic and NBPT tools [20].

3. Plant Biotechnology and Sustainable Development

The sustainable development of global and country specific food production and distribution systems requires policies that enable growth in the present without harming the future. It has social, economic, and environmental dimensions, and requires that those systems become resilient towards climate and other shocks [21]. Sustainable development can meaningfully be viewed as maximizing economic growth subject to sustaining environmental quality, conserving resource availability, as well as complying with equity and in particular poverty and hunger alleviation constraints [22]. Climate change, food security, and pandemics are some of the major threats that require intervention to assure resilience and sustainable development.

In the broadest contexts, achieving sustainable development relies on the development and introduction of technologies and policies that enhance the efficient use inputs, expand climate change relevant conservation programs, effectively encourage recycling, and support the transition to economies that rely on renewable resources [1]. In the context of agriculture, it will require the expansion of the bioeconomy, where new capabilities in the life sciences enable efficient utilization of renewable resources to produce food, fine chemicals, fuels, and other substances. That expansion would form the basis for a world-wide shift away from a petro-chemical based economy to a sustainable economy that relies on renewable resources [2].

NPBTs are essential for achieving sustainable development. Climate change strategies include both mitigation and adaptation. Mitigation requires decarbonization which can be achieved by the use of alternative energy and sequestration. Biofuels are important sources of alternative energy and likely to be essential for some forms of transportation (aviation). They will be very valuable for other forms, as learning by doing and technological innovation improve input use efficiency and reduce GHG emissions, both in crop production and processing [23]. The continued and expanded production and processing of biofuel feed stocks depends on improved crop yields and new plant traits that can most rapidly, and perhaps only be enhanced by NPBTs [24].

Furthermore, increasing productivity with respect to food crops will increase the capacity to produce biofuels without increasing, and even reducing agriculture's land print [23]. NPBTs also have the potential to play a major role in developing organisms that enhance the capacity of trees and soil to sequester carbon, also mitigating climate change. Adaptation to climate change also requires more rapid innovations in crop varieties to

address pest problems, drought resistance, and resistance to temperature changes, and to improve crop yields [25].

Compared to other methods available for developing new plant varieties with such characteristics, NPBTs accelerate and increase the precision with which new crop varieties can be developed, alongside increasing their capacity for both mitigation and adaptation [3]. Bennett et-al [23] identified multiple traits that have been developed to reduce GHG emissions in agricultural systems, sequester carbon, and increase yields. However, most have not yet become available to or adopted by farmers because of regulatory constraints. Researchers have also neglected the development of many other promising traits because of the regulatory difficulties in introducing NPBT plants. Thus, the capacity of both researchers and food production systems to address some of the major sustainability challenges are being compromised because of regulatory constraints that limit the extent to which the capabilities of NPBTs are currently being utilized.

Gene editing based NPBTs have become a flash point in both an economic and a political context. In the context of the market place, given the precision of the site directed mutagenesis (SDM) tools available for gene editing, the technologies allow researchers to develop crop varieties that have desirable commercial and, often, ecological and environmental characteristics more quickly, and with lower R&D investments than those associated with traditional plant breeding methods [4,17,26]. The new crop varieties may increase yields and/or reduce yield volatility through drought and pest resistance without requiring more use of other inputs or generate the same yields with fewer inputs. They may also improve the attributes of a crop in ways that benefit consumers (for example, golden rice) and mitigate adverse effects on the environment by reducing the use of inputs such as chemical fertilizers, herbicides and pesticides (for example, Bt corn), and water, and reduce greenhouse gas emissions. The literature has already identified the gains from new biotechnologies technologies that have been applied in terms of higher yields, lower pesticide use, increased farm incomes, reduced pollution, and increased resilience to weather (for example, [17] and [26]). They have also already contributed to reducing commodity crop prices, increasing consumer welfare, and mitigating GHG emissions [27–29]. However, modern biotechnology has not reached its potential because of regulatory constraints, especially in Africa and other parts of the developing world [28].

The evidence about the impacts of these technologies has several important implications for R&D investment decisions, agricultural productivity and the environment. First, they reduce the cost of carrying out research, enabling scientists to do more with any given amount of public or private funds, encouraging private firms, philanthropically funded organizations and governments to make more extensive investments in crop development initiatives. If any benefits from R&D investments are likely to be squashed by regulatory barriers that make product innovations infeasible or prohibitively expensive then organizations ranging from the US, UK, Canadian, EU, Japanese, Australian and Indian governments to the Rockefeller and Bill and Melinda Gates foundations have much reduced incentives to invest in those programs.

Second, newer and more productive varieties generally enable farmers to produce crops at a lower cost. Some of the cost savings may accrue to the firms developing the new varieties through patents and trade secrets that give them, in varying degrees, the power to set prices for new varieties that lead to increased profits. Nevertheless, the scope for exercising market power is also limited because of the availability of alternatives [29,30].

Third, by increasing crop supplies in the market place, the new technologies lead to lower commodity prices, cheaper and more widely available food, and more food secure populations, especially in developing countries.

Fourth, by reducing chemical use and in many contexts reducing the amount of land needed for crop production, NPBTs can lead to significant reductions in environmental pollution and agricultural production practices that have fewer impacts on ecological systems and climate.

4. The Economic Impacts of Biotech Regulations

In many countries, regulators are required to subject NPBTs based on SDM processes to considerably more stringent regulatory processes because, axiomatically, they are required to view them as not necessarily “safe.” The additional regulatory requirements can be extremely costly for plant breeders for several reasons. First, they create barriers to adoption by requiring more extensive approval procedures for use within country specific markets. Second, different countries make approval decisions at different times (some earlier, others years later) that often restrict a developer’s access to international markets for varieties developed using NPBTs. In addition, country specific labelling, tracking and tracing requirements increase costs at almost every stage of the food supply chain, making products that include NPBT varieties more expensive for consumers than similar products using conventionally developed varieties.

All of these regulation related impacts act as disincentives for both public and private plant breeders to invest in research and development programs that use new plant breeding technologies. The justification for the increased scrutiny is typically based on the precautionary principle. The argument is that NPBTs involve potentially catastrophic outcomes for communities (for example, the introduction of varieties that have extreme adverse human or plant health effects) even though the probability that the adverse outcomes of concern will occur is extremely low, and no higher than for new varieties obtained through conventional breeding techniques.

However, the more extensive regulatory environments for NPBTs also impose substantial costs and risks on societies because of a wide range of benefits that have to be given up entirely or delayed. NPBTs enable breeders to develop plants that are rich in micro nutrients such as Vitamin A or zinc, allow for the development of plants that are tolerant towards abiotic stress (for example, drought) and resistant towards pest and diseases, and reduce the use of toxic pesticides and herbicides. By increasing yields, they enable farmers to address and reduce adverse climate change related impacts on land use and adopt production methods that mitigate greenhouse gas emissions [3]. Varietal developments obtained using NPBTs are expected to be especially important for agricultural production in Africa [31] and the economic benefits for low income “two dollar a day” farm-households can be substantial [28].

In addition, site directed mutation techniques are platform technologies that not only are promising for plant breeding but also for converting biomass into high value food products and other bio-based materials. Through SDM based NPBTs the properties of plants for conversion can be improved. For example, plants can be developed that are high in biopolymers such as cyanophycin. In addition, SDM processes enable scientists to develop microorganisms that increase the efficiency of converting biomass for producing plant based meat substitutes and other innovative products that reduce land and other resource requirements for food and fiber production. Further, SDM technologies are also important for developing medical products such as vaccines [4].

4.1. Understanding the Impact of Technology Regulations on Investments in R&D

The regulatory environments that these technologies face in different countries are diverse and in many ways uncoordinated [20,32]. As discussed above, the cross-country differences in technology specific regulations have been shown to substantially, and potentially prohibitively increase the investment costs associated with the innovation and adoption of plant varieties developed using NPBTs [33–35]. The impacts of regulations on investment became apparent around 1998 when the EU started imposing strict restrictions on agricultural GMOs. Prior 1998, the numbers of startups and investments in GMO were accelerating, but leveled off from that point on [36].

The decision to invest in an NPBT can be viewed as a sequence of options [37,38]. The issue is not whether to invest now or never, but whether to invest today or postpone the decision, wait for the arrival of new information and then re-evaluate whether or not to make the investment. Investors are constrained by financial considerations, and are

concerned about economic risks and interest costs associated with the length and severity of regulation of biotechnology. The impact of regulations on investment in NPBT was apparent in 2018 when the European Court of Justice (ECJ) decided that plants developed by NPBTs would need to follow the approval process for GMOs in the EU [39].

For NPBTs, the sequence from invention to adoption involves four stages. The first is a research and development phase (R&D), followed by a regulatory approval phase, a market phase, and an ex-post liability phase. From an ex-ante perspective, both the lengths of each phase and their benefits and costs are uncertain [35].

The four phases may overlap to a certain extent. Regulatory policies affect the benefits and costs associated with each phase. If, from a legal perspective, the EU considers GMOs to be NPBTs, the costs to acquire approval for access to the EU market increase substantially. This also has implication for the R&D phase as requirements for generating the data needed for approval may change, extending the R&D phase and increasing R&D costs. However, the new biotechnology itself can substantially reduce R&D costs. The R&D phase for developing new seeds using “conventional” plant breeding methods is generally expected to be about ten years. Gene editing technologies can reduce the length of that period substantially, with associated reductions in costs. For example, some researchers have argued that the R&D phase can be as short as one year when NPBTs are used.

The market phase is critically important, as this is the period during which revenues for covering the R&D and approval phase costs are generated. Those revenues depend on the size and scope of the markets in which the new varieties are offered. Regulatory policies can either increase or decrease the size and scope of those markets, with clear implications for investment decisions. Co-existence policies can have a direct impact on the area available for cultivation and hence market size [40].

Ex-post liability policies are an important concern because they can truncate the market phase for a biotechnology. Subsequent to a product’s advent on the market, companies that developed or use the product could face legal challenges. Glyphosate is one example, where legal challenges have affected the sales of both the herbicide and herbicide resistant seeds. In the United States, the 1948 Lanham Act is a potential issue for seed companies, because they may be legally liable if the introduction of a new GM variety threatens export opportunities [41]. The Star-Link case in the United States [42], the honey case in the EU [43], and violation of seed purity standards in Germany [44] are other examples in which ex post liability issues have occurred.

Simulation models of the investment decision for NPBTs indicate that marginal changes in the costs and length of the R&D and approval phases can have substantial effects on firms’ incentives for immediate investments in the innovation and product development process. Using reasonable parameter values, Purnhagen and Wessler [35] show that a one-dollar increase in R&D or approval process costs leads the investor to require an increase of more than \$14 in expected benefits to induce a firm to make an immediate investment.

4.2. The Role of International Agreements

Given the diversity of regulatory regimes among countries, a natural concern is the extent to which those regimes can be harmonized through a universally or widely accepted set of rules. The Convention on Biological Diversity (CBD), implemented in 1993, which now incorporates the 2003 Cartagena, 2011 Nagoya, and 2018 Nagoya-Kuala Lumpur (NKLs) protocols, is an international agreement on sustaining biodiversity that now includes protocols for addressing international transfer and use of what are defined in the agreement as Living Modified Organisms (LMOs). As discussed and defined by Husby [45], LMOs include GMOs. As such, in its current form, the CBD represents the most obvious and extensive attempt to create an international framework for regulating the transfer and use of LMO plants. The most significant implementation problem for the agreement is that while over 170 countries have ratified the CBD, the United States has not and, therefore, is not bound by any of its provisions, including the 2003 and 2018 protocols that address LMO products.

The problem related with the NKL protocols involves the access and benefit sharing agreement. This adds legal uncertainty for plant breeders. Using genetic resources that fall under the NKLs requires that the resulting benefits from commercial use be shared. The problem is that it is not obvious how large the benefit to share should be and with whom to share the benefit. Who will be the contact person or agency and which country to include? The response by plant breeders has been to reduce the use of genetic resources that fall under the NKLs. These are mainly plant genetic resources from the global south. Reducing their use in plant breeding will mainly affect plants for the global south [46]. Additionally, plant breeders from the global south using the genetic resources will be more affected than plant breeders working for crops in the northern hemisphere. The NKLs also discriminate against smaller plant breeding companies as compliance with the NKLs requires additional legal expertise and increases plant breeding costs. For the most part, these are fixed costs related to using plant genetic resources and therefore proportionally discriminate against smaller plant breeders, as discussed above with respect to the approval of NPBTs.

4.3. The Implications of Biotech Regulation for International Trade and the Adoption of GMO and GE Agricultural Commodities

The complex global structure of GMO and GE regulations creates a wide range of impacts among different countries with respect to the adoption of GE crop and livestock technologies, as well as having impacts on private and public investments in GMO and GE R&D initiatives [47]. The implications for international trade and global market clearing prices for any given commodity, and for trade in agricultural commodities more broadly defined, are contingent on several factors. One critical issue concerns which countries adopt the new technologies in producing the commodities of interest: exporting countries, importing countries, or both. A second factor is whether importing countries approve or prohibit imports of GMO and GE products. The fact that adoption almost surely results in a measurable increase in a country's ability to produce the commodity is a major reason why the issue of who adopts is so important for international trade in agricultural commodities [41]. While therefore, the following taxonomy is far from exhaustive, in understanding the implications of GE technologies for international trade it is useful to consider the following alternative situations with respect to adoption of GE varieties of a commodity for cultivation:

- A. Exporters adopt; importers adopt
- B. Exporters adopt; importers do not adopt but allow imports of GE commodities
- C. Exporters adopt; importers do not adopt or allow imports of GE varieties
- D. Exporters do not adopt because major importers have zero tolerance for any shipment with even a trace of GE content.

In scenario A, when both exporters and importers adopt the new technology, the implications for international trade are potentially ambiguous. Domestic production increases in both exporting and importing countries. While export supply to world markets increases, because importing countries now produce more of the commodity, import demand falls. We can be certain that the price of the commodity on world markets will fall because global production has increased, but whether importers will purchase a larger amount of the product from the world market is not clear. It depends on whether the increase in export supply is larger than the decline in import demand; that is, whether production expands more rapidly in exporting countries than in importing countries. Consumers in all countries benefit from the new technology through lower prices, and if all countries adopt the new technology then prices will fall by more than if only exporting countries adopt the new technology because global production will increase more rapidly. The effects on farm incomes are harder to sort out. If on average costs of production fall by more than prices, then farmers will be better off, and that may well be the case at the global level. However, regional effects can be complex.

In scenario B, major exporting countries adopt the new technology, and in those countries domestic production increases. So too does the surplus of domestic production over

domestic consumption of the commodity and more of the product is available for export. At a global level, the quantity of exports offered to importers at any given price increases (export supply has increased). Importing countries do not adopt the new technologies, so domestic supply conditions do not change and their demand for imports from abroad does not shift. Thus, at a global level, import demand has not changed but export supplies have increased and international prices for the commodity fall. Trade in the commodity increases because importers buy more of the commodity at the lower price. In all countries, consumers are winners because, all other things being equal, prices for the commodity decline. Farmers in the exporting countries are likely to be winners, along with the companies who have developed the new varieties, but producers in importing countries now receive lower prices. Those farmers, along with companies supplying them with inputs, may therefore lobby their political representatives for constraints on imports.

In scenario C, exporting countries adopt the new technology, and both domestic production and export supply increases. However, importing countries refuse to accept any shipments of the commodity that include even minute traces of GE crops. Assuming exporting countries can effectively segregate GE varieties of a commodity from non-GE varieties in their supply chains, they will continue to export non-GE varieties to the importing countries and market GE varieties in their domestic markets. Given that only non-GE crops are exported, at the farm level the cost of producing those crops has not changed. However, there are costs associated with segregating non-GE crops from other crops, and export supplies may well decline. In that case, at any given international price, though importers may still want the same amounts of imports, fewer exports are available for purchase and the price of non-GE exports is likely to go up. Consumers in the importing countries will be worse off, but farmers producing the commodity in those countries will be better off, as well the companies who supply them with inputs.

In the exporting country, domestic consumers will likely benefit from the ability of farmers to produce GE commodities at a lower cost, and producers may benefit as long as costs decline by more than prices for the GE commodity. However, if export markets account for a large share of an exporting country's production of a commodity and cross contamination risks are high then, to avoid the high segregation costs and substantial contamination costs, it may be optimal for producers in that country to lobby for a ban on GE varieties of the commodity. That has been the case for wheat in both Canada and the United States, where exports account for 50% or more of domestic production, leading to the fourth scenario.

In scenario D, which for many crops reflects current realities, exporters do not adopt GE technologies because major importers have zero tolerance for any shipment of the product with even a trace of GE content. In the absence of any impact on domestic production in either the exporting or importing countries, the outcome is that GE technologies have no effects on world prices, consumer welfare or international trade. The problem with that outcome is that new technologies, which have the potential to increase global production using fewer chemical inputs, less land and generating lower levels of carbon emissions, will not be developed. Firms and governments also have substantially reduced incentives to invest in NPBT R&D programs and, as a result, agricultural productivity growth atrophies, as for many years has been the case with golden rice [48], and for wheat [49].

A major concern is that scenario D has become a relatively common outcome. In the United States, for example, to this point no GMO varieties of wheat have been planted on a commercial basis even though Monsanto (now Bayer) developed such varieties over a decade ago. Further, in response to lobbying by such groups as the Montana Grain Growers Association and similar groups in North Dakota and Kansas, state legislatures have introduced legislation prohibiting farmers from planting GMO wheat varieties. The reason those wheat farm organizations have lobbied for zero cultivation of GMO crops has been their concerns about adversely affecting major markets for a crop for which exports account for 50 percent of annual production, including Japan and some European Community members [49].

5. The Political Economy of Agricultural Biotechnology Regulation

Political issues, in many countries linked to community perceptions fostered by special interest groups, can affect how markets function and whether it is worthwhile for farmers to adopt NPBT derived crop varieties and companies to invest in the R&D programs to develop them in the first place. The reason is straightforward. Most societies determine how resources are used through two mechanisms. One is the political process; the other is through markets in which trades are largely voluntary [50].

The two resource allocation processes are synergistically linked. The political process establishes the rules and policies under which markets function. These involve regulations about how trades take place, including food safety and other product standards and quality regulations; laws about contracts and contract enforcement; laws about rights over property and its use; sales taxes levied on specific goods and services; and bans or restrictions on product use (for example, restrictions on sales of alcohol and tobacco products). They also include policies that have important effects but are more distant from the market for a specific commodity, such as income taxes and social safety net subsidies that affect the demand for goods and services, and in the case of corporate taxes firm level investment decisions.

Nevertheless, the rules, policies and regulations that establish the framework within which markets function are not created in a vacuum. Policies and regulations evolve and are developed through a country's political process. In that process, interest groups, often explicitly concerned about specific market outcomes such as the development or prohibition of NPBT based products, exert pressure on policy makers to try to establish rules of the game that lead to the outcomes those interest groups seek. The mechanisms those groups use are often characterized as making campaign contributions (through in-kind services, monetary contributions, or in some cases bribes to key decision makers) or by directly influencing voter preferences and behavior [51,52].

The outcomes interest groups seek to achieve depend on the underlying structure of the markets in which goods are exchanged; for example, the technological options available to researchers who develop product innovations and consumer responses to differences in the prices of NPBT and non-NPBT products that are otherwise very similar (for example NPBT soybeans and non-NPBT soybeans). Those underlying market conditions therefore also often play important roles in determining the policy interventions interest groups seek [53,54].

When the underlying market conditions change substantially, some groups are likely to benefit from the impacts (they are winners) while others are likely to be worse off (they are losers). Often, the potential losers then engage in the political process to obtain legislation or regulations that either roll back or prevent the changes from occurring. Potential winners, on the other hand, are also likely to become involved, lobbying to protect their gains [55,56].

Unequivocally, GMOs and NPBTs have changed the underlying conditions within which markets for agricultural products operate, creating potential winners and losers. In most, if not all countries, therefore, the political landscape with respect to NPBT issues is complex, as indicated in Table 1. Many interest groups have, or believe they have, a stake in the policy debate. Those groups often have different and conflicting goals, and depending on the country, in the public domain and the policy making process any individual group may have more or less credibility and more or less influence over policy.

Policy makers may have many objectives, including benefitting their communities, serving their own interests (reelection, increasing their own incomes and wealth, etc.), and given their roles are often likely to have substantial influence, but often as a response to the interest groups they serve [57].

As consumers, many households may have a positive view of the advent of the new technologies, because they lower the prices of foods in the supermarket. Those households would also be winners. Other households may be much less sanguine and have concerns about ecological, environmental, food safety and human health impacts. As a group, consumers' concerns are typically viewed as credible. However, consumers

are heterogeneous and not well organized, and have limited influence in the regulatory process, while some smaller sub-groups have considerable influence. Nevertheless, as voters, they are influential, and other interest groups often seek to affect their votes. The literature [58–61] has found significant heterogeneity among consumers' attitude about GMOs. A substantial segment (sometimes a majority) are not willing to pay extra costs to avoid GMO products, while a small segment has a strong preference to avoid GMOs. However, consumers are willing to pay extra for GMO products with improved traits, for example better appearance or improved nutritional content. [60].

Biotechnology focused organizations, including well-established biotech firms and small start-ups, as well as academic and research institutions, tend to be viewed as credible, but may have different levels of influence on policy and regulation decisions and have different objectives. For example, firms and researchers with property rights over the new technologies (e.g., biotechnology start-ups, manufacturers, and distributors) are likely to be winners, and seek legislation that protects the economic value of those rights [55]. Firms that have not developed competing products, or produce other products such as herbicides that the technology makes partially or wholly redundant face sharp declines in the demand for their goods and are likely to seek ways to prevent the use of the products the new technologies generate [43,57]. Activists with those concerns may then seek to limit or ban the use of those technologies, often by influencing public opinion.

Farmers as a group are often influential in the policy process and depending on the issue often seen as credible, but have mixed perspectives on NBPTs [16,44,61]. They may worry about potential supply enhancing impacts that lead to lower commodity prices, especially when new traits do not address production problems. However, they will strongly support NBPTs for crops with traits that address those problems.

Food manufacturers and retailers may or may not be viewed as credible sources of information but tend to be influential in the policy process. They may be interested in using or selling NBPT products unless they meet strong objections from activists. For example, pressure by activists opposed to the use of GM potatoes by Macdonald's halted commercialization of the variety [62]. Several food processors and retailers in Europe changed their policies to comply with demands from such lobby groups, but also recognized the gains from product differentiation that allowed them to charge higher prices for non-GMO products. Hence, some retailers support labeling policies [63,64].

Well-organized activist special interest groups, frequently focused on a single issue or narrow range of concerns, are often highly influential. Organizations that oppose GMO products are likely to be much more active in the political arena than individual consumers who do not oppose GMO based products and benefit from them. Such interest groups may influence policy makers' decisions because they are large and their members and supporters tend follow their leaders' voting recommendations. However, even small interest groups can have a significant impact on voter perceptions of an issue through the information they share via traditional and newer forms of social media and their access and financial contributions to policy makers [65].

The extent of such influence is often tied directly to the credibility of the activist interest group and its spokespersons but also to the scope of the lobby's political influence. One recent example is the Peasant Farmers Union in Ghana, who sought an effective ban on GMO and gene editing crops and were able to persuade the Minister of Agriculture to support their position. In the European Union, relatively small but vocal lobbies have been successful in obtaining regulations that effectively prohibit farmers from raising GMO and gene edited plant varieties [15,66]. In contrast, as discussed above, in the United States companies have been more successful in gaining approval for such plant varieties.

A country's domestic political environment can also be affected by the interests and actions of other countries. For example, developed countries that serve as donors to developing countries, or players in large global input markets may affect GMO regulation in these developing countries. We can view these phenomena as "political externalities" because actions in one country affect decisions in another. Paarlberg [16] has argued that

the limited use of GMOs in Africa, where they probably have the most potential to make a difference, is because of the influence of the EU. The more positive attitude to GMOs in Latin America reflects the stronger influence of the US. China's attitude towards GMOs is affected by its capacity to master and control the technology. When China owns significant intellectual property rights in NPBTs, it may use its influence on countries to allow for the use of the technology by their farmers and food processors.

Table 1. Credibility and policy influence of different interest groups.

Segments of the National Political Landscape	Objectives	Credibility	Influence
Polymakers	Being elected/promoted, doing well/obtaining financial rewards/serving the welfare of their communities [57].	High/ Low	High
Consumers	Low prices, human health, the environment [58–61]	High	Low as group
Farmers	High prices, low costs, higher yields, lower risk [43,57]	Medium	High
Retailers	Sales (food), satisfied customers, positive public image, product differentiation, [63,64]	High	high
Major biotechnology companies	Profits, market power, low risk [43,57]	Low	High
Start-up biotech companies	Growth, profits, market share, [55]	Low	Low
Input suppliers and food processors	Profits, market size [43,57]	Low	High
Academic institutions/research scientists	Research support, prestige [55]	High/Low	Medium
Activist organizations	Influence, donations [15,65,66]	High/ Low	Medium
Donor organizations and countries	Social and economic change, poverty alleviation, sustainability [15]	High/ Low	High
Trading partners	Affect technology, foreign policy and economic gains [16,21]	High/ Low	High

Source. The Authors.

6. Biotechnology Opportunities and Political Economy Challenges for Developing Countries

NPBTs are especially important for developing countries. China is among those countries that heavily supports the technology and some other countries such as Argentina and Brazil also view the technology favorably [19,32]. In contrast, many African countries are skeptical [61]. Nigeria might be an exception, having recently approved the cultivation of an insect resistant cow pea variety using Bt technology. However, other African countries such as Kenya and Uganda still seem to be reluctant to approve such technologies [28].

In other parts of the world, India, among the earliest countries to approve Bt-cotton, has not approved the cultivation of some GM crops used for human consumption such as Vitamin A enriched rice and pest resistant eggplants. Bangladesh has adopted Bt-eggplants but remains reluctant to approve Vitamin A enriched rice. The Philippines have approved GM maize, but they too are reluctant to approve Vitamin A enriched rice.

Many developing countries could derive substantial benefits from NPBTs using assessment protocols that are similar to those used for GMOs. Most of those countries would be substantial net beneficiaries in scenario A, as described above, where in the global market place both importing and exporting countries approve the new technology. In scenario B, they will be mainly be in the position of an importing country. As imports would require approval by the country's regulators, if a developing country decides to regulate them as GMOs, imports will likely be restricted, given how most of those countries have previously dealt with such NPBTs. That outcome would create an environment closer to scenario C in which only non-GMO products are imported. In both cases, developing countries are likely to forego substantial welfare gains.

In the near future, the losses associated with rejecting NPBTs are likely to increase, as options for adaptation in the face of climate change will be reduced. In Africa, the invasion of the Latin American version of the fall army worm and the recent locust invasion are just two among several examples of how lack of access to NPBTs are imposing substantial costs in those countries. For example, there is new evidence that some Bt-maize varieties are resistant to the fall army worm [67]. Similarly, there is new evidence that gene drive technologies developed using tools also applied under NPBTs would enable farmers to control the spread of locusts, or invasive species more generally [68].

The response to GMOs, particularly in African and some other developing countries, also has a geopolitical dimension. China invests heavily in NPBTs and also seeks to build alliances with countries in Africa. Providing NPBTs for important crops for those countries and at the same point in time offering export opportunities to China strengthens bilateral ties and weakens the influence of Europe and the United States in the region. However, countries in Africa that adopt crops derived from NPBTs are also likely to face substantially diminished export opportunities in the EU and some Southeast Asian markets such as Japan. In relation to EU countries, an approval for export would be needed. Secondly, even if exports to Europe are not envisioned, maintaining a zero tolerance level for exporting to the EU would be very difficult and costly to maintain.

Another layer of difficulty is added by the NKL protocol on “Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization,” and the NKL provision on “Supplementary Protocol on Liability and Redress.” Both have been incorporated in the Convention on Biological Diversity (CBD), as discussed previously. The effect of the NKL Protocol on developing and using NPBTs depends on how rigorously countries enforce the protocol. For example, the United States has not signed the protocol or the CBD. China may also not have much interest in enforcing the protocol if they see benefits from alternative approaches. In contrast, the EU belongs to those countries strongly enforcing the protocol because of interest groups that act as watch dogs to prevent protocol violations. Thus, the NKL Protocol is shifting the geopolitical landscape with respect to NPBTs in ways perhaps not anticipated by its authors and signatories, as well as reducing the contributions of NPBTs to food security and climate change mitigation.

7. Possible Ways Forward

The current situation with respect to the status of NPBTs seems to be problematic and the outlook for their future pessimistic. A primary concern is that the EU is a major market player and EU policies, in part affected by European Court of Justice (ECJ) decisions, have had substantial direct and indirect effects on the global development and application of NPBTs, with potentially important adverse implications for international food security, climate change and climate change adaptation.

One possibility might be a policy change within the EU [35]. The decision-making procedures in the EU and the current precedents set by the ECJ either prevent or heavily circumscribe any approval of crops derived by NPBTs for cultivation or imports to the EU. One possibility is to challenge the decision by the ECJ effectively to consider all such products as subject to being regulated as GMOs. Eriksen et al. [17] argue that such a challenge might result in a different interpretation of how NPBTs would be regulated; that is, they might continue to be described as GMOs, but excluded from regulatory oversight as GMOs under the mutagenesis exemption.

Another perhaps more long-lasting solution would be to have agreements at the international level that include a harmonized approval process for importing and processing NPBTs [7]. The result would be to avoid frictions in international trade and costly tracking and tracing systems as well as barriers to trade associated with country specific delays in approvals. A practical political advantage of an international agreement on approval is that it only affects trade and not cultivation. Countries would not have to agree on cultivation within their territory but only permit imports and processing. The agreement would therefore focus on food and feed safety, not on environmental safety.

The World Health Organization or a similar international institution then could act as a food and feed safety standard setting organization. This approach would also reduce duplicative testing costs, which many low-income countries cannot afford, as approval for access would be granted for all participating countries. It would also almost certainly increase the incentives for investments in the technology by private companies by reducing R&D costs and expanding the markets for the resulting NPBTs [35]. Incentives for investments by government agencies and philanthropic organizations, including major donors to aid for developing countries, would also increase.

Such an agreement would not necessarily force any given country to import an NPBT. Nevertheless, it would make it more difficult for individual countries that are members of the World Trade Organization and signatories to the WTO Sanitary and Phytosanitary Agreement to exclude such products on the basis of threats to human or animal health. Effectively trade would take place if, within a country, consumers were willing to buy NPBT-derived products and individual companies chose to import the products, substantially enhancing food security [47].

8. Conclusions

Recent advances in biological knowledge have increased our portfolio of tools for improving sustainable development. NPBTs such as CRISPR are some of these tools, and more are likely to emerge. Applications in medicine have yielded many valuable therapies including the vaccines that provide protection against the COVID-19 viruses. However, the application of biological knowledge in agriculture has been severely constrained by heavy regulatory burdens in the European Union and elsewhere. The rationales for and implications of these regulations are a result of the political economy of regulation and often not based on the biological knowledge about the products that are developed.

In fact, crop varieties generated using modern biotechnology have contributed to increasing food supplies, reducing food prices, and improving environmental quality. They have also mitigated incentives for production choices that adversely impact the rate of climate change and hence the sustainability of the global food supply chain, both with respect to land and water use decisions [3,69]. However, their potential to contribute to a sustainable bioeconomy, global food security, and more viable ecosystems has by no means been fully realized [4,8,21].

A major concern is the limited extent to which modern biotechnology has been utilized to improve the nutritional content and availability of food for humans, and to meet their potential for solving food security and sustainability challenges. The current complex of inconsistent country specific regulations urgently needs to be reformed to accommodate recent advancements in biological knowledge. Those regulations should apply the same science based criteria in assessing the safety of all new plant varieties and the products in which they are applied, regardless whether the process has involved using “traditional” plant breeding methods or NPBTs. That is, regulation needs to be based on outcomes rather than methods, and on scientific rigor, not political sentiments that are often driven by small, media savvy interest groups to the detriment of the rest of the local and global community.

In many countries, there is a perception that consumer acceptance is a major obstacle to the adoption of food produced using NPBTs and so the costs of burdensome regulations are modest. However, the empirical evidence strongly suggests that large segments of the population are willing to buy and consume such foods, even when they are minimally less expensive. Further, consumers are willing to pay premiums when it is clear that a new food product derived from NPBTs is of higher quality. In addition, once such foods are put on the shelves and consumers become more experienced with them, they become more widely, and often much more widely accepted.

Finally, the reality is that thus far no incidents of loss of life or serious environmental damage have been attributed to the use of modern biotechnology, and there is substantive evidence that its use improves environmental sustainability and sustainable development. The main losers in the current state of affairs are poor people in developing countries who are the most food insecure populations in the world and who urgently need access to a more abundant, safe food supply. Introducing streamlined, science-based regulation is likely to lead to the increased utilization and development of genetic material based on modern biology that will increase global food security, and by mitigating practices that engender climate change, contribute to the sustainability of the planet. Regulatory reform based on scientific evidence and aimed to induce the efficient and safe utilization of modern biotechnology along the lines presented here is needed as soon as possible.

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Abbreviations

Abbreviation	Definition	Source
BDA	Bayh-Dole Act	[12]
CBD	Convention on Biological Diversity	[70]
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeat	[11]
EC	European Commission	[71]
ECJ	European Court of Justice	[71]
EU	European Union	[71]
GE	Gene editing	[11]
GHG	Green House Gas	[72]
GMM	Genetically modified microorganisms	[73]
GMO	Genetically modified organism	[74]
LMO	Living Modified Organisms	[10]
NKL	Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity and The Nagoya—Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety	[75,76]
NBPT	New Plant Breeding Technology	[39]
ODM	Oligonucleotide-Directed Mutagenesis	[11]
OECD	Organization for Economic Cooperation and Development	[77]
SDM	Site Directed Mutagenesis	[39]
TALEN	Transcription Activator-Like Effector Nucleases	[11]
US	United States	[78]
USDA	United States Department of Agriculture	[79]
WHO	World Health Organization	[80]
WTO	World Trade Organization	[81]

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