

A COMPARATIVE PERSPECTIVE ON NATIONAL POLICIES ADDRESSING GENETICALLY MODIFIED ORGANISMS. HOW DOES THE US - EUROPEAN UNION DEBATE ON THIS TOPIC AFFECT OTHER COUNTRIES?

Abstract

The paper explores the topic of genetically modified organisms (hereafter GMOs) and focuses on national and international regulatory approaches to this field. The analysis herein addresses a multitude of interconnected issues on GMOs as the authors' intention is to explain how a policy problem that is environmental in nature can generate debates and consequences that go beyond the realm and scope of environmental policy. Each of the sections of the paper could be expanded into an autonomous paper.

The discussion herein is framed using a comparative case study analysis. The US domestic policy on GMOs¹ is contrasted against the EU policy. These two domestic policies are relevant as they represent the two main contemporary approaches to how GMOs are to be regulated. Furthermore, the clash between the two powers with regard to GMOs is described and explained. Its relevance stems from the profound consequences it generates within the international arena.

[¹ US decision makers have long supported a *laissez fair* approach with regard to GMOs, with regulatory governmental agencies playing a minimal role. The *laissez fair* attitude can be considered a public policy in light of the definition of this concept: "a public policy is what governments decide to do or not to do".]

Dacian C. DRAGOS
Bogdana NEAMȚU

Dacian C. DRAGOS

Associate Professor, PhD, Department of Public Administration,
Babes-Bolyai University, Cluj-Napoca, Romania

Tel/fax: 0040-264-431361

Email: dragos@apubb.ro

Bogdana NEAMȚU

Assistant Professor, Public Administration Department,
Babeș-Bolyai Univesity, Cluj-Napoca, Romania

Tel/fax: 0040-264-431361

Email: bogdananeamtu@apubb.ro



Transylvanian Review
of Administrative Sciences,
23E/2008 pp. 18-42

I. Introduction

a) Definitions of GMOs

Genetically modified organisms (GMOs hereafter) are living organisms whose genetic makeup has been altered through recombinant DNA technology to produce desirable traits such as disease resistance or better nutritive content (Gaines and Palmer, 2005). By using the recombinant DNA technology the genetic material is altered in a way that does not occur naturally by mating and/or natural recombination. GMOs are also referred to as “living modified organisms” (LMOs), “genetically engineered organisms,” or “transgenic organisms.” In substance, however, all these terms refer to the same or similar processes (European Union First Submission). US for example use the concept of “biotech products” instead of genetically modified organisms. Other countries, especially European countries, argue that such a terminology is misleading. Biotech products include besides GMOs a number of applications in the pharmaceutical field that do not imply genetic transformations. However, the terminology used by US suggests from the very beginning that GMOs are considered the result of technology innovation and do not require a different treatment from other modern applications of biotechnology.

Various scholars also disagree with regard to whether organisms modified through conventional breeding methods are also GMOs. In a recent book Fedoroff (2003) makes the argument that prehistoric corn was also genetically modified. Her claim is that conventional breeding methods also alter plants’ genetic makeup, even though the techniques were somewhat more primitive than today. Other scholars have responded to her arguments by claiming that meaningful discourse requires making a distinction between traditional selective breeding and biotechnologies based on recombinant DNA (Fedoroff 2004). This dispute aside, from a scientific standpoint the difference between genetic modification and conventional breeding practices is that the latter do not allow for the crossing of natural species barriers, or for the transfer of single or few genes instead of the whole genomes² (European Commission First Submission).

b) Historical background: The science behind GMOs

GMO research and development is an ever-evolving science. Since its creation in the early ‘70s³, enormous progress has been made; the new technology held the promise of increased agricultural output, added nutritional value to foods, and certain environmental benefits such as reductions in the use of pesticides. It also gave hope to many people that finally the problems of Third World countries would be solved (especially famine).

² A genome represents the whole of an organism’s genetic material;

³ The first GMO was created in 1973, but the first GMO plant was not produced until 1983. The first GMO crop was produced as recently as 1983. These crops were tested in field trials throughout the 1980s. It was only in the early 1990s that the first GM crops were ready for commercialization (European Commission First Submission).

There have been three distinct stages in the development of genetically modified products (European Commission First Submission):

- a) In the first stage, genetic modification techniques were focused on the creation of insect-pest resistant crops. Herbicide-tolerant crops have also been developed during this initial stage. The main goal was to increase agricultural yields and to limit losses. More recently scientists have started to combine genes from two first generation GMOs. They are trying to obtain new varieties that are both insect-pest resistant and herbicide tolerant.
- b) The second generation of GMOs has been created not just to in order to maximize farm yields but also to make certain products more appealing for consumers. Some of the “inventions” of this period include: high oleic acid soybeans that contain less saturated fat than conventional soybean oil; high sucrose soybeans that improve food quality (taste and digestibility); and potatoes resistant to browning.
- c) The most innovative GMOs include the so-called “functional foods”. These plants have been modified as to contain an increased amount of vitamins or micronutrients. At least initially they have been developed in order to respond to some of the most common diseases in the Third World countries. An example of such a development is a strain of rice modified to produce pro-vitamin A, which might assist in reducing the incidence of blindness in developing countries.

c) Possible negative effects associated with GMOs

The advantages of GMOs are undeniable for both farmers/farming operations and consumers. GMOs may also represent the answer to the severe problems Third World countries are confronted with. Despite these advantages, there are also risks associated with the production, release into the environment, and consumption of GMOs. The main reason governments need to regulate GMOs is precisely because of these risks. National regulations would respond differently to the real or the perceived risks associated with GMOs. This section tries to briefly summarize some of the risks associated with GMOs.

Negative health impacts

Gene insertion is very imprecise, resulting in haphazard alterations to an organism's DNA. It may result in the appearance of wholly new allergens and toxicants, an increase in the levels of known allergens and toxicants, or diminished levels of nutrients (Caplan and Spitzer, 2001). There are several examples that seem to support these arguments.

- A soybean variety has been genetically engineered as to become more nutritious through the insertion of a protein from the Brazil nut. Brazil nuts are known to cause severe allergies in a relatively small portion of the population. The new soybean variety was later discovered to cause the same allergic reactions because of the inserted protein (European Commission First Submission).
- Genetically engineered yeast was found to contain a substantially increased amount of methylglyoxal, a highly toxic substance, as compared to control groups (Caplan and Spitzer, 2001).

- Perhaps the best-documented example with regard to the negative health impacts of GMOs is the case of rBGH hormone (Caplan and Spitzer, 2001). Recombinant Bovine Growth Hormone (rBGH) is a genetically engineered hormone that is injected into cows to make them produce more milk. In 1990, FDA (US Food and Drug Administration) said rBGH was safe for human consumption. Based on lab tests conducted on rats it was concluded that rBGH produced no toxicologically significant changes in rats administered rBGH orally; based on these findings FDA did not require human toxicological tests usually required for a veterinary drug. In 1999 Canadian researchers showed the results of other studies that largely contradict the study done by FDA. Based on these new studies, several key findings include: between 20 and 30% of the rats were developing distinct immunological reactions; also cysts formed in the thyroid of some male rats and infiltrated the prostate.

All these examples illustrate the need for the regulation of GMOs. In the aforementioned examples, GM products have been incorporated into human food without any specific human health risk assessment being previously conducted.

Environmental impacts

The loss of biodiversity is one of the most significant impacts GM crops may have on the environment. Loss of biodiversity may be generated because of non-target effects (European Community First Submission). As mentioned before, insect pest resistant crops are designed to produce proteins that are toxic for specific groups of insects. It was found however, that the inserted toxins have adverse effects on non-target organisms, namely insects that are not pests of crops, birds, micro-flora and micro-fauna (soil microorganisms). It is not known yet however how severe these non-target effects are and if they may gradually lead to the extinction of various species.

Cross-pollination between GM and non-GM plants is another phenomenon that poses threats to biodiversity. Some GM crops that are pest resistant may transfer this property through cross-pollination to their wild relatives. This trait may give the wild relatives a competitive edge over other members of the same species and other plant species in the same community. Therefore the plant could become invasive of and persistent in natural habitats (European Community First Submission). Cross-pollination is also a threat because even when its effects are known, the management of GM crops in the proximity of non-GM crops is complicated. In the US the case of the StarLink GM corn is perhaps the most relevant example. StarLink was a GM maize hybrid, containing the Cry9c protein from *Bacillus thuringiensis*; the StarLink's potential allergenicity in humans was suspected from the very beginning and as a result a split registration was granted: the maize was to be used in animal feed but not in human food. After several years, Starlink DNA was discovered in a number of processed foods. The most reasonable explanation was that non-GM corn and StarLink GM corn crops were grown in close proximity and they have been cross-pollinated (Busch, Grove-White, Jasanoff, Winickoff, and Wynne, 2004).

Though there are many examples that seem to point toward the fact that GM crops are negatively impacting biodiversity, scientific evidence is not always clear-cut.

In a recent study commissioned by the UK government and called UK farm scale evaluation, it was found that GM herbicide tolerant maize was better for many groups of wildlife than conventional maize. The study showed that this finding does not apply to other types of GM crops, such as beet and spring rape. The study concluded that though biodiversity is at risk because of GMOs, there are instances when GM plants may be better.

Equity impacts

When assessing the usefulness of GMOs, equity considerations should be kept in mind as well. Both at the national and international level there are concerns that GM technologies will only be available to few and at a substantial cost, thus further deepening the gap between the better off and the worse off.

Five large multinational corporations are currently dominating the agricultural research (both GMO and non-GMO). They are: Monsanto, Dupont, Syngenta, Bayer, and Dow. In 2001 Monsanto products were used on 91% of the total world area devoted to GM crops (Meijer and Stewart 2004). This fact has triggered equity concerns with regard to the possibility that these companies will dominate the seed market and will be able to impose their prices and practices on small farmers. Most of the GM seeds can also be used only once, this is due to a technology that causes plants to have sterile seeds, thus forcing farmers to buy them every year instead of saving them, as they normally used to do (Caplan and Spitzer, 2001). Dependency on these multinational corporations is therefore a real threat.

At the international level, the equity concerns are even more stringent. The advocates of GM technologies and products are trying to sell them as being the solution to the problems of Third World countries. However the African countries for example do not have the research capability or the financial resources to become active players. When international corporations are providing developing countries with assistance in this field, they are doing it at a substantial cost. International corporations are controlling the dissemination of GM technology through intellectual property rights. In India, for example, farmers using Monsanto's seeds pay an extra \$50-65 per acre as a "technical fee" over and above the price of seed (Meijer and Stewart, 2004). This raises concerns about the equity with regard to the distribution of the benefits associated with GM technology. The idea of dependency is reiterated in the context of developing countries. Farmers doing businesses with Monsanto's herbicide-resistant crop seeds must sign a contract stating that they will not buy herbicides or other chemicals from other companies (Meijer and Stewart, 2004).

The science of GMOs has been characterized as low certainty and low consensus. Scientists and scholars disagree when it comes to defining a GMO and to distinguish GM technology and techniques from more conventional breeding practices. The disagreement with regard to potential risks is mostly triggered by the lack of conclusive, clear-cut scientific evidence. These two characteristics underlying the science of GMOs – low certainty and low consensus make it hard for decision-makers to regulate the field. The following section summarizes the regulatory struggle of two different countries with regard to GMOs. The lack of scientific evidence and low consensus on

the issue coupled with social/cultural factors will influence the nature of the solution chosen and will determine impacts that extend beyond the national borders into the international community.

II. Different national regulatory approaches to GMOs: US versus EU

1. Overview

Through the mid-1980s, officials within the EU, the US, and other countries were divided over whether to promote emergent agricultural biotechnologies, and whether to regulate the technology only through its products or also on the basis of production processes. The “product approach” to regulation assumes that nothing uniquely risky occurs in applying the technology to agricultural production as a function of the GM process itself. Genetically engineered products are subjected to stricter rules only when the end products are not “substantially equivalent” to their conventional counterparts. In contrast, the “process approach” rests on the idea that genetic engineering may entail novel and unique risks to human health and/or the environment even if the product is ostensibly ‘equivalent’ to a non-GM product. Whereas the US in the 1980s adopted the products approach to GM agricultural products, the European Union and its member states have tended to adopt a more precautionary process approach (Busch, Grove-White, Jasanoff, Winickoff and Wynne, 2004). Within the EU there has also been a difference of opinion as to which production processes require separate treatment. It has been the position of the European Commission that EU regulations should cover those products produced *from* GM materials but not those produced *with* GM materials. The European Parliament believes regulation should extend to those products produced with GM material as well (Rafferty, 2004).

2. EU regulatory framework

The EU GM regulatory framework began in 1990 with the adoption of the Council Directive 90/119 which it governs the release of GM products in the environment, and the Council Directive 90/200, which requires that a risk assessment be conducted before a GM product is approved for release. In addition to acceptable results from risk assessment studies, a producer of GM products must obtain consent from each member state before it can market the product (Rafferty, 2004).

The first GM food marketed in the United States and available for imports into other countries (including European Union) was the “Flavr Savr®” tomato, but it was the subsequent marketing of GM dietary staples such as corn and soybeans that caused strong trade frictions. In 1996, farmers in the United States began growing Monsanto Corporation’s GM soybeans. The new seeds had easily passed regulatory muster in the United States, and imports into the EU were also authorized without segregation or labeling under Directive 90/220 in an EC decision dated 3 April 1996 (Busch, Grove-White, Jasanoff, Winickoff and Wynne, 2004). It seemed at that time that though the directive called for a more thoroughly risk assessment process than the one required under US laws, the overall goal of the regulation was not to keep GM products off the shelves. However, the veto feature of the 90/220, where any member

state can prevent the approval of a GM product, proved to be highly susceptible to political pressure, and it eventually caused its undoing (Rafferty, 2004). It has also generated a trade conflict between the EU and US.

At a meeting of the EU Council of Environment Ministers in June 1999, France, Denmark, Greece, Italy and Luxembourg stated that they would block new authorizations of GMOs until the Directive 90/220 was revised and there was legislation in place to cover labeling and traceability. As a result of this policy, no new approvals of GMOs were granted within the European Union by the member states (Busch, Grove-White, Jasanoff, Winickoff and Wynne, 2004).

The period between 1998 and 2003 was one characterized by major regulatory changes in the European GM legislation. The 2003 regulations that ended the de facto moratorium instituted by several of the member states was not necessarily regarded as a victory by GM products advocates. The labeling and traceability requirements are increasing the cost of production and make it almost impossible for producers to effectively compete in the European market. There are three main important pieces of legislation adopted during this time interval:

- The revised EU Deliberate Release Directive 2001/18. Perhaps the most important amendment refers to risk assessment and the provision that the risk assessment is based on the precautionary principle.
- EU “Food and Feed Regulation” 1829/2003. It specifies the procedure and requirements GMO producers need to follow in order to release a GMO into the environment. Feed as well as food is covered by this new regulation. The concept of substantial equivalence is completely abandoned (Tsoumani, 2004) and no simplified procedure is available to producers (such a procedure was available until the adoption of this regulation for food produced from but not containing GM material in the end product).
- Regulation 1830/2003 regarding traceability and labeling. It requires that both food and feed would be labeled for GM material. The labeling requirement applies to all food and feed containing, or consisting of, GMOs or produced from GMOs, irrespective of the detectability of DNA or protein in the final product. The GMO content threshold was set at 0.9%, despite of the public outcry for a lower percentage (Tsoumani 2004).

It can be concluded that the new regulations are trying to provide a more unitary framework with regard to GMOs. Based on these provisions, there is now a unitary and consistent definition of what a GMO is (see Regulation 1830/2003 above). The application procedures have also been redefined and made less time consuming for producers. After these regulations have been adopted, GMO applications were resubmitted. Though there are no official data available, various sources are estimating the number of new application as being above 20 (various sources cited in Busch, Grove-White, Jasanoff, Winickoff and Wynne, 2004).

3. The US *laissez fair* policy

The US regulatory framework with regard to GM products has often been characterized as an example of *laissez-fair* policy, with the role of governmental

agencies being minimal. US are currently implementing the “product approach” with regard to GMOs and there are no indications of a major policy change in the future (at least on the short and medium term).

The development of national biotechnology policy under Presidents Reagan and Bush set the stage for the current regulatory regime (Caplan and Spitzer 2001). Following considerable debate whether the regulation of biotechnology was to be addressed with special legislation or through existing laws and agencies, in June 26, 1986, the Office of Science and Technology Policy of the Executive Office of the President of the United States, issued the Coordinated Framework for Regulation of Biotechnology, preferring the latter approach (Meléndez-Juarbe and Rivera-Torres, 2002). The 1986 regulatory framework has divided the responsibilities with regard to GM products along three main federal agencies. The three agencies primarily responsible for regulating biotechnology in the United States are: the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). Each of them is responsible for a certain type of genetically modified products /organisms (Uchtmann, 2002).

It can be argued that two main principles have emerged from the Coordinated Framework: (1) these new technologies “are an extension of traditional breeding techniques and therefore they produce similar or identical products; and (2) genetically modified foods will not be regulated according to the process used to make them, but rather, according to the use and final characteristics of the product (Meléndez-Juarbe and Rivera-Torres, 2002). These two principles have represented the working premises for the US policy with regard to GMOs since late ‘80s.

Another key aspect that differentiates the regulatory framework of the US from the one of EU stems from the role the private sector is credited with. Currently, US food manufacturers are not required to notify FDA of genetic modifications unless they fail the test of substantial equivalence. By substantial equivalence it is meant that GM products are a priori presumed to exhibit exactly the same qualities as products that are obtained using “traditional” methods. Private producers are the ones who determine whether the GM foods meet the requirements of substantial equivalence, and the consequent lack of need for a risk assessment (Busch, Grove-White, Jasanoff, Winickoff and Wynne, 2004). In January 2001 FDA proposed a rule which would have required food developers to notify FDA at least 120 days in advance of their intent to market food or feed developed through biotechnology and to demonstrate that the product is as safe as its conventional counterpart. However, because of lobby pressures on the behalf of the GMO producers the new rule was abandoned (Busch, Grove-White, Jasanoff, Winickoff and Wynne, 2004).

While the federal government continues to support a lax regulatory system of GMOs, state and local governments have decided to no longer ignore the potential problems associated with GMOs and to adopt a more precautionary stance. In the fall of 2002 an initiative regarding the mandatory labeling of foods containing genetically modified products was placed on the ballot on Oregon. However, more than 70 percent of Oregon’s voters rejected the broadly worded initiative, Ballot Measure 27, which would have required all processed foods sold in the state containing gene-spliced

ingredients such as corn, wheat and soy, and even milk produced by cows eating those feeds, to be identified on product packaging. The rejection was the result of a lack of support on the behalf of federal agencies as well as of a campaign carried out by national grocery retailers. The FDA warned the governor that such a measure would impermissibly interfere with manufacturers' ability to market their products on a nationwide basis. In the same time producers argued that such a measure would be futile in light of the fact that more than 70% of the food that was being sold at that time had at least traces of genetically modified ingredient/products (The New Farm, 2002).

It is often argued that the US and the EU have a radically different policy approach with regard to GMOs because of the way each nation implements the precautionary principle. While it is true that the US and the EU differ with regard to their implementation of precaution, there are also other factors that generate this difference.

The precautionary principle states: "when 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 (Martuzzi and Bertollini, 2004). EU uses precaution when it needs to decide on policy issues that present themselves in terms of a dichotomy: should the import of GMOs be banned or not? Once a decision is made, regulations are used in order to enforce and legitimize the decision made based on a precautionary approach. In the US precaution is more of an overarching threshold that is taken into consideration during the whole policy process (Martuzzi and Bertollini, 2004). Precaution is never used in the US context as to legitimize a "guilty until proven innocent" approach.

Precaution aside, it needs to be acknowledged that the US and the EU differ with regard to their perception of different environmental risks. Scholars have argued that both the US and the EU adopted precautionary policies with regard to specific environmental risks. However, interestingly enough, the two governments and their citizens did not seem to be interested or worried by the same types of environmental risks. US and European concerns have diverged at the stage of hazard identification, with different hazards commanding different levels of public concern and attention across countries. Thus, in the context of environmental protection, cancer has been more a concern in the US than in Europe and risks to forests and countryside have attracted more attention in some European countries. Also, even in instances where the US and the EU scientists have agreed on the nature of the hazard, they have not always agreed on how the hazard should be managed. In the case of food, for example, many EU nations permit the sale of fresh cheeses made from unpasteurized milk, while they are banned from the US (Busch, Grove-White, Jasanoff, Winickoff and Wynne, 2004).

With regard to GM foods, it is argued that Europeans perceive the potential risks associated with them more acutely than their American counterparts also because of the nature of the political and legal system. In the EU citizens are constantly complaining about the impersonal nature of the EU government that lacks close contact with the citizens in each member state. They are also worried about the

European bureaucracy that does not seem to be accountable or within the reach of ordinary citizens. Therefore European citizens are worried that once GM foods are accepted into the EU they will no longer have any control or possibility to revert this trend proving that health/environmental risks exist. The legal system in most of the EU states is also very weak in terms of tort law. US have a strong tort liability system that provides for substantially recovery from at-fault parties. Ex ante precaution may be less necessary in states where ex post remedies tort system is strong. However, this is not the case in the EU where except England most countries have a very weak tort system. Therefore, US willingness to adopt an extreme version of precaution like their European counterparts may stem from the trust in the tort system and not the indifference toward environmental protection (Rafferty, 2004). One last factor deals with the role of scientists and their perception by the general public. In the regulatory process of the EU, scientists play a tremendous role, however the process is never transparent and within the reach of lay people. In the US there is a perceived openness of the regulatory system and grassroots groups and citizens' associations seem to play a role, no matter how minor.

These systematic variations demonstrate that risk assessment includes not only an objective, science-based analysis of technical evidence; it also encompasses political understandings about appropriate forms and means of governance that influence technical analysis even though they are conventionally seen as falling within the domain of risk management (Busch, Grove-White, Jasanoff, Winickoff and Wynne, 2004). It is important to keep these differences in mind as they have triggered the biotech dispute between the US and the EU. Because they are so embedded in the national context it is hard to find a solution that would not make these two countries feel like their systems of values or sovereignty are challenged. However, they represent real barriers toward the solving of the dispute between the EU and the US with regard to GMOs.

III. Implications associated with this dichotomist approach to the field of GMOs

In the previous section the US and the EU domestic policies with regard to GMOs have been briefly analyzed. This section focuses on the conflicts generated by specific national policies/attitudes on GMOs in the international arena. The main frame of reference for these conflicts is international trade and World Trade Organization's Agreements. However, these conflicts impact international order in a way that goes beyond trade per se. Some of these not-so-obvious impacts are also addressed in the analysis herein.

1. The EC Biotech Dispute – evolution

The profound differences in the legal treatment of international trade of GMOs between the member states of the World Trade Organization (WTO hereafter) have given rise to various disputes. In August 2003 US decided to request the establishment of a WTO dispute-settlement panel to determine the compatibility of the so-called European de facto moratorium on GMOs with WTO rules. The actual dispute began in May 2003 when the US, Argentina, and Canada requested formal consultations at

the WTO on this subject, arguing that the de facto European Community moratorium on GMOs since 1999 arose rather out of trade protectionism than from concerns for consumer health or for the environment (Boisson de Chazournes and Mbengue, 2004). The US complains were decided by a dispute settlement panel at WTO. On September 29, 2006, the panel reports were circulated to Members. Some of the most important findings are summarized below. On December 19, 2006, the European Communities announced its intention to implement the recommendations and rulings of the DSB in a manner consistent with its WTO obligations. However, due to the complexity and sensitivity of the issues involved, the European Communities would need a reasonable period of time for implementation. After numerous delays, the period of time is supposed to expire June 11th, 2008. There is no information to date on whether this time frame will be extended.

The most important findings of the panel include:

- Europe did have a moratorium on GMO approval;
- The moratorium was not a measure under SPS rules but concerned the operation of Europe's human and environmental safety rules;
- Europe's moratorium violated WTO rules because it led to undue delay in assessing marketing applications for GMOs;
- Member states bans on certain GMOs were measures under SPS rule;
- Member state bans violated WTO rules because they were not based on a risk assessment.

In order to understand this ruling we need to take a closer look to the agreements that exist at the international level; and are referred to as GATT 1994 (General Agreement on Tariffs and Trade), SPS (WTO Sanitary and Phytosanitary Measures) and TBT (Technical Barrier to Trade).

a) GATT 1994, SPS, and TBT

GATT 1994 contains the general obligations of WTO members relating to trade in goods. The overall goal of the GATT Agreement is perhaps best summarized in article III. It states: "internal measures should not be applied to imported or domestic products so as to afford protection to domestic production." There are three cumulative conditions that need to be satisfied in order for a violation of article III: (1) the domestic and imported products at issue are "like products"; (2) the measure at issue are laws, regulations, or requirements affecting their internal sale, offering for sale, purchase, transportation, or use; and (3) the imported products are accorded less favorable treatment than the accorded to like domestic products. If the imported GMOs and the domestic non-GMOs are not "like products" then no violation of the GATT rules occurs (Boisson de Chazournes and Mbengue, 2004). Article XX provides limited and conditional exceptions for measures otherwise found inconsistent with general GATT obligations. These include measures taken to protect life and health of humans or to preserve the environment and biodiversity (Morgan and Goh, 2004).

The SPS Agreement elaborates on one of the conditional exceptions granted under GATT 1994. It applies to national regulations that aim to: protect people from food-borne risks, risks from animal and plant diseases, and risks from pests;

protect animals and plants from diseases and feed-borne risks; and to prevent or limit damage from the entry, establishment or spread of pests. Not all policies that address the aforementioned goals will be considered SPS measures. SPS measures may include end product criteria; process and production methods, packaging and labeling requirements directly related to food safety. In order for national policies to be considered SPS measures stringent requirements need to be met: they need to have a scientific basis; be based on sufficient scientific evidence and risk assessment where they do not conform to an international standard; be no more trade restrictive than necessary to achieve the appropriate level of sanitary and phytosanitary protection (Morgan and Goh, 2004).

The TBT Agreement is broader in scope than the SPS Agreement and it deems as acceptable national regulations that set standards and technical requirements for the production methods. The TBT Agreement is not likely to be applicable when the national policy sets a general ban on a certain product. In the case of the GMO debate the TBT Agreement may apply with regard to labeling and traceability requirements outlined in the EU current legislation. Similar to the SPS Agreement, TBT Agreement sets stringent requirements for considering a national policy as technical regulation: non-discriminatory treatment of like products; a least-trade restrictive test; the need for the technical regulation to fulfill a legitimate objective; and a basis on relevant international standards where such standards exist or their completion is imminent unless they would be ineffective or inappropriate.

b) Specific claims and counterclaims in the EC biotech dispute

In pleading their cases in front of the dispute settlement panel both countries have made clear their claims with regard to how the other party's domestic GM policy impacts international trade. There seem to be three major sets of claims and subsequent arguments (Agricultural and Resource Economics, University of California at Berkley, Course pack). These are:

- EU claims that SPS Agreement allows members to “take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life (see the conditional exceptions listed in the previous section) and adopt packaging and labeling requirements directly related to food safety”. The US counter claim emphasizes that food safety is not the same as protecting consumers' interests based on uncertain scientific evidence of potential risks.

There is really no easy way to assess if food safety is at risk when it comes to GMOs. The WTO panel has referred this question to another international organism that is more focused on food related issues (Codex Alimentarius). They have not reached a conclusion yet. EU has suggested that the Cartagena Protocol on Biosafety would be considered. However, the US strongly opposes this alternative, as this type of international treaties should not become binding law for all the international community⁴.

⁴ US have signed the Cartagena Protocol but it was never ratified.

- EU claims that under TBT Agreement “no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal, or plant life or health”. US counter claim is that TBT serves “to ensure that technical regulations and standards, including packaging, marketing and labeling requirements do not create unnecessary obstacles to international trade.”
- GATT disallows discrimination based on process and production methods if physical characteristics of final product are identical. EU claims that imported GMOs and domestic non-GMOs products are not “like products” or “substantially equivalent”. US counter claim is that these products should be considered “substantially equivalent” mainly because there are no proven health risks associated with them.

c) “Like Products” and “Scientific Certainty”

The claims and counter claims listed above reflect each country’s domestic policy approach with regard to GMOs. The arguments brought to the table mainly focus on two major dimensions: whether GMOs and non-GMOs are “like products” (the process approach versus the products approach) and whether scientific uncertainty and precaution are valid reasons for restraining/limiting international trade.

European Union’s claim that imported GMOs and domestic non-GMOs are not “like products” is based on the interpretation of the WTO rules via case law. EU points out that the Appellate Body at WTO has ruled that consumers perceptions or preferences are relevant, given they relate to the competitive relationship between products. Consumer differentiation may also be on the basis of perceived environmental, safety, or quality properties of goods. Within the EU consumers are clearly against GMOs or at least against GM foods that are not labeled as such. In a 2000 Eurobarometer called “Europeans and biotechnology” 66% of the citizens interviewed said that they would not buy GM fruit if it tasted better, 55% would be ready to pay more for non-GM food, and 94.5% wanted the right to choose whether to consume GM food or not (Tsioumani 2004). US tends to assess the likeliness of products based on more “traditional criteria”. US contend that there is no physical difference between GMOs and non-GMOs products. It is also claimed that as long the international tariff policy does not distinguish between GMOs and non-GMOs products, they should be considered alike. The US arguments are framed from the perspective of the supply side of the market (producers) while the EU arguments are framed in terms of what the demand side (consumers) wants.

With regard to science uncertainty, the EU considers that uncertainty with regard to potential risks should not be discounted. The US on the other hand argue that there is a distinction between insufficient information and science uncertainty. The former is considered a valid for measures that may limit international trade. However, the US claim that the concept of insufficient information implies that this information will be eventually available proofing more research is done. Scientific uncertainty is different. Apparently, the language of the WTO rules seems to support the US approach. Further more, the organization abstained from taking a position on the status

of the precautionary principle and refused, as a result, to recognize its prevalence in the right and obligations contained in the WTO agreements (Boisson de Chazournes and Mbengue, 2004).

2. Spreading consequences

There is a growing body of literature discussing the EU-US debate on GMOs. Its relevance stems from the fact that there are numerous implications associated with both the way in which WTO will rule in this case and also with future policy developments at the national level. This section explores some of these “what if” scenarios.

The war on GMOs between the US and the EU has some major economic implications, as the European Union is one of the biggest markets currently in place. 80% of the plant protein being used in the EU is imported. This dependency has continued to increase in the last years at a rate of 3% per year (<http://are.berkeley.edu/courses/EEP131/studentpresentations05/GMO%20-%20PRESENTATION%20OUTLINE.pdf>). While the EU ban and subsequent regulations on labeling and traceability have hurt American producers, they have also created economic opportunities for other countries. For example, US corn market is suffering dramatically from the European Union’s ban on its corn varieties. On the flip side, Argentina and other Latin America countries have increased their corn exports to the EU. Argentina alone has since 1995 tripled its corn exports to the EU (Gaines and Palmer 2005). This debate has thus the potential to reshape the international agricultural market and to create niche opportunities for countries that would not have been able to compete with the US in an international market.

Another international impact that stems from the EU-US dispute at World Trade Organization deals with the future ability of member states to discretionary decide with regard to their environmental policy and standards (the issue of precaution); this dispute also brings into discussion the role of WTO with regard to issues that transcend trade liberalization and challenges the future role the organization may play.

WTO is a trade liberalization organization and traditionally it had not participated in policy formulation. The organization constantly refrained from interfering with environmental issues and encouraged member states to define their own standards. However, if a member state(s) challenges the policy adopted by another member state, the WTO through its dispute settlement panel needs to make a decision. In the case of the GMO debate the WTO competence and jurisdiction was easy to prove since GMOs are clearly tradable goods. Once the WTO reaches a decision, that decision is legally binding for all the member states (Gaines and Palmer, 2005). The implications are huge, as a certain policy decision on GMOs will implicitly mean that member states are willing to concede a part of their sovereignty to an international organization and to reshape their domestic policy based on such a decision.

A similar conflict took place a little more than a decade ago when the EU decided to ban the use of growth-promoting hormones in beef cattle and to prohibit the import of hormone-treated animals or meat. The US took the case to the WTO’s dispute-settlement panel in 1995, arguing that the EU’s decision was in violation of SPA Agreement. The dispute settlement panel ruled against the EU; though the

EU appealed the decision, the Appellate Body confirmed it. The EU then refused to comply, prompting the US to retaliate with punitive tariffs on \$116 million worth of EU exports, including foie gras, Roquefort cheese, and other delicacies. In Europe the WTO ruling and subsequent US sanctions were resented as attempts to force the extra-territorial adoption of American regulatory norms (Cadot and Vogel, 2001).

At this point in time it is hard to estimate how the ruling of WTO will affect this field. The ruling against EU means that the precautionary principle in the field of environmental policy is going to be seriously challenged. “Innocent until proven guilty” will become the approach legitimized by the WTO ruling. This kind of disputes between member states also weakens the WTO on the long run and it also runs against the philosophy of the organization; it was created in order to bring all the countries around the world at the same table and to try to determine in common the best measures that would lead to trade liberalization (Gaines and Palmer 2005).

Perhaps the most insidious consequence of the US-EU biotech dispute is manifesting itself in relationship to developing countries. The circumstances in these countries are different from both the American and European context and therefore they should be able to choose a GMO policy that best fits their national circumstances. Most scholars agree that developing countries would be ill advised simply to copy the GMO policies of developed countries (Meijer and Steward 2004).

A special type of developing (or transition) countries is formed by the countries in Central and Eastern Europe that have recently joined the European Union (Romania and Bulgaria) or are already members (Hungary, Poland, Czech Republic, etc). In their case there is a need for harmonizing their domestic legislation in the field of GMOs with the one of the EU. However, in many of these countries enforcement of the laws on GMO is weak and in many cases the national governments struggle with the need to comply with EU rules, on the one hand, and the need to support the US laissez fair approach in this field in return for other benefits, on the other hand (see the case of Romania in the next section).

IV. GMO debate within the Central and Eastern European countries

a) Overview: State of the problem in several Eastern European Countries

It was observed (Kruszewska, 2000) that, as Western Europe turns against genetically modified crops the transnational “life sciences” companies such as Monsanto and Pioneer are turning their attention to the more vulnerable Eastern part of the continent. They know that their activities are safe from public scrutiny and legal challenge. Many countries in the region still have no specific GM laws, and even in those that have laws, they are either weak or non-enforced.

First-round EU accession countries, such as Hungary, Czech Republic and Poland, and those torn by war in the former Yugoslavia, like Croatia, have been spared some of the worst corporate excesses. Yet second-round countries, like Bulgaria, Romania and certainly the Newly Independent States of the former Soviet Union, offer the best chances for transnational companies (TNCs) to push their GM seeds.

Information held by officials in most of these countries is closely guarded. They prefer to bend to the wishes of industry which demands that information on field

trials be confidential, despite the fact that these same companies accept extensive lists of their field trials in Western Europe to be publicly available on the Web. Some information about field trials then may not even reach officials, since few countries require the maintenance of a publicly accessible central database of all GMO releases. Information on the presence of GM food on the market is non-existent.

Hungary has the strongest regulatory and civil oversight over activities that involve genetically modified organisms, and also one of the longest-running NGO campaigns against genetic engineering in the region. A comprehensive law on genetically modified organisms, complying with EU Directive 90/220 has been in place since 1999, with model participation provisions. The 17-member Genetech Committee that evaluates applications for releases of GMOs includes four representatives of environmental NGOs and two from consumer groups.

In the **Czech Republic**, a law on GMOs was adopted only in May 2000, despite the fact that field trials have been going on for several years and GM food was on the market. However, due to intense lobbying by the pro-biotech group, Biotrin, which is funded in part by Monsanto and other TNCs, the new law is weak on public participation. It does not cover GM food and its labeling, despite the fact that testing of foods by the media and Greenpeace has revealed GM-contaminated foods on the market. A new law on GM labeling was introduced in summer 2000, but it does not cover GM food additives.

Poland was the first country in Eastern Europe where NGOs started campaigning on GMOs. In November 1996, the Polish group, Green Federation, working with international NGOs, released a report called "Playing God" to alert officials and the public to the releases of GMOs taking place in Poland and elsewhere in the region, in the complete absence of any legal framework. It revealed releases of GM carp in Poland, field trials of GM tobacco and alfalfa in Bulgaria, GM potatoes in Russia and of potatoes, tobacco, maize, oilseed rape and alfalfa in Hungary.

The Polish parliament passed a GMO regulation in late 1999 that introduced a permitting system for field trials. However, field trials with potatoes, corn and beet had already started in 1997 and some 10-20 trials with corn, potato and oilseed rape had taken place in 1998 - mainly by AgrEvo, Pioneer and Monsanto. Unfortunately, permits for field trials are approved by the same geneticists that are working on GM plants. In 1999, 10 permits were granted for oilseed rape, sugar beet, fodder beet, maize and potato, each of which can cover several sites.

A recently introduced regulation requires approval and labeling of GM food, but it was not enforced and no labeled food can be found in Polish supermarkets. Even Environment Ministry officials admit that the law is "just a paper tiger", since there are no reference laboratories and no enforcement procedures (Kruszewska, 2000).

If the situation seems lawless in first-round accession countries, elsewhere in the region, it really is the "wild east". The activities of Monsanto in Ukraine and Monsanto and Pioneer in Bulgaria provide a picture of the chaos that parts of this region suffer from and that these companies exploit.

There is a serious threat that countries in Central and Eastern Europe (CEE) and the Newly Independent States NISs are becoming a dumping ground for genetically

engineered (GE) seeds and products, as EU farmers and consumers reject them. In the short term, if this region chooses to go the route of GM agriculture, there is the increasingly threat that it will close itself off from EU markets, as consumers there reject GM food. The lack of any regulations to ensure segregation and labeling of GE foods, plus the threat of genetic contamination will undermine consumer confidence in agricultural products from throughout the region. Even EU consumers' suspicion of GM contamination of foods imported from CEE-NIS will be sufficient to destroy this market for the farmers there. This would have disastrous impacts on the economies of CEE countries and NIS and the farmers there, given their reliance on agriculture.

The only viable alternative for agriculture in this region and entry into the EU market is to move towards organic and other more sustainable farming methods. The millions of smallholdings in this region, particularly in Poland and Croatia, the reduced use of agro-chemicals during the last decade and the availability of traditional varieties of plants provide an excellent base on which to build organic farming.

In a recent development which indicates the will of Poland to go on the right path and even further than EU standards impose, this country has asked (and received) permission from EU to ban corn seeds genetically modified. It has to be noted that these seeds are approved for commercialization in the EU. Furthermore, Poland has promised to ban in the near future all GM crops (The Associated Press 08/05/2006).

b) The case of Romania

Massive illegal cultivation of GE crops threatens farmers and the economy in Romania. At a Greenpeace press conference in Bucharest, Monsanto's former general manager in Romania warned that Romanian authorities have totally lost control over genetically modified organisms in the country (Greenpeace 2005, Johnson and Niculescu 1999)

During a research tour in Romania, Greenpeace discovered illegal growing of GE soy in ten counties of the country's total 42. Romania, a future member of the EU, is the only country in Europe where planting of the controversial Roundup Ready (RR) soy is allowed. If the farmers want to plant Roundup Ready soy, they only need to register with the authorities. It is only considered illegal if they don't register.

As debates over the safety of genetically modified crops continue, companies using the controversial methods have met little resistance in Romania due to the lax attitude among local environmentalists and the authorities' wish for bigger crops. But if the introduction of GMO poses a threat to the county's agriculture, the damage has already been done. The country currently has the largest GE-cultivated landscape in Europe; officially half the 140,000 hectares of soy planted in 2005 is registered to be GE. However, according to representatives of farmers' associations and even biotech giant Monsanto's former Romanian manager, up to 90% of soy is GE. The core of the problem is due to genetically engineered crops contaminating the traditional cultures, as well as the illegal selling of GE soy seeds. GM potatoes and plums were also found (Institute of Science in Society London 2005).

Mr. Dragos Dima, former Monsanto general manager in Romania declared after resigning from the company that "such a huge surface of uncertified GM soy is not

tolerable due to lack of monitoring and control systems. I left the company because I expressed my concerns regarding the introduction of GM technology in Romania". The first GE soy is believed to have been introduced in Romania in 1999.

The first releases of GM seeds in Romania took place in the absence of a specific legislative framework concerning solely the field of genetically modified organisms that would also target, among other goals, biological security. Until the adoption of a Governmental Ordinance regarding GMOs, the tests involving GMOs were conducted following the provisions of Law no. 266/2002 regarding the production, certification, quality control and commercialization of seeds. Article 13 (2) of the aforementioned law states: "in the case of genetically modified seeds all the labels and accompanying documents should indicate this fact".

In January 2000 the Governmental Ordinance no. 49 was adopted. It regulates the production, testing, use, and commercialization of GMOs by means of modern biotechnology as well as of the products derived from GMOs. This ordinance was then amended by Law no. 214/2002. According to the new regulation the governmental authority in charge with monitoring and enforcing legal provisions in this field is Ministry of the Environmental Protection.

The 2000 governmental ordinance comprises legal provisions regarding the establishment of a Commission for Biological Security formed by 19 members (12 members representing the academic community and 7 members were governmental representatives). It has to be said though that none of the members were representatives of the civil society. The Commission was responsible for the enforcement of the ordinance's provisions as well as for issuing permits for the testing, release, and commercialization of GMOs.

In 2002 the Commission's activity was brought to an end. Another Commission featuring much more limited attributions was created in order to replace the former one. The Commission under the new regulation was merely responsible for supervising the activity in this field; it was no longer its task to authorize the testing, release, and commercialization of GMOs. The final decision in all these matters is to be taken by the Ministry of the Environment. The new Commission is formed of 12 members, all coming from the academic community. Until now the Commission met twice in order to analyze two requests for GE activities. Both requests received a favorable opinion on the behalf of the Commission (it is the ministry nonetheless who has the final saying). There are numerous debates currently taking place with regard to the independence/autonomy of this type of Commissions both in the other CEE countries and in Romania. In Romania some of the members of the Commission were accused by environmentalists of having a conflict of interest in this matter. Most of them are professors who coordinate grants and research projects financed by the World Bank (a specific project mentioned regards the cultivation of Bt potatoes) (Kruszewska, 2003).

The governmental ordinance regulates the labeling of foods that contain GMOs and the annex of the law clearly specifies the information that should be found on the label. The ordinance also stipulates a simplified procedure for the approval of GMOs that are already authorized in the European Union.

At the end of 2005, a governmental ordinance concerning the protection of the environment was adopted. Chapter VI of this regulation deals exclusively with GMOs that are obtained by means of modern biotechnology. Its provisions are however very broad, stating that activities involving GMOs should be governed by a special legal regime. Even though the Romanian legislation in the field of GMOs encourages transparency and openness regarding the decision-making process in this field, its enforcement is weakened by a refractory public administration as well by the US interests in this field (Kruszewska, 2003).

In July 2000 Romania ratified the Aarhus Convention of UNECE regarding the participation of the general public, free access to information and free access to justice in all matters that regard environmental issues. According to article 5 of the law the general public is entitled to information on GMOs. Even more chapter IV clearly specifies that the Commission, the Ministry and other public authorities are responsible for providing information on this topic to the general public. Article 16 states that the Ministry of the Environment is responsible to inform about and consult with the general public about any request regarding activities that involve GMOs. Chapter VI clearly specifies which information cannot be considered confidential.

Despite these provisions, numerous citizens in Romania are ignorant with regard to the extent of GE soy cultivation in our country as well as with regard to other GE crops that grow here. Romanians are consuming, without their knowledge or explicit consent, foods that had been derived from GMOs. An official working for the Ministry of Agriculture stated that in 1999 several types of seeds were registered with the National Official Seeds List. However, their GM origin was never mentioned. The same individual argued that the public has never been informed of such matters because of a lack of money (Kruszewska, 2003).

Not even the NGOs working in the field of environmental protection were asked by the Ministry of the Environment to give their opinion regarding the request of the Institute for research in Fundulea for the release of wheat seeds resistant to fusarium. The Law on GMOs stipulates a 10 days period upon receiving the request for any activities involving GMOs during which the Ministry of the Environment can ask for opinions from the interested parties and the general public. They have 30 days to provide the requested feedback and the Ministry should take into consideration these opinions and comments when making the final decision.

No real public participation to the decision-making process in this field can take place without proper access to information. Within the Commission for Biological Security there are no representatives of the civil society. As opposed to the situation in our country, a similar commission in Hungary comprises among its members four NGOs, two of them representing NGOs with interest in the field of environment and two NGOs representing the consumers. Also in Poland three of the nineteen members of the Commission are NGOs.

In this context, it should be mentioned that further developments are undergoing at international level. Thus, an agreement to extend the public's legal right to participate in decision-making on the release and placing on the market of GMOs was reached on May 25th 2005 by the Parties to the UNECE Aarhus Convention holding their second

meeting in Almaty, Kazakhstan. The amendment to the Convention would require the Parties to inform and consult the public in decision-making on the deliberate release and placing on the market of GMOs. The public would have the right to submit comments and the public authorities would be expected to take these into account in the decision-making process. Once made, the decision made should be publicly available together with the reasons and considerations upon which it is based. Excepting cases of commercial confidentiality, information associated with GMO decisions would be made available to the public. In no cases could Parties withhold as confidential information on the intended uses of the release or assessment of environmental risk, however. It would not foreclose the right of its Parties to adopt more extensive measures expanding the public's right to participate in GMO decisions (UNECE Press Release, 26 May 2005).

c) The implications of Romania's accession to EU on GMOs regime

Taking into account the numerous debates at the European level on GMOs and the political sensitivity of this subject - the majority of the EU member states and the majority of the European consumers are opposing the cultivation and the consumption of products derived from GM plants - (Lee, 2005), the Romanian Ministry of Agriculture announced in 2005 that "it is necessary to clarify the status of GM-soy in our country, because this type of soy is not approved for cultivation in the EU" (Press release, 3/02/2006, <http://www.genet-info.org/>). Consequently, The Ministry of Agriculture organized, in autumn 2005, a series of debates, with the participation of specialists from institutions involved in GMO regulation (the Ministry of Agriculture, The Ministry of Environment, The National Sanitary - Veterinary and Food Safety Authority, The National Authority for Consumers Protection, The Ministry of Health), agricultural research and education institutions (including universities) from Romania, parliamentarians, representatives of GM seeds producers, cultivators and GM soy seed processing companies, ecological agriculture associations and NGOs for environmental protection. A strict analysis of all the aspects connected to this sector was made, taking into consideration the technical, economic and social advantages but also the risks of GM plant cultivation for the environment, health, conventional and ecological agriculture as well as the ethical aspects of this technology.

In 2006, in light of the European integration it was decided to *ban GM soy*, starting with January 1st 2007, in accordance with current European Union regulations. For the 2006, the GM soy cultivation was allowed upon meeting several conditions. However, producers have been required to show on food product labels the presence of GMOs. Beginning June 30, 2008, producers of all genetically modified crops will be forced to label these products accordingly. Until now this rule has been applied only to products containing genetically modified soy and corn. Romania will continue harmonizing the national legislation with the European legislation and constituting the institutional framework to implement it, in order to enforce the inspection and control system of GMO related activities.

Ecologists and traders believe that Romania's decision to forbid genetically modified (GM) soy cultures beginning with 2007 did not impede its presence on the European

market. Nevertheless, there is a strong belief that the restrictions should have been applied starting with 2006: “The time is too brief to stop uncontrolled cultures. The traditional cultures are contaminated with GMOs even after Romania’s accession to EU” a representative of Greenpeace argued. The representatives of ecological groups believe that GM cultures are impossible to stop because of artificial breeding, natural dispersion of seeds and illegal trade. The government showed that additional regulations for the soy cultures are being developed and compensation for their losses could be given.

Soy cultivators who used genetically modified seeds and gave up natural seeds, which cost more money, said that the future interdiction will cause losses to soy producers. Monsanto Co. also expressed its disappointment concerning the government’s decision, explaining that the most affected producers will be those who reported double profits, transforming Romanian soy production. Data from the Ministry of Agriculture showed in February 2005 that the average production of GM soy surged by 500 kilograms to 2.5 tons per hectare last year. The soy is chiefly farmed in the southeastern part of the country, in counties such as Braila, Calarasi, and Ialomita. Romanian consumers have been using imported edible oil from transgenic soy for over 13 years (in 2004, the leading countries producing genetically modified soy were the United States - 47.6 million hectares, Argentina - 16.2 million hectares, Canada - 5.4 million hectares and Brazil - 5 million hectares) (Comanoiu 2006).

The Environmental Inspectorate has already fined those who cultivate GM soy without having obtained the necessary approvals. However, many producers are difficult to identify and there is the risk that the authorities could lose control over this issue. Romanian farmers are reticent also because the scientific tests which producers must undergo are not completely reliable. There are scientists (like professor Gilles-Eric Serallini, a former European Commission consultant) who contest the tests, who thus provide a sort of second opinion, offering proofs that GMOs put people’s health or the environmental balance at risk (Lescu, 2006).

Starting with 2007, Romania has to comply with the EC Directive 90/220 which provides that every manufacturer or importer must notify the competent authority of the Member State in which such product is to be placed on the market for the first time of his intention and add the necessary information on the product (art.11). The competent authority, after assessing the risk, either rejects the proposed release or forwards to the Commission the favorable opinion, for decision. The final decision is to be made by the Commission only after every Member State is consulted and has no objection to it. The effective authorization is given by the national competent authority and covers the whole Community territory. The national authority has no discretion whether to issue or reject the authorization, after a Commission decision has been taken (Case C-6/99 *Greenpeace France and Others v. Ministere de l’Agriculture et de la Pêche and Others*).

V. Concluding remarks

GMOs can be described as representing the object of national environmental policies mainly because there are potential human health and environmental risks

associated with their production and consumption. Because the science of GMOs is low certainty and low consensus different regulatory approaches are currently in place around the world. The US and the EU are implementing completely divergent GMO policies because of several main factors: approach to precaution; risk identification and management, cultural and political values and beliefs that are embedded within the local context.

In the same time, GMOs are tradable goods within the international market. Contemporary international trade legislation states that the barriers to free trade should be minimal. Environmental policies that imply a restriction of trade are allowed as long the scientific community unanimously agrees that there is a risk. As described in the paper, this is not the case with GMOs. The trade war between the US and the EU with regard to GMOs is relevant, as it will determine the future of national environmental regulations that interfere with trade. Currently most of the environmental problems nations are confronted with extent beyond the boundaries of their national jurisdiction and interfere with other policy areas.

This debate on the role GMOs will play in the future and how they are going to be regulated has specific implications for developing countries. Among them, the countries in Central and Eastern Europe have a special situation because of their need to harmonize their legislation – including laws on GMOs – with the regulations set forth by the European Union.

Romania is one of the biggest producers of GM soy and other crops and faces significant challenges in complying with the EU regulations in this field.

The solution offered by the environmental NGOs is for the government to establish a moratorium regarding the release of all GMOs into the environment while simultaneously revoking all the authorizations involving GE activities and destroying all GM crops found on the Romanian territory. Such an effort is necessary in order to avoid the situation in which Romania will be refused the right to export agricultural products into the EU. Even more GM seeds and foods produced in Romania might be banned from commercialization even on the domestic market because of a lack of harmonization with the EU rules. This will lead to the bankruptcy of farmers and to serious perturbations regarding the functioning of the EU common market (Kruszewska, 2003).

In its rush toward a modern agriculture Romania has to reject the techniques of biotechnology and to preserve its traditional cultivation methods. The cultivation of GM crops might affect on the long term the food safety while on the short term the country will face the impossibility of exporting its GM crops on the EU market. This will have serious consequences for farmers that will thus loose the European and Asian markets where consumers demand organic foods.

The Romanian legislation is still not completely harmonized with the EU regulations in this field and its enforcement is still weak. The EU policy in this field can be described as restrictive mainly as a response to the concerns regarding the food safety expressed by European consumers (Lee, 2005; Duțu, 2005). The 1998 EU moratorium will probably be maintained in the near future. There are numerous types of GM seeds that are currently cultivated in Romania and which are not authorized in the

EU. For example the RR soy of the Monsanto Company cannot be produced in EU but merely imported and incorporated into other final products. The Bt potatoes has not received any kind of authorization in the EU. Other types of GM seeds currently cultivated in Romania or imported include: the LibertyLink corn (Aventis) or the Roundup corn (Monsanto).

One possible solution for Romania would be to engage its agriculture on the path of organic crops and foods. There is mounting evidence that this may be the way to go.

In 2001 in the European Union the percentage of organic crops was 25%. In the previous years from 1993 to 1998 the area cultivated with organic crops tripled, from 890,000 hectares to 2.9 million hectares. Starting with 2001 EU has almost 4.5 million hectares cultivated with organic crops (3.24 % of the agricultural surface). Italy leads the way (1.23 million hectares which account for 7.9 of the agricultural surface) followed by Great Britain (679,631 hectares which account for 3.96% of the agricultural surface), and Germany (632,000 hectares which account for 3.7% of the agricultural surface). Austria has the largest percentage of organic crops - 11.3% - out of the total agricultural surface (Organic agriculture in Europe – Statistical forecast 2001 – www.organic-europe.net/europe_eu/statistics.asp)

In a recent development towards a GM-free agriculture in Romania, 26 localities in Bistrita Nasaud County announced that they will stop using genetically modified organisms, thus forming the first area in Romania that will not use such products. Local authorities in Bistrita Nasaud asked the relevant national and regional politicians to make sure that no genetically modified plants will be cultivated in the entire country. The rights of the farmers who want to produce GM-free crops are legally protected and all suitable measures are employed, said the release. The “GMO Free Romania” project is funded by the Grassroots Foundation in Germany. The goal of the project is to make local authorities aware of the risks posed by GMOs, to convince them to take practical measures to protect their regions and to start public debate on this issue throughout the country (Pocotila, 2006, citing a press release from the National Federation of Organic Farmers and the Information Centre on GMOs).

References

- Agricultural and Resource Economics, University of California at Berkley, Course pack available on line at <http://are.berkeley.edu/courses/EEP131/studentpresentations05/GMO%20-%20PRESENTATION%20OUTLINE.pdf>;
- Boisson de Chazournes, L., Mbengue, M.M., “GMOs and trade: Issues at stake in the EC Biotech Dispute”, 2004, *RECIEL* 13: 3;
- Busch, L., Grove-White, R., Jasanoff, S., Winickoff, D., Wynne, B., “Amicus Curie Brief”, submitted to the Dispute Settlement Panel of the World Trade Organization in the case of EC: Measures affecting the approval and Marketing of biotech products, April 30, 2004;
- Cadot, O., Vogel, D., “France, the United States, and the biotechnology dispute”, 2001, available on line at <http://www.brook.edu/fp/cusf/analysis/biotech.htm>, accessed December 3, 2006;
- Caplan, R., Spitzer, S., “Regulation of genetically engineered crops and foods in the United States”, 2001, available on line at <http://207.58.168.163/resources/document>;

- Comanoiu R., "Genetically modified soy trade expected to continue", *Bucharest Daily News*, 2006, No. 538;
- Duțu, M., *Principii și instituții de drept comunitar al mediului*, Bucharest : Economica, 2005, pp.325-335;
- European Court of Justice, Judgment of 21 March 2000, Case C-6/99 *Greenpeace France and Others v. Ministere de l'Agriculture et de la Pêche and Others*, in Krämer, L., *Casebook on EU Environmental Law*. Oxford - Portland Oregon: Hart Publishing, 2005 p. 233;
- Fedoroff, N.V., "Letter to the editor", *Science*, 2004, Vol. 303;
- Gaines, J., Palmer, K. V., "Genetically modified organisms and WTO trade rules", 2005, *Aussenwirtschaft*, 60:1;
- Greenpeace, "A Documentation of Contamination and Illegal GM Soya cultivation in Romania", 2005, available in Romanian language and based on findings of Greenpeace in August 2005;
- Greenpeace, "Genetically Engineered Organisms Out of Control in Romania. Ex-Monsanto director speaks out", Press release, October 10, 2005, <http://www.commondreams.org>;
- Institute of Science in Society London, "GM Contamination Accelerating. No Co-Existence Possible", 2005, ISIS Press Release 16/12/05, <http://www.i-sis.org.uk/GMCANCEP.php>;
- Johnson, T. and Niculescu, A., "Government to investigate GM crop trials", 1999, *Bucharest Business Week*, Vol. 3, Nr. 38;
- Judy, T., "GMO testing on hold", 2001, *Bucharest Business Week*, Vol. 5, No. 3;
- Kempf, H., 'L'Europe et les OGM: un défi culturel', 2005, *Le Monde*, July 8th ;
- Kruszewska I., "România - invadată de organisme modificate genetic. O amenințare pentru agricultura românească, biodiversitate și aderarea la Uniunea Europeană", 2003, available at <http://www.ngo.ro/omg/raprom>.
- Kruszewska, I., "The Modified East - genetically modified crops - Monsanto Co - Advanta Seeds Inc". *The Ecologist*, Sept, 2000, MIT Press;
- Lee, M., *EU Environmental Law - Challenges, Change, and Decision-Making*. Oxford – Portland, Oregon: Hart Publishing, 2005, pp. 255 – 266;
- Lescu, C., "Controversies over genetically modified organisms", 2006, available at Radio Romania International, <http://www.rri.ro/index.php?lmb=4&art=15371>;
- Martuzzi, M., Bertollini, R., "The Precautionary Principle, Science and Human Health Protection", 2004, *International Journal of Occupational Medicine and Environmental Health*;
- Meijer, E., Stewart, R., "The GM cold war: How developing countries can go from being dominos to being players", 2004, *RECIEL* 13: 3.
- Meléndez-Juarbe, H. A., Rivera-Torres, O., "Labeling of genetically modified food in the United State: the Roads not taken", Harvard Law School, 2002, available on line at <http://leda.law.harvard.edu/leda/data/438/MelendezJuarbeRiveraTorres.html>;
- Morgan, D., Goh, G. (), Genetically modified food labeling and the WTO Agreements, 2004, *RECIEL* 13: 3.
- Pocotila A., "First genetically modified organisms' free zone in Romania", Knight-Ridder Tribune, 2006, March 16. http://archives.foodsafetynetwork.ca/agnet/2006/3-2006/agnet_march_18.htm;
- Rafferty, P., "The door opens slightly: Recent European Union regulations on genetically modified products and the ongoing United States-European Union GM product dispute", 2004, *Georgetown International Environmental Law Review*, 16:2;
- The New Farm, "Oregon GMO label defeat spells uphill battle ahead, but supporters promise to renew their efforts" available on line at http://www.newfarm.org/news/2002/111502/oregon_defeat.shtml.

- Tsioumani, E., "Genetically modified organisms in the EU: Public attitudes and regulatory approaches", 2004, *RECIEL* 13: 3;
- Uchtmann, D. L., StarlinkTM: A case study of agricultural biotechnology regulation, 2002, *Drake Journal of Agricultural Law*, Vol. 7;
- United Nations Economic Commission for Europe, "Governments reach agreement on public participation in decision-making on genetically modified organisms", Press release, available at http://www.unece.org/press/pr2005/05env_p06e.htm;
- USDA, Foreign Agricultural Service, "GAIN Report nr RO0005", 2000, by Holly Higgins, US Embassy in Romania, www.fas.usda.gov;
- *** European Community First Submission at the World Trade Organization Dispute Settlement Panel, 2004.
- *** "EP Environment Committee strengthens Commission proposals to label GM Food", *FoEE Biotech Mail-out*, Vol. 8, Issue 3, June 2002 available at www.foeeurope.org/biotechnology/about.htm