Regulation of GMOs: the commercial conflict between the United States and the European Union

RAÚL COMPÉS LÓPEZ*, JAVIER GUILLEM CARRAU**

Abstract

The United States is the leading country in the application of biotechnology to agricultural methods. One of the principal reasons for this is the flexibility of its legislation on Genetically Modified Organisms (GMOs). A significant part of its production of soya or corn is already genetically modified, so that its companies need to avoid technical barriers to their exports in the world markets. In the EU, negative public opinion has contributed to the adoption by the authorities of demanding legislation in order to avoid the possible risks to human health and the environment posed by GMOs. The rules of international trade are regulated by agreements signed up by the members of the WTO. The EU can argue that its authorisation procedure is designed to reduce the risks to health and the environment. This line of argument is compatible with the Agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT). The Protocol of Biosafety further supports the EU position since it advocates a cautious approach exemplified by the fact that the Protocol permits consideration of non-scientific risks during risk assessment. However, the Protocol is not yet in force, it is pending ratification by at least 50 countries and, now more than ever, it is uncertain whether the United States will be willing to ratify the Protocol. However, we cannot be sure that there will be future commercial controversy which will show the contradictions between the commercial agreement and the environmental one.

Résumé

Les Etats Unis sont le pays leader dans l'application des biotechnologies aux méthodes agricoles. Une des principales raisons est la flexibilité de leur législation sur les Organismes Génétiquement Modifiés (OGM). Une partie importante de leur production de soja ou de maïs est déjà génétiquement modifiée, ce qui pose, pour les entreprises qui s'occupent de ces cultures, la nécessité d'éviter les barrières techniques à leur exportations dans les marchés mondiaux. Dans l'UE, l'opposition de l'opinion publique a favorisé l'adoption, de la part des autorités, de législations exigeantes visant à éviter les risques possibles pour la santé humaine et l'environnement posés par les OGM. Le commerce international est réglé par des accords paraphés par les membres de l'OMC. L'UE soutient que sa procédure d'autorisation est conçue pour réduire les risques à la santé et à l'environnement. Cet argument est compatible avec les Accords sur les Mesures Sanitaires et Phytosanitaires (Sanitary and Phytosanitary Measures (SPS)) et les barrières techniques au Commerce (Technical Barriers to Trade (TBT)). Le protocole sur la bio-sécurité soutient la position de l'UE car il défend une approche de prudence simplifiée du fait que le Protocole prend en compte, dans l'analyse des risques, les risques non scientifiques. Toutefois, le Protocole n'est pas encore en vigueur, il attend la ratification de la part d'au moins 50 pays et, maintenant plus que jamais, il n'est pas sûr si les Etats Unis voudront ratifier le Protocole. On doute qu'une controverse commerciale fasse ressortir les contradictions entre l'accord commercial et l'accord environnemental.

1. Introduction

The United States is the world leading producer of genetically modified agricultural products. The growth in this technique in the US in the second half of the 90s has been so spectacular that, at present time, a very high percentage of its production of corn, soya and cotton is genetically modified. It is therefore imperative for the US, as the world leading exporter of foods, to ensure access to external markets for its products which are produced using this new technique. The first genetically modified product on the world market was a variety of soya resistant to herbicides, which was exported from the US to Europe and Australia during 1996.

The first significant stumbling block to US GMO exports arises in the EU where GMO cultivation, commercialisation and authorisation rules are different from the American ones. There are fundamental differences on scientific and ethical questions between the two sides of the Atlantic. Present regulations indicate a different political evaluation of the effects of GMOs on health and the environment and in the technique used to do the assessments. The EU's political position does not reflect the opinion of the scientific community but the feeling of the majority of European citizens, who are concerned with the safety of this new technology. Due to commercial interests, EU politicians are supporting consumers and their interests. Consequently, the expansion of GMOs has been much greater in the US than in the EU.

Representatives of the industry and of the US Administration have expressed, on several occasions, their concerns about the delays and the costs incurred by companies in obtaining the necessary authorisations to market their GM products in the community market. They believe this procedure is a technical barrier to trade under the terms of the WTO rules and it has already negatively affected their exports (Kelch et al., 1998)[1]. This criticism has been fuelled by the EU compul-

* Professor of Social Sciences and Economics, Universidad Politécnica de Valencia

**Lawyer, SJ Berwin

[1] The most relevant affairs have been Novartis corn and Soya Monsanto.

Approvals of GMOs in the EU and US				
	United States		EU	
Crops	Approved	Sown %	Approved	Pending
Corn	11	35%	4	5
Soya	3	60%	1	0
Rapeseed	3	15%	4	3

Source: International Grain Council, 1999; in Commission, 2000

sory labelling rules of 2000.

Although the GMO conflict has not reached the same level as in the case of Hormone meat or the Bananas affair, we have to take into account that in those cases the EU had already been condemned by the WTO[2]. The eventual impact on transatlantic commercial relationships is greater, because of the volume of commercial business; because genetic technology will maintain its attractiveness among some countries and producers (OECD has pointed out the potential benefits to farmers in the production of varieties resistant to herbicides and insects); and because the EU position has begun to be supported by other countries which indeed are taking even harder measures[3].

If US and EU positions do not change, the controversy over the regulation of GMOs will be settled in the WTO, the last resort for countries to resolve their commercial conflicts. This real possibility raises several questions. Firstly, do the current WTO Agreements legitimise or not the measures adopted by the EU? Secondly, considering that the Protocol of Biosafety has been added to the WTO rules, what are the rules that will prevail in the event of a conflict? Finally, if the current institutional framework doesn't guarantee the existence of a European legal framework different from the United States, is the goal to consider the reforms necessary to defend the EU position?

Given the complexity and scale of the topic, this thesis has two major objectives. The first one is to explain why an underlying potential conflict exists between the EU and United States over the issue of GMOs. The second which is a consequence of the first, consists in analysing EU manoeuvres in the WTO in order to defend its regulation model.

This thesis is structured in four main sections. In the following section, we try to explain the main differences between community regulations and American regulations as for commercial exchanges. Secondly, we analyse the compatibility of the European legal framework with the agreements of the WTO, especially the SPS and TBT Agreements. Thirdly, we assess the impact of the Protocol of Biosafety on trade policies and its compatibility with the agreements of the WTO. Finally, we conclude mentioning the necessary changes to be made to the current Agreements or whether new ones are be introduced for these types of products.

2. The regulation in the United States and the EU

Guerra Daneri (2000) considers that one of the important aspects of the new biotechnical agriculture in legal terms, is that it implies an assumption of unknown magnitude's risks and it affects goods and rights legally protected as the biodiversity and the consumer's health. Facing this dilemma, the USA and the EU have adopted different solutions to those risks.

In 1992 the USA decided that transgenic food did not need specific regulation different from conventional food[4]. On the other hand, applying the precautionary principle, the EU has regulated in a more restrictive way on labelling of these foods, whose labelling is approved by national and community scientific experts' committees.

The US Federal Agencies, which are working jointly on approval of the GMOs, are the APHIS (Animal and Plant Health Inspection Service), EPA (Environmental Protection Agency) and FDA (Food and Drug Administration)[5]. These Agencies are the main bodies responsible for the environment and consumer's health protection. When an application is presented, APHIS should deliver authorisations for the applicant to:

- be able to use facilities (hothouses) to develop the cultivation,
- carry out trials in fields,
- transport seeds from the hothouse to the trial fields,
- determine whether the product should receive the status of "not regulated" which permits cultivation, use and marketing of the product.

[2] In June 1999, the USA trade representative, Charlene Barshesfky, announced that the US administration was thinking of the possibility of set a dispute panel in the WTO against the EU because of its delay in GMO authorisation. Consequently, the US have manifest in a WTO Committee that the EU labelling legislation relating to the GMO is not compatible with the WTO rules.

[3] This is the case in Australia and New Zealand with their labelling rules and Brazil and Sri Lanka with their import restrictions. Without having arrived to the OSD, Thailand has forbidden imports of tuna in oil supposed to have been genetically modified.

[4] Statements of Policy: Foods derived from new plants varieties", FDA, Federal Register of May 29, 1992 (52 FR 22984). This position is based on the afirmation of the Science National Academy, which considers that the transgenic products have the same risks as conventional products.

[5] By mandate of the National Institute of Health (NIH), a Biosecurity Committee evaluates every genetic improvement's project before its launching and it is able to recommend that a project is not developed.

The process lasts approximately 10 months.

On the other hand, the EPA is the body responsible for authorising liberation in the environment and for authorising pesticides obtained by means of genetic manipulation or of plants modified to have characteristics of pesticides. In particular, the EPA should authorise the following acts:

- the carrying out of trials in fields of more than 10 acres.
- the establishment of thresholds of tolerance (maximum limits of modified proteins in the food).
- the registration of the product for commercial use.

Finally, the Food and Drug Administration (FDA) is the agency responsible for the safety of all foodstuff. It advises and supervises companies in the GMO's development process. The advice process is voluntary, but the requirements are compulsory, and all the companies involved use to complete it.

Labelling is also ruled by the general principle that products obtained by means of genetic manipulation are not different from conventional ones – they are "substantially equivalent", according to the concept coined by the OECD and the WHO - and, therefore, they are regulated in the same way. The FDA only requires specific labelling of GMOs when the product carries some risk – for instance causing an allergic reaction - or if its nutrient characteristics or composition are significantly different from its equivalent conventional one, and therefore the difference should be indicated in its label.

This regulation, however, may change in the near future. The recent food scandals, such as the one caused by the appearance of GMOs in certain foods in the Taco Bell chain of restaurants, have opened a debate on the segregation of GMOs from conventional foods in the North American food system (Pasco, 2000). In that way, certain opinion groups have pursued the US Congress that legislation should be introduced which will establish a GMO compulsory pre- marketing test to be carried out by the FDA, enforced GMO product labelling and an obligation on bio - technological companies to assume responsibility for any problems caused by their products. In this line, the FDA presented a proposal in February of this year that determines the mandatory communication to the foods coming from the biotechnology, previously to its commercialisation with the purpose of contrasting its coherence with the FFDCA.

In the EU, specific legislation has been developed for the products in question which is based on the difference between the final product and the techniques used to make it (Ramón, 2000). The EU rules reflect this particular view that consist in considering that a GMO, for the fact of its novelty, generates a scientific uncertainty and, therefore, a potential danger that will appear in the future. This view justifies, based on the precautionary principle, that a complete evaluation of the environmental and health risks must be done.

The confined use of genetically modified micro-organisms for the research or for industrial objectives is controlled by some specific procedures that prescribe the authorisations sent by each Member State for their territory[6]. The voluntary liberation of GMO in the environment to investigate or innovate and the commercialisation of products that are going to be disseminated lately, are regulated specifically[7]. This regime affects the living GMOs, which are those able to reproduce or transfer genetic material when they are introduced in the environment for all possible uses (medicinal, nutritional, and industrial). For example, tomatoes, soya or modified corn, but not their derived industrial products. The General Directorate of Environment answers all of these questions.

The authorisation process for the voluntary liberation is more complicated and it involves the different Member States and the EC authorities. Before approval, a compulsory evaluation of human health, animal welfare and the environment aspects of each case must to be carried out. The procedure can last up to 18 months and it firstly evaluates the national authority of the country in which the application is commenced and, secondly, of the rest of the community countries. If some of the Member States object, it is necessary to take a decision at community level. The intervention of the Scientific Committees, Regulatory Committee, the Commission and the Council is the hardest part of the process. A country can suspend approval temporarily if it considers that risks exist, in this case approval is needed by means of a formal decision by the European Commission[8].

The operation of this procedure is unsatisfactory for many reasons. From October 1991, when the Directive came into force, until July 2000, 18 authorisations were approved, 14 still remain pending from 1998. In a meeting of the Council of Ministers on 24 and 25 June 1999, the French, Greek, Italian, Luxembourg and Danish delegations made a declaration to block any new commercialisation applications as long as the system did not warrant a transparency and perfect traceability. Therefore, a moratorium commenced whilst a revision of the system was carried out.

As a result, a new Directive was adopted in April 2001[9]. Currently, the countries have 18 months to implement it. The new Directive establishes deadlines to decide a GMO authorisation, which will cause further controversy between the US and the EU. The procedure is redefined: the phase limits are quite well defined, decisions will be taken according to a majority vote, and several changes will be made to traceability, labelling and environmental responsibility.

The authorisation (and labelling) of novel foods or deri-

[6] Directive 90/219/EEC of the Council.
[7] Directive 90/219/EEC of the Council.
[8] As Germany, France, Luxembourg, Portugal and Austria have done in Novartis BT grain case.
[9] Directive 2001/18/EC of the European Parliament and the Council, of 12 March 2001.

ved food ingredients of GMOs is managed by the SANCO General Directorate of the EC, competent in Health and Protection of the Consumers[10]. In particular, the approval process allows each Member State to determine its own thresholds, its methods of analysis and the products to evaluate. Furthermore, a simplified procedure has been established for novel foods derived from GMO that do not contain transgenic material; these offer a substantial equivalence with other foods in composition, nutritional value and metabolism and the use to which they are dedicated. In these cases, the product can be marketed in the EU and notified to the European Commission with a justification of this equivalence issued by the competent authority of a Member State. In fact, as at July 2000 at the time products were authorised, 9 pending applications and 11 equivalencies had been notified.

The evolution of the European rules on labelling has been slow and complex. Slow, because the authorisations v :re implemented in1990 (Directive 90/220) and the compulsory labelling was not introduced in some cases until 1997 (Regulation 258/97 on novel foods[11]); and complex because the labelling was regulated on the principle of "substantial equivalence" (Regulation 258/97). Subsequently, a specific label was established for the Monsanto soya and the Novartis corn (Regulation 1139/98); and there after the labelling was deemed compulsory over a certain threshold of transgenic material being present (Regulation 49/2000). Although the new Directive 2001/18/CE enlarges the regulatory field, it does not cover every situation. As a consequence, the performance of the EU can be criticised in failing to resolve these problems, albeit difficult ones.[12]

Livestock feeding products are not under a specific rule and only eight items have been authorised, all of which are in the framework of Directive 90/220. Apart from the specific legislation for seeds, the authorisation of transgenic seeds is also under Directive 90/220/EC but, eventually will be covered by the EC Regulation covering novel foods. Specific rules regulate forest material of reproduction for vineyards, for medical products of human and veterinary use and for workers' protection and transport. The plants authorised before 1997 were not subjected to compulsory labelling (soya, corn and two rapeseed plants). However, the revision of Directive 90/220/EEC forces labelling in all stages of commercialisation.

Regarding the labelling of certain foods and feeding ingredients, the presence of genetically modified content must be indicated unless each ingredient contains less than one percent of a genetically modified material (corn or soya[13]) and their presence is accidental[14]. Foodstuffs, which contain genetically modified additives and flavours or are produced from genetically modified organisms, should be labelled as such[15]. Some European countries add their own requirements on labelling. The label "GMO-free" is not regulated, and this is the reason why it cannot be used.

Producers and importers are responsible for damage caused to health of consumers[16]. The responsibility does not cover environmental damage. Also insurance is not regulated[17].

3. The concerned agreements of the WTO

The rules over GMOs, as with any other norm with commercial effect, must be consistent firstly with the general principles of GATT of non-discrimination, national treatment, transparency and predictability. Also, article XX of GATT can be applied. This allows a country to take restrictive measures to protect health and preserve natural resources.

The regulation of GMOs in the EU tries, in particular, to protect the health of consumers and the environment, as well as maintaining the principles and approaches of the SPS and TBT agreements. The SPS is applied to those measures dedicated to protect the health of people, animals and plants, and the TBT to those measures that pursue the protection of the environment and the protection of the consumer against fraud. They are two complementary agreements whose applications are determined by their goals and not by the type of measure adopted. Both agreements apply to the norms that regulate the products and the productive processes that influence the characteristics of the product.

According to the SPS Agreement, the WTO Member States are not forced to continue the international standards. However, when these exist, and Member States adopt measures to protect the health in their territory, it should be ensured that the measures are scientifically justified, based on the risk assessment, not stricter than in a necessary level and not constituting a hidden restriction to the trade. If sufficient scientific evidence does not exist to judge the security of a product or a process, the Agreement allows a member country to adopt measures of caution, at the same time urging the member country, within a reasonable period, to seek for additional information to enable a scientific evaluation of the risk. These conditions govern all measures that can affect trade, including, therefore, those regulating the entrance and commercialisation

[10] Regulation EC n° 258/97.

[11] The Monsanto Soya and the Novartis corn were marketed before the entry into force of the rule concerning the novel foods(Regulation EC n° 258/97) and, consequently, they were not covered.

[12] It is a fact that, as consequence of this disbalanced legal developments, transgenic products have arrived to the EU food chain without a regulated labeling.

[13] Or whatever material approved by Regulation 258/97.

[14] Regulation EC n° 44/2000, of 10 January 2000, modifying the Regulation EC n° 1139/98, that obliged to special label when NDA or trasngenic proteins were detected.

[15] Regulation EC n° 50/2000 of 10 January 2000.

[16] Directive 85/374/ECC modified by the Directive 99/34/EC.

[17] The European Commission will propose a Directive relating to the environmental liability in this coming year.

of derived products of biotechnology in the community market.

The consensus of opinion in the scientific community is that GMOs are not harmful to health, although there is a fear that they may cause allergic reactions, increase resistance to antibiotics and increase the negative effect of chemical substances in live tissues (Babinard, 1999). Fears for the environment are increasing. Such fears include the development of grasses, which are resistant to herbicides, and the reduction of biodiversity (Barling, 1999) such as in the case of the monarch butterfly studied by the European Commission. Consequently, the EU does not ban the import of products obtained from GMOs, though the EU does subject products to extensive analysis. However, an American criticism points out that the long and expensive approval process acts like an unjustified barrier to trade which is not based on scientific tests. Otherwise, such a barrier is to be set more by pressure groups of consumers and environmentalists (Kelch, 1998). Actually, the position of the EU on this topic stems from the mistrust of European consumers in the institutions in the aftermath of the BSE crisis.

The EU approval procedure is, indeed, long and complex. This is due to the fact that the existence of risks is ignored and the long-term effects are not investigated. The EU has not explicitly manifested if its approval system is based on human health risks, environmental risks or on both of them. What is relatively unimportant in the domestic environment, is important in a WTO perspective. If measures are adopted to protect health by the SPS, then the SPS should be respected. However, if they are made to protect the environment, then the TBT is to be applied .

In the SPS, it is impossible to maintain an approval system if scientifically proven health risks do not exist. Therefore, if these risks are very low, the long community approval system would have difficulties leaning on this argument. The problems which outline the risks for the environment and the TBT are different. It is admitted that the production of GMOs can affect the environment negatively, which means that a country could establish conditions to protect the production in its territory to reduce or to eliminate that damage. Within this limitation, the production could be banned if the same can be justified scientifically. Nevertheless, the import of GMOs could also be banned alleging that their production supposes a risk for the environment even abroad. We have not an affirmative answer to this, as was established in the case relating to Dolphin/Tuna (Mexicovs.US). The EU system is reasonable because there is not a ban of import or commercialisation, but rather it subjects each application to specific analysis to verify their impact on the environment of each country. Furthermore, it is still more flexible than the system involved in the approval of novel foods.

As a result, the system of approval of the EU has its limits and procedures which are very well defined–it establishes the new Directive 2001/18/CE- which is incompatible with the Agreements of the WTO. If the procedure designed to grant authorisations, although tortuous in the eyes of the Americans, had worked appropriately, for example, as with the procedure for the solution of the differences of the WTO, the criticism of the Americans would loose its relevance. What has really spurred their criticism is the community moratorium adopted in fact in 1999 that has acted as an embargo, without having contributed an overwhelming scientific justification. It is now needed to see how the new Directive will work.

The US also criticises community forceful legislation on labelling products that contain GMOs. The norms of labelling are to provide information to the consumer about the characteristics of the product that cannot be known otherwise. This is regulated by the Agreement TBT, unless its end is to protect the health of consumers, in which case the pertinent agreement is the SPS. The norms on GMO labelling should be compatible with the TBT Agreement. Unlike the SPS Agreement, the TBT Agreement forces Member States to follow the international standards, except if these are inappropriate. In the case we are dealing with, this standard doesn't exist, although the Codex, and the committee on Food Labelling, has started to create norms or international recommendations related with the foods obtained by genetic manipulation.

In the absence of international regulations, the operating margin for countries is higher, but even so, the TBT Agreement forces to label based on the characteristics of the product. This means that the compulsory labelling would be justified if the genetically modified product is substantially equivalent to the conventional product. If the products were 'like' or 'similar', obligation would not be justified, because the only difference would reside in a characteristic of the productive process - the transgenic technology - that doesn't impact the appreciable characteristics of the final product neither its safety, and this would also suppose a treatment discrimination that is not accepted by the Agreement. Therefore, if it is not possible to show that the products are different or that the transgenic one is not safe, then the products are 'similar'; compulsory label is not justified, neither any other measure that restricts the imports.

The presence or absence of transgenic material can be considered a difference just like other properties of the product. The European rule is based on the principle of detection of proteins and transgenic DNA. It forces to label when the presence of genetically modified ingredients is above 1%. Therefore, it may be proven that the product has a composition different from its equivalent.

But the controversy over the labels is not only a juridical matter but rather an economic dimension. A compulsory labelling based on the technique employed would

force producers to separate their transgenic production from conventional products, and to assure the traceability of the product, that means a comprehensive documentation of the productive process. The European Commission (2000) has estimated that this would increase the production costs from 6 to 17%.

On the other hand, producers of GMOs that could not be discovered during a conventional inspection, because transgenic substances disappear along the production process, would not have incentives to label their products on a voluntary basis, raising high enforcement costs. The main reason is that the cost in which they would afford would not be compensated by the price, which would be even lower than that of the equivalent product, because of the poor image of GMOs in some countries. Anyway, the decision of some producers and European supermarkets to prohibit GMOs in their chains is forcing farmers to separate their products.

These institutional and economic difficulties explain why other alternatives are being explored. It is the case of the voluntary labels that indicate that a product is GMO-free.

4. The Biosafety Protocol

The Agreement on Biodiversity of the United Nations is the framework for the negotiation of the Protocol of Cartagena signed in Montreal in January 2000. This agreement, that is one of the main results of the 1992 Rio Summit, recognises two aspects of the modern biotechnology: its potential to promote the mankind well-being and the necessity to protect the human health and the environment.

It cannot be stated that the genesis of the Protocol of Cartagena has been peaceful. On one hand, the EU and numerous developing countries tried to reach an agreement containing the principle of caution, not only concerning transgenic seeds but also genetically modified products used for animal feeding or agricultural products (Audier,2000). On the other hand, the countries organised as Miami group (US, Argentina, Australia, Canada, Chile and Uruguay) sought to introduce a safeguard clause in the Protocol to guarantee the superiority of the WTO Agreements in case of conflict.

The Protocol sets the idea that the application of biotechnology should be carried out in order to obtain the maximum benefits from its vast potential with the minimum risk for the environment and the human health. The Protocol contains one of the clearest definitions of the principle of caution and the sum-up of the international right.

The main objective of the Protocol of Cartagena is to achieve that the trade of modified living organisms (MLO) is carried out in a safe way. For that, a previous appropriate evaluation of the risks is required founded on the principles of caution, of preliminary consent and of responsibility. This is due to the fact that the Protocol recognises that the handling, the use and the transfer of MLOs are riskful activities that may cause collective or individual damages. Guerra Danieri (2000) estimates that this recognition supposes a great advance but that, at the same time, the given step underscores the necessity of a definition about the basic aspects of the operation of the international system of responsibility when a damage is likely to occur.

The Protocol offers a range of means and instruments for the prevention of biotechnical risks such as:

- The procedure of previous agreement with deep knowledge. The Protocol develops a preliminary procedure of information. The exporter should notify to the importing country the arrival of the MLV product that will be released in the environment, so that the receiving State can evaluate the risk, accept or not its entrance, and set the conditions.
- The creation of a Centre for the Exchange of Information for the prevention of biotechnical risks.
- The framework of prevention and evaluation of risks. In the Protocol a series of general and specific rights and obligations are included for the Parties.
- The reinforcement of the skills of developing countries and those of economies in transition, mainly for the setting up of institutions, management and evaluation of the risk.
- The public awareness.

From the point of view of their identification, the Protocol requires that the GMO is identified as MLO. If they are used for animal feeding or processed, an indication is required pointing out that they 'can contain' those organisms. Labelling is not required for such processed foods as oils to cook or eat (Anderson and Nielsen, 2000).

In the two years term from the entry into force of this juridical instrument, it will be necessary to establish detailed regulations. The key issue s the creation of a centralised system of exchange of information for the prevention of biotechnical risks; the evaluation of the international rules relative to manipulation, transport, packing and identification of GMOs; negotiating more specific requirements of labelling, the options to enforce the system of compliance with those obligations and the simplification of the of decision-making procedures for the parties when they want to allow the import of GMOs.

Among other juridical questions, fundamental matters are still pending such as determining who is responsible for risk and damages; establishing a subjective approach on the blame which might request some rules of diligent behaviour; or the adoption of an approach based on objective responsibility, based on the assumption of the risk-benefit or risk-danger; and many other decisive questions and characteristics of a juridical classification according to the novel issues outlined by the transgenic products.

All these pending aspects of decision hinder the valuation of the future impact of this Protocol in the international trade (Pasco, 2000). A priori, the final agreement is satisfactory for both sides, since a declaration exists affirming that the international agreements of environmental and commercial matters should lean on mutually. However, the US, the leader in the use of biotechnology, have signed neither the Agreement of Biodiversity nor the Protocol of Cartagena, because they seek to maintain their right to a panel of resolution of conflicts before the WTO and the superior role of the WTO against any prohibition of import of GMO - "WTO savings clause" -

(Sheridan,2000), although their companies will have to complete the rules of the protocol when they will export to the countries that ratify the Protocol.

This position of the United States doesn't allow raising an unequivocal answer to the old controversy of if the multilateral agreements are subordinated or can be applied to the norms of the WTO. Clear differences of principles exist between the two agreements, and their application can arise different results. SPS follows the principle of the scientific evidence, while the Protocol grants priority to the caution principle. In second place, the agreements of the WTO are not explicit about how to treat the non-commercial concerns; while the Protocol contemplates the possibility to include the socio-economic consequences in the evaluation of the risk.

The Protocol doesn't clarify the doubts since, in its preamble, it says that it doesn't modify the rights and obligations contracted with existent agreements, but later add that it is not subordinated to other international agreements.

5. Conclusions

The biotechnical innovations will continue in the future, offering new opportunities to agriculture. Although all the countries share the objectives of protecting the health and the environment, the regulation on the use of GMOs is quite different. The main reason is the attitude of the citizens. The fear and the distrust of the European consumers explain the cautions adopted by the community regulation. In short, the system of authorisations and the compulsory labelling will raise problems with the United States.

The multilateral system of trade should assure, at the same time, the freedom of exchanges and the desire of the countries of maintaining high standards of Health and Environment protection . The national requirements that affect trade should be evaluated according to GATT 94 and the SPS and TBT Agreements. The current community regulation fulfils these Agreements. The authorisation procedure "case-for-case" and "step-by-step" can be defended from the threats to the environment, which needs a long-term evaluation. The compulsory labelling from the !% threshold of GM content it is also consistent because the product that contains that percentage of modified DNA cannot be considered as equivalent to the traditional product.

What is more difficult to argue is the suspension of new authorisations granted in1998, mainly for new foods, that is acting as an embargo. Without new evidence, the EU could defend in the WTO invoking the right to adopt the measures of caution established in the SPS Agreement. The case of the hormone beef endorses this argument. In case of TBT Agreement, the proposal of some environmentalist groups to establish a compulsory labelling when the product has been obtained by means of genetic manipulation does not sound consistent. To make these radical opinions compatible with the Agreements, some substantial changes are needed. Therefore, in SPS Agreement it would be necessary to incorporate the principle of caution. In TBT Agreement it would be necessary to regulate all the production methods, independently of their effects on the characteristics of the product. Also, it would be necessary to define in broader terms the meaning of similar or equivalent products.

Nowadays, in the political arena, the plausible reform of the SPS and TBT Agreements in order to cover more restrictive options is living a hard time. The United States is opposed and, these Agreements, although can be improved, suppose a clear advance in the process of trade liberalisation. They reinforce the security of the trade. They produce more predictably, and avoid the creation of barriers that could be claimed in the event of giving priority to the preferences of the consumers. A better alternative seems to be a multilateral environmental agreement, but this is just what the Biosafety Protocol represents. Their principles are better adapted to the philosophy followed by the EU and, even, could allow more restrictive measures.

However, it is still an incognito to know if this Protocol will be effective and applicable. In that case it will prevail on the agreements of the WTO in the event of a conflict. United States has not still signed the Protocol. If the US does not agree and sign, the disputes between a WTO member and one of the Protocol would be solved probably in the DSO. Both the WTO and the United States have pointed out the pre-eminence of the multilateral system of trade on a sectorial Agreement on the Environment. This motivates our opinion because it will be difficult to have a conflict solved out of the WTO arena.

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