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Policy Gridlock or Future Change? The Political Economy Dynamics of EU Biotechnology Regulation

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There are major differences in biotechnology regulation among various countries and in particular between the European Union and the United States. We summarize a formal and dynamic model of government decision-making on technology regulation, which shows that minor differences in consumer preferences can lead to important differences in regulation and that temporary shocks to preferences can have long-lasting effects. We argue that this model may contribute to explain the difference between EU and US biotechnology regulation. We discuss the European Union's current authorization procedure of GMOs and illustrate its regulatory gridlock. We describe some institutional reforms that are being proposed and undertaken at the EU level to overcome this policy gridlock.

Key words: political economy, biotechnology, EU regulation.

Introduction

There are major differences in biotechnology regulations among various countries. Vigani, Raimondi, and Olper (2010) illustrate how much countries differ in regulating genetically modified organisms (GMOs) with an index for GMO regulation that measures, amongst others, risk assessment regulations, labeling policies, and co-existence measures (Figure 1). A remarkable difference in GMO regulations exists between the European Union and the United States. Since the end of the 1990s, the European Union has followed a precautionary approach in establishing new legislation to regulate GM technology. As a result of its legislative approach, the European Union has put a de facto moratorium on the approval of GM products. In fact, the European Union has approved only two GM crops for cultivation, namely Monsanto's MON810 maize in 1998 and BASF's Amflora potato in 2010. In contrast, the United States has chosen to rely on pre-existing laws and agencies, considering GM technology as substantially equivalent to conventional agriculture (Sheldon, 2002).

A wide range of arguments are used to explain this difference between EU and US GMO regulations. Amongst others, it has been argued that EU consumers are more averse towards GM technology (see e.g., Curtis, McCluskey, & Wahl, 2004), that food scares (such as the 'mad cow disease' and the 'dioxin crisis') that plagued Europe in the 1990s triggered new EU regulations to protect consumers (see e.g., Scholderer, 2005), and that citizens' trust in public institutions is lower in the European Union (see e.g., Gaskell, Bauer, Durant, & Allum, 1999). Others have suggested that US farmers are better able to reap the benefits from GMOs (see e.g., Anderson, Damania, & Jackson, 2004), and that EU GMO legislation protects the interests of European chemical companies who are dominant in the traditional crop protection market (see e.g., Graff & Zilberman, 2004). However, none of these explanations is fully satisfactory and they lack a historical and dynamic perspective.

The difference between EU and US GMO regulations is not evident from a historical perspective. Vogel (2003) argues that over the past decades there has been an important shift in regulatory differences between the European Union and United States concerning consumer protection policies. According to Cameron (1999, p. 250), "no country […] so fully adopted the essence of the precautionary principle in domestic law as the United States." Vogel (2003, p. 557) confirms that "[f]rom the 1960s through the mid 1980s, American regulatory standards tended to be more stringent, comprehensive, and innovative than in either individual European countries or in the European Union." However, as illustrated by the European Union's precautionary approach towards GMOs, "since around 1990, the obverse has been true; many important EU consumer and environmental regulations are now more precautionary than their American counterparts" (Vogel, 2003, p. 557).

In the rest of this article, we first present the insights from a new political economy model of technology regulation, which was formally developed in Swinnen and Vandemoortele (2010) and allows one to interpret the United States' and European Union's different GMO regulations by taking a dynamic perspective. Then, we discuss the EU's current authorization procedure of GMOs and illustrate its regulatory gridlock. We end by describing some institutional reforms that are being pro-

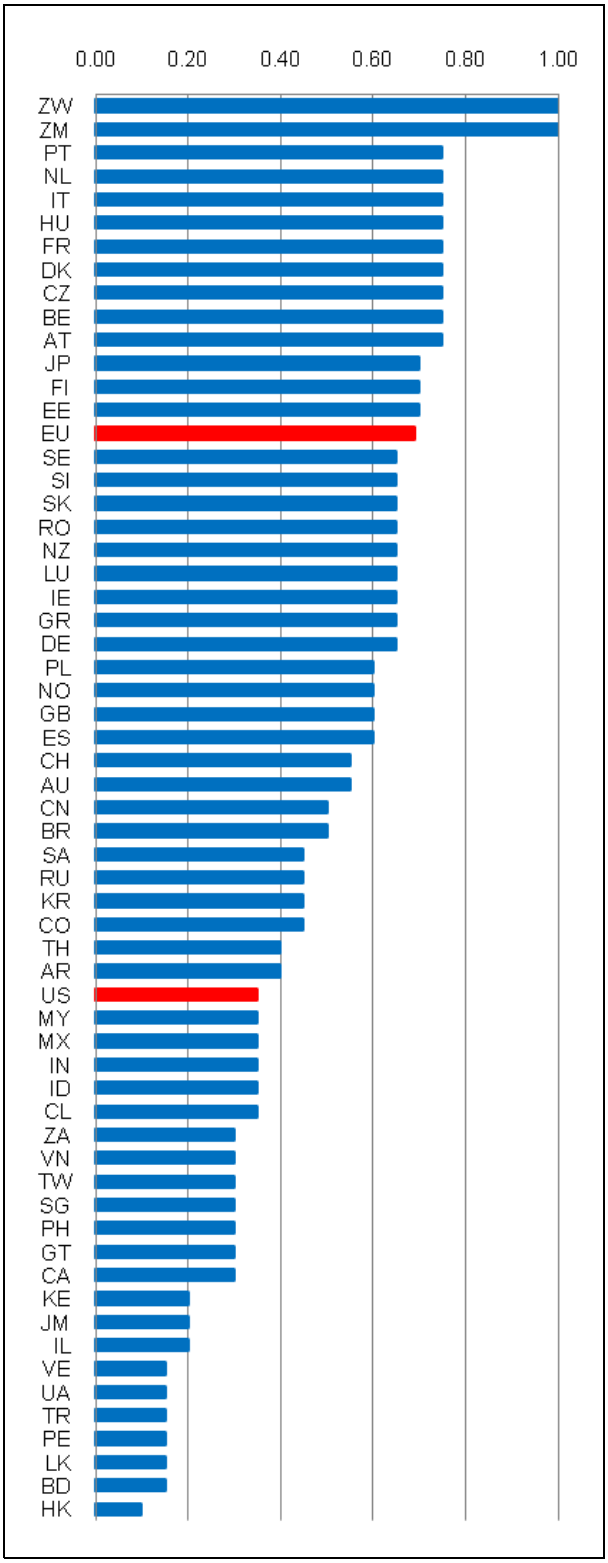

Figure 1. Index of GMO regulation.
Source: Vigani et al. (2010)

posed and undertaken at the EU level to overcome this policy gridlock.

A Dynamic Political Economy Theory of Technology Regulation

Central to our theory is the observation that in many cases technology regulation is introduced when preferences change or when new technologies become available. These changes induce new policy questions for regulators and governments to either allow (approve) new technologies or not. Consider two identical countries and two periods. At the start of the first period, a new technology becomes available (e.g., GM technology) in both countries, and the new technology allows users to produce the same product as the existing technology. Adoption of the new technology provides the ability to produce at lower marginal costs, but consumers have some aversion to its use and may adjust their consumption behavior depending on the type of technology involved in the production process. Consumers are heterogeneous in their preferences for the old technology, or put differently, in their aversion to the new technology. In both periods, the countries' governments decide whether to put a ban on the new technology or not, and producers incur investment costs if they switch technologies between periods. Producers are organized into interest groups who lobby their respective governments, and in the style of Grossman and Helpman (1994), governments decide on the optimal policy (whether to allow the new technology or not) by taking into account these interest groups' contributions and domestic social welfare.[1]

We analyze several cases of differences in consumer preferences between countries and over time. We show, first, that there exists a critical level ('threshold') of consumer preferences which separates the governments' decisions to approve and to prohibit the new technology. Hence, small variations in consumer preferences between countries and over time may cause significant differences in technology regulation, such as adoption of GM technology. Second, if different technologies are adopted, the country that opts for the new, cheap technology (GM technology) always endorses the status quo in the long run, i.e., always allows producing with the cheap technology, independent of the other country's

1. *We assume that consumers are not politically organized. This makes the derivation simpler but is not essential for the results. Consumer interests still play a role but through the social welfare function in the government's objective function.*

regulation. Similarly, the government that prohibits the new technology sticks with the old technology in the long run, even though consumers may wish to change, because producers' interests switch around in the long run. Producers are initially indifferent towards technology regulation. However, because of the costs of switching between technologies, producers of the country that prohibits the new technology suffer a competitive disadvantage in applying the new technology. Therefore, they lobby in favor of maintaining the ban on the new technology to protect themselves from cheaper imports from the country that adopts the new technology, and succeed if their political power is sufficiently strong.

Possibly most important, we show that these results may also hold when the initial choice in the first period is due to a 'temporary' change in consumer preferences—for example, due to a food scare. A temporary difference in consumer preferences may trigger different technology regulations, and thus different producer investments in technology. In that case, while consumer preferences converge again after the temporary difference, producers in both countries favor in future periods technology regulation that protects them against cheaper foreign imports, either because the other country's producers have already invested in the new technology, or have not. Hence, despite identical consumer preferences in the long run, regulatory differences may continue to exist in the long run because governments respond to pressures of domestic (producer) interests, thus creating hysteresis in technology regulation. Similar results can be obtained when shocks cause temporary differences in company strategies that result in different investment costs.

Temporary higher European consumer preferences are said to have been triggered by the food scares that plagued Europe in the second half of the 1990s, such as the bovine spongiform encephalopathy (BSE, commonly known as the 'mad cow' disease), foot and mouth disease (FMD), and dioxin crises (Bernauer, 2003; Graff & Zilberman, 2007; Scholderer, 2005). These food-safety crises may have induced people in Europe to (temporarily) believe that GM technology increases the risk on food-safety crises (Vogel, 2003). According to our results presented above, these temporary higher European consumer preferences may have triggered the difference in initial GM regulations between the United States and Europe. However, as the model demonstrates, the producers' interests are the reason that initial differences in GM regulation continue to exist even if there is no longer a difference in consumer preferences. This argument is supported by Graff and Zilberman (2004), who argue that GM regulation in name of consumer interests may equally support agrochemical companies and farmers by protecting against the comparative disadvantage from either investing or not investing in GM technology. Thus, it is the difference in consumer preferences that created initial differences in GM regulation, but producer interests that lead to hysteresis in GM regulation. The conclusions of the model are also consistent with the fact that, before the food safety crises, European producers were less opposed to GMOs (Bernauer, 2003) and that initially EU and US GM regulations were on the same track (Vogel, 2001).

Policy Gridlock or Regulatory Change in the European Union?

The question then arises whether this policy dynamic therefore implies that we should not expect major regulatory changes in the future in the European Union concerning GM technology. Vogel (2003, p. 580) presents an interesting perspective on this:

> "[t]he American experience suggests that this policy dynamic can persist for an extended period of time. […] It, however, does not last indefinitely. […] [T]he result is not so much a rolling back of existing consumer or environmental regulations, but rather policy gridlock. This took place in the United States after 1990 and will at some point occur in Europe."

Interestingly, there are signs that such regulatory gridlock is indeed occurring in the European Union. In 2010, for the first time in twelve years, the European Union authorized the cultivation of a GM crop, namely BASF's Amflora potato. However, this regulatory change was not due to a change in consumer preferences. According to Eurobarometer data (Eurobarometer, 2006, 2010), consumers' optimism about biotechnology increased from an all-time low of 24% in 1999 to 77% in 2010—the highest ever. However, at the same time, 58% of the 'decided public'[2] still is opposed to GM food.

The authorization of the Amflora potato was neither a consequence of a change in the EU's decision-making process. The current EU authorization process for GMOs consists of six steps. First, a company that devel-

2. *The 'decided public,' about 50% of all respondents, are those respondents who have a view on four key questions about GM food (Eurobarometer, 2006).*

Table 1. Votes of Member States in the SCoFCAH on April 19, 2010, and the Farm Council on June 29, 2010.

	For	Against	Abstain
Bt11xGA21	BE, CZ, DK, DE, EE, ES, NL, RO, FI, SE, GB	GR, CY, LV, LT, LU, HU, MT, AT, SI, PL	BG, IE, FR
MON89034XNK603	BE, CZ, DK, DE, EE, ES, NL, RO, FI, SE, GB	GR, CY, LV, LT, LU, HU, MT, AT, SI, PL, FR	BG, IE
Bt11 for renewal	BE, CZ, DK, DE, EE, ES, NL, RO, FI, SE, GB, MT	GR, CY, LV, LT, LU, HU, AT, SI, PL	BG, IE, FR

Source: Agra-Europe (2010)

ops a new GMO must scientifically assess and document the human and animal health effects and environmental safety of the GMO. Second, with these documents, the company has to apply for European authorization to a Member State, who then passes the documentation on to the European Food Safety Authority (EFSA). Third, the EFSA prepares an opinion, based on a scientific risk assessment conducted by independent experts, and submits this (publicly accessible) report to the European Commission (EC) and the Member States. Fourth, the EC submits a recommendation, either to grant or refuse the authorization, to the Standing Committee on the Food Chain and Animal Health (SCoFCAH). Usually the EC's recommendation follows the opinion of the EFSA. Fifth, the SCoFCAH—which is composed of Member State representatives—may accept or reject the EC's proposal, but only by a qualified majority.[3] Three scenarios are possible: (i) the SCoFCAH accepts the EC's recommendation, which then takes effect; (ii) the SCoFCAH rejects the EC's recommendation, and the EC then needs to rework its proposal and provide a new recommendation; or (iii) the SCoFCAH does not reach a qualified majority. In the last case, the recommendation has to be passed on to the Council of Ministers for Agriculture for a decision. In this sixth step, the Council approves or rejects the EC's proposal, again by a qualified majority. If the Council fails to reach a qualified majority, the proposal goes back to the EC, which adopts its own recommendation.

In reality, in the last decade neither the SCoFCAH nor the Council of Ministers has *ever* been able to make a decision on GMO issues. For example, at both the SCoFCAH meeting on April 19, 2010 and the Farm Council meeting on June 29, 2010, no qualified majority was reached on two proposed authorizations and one renewal of authorization for the marketing of GM maize, while all three proposals had been given the green light from the EFSA and the EC. The Member State representatives' votes are summarized in Table 1 and, not surprisingly, the votes are identical for both meetings. By now, the decision has come back to the EC, which followed its own proposal and authorized the marketing of these GM crops on July 28, 2010.

The recently authorized GM starch potato, Amflora, underwent a similar process involving all six steps of the procedure. No qualified majority was reached in the SCoFCAH or in the Council of Ministers, and finally the EC adopted its own proposal—following the EFSA's advice—to authorize the cultivation of Amflora. Hence, the Amflora potato was authorized not because it was approved upon by the SCoFCAH or the Council of Ministers, but because the meetings were unable to reach a qualified majority either in favor or against authorization.

Despite this authorization at the EU level, several Member States have already banned the cultivation of the Amflora potato. In principle, according to the EU's 'free circulation clause,' Member States may not prohibit, restrict, or impede the placing on the market of authorized GMOs. However, Member States may install co-existence measures to avoid the unintended presence of GMOs in other products. Additionally, under the EU's 'safeguard clause,' Member States may provisionally restrict or prohibit an authorized GMO on grounds of new information that indicates the GMO to be risky. Currently, eight Member States (Austria, Bulgaria, France, Germany, Greece, Hungary, Italy, and Luxembourg) are applying or have applied safeguard measures to GMOs that have been approved at the EU level. Member States who invoke the 'safeguard clause' must notify the EC, who then decides on the issue based on the EFSA's opinion. Without exception, the EFSA has always opposed the Member State's measure because no new information was provided by the Member State that challenged the EFSA's prior risk assessment. Following EU legislation, the EC asks for repeal of the Member State's provisional safeguard measures if the EFSA's opinion is negative. However, in most cases, the Council of Ministers rejects (with a qualified majority) the forced lifting of the provisional safeguard measures. This regulatory gridlock puts the EC in constant viola-

3. *According to the definition in the Treaty of Nice, a qualified majority requires the majority of the Member States, voting weights (74%), and population (62%).*

tion of both EU legislation and international law (Christiansen & Polak, 2009).

To end this regulatory gridlock, the European Union is proposing and undertaking several institutional reforms. On July 13, 2010, the EC issued a unilateral 'recommendation' on co-existence regulations that grants Member States more flexibility in taking co-existence measures. This fast initiative is however 'soft law'—it has no legal force—although it does allow Member States to 'ban' GMO cultivation by imposing nearly prohibitive co-existence regulations, as for example in Bulgaria. Furthermore, the EC is working on a legislative proposal to allow Member States to 'opt out' of GM technology, thus effectively nationalizing GMO implementation, while the EU-wide authorization system would remain in place (Europa RAPID, 2010).[4] Developing this proposal may take 1-2 years if successful, and it targets a limited number of amendments to legislation. However, the success of this second initiative remains doubtful, as it has been received with much criticism by Member States, the biotechnology industry, farmers, and green non-governmental organizations (NGOs). Some Member States fear that allowing Member States to individually decide on the cultivation of specific GM crops will undermine the integrity of the EU's internal market and could lead to the European Union and its Member States being challenged in the World Trade Organization (WTO). Other Member States fear that the proposal will come in exchange for support in approving new GM varieties at the EU level. The biotechnology industry claims that the proposal will lead to legal uncertainty for farmers who wish to grow GMOs because they may face arbitrary decisions by their national governments. This would give rise to legal disputes between farmers, biotechnology companies, and national authorities. Green NGOs reject the proposal because they ask for a moratorium on the authorization of new GMOs until a full reassessment of the risk of GM crops has been completed. Even if this initiative is successful, the outcome (i.e., more or less authorizations of GM crops) remains difficult to predict. According to our model, as long as the European producers' interests are not altered (e.g. by reducing their costs of switching technologies), Member States will not adjust their voting behavior, and the current policy gridlock will persist. A third initiative, as part of the implementation of the Lisbon Treaty, looks at reforming the 'Comitology'[5] system for those cases where it does not work, such as for GM crop authorization. One potential reform of the Comitology system would be to move from a 'qualified majority' to a 'simple majority' decision-making in specific cases, such as GM regulation. This would allow the committees to reach a decision in cases where they previously failed, but whether this reform would lead to more or less authorizations of GM varieties remains unsure.[6]

Conclusion

Large differences in GM regulations exist between countries, with the difference between the regulatory approach of the United States and the European Union as a notable example. We have presented the results of a formal dynamic political economy model that may explain this regulatory discrepancy between the United States and European Union, based on temporary differences in consumer preferences and lobbying by producer interest groups who try to protect their home markets from foreign imports. We have given an overview of the EU's current GMO authorization process, and illustrated the EU's regulatory gridlock. We have described several (proposed) institutional reforms that aim at ending this gridlock, but it remains unsure whether these reforms will be successful and whether they will lead to more or less authorizations of GMOs. Our formal model indicates that if European producers' interests remain unaltered, i.e., if their costs of switching technologies and competitive disadvantage are not reduced, Member States will not adjust their voting behavior and the current policy gridlock will persist.

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4. *This proposal has been launched by José Manuel Barroso, President of the European Commission, and is frequently referred to as the 'Barroso proposal.'*

5. *The term 'Comitology' refers to the system in which the EC is assisted by committees (e.g., SCoFCAH), consisting of Member State representatives, when implementing legislation at Community level. It aims at ensuring that measures reflect as good as possible the situation in each of the countries concerned.*

6. *A study by Dillen, Tollens, and Wesseler (2010) suggests that, when granted individual decision rights on GMO cultivation, a large majority of Member States would allow the planting of GMOs. However, these conclusions seem somewhat at odds with the spread of GMO-free regions in the EU.*

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Authors' Notes

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