A Tale of Two Continents: GMO Regulations in the United States and the European Union

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On February 18, 2015, the European Parliament enacted a law enabling Member States to ban Genetically Modified Organisms (GMOs) even if their use was approved at the European Union (EU) level. This new opt-out mechanism allows Member States to prevent the cultivation of GMOs on their territory, not only for health and consumer protection purposes, but also on socio-economic or public policy grounds. However, this new directive leaves many questions unanswered and seems contrary to World Trade Organization (WTO) rules. On the other side of the Atlantic, the battle rages on in the United States as to whether GMOs must be labeled or not. While the states of Vermont, Maine, and Rhode Island enacted GMOs labeling laws, ballots in the states of California, Colorado, and Oregon have been defeated. Recognizing that this issue had become controversial, Congress decided to get involved. The biotech industry supports a law that would prevent States from adopting their own GMOs labeling rules. This act, also known as the DARK (Denying American the Right to Know) Act by its critics, counters the Genetically Engineered Food Right to Know Act that tries to compel GMO producers to label their products. These developments create the necessity to analyze the diverse approaches adopted both in the EU and in the United States regarding GMO cultivation.

The biotech industry often faces difficult questions regarding ethics and social responsibilities. The creation and development of new products often requires investments of dozens if not hundreds of millions of dollars. A ban on the commercialization of these products can result in substantive financial losses for biotech companies. In addition, US and EU decisions to commercialize or ban GMO goods have consequences beyond their respective domestic markets. In fact, the position of these two leading actors have a large influence on the world, particularly on countries that are not able to finance complete impact studies or that have strong ties with either the EU or the United States. This is particularly true for GMOs, and the basic principles governing GMO regulations both in the United States and the EU are significantly different. Though the cautious European approach seems more responsible than the highly permissive US approach, the former has strong economically-adverse effects.

Precautionary Principle vs. Substantial Equivalence Principle

GMOs alter the building blocks of life itself through DNA adjustments. Because many citizens and scientists believe that they are a potential threat for consumers and for the environment, it has become a matter of public concern. For this reason, governments have played an important role in the GMO industry by regulating sales and commercialization. Regulations and governmental approaches towards GMOs are very different globally, in particular between the United States and the EU. The former bases its regulations on the “substantial equivalence principle” while the later bases its regulations on the “precautionary principle.” While the European cautionary

approach seems to be a more suitable solution to protect consumers and the environment, it is not ideal from an economic standpoint.

EU's regulations are strict, have a broad scope, and are based on the precautionary principle. This principle states that when a product may cause severe or irreversible damages, it should be prohibited. According to the EU, the precautionary principle "enables rapid response in the face of a possible danger to human, animal or plant health, or to protect the environment." The principle may "be used to stop distribution or order withdrawal from the market of products likely to be hazardous." When in doubt, the principle directs EU countries to ban the product. This principle, and the stringent regulations it entails, are driven by the historical and general skepticism regarding the manipulation of living organisms in Europe. However, the precautionary principle has not led the EU to ban all GMOs from Europe. The European Commission established a set of rules specific to GMOs, banning some of them, authorizing others and, most importantly, organizing an opt-out mechanisms for Member States that want to stay GMO-free.

The situation is significantly different in the United States, where the "substantial equivalence" principle prevails. According to this principle, when a new product contains similar quantities of basic components as a product already existing on the market, the products are considered substantially equivalent. Consequently, when genetically modified products are considered as substantially equivalent to non-genetically modified products by the US Food and Drug Administration (FDA) or the US Department of Agriculture (USDA), new GMOs do not require any further test from regulatory agencies when entering the US market.

Is the Precautionary Principle a Suitable Solution?

The US GMO approval approach is highly criticized and lacks credibility for several reasons. First, this substantial equivalence principle was adopted by the George Bush Sr. Administration during his deregulation years in order to stay at the forefront of the biotech industry. Further, the author of the regulation for the FDA was Michael Taylor, who was one of Monsanto's primary lawyers at the time. Monsanto, a US multinational corporation, is the largest GMO producer in the world. It has developed and often commercialized many controversial and dangerous products, including Agent Orange. Monsanto is also known for using the "revolving door" technique extensively by attracting FDA and Environmental Protection Agency (EPA) personnel with competitive salaries while sending a significant number of Monsanto personnel to these agencies. Dozens of individuals are involved in this "revolving door" process. Finally, several studies demonstrated that GMOs and non-GMOs could not be considered equivalent because the metabolism, biochemistry, and chemical composition of the organisms are altered. It is indeed difficult to believe that two organisms are equivalent when their DNA, and thus the very heart of these organisms, has been modified. Despite its well-documented questionable foundation, the principle of substantial equivalence is still in force more than twenty-five years later. The US principle regarding GMOs seems to be politically-driven rather than scientifically-driven and therefore potentially harmful in terms of social responsibilities.

As for the precautionary principle, it is considered by the European Commission as a "central plank of Community policy" and it is appealing to most European citizens who are concerned about the spread of health and environmental dangers through globalization and free trade. This more cautious European approach seems to favor consumer health as well as the environment. However, the precautionary approach presents significant disadvantages and raises some important issues, as well. First, it led the European Commission to provide an opt-out mechanism for EU Member States. These States can invoke socio-economical reasons for opting out, such as town and country planning requirements. This could potentially be misused by EU Member States, in particular for economic protectionist purposes. This would be the case if a country invokes socio-economical reasons in order to prevent foreign products from entering its market and favoring its own products. This threat of protectionism can only be overcome by the elaboration of a clearer and more defined policy from the EU. Since the precautionary principle is not defined in any European legal document, it does not satisfy the WTO minimum requirements and consequently creates a triple standard at the national, European, and international levels. Additionally, it leaves the door wide open for multinational companies like Monsanto to pressure the US government to use these legal weaknesses to challenge EU Member States' bans before the WTO. These multinationals can also challenge European bans in front of arbitral tribunals if the Transatlantic Trade and Investment Partnership (TTIP) is finalized.

Despite the EU's cautiousness towards GMOs, the European Food Safety Authority (EFSA), the European regulatory body in charge of food safety, tends to consider that GMOs do not present any threat for consumers. Yet, the European Parliament has often disregarded the EFSA's advice and applied the precautionary approach. American and European citizens have very different attitudes towards their regulatory agencies. European regulatory agencies experienced a series of regulatory failures that American agencies have not. Moreover, the lack of credibility of European agencies is directly linked to the lack of credibility of the EU itself. This ever-changing supranational body is going through an important legitimacy and identity crisis that may explain consumers' disregard for the advice of European regulatory agencies.

The European prudence towards GMOs also impacts technological development and the European biotech industry. There are very few state aids and subsidies available to fund innovation in the biotechnology sector even though it is considered by some as a promising means to address world hunger amidst a growing population. Moreover, there has been no approval for any new major biotech product in Europe since 1998. The process is stagnant and this is partly the reason why, in October 2014, 14,000 biotech companies were registered in the United States compared to only 2,083 in Europe of which approximately 1,400 are based in the United Kingdom.

A significant proof of the desperate situation for biotech crops in Europe is the recent decision from the usually tireless Monsanto to stop lobbying the European Commission regarding the commercialization of new genetically modified seeds in Europe. Monsanto has "withdrawn all application for cultivation of new biotech crops in Europe", and has "no plans to submit any new ones anytime soon". Three other companies had pending GMO approvals before the EFSA. BASF, the German chemical company, also decided to withdraw from the EU GMO market. DuPont

Pioneer, an Iowa based firm, and Syngenta, a Swiss firm, decided to pursue their applications but expressed great concerns about their future in Europe. The lack of sufficient funding for biotech research and the related brain drain may be highly damaging for the EU. If further long-term studies prove that GMOs are harmless to people, Europe will have lost an enormous amount of talent, time, and scientific progress.

Finally, if the European approach appears to be beneficial to solve some important social, human, and environmental issues, it has other negative aspects. These adverse effects, such as the triple standards, the brain drain, or the lack of subsidies are mainly economic. GMOs currently appear to be harmless for consumers but after longer period of time, the harms that it can cause are uncertain, especially considering the increasing number of genetically modified seed planted each year. Further, GMOs allow the indiscriminate use of powerful herbicides leading to the apparition of “super-weeds” and “super-bugs”, resistant to all sorts of herbicides. The effect of these herbicides on human health is disputed but much more concerning. Since the guinea pigs are humans in this case, a more cautious and responsible approach is probably recommendable. In the end, given the uncertain effects of GMOs, it is impossible to determine whether the US or European approach is the most appropriate. What is clear though is that consumers have at least the right to know what ingredients are contained in the food they purchase. Public authorities should impose an obligation on producers to be completely transparent in order for individuals to be able to make a conscious choice.