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Summary

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 (GMO). 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 exigent legislation in order to avoid the possible risks to human health and the environment posed by GMO. The EU's authorisation procedure for these organisms is long and meticulous. Furthermore, a compulsory labelling system has been adopted for products, which contain GMO or genetically modified materials (GM materials). In 1998, American interests started to be adversely affected by European legislation. The USA Administration threatened to sue the EU before the World Trade Organisation (WTO).

These threats have yet to be followed up with any action. The rules of international trade are regulated by agreements signed up to 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 compulsory labelling system is also compatible with the Agreement on TBT if the WTO accepts that a product in which GM material is detected is not similar to a conventional one. 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.

WORDS KEY: GMO, REGULATION, WTO, PROTOCOL OF BIOSAFETY

THE GMO REGULATION IN THE EU AND THE COMMERCIAL CONFLICT WITH THE UNITED STATES

1. - Introduction

The United States is the world's 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 the 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's 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 at the EU where GMO cultivation, commercialisation and authorisation rules are different to 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 GMO 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 GMO has been much greater in the US than in the EU.

APPROVALS OF GMO IN THE EU AND US				
	USA		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

Representatives of the industry and the Administration of the US 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 compulsory 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 in to account that in those cases the EU had already been condemned by the WTO[2]. The eventual affect 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?

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

[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

(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 GMO will be settled in the WTO, the last resort for countries to resolve their commercial conflicts. This real possibility raises several questions. Firstly, whether 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 eventuality of conflict. Finally, if the current institutional framework doesn't guarantee the existence of a European legal framework different from the United States, the goal is 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 GMO. 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 set out in four main sections. In the following section, we try to explain the main differences between community regulations and American regulations in those points in relation to the 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 what necessary changes need to be made to the current Agreements or whether new ones need to be introduced for these types of products.

2. - The regulation in 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 unknown magnitude's risks and it affects goods and rights legally protected as the biodiversity and the consumer 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 approve by national and community scientific experts' committees.

The US Federal Agencies, which are working jointly on approval of the GMO, are the APHIS (Animal and Plant Health Inspection Service), EPA (Environmental Protection

[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 prodcts.

Agency) and FDA (Food and Drug Administration)[5]. These Agencies are the main bodies responsible for the environment and consumer health protection. When an application is presented, the APHIS should deliver authorisations in order 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.

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 security 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 WOH - 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 alimentary scandals, such as the one caused by the appearance of GMO in certain foods in the Taco Bell chain of restaurants, have opened a debate on the segregation of GMO from conventional foods in the North American alimentary 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 vein, the FDA presented a proposal in February of this year that determines the mandatory of communication to the foods coming from the biotechnology, previously to its commercialisation with the purpose of contrasting its coherence with the FFDCA.

[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.

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 their 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 micro-organisms modified genetically 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 live GMO, 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 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 process. A country can suspend approval temporarily if it considers that risks exist, in which 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 phases 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.

[6] Directive 90/219/EEC of the Council.
[7] Directive 90/220/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.

The authorisation (and labelling) of novel foods or derived alimentary ingredients of GMO 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 which products to evaluate. Furthermore, a simplifies procedure has been established for novel foods derived from GMO that do not contain transgenic material, and these offer a substantial equivalence with other existent foods in composition, nutritional value and metabolism and is a use to which they are dedicated and at a level of non envisagable substance terms. In these cases, the product can be marketed in the EU and notified to the European Commission with a justification of this equivalence emitted 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 were implemented by the 1990 (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, firstly, 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 regulator 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 organisms modified genetically, should be labelled as such[15]. Some

[10] Regulation EC nº 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 nº 258/97) and, consequently, they were not covered.
[12] It is a fact that, as consequence of this disbalanced legal developments, trasgenic products have arrived to the EU food chain without a regulated labeling.
[13] Or whatever material approved by Regulation 258/97.
[14] Regulation EC nº 44/2000, of 10 January 2000, modifying the Regulation EC nº 1139/98, that obliged to special label when NDA or trasngenic proteins were detected.
[15] Regulation EC nº 50/2000 of 10 January 2000.

European countries add their own requirements on labelling. The label "GMO free" is not regulated, so that is the reason because of 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 GMO, 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 conserve natural resources.

The regulation of GMO 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 ones and not for the type of measure adopted. Both of the 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 Members States are not forced to continue the international standards. However, when these exist, and Member States adopts measures to protect the health in their territory, it should be ensured that the measures are scientifically justified, based on the valuation of risk, 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 country member to adopt measures of caution, at the same time urging the country member, within a reasonable period, to seek additional information to enable a scientific evaluation of the risk to be carried out. These conditions govern all measures that can affect trade, including, therefore, those conditions that regulate the entrance and commercialisation of derived products of biotechnology in the community market.

The consensus of opinion in the scientific community is that GMO 's 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 GMO's, though the EU does subject products to extensive analysis. However, an American critic points out that the long and expensive approval process acts like an unjustified barrier to trade It is also not based on scientific tests. Otherwise,

[16] Directive 85/374/ECC modified by the Directive 99/34/EC.
[17] The European Commission will propose a Directive relating the environmental liability in this coming year.

such a barrier is to be evidenced more from pressure groups of consumers and environmentalists (Kelch, 1998). Actually, the position of the EU on this topic results from the mistrust of European consumer of 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. As the EU has not explicitly manifested if its approval system is due to human health risks, environmental risks, or both of them probably, 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 n approval system if scientifically proven health risks do not exist. Therefore, if these risks were 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 GMO's 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, it could be banned the production if the same can be justified scientifically. Nevertheless, it could also be banned the import of GMO alleging that their production supposes a risk for the environment abroad the country. We have not an affirmative answer to this, as was established in the case relating to Dolphin/Tuna (Mexico vs. US). The EU system is reasonable because of there is not a ban of import or commercialisation, but rather it subjects each liberation application by means of specific analysis to verify their impact in the environment of each country, besides, it is still more flexible than the system involved in the approval of novel foods.

In consequence, 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 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 lose its relevance. What has really given wings to their critic is the community moratorium adopted in fact in 1999 that has acted as an embargo in the practice, without having contributed an overwhelming scientific justification. It lacks to see how the new Directive will work.

The US also criticises community forceful legislation on labelling products that contain GMO. The norms of labelling are to provide information to the consumer of 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. Although can be challenged, the norms on GMO labelling should be compatible with the Agreement TBT. Contrary to the Agreement SPS, the Agreement TBT forces to the Members States to follow the international standards, except if these are inappropriate. In the case that occupies us, this standard they don't exist, although the Codex, in short their committee on Food Labelling has begun the process to create norms or international recommendations related with the foods obtained by genetic manipulation.

In absence of international norm, the manoeuvre margin for countries is bigger, but even so, the Agreement TBT forces to label basing on the characteristics of the product. This means that the compulsory labelling would be justified if the product genetically modified were 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 technical - that it doesn't influence in the appreciable characteristics of the final product neither its security, 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 is not safe, then the products are 'similar', and it is not justified the compulsory label - although yes the volunteer - neither any other measure that restricts the imports.

The presence or not presence of transgenic material can be considered a difference, as 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 superior to 1%. That means that it can be proven that the product has a composition different to its equivalent one.

But the controversy on the labels is not only a juridical matter but rather has an economic dimension. A compulsory labelling based in the technique employee would force to the producers to separate their transgenic production of which it is not, and to assure the traceability of the product, that means an exhaustive documental pursuit of the productive process. The European Commission (2000) has estimated that this would increase the production costs between a 6 and 17%.

On the other hand, those producing of GMO that could not be discovered as such in a conventional inspection, because disappearance of the transgenic material long the production process, would not have incentives to label them in a voluntary way, raising high enforcement costs. The main reason is that the cost in which they would incur would not be compensated by the perceived price, which would be even inferior to that of the equivalent product given the bad image of the GMO in some countries. Anyway, the decision of some producers and European supermarkets of prohibiting GMO in their chains is forcing the 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 free of GMO.

4. - The protocol of Biosafety

The Agreement of Biodiversity of the United Nations constitutes the framework of the negotiation of the Protocol of Cartagena, signed in Montreal on January 2000. This Agreement, one of the main results of the Summit of Rio of 1992, recognises two related aspects of the modern biotechnology: its potential to promote the humanity's well being and the necessity of protecting the human health and the environment.

It cannot be affirmed that the genesis of the Protocol of Cartagena has been peaceful. On one hand, the EU and a numerous developing countries tried to reach an agreement

that contained the principle of caution formulated in their maximum extension, not only having for object the transgenic seeds but also the products genetically modified used for the animal feeding or the agricultural products (Audier, 2000). On the other hand, the countries organised as group of Miami (US, Argentina, Australia, Canada, Chile and Uruguay) sought to introduce in the Protocol a safeguard clause to guarantee the superiority of the WTO Agreements in case of conflict.

The Protocol consecrates the idea that the application of the biotechnology should be carried out so that it is possible to obtain the maximum benefits of its vast potential with the minimum risk for the environment and the human health. The Protocol contains a definition of the principle of caution that is one of the clearest and you sum up of the international right.

The main object of the Protocol of Cartagena is to achieve that the trade of modified alive organisms (LMO) was carried out in a sure way. For that, a previous appropriate evaluation of the risks is required founded in the principles of caution, of previous consent and of responsibility. This is due to that the Protocol recognises that the handling, the use and the transfer of LMO are activities of risk susceptible of causing collective or singular damages. Guerra Danieri (2000) estimates that this recognition supposes a great advance but that, at the same time, the given step has put to the overdraft the necessity of a definition about basic aspects of the operation of the international system of responsibility when the opportunity exists of causing a damage.

The Protocol offers a series of means and instruments for the prevention of the biotechnical risks, of which highlight the following ones:

- The procedure of previous agreement with cause knowledge. The Protocol develops a previous procedure of information. The exporter should notice to the country importer of the arrival of the product LMO dedicated to be liberated in the environment, so that the receiving State can evaluate the risk, to accept or not its entrance, and to establish the conditions.
- The creation of the Center of Exchange of Information for the prevention of biotechnical risks.
- The framework of prevention and evaluation of risks. In the Protocol a series of rights and obligations are included so much general as specific for the Parts.
- The reinforcement of the capacities of the developing States and those of economies in transition, mainly in the areas of creation of institutions, administration of the risk and evaluation of the risk.
- The public's sensitisation.

From the point of view of their identification, the Protocol requires that the GMO that will be liberated in the means be identified as LMO. If they will be used as foods, in the animal feeding or they will be processed an indication it is required pointing out that they ‘can contain’ those organisms. Labelling is not required for such processed foods as oils to cook or eaten (Anderson, Nielsen, 2000).

In the two years term from the entry in force of this juridical instrument, it will be necessary to establish detailed norms. The key questions are the creation of a system of exchange of information centralised for the prevention of biotechnical risks; the exam of the international norms relative to the manipulation, transport, packing and

identification of the GMO; negotiating requirements of labelling more specific, the options to put into practice the system of respect of those obligations and the simplification of the procedures of taking of decision for the parts when they want to allow the import of GMO.

Among other juridical questions, they are pending such fundamental matters as to determine who are the responsible direct of the situations of risk and the damages, the chain of casualties; the establishment of an approach of subjective nature based on the blame, for that which would be indispensable to even establish some rules of diligent behaviour with admission of the accusation; or the adoption, on the other hand, of approaches of objective responsibility, based on presumptions and in the predetermined objection, like they can be the fact of the assumption of the risk-benefit or risk-danger; or establish illicitness, and many more decisive questions and characteristic of a classification juridical according with the novel questions outlined by the transgenics.

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 the biotechnology, have not signed yet 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 United States doesn't allow raising an unequivocal answer to the old controversy of if the multilateral agreements are subordinate or they can be applied on the norms of the WTO. That can be affirmed it is that clear differences of principles exist between the two agreements, and that their application can arise different results between both. In the first place, the 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 the agriculture. Although all the countries share the objectives of protecting the health and the environment, the regulation of the use of the GMO 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 normative one community. In short, the system of concession of authorisations and the compulsory labelling will raise problems with 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 to trade should be evaluated according to the GATT 94 and the SPS and TBT Agreements. The current community regulation fulfils these Agreements. The authorisation procedure "case-for-case" and "step-to-step" can be defended for the threats to the environment, which needs a long-term evaluation. The compulsory labelling from the threshold 1% 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 of arguing is the suspension of new authorisations that comes making from 1998, mainly for new foods, that it is acting as an embargo in the practice. Of being prolonged this moratorium, and without new proofs, the EU difficulty could defend in the WTO invoking the right to adopt the measures of caution established in the SPS Agreement. The precedent of the case of the hormone beef endorses this argument. As well it do not sounds consistent, in case of TBT Agreement, the proposal of some environmentalist groups in relation to establish a compulsory labelling when the product has been obtained by means of genetic manipulation. To get these radical opinions compatible with the Agreements, it would be necessary substantial changes. 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 in the characteristics of the product. Also, it would be necessary to define in a wide way, which is 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 the more restrictive options fancies low. United States is opposed and, these Agreements, although can be improved, suppose a clear advance in the process of liberalisation of trade. They reinforce the security of the trade. They produce more predictable, 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 agree a multilateral environmental agreement, but this is just that the Protocol of Biosafety represents. Their principles are adapted better up to now to the followed philosophy by the EU and, even, could allow a 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 US do not agree and sign, and do outline the conflict with the EU, the disputes between a WTO member and one of the Protocol with a Member only of the WTO would be solved probably in the DSO. So much the WTO veiledly, as United States openly, have pointed out the pre-eminence of the multilateral system of trade on a sectorial Agreement on Environmental. This motivates our opinion because it will be difficult to have a conflict solved out of the WTO arena

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