Technology in Society 35 (2013) 129–138

Contents lists available at SciVerse ScienceDirect

Technology in Society

journal homepage: www.elsevier.com/locate/techsoc

What risks and for whom? Argentina's regulatory policies and global commercial interests in GMOs

Pablo A. Pellegrini*

CONICET/Instituto de Estudios sobre la Ciencia y la Tecnología, Universidad Nacional de Quilmes, Roque Sáenz Peña 352, B1876BXD Bernal, Provincia de Buenos Aires, Argentina

ARTICLE INFO

Article history:
Received 20 July 2012
Received in revised form 13 September 2012
Accepted 3 January 2013

Keywords:
GMO
Regulation
Biotechnology
Argentina
Risk
Commercial interests

ABSTRACT

Regulatory frameworks on genetically modified crops present several differences, according to the specific procedures they take to deal with what they consider to be risks. Some of these differences have been studied between the United States and Europe, but there are other scenarios and subjects that may also be involved. Argentina not only has one of the major land areas devoted to transgenic agriculture, but it also has one of the first regulatory agencies in the region. Nevertheless, its regulatory policies towards genetically modified organisms (GMOs) have several differences with some international regulatory policies, such as the precautionary approach, the Cartagena Protocol on Biosafety and the labeling of food derived from GM crops. In order to understand this position, we analyze the development and function of GMOs' regulatory framework in Argentina, comparing it with Europe and showing how commercial interests in agriculture may explain each regulatory approach.

1. Introduction

There are different ways in which intellectual property may be involved in plant biotechnology developments, including patent, breeders' rights and regulatory systems specifically designed for genetically modified organisms (GMOs) [1]. The regulatory framework defines what can be done with GMOs by explicitly stipulating the procedures involving their utilization, evaluation and appropriation. However, usually at a more implicit level, each regulatory framework also reflects a position over a complex issue: what it is considered as a risk in these technologies and how to mitigate it.

These regulatory frameworks may diverge between countries, but the study of this diversity of regulatory styles is concentrated mainly in the regulatory frameworks of the United States and Europe [2–6]. The rivalry between them has been analyzed by Daniel Drezner, who shows the GMO-friendly regulations sustained by the United States and the promotion of the precautionary principle and the resistance to GMOs by the European Union. Both great powers have struggled in international forums to impose their position. On occasion, the lobbying they have displayed to recruit other countries has been notable, as the case when Zambia was confronting a drought and a subsequent food crisis, but rejected food aid with GM corn, fearing that its own agricultural exports would be blocked from the European Union if it showed itself to be permissive to GM products [7–9]. Nevertheless, not all regulatory policies on GMOs may be explained as a mere follower of one or the other block. Argentina's regulatory policies, which we'll be analyzing in this article, have been aligned in some issues with the United States position, but it also differs on many issues. The main interest of this article is to show that biotech regulatory policies cannot be understood as a matter of preference between standards, but that diverse interests are involved. With this purpose, we focus on Argentina, analyzing the development and function of its GMOs' regulatory framework.

* Corresponding author. Tel.: +54 11 43657100x5851.
E-mail address: ppellegrini@unq.edu.ar.

0160-791X/$ – see front matter © 2013 Elsevier Ltd. All rights reserved.
http://dx.doi.org/10.1016/j.techsoc.2013.01.003

Argentina presents a particularly interesting milieu for the analysis of these issues. It has been one of the first countries to adopt transgenic crops in its agriculture in 1996. It is one of the major countries regarding the quantity of acres devoted to this kind of agriculture: 23.7 million hectares of GM soybean, maize and cotton in 2011 [6]. The economic importance of this agriculture is not marginal – revenues derived from GM soybean constitute 25% of income from all of Argentina's exports. There are also several enterprises participating in vegetal biotechnology developments in Argentina. In addition it has scientists and public research institutions that have developed transgenic plants soon after the first ones in the world were obtained. Lastly, and fundamentally, in direct relationship to this work, it has been a pioneer in having a regulatory framework for agricultural biotechnology. In other words, genetically modified crops have a significant place in Argentinean agriculture, science and several institutions. This implies that in Argentina diverse institutions and mechanisms regarding GMOs regulation can be found, with a relatively long history, that presents singular characteristics. We show in this paper the specifics of the Argentinean regulatory framework, which presents some differences with others, such as the European framework.

The analysis that we present in this article has been done through documentary work with institutional archives, laws and regulations and by interviewing the main persons involved in GMOs regulatory issues.[1]

2. Precautionary principle or cost-benefit analysis?

There is no agreement among policy makers and in social theory between the "precautionary principle" and the "substantial equivalence" as the proper framework for regulating biotechnology. In this section, we describe these different frameworks.

The international norm related to biosafety regulation of biotechnology is the Cartagena Protocol, which a few countries, including Argentina, refuse to ratify. The Cartagena Protocol had its origin in the Convention on Biological Diversity of the United Nations, in 1992, where it established the need to have a protocol for settling the procedures related to the proper use and exchanges of GMOs. Reunited again in 1995, the parties of the Convention agreed to form a special working group for that purpose. Finally, the Cartagena Protocol on Biosafety was approved in 2000.

The Protocol is based on the fear that modern biotechnology may display new and grave risk problems. It states that the very term of *biosafety* "refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology" [10]. The Protocol is based, as it recognizes in its preamble and in its first article, on Principle 15 of the Rio Declaration, the renowned "precautionary principle".

The precautionary principle states that if there are "threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" [11]. The concept of the precautionary principle was first included in the 1970's, in German legislation [12], but it wasn't until the 1992 Rio Declaration, that the principle began to be incorporated in several norms, although in each norm the precautionary principle may present variations that modify its scopes [13,14].

The conceptual roots of the precautionary principle "can be traced back to the writings of the German philosopher Hans Jonas and the German sociologist Ulrich Beck" [15]. The idea of uncertainty as the main feature of contemporary society is characteristic of these perspectives. As far as these social theorists are concerned, modern technologies may unleash catastrophes of an unpredictable magnitude and to prevent them all measures that confront risk should be deployed. According to Beck, "what cannot be known must be prevented" [16]. Some analysts argue that the precautionary principle is needed when risks may be ubiquitous, persistent and irreversible [17,18].

The precautionary principle seems to carry a reasoning of unquestionable strength: it is better to avoid problems now than regret them in the future. Nevertheless, it also carries a much diffuse criteria: what stands as proof of a threatening technology and who decides that, for a specific issue, there is "a lack of full scientific certainty"? The precautionary principle sets its sphere of intervention within the lack of scientific consensus. However, who defines the lack of certainty between scientists? One indicator could be the studies published by the main researchers in the most renowned scientific journals, or, it may be enough to find a couple of studies in any scientific journal. In the case of GMOs, there has certainly been controversy within the mainstream of scientists involved in the subject between 1999 and 2002, when diverse studies published in *Nature* showed some ecological threats with the use of genetically modified crops [19,20]. Those studies have been involved in controversies, but afterwards, studies showing possible risks of GMOs appeared in journals of less prestige. A completely different scenario involves public opinion. Generally, in European countries, the public shows a strong rejection to the use of food derived from genetically modified crops [21]. Therefore, defining the presence of a threatening technology or the lack of full scientific certainty is not an uncontested issue. According to Mary Douglas and Aaron Wildavsky, public concern about the environment can never be explained by evidence of harm from technology, because the idea of risk and its acceptable levels are collective constructs [22]. In that sense, the notion of *technological risk* may even refer to very different things, for some people it may refer to a global uncertainty, while for others it may imply the presence of immanent dangers [23].

When analyzing the precautionary debate over the GMOs in Europe in the 1990s, Les Levidow showed that the problem was not about incomplete scientific information, as uncertainty even increased as more information became

[1] 15 in-depth interviews were realized to key-actors involved in biotech regulatory affairs in Argentina, some of them functionaries of regulatory agencies, others members of biotech companies and others scientists from public research centers.

available and that precaution was in fact operating on values related to agriculture, not simply on scientific facts [24].[2]

The precautionary principle has its critics. It has been argued that the precautionary principle has become an excuse for imposing arbitrary regulations [12,25]. Frank Cross argued that the precautionary principle is an illusion, as all efforts to eliminate any given risk will create new risks [26]. In a similar reasoning, Indur Goklany points out that the precautionary principle is founded in technological skepticism and it has been used to prohibit certain technologies, never evaluating the risks of not using them [27]. Goklany argues that GM crops may, among other properties, increase the productivity, the quantity and nutritional quality of food supplies, and in contrast the health effects of ingesting GM crops are uncertain. Therefore, he argues that the use of the precautionary principle for banning GM crops does not include consideration of the overlooked health and environmental risks of not using GM crops.

The political scientist Aaron Wildavsky considered that the precautionary principle should simply be rejected [28]. He argues that it is only a rhetorical piece, as it places the speaker as a representative of public health, but it only assumes what should actually be proved – that the (health) benefits of banning the technology are empirically greater than its costs.

All the detractors of this principle propose instead an evaluation of the risks based on a cost-benefit analysis. Cass Sunstein argues that cost-benefit analysis allows one to overcome cognitive limitations by ensuring that people have a wider sense of what is at stake. By counting the consequences of adopting a risk reduction measure in both quantitative and qualitative terms, by realizing an analysis of the costs and benefits of taking the regulatory measures, it could help to put things in perspective [29].

Regarding regulatory frameworks for GMOs, those who disagree with the precautionary approach tends to embrace the "substantial equivalent" approach, taken from OECD, FAO and WHO [30,31]. It considers that, when analyzing food derived from GMOs, its innocuity is evaluated comparing it with the equivalent food obtained from conventional methods. It implies a comparative analysis as the "orientation" of the evaluation, going through different aspects of the biotech product (its morphology, yield, chemical composition, molecular characteristics, allergenicity, biological activity and environmental impact). Again, from a precautionary approach, this evaluation isn't suitable, as the specific characteristics of each part of a biotech product are not the main issue to consider, but the unknown risks of the new product as a whole [32].

Social theories may often differ greatly around the precautionary principle, but policy makers seem much more pragmatic. The opposition between the European Union and the United States is not necessarily an epistemic one. In fact, according to David Vogel, in both blocks the precautionary principle has been applied, but to different kind of risks: the European Union facing possible risks of GMOs, the United States against possible risks of weapons of mass destruction in Iraq [33]. So the precautionary principle is in fact a common tool in contemporary political decisions, used to act against what is said to be a dangerous risk. Regarding genetically modified crops' technology, the precautionary principle is used to act against the suspicion of environmental and health risks, while other considerations of the use of GMOs, notably socio-economic ones, are not taken as part of what should be regulated [34]. Nevertheless, as we will show afterwards, economic interests lie behind all kinds of regulations.

The Cartagena Protocol on Biosafety, which recalls the precautionary principle in order to approach the risks of "transfer, handling and use of living modified organisms resulting from modern biotechnology", has been adopted by 164 countries.[3] Yet, Argentina is one of the few countries (as well as the United States and Canada) that refuses to ratify the Protocol. The United States reluctance to ratify the Protocol is well known [35], but what compels Argentina to adopt such a position? What are the arguments exposed? What kind of GMOs regulation is displayed instead? In order to answer these questions, we will describe Argentina's regulatory framework for genetically modified crops.

3. GMOs' regulation in Argentina

We begin this section by presenting the main aspects of plant legislation in Argentina and the conflicts it aroused with biotech companies, then we describe the specificities of agri-biotech framework in Argentina, its origins, the institutions involved and the way they act, finally focusing on its costs.

3.1. Plant varieties legislation and conflicts in Argentina

Following a global tendency to establish legal frameworks for protecting intellectual properties of plant varieties, Argentina passed a law of "Seeds and phytogenetic creations" at the beginnings of the 1970s [36]. Plant varieties in Argentina do not register in a patent system. Instead, the intellectual property framework is established within a "plant breeder's rights" system, which is a form of *sui-generis* intellectual property regime that assigns to a plant variety breeder an exclusive right of exploitation over his creation. Argentina's agricultural biotechnology regulatory system combines seeds' intellectual property laws with specific procedures for the evaluation of genetically modified organisms. Seeds' laws demand new varieties to meet requirements of novelty, uniformity and stability, in addition to the obligation to register the new seeds in the proper organism, the national institute of seeds (INASE). The seed law consents the "farmer's privilege", by which he may retain the seeds of his harvest for his own use.

[2] This seems to support Douglas and Wildavsky's idea that between subjective perception of risk and public science "there lies culture, a middle area of shared beliefs and values" [22].

[3] The Cartagena Protocol was adopted on January 2000, and entered into force on September 2003. Since then, other countries may ratify the Protocol. Until January 2013, 164 countries have ratified it. The European Union was one of the first parties to sign the Protocol.

Some aspects of this regulatory framework were seriously challenged by Monsanto and the United States government. Monsanto could not protect its soybean (the one with the *RR* gene, which provides resistance to glyphosate herbicide that Monsanto commercializes under the label "Roundup Ready") in Argentina, since in the country the technology has remained in the hands of another company (Nidera). Nevertheless, Monsanto negotiated with Nidera a compensation for the seeds sold. Also the fact that the seed technologies can be protected according to Argentinean regulation was a matter of conflict. The remuneration for the right of using seeds' technology is included in the seeds price, by purchasing the genetically modified soybean seed. However, many farmers buy the seed once and then use the seeds of their own harvest (using the "farmer's privilege"), or they buy it on the black market, mechanisms called "brown bag" [37,38]. In 2004, Monsanto claimed that illegal seeds represented more than 80% of the market, though those numbers were contested by government authorities [39]. As Monsanto has patented the *RR* gene in other countries, where Argentina exports its grains, Monsanto has initiated legal actions to require European importers to pay Monsanto for the use of RR soybeans coming from Argentina. At the center of the conflict, Monsanto wanted to change Argentinean legislation in order to eliminate the possibility that the farmer can use the seeds of its own harvest to establish a greater control over the "brown bag", that way Monsanto could earn much more for the use of RR technology [40,41]. The United States government supported Monsanto, by lobbying the Argentinean government to accede the demands; but despite the pressures, the Argentinean government didn't concede the claim.[4] Ultimately, GM soy in Argentina reported extraordinary profits, Monsanto sought to take part in them, but the Argentinean government also tried to dispute such income for the State, as shown the unprecedented conflict deployed in 2008 with agricultural producers regarding the withholdings on soybeans exports [43].

Companies argue that collecting royalties is essential in order to support the investment in research and development of new plant varieties. In any case, Monsanto is the only company to have deployed such an aggressive strategy as to stop the ships coming from Argentina, a strategy not followed by the rest of the industry. Moreover, seed companies in Argentina have implemented a new royalties system called "extended royalties", by which the farmer pays a greater amount than that corresponding to the use of seeds but allowing afterwards the use of the seeds for his own harvest. Thus, seed companies eventually recognized and allowed the farmers' practice of buying only once in a while legal seeds and then using the ones of their own harvest. At the same time these companies get more profit from fees than before.

3.2. Agri-biotech regulatory framework in Argentina

In Argentina there is no law that specifies the way in which GMOs should be regulated (unlike Brazil, for example, that has a "Biosafety Law"). However, there are a series of institutional procedures that deal with the control of GMOs. These regulatory procedures were settled through a series of events.

One of those events was a scandal that involved a biotech experiment at the end of 1980's. The Wistar Institute of the United States and the Mérieux lab in France developed a recombinant vaccine against rabies to immunize certain north-American animals, such as raccoons. In 1986, they began a trial on cows in the Argentinean town of Azul, in the Province of Buenos Aires. The experiment began in a secret manner and the vaccine would have entered the country in a diplomatic bag [44,45]. The experiment turned public, and the government banned it and ordered the sacrifice of the cows that was in the trial. The episode had repercussions in the United States, where investigations about the procedures were also taken. However the Wistar Company was absolved, arguing that it didn't break United States' norms [46]. Although this case was not about genetically modified plants, the conflict showed that there was a legal vacuum in Argentina regarding research in the agri-biotech field, since there were no guidelines to indicate how experiments should be performed, under which conditions, nor who should be the organization in charge of supervising.[5]

Soon after this episode, local scientists from public laboratories obtained the first transgenic plants in Argentina and wanted to perform field assays. At that moment, at the beginning of the 1990s, transnational seed companies were also trying to commercialize their own GM crops in Argentina. The organization in charge of seed control, INASE, began to receive applications for genetically modified seeds. INASE functionaries called the Secretariat of Agriculture, as they didn't know how to deal with these new technologies.[6] The Secretariat of Agriculture called on local scientists to help in dealing with the issues.[7] Those meetings produced the initiative of creating a specific organization for dealing with these technologies. Following these issues, in October 1991 the National Advisory Committee on Agricultural Biotechnology (CONABIA) was created, within the Secretariat of Agriculture, Livestock, Fisheries, and Food (SAGPyA). It is one of the first GMO regulatory institutions in the world.

The evaluation of genetically modified organisms for field trials or commercialization is under the responsibility of CONABIA, but the regulatory framework includes other entities as well [48,49]. In particular, SENASA (National

[4] Diplomatic actions of the United States in defense of Monsanto can be traced in Wikileaks [42]. The most significant answer of the Argentinean government is, in fact, its absence: as years pass by, it doesn't change its policies, with the result that Monsanto rescinded its claims and concentrated on how to better profit from the developments that followed.

[5] This episode was reported in a researchers' meeting in 1988 at an international conference on genetically modified organisms, to demand more regulations to experiments in the area [47].

[6] Personal communication with the Technical Coordinator of Biosafety, Office of Biotechnology, Secretariat of Agriculture, Livestock, Fisheries, and Food (SAGPyA). Buenos Aires, May 8, 2008.

[7] Personal communication with one of the first Argentinean scientists that developed a local transgenic plant, and member of CONABIA. Castelar (Argentina), August 12, 2010.

Health Service and Food Quality) is responsible for overseeing food safety of transgenic crops and the Direction of Agricultural Markets (DMA) deals with the analysis of trade impacts of GMOs. In addition, transgenic seeds must be registered by INASE and this institution also inspects GMO fields. Therefore, the regulatory framework on GMOs involves all these agencies, everyone dependent from the Secretariat of Agriculture (since 2009 raised to the level of Ministry). In formal terms, the CONABIA *advises* the Secretariat of Agriculture in biotechnological affaires. Once the CONABIA concludes the analysis of a GMO, it prepares a report that may be favorable or not to the liberation of the GMO. SENASA evaluates the analysis regarding the safety of the food and DMA examines the potential, commercial impact of the GMO in order to look after Argentina's agro-exporting profile. The Secretariat of Agriculture receives these reports and decides whether to approve or not the transgenic crop.

3.3. Regulation in action

CONABIA was conceived as a mixed organization, with representatives from the public and private sector.[8] Members of the private domain are not called as representatives of a company, but as experts from chambers of commerce, related to the production of seeds, fertilizers and other agricultural inputs. This way, business associations and some NGOs play a key role in CONABIA. In practice, these places are devoted to private experts, functioning as a sphere of distribution of power between the transnational companies of the sector. Since 2008 there are two representatives from the Seed Chamber (ASA) to CONABIA – one of them belongs to Syngenta and the other one to Dow AgroSciences. On behalf of the Chamber of Fertilizers (CASAFE) there is a representative who belongs to Monsanto and the other one to Bayer CropScience. CONABIA also receives experts from the Argentinean Biotechnology Forum – one of these experts is a directive from Pioneer and the other one from Biosidus (a local biotech company).

This way, even if companies, as such, have no representation in CONABIA, as it is an exclusively expert organization, in fact, experts coming from the private sector belong to the major transnational biotech companies operating in Argentina. Certainly, this presence of private experts in the main regulatory institution may not be a problem in itself, but it gives rise to some questions: are the transnational companies just regulating their own activity? Is there a place for other actors?

Public research centers do have direct representation in CONABIA: public universities, state institutions and public laboratories related with agronomic issues send their own representatives to CONABIA. Regarding local biotech companies, there are very few, and they have little representation.

CONABIA is devoted to regulate all agri-biotech activities, but in fact, genetically modified plants are the focus of all its attention. The reason is that almost all applications that CONABIA receives for biotech evaluations are of this kind. This reflects the importance of vegetal experimentation in biotech activities in Argentina.

But how does regulation actually work? CONABIA's first mission was the creation of specific norms for the release of genetically modified organisms. Taking elements of different regulations that already existed in some countries, CONABIA established in 1992 the first norm to be followed for experimentation or releasing to the environment of genetically modified organisms.[9] In order to recommend commercial authorization, CONABIA must conclude that the GMO is as safe as its conventional counterpart for the environment and for human or animal health. Its guidelines are based on the concept of substantial equivalence [49,50]. As mentioned in Section 2, the central idea is that for the analysis of foods derived from GMOs the most practical approach for safety is to assess whether they are substantially equivalent to their analogous counterparts produced by conventional methods. This entails a comparative analysis as a guide for evaluation.

The whole regulatory process may be long and costly. The process from when applications for field trials with a GM crop are approved, until finally adopting its commercialization, takes approximately six years.[10]

Another feature of the Argentine regulatory framework is that it comes through an analysis of "case by case". That is, it is considered that when CONABIA receives very similar applications, where it only changes the applicant, the transformation event, or the scale of the release, CONABIA still considers that these are different cases and therefore proceeds to the evaluation of each one [51,52].

The Argentinean regulatory framework aspires to evaluate GMOs considering them as novel *products* and not focusing on the *process* of obtaining GMOs [51]. According to many authors, the focus of regulation in the process or product is what differentiates the regulatory perspective of the U.S. and Europe on biotechnology [53–57]. In the United States the risks of biotechnology have been defined as depending on the type of products. That is to say, by studying the characteristics presented by the biotechnology product, there was no need to establish special legislation for biotechnology. Instead, biotechnology in Europe has been regulated under the predominant view that this was a new scientific process, therefore, considering biotechnology may pose risks inherent to the process of manipulating DNA. Argentine regulation is based on the properties of the new product and not on the process of obtaining it. However, under this regulation, only the products obtained by genetic engineering are subject to intense scrutiny [58,59]. This means that although the authorities and general principles argue that biotechnology

[8] Since its recent composition reform of August 2012, CONABIA has 49 members in representation of 20 institutions.

[9] The creators of CONABIA argue that they have built regulatory norms based in those already existing in other countries and without pretending to innovate in this policy area, because they wanted their regulatory system – the first one in Latin America – to be seen as carrying the same quality and the same requirement as that of the central countries (Personal communication with members of CONABIA. Buenos Aires, June 17, 2008).

[10] Personal communication with the Director of Biotechnology Directorate of the Ministry of Agriculture. Buenos Aires, June 6, 2008.

cannot be under suspicion and one must evaluate the final characteristics of its products, they still examine these products more than others, just because they are biotechnology products.

Canada may be the only country to truly adhere to the principle that biotechnology poses no inherent risks and that control should be based exclusively on the new product lines and not in the technologies used in their production [59,60]. This has practical consequences in the orientation of technological development. In Argentina, a local seed company, in collaboration with the multinational BASF, has developed a herbicide-resistant sunflower, through induced mutagenesis, a much less specific technique than transgenesis, which causes random changes in various parts of the plant genome in order to create variability [61]. One of the main reasons why they used this technology instead of transgenesis is that the regulatory system resulted, paradoxically, in making it much more accessible. Since legally it was not considered a GMO it was subject to much less stringent requirements. The local company argues that to fulfill the regulatory requirements for a sunflower obtained by mutagenesis has a lower regulatory threshold because it is more accessible in Argentina and almost all countries except Canada.[11] This is because in Canada crops with novel traits have to pass a regulatory process, independent of the technology used. Its regulation applies to all novel food, GM or not [62]. So in Canada, having used mutagenesis would not represent an advantage. This particular case shows how the constraints of regulations worried about the safety of a technology, may direct innovation towards a possibly much riskier technology, but with a lesser presence in public concern.

There are also commercial constraints in the regulatory framework. As indicated in Section 3.2, the Direction of Agricultural Markets (DMA) of the Ministry of Agriculture are involved in the regulation of genetically modified organisms with a very specific role – to assess on their commercial impacts. In practice, this involves analyzing how it could affect the approval of a GM crop in the country's trade. Given that Argentina has a strong agricultural export business profile, the DMA should evaluate whether the local approval of a GM crop may open or close export markets. If CONABIA and SENASA consider that a particular new genetically modified maize will have no impacts on health and environment, but in countries where maize is usually imported from Argentina that GM maize is not approved, then the DMA wouldn't recommend the local approval of that GMO as it would be detrimental to Argentine trade. The reason is that those importing countries may suspect that the usual crop coming from Argentina contains the new GM product, thus complicating the whole commerce of the crop. This implies that, in fact, Argentina assumes what is called a "policy mirror" – the DMA evaluates positively only those GM crops that are approved in Europe and considers negatively GM crops that have not been approved there.[12] In fact, the role of DMA in Argentina's regulation was incorporated in 1997, just when the European Union began to tighten its policies on GMOs. Between 1998 and 2001, Argentina didn't approve the commercialization of any transgenic crop, CONABIA sent approval recommendations on several GM crops, but the DMA emitted negative opinions. In brief, the DMA sought to imitate the way importing crops countries treat GMOs. This is because of the need not to prejudice the commercial channels of agricultural exports. However, the result is a regulatory policy that tends to reflect the GM adoption scenario of importing crop countries.

3.4. Regulatory steps and costs

Monsanto considers that passing through the regulatory step is the hardest phase of the whole development process of a transgenic crop, a step that may be suited to around 40 million dollars [63].[13] In a recent survey among the six major biotech companies, it emerged that the overall cost of producing a new transgenic plant is US$136 million, of which regulatory issues is the longest single phase in product development and is estimated to account for 25.8% and 36.7% of total cost and time involved respectively [64].

For Argentine researchers, the regulatory step is also the most expensive, which can represent more than ten times the cost of obtaining the transgenic event.[14] This does not mean that costs are the same as Monsanto reports since they could also include marketing issues and lobbying. Furthermore, no Argentine development has completed all the steps required by regulation, so it is not possible to have a clear idea of the concrete costs they entail for local actors, although it seems rather clear that is not easy for them to afford the economic investment. In any case, this highlights an important limitation when it comes to commercialization of genetically modified crops. The regulatory system would turn out to be a high barrier of entry for developing transgenic technology that only a few can fund.

There are a series of tests required by the regulatory system that are being done in the country regarding the analysis of environmental impacts of GMOs. First comes a series of greenhouse assays, but the open field experiments are more expensive. However, much more expensive are the tests that are used to assess food safety: toxicity, allergenicity, proteins, metabolism, chemical composition, nutrient profile, etc. These tests are done in laboratories that must be certified by international quality accreditation, which requires an adjustment to certain standards, procedures and equipment. There are no laboratories in Argentina who do these tests, so they must be conducted abroad.[15]

[11] Personal communication with the Director of Biotechnology Research of local seed company. Venado Tuerto (Argentina), July 14, 2009.

[12] Later on, Europe would not be the only reference to the DMA, as according to the crop, it may be important to assess other commercial destinations such as China or India.

[13] Personal communication with the Director of Regulatory Affairs of Monsanto. Buenos Aires, April 16, 2008.

[14] Personal communication with one of the first Argentinean scientists to develop a local transgenic plant, and member of CONABIA. Castelar (Argentina), August 12, 2010.

[15] Personal communication with INTA' (*Instituto Nacional de Tecnología Agropecuaria*) researcher and member of CONABIA. Castelar (Argentina), May 20, 2010.

All the years of these experiments that the regulatory system requires, results in a scenario where, until now, only transnational companies can develop and commercialize a transgenic crop. In Argentina, there are public laboratories that have developed transgenic potatoes, but their chances of being traded are very small.[16] Thus, the number of actors who have the financial capacity to adapt to the system of regulation of GMOs is reduced. In addition, companies that already have approved GMOs have more ease to approve new products, at least due to their expertise in the complex regulatory system [65].[17]

4. Interests in the regulation of GMOs' risks

The use of GM crops has, in many instances, enhanced yields and reduced net input costs [66]. In Argentina, the result of the adoption of GM soybean has been a quick increase in economic and productive performance from the agricultural sector as a whole [67,68].[18]

On the other hand, the rejection of GMOs in the European Union is well known, but the creation of the European Union biotech regulation is very complex, due in part to the complexity of the European Union institutional structure and its diversity. According to Mark Cantley's detailed overview of the first decades of European biotech regulation, during the 1980s biotech in Europe fell under a stigmatization produced by a combination of many factors, such as a widespread scientific illiteracy, sensationalism in the media, political opportunism, agricultural protectionism, mistrust of industry, and even anti-intellectual and anti-technological traditions [71]. By the mid-90s, when GMO's were introduced in agriculture, Europe was dealing with a serious consumer and citizen mistrust on European expert institutions due to the bovine spongiform encephalopathy scandal in the UK [72,73]. All these elements impacted GMO issues. Between October 1998 and May 2004, Europe had a *de facto* moratorium and during that period no GM crop was allowed, due to the asseveration of several European Union countries that GMOs' regulatory procedures should be modified. The European Parliament adopted a new regulation on dissemination of GMOs in March 2001 (which replaced the previous regulation of 1990), although the methods of traceability and labeling of GMOs were finally approved in September 2003 [74–76]. While in recent years the European Commission began to be in favor of the adoption of some transgenic events, some countries, notably France, Austria, Hungary and Greece, maintained a moratorium on GMOs, even going against the decisions of the European Commission [77,78].

It has been argued that government actions that tend to prohibit or restrict the use of GM crops in Europe are due to the fact that the biotechnology industry and European agriculture are lagging behind the American developments, and for this reason they take restrictive measures to GMOs [79]. The European Union spends around 50% of its budget in subsidizing their agriculture, through the "Common Agricultural Policy", in order to maintain its competitiveness in the international market [7].[19] In this scenario, EU farmers may have an interest in banning the domestic production and sale of GM crops [81]. These interests may explain the properties and objectives of the regulation.

The first European norm about genetically modified organisms, in 1990, defines them as "an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination" [75]. Here it can be seen that under European regulation biotechnology enters in the "natural–artificial" dichotomy. The following resolution, of 2001, follows the same criteria.[20] Argentinean normative, on the contrary, considers a GMO as "an organism in which some modification in its genetic material has been introduced in a deliberate and controlled way using modern techniques of molecular biology" and adds that "this modification consists in the incorporation of information in order to obtain an organism with a precise new characteristic" [51,82].[21] That way, the Argentinean normative focuses on the use of genetic information through biotechnological techniques, avoiding any discussion about the "natural–artificial" essence of those products.

When defined as "artificial", hence opposed to something "natural", it appears to be reasonable to indicate the user/consumer the "artificial nature" of the product. Thus, labeling is part of the European regulation on GMOs.

On the contrary, there are no national norms in Argentina that force the labeling of transgenic products. Moreover, agricultural governmental authorities expressed their rejection to those kinds of norms through diverse arguments. On the one hand, they consider that there is no transgenic food, but food derived from GMOs, and it can be chemically identical to a conventional food; also, they argued that labeling wouldn't be reasonable, as is not simple to distinguish the ingredients derived from a GMO [84].

These differences were also reflected in the Precautionary Principle and the Cartagena Protocol. Since the enforcement of the Protocol, in 2003, discussions among the parties were about the detection of GM products. In particular, discussions focused on fixing a threshold beyond

[16] Personal communication with UBA' (University of Buenos Aires) scientist and member of CONABIA. Buenos Aires, November 23, 2009.

[17] There is an initiative of researchers from public laboratories of Argentina to transform this scene, configuring a network of local laboratories able to complete the entire process of regulation in the country, which would reduce some costs.

[18] Instead, this may not have been the case for many small farmers that produce cotton, which may had difficulties buying the GM cotton seeds [69]. Nevertheless, some authors point out that cotton production in Argentina had faced a serious crisis due to many factors, mainly the introduction of mechanization, so GM seeds wouldn't be at the origin of their difficulties [70].

[19] In 1985, the funding of agriculture amounted to about 75% of the total EU budget, and in the recent years is about 40%, and it is expected to maintain at that levels [80].

[20] It states that a GMO "means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination" [74].

[21] In a similar way, it defines a GM crop as "any vegetal organism that possesses a novel combination of genetic material obtained through the application of modern biotechnology" [83].

which any shipment was considered to contain GMOs. After the European moratorium on GM production was lifted in late 2003, all food containing or produced from a GMO needed to be labeled. The tolerances for the unintentional presence of GMOs are the lowest in the world: 0.9% for approved GM and 0.5% for yet-to-be-approved GM food [81,85]. In order to properly label a GM product, it's necessary to trace it. Traceability means following the product to its origin, which implies keeping a record of its composition all along the productive and commercialization chain.

Argentinean agricultural functionaries undertook a study in 2004 in order to evaluate the economic impacts of the traceability requirement. It would imply the building of grain storages exclusive for GMOs, separated transportation and shipping equipment for each chain (transgenic and conventional), among other infrastructures. The higher the labeling threshold, the higher the productive and commercial chain separation that is required. The study presented two scenarios: a 5% and a 0.9% GMO threshold. The conclusion was that for a threshold of 5%, the total costs of investment per million tons would be US$7,413,000 for maize and US$10,206,000 for soybean. With a threshold at 0.9% (as settled by the European Union), the chains of production and marketing of grain should be even more differentiated, leading to costs of US$39,742,000 for maize and US$40,039,000 for soybeans [86]. The total production cost per ton would be higher with the labeling measures. That way, the highest GM crops productivity would be diminished by the cost of the segregation measures necessary to reach the traceability and labeling requirements. Hence, transgenic agriculture would diminish its competitiveness, favoring European agriculture.

Therefore, GMO exporting countries consider the traceability and labeling requirements as a trade barrier [87,88]. In particular, Argentina, Canada and the United States (three major GM crop producers) refuse to ratify Cartagena Protocol. There seems to be a clear dispute between GM crop exporters and importers, in relation to the Cartagena Protocol, which strengthens the prerogative of importing nations [89].[22] The only – and remarkable – exception is Brazil, which being an important GM crop exporter has ratified the Protocol in 2003. Brazil's position may be explained by its internal dynamics and conflicts in relation to GMOs, since although it has become one of the countries with the largest lands devoted to transgenic crops, it has also undergone a high public controversy over the use of GMOs, due to its complex and heterogeneous kind of agricultural producers, regarding its types and size [58,92].

In this way, a diverse kind of argument pulls apart the Argentinean and European GMOs' normative. Labeling expresses with more clarity the economic interests that lie behind them. For a GM crop producer as Argentina, labeling implies a differentiated system of production, transportation, processing and elaboration for GM products and for conventional products, and the maintenance of such a double production chain would raise its prices.

5. Conclusion

Genetically modified organisms, in particular transgenic crops, have raised doubts about diverse kinds of risks: environmental, health, commercial or even public reactions are assumed as possible risks. Each regulatory system has its own way of understanding these risks and dealing with them.

The European regulatory approach is based on the precautionary principle, considering the GMO as a technology that carries new potential risks and advocating in favor of its labeling.

The Argentinean regulatory approach towards GMOs is based on a cost-benefit analysis, arguing that its evaluation procedures may guarantee the safety of agri-biotech developments. Nevertheless, as one of the earliest GMO regulatory systems in the region, those who implemented it wanted to show an especially secure and strong system, demanding more trials and requirements to GMOs than to other technologies, which seems more typical of an approach that considers dealing with an inherently dangerous technology.

With a less competitive and strong subsidized agriculture, Europe has developed a GMO regulatory system with high barriers of entry and lots of suspicion towards GMOs. On the contrary, with an agricultural export profile, Argentina promotes GMOs' regulation taking into account its benefits. Disputes over the Cartagena Protocol and the labeling of products derived from genetically modified crops fall in these divergent interests, as those measures would elevate the cost of GM crop production.

Still, Argentina faces other kinds of regulatory barriers to the development of GMOs, such as the high costs of the regulatory procedures for local actors or the role of the Direction of Agricultural Markets. Indeed, the commercial impacts on import countries, assessed by Argentina's own Direction of Agricultural Markets, in practice, implies the requirement that for the transgenic crop to be locally approved, it must have also been previously approved in the country where the exports are destined to go. Developments that have a local utility, such as transgenic maize resistant to local disease, have no possibilities to satisfy this requirement, as grains and oils derived from that maize may be rejected by other countries. This reveals the weight of commercial interests: as a GM crop producer, Argentina promotes the commerce of transgenic crops with no special barriers, but it may stop the approval of local GMO technology in order to avoid conflicts with international agricultural commerce.

Introducing the idea of "interests" in GMOs does not pretend to reduce the necessary complexity in the risks debate, but such an element shouldn't be absent in the analysis of GMOs' disputes. It is usually considered that developing countries have little choice but to comply with regulations set by international institutions. In this paper, we've shown that when opposing or accepting some international regulations, a developing country may not be

[22] This dispute may also be seen in the WTO, where in August 2003, the U.S., Canada and Argentina initiated dispute settlement procedures against the European Community (EC) for the adoption of prohibitions against certain GM products previously approved by the EC [90,91].

just following central countries' policies, but pursuing its own interests.

Acknowledgments

This research has been possible thanks to CONICET postdoctoral fellowship and was also supported by the Agencia Nacional de Promoción Científica y Tecnológica through funding PICT-2011-1713.

References

[1] Chandler S, Rosenthal J. Freedom to commercialize transgenic plant products: regulatory and intellectual property issues. Biotechnology in Agriculture and Forestry 2007;61:411–29.
[2] Dunlop C. GMOs and regulatory styles. Environmental Politics 2000; 9(2):149–55.
[3] Vogel D. The new politics of risk regulation in Europe. CARR discussion papers, DP 3. London: Centre for Analysis of Risk and Regulation, London School of Economics and Political Science; 2001.
[4] Vogel D, Lynch D. The regulation of GMOs in Europe and the United States: a case-study of contemporary European regulatory politics. New York: Council on Foreign Relations Press; 2001.
[5] Prakash A, Kollman KL. Biopolitics in the EU and the U.S.: a race to the bottom or convergence to the top? International Studies Quarterly 2003;47:617–41.
[6] James C. Global status of commercialized biotech/GM crops: 2011. ISAAA Brief No. 43. Ithaca, New York: ISAAA; 2011.
[7] Drezner DW. All politics is global: explaining international regulatory regimes. Princeton: Princeton University Press; 2007.
[8] Paarlberg RL. Starved for science: how biotechnology is being kept out of Africa. Harvard: Harvard University Press; 2008.
[9] Cleaver K, Okidegbe N, de Nys E. The challenge of food security: strategies to reduce global hunger and malnutrition. In: Bhargava V, editor. Global issues for global citizens. Washington, D.C.: The World Bank; 2006. p. 145–63.
[10] Secretariat of the Convention on Biological Diversity. Cartagena protocol on biosafety to the convention on biological diversity: text and annexes. Montreal: Secretariat of the Convention on Biological Diversity; 2000.
[11] United Nations Conference on Environment and Development. Rio declaration on environment and development. Rio de Janeiro: United Nations; 1992.
[12] Morris J. Rethinking risk and the precautionary principle. Oxford: Butterworth-Heinemann; 2000.
[13] Drnas de Clément Z. El Principio de Precaución Ambiental. La práctica Argentina. Córdoba, Argentina: Lerner; 2008.
[14] Bergel S. El principio precautorio y la transgénesis de las variedades vegetales. In: Bergel S, Díaz A, orgs, editors. Biotecnología y Sociedad; 2001. p. 69–108. Buenos Aires: Ciudad Argentina.
[15] Ferrari M. Risk perception, culture, and legal change: a comparative study on food safety in the wake of the mad cow crisis. Surrey, England: Ashgate Publishing; 2009.
[16] Beck U. World at risk. Cambridge, UK: Polity Press; 2009.
[17] Renn O. Risk governance: coping with uncertainty in a complex world. New York: Earthscan; 2008.
[18] Murphy R. Managing risk under uncertainty. In: Measham T, Lockie S, editors. Risk and social theory in environmental management. Collingwood, Australia: CSIRO Publishing; 2012. p. 17–26.
[19] Losey JE, Rayor LS, Carter ME. Transgenic pollen harms monarch larvae. Nature 1999;399(6733):214.
[20] Quist D, Chapela I. Transgenic DNA introgressed into traditional maize landraces in Oaxaca, Mexico. Nature 2001;414(6863):541–3.
[21] Gaskell G, Stares S, Allansdottir A, Allum N, Castro P, Esmer Y, et al. Europeans and Biotechnology in 2010: winds of change?. A report to the European Commission's Directorate-General for Research; 2010.
[22] Douglas M, Wildavsky A. Risk and culture. An essay on the selection of technological and environmental dangers. Berkeley/Los Angeles: University of California Press; 1983.
[23] Pellegrini PA. Riesgo y contexto. Un análisis sobre el discurso del riesgo tecnológico en los movimientos sociales. Ciencia, Docencia Y Tecnología 2007;35:51–87.
[24] Levidow L. Precautionary uncertainty: regulating GM crops in Europe. Social Studies of Science 2001;31(6):842–74.
[25] Peterson M. The precautionary principle should not be used as a basis for decision-making. EMBO Reports 2007;8(4):305–8.
[26] Cross FB. Paradoxical perils of the precautionary principle. Washington and Lee Law Review 1996;53(3):851–925.
[27] Goklany IM. The precautionary principle: a critical appraisal of environmental risk assessment. Washington DC: Cato Institute; 2001.
[28] Wildavsky A. But is it true? A citizen's guide to environmental health and safety issues. Cambridge: Harvard University Press; 1997.
[29] Sunstein CR. Risk and reason: safety, law, and the environment. Cambridge: Cambridge University Press; 2002.
[30] OCDE. Evaluation de la sécurité des denrées alimentaires issues de la biotechnologie moderne: concepts et principes. Paris: Organisation de Coopération et de Développement Économiques; 1993.
[31] FAO. Evaluación de la inocuidad de los alimentos genéticamente modificados. Rome: Organisation des Nations Unies pour l'alimentation et l'agriculture; 2009.
[32] Ibarra A, Rodríguez H. Biotecnología agroalimentaria: más allá de la casuística. REDES 2003;10(20):121–38.
[33] Vogel D. The politics of precaution: regulating health, safety, and environmental risks in Europe and the United States. New Jersey: Princeton University Press; 2012.
[34] Chaturvedi S, Ravi Srinivas K, Joseph RK, Singh P. Approval of GM crops: socio-economic considerations in developing countries. Economic & Political Weekly 2012;XLVII(23):53–61.
[35] Pollack MA, Shaffer GC. Distributive conflicts, regime complexes and the international regulation of genetically modified organisms. Workshop on nested and overlapping regimes. Princeton University, http://www.princeton.edu/~smeunier/Pollack%20Shaffer%20 memo.pdf; 2005 [accessed April 2012].
[36] Gutiérrez M. El debate y el impacto de los derechos de obtentor en los países en desarrollo: el caso argentino. Buenos Aires: IICA; 1994.
[37] Halapin H. Rastrojos y algo más: Historia de la siembra directa en Argentina. Buenos Aires: Teseo; 2008.
[38] Trigo E, Chudnovsky D, Cap E, López A. Los transgénicos en la agricultura argentina: una historia con final abierto. Buenos Aires: Libros del Zorzal/IICA; 2002.
[39] Rossi D. Regalías globales: algunos interrogantes. Agromensajes de la Facultad, vol. 12; 2004. p. 29–31.
[40] Martinolich A. Derechos de propiedad intelectual en las obtenciones vegetales: el caso de la soja y el conflicto Monsanto – Productores agropecuarios. Rosario: Lecturas N° 12, Ediciones Bolsa de Comercio de Rosario; 2008.
[41] Correa C. Monsanto contra Argentina por la exportación de harina de soja a la UE. In: Tansey G, Rajotte T, editors. El control futuro de los alimentos. Madrid: Mundi-Prensa; 2009. p. 230–1.
[42] O'Donnell S. ArgenLeaks. Buenos Aires: Sudamericana; 2011.
[43] Barsky O, Dávila M. La rebelión del campo. Buenos Aires: Sudamericana; 2008.
[44] Martínez SM. Aprendiendo de un incidente olvidado: el episodio de Azul. Revista Médica de Rosario 2003;69(3), http://www.cimero.org.ar/verrevista.php?i=7 [accessed March 2012].
[45] Connor S. Argentinian scandal prompts new gene rules. New Scientist 1988;118(1608):18.
[46] Crawford M. NIH finds Argentine experiment did not break U.S. biotechnology rules. Science 1987;235(4786):276.
[47] Dixon B. Genetic engineers call for regulation. The Scientist 1988; 2(8):2.
[48] Jaffe G. Regulating transgenic crops: a comparative analysis of different regulatory processes. Transgenic Research 2004;13(1):5–19.
[49] Burachik M, Traynor PL. Analysis of a national biosafety system: regulatory policies and procedures in Argentina. International Service for National Agricultural Research; 2002. Country Report 63.
[50] Rubinstein C. Criterios científicos para la evaluación de la bioseguridad de organismos genéticamente modificados. In: Echenique V, Rubinstein C, Mroginski L, editors. Biotecnología y mejoramiento vegetal. Buenos Aires: Ediciones INTA; 2004. p. 375–85.
[51] Burachik M. Bioseguridad de Organismos Genéticamente Modificados – Marcos Regulatorios. In: Echenique V, Rubinstein C, Mroginski L, editors. Biotecnología y mejoramiento vegetal. Buenos Aires: Ediciones INTA; 2004. p. 387–98.
[52] UNEP-GEF. Informe sobre los progresos realizados en Argentina en el ámbito del proyecto PNUMA-FMAM Desarrollo de un Marco Nacional de Bioseguridad (MNB). Talleres subregionales PNUMA/FMAM de bioseguridad para América Latina sobre la elaboración de sistemas reglamentarios y administrativos en relación con los marcos nacionales de bioseguridad, UNEP-GEF project on development of national biosafety frameworks. Santiago (Chile), http://

www.unep.ch/biosafety/old_site/development/countryreports/ARprogressrep.pdf; 2003 [accessed February 2012].
[53] Skogstad G. Constructing a transnational policy paradigm in the European Union: the case of GMO risk regulation. In: Skogstad G, editor. Policy paradigms, transnationalism, and domestic policies. Toronto: University of Toronto Press; 2011. p. 91–118.
[54] Jasanoff S. Designs on nature: science and democracy in Europe and the United States. Princeton: Princeton University Press; 2005.
[55] Marden E. Risk and regulation: U.S. regulatory policy on genetically modified food and agriculture. Boston College Law Review 2003; 44(3):733–87.
[56] Isaac GE, Phillips PWB. Regulating domestic markets. In: Phillips PWB, Khachatourians GG, editors. The biotechnology revolution in global agriculture: innovation, invention, and investment in the canola industry. New York: CABI Publishing; 2001. p. 213–42.
[57] Meins E. Politics and public outrage: explaining transatlantic and intra-European diversity of regulations on food irradiation and genetically modified food. Münster: LIT Verlag; 2003.
[58] Cantley M. An overview of regulatory tools and frameworks for modern biotechnology: a focus on agro-food. OECD International Futures Programme, http://www.oecd.org/dataoecd/11/15/40926623.pdf; 2007 [accessed April 2012].
[59] MacKenzie DJ. International comparison of regulatory frameworks for food products of biotechnology. Ottawa: Canadian Biotechnology Advisory Committee; 2000.
[60] Flint J, Gil L, Verastegui J, Irarrazabal C, Dellacha J. Biosafety information management systems. A comparative analysis of the regulatory systems in Canada, Argentina, and Chile. Electronic Journal of Biotechnology 2000;3(1):9–29.
[61] Murphy DJ. Plant breeding and biotechnology: societal context and the future of agriculture. New York: Cambridge University Press; 2007.
[62] Lusser M, Rodríguez Cerezo E. Comparative regulatory approaches for new plant breeding techniques. JRC Scientific and Technical Reports. Spain: European Commission; 2012.
[63] Ramsay J. Pipeline review. Seville: Monsanto, JRC; November 2008.
[64] McDougall P. The cost and time involved in the discovery, development and authorisation of a new plant biotechnology derived trait. A consultancy study for crop life international, September 2011. Saughland, United Kingdom: Vineyard Business Centre; 2011.
[65] Harhoff D, Regibeau R, Rockett K, Schnitzer M, Jullien B. Some simple economics of GM food. Economic Policy 2001;16(33):265–99.
[66] Meijer E, Stewart R. The GM cold war: how developing countries can go from being dominos to being players. Review of European Community & International Environmental Law 2004;13(3):247–62.
[67] Bisang R. Diffusion process in networks: the case of transgenic soybean in Argentina. Rio de Janeiro: First Globellics Conference; 2003.
[68] Trigo EJ. Quince años de cultivos genéticamente modificados en la agricultura argentina. Buenos Aires: ArgenBio; 2011.
[69] van Zwanenberg P, Ely A, Smith A, Chuanbo C, Shijun D, Fazio ME, et al. Regulatory harmonization and agricultural biotechnology in Argentina and China: critical assessment of state-centered and decentered approaches. Regulation & Governance 2011;5(2):166–86.
[70] Barsky O, Fernández L. Cambio técnico y transformaciones sociales en el agro extrapampeano. Buenos Aires: Editorial Teseo; 2008.
[71] Cantley MF. The regulation of modern biotechnology: a historical and European perspective. In: Brauer D, editor. Biotechnology. Legal, economic and ethical dimension. 2nd ed., vol. 12. Weinheim, New York, Basel, Cambridge, Tokyo: VCH; 1995. p. 505–681.
[72] Scholderer J. The GM foods debate in Europe: history, regulatory solutions, and consumer response research. Journal of Public Affairs 2005;5:263–74.
[73] Dickson D. Science and its public: the need for a 'third way'. Social Studies of Science 2000;30(6):917–23.
[74] Directive 2001/18/EC of the European parliament and of the council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing council directive 90/220/EEC, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0018:EN: HTML; 2001 [accessed March 2012].
[75] Council directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0220:EN: HTML; 1990 [accessed March 2012].
[76] Regulation (EC) no 1830/2003 of the European parliament and of the council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003R1830:EN:HTML; 2003 [accessed March 2012].
[77] Friant-Perrot M. The European Union regulatory regime for genetically modified organisms and its integration into community food law and policy. In: Bodiguel L, Cardwell M, editors. The regulation of genetically modified organisms. Comparative approaches. Oxford: Oxford University Press; 2010. p. 79–100.
[78] The council of the European Union. Press release (2928th Council meeting) 7042/1/09 REV 1 (Presse 53), environment, Brussels, 2 March 2009. http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/envir/106430.pdf [accessed April 2012].
[79] Tambornini E. Biotecnología: la otra guerra. Buenos Aires: Fondo de Cultura Económica; 2003.
[80] European Parliament resolution of 8 July 2010 on the future of the common agricultural policy after 2013. http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2010-0286+0+DOC+XML+V0//EN [accessed April 2012].
[81] Anderson K, Jackson LA. Why are US and EU policies toward GMOs so different? AgBioForum 2003;6(3):95–100.
[82] Preguntas y respuestas en Biotecnología Agropecuaria. Dirección de Biotecnología. Ministerio de Agricultura, Ganadería, Pesca y Alimentos de la Nación. http://64.76.123.202/site/agricultura/biotecnologia/80-DE%20INTERES/_archivo/000400_Preguntas.php [accessed May 2012].
[83] Biotecnología Agropecuaria. Resolución 39/2003. Secretaría de Agricultura, Ganadería, Pesca y Alimentos, http://www.infoleg.gov.ar/infolegInternet/anexos/85000-89999/86871/norma.htm; 2003 [accessed December 2011].
[84] Schiavone E, Morón P, Lema M. Alimentos "transgénicos" e información del consumidor. Revista Alimentos Argentinos 2006; 32:12–5.
[85] European Commission. Questions and answers on the regulation of GMOs in the EU. Memo/02/160-REV, 1st July 2003. Brussels: European Commission, http://ec.europa.eu/dgs/health_consumer/library/press/press298_en.pdf; 2003 [accessed May 2012].
[86] Alais F. Alimentos y OGM: Seguridad, sí. Discriminación, no. Alimentos Argentinos, vol. 34; 2006. p. 4–7.
[87] Sarquis MA. Protocolo de Cartagena. Algunas consideraciones sobre la implementación de sus requisitos comerciales, vol. VI(1). Publicación periódica del Instituto Interamericano de Cooperación para la Agricultura en la Argentina; 2003. p. 59–62.
[88] UNEP-GEF/SAGPyA. Revisión del marco nacional sobre bioseguridad en Argentina. Proyecto UNEP-GEF – SAGPyA, GF/2716-02-4406; 2004.
[89] Brack F, Falkner R, Goll J. The next trade war? GM products, the cartagena protocol and the WTO, vol. 8. The Royal Institute of International Affairs, Sustainable Development Programme. Briefing Paper. p. 1–12, http://www.chathamhouse.org/sites/default/files/public/Research/Energy,%20Environment%20and%20Development/next_trade_war_gm__cp_&_wto_brack_et_al_sept_03.pdf; 2003 [accessed May 2012].
[90] EU and Canada settle WTO case on genetically modified organisms, http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/1142&format=HTML; 2009 [accessed May 2012].
[91] Stewart RB. GMO trade regulation and developing countries. New York University Public Law and Legal Theory Working Papers. Paper 165, http://lsr.nellco.org/nyu_plltwp/165; 2009 [accessed May 2012].
[92] Pellegrini P. Knowledge, identity and ideology in stances on GMOs: the case of the Movimento Sem Terra in Brazil. Science Studies 2009;22(1):44–63.

Pablo Pellegrini is PhD in Social sciences and knowledge philosophy (Sorbonne-Paris IV and FLACSO Argentina), and Master in Science, Technology and Society. He is a CONICET' researcher and works at the Institute for the Social Studies of Science and Technology (National University of Quilmes, Argentina), researching in the articulation between science and agriculture and in knowledge production and controversies in biotechnologies. He has recently published a book about the development of plant biotechnology in Argentina.