Editorial

This issue of the European Food and Feed Law Review contains five papers on different aspects of GMOs written by the nine members who have constituted the Advanced Research Group 2008 of the Real Colegio Complutense at Harvard University on the topic *"Regulating liabilities in the international trade of food and GMO: towards an international food safety system?"*. The Advance Research Group 2008 has performed at the Real Colegio Complutense at Harvard University (Cambridge, Massachusetts), important work, debating legal and scientific food safety-related issues, having the opportunity to interact by organizing seminars with different University Professors from various United States Universities (Harvard and Yale) and recognized professionals to seek their views on the main objective of the Advance Research Group.

As a consequence of globalization, trade in food, genetically modified organisms (GMOs) and substances entering the food chain has dramatically increased in recent years. The expansion of trade promotes not only the liberalization of trade, but also the establishment of international trade rules in fields traditionally concerned with domestic regulations. In some cases, this expansion has become a new source of disputes among countries adapting their domestic regulations to international standards. As harmonization has not been developed into compulsory regimes at the international level, industrialized states impose, in fact, their food safety rules on developing countries.

The use of international standards, such as those set by the FAO/WHO Codex Alimentarius, the International Animal Health Organization (for animal health) and the FAO's Secretariat of the International Plant Protection Convention (for plant health), is encouraged but most of the domestic systems (including those of the European Union as a whole) adopt their own approaches.

Application of the precautionary principle in the boundaries between "legitimate" protection and "unnecessary barrier to trade" is also a major source of uncertainty. The different interpretations of this principle are also highly disputed not only at the international level but at the European level as well. Differences in risk analysis and risk assessment lead to scientific and legal uncertainty.

Analysis of these subjects and others were being carried out by this multidisciplinary Advanced Research Group 2008 composed of nine researchers, five from the Universidad Complutense of Madrid (Arturo Anadón, María Rosa Martínez-Larrañaga, Pedro Diaz Peralta, Lucia Roda Ghisleri and Fernando Gonzalez Botija), one from the University of Granada (Miguel Ángel Recuerda Girela), one from the University of Illes Balears (Anselmo Martínez Cañellas), and one from the Unesco Chair of Spatial Planning and Environment at the University Rey Juan Carlos

(Alejandro Lago Candeira). The Group also had the occasional collaboration of a Permanent Counsellor of the Spanish Council of State (Enrique Alonso García).

They come from different fields such as Toxicology, Food and Health Law, Administrative and EU Law, Environmental Law, Environmental Sciences and International Commercial Law.

I thank all the authors for their great contributions to this number of the European Food and Feed Law Review and for their great job while at Harvard. I would especially thank Pedro Díaz Peralta and Alejandro Lago for the initial preparation of the application for the project that was granted at Harvard, and Professor Miguel Á. Recuerda for the coordination and revision of this publication.

The group members are indebted and grateful to the Real Colegio Complutense at Harvard University and to its Director, Professor Ángel Saez-Badillos, for his invaluable attention, organizing the different events, and providing the occasion to debate the key challenges in food safety with the other participants in those organized seminars.

It has been a great privilege for me to lead the Advance Research Group 2008 to its goal and to have had the opportunity to work closely with such an outstanding group of researchers and professors.

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Legal Regulation of Risk Analysis and Genetically Modified Foods

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A comparative analysis of the main differences between procedures for granting approval to release and place on the market of genetically modified organisms (GMOs) as those set up at the European Union as a whole are compared against the rules for approval in the United States of America. The analysis focuses on the role and the legal binding-character of guidelines and guidance documents in both systems, a sort of domestic soft law regulating technical and regulatory aspects of the approval procedure. In spite of its non-mandatory role, compliance with rules itself is a condition for approval. In the EU, the step-by-step and case-by-case approach introduces a more proactive role in the procedure itself of the scientific committees dealing with assessment, while in United States of America a preliminary condition is to establish the Generally Recognize as Safe (GRAS) status. To establish a threshold to consider a risk unacceptable requires consultation with scientific committees, the scientific uncertainty arising from the procedure is underlined in both cases, especially in EU procedures, since non-commercial values are frequently taken into consideration.

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1 Recuerda, M.A. (2006), Seguridad Alimentaria y Nuevos Alimentos. Régimen inrídico-administrativo. Thomson-Aranzadì.

I. The relevant role of the guidance and guidelines in the European Union and the United States of America

1. European Union

Applicants who want to apply for approval to release and place on the market a genetically modified organism (GMO) shall submit with the application a technical dossier which includes a comprehensive Environmental Risk Assessment (ERA) of the release.[1] This technical dossier is supported with relevant data in order to evaluate the foreseeable or potential risks or adverse effects, whether immediate or delayed, directly or indirectly, which the GMO or combination of GMOs may pose to human health or the environment. The applicant technical dossier shall be in compliance with rules

laid down in Annexes of Directive 2001/18[2], including description of the achievable objectives, the elements to carry out the assessment and the general principles and methodology to perform the ERA taking into account the impact on human health and environment of the release of the organism. Annexes of the Directive shall be completed, especially in the technical aspects[3], with a set of detailed rules containing guidelines and guidance documents, with a view to contributing to a common understanding of the terms of appraisal and assessment.

To this end, the Commission and the Council of the EU have adopted "Guidance notes", which supplements Annex II to Directive 2001/18/EC, with the aim of establishing the common methodology to perform the ERA, as well as to assist applicants and to facilitate the task of the competent authorities to conduct ERA transparently and accessibly to the public[4].

In the case of the GMO intended to be used as food and feed, art.5 (6) and art.17 (8) of Regulation 1829/2003 establishes that the European Food Safety Agency (EFSA) shall publish prior detailed guidance to assist the applicant in the preparation and the presentation of the application[5].

2. United States of America

The United States of America have a similar concept of the risk analysis[6]. Nevertheless the main difference is the freedom of marketing under GMO's regulations for placing on the market a product or added substance which is *recognized generally as safe* (GRAS). On the contrary, the marketing of a non-GRAS product or additive requires a prior premarketing review by FDA[7].

Although Section 402(a)(1) of the Federal Food, Drug and Cosmetic Act (FFDCA) is the FDA's primary legal tool for regulating the safety of whole foods, including foods derived from plants genetically modified by the new techniques, sections 402 and 409 of the Act do not specify the particular requirements with which a producer must comply to release a GMO. So, FDA adopted a Guidance in 1992[8], which put forward recommendations consistent with the scientific principles in the 1992 policy for food safety evaluation of a new protein. The document explains how the current framework will apply specifically to foods derived from new plant varieties, including plants developed by recombinant DNA techniques.

2 See art. 17.5 of Regulation 1829/2003 for approval of food and feed containing or consisting of GMO.

3 RODA, L, "Organismos modificados geneticamente y bioseguridad: Análisis Comparado de los Procedimientos de Autorización y Evaluación de Riesgo", (doctoral thesis) has pointed out that as a step for completion of the risk assessment, the assessment of the impact on a large scale on the environment of the modified genes and their combinations and its interaction with the function of the ecosystems.

4 See, COMMISSION DECISION of 24 July 2002 (2002/623/EC) establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, (notified under document number C(2002) 2715), OJ L 200, p. 22–33 (establishes guidance notes on the objective, elements, general principles and methodology of the ERA referred to in Annex II to Directive 2001/18/EC); Counsel Decision (2002/ 811/EC) of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. OJ L 280: 27–36 (describing the objectives and general principles to be followed to design the monitoring plan) and Council Decision 2002/ 812/EC (EC, 2002e) (establishes the summary information format). Finally, Commission Recommendation of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003 Text with EEA relevance (OJ L 348, 24.11.2004, p. 18–26).

5 See: 1) Guidance Document for the risk assessment of genetically modified plants containing stacked transformation events by the Scientific Panel on Genetically Modified Organisms (GMO) Question number: EFSA-Q-2003-005D Adopted date: 16/05/2007; 2) Guidance document for the risk assessment of genetically modified microorganisms and their derived products intended for food and feed use by the Scientific Panel on Genetically Modified Organisms (GMO), Published: 06/07/2006, Adopted: 17/05/2006 and 3) Guidance document for the risk assessment of genetically modified plants and derived food and feed by the Scientific Panel on Genetically Modified Organisms (GMO) – including draft document updated in 2008 Published: 28/04/2006.

6 See: National Advisory Committee on Microbiological Criteria for Foods. Statement adopted August 14, 1997. The three components of the risk analysis are: Risk Assessment, Risk Management and Risk Communication.

7 "FDA has ample authority under the act's food safety provisions (Section 402 (a) (1) of the Act) to regulate and ensure the safety of foods derived from new plant varieties, including plants developed by new techniques. This includes authority to require, where necessary, a premarket safety review by FDA prior to marketing of the food". That piece of legislation also includes provisions for unsafe food: "Under section 402(a)(1) of the act, a food is deemed adulterated and thus unlawful if it bears or contains an added poisonous or deleterious substance that may render the food injurious to health or a naturally occurring substance that is ordinarily injurious. Section 402(a)(1) of the act imposes a legal duty on those who introduce food into the market place, including food derived from new crop varieties, to ensure that the food satisfies the applicable safety standard. Foods that are adulterated under section 402 (a) (1) of the act are subject to the full range of enforcement measures under the act, including seizure, injunction, and criminal prosecution of those who fail to meet their statutory duty".

8 See, Food and Drug Administration. Statement of policy: Foods derived from new plant varieties.

From 1992 the United States of America adopted several guidance documents referring to the GMOs and antibiotics to be used in the feeds.[9]

II. Guideline and Guidance Documents

The terms guideline and guidance are well known in the European Union and the United States of America legal literature. In EU legislation, reference to guidance is included in art.5 (6) and art.17 (8) of Regulation 1829/2003 of the European institutions (Commission and Council) and the European Food Safety Authority (EFSA). We can also read the expression "guidance" in Annex IV of Directive 2001/18/EC, which describes in general terms the additional information to be provided in the case of notification for placing on the market and information for labelling requirements regarding GMOs, and also as directions for proper use in accordance with the procedure laid down in Article 30(2). Furthermore, the term "guideline" appears in Annex VI of Directive 2001/18, entitled: "Guidelines for the assessment reports" or in Regulation 1831/2003 on additives for use in animal nutrition, where art.7,5 thereof set up that *"specific guidelines"* for the authorization of additives shall be established by the Commission in cooperation with the EFSA.[10]

In the United States of America legal system the word "guidance" is also the most used, which is preferred to expression the "guideline". Nevertheless appears in *"General principles for evaluating the safety of compounds used in food-producing animals"*[11], and in the *"FDA approval of new animal drugs for minor uses and for minor species"*[12], guideline.

In any case, both in EU and United States of America there is no difference in the meaning of these terms, which are equivalents in order to avoid confusions because, it would be more adequate to uniform the terminology in other scientific fields. In any case, the terminology itself is a minor problem because the real problem seems to be the legal binding-character of these administrative documents.

III. Concept and legal nature

From a legal point of view, the question is the legal nature of the guidelines and guidance documents, whether they are compulsory piece of legislation, technical regulations, administrative measures or mere declarations of opinion of the competent administration, or none of the above.[13]

Neither in the European Union nor in the United States legislation can we find a definition of both concepts, where guidance is of paramount relevance to carry out risk assessment, in order to proceed correctly to place on the market a GMO. Taking into consideration the lack of legal definition, two aspects should be analyzed: the comprehensive definition and legal nature of guidance.

"Guideline" could be defined as a "*statement or other non-mandatory indication of procedure or any document aimed to set routine within of governance processes,* "Guidance" as *"document which provides direction or advice or defines course of action aimed to guiding"*[14].

9 See CFSAN/Office of Premarket Approval CVM/Office of Surveillance and Compliance. October 1997. 2) Guidance for Industry: Use of Antibiotic Resistance Marker Genes in Transgenic Plants 3) Guidance for Industry. Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering. Draft Guidance; 4) Guidance for Industry Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition; 5). Guidance for Industry. Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use.

10 Council Directive 87/153/EEC of 16 February 1987, OJ L 64, 7.3.1987, p.19, fixing guidelines for the assessment of additives in animal nutrition.

11 Revised July 27, 2006. U.S. Department of Health and Human Services Food and Drug Administration Center for Veterinary Medicine.

12 Revised May 29, 2008 U.S. Department of Health and Human Services Food and Drug Administration Center for Veterinary Medicine.

13 The European food Safety Agency (EFSA) establishes in its guidances that EFSA and the GMO Panel shall consult stakeholders prior to the final adoption of any document providing guidelines. In USA, guidances are based on existing practices followed by the traditional plant breeders to assess the safety and nutritional value of new plant varieties and are not intended to alter these long-established practices. For FDA reflect the current state of scientific information. When new information was developed, FDA receives several inquiries from developers of bioengineered foods regarding the appropriate procedures for informing the agency about their market entry plans. In order to respond to these inquiries, FDA has developed guidance document.

14 It is defined also as the reference points: superintendence or assistance of a guide; direction; government; leading.

This definition of guideline and guidance, based on the idea of a non mandatory statement, seems to be corroborated by the description of these documents adopted by the competent authorities:

At EU level, EFSA establishes the following procedure for adoption of guidance and guideline:

1. guidance documents are to assist the applicants, with the aim of establishing a harmonized framework for risk assessment,
2. guidance documents are subordinate to legal rules. The guidance is without prejudice to the supplementary guidance notes 2002/623/EC (EC 2002a), 2002/811/EC (EC, 2002b), 2002/812/EC (EC, 2002b) and 2003/701/EC (EC, 2003e) established within the framework of Directive 2001/18/EC. These guidance documents complement, but do not replace other requirements, as set out in specific legislation (e.g. plant-propagating materials), that a product has to fulfil in order to be approved for the European market. The EU Regulations, Directives and Decisions published in the Official Journal establish the procedures to be followed in seeking approval for GMOs as well as the requirements for the applications and are, therefore, always the primary source for advice.
3. *"preferably"* refers to its non-mandatory character[15].

This non-mandatory character is even enhanced in the United States of America guidance documents:

– Guideline shall nor create new regulatory obligations or regulatory requirements for enterprises, nor establish legally enforceable responsibilities, nor to bind FDA.
– They shall not confer any rights.
– Guidance on animal drugs states that it contains *non-binding recommendations.*[16]
– They are only opinion declarations or recommendations of the US Administration, unless specific regulatory or statutory requirements are cited.
– They are a clarification of FDA's interpretation of the Federal Food, Drug, and Cosmetic Act, with respect to new food producing technologies.
– An alternative approach to fulfil the requirements of the applicable statute, regulations, or both.[17]

These documents reflect an opinion given by the competent authority on a particular matter, normally with the aim to comply with the law.

On the contrary it is feasible to discuss at the end, on its strict technical character because, even if they come from advisory body, any person seeking to be granted authorization to marketing a GMO have to comply with them.

IV. The problems of the delegated competencies conferred by the guideline or guidance on GMOs

1. Introduction

GMOs are released by large agricultural biotechnology companies which spend a lot of resources in research in order to place a safe product into the market. Then, enterprises require a legal framework which guarantees them that those huge investments are properly addressed. Do guidance and guideline provide legal certainty to the biotech enterprises operating in the food market?

From a theoretical point of view, a certain level of legal uncertainty exists due to the legal nature of these documents. If they consist of mere opinions of the Administration, obviously applicants cope with a simple interpretation of the law which might be wrong. That circumstance leads us to several key questions rising on the issue:

– Applicant's lack of compliance with the legal schedule of guideline and guidance
– Comprehensiveness of the evaluation dossier
– Setting up acceptable/unacceptable level of risk
– Evaluation of substantial equivalence

15 According to EFSA"…the application should preferably also be compiled according to this EFSA guidance document. The summary of the dossier shall be preferably presented in English in an easily comprehensible and legible form and follow the structure of the EFSA guidance on GMMs and derived products intended for food and feed use as specified in Annex IV".

16 See Guideline no. 61: FDA approval of new animal drugs for minor uses and for minor species. Revised May 29, 2008 U.S. Department of Health and Human Services Food and Drug Administration. Center for Veterinary Medicine.

17 See Guideline no. 3: General principles for evaluating the safety of compounds used in food-producing animals. Revised July 27, 2006. U.S. Department of Health and Human Services Food and Drug Administration Center for Veterinary Medicine.

– Review of compliance of guideline and guidance with an OECD/FAO guidelines

Analysis of these questions reveals great discretionary power in the hands of the Administration; nevertheless, in the light of the examination of the practice of the competent authorities in both administrations, a preliminary conclusion is that companies operating in the market have an important degree of legal certainty under a regulatory framework consistent with objectives.

2. Lack of compliance with the legal schedule of guidance and guideline

At EFSA level, applicant has a degree of freedom to comply with technical dossier. Guidance sets up that technical dossier should contain all necessary information to carry out risk assessment structured according to the format of Annexes of guidance document on GMOs and their derived products intended for food and feed use which should comprise the complete information required by Regulation (EC) 1829/2003[18]. In the case of GMOs or food containing or consisting of GMOs, the technical dossier should also comprise the information required. Applications have to be submitted in the framework of Directive 2001/18/EC with respect to the technical requirements and formats set up by the Directive.

In the case of the United States agencies, guidance expressly allows the petitioners to use an alternative approach if it satisfies the requirements of relevant statute or regulations[19].

Since most of formal requirements are in the guidance documents, the question is what happens if the applicant doesn't comply with the formal schedule of guidance: Might the Administration reject the petition on formal grounds? In the case of the United States the answer seems clear. Since guidance has no mandatory force, the applicant is free to submit the information as he wishes and the Administration shall not reject it[19]. Petitioner may consult the Administration before submitting his petition, giving an opportunity to clarify some aspects with the competent authority[21].

In the case of the EU, EFSA procedure seems to be more open. According to EFSA Guidance documents applications should preferably be compiled in line with guidance document and a summary of the dossier shall be preferably presented in English. The use of the word *"preferably"* involves the idea that the applicant is completely free to meet or not the formal requirements of the guidance[22]. In the case of the use of official languages, applications that are not submitted in English will cause a delay in the assessment process. EFSA may ask the appli-

18 Articles 5 and 17 (3) (a), (b), (d), (e), (h), (k) Regulation (EC) 1829/2003.

19 See, for instance, Sec. 409 [21 U.S.C. 348], FOOD ADITIVES, of the Federal Food, Drug & Cosmetic Act.

20 2006 Guidance introduce a possible format for submission of early food safety evaluation. This optional format consists of two parts: Part I, which is a cover letter informing FDA that someone is submitting an early evaluation of the food safety of a new protein. In this cover letter should be included the name, position or title, address, telephone number, and electronic address. Part II of the submission is where the enterprise explains its scientific evaluation of the food safety of new protein by providing a synopsis of the safety data and information. These data and information should focus on whether the new protein is an allergen or a toxin. They should include:1) The name, identity, and function of any new protein produced in the new plant variety; 2) Data and information as to whether the new protein has been safely consumed in foods; 3) A list of the identity (ies) and source(s) of the introduced genetic material; 4) A description of the purpose or intended technical effect of the new protein; 5) An assessment of the amino acid similarity between the new protein and known allergens and toxins; 6) The overall stability of the protein, and the resistance of the protein to enzymatic degradation using appropriate in vitro assays; and, 7) Any other pertinent information. When data or information from 1-7 indicate that the new protein could potentially cause an allergic reaction in susceptible people or could be a toxin in people or animals, further evaluation is necessary.

21 For example, in 2006 Guidance provides direction to the following questions: 1) May I send my safety evaluation as an electronic file? Yes, you may send your safety evaluation as an electronic file plus one paper copy. Please contact OFAS before sending an electronic file to obtain specific guidance on electronic submission. 2) If I choose to send a paper copy of my safety evaluation, how many copies do I send? A single copy of your safety evaluation is sufficient. 3) May I submit any data or other information, such as a reprint of a published scientific article, in a foreign language? If you submit any material in a foreign language, we request that you provide an accurate and complete English translation.

22 In EFSA guidances, information should be presented in conformity with the format proposed in this document and a detailed index should be included. All parts of the dossier should be fully legible as well as experimental data including tables, physical maps and statistical analysis. A summary of data should be introduce in the main text while technical data in appendices containing the full data. Data presented in sections of the dossier should be clearly structured in the form of tables, figures, photographs, etc.

cant to translate those parts of the dossier not submitted in English and to confirm accuracy of any translated text with the original. But EFSA guidance on October 2006 seems to be very stringent with the formal requirements provide that *"the application will be considered valid if it fulfils the requirements as specified in the EFSA guidance document and accompanying annexes".*

3. Comprehensiveness of the evaluation dossier

Neither the EU nor the United States statutes specify if comprehensiveness of information required is more or less relevant for the decision taken. Nevertheless some matters seem to be more sensitive (for example those related to the potential toxicity or allergenicity of the GMO).

In the case of the EU, the applicant shall present an application as complete as possible. This means that applications should develop all the aspects covered by the guidance. Not all the points included in the guidance document are applied in every case. In cases where a part of the dossier does not match any particular requirement, additional explanations shall be given for the omission of such essential data. So, depending on the scope of the application, some of the specifications may not be applicable. If EFSA consider that the missing information is essential, the application shall be rejected.

Flexibility of United States guidance documents allows applicants the possibility to discuss with the Administration if a certain issue should or not be treated[23]. In any case, in 2006 Guidance FDA suggest that the submission should consist of two parts. If any information requested in Part II does not apply, FDA could require further explanations of the applicant. Lack of motivation on the grounds of rejection of the application could violate the rights of the applicants.

4. Setting up acceptable/unacceptable level of risk. Substantial equivalence

a. European Union

In the EU procedure, regardless of the additional request for more information from member States[24], EFSA is in charge of dealing with the applicant's dossier[25].

In some cases, statistical differences were occasionally observed in some genetically modified plants, with regard to their natural equivalent[26]. These differences are accepted because they are on a small scale and within the historical background range of no biological significance. Moreover the GMO Panel considers it unlikely that these differ-

23 2006 Guidance foresees the incorporation by reference of data or other information already retained in FDA's files. If someone else previously submitted information to FDA, the procedure to incorporate that information by reference depends on whether the information is publicly available. If yes, it may incorporate by reference.

24 For example: further animal feeding studies (sometimes requested using typical target animals which reflect the commercial use of the product); additional toxicological testing, including chronic testing; additional information to rule out a potential allergenic risk of the product, levels of glyphosate residues; potentially adverse effect observed in vitro studies, direct and indirect effects of the Cry1F toxin on non-target organisms, (soil biota, arthropods and other invertebrates); general surveillance and monitoring of non-target effects, etc.

24 See: Opinion of 2 April 2004 of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference C/DE/02/9) for the placing on the market of insect-protected genetically modified maize MON 863 and MON 863 x MON 810. EFSA Journal (2004) 1–25/Opinion of 2 April 2004 of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the safety of foods and food ingredients derived from insect-protected genetically modified maize MON 863 and MON 863 x MON 810, The EFSA Journal (2004) 50, 1–25/Opinion of 24 September 2004 of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the notification (Reference C/NL/00/10) for the placing on the market of insect-tolerant genetically modified maize 1507, EFSA Journal (2004) 124, 1–18/Opinion of 13 October 2005 of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-UK-2004-01) for the placing on the market of glyphosate-tolerant and insect-resistant genetically modified maize NK603 x MON810, for food and feed uses. EFSA Journal (2005) 309, 1–22/Opinion of 13 October 2005 of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the notification (Reference C/GB/02/M3/3) for the placing on the market of glyphosate-tolerant and insect-resistant genetically modified maize NK603 x MON810, for import and processing, EFSA Journal (2005) 182, 1–22/Opinion of 19 January 2005 of the the Scientific Panel on Genetically Modified Organisms on an application (reference EFSA-GMO-NL-2004-02) for the placing on the market of insect-tolerant genetically modified maize 1507. EFSA states that the measurements on animals included feed consumption, body weight, clinical pathology (serum, blood, urine), and anatomical pathology (organ weights, histopathology). Observed differences were not considered to be biologically relevant. A number of histopathological changes were observed, in particular inflammation of the liver, nephropathy, and cardiomyopathy (kidney and heart damage) in animals of both sexes.

26 Some differences concerns small changes in haematological parameters.

ences would lead to adverse health effects for humans and animals[26] when all analytical data are in range with others published in the scientific literature or EFSA Panels rule out a serious probability of hazard because of the notification under Directive 2001/18/EC is for import and processing only, and thus there is no requirement for scientific information on environmental effects associated with the cultivation[27]. Finally, in some cases, EFSA accepted a reasonable explanation given by the applicant to collect data.[28]

Concerning authorized varieties of genetically modified maize EFSA states that maize is not generally able to survive in the environment without cultivation. In addition, there are no cross compatible wild relatives in Europe, and gene flow via pollen is largely restricted to neighbouring crops. The Panel considered the possibility that gene products, particularly Cry proteins might enter the environment either from the intestinal tracts of animals or through horizontal gene flow to bacteria. Data supplied by the applicant and other literature suggests that most protein would be denatured by enzymatic activity in the intestinal tract. There would subsequently be further degradation of proteins in the manure due to microbial processes. Thus amounts of Cry proteins being distributed onto land in manure would be very low minimizing the possibility for exposure of potentially sensitive non-target organisms (e.g. soil coleoptera)[29].

Only on one occasion could the OGM Panel not reach agreement on the safety evaluation of the hybrid MON 863 x MON 810[30]. This occurred because Monsanto presented a study about MON 863 and MON 810 separately as the company looked to extrapolate the existing safe data of these two single lines to the hybrid. Although that procedure is usual at FDA level since t substantial equivalence can be argued by the applicant, it is not usually accepted by EFSA.

After the production of the requested data by the applicant, the Panel concluded that there were valid scientific arguments that the data provided for MON 863 and MON 810 support the safety evaluation of the hybrid. However, the Panel was divided on the need for additional data for the risk assessment on the MON 863 x MON 810 hybrid itself, in particular a 90-day sub-chronic toxicity rat study in order to complete its safety assessment of maize expressing both, Cry proteins and a nutritional equivalence study in chickens.

The only adverse effect identified was the possibility that resistance to protein or toxin might arise after cultivation for some years. The Panel concludes that large scale cultivation of GM maize over several years will increase resistance in natural counterpart. This could have several consequences including the use of alternative phytosanitary measures to control the pest involving the use of insecticides other than *Bt* toxins[31]. The OGM Panel recom-

27 These differences are not considered to be biologically relevant since they were generally within the normal variation of conventional maize hybrids. A nutritional assessment was carried out by comparison of effects of using maize silage and maize kernels derived from transgenic maize on respect to non-GM control variety.

28 See: Opinion of 20 April 2005 of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the notification (Reference C/F/96/05.10) for the placing on the market of insect resistant genetically modified maize Bt11, for cultivation, feed and industrial processing, under Part C of Directive 2001/18/EC from Syngenta Seeds1 (Question No EFSA-Q-2004-012) EFSA Journal (2005) 213, 1–33. In this opinion EFSA states that "the authors concluded that lower decomposition rates may be beneficial as organic matter derived from plants would persist for a longer period improving soil structure and reducing erosion". In addition, Flores et al. (2005) discussed potential effects on target and non-target insects due to the longer persistence of Bt toxins in soil. / Opinion of 19 January 2005 of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the notification (Reference C/ES/01/01) for the placing on the market of insect-tolerant genetically modified maize 1507 for import, feed and industrial processing and cultivation, (Question No EFSA-Q-2004-072) The EFSA Journal (2005) 181, 1–33 where it is stated that "lignin levels[…] might be increased in transgenic maize lines expressing B. thuringiensis insecticidal proteins (Saxena & Stotzky, 2001a, Flores et al., 2005). However, a broader and more extensive study on lignin content in Bt-maize does not support this conclusion (Jung & Sheaffer, 2004)."

29 The altered level of glucosinolates linolenic acid is not considered to be biologically relevant.

30 The cry1Ab gene in MON 810 is synthetic producing a changed amino acid sequence in the Cry1Ab protein so as to enhance its toxicity to target insects. The possibility that this synthetic gene could transfer to gut, faecal or soil bacteria such that wild bacteria become transformed to produce this toxin was considered. It is well established that DNA is degraded during transit through the gastro-intestinal tract and thus much of the transgenic DNA would be destroyed thereby reducing the possibility for gene exchange with gut, faecal or soil bacteria.

31 See Opinion on 2 April 2004 of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference C/DE/02/9) for the placing on the market of insect- protected genetically modified maize MON 863 and MON 863 x MON 810, for import and processing, under Part C of Directive 2001/18/EC from Monsanto1 (Question No EFSA-Q-2003-089) EFSA Journal (2004) 49, 1-25.

32 The Panel agrees that the likelihood of occurrence of cross resistances is low since, under field conditions and several years of cultivation, no resistance has been reported. However, cultivation of Bt maize in Europe is currently on a small scale and limited to a few geographic regions.

mends that cultivation should be accompanied by appropriate risk management strategies to minimize exposure of non-target insects and to delay the development of resistance to the protein or toxin in target insects[33].

European consumers have expressed their concerns on the consequences of the release and marketing of the new varieties of genetically modified crops. In this regard, the EU Economic and Social Committee have addressed several statements over the years[34], focused in the appropriate assessment of risk through implementation of horizontal legislation at European Community level. Report on the adoption of Directive 90/220/EC stated that (among others):

a) They assume the need for establishing common risk assessment methods for specific assessment schemes addressed at harmonization of results among Member upon which the vertical legislation.
b) The progress of the directive does not seem sufficiently coordinated with other pieces of legislation concerning the release of GMOs, specifically with existing legislation on environmental impact assessments (EIA) as in Directive 90/219/ EC, but it is equally important to ensure coordination also in the case of GMOs entering the market.
c) The definition of the criteria for analyzing transgenic organisms still leaves much to be desired.
d) Undue stringency could well discourage industry

In another 2002 Report the EU Committee of the Regions stated that, as regard GMOs, EU institutions should also boost consumer confidence with regard to public health and food safety, developing Community rules and guarantee the implementation of control policy[35]:

1. The goal for affording a high level of protection for life, health and the environment can be achieved only through a coherent body of Community rules, defining the responsibility of all the players in the agri-food chain.
2. The body of Community rules in force since the early 1990s has been supplemented over the last ten years aimed at a contained use of genetically modified microorganisms for research or for industrial purposes.
3. Establishing the necessary regulatory basis for ensuring a high level of protection of human life and health requires the strengthening and clarification of the assessment procedure for genetically modified food and feed

More recently, the biotech industry also called for the enhancement of harmonization of Part B of Directive 2001/18 applications across the EU, cause of differences amongst member States criteria regarding data requirements, timelines and information to the public. Industry expressed particular concern about the delay in adopting authorization which was sometimes issued after the planting season[36]. The

33 See, Opinion of 20 April 2005 of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the notification (Reference C/F/96/05.10) for the placing on the market of insect resistant genetically modified maize Bt11, for cultivation, feed and industrial processing, (resistance to Cry1Ab protein) (Question No EFSA-Q-2004-012) EFSA Journal (2005) 213, 1–33/Opinion of 19 January 2005 of the Scientific Panel on Genetically Modified Organisms on an application (reference EFSA-GMO-NL-2004-02) for the placing on the market of insect-tolerant genetically modified maize 1507, for food use (resistance to Bt toxin) (Question No EFSA-Q-2004-087) EFSA Journal (2005) 182, 1–22/Opinion of 19 January 2005 of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the notification (Reference C/ES/01/01) for the placing on the market of insect-tolerant genetically modified maize 1507 for import, feed and industrial processing and cultivation, (Question No EFSA-Q-2004-072) EFSA Journal (2005) 181,1–33. Concerning to interactions between the GM plant and target organisms, the Panel considers that the evolution of resistance is an environmental concern. Although resistant Ostrinia nubilalis or Sesamia nonagrioides have not been found in fields in the US or in Europe (Evans 2002, Tabashnik et al., 2003, Bourguet et al., 2003, Farinós et al., 2004), it is likely that it arise in the future since another lepidopteran pest (Plutella xylostella) has developed resistance to Bt toxins under laboratory conditions (Tabashnik et al., 2003).

34 See Opinion of the Economic and Social Committee on the 'Proposal for a European Parliament and Council Directive amending Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms'. The ESC has adopted a specific own-initiative opinion on the impact of GMOs on the Common Agriculture Policy (CAP)

35 See Opinion of the Committee of the Regions on the 'Proposal for a Regulation of the European Parliament and of the Council on genetically modified food and feed', the 'Proposal for a Regulation of the European Parliament and of the Council concerning traceability and labeling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC', and the 'Proposal for a Regulation of the European Parliament and of the Council on the transboundary movement of genetically modified organisms' of 14 November 2002.

36 See, Second report from the Commission to the Council and the European Parliament on the experience of Member States with GMOs placed on the market under Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. [SEC(2007) 274] COM/2007/81 final. The report proposes a series of measures with a view to reassuring Member states, stakeholders and the general public that Community decisions are based on high quality scientific assessments which deliver a high level of protection of human health and the environment by improving the scientific consistency and transparency for risk assessment and decision making procedures under the current legislative framework.

industry also criticized the lack of competitiveness in respect to U.S. Biotech sector. In spite of the fact that more European member States considered that the Commission had provided clear guidance on environmental risk assessment, nevertheless several member States have adopted additional guidance on what are considered to be acceptable and unacceptable risks and on long-term cumulative effects. Industry also called for harmonization of the environmental risk assessment requirements.

Some NGOs pointed out the need of adopt stronger guidelines for allergenicity testing in line with opinion of some European member States that have claimed greater stringency on application of specific aspects of environmental risk assessment with a view to increasing the overall transparency of the evaluation process. That included an increasing harmonization of the process for releases in EU territory, including gene therapy trials, a new definition of "location" of field trials, environmental risk assessment and management measures to prevent contamination of neighboring crops.

In the light of the practice of the EFSA, there is legal certainty[37], for a decade there have been calls for better wording of the legislative texts.

b. The United States of America

In the United States of America, all producers of novel foods[38] entering the food chain have the statutory obligation of ensuring that such a food is safe and in compliance with applicable legal requirements. Regarding authorization of GMOs, FDA must carefully evaluate the potential adverse effects that could result from the presence of these substances in new plant varieties.[39] To enforce compliance, FDA adopted in 1992 Guidance, whose section VII is dedicated to industry for foods derived from new plant varieties. This guidance section describes many of the scientific considerations for evaluating the safety and nutritional aspects of food derived from new plant varieties obtained also by traditional methods (such as hybridization or mutagenesis), tissue culture methods (such as somaclonal variation and protoplast fusion) or recombinant DNA technology.[40]

A summary flow chart describes the FDA's safety assessment process which mimics the current state of art information not intended as regulatory requirements. Guidance provides a basis for determining whether new plant varieties are as safe and nutritious as their parental varieties (substantial equivalence).[41]

The assessment scheme describes, in a general way, the assessment for unexpected or unintended effects that may arise as a result of the specific characteristics that are associated with the host plant and donor and it is focused on characteristics of the new plant variety, such us the nature of the genetic change, the identity and function of newly introduced substances and the assessment of the expected or intended effects linked to the genetic modification.[42]

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37 Obviously in case of disputes between EFSA and the applicant EFSA's opinion prevails, because of discretionary powers, except misuse of power or factual mistake.

38 On the European legal concept of novel food, see, Recuerda, M.A. (2009), "Autorizaciones administrativas y presunción del riesgo en el Derectio alimentario europeo: el caso de los nuevos alimentos". Revista Española de Derecho Europeo, 31.

39 Examples of substances falling under FDA's authority include: (1) Substances intended to alter the nutritional composition of the food (e.g., amino acids or carbohydrates); (2) substances intended to enhance the plant's resistance to chemical herbicides (e.g., glyphosate, sulfonylurea); and (3) substances intended to alter the flavor or the texture of the food.

40 Although some of the safety considerations are specific to individual technologies, many other are similar regardless of the technology used. Doing it, FDA expects plant breeders to adhere to currently accepted scientific standards of practice within each technology.

41 The assessment focuses on the following considerations:
1. Toxicants known to be characteristic of the host and donor species;
2. The potential that food allergens will be transferred from one food source to another;
3. The concentration and bioavailability of important nutrients for which a food crop is ordinarily consumed;
4. The safety and nutritional value of newly introduced proteins; and
5. The identity, composition and nutritional value of modified carbohydrates, or fats and oils.

This guidance section, however, discusses only proteins, carbohydrates, and fats and oils, in the belief that these are the principal substances that are currently being intentionally modified or introduced into new plant varieties. Using the new techniques, it is possible to modify a carbohydrate, or fat or oil, such that it differs significantly in composition from such substances currently found in food.

42 Genetic modifications of plants developing unintended or unexpected effects on the phenotype of the plant, such as growth delay or reduced tolerance to environmental stress, can be effectively managed by appropriate selection procedures. However, changes in the concentration of nutrients, level of natural toxicants, or transfer of allergens from one species to another may require specific test procedures. FDA states that in cases where the host plant has little or no history of safe use, the assessment of new plant varieties should include evidence that unknown toxicants are not present in the new plant variety at levels that would be injurious to health

General Risk assessment is aimed at:

1. Test results shall provide evidence that toxicant levels in the new plant variety do not present a safety concern[43].
2. Concentration and bioavailability of main constituents in the new variety must be within the range ordinarily seen in the natural occurring species[44].
3. In cases of being a natural allergenic, a careful examination shall be carried out in the modified variety in order to demonstrate that the allergenic agent has not been transferred[45].
4. To detect alterations that could affect digestibility or nutritional qualities of the main macroconstituent of the consumer's daily diet.

Guidance focused on food safety and nutritional concerns, rather than new performance characteristics. In some cases, additional factors may need to be considered and then the applicant should contact FDA for scientific assessment prior to marketing or release onto the market, including the design of appropriate test protocols (f.i., to assess allergenicity) covering a specific labelling[46]. Also includes cases where it is not necessary to conduct comprehensive scientific reviews[47].

In 1994, after consultation process to Food, and Veterinary Medicine Advisory Committees to FDA, the committee members agreed with the FDA that the scientific consultations provide an appropriate level of official surveillance on release of new types of bioengineered foods and feeds. Consequently FDA has developed the 1997 Guidance on Consultation Procedures which describes the consultation process involving Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM). However, some criticisms involved that official consultation procedure[48] since assessment of side effects from genetic engineering are based on an analysis of the levels of a limited list of chemicals in the GMO, such as key nutrients and toxins. If the GMO as a whole is deemed "substantially equivalent" to non-GM plants, only limited safety trials and evaluation are required, for example, as those focuses in assessment of the protein products expressed just by the new insert gene but not the whole GMO.

In cases where applicants could develop new plant varieties intended for food use where new proteins could be detected, compulsory consultation with FDA is indicated prior to the stage of development. This safety evaluation is defined an "early" food safety evaluation of new proteins.

This rule supposes in fact a "derogation" of assessment requirements in the case where a new protein has been evaluated in an early food safety evaluation and no risks are identified, FDA does not require additional early food safety evaluation when the same protein is introduced into another species. This guidance does not apply for plant-incorporated protectants (PIPs), which are regulated by EPA.

5. Review of the compliance of guideline and guidance with OECD/FAO guidelines

Regarding the question of the compliance with OECD documents, EU and United States of America refers to Organization for Economic Cooperation

43 According to FDA, if characteristics properties provide enough evidence (bitter taste associated with alkaloids) specific analytical or toxicological tests may not be necessary. Due to his natural variation, analytical tests, when necessary, should be performed using as a control the parental variety that has been grown, harvested, and stored under the same conditions as the new plant variety.

44 If levels of important nutrients differ of the range ordinarily seen in the host species, appropriate labeling may be required, especially when test results indicate that food derived from the new plant variety may be unsafe or it contains unacceptable levels of toxicants.

45 Some examples of foods that commonly cause an allergenic response which may be transferred from a donor to a new variety of modified food are: milk, eggs, fish, crustacea, molluscs, tree nuts, wheat, and legumes (particularly peanuts and soybeans).

46 This evaluation is carried out on a case-by-case basis. If a protein whose safety is dependent of appropriate cooking (for instance alkaloid solanin in potatoes) has been transferred from a species that is commonly cooked before consumption to a species that may be eaten raw, safety questions includes those unresolved issues which comprises significantly increased levels of plant toxicants or anti-nutrients presence.

47 The first request by a producer for consultation with FDA was the request submitted by Calgene, concerns the FLAVR SAVR tomato, a new variety claimed to exhibit improved new properties.

48 A Rapport of the Soil Association states that in 1992, that a majority of the US FDA's scientific advisers did not support the government's proposed assessment regime for GMOs, contrary to the public statements made by the FDA. Sometimes negative effects did occur but were ignored.

and Development (OECD) and Codex Alimentarius Guidance for references[49].

The U.S. 1992 Guidance states that it is consistent with the concepts of substantial equivalence of new foods discussed by the Group of National Experts on Safety in Biotechnology of the OECD. It is also consistent with the principles for food safety assessment discussed in the Report of a Joint Food and Agriculture Organization/World Health Organization Consultation. U.S. 1997 Guidance also included in the scope the bioengineered plants as "recombinant-DNA plants" as defines Codex Alimentarius[50] Also included were the approaches of the Codex Alimentarius "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants" (CAC/GL 45-2003) Paragraphs 34–43 under *Expressed Substances (non-nucleic acid substances)* and the Codex Allergenicity Annex for additional guidance. The enterprise may also consult with medical federal institutions when food safety issues affect human health[51].

At E.U. level, although community legislation provides a framework of more stringent rules, nevertheless guidelines established by the OCDE and the Codex Alimentarius are taken into consideration[52].

L. RODA points out the case of the allergenicity and the differences between the EFSA Guidelines and the FAO/WHO/2001 Guidelines. In the case of the EFSA, the European Authority states that, although the notification has not been updated to include all relevant constituents suggested by OECD (2001), the GMO Panel accepts the data provided since all key components have been considered. Comparative measurements of these compounds do not indicate that the genetic modification produced compositional changes indicative of unintended effects[53]. In other cases EFSA highlight that the study has been presented by the applicant followed the OECD guidelines 408 (OECD, 1998)[54].

V. Conclusions

This part focused in the analysis of the legal nature of the guidelines and guidance, whether they are compulsory piece of legislation, technical regula-

49 See, for example, OECD documents produced by Environment Directorate. (Joint meeting of the chemicals committee and the working party on chemicals, pesticides and biotechnology)
1) Series on Harmonization of Regulatory Oversight in Biotechnology, N 26. Output on the questionnaire on national approaches to monitoring/ Detection/ Identification of transgenic products. ENV/JM/MONO(2003) 8. 27.5.2003;
2) Environmental Health and Safety Publications. Series on the Safety of Novel Foods and Feeds: N 9 Considerations for the Safety Assessment of Animal Feedstuffs Derived from Genetically Modified Plants. ENV/JM/MONO(2003) 10. 23.7.2003;
3) Series on Harmonization of Regulatory Oversight in Biotechnology, N 23. Revised 2006: OECD guidance for the designation of a unique identifier for transgenic plants. ENV/JM/MONO(2002)7/REV1. 7.11.2006. See also: Council. Report of the working group on harmonization of regulatory oversight in biotechnology. C(2000)86/ADD2. 25.5.2000.

50 See Codex Alimentarius Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants" (CAC/GL 45-2003).

51 When the source of the introduced genetic material is wheat, rye, barley, oats, or related cereal grains, the new protein may have the potential to elicit gluten-sensitive enteropathy in sensitive individuals. For additional guidance that may be helpful in resolving this issue, the companies may consult with OFAS.

52 See Opinion of 6 July 2005 of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-BE-2004-07) for the placing on the market of insect-protected glyphosate-tolerant genetically modified maize MON863 x MON810 x NK603, for food and feed uses, and import and processing under Regulation (EC) No 1829/2003 from Monsanto1 (Question No EFSA-Q-2004-159) EFSA Journal (2005) 252, 1–23. As stated above, the toxicological safety of the parental lines has been assessed in previous opinions (SCP 1998b; EFSA 2003a,b; EFSA 2004a,b). A 90-days oral toxicity study with MON 863 x MON 810 x NK603 maize in rats, which was submitted at a later date, has been assessed by the GMO Panel. Also see Opinion of 8 June 2005 of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-DE-2004-03) for the placing on the market of insect-protected genetically modified maize MON 863 x MON 810, for food and feed use, under Regulation (EC) No 1829/2003 from Monsanto1 (Question No EFSA-Q-2004-112) Opinion adopted on Maize lines MON 863 and MON 810 were tested separately for toxicity as part of the diet for rats in 90-day studies.

53 See Opinion on 11 February 2004 of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference C/NL/98/11) for the placing on the market of herbicide-tolerant oilseed rape GT73, for import and processing, under Part C of Directive 2001/18/EC from Monsanto (Question N° EFSA-Q-2003-078) EFSA Journal (2004) 29, 1-19.

54 The design and execution of this study complied with OECD Guideline 408 (OECD, 1998). Three groups of rats consisting of 20 rats per sex within each group received maize-containing diets ad libitum for 90 days. One group received a diet containing 33% MON 863 x MON 810 maize. Another group received a diet containing 11% MON 863 x MON 810 maize, supplemented with 22% control maize. A concurrent control group was fed. All animals were examined daily for appearance, morbidity, and mortality. Individual body weights and food consumption were also recorded weekly. Small deviations in food consumption by females on test diets containing MON 863 x MON 810 were observed as compared with those on the control diet.

tions, administrative measures or mere declarations of opinion of the competent administration.

A comparative legal analysis of regulatory framework in both, the European Union and the United States of America, is carried out in the following areas of study.

- Applicant's lack of compliance with the legal schedule of guidelines and guidance
- Comprehensiveness of the evaluation dossier
- Setting up acceptable/ unacceptable levels of risk
- Evaluation of substantial equivalence.
- Review of compliance of guidelines and guidance with an OECD/FAO guidance

Companies operating into the market have an important degree of legal certainty in a framework of equivalent consistency. Nevertheless, compliance of the technical dossiers with statutory rules is advisable in both systems.

In general, procedures set up in the EU GMOs legislation are more stringent, in general terms than adopted by U.S. government agencies, where approaches such as "substantially equivalence" or the "early food safety evaluation of new proteins" allow applicants to supersede some steps of the evaluation process.

In any case, the legal certainty for applicants is similar in both systems.

Risk Analysis and GM Foods: Scientific Risk Assessment

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Modern biotechnology has been developed is the last four decades using several in vitro acid nucleic techniques beyond the taxonomic family that have produced a lot of discussions and controversies, and various decisions have taken place. In this paper the concepts of biosafety and food safety, the different components of the risk analysis framework and the comparative setting food safety standards, especially the scientific approaches used by international organizations (OECD and Codex Alimentarius), the European Union the United States of America and other countries respecting the food and feed derived from modern biotechnology are described. Some controversial cases are described. The regulation of the risk analysis, and the different interpretations of the precautionary principle are also described and discussed besides the disputes at the international food trade level.

I. Introduction

Modern biotechnology, also known as "recombinant DNA technology"[1] or "genetic engineering" arose in the 1970's when the first restriction enzymes were studied, leading to the development and use of genetically modified organisms (GMOs) for agriculture, food and feed supply, healthcare and other purposes. Modern biotechnology is defined according to Article 3 of the Cartagena Protocol on Biosafety of the Convention of Biological Diversity[2] as the application of: (i) in vitro nuclei acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into

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1 The recombinant DNA (deoxiribonucleic acid) methods are enabling the transfer of single genes from close or distant species, also allows the identification and potential removal of undesirable traits (e.g., potential removal of undesirable traits responsible of peanut allergy or celiac disease.

2 The Cartagena Protocol on Biosafety of the Convention on Biological Diversity, adopted in Montreal (Canada) on 29 January 2000. United Nations Environmental Program (UNEP) (http://www.cbd.int/biosafety/) (Last visited 02/24/09). Kinderlerer, J. and Adcock, M. Agricultural Biotechnology, Politics, Ethics, and Policy Sheffield Institute of Biotechnological Law and Ethics, University of Sheffield Working Paper No. 3.

cells or organelles, or (ii) fusion of cells beyond the taxonomic family[3], that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding selection.[4]

Genetically modified organisms or Living modified organisms (LMOs)[5] can be defined as organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating or natural recombination. As an application of modern biotechnology, this recombinant DNA technique allows transfer of simple genes from one organism into another, and also between non-related species (i.e. from close or distant species).

Biotechnology used to produce foods refers to those processes whereby foreign genes (transgenes) are transferred to micro-organism, plants or animals, or where the expression of existing genes is permanently modified, using the techniques of genetic engineering; foods produced through biotechnology are commonly termed GM foods or biotechnology-derived foods[6]. Life sciences and biotechnology are widely regarded as one of the most promising frontier technologies for the coming decades and they may be used for a wide range of purposes.[7]

On the basis of scientific knowledge on living systems, a continuous stream of new applications to biotechnology is in progress. Regarding the agro-food area, biotechnology was used in the first generation of so-called "GM" (genetically modified) crops to provide growers with complementary and sometime alternative crop management solutions to pesticides; selected host genes or genes identified from other plants or non-plant sources are modified or transferred to a crop plant.[8] The new or altered protein expression resulting from these modifications confers on the plant a desired physiological trait, such as resistance to particular herbicides or insect pests. Second generation of genetic modifications provides traits such as enhanced nutritional or health-promoting characteristics that are of benefit to consumers.[9]

Food and feed quality may be linked to disease prevention and reduced health risks. Foods with enhanced qualities ("functional foods")[10] are likely to become increasingly important as part of lifestyle and nutritional benefits (i.e. increased level of β-carotene, the most important provitamin A carotenoid[11] in Golden Rice 2 or increased content of stearic acid in corn and canola oils to make foods that are suitable for certain applications without the need for chemical hydrogenation and the production of trans fatty acids[12]). In addition, modern biotechnology is being used increasingly to improve food micro-organisms for the enhanced production of essential components or products, as well as the improvement of nutritional values, flavour, texture, and the self life of fermented foods.

Concerning the second generation of GMO, from 2001 to 2003, four companies planted corn and sugarcane that had been genetically modified to produce experimental pharmaceutical products. The companies modified the genetic structure of the corn or sugarcane so that, when harvested, the plants would contain hormones, vaccines, or proteins that could be used to treat human illnesses.

3 Codex Committee on Food Labeling. Draft Recommendations for the Labeling of Foods Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering. Halifax 2002.

4 The term "Living Modified Organism" is defined in the Cartagena Protocol on Biosafety of the Convention on Biological Diversity as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. The definitions of these terms contained in the Cartagena Protocol and used in many international fora are specific, and may not be exactly equivalent to common definitions of similar terms such as genetically modified organism (GMO).

5 Society of Toxicology Position Paper, The Safety of Foods Produced Through Biotechnology, 2000.

6 Anadón, A., Roda, L., Martínez-Larrañaga, M. R. and Martínez, M. A. (2005). Regulatory aspects on assessing the risks of genetically modified organisms (GMOs) in the EU. Regulatory Affairs Journal Pharma 16(4): 257–266.

7 Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions COM(2002) 27.

8 Trish Malarkey Human health concerns with GM crops. Mutation Research/Reviews in Mutation Research Volume 544, Issues 2–3, November 2003, Pages 217–221. Recuerda, M.A. (2006), Seguridad alimentaria y nuevos alimentos. Régimen jurídico-administrativo. Thomson-Aranzadi.

9 Ye, X., Al-Babili, S., Kloti, A., Zhang, J., Lucca, P., Beyer, P. and Potrykus, I. (2000). Engineering the provitamin A (beta-carotene) biosynthetic pathway into (carotenoid-free) rice endosperm. Science 287: 303–5.

10 Mazur, B., Krebbers, E. and Scott, T. (1999). Gene discovery and product development for grain quality traits. Plant Biotechnology: Food and Feed Science 285, 372–375.

11 Case: Center For Food Safety et al. vs. Johanns. CIV. NO. 03-00621 JMS/BMK. United States District Court For The District Of Hawaii. 451 F. Supp. 2d 1165; 2006 U.S. Dist. LEXIS 62981; 64 ERC (BNA) 1650. August 31, 2006, Decided. Cockburn, A. Assuring the safety of genetically modified (GM) foods: the importance of an holistic, integrative approach. Journal of Biotechnology Volume 98, Issue 1, 11 September 2002, Pages 79–106.

12 James, C. (2009). Global Status of Commercialized Biotech/GM Crops: 2008. International Service for the Acquisition of Agri-biotech Applications (ISAAA). (http://www.isaaa.org/resources/publications/briefs/39/executivesummary/default.html).

For example, one company engineered corn to produce experimental vaccines for the Human Immunodeficiency Virus and the Hepatitis B virus, while another company engineered corn and sugarcane to produce cancer-fighting agents.[13]

Regarding food derived from GM crop plants, the issues associated with applying traditional testing methodologies to conventional crops and whole food are added to in the case of GM crops by the presence of a novel component(s), the insert trait[14].

The world global area of biotech crops has continued to increase from the beginning of commercialization (1996 to 2008). In 2008, the global hectarage of biotech crops continued to grow strongly reaching 125 million hectares, up from 114.3 million hectares in 2007.[15] In the last year, GM crops have been cultivated in 25 countries (15 of them are developing countries), most of them in the USA, Argentina, Brazil, Canada, India, China and Paraguay. The most relevant planting biotechnology crops for food and feed supply mainly are maize, soybean, canola and cotton with the increasing use of two or more "stacked transformation events"[16] (for instance herbicide tolerance, insect resistant, virus resistant, increased nutritional characteristics or health benefits among others) which confer multiple benefits in a single biotech variety. More recently, productivity enhancing technologies, such as biotechnology, have the potential to make efficient biofuels crops a sustainable energy choice provided that sustainability criteria are implemented effectively and applied consistently without constraint on food supply.[17]

II. Biosafety versus Food Safety

The introduction of recombinant DNA technology in the early 1970s initiated the debate on the safety of the modern biotechnology and its products and remains prominent on the policy agenda. When the possibility of transferring genes among not-related organisms was already a fact, the Asilomar Conference, held on Recombinant DNA,[18] introduced the discussion on the potential biohazards and regulation of biotechnology.

For biotechnology applications to the environment and health fields, biosafety is defined as "the policies and procedures adopted to guarantee the sure application of the biotechnology in health and environment".

Foods, whether or not they are genetically engineered, carry potentially hazardous substances that must be assessed for safety. Unsafe food usually results from contamination due to biological, chemical or physical hazards. To ensure food safety, practicing good personal hygiene, maintaining a sanitary facility, preventing cross-contamination, have to be established.[19] The safety of genetically engineered foods takes in considerations the approaches to assess unintended health effects assisting the policy-makers in evaluating appropriate scientific methods requires detecting unintended changes in food and assessing the potential for adverse health effects from genetically engineered products that sometimes can increase the levels of the hazardous substances (e.g. celery, naturally produces psoralenes which can be elevated in genetically engineered celery).[20]

For both cases a structured risk analysis where the risk assessment must be based on the scientific knowledge and on harmonized protocols and methods for the scientific tests. Risk analysis in food is an approach made up of three components: Risk assessment, risk management and risk communication. This implies proceeding using "stepwise" and "case by case" approaches. During the risk analysis process, in the EU, the recourse to the Precautionary

13 Stacked events are defined as those combined by conventional breeding as indicated in the Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants containing stacked transformation events (Question No EFSA-Q-2003-005D) (The EFSA Journal 2007, 512, 1–5.

14 Cockerill, S and Martin, C. (2008). Are biofuels sustainable? The EU perspective, Biotechnology for Biofuels 1:9 (2008).

15 Berg, P., Baltimore, D., Brenner, S., Roblin III, R.O. and Singer, M.F. (1981). Summary statement of the Asilomar Conference on recombinant DNA molecules. Proceedings of the National Academy of Sciences 72 (6), 1981–1984.

16 Johnson County Environmental Department, Kansas Government, USA. http://jced.jocogov.org/food_safety/fp_definitions.htm); See, Recuerda, M. A. (2006) "Food Safety: Science, Politics and the Law". European Food and Feed Law Review, n. 1.

17 The National Academy of Sciences "Safety of Genetically Engineered Foods. Approaches to Assessing Unintended Health Effects" (2004).

18 Recuerda, M.A. (2008) "Dangerous Interpretations of the Precautionary Principle and the Foundational Values of the European Union Food Law: Risk versus Risk". Journal of Food Law & Policy, vol. 4, n. 1.

19 Rogers, M. Risk analysis under uncertainty, the Precautionary Principle, and the new EU chemicals strategy Regulatory Toxicology and Pharmacology. 37, Issue 3, June 2003, Pages 370–381.

20 Pan-European Conference on Food Safety and Quality (2003). General Principles of Food Law in the European Union.

Principle[21] has become relevant, which presupposes that potentially dangerous effects deriving from a phenomenon, product or process[22] have been identified. When faced with these circumstances, decision-makers must consider taking action, whether this is adopting legal measures or other appropriate actions, or even not to take action.[23]

Public opinion has become a major factor in the societal response to biotechnology. Politicians quote the public for increasingly restrictive legislation (or, as recently in Europe, *de facto moratoria* or approval deferral)[24], and too much credibility granted to Non-Governmental Organizations and media campaigns, disregarding both scientific opinion and the fact that real-life consumer behaviour is not as predicted by opinion polls (e.g. in the Netherlands).[25]

III. Risk analysis framework

International consensus has been reached on the main principles regarding food safety assessment of GMOs, particularly the genetically modified plants and derived food and feed. The concept of *substantial equivalence* has been developed as part of a safety evaluation framework, based on the idea that existing foods can serve as a basis for comparing the properties of genetically modified foods (GM foods) with the appropriate counterpart or comparator.[26] Nevertheless, there has not been a universal consensus on the application of this concept and an alternative approach is advisable.[27]

From the early 90s the Codex Alimentarius Commission (FAO/WHO) has developed safety standards, guidelines or recommendations, as appropriate, for foods derived from biotechnologies or traits introduced into foods by biotechnological methods. These two international bodies have played a leading role in the development of food safety risk analysis and for the application of risk analysis to food standard issues.[28]

Risk analysis is comprised of a structured decision-making process which consists of three basic components: risk assessment, risk management, and risk communication.[29] Risk assessment includes a safety assessment, which is designed to identify whether a hazard, nutritional or other safety concern (i.e. its nature and severity) is present. This assessment should include a comparison between the food derived from modern technology and its conventional counterpart focusing on determination of similarities and differences. The risk associated should be characterized to determine its relevance to human health. A safety assessment is characterized by an assessment of a whole food or a component thereof relative to the appropriate conventional counterpart[30]: (i) taking into account both intended[31] and unintended[32] effects; (ii) iden-

21 Cantley M. How should public policy respond to the challenges of modern biotechnology? Current Opinion in Biotechnology. 15, 3, June 2004, p. 258–263, Recuerda, M.A. (2008), op. cit.

22 Marks, L., Kalaitzandonakes, N. and Vickner, S.S. (2004). Consumer purchasing behavior towards GM foods in the Netherlands. In Consumer Acceptance of Biotechnology Foods. Edited by Evenson R.D., and Santaniello, V., Wallingford UK, CABI Publishers Ltd., pp. 23–39.

23 Kuiper, H., Kleter, G, Noteborn, H and Kok, E. (2001). Assessment of the food safety issues related to genetically modified foods. The Plant Journal 27(6), 503–528.

24 Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology: Safety aspects of genetically modified foods of plant origin. Geneva, 2000.

25 Department of Food Safety, Zoonoses and Foodborne Diseases. WORLD HEALTH ORGANIZATION. Modern food biotechnology, human health and development: an evidence-based study. Geneva. 2005.

26 FAO/WHO (2006). Food Safety Risk Analysis. A Guide for Food Safety Authorities.

27 Codex Alimentarius: Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44–203.

28 Codex Alimentarius: Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA microorganisms CAC/GL 46–2003: intended effects are those that are targeted to occur from the introduction of the gene(s) in question and which fulfill the original objectives of the genetic modification process. Alterations in the phenotype may be identified through a comparative analysis of growth performance, yield, disease resistance, etc. (Updated guidance document for the risk assessment of genetically modified plants and derived food and feed, EFSA draft document for consultation adopted in May 2008).

29 Unintended effects are considered to be consistent differences between the GM plant and its appropriate non-GM comparator(s), which go beyond the primary intended effect(s) of introducing the target gene(s). Unintended effect(s) could potentially be linked to genetic rearrangements or metabolic perturbations (Updated guidance document for the risk assessment of genetically modified plants and derived food and feed, EFSA draft document for consultation adopted in May 2008).

30 South Asia Biosafety Program Foods Derived from Genetically Modified Crops: Issues for Consumers, Regulators and Scientists 2005.

31 These decisions include the Statements of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account and the Statements of principles relating to the role of food safety risk assessment (Codex Alimentarius Commission Procedural Manual; Thirteenth edition).

32 Vid. Recuerda, M. A. (2008), op.cit.

tifying new or altered hazards; and (iii) identifying changes, relevant to human health, in key nutrients.

The risk analysis approach can be applied to foods derived from modern biotechnology. However, it is recognized that this approach must be modified when applied to a whole food rather that a discrete hazard that may be present in food. The risk analysis approach for these foods is based on a consideration of science-based multidisciplinary data and information taking into account the factors considered by the Codex Alimentarius Commission.[33]

Scientific data for risk assessment are generally obtained from a variety of sources such as the patent holder of the product, scientific literature, general technical information, independent scientists, regulatory agencies, international bodies and other interested parties.

It is generally accepted that risk management measures for foods derived from modern biotechnology should be proportional to the risk and based on the outcome of the risk assessment and, where relevant, taking into account other legitimate factors in accordance with the general decision of the Codex Alimentarius Commission[34] as well as the Codex Working Principles for Risk Analysis. Risk managers should take into account the uncertainties identified in the risk assessment and implemented appropriate measures to manage these uncertainties. Finally, risk management measures cover appropriate food labelling and post-market monitoring (i.e., to verify the impact and significance of potential consumer health effects, and monitoring changes in nutrient intake levels associated with the introduction of foods likely to significantly alter nutrition status to determine their human health impact).

Risk communication is essential at all phases of risk assessment and risk management. It is known as an interactive process involving all interested parties, including government, industry, academia, media and consumers. This part of risk analysis should include transparent safety assessment and risk management decision-making processes.

Many countries have adopted specific legislation on biosafety and food safety to regulate the use of GMO in agriculture, food and feed, health or the environment, which puts into place the authorization procedures and the risk analysis methodologies. In some cases these regulations show significant differences in the consent procedures for the GMOs. In the case of GMOs it is necessary to examine how the different legal perspective determines the decision making for the final authorization of the product. International trade agreements developed under the World Trade Organization (WTO) emphasize the need for regulations governing international trade in foods to be based on science and risk assessment and not always seem to be the case.

Additionally, the more or less restrictive approach of the "Precautionary Principle[35] application" in different countries or international organisations is also a major source of scientific and legal uncertainty, and all these divergences are leading to asynchronous authorizations of GMOs with an obvious economic impact for the exporter countries. The *Codex Alimentarius* Commission is trying to find a consensus resolution of this matter.

IV. Safety principles and standards of International Organizations for GMOs

The first debates with regard to the safety of the uses of GMOs took place in the middle of the 80s. These discussions led to proactive approaches to evaluate the GMOs by the governments, scientists and other stakeholders. The publication of the OECD "Blue Book" on "DNA Recombinant Biosafety Considerations"[36] was an important synthesis of these approaches, being the first intergovernmental document orientated to the health and environmental safety. These guidelines have been the basis for other international regulations and standards (i.e. the EU and US biosafety legislation, the Codex Alimentarius Guidelines or the Cartagena Protocol on Biosafety). For OECD the risk/safety analysis comprises the hazard identification and, if a hazard has been identified, the risk assessment.

33 OECD (1986). Recombinant DNA Safety Considerations. [http://www.oecd.org/dataoecd/45/54/1943773.pdf].

34 OECD (1993). Safety Considerations for Biotechnology: Scale-up of Crop Plants. (http://www.oecd.org/dataoecd/26/26/ 1958527.pdf).

35 Bergkamp, L. "Biotech Food and the Precautionary Principle under EU and WTO Law", SSRN, Working Papers; Bratspies, R., "The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops", SSRN, Working Papers.

36 Means a related organism/variety, its component and/or products for which there is experience of establishing safety based on common use as food (Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44–2003).

The OECD in 1993 developed the concept of "familiarity" in the risk assessment and management for GM crops. Familiarity comes from the knowledge and experience available for conducting a risk/safety analysis prior to scale-up of any new plant line or crop cultivar in a particular environment. Familiarity takes account of but need not be restricted to knowledge and experience with the crop plant.[37] Familiarity with the crop plant, environment, trait and interactions, does not determine whether the new combination is either safe or risky. The familiarity can be described with the crop plants, environment, trait, and interactions.

The "familiarity" concept relates to the fact that the more familiar we are with something, the more capable we are of accurately assessing and managing any potential risks its use might pose. This concept, already used for biosafety, could logically be extended for assessing food safety. In this respect, the *Codex Alimentarius* approached this issue as well.

Also in 1993 the OECD formulated the concept of "substantial equivalence"[38] as the starting point for safety assessment based on the comparison between the GMO and its closed traditional counterpart[39] as indicated previously. The idea is that if a new food or food component can be demonstrated to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety.

The "*Ad hoc* Intergovernmental Task force on Foods Derived from Modern Biotechnology" was established by the Codex Alimentarius Commission to elaborate standards, guidelines, or recommendations, as appropriate, for foods derived from modern biotechnology or traits introduced into foods by modern biotechnology, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and the promotion of fair practice in the food trade. The Principles for the Risk Analysis of Foods derived from Modern Biotechnology were developed with the "substantial equivalence" concept as well as a guiding tool to the process of risk assessment.

The Codex principles determine that risk assessment includes a safety assessment, which is carried out to identify whether a hazard, nutritional or other safety concern is present, and if present, to gather information on its nature and severity. The safety assessment should include a comparison between the food derived from modern biotechnology and its conventional counterpart focusing on determination of similarities and differences and may include additional toxicological and nutritional testing if a new or altered hazard, nutritional or other safety concern is identified by the safety assessment, the risk associated with it should be characterized to determine its relevance to human health.

The safety assessment of a whole food or a component thereof relative to the appropriate conventional counterpart should be undertaken on a case-by-case basis, and founded on sound science, taking into account both intended and unintended effects; identifying new or altered hazards and changes in key nutrients, relevant to human health. As soon as the risk is identified it must be well characterized to determine its relevance to human health.

Under the stepwise process of addressing relevant factors for human health has to be tackled: the description of the Recombinant-DNA plant, the host plant and its use as food; the donor organisms, the genetic modification; the characterization of the genetic modification and the safety assessment which includes the evaluation of the expressed substances (including the toxicological and allergic effects), the compositional analysis of the key components, the evaluation of metabolites, the food processing, the nutritional modification and other considerations, if any (i.e. use of antibiotic resistance marker genes).

Although the substantial equivalence concept is an important component of the GM food safety evaluation, nevertheless, it is not a safety assessment in itself; rather it represents the starting point. In fact, it has been subject to a lot of criticism from various sectors and a part of scientific community. Even the *Codex Alimentarius* Commission is looking at different ways of developing and applying the concept of substantial equivalence and reviewing other methods for science-based risk assessment. Nowadays, it is considered that the safety assessment carried out in this way does not imply absolute safety of the new product; rather, it focuses on assessing the safety of any identified dif-

37 Report of the Seventh Session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (Chiba, Japan, 24-28, September 2007). Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission, 31st Session Geneva, Switzerland, 30 June–5 July 2008.

38 OJ No L 330, 5.12.1998.

39 OJ No L 106, 17.4.2001.

ferences so that the safety of the new product can be further considered relative to its conventional counterpart.[40]

V. Risk assessment methodology for GMOs in the European Union

Wide and diverse biosafety legislation on genetically modified organisms is being applied in the EU. The risk assessment for the environment and human health for deliberate releases at the research stage remain under the horizontal directives (Directive 90/219/EEC, amended by Directive 98/81/EC[41] on contained use of genetically modified organisms and Directive 2001/18/EC on the deliberate release of genetically modified organisms[42]). For the placing on the market of genetically modified products the EU specific legislation ("vertical") for different sectors is applied.

In 1997 the Regulation (EC) No 258/97 on novel foods and novel food ingredients came into force in the European Union[43]. This regulation also refered to products derived from GMOs. The concept of substantial equivalence was fully endorsed in the European approach at this stage.

In 2003, the Scientific Steering Committee by The Joint Working Group on Novel Foods and GMOs44 stated that the outcome of this comparative approach should go further. Analysis of substantial equivalence involves not only a comparison of the chemical composition between the new and the traditional food or feed, but also of the molecular, agronomical and morphological characteristics of the organism in question. Such comparisons should be made with GM and non-GM counterparts grown under the same regimes and environments. When the degree of equivalence is established as substantial, a greater emphasis is placed on the newly introduced trait(s), while where substantial equivalence does not occur; this does not necessarily identify a hazard. Where a trait or traits are introduced with the intention of modifying composition significantly and where the degree of equivalence cannot be considered substantial, then the safety assessment of characteristics other than those derived from the introduced trait(s) becomes of greater importance.

Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003, on genetically modified food and feed[45] puts in place a centralized and transparent consent procedure ("one door-one key") for all GM food and feed applications for placing on the market, whether they concern the GMO itself or the food and feed products derived there from and sets out rules for labelling of foods and feeds enables the consumer to make an informed choice and facilitates transactions between seller and purchaser. It draws from Regulation (CE) No 178/2002[46], which establishes the general principles and requirements of food legislation, and also by which the European Food Safety Authority (EFSA) has been created.[47]

Like any food, genetically modified or other novel foods are complex mixtures of thousands of different substances in varying proportions. With trusted foods that have been eaten for generations there is little concern and they are considered safe based on experience, not necessarily based on scientific proof. For novel or GM foods, proving safety is a legal obligation.

Regarding GM foods and feeds, EFSA (2004) has developed guidance for the risk assessment for GM plants[48] and GM microorganisms[49] and derived food and feed. The main issues that have to be con-

40 Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ. No L 43, 14.2.1997).

41 European Commission (2003). Risk assessment of genetically modified plants and derived food and feed. Prepared for the Scientific Steering Committee by The Joint Working Group on Novel Foods and GMOs.

42 OJ No L 268, 18.10.2003.

43 OJ No L 31, 1.2.2002, see Recuerda, M.A. (2009), "Autorizaciones administrativas y presumción de riesgo en el Derecho alimentario europeo: el caso de los nuevos alimentos". Revista Española de Derecho Europeo, 31.

44 Van der Meulen, B. (2007). The EU Regulatory Approach to GM Foods. Kansas Journal of Law & Public Policy 14 (3).

45 EFSA (2004) Guidance Document on the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed. EFSA Journal 99:1–94 (2004)

46 EFSA (2006). Guidance Document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Microorganisms and their Derived Products Intended For Food and Feed Use (Question No EFSA-Q-2003-005B). Adopted on 17 May 2006.

47 Society of Toxicology (2003). Position Paper, The safety of genetically modified foods produced through biotechnology. Toxicological Sciences 71, 2–8.

48 See GMO-Compass Organization Report: Evaluating Safety: A Major Undertaking.

49 Cockburn, A. (2002). Assuring the safety of genetically modified (GM) foods: The importance of a holistic, integrative approach. Journal of Biotechnology 98, 79–106.

sidered in the risk assessment are the following: the characteristics of the donor and recipient organisms; the genes inserted and expressed; the potential consequences of the genetic modification; the potential environmental impact following a deliberate release; the potential toxicity and allergenicity of gene products and metabolites; the compositional, nutritional, safety and agronomic characteristics; the influence of food processing on the properties of the food or feed; the potential for changes in dietary intake and the potential for long-term nutritional impact. The stepwise approach used take into account the hazard identification, the exposure assessment and the risk characterization. For GM foods, the U.S. Society of Toxicology (2003)[50] underlined the key issues respecting to human health effects: Is the transgene itself toxic? Can it be transferred to the genome of a consumer? Does the product encoded by the transgene present a risk to consumers or handlers? (e.g. production of toxins and allergens), will insertion of the transgene increase the potential hazard from toxins or pharmaceutically active substances present in the host? does the possible transfer of antibiotic resistance marker genes from the ingested GM food to gut microbes present a significant human hazard? will genetic transformation adversely affect the nutritional value of the host? will the transgene product adversely affect non-target organisms?

Different outcomes of a genetic transformation event can be envisaged: 1) the intended effects are those that are targeted to occur from the introduction of the gene(s) and which fulfils the original objectives of the genetic transformation process.; and 2) the unintended effects are considered to be consistent differences between the GM plant and its appropriate control lines, which go beyond the primary expected effect(s) of introducing the target gene(s). These can often be predicted knowing in depth derived food and feed biology and metabolic pathway integration and interconnectivities. Additionally, molecular and biochemical analyses can be used to determine changes at the level of transcription and translation that could lead to unintended effects. For instance, a new gene can interact with existing genes and could deactivate an existing gene, thereby causing shifts in a plant's metabolism. In certain cases, this kind of change could potentially impact human health.[51]

The analytical comparison to assess whether or not a GM food product is "substantially equivalent" to a product that is already on the market is, at the same time, the basis for both toxicological and nutritional assessments. Additional *in vivo* experiments are deemed necessary to have sufficient knowledge on the nutritional characteristics of the GM food, for example, the energy content, protein content, and bioavailability of micronutrients. The highest test dosage should be the maximum amount of GM food product that can be included in a balanced animal diet, while the lowest test dosage should be comparable to the expected amount in the human diet. If desirable safety factors cannot be achieved in this way, additional investigations on metabolism of the GM food in animals, and eventually humans, are required. The exposure assessment should include specific vulnerable consumer groups and consider also inter-individual variation. For the nutritional assessment, it may be necessary in some cases to set up post-launch monitoring programmes (surveillance). Post-launch monitoring has now been called for concerning the revised Directive 2001/18/EC. The two possibilities are either through epidemiological studies, for which there are several possible approaches, or by randomized controlled clinical trials.[52]

The EU will include also in the comparative approach for the risk assessment of GM plants the concept of familiarity, already described and based on the OCDE document on Safety considerations for biotechnology: Scale-up of crop plants.

Regarding the safety of the novel GM trait, when a new gene is introduced into a plant, the general outcome is the formation of a new protein and these proteins are oftentimes new for human consumption. Only in the case of newly expressed proteins with an insufficient database and, in particular, if the available data suggest the existence of any cause for concern, specific toxicity studies should be carried out. The safety of a particular protein regarding toxicity is assessed using animal feeding tests like it is done for food additives or food con-

50 OECD (1995). OECD Guidelines for the Testing of Chemicals. Test No. 407: Repeated Dose 28-day Oral Toxicity Study in Rodents (adopted 27th July 1995).

51 Society of Toxicology Position Paper (2003).The Safety of Genetically Modified Foods Produced through Biotechnology. Toxicological Sciences 71, 2–8.

52 Codex Alimentarius (2003). Codex Guideline for the Conduct of Food Safety Assessment of Food Derived from Recombinant-DNA Plants (CAC/GL 45–2003).

taminants. Normally a 28-day oral toxicity study with the newly expressed protein in rodents should be performed according to OECD guideline 407.[53] Depending on the outcome of the 28-days toxicity study, additional targeted investigations may be required, including an analysis of immunotoxicity.

The potential toxicity of the transgene product must be considered on a case-by-case basis. Particular attention must be paid if the transgene produces a known toxin (such as the *Bacillus thuringiensis* [Bt] endotoxins)[54] or a protein with allergic properties. The level of risk of these gene products to consumers and those involved if food production can be and is evaluated by standard toxicological methods. Allergenicity is one of the major concerns about food derived from transgenic crops. Allergenicity is not an intrinsic, fully predictable property of a given protein but is a biological activity requiring an interaction with individuals with a pre-disposed genetic background. Given this lack of complete predictability it is necessary to follow an integrated, stepwise; case-by-case approach that should be used in the assessment of possible allergenicity of newly expressed proteins in line with the recommendations of the Codex Alimentarius[55]. Regarding the polemic case of the "StarLink yellow corn" (GM corn that expressed the Cry9C protein which confers insect resistance) approved for animal feed in the US, and in which were found homologous sequences shared with human allergens, finally was not approved by the US Environmental Protection Agency (EPA) for human health[56] and served to orientate further needs of methodological research on this issue.[57]

The most important tests, under a decision-tree evaluation, are the degree of structural similarity to other allergens; stability of the protein during digestion; tests with blood from individuals who are sensitive to allergies and animal tests. Testing strategies for allergens and protein allergy research are still evolving. These approaches outlined above, when used in combination and with the following knowledge, allow scientists to assess potential allergenicity: protein identity, protein source, previous dietary exposure and effects of processing/cooking.[58] In the cases of homologies in the sequence comparison between the new gene and other allergens it is recognized that the FAO/WHO suggested moving from 8 to 6 identical amino acid segment searches, meanwhile EFSA can accept the comparison of 8 amino acids.[59] Some EU countries support the FAO/WHO approach and this issue triggers misunderstanding between EFSA and these countries. Also, the polemic case of the "Starlink yellow maize in USA which raised the concern of potential allergenicity of a GM food for humans, though there was no conclusive confirmation of their possible allergenicity served to orientate further needs of methodological research on this issue.

To establish the safety of new constituents other than proteins, information as to that described in the "Guidance on submissions for food additive evaluations by the Scientific Committee on Foods"[60] and Directive 2001/79/EC[61] is needed. This implies the submission of information on a core set of studies which include information on metabolism (toxicokinetics, sub-chronic toxicity, genotoxicity, chronic toxicity); carcinogenicity and reproduction and developmental toxicity.

In relation to unintended effects or unforeseen changes in plant metabolism as a result of gene transfer, two types of tests are carried out: an analy-

53 Agra Marke, Inc., vs. Aventis Cropscience Usa Lp, and Starlink Logistics, Inc. No. 03 C 4385, MDL No. 1403. United States District Court for the Northern District Of Illinois, Eastern Division, 2005 U.S. Dist. LEXIS 5556, February 8, 2005.

54 Kiera, L.D., Petrickb, J.S (2008). Safety assessment considerations for food and feed derived from plants with genetic modifications that modulate endogenous gene expression and pathways. Food and Chemical Toxicology 46, 8.

55 Malarkey, T. (2003). Human health concerns with GM crops. Mutation Research 544 (2003), 217-221.

56 The smaller the peptide sequence used in the stepwise comparison, the greater the likelihood of identifying false positives. Conversely, the larger the peptide sequence used the greater the likelihood of false negatives, thereby reducing the utility of the comparison.

57 Opinion of the Scientific Committee on Food (SCF) (2001). Guidance on submissions for food additive evaluations. SCF/CS/ADD/GEN/26 Final, 12 July 2001, Brussels. (http://europa.eu.int/comm/food/fs/sc/scf/out98_en.pdf).

58 Commission Directive 2001/79/EC, of 17 September 2001, amending Council Directive 87/153/EEC fixing guidelines for the assessment of additives in animal nutrition (OJ N 267, 2.10.2001).

59 OECD guidelines for the testing of chemicals. OECD, Paris. (http://www.oecd.org/document/13/0,2340,en_2649_34377_2740429_1_1_1_1,00.html).

60 EC (2002). Policy areas: the directive on dangerous substances. European Commission 2002, Brussels. (http://europa.eu.int/comm/environment/dansub/home_en.htm).

61 EC (2004). Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances. OJ L 50: 44–59.(http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_050/l_05020040220en00440059.pdf).

sis of the most important chemical components of the GM plant and animal feeding trials.

Nutritional value and vitamin content are measured along with levels of toxins that occur naturally in some foods. A potential increase in toxin content to unsafe levels has to be thoroughly investigated (i.e. significant differences in composition are expected to be observed in the case of nutritionally enhanced crops and must be assessed on a case-by-case basis).

The toxicological assays more commonly carried out with these products are acute and repeated dose toxicity tests (subacute and subchronic toxicity). The 90-day feeding studies using rodents is generally considered to be appropriate to demonstrate the safety of repeated consumption of a foodstuff in the diet. The highest dose level used in any animal study should be the maximum achievable without causing nutritional imbalance while the lowest level used should be comparable to the anticipated human intake. The need for additional toxicological tests should be considered from case to case taking into account the results of the 90-day study and other studies. Nowadays, some competent authorities in the EU are requesting that the chronic toxicity test should be also carried out. Those toxicological studies which are carried out should be conducted using internationally agreed protocols. Test methods described by the OECD[62] or in the most up-to-date European Commission Directives on dangerous substances are recommended[63]. Use of any methods that differ from such protocols should be justified. Studies should be carried out according to the principles of Good Laboratory Practice (GLP) described in Council Directive 2004/10/EC[64] and be accompanied by a statement of GLP-compliance. However, it has been pointed out that animal feeding trials for safety and nutritional testing of GM plants modified for nutritional or health benefits should be more elaborated. It is known that the uptake and metabolism may still show differences between species and between humans and animals (e.g. animal models for beta-carotene).

In feeding tests, the whole food is fed to animals such as rats or chickens over an extended period of time (e.g. for nutritional studies a 42-day boiler chicken study). It is anticipated that any dangerous "side effects" of the GM food would be made noticeable by changes affecting, for instance, the animal's immune system or its internal organs. Toxicological assessments on test animals which are not explicitly required for the approval of a new food in the US, nonetheless, are routinely presented to the European safety assessment authorities. In recent years, biotech companies have tested their transgenic products (maize, soybean, tomato) before introducing them to the market on several different animals over the course of up to 90 days and significant negative effects have not yet been observed.

However, in the EU, after some scientific uncertainties raised with whole-food toxicology tests (i.e. MON 863 maize), procedures moved towards more extensive and rigorous test methods for assessing GM food safety, in part caused by the politicization of science and EFSA's safety claims started being criticized. To address this conflict, in April 2006 the Commission invited EFSA to clarify which specific protocols should be used by applicants to carry out scientific studies demonstrating safety (e.g. toxicology tests). In September 2007, EFSA published a document on the role of animal feeding trials in the safety and nutritional assessment of GM plants and derived food and feed.[65]

In 2004 the GMO Panel of the ESFA gave its opinion on the safety of MON 863 maize for import and

62 EFSA (2007). Scientific Panel on Genetically Modified Organisms. Safety and nutritional assessment of GM plants and derived food and feed: The role of animal feeding trials Report of the EFSA (2008). GMO Panel Working Group on Animal Feeding Trials. Food and Chemical Toxicology 46, 2–70.

63 EFSA, 2004a. Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference C/DE/02/9) for the placing on the market of insect-protected genetically modified maize MON 863 and MON 863 x MON 810, for import and processing, under Part C of Directive 2001/18/EC from Monsanto. The EFSA Journal, 49, 1-25. (http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_opinions/381.Par.0001.File.dat/opinion_gmo_06_en1. pdf). EFSA, 2004b. Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the safety of foods and food ingredients derived from insect-protected genetically modified maize MON 863 and MON 863 x MON 810, for which a request for placing on the market was submitted under Article 4 of the Novel Food Regulation (EC) No 258/97 by Monsanto. The EFSA Journal, 50, 1–25. (http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_opinions/383.Par.0001.File.dat/opinion_gmo_07_en1.pdf).

64 EFSA, 2004c. Statement of the Scientific Panel on Genetically Modified Organisms on the evaluation of the 13-week rat feeding study on MON 863 maize, submitted by the German authorities to the European Commission. (http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/statements/666.Par.0001.File.dat/sr_gmo01_statement_study_MON 863_en1.pdf).

65 Hammond, B.G., Dudek, R., Lemen, J.K., Nemeth, M.A., 2006. Results of a 90-day safety assurance study with rats fed grain from corn borer-protected corn. Food Chem. Toxicol., 44, 1092–1099.

processing, food and feed uses[66] and released a statement on the same topic shortly after.[67] In these documents it was concluded that the MON 863 maize would not have an adverse effect on human and animal health or the environment in the context of its proposed use. Since then, two scientific papers dealing with a 90-day (subchronic) feeding study in rats using kernels of MON 863 maize have been published.

Hammond et al. (2006)[68] described the study and its outcomes, but in less detail than the original report provided by Monsanto (2002)[69]. Séralini et al. (2007)[70] published a statistical re-analysis of the original data from Monsanto. In their study applied certain statistical methods in the analysis of growth curves, and concluded that rats fed kernels from MON 863 maize showed slight but dose-related significant variations in growth for both genders. Moreover biochemical measurements of hematological, clinical-chemistry, urinalysis and histopathological parameters and of organ weights revealed a large number of statistically significant differences. Some of these differences, according to the authors, are indicative for hepato and/or renal toxicity. They concluded that "with the present data it cannot be concluded that GM corn MON 863 is a safe product".

The European Commission asked EFSA in March 2007 to consider, in cooperation with the Member States, what impact the re-analysis might have on the earlier opinions and statement of the EFSA GMO Panel. In response to the question EFSA set up a Task Force to assess the statistical methodology applied by Séralini *et al.* (2007), and to perform an additional statistical analysis. The GMO Panel considered, in contrast to Séralini *et al.* (2007), the biological relevance of all statistically significant differences in test parameters identified between the GM fed animals and their respective non-GM near-isogenic controls, which is a crucial element in risk assessment. To this end, natural variability in test parameters have been taken into account, as estimated from data obtained from animals fed several commercial maize varieties. Given the fact that deviations in test parameters were relatively small and for the greatest part within natural variation ranges, the GMO Panel did not consider these effects as biologically relevant.

The outcome of the "Task Force" analysis[71] indicated that in the absence of any indications that the observed differences in test parameters were indicative of adverse effects, the GMO Panel did not consider that the publication by Séralini *et al.* (2007) raised new issues which are toxicologically relevant. Therefore, the GMO Panel did not see reason to revise its previous opinion that the MON 863 maize would not have an adverse effect on human and animal health or the environment in the context of its proposed use.

The GMO Panel was aware of the fact that different approaches are applied in the statistical analysis of data obtained from animal experiments and pointed out the need for a harmonized approach in this area. A working group of the Panel is currently addressing this issue.

Another critic issue which has to be assessed is the horizontal gene transfer from GM plants to bacteria. The potential impact due to the risk of gene transfer and subsequent integration and expression of the gene insertion may be enhanced by the presence of bacterial sequences within the GM plant insert DNA (*e.g.* presence of replication origins or genes/sequences that might enhance homologous recombination). During the process of genetic modification of plants and other organisms, marker genes are normally used to facilitate the selection and identification of genetically modified cells, among the vast majority of untransformed cells. The most commonly used marker genes are those that encode for resistance to herbicides and antibiotics. Safety assessment must include a considera-

66 Monsanto, 2002. 13-Week Dietary Subchronic Comparison Study with MON 863 Corn in Rats Preceded by a 1-Week Baseline Food Consumption Determination with PMI Certified Rodent Diet #5002. (http://www.monsanto.com/monsanto/content/products/ technicalandsafety/fullratstudy.pdf).

67 Séralini, G.E., Cellier, D., de Vendomois, J.,S., 2007. New analysis of a rat feeding study with genetically modified maize reveals signs of hepatorenal toxicity. Arch. Environ. Contam. Toxicol., 52, 596–602.

68 EFSA, 2007. EFSA review of statistical analyses conducted for the assessment of the MON 863 90-day rat feeding study. (http://www.efsa.europa.eu/en/science/scientific_reports/statistical_analyses_MON863.html).

69 Anadón, A., Roda, L. Martínez-Larrañaga, M. R. and Martínez, M. A. (2005). Regulatory aspects on assessing the risks of genetically modified organisms (GMOs) in the EU. Regulatory Affairs Journal Pharma 16(4), 257–266.

70 Kresken, M., Hafner, D., and von Rosentiel, N. (1999). Zeitliche Entwicklung der Antibiotikaresistenz bei klinisch wichtigen Bakterienspezies in Mitteleuropa. Bundesgesundheitsblatt 42, 17–25.

71 EFSA (2004). Opinion of the Scientific Panel on Genetically Modified Organisms on the use of antibiotic resistance genes as marker genes in genetically modified plants (Question N° EFSA-Q-2003-109). The EFSA Journal, 48, 1–18.

tion of the potential for horizontal gene transfer, particular concerns have been raised over the use of antibiotic resistance marker genes (ARMGs) (such genes come from bacteria), and the potential for increased resistance to antibiotics in humans and animals. During the risk assessment the potential gene transfer from micro-organisms residing in the gastro-intestinal tract of humans and animals has to be focused[72]. With the pre-existing levels of resistance, even in the extremely remote situation of horizontal gene transfer of ampicillin or kanamycin resistance genes, it would not add significantly to the current high frequency of resistant bacteria in humans and animals[73].

The GMO Panel of EFSA has evaluated the potential risks associated with specific ARMGs taking into account their current usage in human and veterinary medicine, the likely occurrence of horizontal gene transfer from GM plants to microbes and the potential impact of horizontal gene transfer where naturally occurring resistance to the relevant antibiotics exists in the microbial gene pool.[74] These factors will impact on the likelihood of any adverse effects on humans or the environment of ARMGs used in GM plants.

The GMO Panel considers the frequency of horizontal gene transfer from GM plants to other organisms as very low for all ARMGs considered. However, with respect to clinical importance the Panel has categorized ARMGs into three groups with different potentials for compromising human health and the environment. ARMGs in the first group include genes conferring resistance to kanamycin and hygromycin. In this group the *npt*II gene, which confers kanamycin resistance, has a 13-year history of safe use in food crops and resistance to this group of antibiotics is widespread in naturally occurring microbes in humans and the environment. The Panel is of the opinion that with regard to safety there is no rationale for inhibiting or restricting the use of genes in this category, either for field experimentation or for the purpose of placing on the market. The second group of ARMGs, which includes resistance to chloramphenicol, ampicillin, streptomycin and spectinomycin, should be restricted to field trial purposes and should not be present in GM plants to be placed on the market. Given their current importance in clinical usage, the GMO Panel recommends that ARMGs placed in the third group, which includes those conferring resistance to amikacin and tetracyclines, are not present in GM plants to be placed on the market or in plants used for experimental field trials.

Nonetheless, afterwards a WHO working group made a classification of aminoglycosides (antibiotics for which the *npt*II gene confers resistance) as critically important antibacterials).[75] Then the European Commission sought confirmation from the European Medicines Agency (EMEA) as to whether the current or possible future uses of these antibiotics are still in line with the earlier EFSA opinion.

In response to the Commission's request, the EMEA indicated that aminoglycosides comprise a class of antibiotics that has become increasingly important in the prevention and treatment of serious invasive bacterial infections in humans, since Gram-negative bacteria (and tuberculosis bacteria) are becoming resistant to other classes of antibiotics.[76] The EMEA also stressed that, although kanamycin and neomycin are used relatively infrequently, the potential development of new chemical entities similar to kanamycin and neomycin should also be taken into account and, in addition, aminoglycosides as a group are a class of antibiotics critically important for veterinary medicine.

The EMEA considered that its competence did not extend to a detailed consideration of the likelihood of gene transfer of antibiotic resistance genes from plant material to bacteria of man and animals and derived food and feed.

Finally, the GMO Panel agreed with the EMEA that the preservation of the therapeutic potential of the aminoglycoside group of antibiotics is impor-

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72 WHO (2005). Critically Important Antibacterial Agents for Human Medicine for Risk Management Strategies of Non-Human Use. Report of a WHO working group consultation, 15–18 February 2005, Canberra, Australia, World Health Organization.(http://www.who.int/foodborne_disease/resistance/FBD_CanberraAntibacterial_FEB2005.pdf.).

73 EMEA (2007). Presence of the antibiotic resistance marker gene nptII in GM plants for food and feed uses. Committee for Medicinal Products for Veterinary Use and Committee for Medicinal Products for Human Use, 22 February 2007 (ref. EMEA/CVMP/56937/2007-Final).

74 FDA (1992). Statement of policy: foods derived from new plant varieties. Federal Register 57, 22984-23005 (May 29, 1992). (http://vm.cfsan.fda.gov/~lrd/bio1992.html).

75 Office of Science and Technology Police (OSTP), 1986. Coordinated framework for regulation of biotechnology. Federal Register 51, 23303.

76 MacKenzie, D.J. (2002). International Comparison of Regulatory Frameworks for Food Products of Biotechnology. Canadian Biotechnology Advisory Committee, Project Steering Committee on the Regulation of Genetically Modified Foods. (http://www.agbios.com/articles/2000350-A.pdf.).

tant and that the therapeutic effect of these antibiotics will not be compromised by the presence of the *npt*II gene in GM plants, given the extremely low probability of gene transfer from plants to bacteria and its subsequent expression. Furthermore, the GMO Panel considered it very unlikely that the presence of the *npt*II gene in GM plants will change the existing widespread prevalence of this antibiotic resistance gene in bacterial sources in the environment. Therefore, the GMO Panel reiterated its earlier conclusions in 2004, that the use of the *npt*II gene as selectable marker in GM plants (and derived food or feed) does not pose a risk to human or animal health or to the environment.

VI. Food safety risk assessment in other Countries

The regulatory frameworks in other countries differ from nation to nation. In Canada and the USA), the regulation of genetically modified (GM) crops, livestock feeds and human foods, shares many similarities: both countries have a coordinated approach whereby regulatory responsibility is shared by several agencies; risk assessments are based on sound science; and each regulated product (sectorial legislation) is assessed on a case-by-case basis under different specific regulation and depending on the scope of application.

In these two countries, their regulations consider genetically modified foods as a novel foods but not a separate entity with respect to other foods. Rather, the focus is on the altered characteristics brought about by genetic modification, and the intended use of the novel crop.[77]

As the basis of their risk assessment process is the principle of substantial equivalence as well. GM foods or plants shall be compared with traditional counterparts that have an established history of safe use, and that this comparison can be based on the evaluation for both of the same types of risk factors (*e.g.*, toxins, potential allergens, weediness, pest potential, etc). The objective is to determine if the novel plant or food presents any new or greater risks in comparison with its traditional counterpart, or whether it can be used as its traditional counterpart without affecting the health or nutritional status of consumers, or the environment where it is going to be grown. The goal is not to establish an absolute level of safety, but rather the relative safety of the new product such that there is a reasonable certainty that no harm will result from intended uses under the anticipated conditions of production, processing and consumption.

According to the 1992 guidance, the FDA expected genetic modification of plants to produce components "substantially similar" to those commonly found in food, e.g. those under the GRAS clause (Generally Recognized as Safe), if they have a long history of safe use or have been determined to be GRAS on the basis of publicly available evidence and in the judgment of qualified experts. In the mid-1980s FDA asserted that it had sufficient legal authority to regulate GM foods either under the adulteration clause of the Federal Food, Drug and Cosmetic Act or FDCA or food additives clause[78] (OSTP, 1986). This meant it was not necessary to involve the US Congress in decisions concerning this new technology. Similarity could be demonstrated by testing chemical composition and in cases where such methods could not resolve safety concerns, feeding studies or other toxicological tests may be warranted. In this way, chemical composition became a central criterion for GM food safety assessment in the US. Sometimes such animal feeding studies are difficult to design and interpret (i.e., it can be difficult to feed large quantities of a specific protein or of a complex substance such as a whole food).

FDA normally applies the adulteration clause to regulate the safety of whole foods and it normally applies the food additive clause to regulate the safety of chemical substances added to food to achieve an intended effect. However, GM foods pose a challenge to this binary choice because they are whole foods and they have been altered to achieve an intended effect through the addition of new segments of DNA and, indirectly, the intended expression product(s). In practice, the goal of FDA under the voluntary consultation process, regulated by the FFDCA, is to ask developers for additional information, if needed, on such issues include significantly increased levels of plant toxicants or anti-nutrients,

77 MHW (2001). Mandatory Requirement for Safety Assessment of Foods and Food Additives Produced by Recombinant, DNA Techniques. Tokyo, Japan: Ministry of Health and Welfare. (http://www.mhlw.go.jp/english/topics/food/sec03.html).

78 FDA (2001). Guidance for Industry: Use of Antibiotic Resistance Marker Genes in Transgenic Plants Center for Food Safety and Applied Nutrition. Office of Premarket (June 18, 2001) Office of Premarket Approval is now Office of Food Additive Safety.

reduction of important nutrients, the presence of new allergens, or the presence in the food of an unapproved food additive. Generally, the developer submits a safety and nutritional assessment summary to FDA that typically includes: the purpose of intended technical effect of the modification on the plant, together with a description of the various applications or uses of the bioengineered food, including animal feed uses; a molecular characterization of the modification including the identities, sources and functions of introduced genetic material; information on the expressed protein products encoded by introduced genes; information on known or suspected allergenicity and toxicity of expressed products; information on the compositional and nutritional characteristics of the food, including anti-nutrients; for foods known to cause allergy, information on whether the endogenous allergens have been altered by the genetic modification; and; comparative feeding tests with foods derived from genetically engineered plants and the non-modified counterpart are only requested in cases of doubt.

Others like Japanese, Brazilian, Argentine and Australian regulations, on the other hand, focus specifically on foods derived from GM crops.[79]

For instance, food additives derived from GMOs are regulated differently in Australia, Canada, the EU, the USA and Japan, and the definition of "food additive" varies between these nations. In Canada, the evaluation of food additives (non-nutrient substances not conventionally present in food) does not distinguish between food additives derived from GMOs or from other sources. In Australia, food additives from GMOs are evaluated for the components that deviate from the existing specifications for food additives. In the USA, a food additive is defined as a non-GRAS (non-Generally Recognized as Safe) food component. Introduced gene products are considered food-additives, i.e. non-GRAS components, unless they have already been declared GRAS. In Japan and the EU, both GM foods and food additives are subject to the same evaluation procedure.[80]

The FDA also considers that an evaluation of the safety of use of an antibiotic resistance marker, if it is expressed, should include an assessment of the safety of the protein or enzyme encoded by the gene, if present in food and to evaluate the potential for therapy with antibiotics to be compromised through transfer of the gene from plants to microorganisms in the gut of man or animal, or in the environment.[81] Safety evaluation of a protein encoded by an antibiotic resistance marker gene should include 1) an assessment of potential toxicity of the protein, 2) an assessment of whether the protein has the potential to elicit allergenic reactions, and 3) an assessment of whether the presence in food of the enzyme or protein encoded by the antibiotic resistance marker gene would compromise the therapeutic efficiency of orally administered antibiotic.

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79 Forbes, J. and Heritage, J. (2002). Assessment of the Risks of Transferring Antibiotic Resistance Determinants from Transgenic Plants to Micro-organisms. Technical Report on the Food Standards Agency Project G01010: 1–7. Gay, P. and Gillespie, S. (2005). Antibiotic Resistance Markers in Genetically Modified Plants: A Risk to Human Health. The Lancet. 5: 637–646. Goldstein, D., Tinland, B., Gilbertson, L., Staub, J., Bannon, G., Goodman, R., McCoy, R., and Silvanovich, A. (2005). A Review – Human Safety and Genetically ModifiedPlants – A Review of Antibiotic Resistance Markers and Future Transformation Selection Technologies. Journal of applied Microbiology. 99: 7–23. Jelenic, S. (2003). Controversy Associated with the Common Component of Most Transgenic Plants - Kanamycin Resistance Marker Gene. Food Technology Biotechnology. 41(2): 183–190. Koenig, A. (2000). Development and Biosafety Aspects of Transgene Excision Methods. In Proceedings of the 6th International Symposium on the Biosafety of Genetically Modified Organisms (Eds: Fairbairn, C., Scoles, G. and McHughen, A.), pp. 155–170. Malik, V. (1999). Marker Gene Controversy in Transgenic Plants. In Biotechnology, Biosafety, and Biodiversity: Scientific and Ethical Issues for Sustainable Development (Eds.: Shantharam, S. and Montgomery, J., pp. 65–90. Miki, B. and McHugh, S. (2004). Selectable Marker Genes in Transgenic Plants - Applications, Alternatives and Biosafety. Journal of Biotechnology 107(3): 193–232. Nap, J., Bijvoet, J.and Stiekema, W. 1992. Biosafety of Kanamycin. Resistant Transgenic Plants. Transgenic Research 1: 239–249. Nielsen, K., Bones, A., Smalla, K. and van Elsas, J. (1998). Horizontal Gene Transfer from Transgenic Plants to Terrestrial Bacteria - A Rare Event? FEMS (Federation of European Microbiological Societies) Microbiology Reviews. 22: 79–103. Ramessar, K., Peremarti, A., Gomez-Galera, S., Naqvi, S., Moralejo, M., Munoz, P., Capell, T. and Christou, P. (2007). Biosafety and Risk Assessment Framework for Selectable Marker Genes in Transgenic Crop Plants: A Case of the Science Not Supporting the Politics. Transgenic Research 16(3): 261–280. Shin, D., Park, S., Woo, G., Kim, H. and Park, K. (2004). Case Study for Natural Gene Transfer from Genetically Modified Food to Food Microorganisms). Food Science and Technology 13(3): 342–346. Smalla, K., Gebhard, F. and Heuer, H. (2000). Antibiotic Resistance Genes as Markers in Transgenic Plants-Risk of Horizontal Gene Transfer. Nachrichtenblatt des Deutschen Pflanzenschutzdienstes 52(3): 62–68.

80 Bennett, P. M., Livesey, C. T., Nathwani, D., Reeves, D. S., Saunders, J. R. and Wise, R. (2004). An assessment of the risks associated with the use of antibiotic resistance genes in genetically modified plants: report of the Working Party of the British Society for Antimicrobial Chemotherapy. Journal of Antimicrobial Chemotherapy 53, 418–431.

81 Levidow, L., Murphy, J. and Carr, S. (2007). Recasting "Substantial Equivalence": Transatlantic Governance of GM Food.

FDA acknowledges that the likelihood of transfer of an antibiotic resistance marker from plants to microorganisms in the gut or in the environment is remote and that, such transfer, if any, would likely be insignificant when compared to transfer between microorganisms, and in most cases, would not add to existing levels of resistance in bacterial populations in any meaningful way. Nonetheless, FDA believes that developers should evaluate the use of antibiotic resistance marker genes in crops on a case-by-case basis taking into account information on 1) whether the antibiotic is an important medication, 2) whether it is frequently used, 3) whether it is orally administered, 4) whether it is unique, 5) whether there would be selective pressure for transformation to take place, and 6) the level of resistance to the antibiotic present in bacterial populations. If a careful evaluation of the data and information suggests that the presence of the marker gene or gene product in food or feed could compromise the use of the relevant antibiotic(s), the marker gene or gene product should not be present in the finished food or feed. FDA notes that certain antibiotics are the only drug available to treat certain clinical conditions (e.g. vancomycin for use in treating certain staphylococcal infections). Marker genes that encode resistance to such antibiotics should not be used in transgenic plants.

Although, the information required for safety and nutritional assessment when foods are or include organisms obtained through recombinant DNA techniques is quite similar to those requested in EU, USA or Canada, nevertheless, there are some differences in the data requirements, and an international harmonization and standardization should be necessary in order to prevent trade barriers.

In conclusion, the safety assessment begins with a comparison of the new GM food or feed with an appropriate conventional line with a history of safe use, but the necessary data should be determined on a case-by-case basis, science sound and in the context of the proposed use of the product in the diet and consequent dietary exposure. Comparative data on the closest conventional counterpart are critically important in the evaluation of a new GM food, including data on chemical composition and nutritional value. The problem arises when such data are not widely available at the present time. Where substantial equivalence is more difficult to establish because the food or food component is either less well-known or totally new, then the identified differences, or the new characteristics, should be the focus of further safety considerations.

The safety of any newly introduced protein(s) into a food needs to be determined, as well as the compositional analysis needs particular attention given to evaluation of the targeted metabolic pathway. Studies in laboratory animals provide added safety assurance by confirming observations from other components of the safety assessment. On the other hand, the phenotypic properties of the crop should be assessed when grown in representative production sites.

The use of antibiotic resistance marker genes in GM plants has been the subject of several reviews[82], and expert consultations: Working Party of the

82 Forbes, J. and Heritage, J. (2002). Assessment of the Risks of Transferring Antibiotic Resistance Determinants from Transgenic Plants to Micro-organisms. Technical Report on the Food Standards Agency Project G01010: 1–7. Gay, P. and Gillespie, S. (2005). Antibiotic Resistance Markers in Genetically Modified Plants: A Risk to Human Health. The Lancet. 5: 637–646. Goldstein, D., Tinland, B., Gilbertson, L., Staub, J., Bannon, G., Goodman, R., McCoy, R., and Silvanovich, A. (2005). A Review – Human Safety and Genetically Modified Plants – A Review of Antibiotic Resistance Markers and Future Transformation Selection Technologies. Journal of applied Microbiology. 99: 7–23. Jelenic, S. (2003). Controversy Associated with the Common Component of Most Transgenic Plants - Kanamycin Resistance Marker Gene. Food Technology Biotechnology. 41(2): 183–190. Koenig, A. (2000). Development and Biosafety Aspects of Transgene Excision Methods. In Proceedings of the 6th International Symposium on the Biosafety of Genetically Modified Organisms (Eds: Fairbairn, C., Scoles, G. and McHughen, A.), pp. 155–170. Malik, V. (1999). Marker Gene Controversy in Transgenic Plants. In Biotechnology, Biosafety, and Biodiversity: Scientific and Ethical Issues for Sustainable Development (Eds.: Shantharam, S. and Montgomery, J., pp. 65–90. Miki, B. and McHugh, S. (2004). Selectable Marker Genes in Transgenic Plants – Applications, Alternatives and Biosafety. Journal of Biotechnology 107(3): 193–232. Nap, J., Bijvoet, J.and Stiekema, W. 1992. Biosafety of Kanamycin. Resistant Transgenic Plants. Transgenic Research 1: 239–249. Nielsen, K., Bones, A., Smalla, K. and van Elsas, J. (1998). Horizontal Gene Transfer from Transgenic Plants to Terrestrial Bacteria - A Rare Event? FEMS (Federation of European Microbiological Societies) Microbiology Reviews. 22: 79–103. Ramessar, K., Peremarti, A., Gomez-Galera, S., Naqvi, S., Moralejo, M., Munoz, P., Capell, T. and Christou, P. (2007). Biosafety and Risk Assessment Framework for Selectable Marker Genes in Transgenic Crop Plants: A Case of the Science Not Supporting the Politics. Transgenic Research 16(3): 261–280. Shin, D., Park, S., Woo, G., Kim, H. and Park, K. (2004). Case Study for Natural Gene Transfer from Genetically Modified Food to Food Microorganisms). Food Science and Technology 13(3): 342–346. Smalla, K., Gebhard, F. and Heuer, H. (2000). Antibiotic Resistance Genes as Markers in Transgenic Plants-Risk of Horizontal Gene Transfer. Nachrichtenblatt des Deutschen Pflanzenschutzdienstes 52(3): 62–68.

British Society for Antimicrobial Chemotherapy[83], FAO/WHO Consultation on Foods Derived from Biotechnology (FAO/WHO, 2000), Scientific Steering Committee of the European Commission (SSC, 1999) and the European Food Safety Authority (EFSA (2004). It has been concluded in these reports that the frequencies of gene transfer from plants to bacteria are likely to be extremely low and that the presence of antibiotic resistance marker genes, and in particular the *npt*II gene, in GM plants do not pose a relevant risk to human or animal health or to the environment. Nevertheless, the use of alternative genes markers, others than ARMGs, that do not result in antibiotic resistance genes in genetically modified foods should be greatly encouraged.

Finally, although the premarket assessment shall demonstrate that the introduction of the genetically modified food or feed will not adversely change in a significant manner the safety and nutrient intake for a large cross-section of consumers, the opportunity for benefits should be also considered along with the possible risks for a balanced assessment. In fact, it is clear that US government policy has been promoting agricultural biotechnology as an economic necessity and as a source of predictably safe products maintaining "risk-based regulation" and thus "avoid excessive restrictions that curtail the benefits of biotechnology to society".[84]

This last consideration seems not to be tackled in the same way in the different countries. For instance, in the EU, the scientific uncertainty drives forward the rigorous application of the precautionary principle while in US the cost-benefit analysis plays a relevant role in the risk assessment.

VI. Conclusions

While genetic modifications to food products are gaining increasingly of greater interest, since they represent a promising way to improve a wide range of food characteristics, on the other hand, concern has been raised about the safety aspects of food derived of genetically modified products. Since 1990 continuously evolving guidelines and recommendations for assessing food safety had basically relied on the concept of substantial equivalence. This principle of safety assessment mainly is linked to relevant issues, such as toxicological and allergenic effects of genetically modified products. A broader assessment approach, on a case by case basis, is deemed necessary when other scientific uncertainties could arise, mainly in relation to unintended or unforeseen effects. For these goals, different strategies and methodologies for the evaluation of safety aspects of genetically modified food products are needed.

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83 Bennett, P. M., Livesey, C. T., Nathwani, D., Reeves, D. S., Saunders, J. R. and Wise, R. (2004). An assessment of the risks associated with the use of antibiotic resistance genes in genetically modified plants: report of the Working Party of the British Society for Antimicrobial Chemotherapy. Journal of Antimicrobial Chemotherapy 53, 418–431.

84 Levidow, L., Murphy, J. and Carr, S. (2007). Recasting "Substantial Equivalence": Transatlantic Governance of GM Food. Science, Technology and Human Values 32 (1).

Administrative Authorizations, Risk and Biotechnology*

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Science and technology have eliminated numerous hazards for human beings, but at the same time they have also brought new risks, the so-called "technological risks". Genetically modified foods are a good example of these new risks. On the one hand, GMOs bring significant benefits to the production of food. On the other hand, there are concerns about the tendencies to provoke allergenicity, gene transfer and outcrossing.[1] This is what someone called technology's collateral effects.[2] Similar effects also arise in promising products and technologies, such as xenotransplants, nanotechnology and many others.

These effects, which are in some cases uncertain, and could be catastrophic, give the precautionary principle its raison d'être[3], because when science is inconclusive and there exists the possibility of grave harm the prudent action is to act with precaution.

The core of the precautionary principle is that scientific uncertainty about risks to health or the environment must not be invoked to paralyze decision-making, since avoiding risks must be our main concern.

But there is no simple unique answer as to how one deals with uncertainty: In the USA there is a prevalence of cost-benefit analysis while in the European Union there is a dominance of the precautionary principle. Cost-benefit analysis is based on the public's willingness to pay for the benefits. Cost-benefit analysis sets out to do for government what the market does for business: add up the benefits of a public policy and compare them to the costs[4]. The precautionary principle mainly focuses on moral values.

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* Some of these ideas were elaborated previously by Miguel A. Recuerda. See Recuerda, M.A., (2006), "Risk and Reason in the European Law", European Food and Feed Law Review, 5; "Dangerous Interpretations of the Precautionary Principle and the Foundational Values of the European Food Law. Risk versus Risk", Journal of Food Law and Policy, n. 4, 1, 2008.

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1 World Health Organization: Modern food biotechnology, human health and development: an evidence-based study (2005).

2 See Ulrich Beck, Risk Society: Towards A New Modernity, (1992); World Risk Society, (1999).

3 A short list of works on the precautionary principle: Roberto Andorno, "The Precautionary Principle: A New Legal Standard for a Technological Age", 1, JIBL (2004); Tim O´Riordan, James Cameron, and Andrew Jordan, (Eds.), Reinterpreting The Precautionary Principle (2001); José Luís Da Cruz, "The Precautionary Principle in EC Law", 10, European Public Law, 2; Nicolas de Sadeleer, "The Precautionary Principle in EC Health and Environmental Law", 12, European Law Journal, 2 (2006); Elizabeth Fisher, "Is the Precautionary Principle Justiciable?", 13, Journal of Environmental Law, 3, (2001); Giandomenico Majone, "What Price Safety? The Precautionary Principle and its Policy Implications", 1 JCMS, 40 (2002); Miguel Á. Recuerda, "Risk and Reason in the European Union Law", 5; European Food and Feed Law Review (2006); Cass. R. Sunstein, Laws Of Fear R. Beyond The Precautionary Principle (2005).

4 Lisa Heinzerling and Frank Ackerman, Pricing The Priceless (2002).

I. The peculiarities of these new risks

It is important to point out that the essential peculiarities of these new risks are that they are created by man, that scientific uncertainty surrounds them, and that they can produce irreversible effects.

Hazards and risks[5] are not an invention of the modern age, nor are they an exclusive consequence of technology. Human beings have always been threatened by natural hazards that they have tried to eliminate by means of science and technology. Diseases have been conquered by medicine, scarcity of food by agricultural innovations and the domestication and breeding of animals. Science and human intervention in the natural order have generated a better knowledge of natural hazards, their causes and their effects[6]. Now the etiology of many diseases is known. But as a result of new technologies, a new category of hazard has also been created. These new hazards are called manufactured hazards, and differ from natural hazards in that man has a direct role in their creation.[7]

These new hazards are global or world-wide in character, and as such, can produce serious and irreversible effects that are devastating, given the range of territory and population that can be impacted almost immediately.[8] Any death is irreversible, but the irreversibility of the manufactured hazards means that the change is permanent. But does this mean that all kinds of irreversible change are relevant? For some people, an irreversible change in a particular species is relevant, but for others the importance of the change depends on it magnitude.

II. The problem of scientific uncertainty

Scientific uncertainty is a very complex issue, depending on the variables selected, the measures made, the samples taken, and the models and causal relations used. For many of the health problems, it is impossible to make definitive cause-effect links because science has it own limitations. Scientific uncertainty can also result from controversy about existing data or from the lack of some pertinent data.[9] Risk evaluators, who have to assess the risks in order to inform risk managers, accommodate these uncertainty factors by incorporating prudential aspects.[10] relying on animal experiments to establish potential effects in man, or adopting levels as a basis for certain toxic contaminants (like the ALARA, as low as reasonably achievable). But in some cases, scientists do not have sufficient data to apply these prudential aspects, i.e., in cases in which extrapolations cannot be made, or when cause-effect relationships have not been demonstrated. In cases like these, decision makers face the dilemma of having to act or not to act. The emergence of unpredictable, uncertain, and unquantifiable risks has been one of the reasons for the development of anticipatory decision-making models[11] like the precautionary principle that in situations of uncertainty follow the "safer" option.

III. The precautionary principle

1. Concepts

The concepts that are explained here are based on the work of Professor Recuerda[12]. There have been debates about the words used to explain the precautionary principle, and about its very meaning.

The first problem is the distinction between "prevention" and "precaution". These two terms are related notions that create confusion because in the common language there is no clear difference between them. However, at least in the European Union, the principle of prevention is one thing, and the precautionary principle another.

The principle of prevention applies to risks that can be quantified in probabilistic terms. An example of the application of the principle of prevention

5 See Miguel Á. Recuerda, "Food Safety: Science, Politics and the Law", 1 European Food and Feed Law Review (2006).

6 A clear example is the sanitary hazards that are associated with certain foods. Technology has eradicated many of these hazards through new systems for processing and conserving foods.

7 Anthony Giddens, Runaway World (2003).

8 Ulrich Beck, op. cit., p. 28.

9 European Commission, Communication on the Precautionary Principle, COM (2000) 1.

10 Andrew Sterling, On Science and Precaution in the Management of Technological Risk, European Commission Joint Research Centre (1999). Some people said that these prudential factors are an example of the application of the precautionary principle. However, the European Commission says the precautionary principle can be applied in risk management but not in risk assessment.

11 Some authors have stated that the precautionary principle is not a good decision-making model because it offers no guidance (Cass. R. Sunstein, Laws Of Fear, op. cit).

12 Miguel A. Recuerda, "Dangerous Interpretations of the Precautionary Principle and the Foundational Values of the European Union Food Law: Risk versus Risk", Journal of Food Law and Policy, n. 4, 1, 2008.

is the regulation of maximum levels for certain contaminants which are considered to be genotoxic carcinogens in foodstuffs. The risks posed by these contaminants are well known, so preventive measures must be applied.[13]

Nevertheless, the precautionary principle applies to unknown and unquantifiable risks such as those posed by nanomaterials.

The second problem arises with the very idea of precaution and its different meanings. Precaution is a common-sense idea related to the virtue of prudence: For Aristotle, the prudent man was the one with the trained faculty of choice. Precaution is also an ethical value and a legal rule, because every person is responsible for his/her free choices in the moral and legal orders. Moreover, precaution is a political idea with roots in the "green" thinking that originated the concept of the precautionary principle and the precautionary approach. At the roots of this principle are at least the ecological critiques[14], environmental ethics[15], intergenerational ethics[16], and the ethics of responsibility[17].

The origin of the precautionary principle is closely linked to the "green" thinking that started to have political influence in the Sixties.[18] The book *Silent Spring,* written by Rachel Carson and published in 1962 in the United States, is in some way a precursor of the precautionary approach, given that she criticized the use of DDT (dichlorodiphenyltrichloroethane) while there was scientific controversy about the safety of this product. The preoccupation with the ability to harm not only existing individuals but also future generations and humanity as a whole is also a key intellectual factor in the development of the precautionary principle.[19]

The distinction between "precautionary principle" and "precautionary approach" is diffuse. The distinction between "principle" and "approach" in some documents is controversial. In the negotiations of international declarations, the United States has opposed the use of the term "principle" because this term has special connotations in legal language, due to the fact that a "principle of law" is a source of law. This means that it is binding, so a Court can quash or confirm a decision applying the precautionary principle. In this sense, it is not a simple idea or a desideratum.

On the other hand, an "approach" usually does not have the same meaning,[20] although in some particular cases an approach could be binding. An approach is a particular "lens" used to identify risk that every prudent person possesses. Precaution, as an approach, has been present in the last few years in all of the debates on environmental policies, and it has been extended to all those matters in which it was possible to see health rights as being affected. In Europe, the precautionary principle has been an omnipresent word, a vague slogan for risk regulation. It has achieved so much importance that it has been introduced into the EU primary legislation and in many EU regulations, and it has been recognized by the Court of First Instance as a general principle of law.[21] A general principle of law is a source of law different from a rule. A general principle is abstract, while a rule is concrete. Principles do not set out legal consequences that automatically result from them, while rules, because of their specificity and concrete character, stipulate answers. However, general principles must be applied by Courts in order to interpret the rules and to fill in gaps.[22] In EU Law, the precautionary principle is not only a general principle of law recognized by the Courts, but also a principle incorporated into numerous legal texts.

On the contrary, in the United States, the precautionary principle is not generally understood as a

13 See Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs.

14 Rachel Carson, Silent Spring, (1963); D. H. Meadows, J. Randers, J., And D. Meadows, The Limits To Growth (1972).

15 H. Rolston, "Is There an Ecological Ethic?", 85 Ethics: 93–109 (1975); A. Brennan, "The Moral Standing of Natural Objects", 6 Environmental Ethics 35–56 (1984); Andrew Light, and Avner De-Shalit, (Eds.), Moral And Political Reasoning In Environmental Practice (2003).

16 J. Feinberg, "The Rights of Animals and Unborn Generations", in W. T. Blackstone (Ed.), Philosophy and Environmental Crisis, (1974); Sylvan, Richard, Bennett, David, The Greening Of Ethics, (Cambridge: White Horse Press 1994).

17 Hans Jonas, Imperative Of Responsibility: In Search Of An Ethics For The Technological Age (University of Chicago Press, Chicago, 1984).

18 Jaap C. Hanekamp, Guillaume Vera-Navas, and Verstegen, "The Historical Roots of Precautionary Thinking: The Cultural Ecological Critique and the Limits to Growth", Journal of Risk Research 8 (4), 295–310 (June 2005).

19 Roberto Andorno, "The Precautionary Principle: A New Legal Standard for a Technological Age", 1 JIBL (2004).

20 During the meetings in the Commission of Codex Alimentarius the U.S. delegation has always lobbied heavily to avoid the use of the term "precautionary principle".

21 European Court of First Instance: Joined Cases T–74/00, T–76/00, T–83/00, T–84/00, T–85/00, T–132/00, T–137/00, & T–141/00, Artegodan GmbH v. Comm of the European Communities, 2002 E.C.R. II-4945.

22 Ronald Dworkin, Taking Right Seriously (1994), p. 24; Takis Tridimas, The General Principles of EU Law, Oxford University Press (2006).

principle of law but as an approach. This does not mean that Europe is more precautionary than the US.[23] However, the European authorities have the tendency to take measures without clear evidence of risk – i.e. the GMOs case, the hormones case or the virginiamicyn case (antimicrobial growth promoter) –.

2. The origin of the precautionary principle and its basis

Most scholars mention the German concept of *Vorsorge* as the origin of the precautionary principle.[24] Some other authors have said that the first use of the precautionary principle appears to be the Swedish Environmental Protection Act of 1969.[25] The notion of *Vorsorge* is very broad and controversial, but in essence it states that, as far as humanly possible, damage must be prevented before it is done even if scientific evidence is insufficient, inconclusive or uncertain. Some authors have found almost a dozen different meanings of *Vorsorge* in German policy, which shows that the idea of precaution is not clear.[26] The concept of *Vorsorge* roughly corresponds to the Anglo-Saxon aphorism "*better safe than sorry*". In this sense, precaution implies the anticipated detection of all hazards to health and to the environment, the careful consideration of its possible negative effects, and the measures available to prevent them. The precautionary principle means "foresight". It was introduced in certain legislative measures adopted in Germany in the Seventies, such as the Federal Law on Emissions of 1974, in order to protect the environment. (*Bundesimmissionsschutzgesetz*). This approach later influenced the content of the EU environmental action programs and was introduced into EU Law not only in the environmental regulations, but also in the area of health protection.

The Federal Law on Emissions addressed the problem of regulation beyond the prevention of known hazards using the *Vorsorgeprinzip*. It was used in the Eighties as a justification for establishing energy policies that dealt with the problems of global warming, acid rain, and the contamination of the North Sea. This principle not only meant looking ahead to eventual environmental impact, but also using the best technologies available to prevent contamination. Following this principle, the German government designed a strategy to reduce environmental unquantifiable risks, acceding to the demands of the environmentalist movement that, sensitized to environmental issues, attempted to bypass the classic cost-benefit analysis in order to confront the problems of the deterioration of habitats. Some critics, such as Lisa Heinzerling and Frank Ackerman, argue that cost-benefit analysis is a deeply flawed method that repeatedly leads to biased and misleading results. According to these authors, cost-benefit analysis ignores the concerns of the citizens and does not pay attention to what the future might hold in store for us.[27] And the concern for future generations is one of the key factors of the precautionary principle.

3. Different versions

There are many versions of the precautionary principle, with different effects. As we have said, some scholars think that the precautionary principle in the United States is merely an approach, yet not an obligatory rule.[28] Of course, this is not the case in Europe as we mentioned before. There are several distinctions between different versions of the precautionary principle. Sunstein, from an original classification made by Stewart, differentiates between weak and strong versions of the precautionary principle.[29] The defenders of the principle's

23 See John S. Applegate, The Precautionary Preference: An American Perspective on the Precautionary Principle, 6 Human & Ecol. Risk Assess. 413 (2000); Peter H. Sand, The Precautionary Principle: An European Perspective, 6 Human & Ecol. Risk Assess. 445, 446 (2000).

24 James Cameron, And Timothy Riordan, (Eds.), Interpreting The Precautionary Principle, (1994); Olivier Godard (Dir.), Le Principe de Précaution dans la Conduite des Affaires Humaines, (1997); Indur Goaklany, The Precautionary Principle, a Critical Appraisal of Environmental Risk Assessment, (2001); Cass. R. Sunstein, op. cit.

25 Per Sandin, Dimensions of the Precautionary Principle, 5 Hum & Ecol. Risk Assess., 889, 1999.

26 Eckard Rehbinder, Das Vorsorgeprinzip im internationalen Vergleich, Baden-Baden (1991).

27 Lisa Heinzerling and Frank Ackerman, Pricing The Priceless (2002).

28 John S. Applegate, "The Precautionary Preference: An American Perspective on the Precautionary Principle", 6 Human & Ecol. Risk Assess. 413 (2000); Peter H. Sand, "The Precautionary Principle: An European Perspective", 6 Human & Ecol. Risk Assess. 445, 446 (2000).

29 Cass. R. Sunstein, Laws of Fear, Beyond The Precautionary Principle (2005); Richard Stewart, "Environmental Regulatory Decision Making under Uncertainty", in Timothy Swanson (Ed.), An Introduction to the Law and Economics of Environmental Policy: Issues in Institutional Design (2002) 71, 78.

weak versions propose that the lack of decisive proof in regards to the possibility of grave harm must not be a reason to negate adopting regulatory measures. This version is adopted by the Rio Declaration (1992):

> [I]n order to protect the environment, the precautionary approach[30] shall be widely applied by states according to their capabilities
> Where 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.

A prudent person should not postpone cost-effective measures taken to protect health or the environment where there are threats of serious or irreversible damage, even if there is no full scientific certainty. This version of the precautionary principle is generally accepted and it is not reasonable to oppose it.[31]

The strong versions of the precautionary principle refer to all kinds of risks (from insignificant to grave ones; reversible or irreversible), even if some cause and effect relationships are not scientifically established and do not take the economic consequences into consideration. The Wingspread Statement is an example of the strong version:

> [W]hen an activity raises threats of harm to human health or the environment, precautionary measures should be taken, even if some cause and effect relationships are not established scientifically. In this context the proponent of the activity, rather than the public, should bear the burden of proof.

This statement is more "protective" or more "aggressive", depending on the point of view, than the Rio Declaration, because it is not limited to threats of serious or irreversible damage. It does not require a cost-benefit analysis and entails the burden of proof for the proponent of the activity.

In any case, what is useful in the real word is to know the content and nature of the main texts that recognize the precautionary principle and its judicial application and interpretation made by Courts of Law. For this reason, two useful criteria to classify the precautionary principle versions can be established:

1) Its content: a) The kind of risk: all kinds of risks, serious, insignificant, reversible, irreversible, short-term, long-term; b) The rights protected: Environment, human health, others; c) The degree of scientific uncertainty; d) The burden of proof; e) Other criteria: Proportionality, cost-benefit analysis, balancing between rights, etc.
2) Its legal status: a) Binding; b) Non binding.

4. The status of precautionary principle in International Law

For more than twenty years, precaution has been present in an explicit or implicit form in most of the famous international treaties that have dealt with the protection of the environment.[32] In all of them pulsed the idea of controlling the activities that could have negative consequences in nature, and the necessity of thorough studies that cleared away doubts about technological hazards and risks – some examples are the World Charter For Nature (1982), the Vienna Convention for the Protection of the Ozone Layer (1985), the Montreal Protocol (1987), the Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter – London Convention – (1982), the Second International Conference on the Protection of the North Sea (1987), the Bergen Declaration (1990), the Convention on the Protection of the Marine Environment of the Baltic Sea Area (1992), the Convention on the Protection and Use of Transboundary Watercourses and International Lakes (1992), the Rio Declaration on the Environment and Development (1992), the Convention on Biological Diversity

30 The Spanish version uses the terms "precautionary principle" and not "precautionary approach".

31 Cass. R. Sunstein, Laws of Fear, (2005); Giandomenico Majone, "What Price Safety? The Precautionary Principle and its Policy Implications", 1 JCMS, 40 (2002).

32 Some excellent works on the precautionary principle in International Law: David Freestone, "The Precautionary Principle",in Robin Churchill, and David Freestone, (eds.), International Law and Global Climate Change, (Graham & Trotman, London, 1991); Timothy Cameron and Juli Abouchar, "The Precautionary Principle: A Fundamental Principle of Law and Policy for the Protection of the Global Environment", 14 Boston College International and Comparative Law Review, (1991); Ellen Hey, "The Precautionary Concept in Environmental Policy and Law: Institutionalizing Caution", 4 Georgetown International Environmental Law Review, (1992); Harold Homann, Precautionary Legal Duties and Principles of Modern International Environmental Law, (Kluwer Academic Publishers Group, Norwell, 1994); David Freestone and Ellen Hey, "The Precautionary Principle and International Law: The Challenge of Implementation", International Environmental Law and Policy Series, 31, (Kluwer Law International, 1996); Owen Mcintyres and Thomas Mosedale, "The Precautionary Principle as a Norm of Customary International Law", 9 Journal of Environmental Law (1997).

(1992), the Kyoto Protocol (1997), the Wingspread Declaration (1998), the Lowel Declaration (2000), the Cartagena Protocol on BioSafety (2000) and the Stockholm Declaration on Persistent Organic Pollutants (2001), among others.

But what is the legal status of the precautionary principle in International Law? As Sadeleer has pointed out, with respect to the nature of this principle and its true legal impact in the international order, it is necessary to examine every declaration, case by case, "if the terms used to describe the principle are sufficiently descriptive to decide if it is susceptible to be applied directly with respect to the States without the interposition of possible norms of execution".[33] The one thing that is certain is that in spite of the great number of international declarations in which the precautionary principle has been incorporated, this principle continues to be, in the international order, vague and imprecise. It is possible to say, in a general way, that the precautionary principle is being tried out by some public authorities to make decisions in matters where scientific uncertainty exists and that could involve irreversible damages. The dimension of the precautionary principle goes beyond the problems associated with a short or medium-term approach to risks. It also concerns the long run, and the well-being of future generations. A decision to take measures without waiting until all the necessary scientific knowledge is available is clearly a precaution-based approach.[34]

Although this principle has been included in many international treaties and declarations, as we have said,[35] and has been invoked in the International Courts, it is not clear whether the precautionary principle is at least part of customary international law. McIntyre, Mosadale and Weeramantry[36] reached the conclusion that it is customary international law.[37] The EU states that the precautionary principle is a general principle of international law.[38] Other scholars think that these people have gone so far as to claim that the precautionary principle is becoming a binding part of international law.[39]

The recognition of a customary international law has two requisites: *Usus* – use of the custom which in international law amounts to consistent state practice –[40], and *opinio iuris* – the belief that a behaviour was displayed because it was a legal obligation –. In this case we cannot state that the precautionary principle is uniformly understood as a legal duty. If the precautionary principle were a customary international law, the next questions would be: What is the content of this principle? In which cases must it be applied? What are the requisites for its application? What kind of measures can be adopted by applying the precautionary principle? and finally: Could a Court review these measures? We are not going to answer these questions here, because the precautionary principle is not understood in a uniform way in international law, but we will answer them when explaining the interpretation of this principle in the European Union Law.

In the international arena, one important text that implicitly recognizes the precautionary principle is the Sanitary and Phytosanitary Agreement of the Word Trade Organization (SPS).[41] Articles 2 and 5 SPS open the door to situations of scientific uncertainty and implicitly recognize the precautionary

33 Nicolas de Saledeer, "Reflexiones sobre el estatuto jurídico del principio de precaución", 25 Revista de Derecho Ambiental (2000).

34 Communication from the Commission on the Precautionary Principle.

35 James Cameron, "The Precautionary Principle", in Gary Sampson and W. Bradnee Chambers (Eds.), Trade, Environment and the Millenium (Hong Kong, United Nations University Press, 1999).

36 International Court of Justice, Court's Judgment of 20 December 1974 in the Nuclear Tests (New Zealand v. France) Case, Order of 22 September 1995, ICJ Reports 1995.

37 See Owen McIntyre and Thomas Mosedale, "The Precautionary Principle as a Norm of Customary International Law", 9 J. Env. Law 221 (1997).

38 Communication from the Commission on the Precautionary Principle.

39 Cass. R. Sunstein, Law of Fear, op. cit, p. 16.

40 See Enrique Alonso Garcia, Introduction to International Environmental Law: Handbook with Cases and Materials for American Lawyers (Friends of Thoreau_IVEN-URJC University Press, 2009), pg 7–2 ff.

41 Annex A: "1. Sanitary or phytosanitary measure – Any measure applied:
(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.
Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety".

principle.[42] Article 2.1 SPS establishes that "[m]embers have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement". Article 2.2 SPS demands that measures be "[b]ased on scientific principles" and cannot be "[m]aintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5". Article 5 regulates the assessment of risk and the determination of the appropriate level of sanitary or phytosanitary protection. The measures must be based on an assessment using the risk assessment techniques developed by the international organizations, and must be based on scientific evidence. The SPS agreement also demands taking into account the relevant economic factors, and the cost-effectiveness of alternative approaches to limiting risks. According to article 5 SPS "[M]embers shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade". But finally, article 5.7 makes a clear reference to the precautionary principle:

> [I]n cases where relevant *scientific evidence is insufficient*, a Member may *provisionally* adopt sanitary or phytosanitary *measures* on the basis of available pertinent information, including that from relevant international organizations as well as from sanitary and phytosanitary measures adopted by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measures accordingly within a reasonable period of time.

On the subject of the European restrictions on the importation of bovine meat treated with hormones coming from the United States and Canada, the European Union invoked the precautionary principle as a justification for its ban.[43] The WTO considered that the EU ban was not sustained in a scientific evaluation of risk[44] and infringed article 5.1 SPS. This ban also infringed article 5.5 SPS because the level of protection demanded for the meat treated with hormones was superior to the one required in comparable situations.[45]

These differences of treatment were considered arbitrary and discriminatory, in other words, a covert restriction on trade. It was significant that the EU on the one hand tried to prohibit the importing of this meat coming from animals treated with hormones, but on the other hand, and in a contradictory manner, allowed higher levels of the same hormones of endogenous production in the untreated meat and other foods, the use of the same hormones with therapeutic aims and from management of herds, and the use of other growth stimulants in the production of pork. According to the WTO the European Union had not been protected by article 5.7 SPS that allowed the adoption of provisional measures.[46] The WTO understood in this case that recourse to the "precautionary principle" did not annul the obligations of a country within the framework of the SPS. Actually, the European Union's scientific studies did not endorse the prohibition imposed on the meat treated with hormones, and the United States and Canada affirmed that there were no tests of adverse effects on human health. The EU maintained that when doubt exists about the safety of a food product, even if the risk has not been completely evaluated scientifically, the consumer must be favoured in place of the producer when adopting precautionary decisions[47]. Therefore, what the EU maintained before the WTO was that the precautionary principle was not only applied in the risk management phase – in the phase of adoption of decisions –, but also in the pre-

42 Ilona Cheyne, Gateways to the precautionary principle in WTO Law, 19 Journal of Environmental Law, 2 (2007).

43 See WTO Cases DS320 (USA vs. EU, Hormones Dispute) and DS321 (Canada vs. EU, Hormones Dispute).

44 "1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations".

45 "5. With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade (…)".

46 "7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time".

47 Jan Bohanes, "Risk Regulation in WTO Law: A Procedure Based Approach to the Precautionary Principle", 40 Columbia Journal of Transnational Law (2002), p. 336.

vious phase of risk assessment – scientific evaluation –, and in that previous phase it was necessary to consider not only scientific opinions but also consumer fears according to a concept of subjective risk. For this reason, some people think that the EU is hiding behind the precautionary principle that does not require scientific proof in order to ban a product and that this issue is more of a political than a scientific issue in Europe[48].

Nevertheless, the WTO rejected the European Union interpretation of the precautionary principle for the reason that it without a doubt introduced some subjective elements which generated a great legal uncertainty, and in addition, it concluded that this principle did not replace, in any case, the commitments acquired by the countries in the international order.[49]

Additionally, the European Union interpreted the term "provisional" contained in article 5.7 SPS in a very broad way as "until complete scientific information is obtained". However, the WTO interpreted the term "provisional" as a temporary measure – "within a reasonable period of time"–.

In the case of Genetically Modified Organisms it is well known that the European Commission established a *moratorium* on the approval of products containing GMOs that leaded to the EC-Biotech decision. US, Canada, and Argentina complained that measures taken by the EU were affecting imports of biotech products into the European Union. The basis of these measures was the European interpretation of the precautionary principle. According to this principle, the EU requested additional assessments of GMOs and further information that leaded to the delay of the approvals of GMOs. Actually, this was a *de facto moratorium* on product approvals. In this case, the WTO considered that the measures were not justified that means that the precautionary principle can not be applied in a strong way.

5. The precautionary principle in European Union Law

a. The precautionary principle in EU Hard Law and Soft Law

The express recognition of the precautionary principle in EU Law is in article 130 R (presently 174) of the *Treaty of Maastricht* of 1992 that established:

> [C]ommunity policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay. In this context, harmonisation measures answering environmental protection requirements shall include, where appropriate, a safeguard clause allowing Member States to take provisional measures, for non-economic environmental reasons, subject to a Community inspection procedure. In preparing its policy on the environment, the Community shall take account of available scientific and technical data; environmental conditions in the various regions of the Community; the potential benefits and costs of action or lack of action; the economic and social development of the Community as a whole and the balanced development of its regions.

In 1997 the European Commission opened a public debate on European Food Law as a reaction to the mad cow disease. These debates ended with the approval of the well-known General Food Law which recognized the precautionary principle as a principle of the European Food Law. This was the path until the approval of this relevant regulation on food safety:

In the April 1997 *Communication on the Consumer health and food safety*[50], the European Commission indicated that:

> [I]n its analysis of risks, the Commission will be guided by a precautionary principle in the cases of insufficient scientific base or about those where there exists uncertainty.

With greater exactitude the precautionary principle is set forth in the *Green Paper on the General principles of food law in the European Union*[51], of 30 of April of 1997, in which the European Commission reiterated that:

48 U.S. Trade Representative's 2002 Foreign Trade Barriers

49 The EU has been very critical of the WTO's position, as can be seen in the Resolution on the conclusions of the special group "hormones" of the WTO.

50 COM (97) 183 final.

51 COM (97) 176 final.

> [T]he Treaty requires the Community to contribute to the maintenance of a high level of protection of public health, the environment and consumers. In order to ensure a high level of protection and coherence, protective measures should be based on risk assessment, taking into account all relevant risk factors, including technological aspects, the best available scientific evidence and the availability of inspection sampling and testing methods. Where a full risk assessment is not possible, measures should be based on the precautionary principle.

On 13 April 1999 the European Council adopted a resolution urging the Commission *inter alia*

> [T]o be in the future even more determined to be guided by the precautionary principle in preparing proposals for legislation and in its other consumer-related activities and develop as priority clear and effective guidelines for the application of this principle.

The *White Paper on Food Safety* (2000) also takes on the precautionary principle in express form and indicates that

> [T]he use of scientific advice will underpin Food Safety policy, whilst the precautionary principle will be used where appropriate. The ability to take rapid, effective, safeguard measures in response to health emergencies throughout the food chain will be an important element; (...) Where appropriate, the precautionary principle will be applied in risk management decisions.

As the application of the precautionary principle began to generate fierce debates at the end of the Nineties, as much in Europe as outside Europe, the European Commission approved a Communication attempting to clarify what its position was regarding the use of the precautionary principle – *Communication from the Commission on the precautionary principle*. The Communication is soft law. The Commission tried to develop a rational and balanced framework for the application of the precautionary principle to avoid protectionist measures within the Community and unjustified limitations on the freedom and rights of individuals, industry, and organizations, while protecting health or the environment.

The essential ideas brought together in this Communication on the application of the principle are the following:

- Factors triggering recourse to the precautionary principle
- Risk: Identification of potentially negative effects for the environment, or human, animal or plant health, resulting from a phenomenon, product or process. No distinction between different kinds of risks (weak vs. strong versions).
- Risk assessment and uncertainty: Risk assessment as complete as possible. Sometimes scientific evaluation does not allow the risk to be determined with sufficient certainty.
- Plausibility/no hypothetical risk: some scientific evidence, even minority.

Measures resulting from reliance on the precautionary principle

- Deciding what is an "acceptable" level of risk for society is an eminently political responsibility. There are no general guidelines.
- Decision-makers must decide to act, or nor to act (discretionary powers[52]).
- Decisions should be based on the acceptable risk, scientific uncertainties and public concerns.
- Subject to review in the light of new scientific data.

Principles for the application of the precautionary principle

- Proportionality: Measures should be proportional to the desired level of protection and must not aim at zero risk. Use of the less restrictive alternatives.
- Non-discrimination: Comparable situations should not be treated differently.
- Consistency: Measures should be consistent with the measures already adopted in similar circumstances or use similar approaches.
- Examination of the benefits and costs of action or lack of action: An economic cost-benefit analysis where this is appropriate and possible.
- Examination of scientific developments: Re-evaluation of the data.

The burden of proof

- Prior approval procedures of some products: novel food, drugs, additives, etc.
- Reversing the burden of proof case by case. It is not a general rule.

52 Limited by manifest error or misuse of power or manifestly exceeding its powers of appraisal.

This principle is additionally being progressively incorporated into numerous legal texts in the European Union in matters such as general product safety[53], the use of additives for use in animal nutrition[54], the incineration of waste[55], the regulation of genetically modified organisms, or the regulation of chemical substances. It has been introduced in the unborn EU Constitution.

The most relevant example in food safety is article 7 of the Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirement of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety:

> [I]n specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment. 2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

In European Law, a regulation is a kind of law that has general application and that is binding in its entirety and directly applicable in all Member States. The Regulation (EC) 178/2002 establishes the following requirements for the application of the precautionary principle in food safety cases: 1. Risk assessment. 2. Possibility of harmful effects on health although scientific uncertainty persists. 3. Provisional measures. 4. Proportionality (no more restrictive of trade than is required to achieve the high level of protection chosen. The measures adopted must be technically and economically feasible). 5. High level of health protection.[56]

b. The application of the precautionary principle by the European Court of Justice and the Court of First Instance

Before 1992, when the precautionary principle was introduced in the Treaty of Maastricht, the logic of this principle was applied by the European Court in several cases without mentioning the precautionary principle. In fact, the logic of the precautionary principle is quite ancient.

The European Courts have faced cases involving scientific uncertainty and the free movement of goods[57]. The principle of free movement is basic for the European Single Market and implies that national barriers to trade within the European Union must be removed. In the absence of harmonization of legislation applicable to one particular product, articles 28 to 30 of the EC Treaty forbid Member States to impose trade barriers within the Community, except in special circumstances: One of these circumstances is "the protection of health". But these restrictions or prohibitions shall not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States; they must be proportionate, and of course should protect health,[58] otherwise the measures would violate the Treaty.

In the case *Officier van justitie v Koninklijke Kaasfabriek Eyssen BV*[59], on a Dutch prohibition on the

53 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety: Article 8.2. "when the competent authorities of the Member States take measures such as those provided for in paragraph 1, in particular those referred to in (d) to (f), they shall act in accordance with the Treaty, and in particular Articles 28 and 30 thereof, in such a way as to implement the measures in a manner proportional to the seriousness of the risk, and taking due account of the precautionary principle".

54 Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition "(6) Action by the Community relating to human health, animal health and the environment should be based on the precautionary principle".

55 Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste "(5) In accordance with the principles of subsidiarity and proportionality as set out in Article 5 of the Treaty, there is a need to take action at the level of the Community. The precautionary principle provides the basis for further measures".

56 Miguel Á. Recuerda, Seguridad ad Alimentaria y Nuevos Alimentos, Régimen Jurídico-Administrativo, (Thomson-Aranzadi, Cizur Menor, 2006)

57 See Fernando González Botija, El Régimen Jurídico del Etiquetado de Vinos, (Atelier, 2005).

58 Art. 36 EC.

59 Judgment of the Court (First Chamber), Case 53/80, of 5 February 1981.

use of nisin to process cheese, there were uncertainties regarding the maximum level acceptable. Nisin is an antibiotic formed by certain types of lactic bacteria and occurs naturally in varying quantities in most varieties of cheese. It has the property of preserving the product for a longer period by retarding the process of deterioration due to the presence of butyric bacteria. The addition of nisin to processed cheese was not uniform in the laws of the Member States. Whereas it was prohibited in the Netherlands it was permitted in other Member States with prescribed maximum levels or without restrictions. The studies conducted until that moment had not reached definite conclusions on the maximum quantity of nisin that a person may consume daily without serious risk to his health. In spite of the scientific uncertainty and the lack of uniformity in the national laws of the Member States regarding the use of this preservative, the Court found that the Dutch prohibition was justified for health reasons. So without mentioning the precautionary principle, this judgment was a model of precautionary thinking.[60]

Anther example of scientific uncertainty appeared in the *Sandoz* case. While this company was lawfully selling, in some Member States, certain food and beverages to which vitamins had been added, the Netherlands started criminal proceedings brought against *Sandoz* for selling those products in its territory without prior authorization. The company had applied for authorization, but it had been rejected on the ground that the vitamins A and D added to the products represented a danger to public health. The Court said:

> [I]n view of the uncertainties inherent in the scientific assessment, national rules prohibiting, without prior authorization, the marketing of foodstuffs to which vitamins have been added are justified on principle within the meaning of Article 36 of the treaty on grounds of the protection of human health.

The Court admitted that in this case it was difficult to make a risk assessment of the addition of vitamins so the Community should permit national rules prohibiting the marketing of these foodstuffs without prior authorization.[61]

In these two examples, we can see that the European Court of Justice has admitted national measures based on the protection of public health in situations of scientific uncertainty[62].

Scientific uncertainty was also the main problem dealing with the crisis of the mad cow disease. In a situation of great uncertainty, dealing with a "serious risk" and given the "urgency"[63], the Commission adopted a temporary ban on exports of bovine animals from the United Kingdom. The European Court of Justice said:

In relation to the regulation of genetically modified organisms, there have been some relevant judgements. In *Monsanto Agriculture and others,* the European Court stated that the safeguard clause envisaged in article 12 of the Regulation 258/97, that allows a Member State to suspend the trade of a food as a result of new information on possible risks, must be understood as giving specific expression to the precautionary principle.[64] In *Austria vs. Commission,* the Court reviewed the provision of one Land [State] of Austria on banning the use of genetically modified organisms in the region of Upper Austria. This draft law was intended to prohibit the cultivation of seed and planting material composed of or containing GMOs and the breeding and release, for the purposes of hunting and fishing, of transgenic animals. This law relied on a report entitled 'GMO-free agricultural areas: Design and analysis of scenarios and implementing measures'. The European Food Safety Authority issued an opinion in which it essentially reached the conclusion that the information did not contain any new scientific evidence, so the law of the Land would not be valid.

The leading case in the explicit application of the precautionary principle is *Pfizer.* This case deals with the withdrawal of an authorization for virginiamycin as a growth promoter.[65] The Court of First Instance applied the principle in an explicit form.

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60 Alemanno thinks that contrary to conventional wisdom, the first manifestation of the precautionary principle in EC law occurred much earlier than in 1992, when the Maastricht Treaty introduced it as one of the guiding principles of the EC environment policy. (Alberto Alemanno, "The Shaping of The Precautionary Principle by European Courts",in Lorenzo Cuocolo and Luca Luparia (Eds.), Vallori Constituzionale e Nuove Politiche del Diritto, (Halley, 2007). Actually, uncertainty is not, and never has been, a foreign concept for Law, that has traditionally solved problems concerning uncertainty.

61 Judgment of the Court (Fifth Chamber), Case 174/82 of 14 July 1983-

62 See also, Case 94/83, Heijn, Judgment of the Court of 19 September 1984, and Case 54/85, Mirepoix, Judgment of the Court (Third Chamber) of 13 March 1986.

63 These two ideas are in the BSE cases.

64 Case C-236/01 of 27 of January of 1997.

65 It can be used, added in very low concentrations to the feeding stuffs of growing poultry, pigs and calves.

Pfizer Animal Health, S.A. was the only producer of virginiamycin in the word. The reason for the withdrawal was the concern that arose in relation with the use of virginiamycin on animals and the possible reduction of effectiveness of antibiotics, not only in animals but also in humans; however, the reasons for the development of resistance to antibiotics in humans had not yet been clarified[66]. Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs established in article 11 establishes that

> [W]here a Member State, as a result of new information or of a reassessment of existing information made since the provisions in question were adopted, has *detailed grounds* for establishing that the use of one of the additives authorized or its use in conditions which may be specified constitutes a danger to animal or human health or the environment although it complies with the provisions of this Directive, that Member State may temporarily suspend or restrict application of the provisions in question in its territory. It shall immediately inform the other Member States and the Commission thereof, giving reasons for its decision.

Prior to the final prohibition of the Community authorities, Denmark informed the Commission and the Member States of its decision to ban the use of virginiamycin in feeding stuffs in its territory based on a report from the National Veterinary Laboratory. During the proceeding Pfizer claimed that scientific knowledge relating to the possible transfer of resistance to virginiamycin from animals to human beings was either totally absent or inadequate. The Scientific Committee for Animal Nutrition (SCAN) concluded that the use of virginiamycin as a growth promoter did not constitute an immediate risk to public health in Denmark[67], so Pfizer maintained that the Community institutions finally adopted the decision without a proper scientific basis. The Court of First Instance said that in a situation of scientific uncertainty, a full risk assessment cannot be required to provide the Community institutions with conclusive scientific evidence of the reality of the risk and the seriousness of the potential adverse effects were that risk to become a reality. Therefore, the Court recognized that a preventive measure cannot be based on a hypothetical risk, but on as thorough a scientific risk assessment as possible. The Court of First Instance literally said:

> [A] preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified (...) Rather, it follows from the Community Courts' interpretation of the precautionary principle that a preventive measure may be taken only if the risk, although the reality and extent thereof have not been fully demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time when the measure was taken.

What is really striking in this case is the departure from the SCAN opinion which concluded that the use of this antibiotic as a growth promoter did not constitute an immediate risk to public health. But the intention of the Council was to ban this antibiotic, as well as three others, despite the opinion of the SCAN. In this case, contrary to the Commission Communication on the Precautionary Principle, the measures adopted were based on a zero-risk approach.

As regards the test of proportionality that limits the discretion of the Community authorities, the Court considered that the prohibition adopted in this case was appropriate to the objective because it was the sole possible response.[68] This conclusion is debatable, because it not clear that a zero-risk approach is compatible with the principle of proportionality.

Another significant case law is *Alpharm,* which is also related to the use of an antibiotic – *bacitracin* – as a growth promoter for animals The Court of First Instance repeated the arguments suggested in *Pfizer*.

The interpretation of the precautionary principle in these judgments is controversial for at least the

66 Although there are several reports on it: WHO, "The Medical Impact of the Use of Antimicrobials in Food Animals" (1997); Economic and Social Committee, "Resistance to antibiotics: a threat to public health" (1998); The Copenhagen Recommendations; the House of Lords Science and Technology Committee (United Kingdom), Seventh Report, (1998); Centre for Science in the Public Interest, "Protecting the Crown Jewels of Medicine" (1998); and others.

67 The SCAN was therefore firmly of the opinion that any risk that might be posed in the future by the use of virginiamycin as a growth promoter will not materialise in the time required to make such an evaluation and most probably not for some years afterwards

68 Otherwise, the Community authorities should adopt less restrictive alternatives.

following reasons: 1. It does not consider the opportunity cost of the precautionary measures. 2. The decision is against the risk assessment made by the bodies of the European Union. 3. The proportionality of the measures is questionable.

Finally, there is a leading case in the recognition of the precautionary principle as a general principle of EU Law. *Artegodan* is a case dealing with the withdrawal of anorectics which are medicinal products for human use. The Court, in another situation of scientific uncertainty, said:

> [I]t follows that the precautionary principle can be defined as a general principle of Community law requiring the competent authorities to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests. Since the Community institutions are responsible, in all their spheres of activity, for the protection of public health, safety and the environment, the precautionary principle can be regarded as an autonomous principle stemming from the above-mentioned Treaty provisions.

Given that this is a general principle of EU Law, it can be applied to other fields different from the environment or the protection of health. We cannot overlook the fact that the *Artegodan* case not only said that the precautionary principle is a general principle of law, but also mentioned another new principle, recognized in Cases C-180/96 R *United Kingdom* v *Commission* [1996] and C-183/95 *Affish* [1997], according to which the protection of public health, safety and the environment takes precedence over economic interests.

IV. Conclusions

In general, there are different effects of the application of the precautionary principle in European Union Food Law. In the case of GMOs some consequences of the European interpretation of the precautionary principle applied to GMOs are: the administrative procedure for the approval of GMOs, the labelling of GMOs, the safeguard clause, the moratorium that was established, etc.

The European interpretation of the precautionary principle is controversial for different reasons. Firstly, this interpretation is controversial because the precautionary principle, as a general principle of law, is an abstract idea that can be interpreted in different ways, depending on the interpreter. This can generate different results regarding the same problem. The Member States could invoke the precautionary principle against the EU to recover their autonomy in health and environment issues, two key issues related with GMOs, imposing stricter national regulations on food safety. This is a serious problem for European integration. France has invoked the precautionary principle to try to ban the drink "Red Bull", out of concern about the effects on pregnant women[69], and Denmark has tried a ban on Cranberry drink, based on a concern about the vitamins added.[70] These two cases have shown that the EU application of the precautionary principle in its territory and in the international arena is completely different. The situation has been the same in some cases of GMOs.

The Member States have to demonstrate that a "real risk" exists in order to apply a precautionary measure in the EU, while the European authorities apply precautionary measures where cause for concern is based on preliminary scientific findings. The EU could invoke, as it has done, the precautionary principle to apply regulations on food safety that are stricter than the international standards, without sufficient scientific evidence. Therefore the precautionary principle can be used to justify protectionist measures.[71]

Why is the European Union promoting this concept of the precautionary principle if it entails a threat to the internal market and could be used to justify protectionism? One reason is because, as Majone has explained, while the European Parliament and the Council respond to domestic political pressures, as well as to diffuse concerns about the globalization of risk, the Commission is tempted to

69 Case C-24/00, Commission v. France: "(…) In certain cases relied upon by the Commission in this instance the French Government has not adduced evidence establishing that the application of the national legislation is necessary to protect effectively the interests mentioned in Article 36 of the Treaty and, in particular, that the marketing of each of the fortified foodstuffs in question presents a real risk for public health".

70 Case C-192/01, Commission v. Denmark.

71 Giandomenico Majone, "What price is safety? The Precautionary Principle and Its Policy Implication", 40 JCMS, 1, 89–109.

see, in the promulgation of the strictest international safety standards, a promising way of strengthening its legitimacy.[72] Another reason is because both the EU and the Member States want to exercise their powers to protect their citizens and to guarantee their peace of mind.

Although the Commission Communication refers to the cost-benefit analysis,[73] it also states that it shall be done where it is appropriate and possible. This means that in some cases, the decision makers forget the opportunity cost of the decision, and in these cases the precautionary measures could result in a high cost for society, or even a cost that society cannot pay. Other people think that society should not have to deal with some kinds of uncertain risks, whatever the price. However, resources are limited, so if we take costly decisions to address risk, these decisions could lead to the impoverishment of our countries.[74] What price is society willing to pay to be, or to "feel", safe?

The application of the precautionary principle that allows governments to ban an activity deemed to involve risks, even if those risks are unproven, or even when its scientific body says that there is no risk, poses enormous risks of losing the advantages of these new products and activities.[75] The defenders of the precautionary principle think that the application of this principle leads to better science.[76] It is true that European scientists must now spend much more time doing research simply to prove that their new product or process is safe. However not only is it impossible to prove the absolute safety of a product or process, it is also true that many European companies would prefer to invest in research in other countries because it would be easier for them to put the new product on the market. In Europe, we adopt a very dangerous presumption of risk about every new product: a new product is always suspicious. A clear example is the regulation of novel foods. A food that has not been significantly consumed in the EU before 15 May 1997 has to pass a risk assessment to obtain an authorization, even if this product has been consumed in other countries for centuries. Is this not excessive? [77]

A decision to avoid a risk can create new risks. A ban on the import of genetically modified seeds in developing countries can generate economic risks for the people of these countries. Some 40.000 people die every day from hunger or malnutrition-related causes that genetically modified products could alleviate.[78] Academics like Graham, Wiener[79], Viscusi or Sunstein have paid attention to risk tradeoff analysis focusing on the negative side effects of regulation when undertaking cost-benefit analysis. The precautionary principle is not a rule to rationalize decisions, but to give precedence to some goods or rights – human health and the environment – interpreted from a particular political point of view.

The precautionary principle has also been criticized because its vague definition can produce arbitrariness in the risk targeting, and in the measures adopted.[80]

It also gives a huge level of discretion to the authorities to adopt measures against products or activities. This discretion could be reduced in the European Union by applying the principle of proportionality. But if the EU Courts recognize the principle of precedence[81] – the protection of public health, safety and the environment take precedence over economic interests – then the role of the principle of proportionality is very limited. In other words, the principle of precedence interpreted in an absolute form – as zero risk in every case – is incompatible with the principle of proportionality. According to the EU interpretation of the precautionary principle in some judgments, decision makers should spend a lot of money to avoid insignificant risks. This interpretation could impoverish our countries while making us fight against unpredictable and improbable risks without truly contributing to the improvement of health, and would restrict certain fundamental rights, such as those of industry.

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72 Giandomenico Majone, op.cit.

73 The European Commission has been criticized by some supporters of the precautionary principle for the introduction of the cost-benefit analysis.

74 Cass R. Sunstein, Law of Fear, op.cit.

75 Gabriel Calzada et al., "The Precautionary Principle: A High Risk Principle", Economic Affairs, September 2005.

76 Nancy Myers, "The Rise of the Precautionary Principle", Multinational Motor, September 2004.

77 See Recuerda, M.A., "Autorizaciones administrativas y presumción del riesgo en el Derecho alimentario europeo el caso de los nuevos alimentos". Revista Española de Derecho Europeo, 31.

78 John Entine, Let Them Eat Precaution, How Politics is Undermining the Genetic Revolution in Agriculture, (2006).

79 John Graham and Jonathan Wiener, Risk Versus Risk: Tradeoff in Protecting Health and the Environment, (1995).

80 Gary E. Marchant and Kenneth L. Mossman, Arbitrary and Capricious, (2005).

81 Cases C-180/96 R United Kingdom v Commission [1996] and C-183/95 Affish [1997].

Everyone agrees that a lack of full scientific certainty should not be used as a reason to postpone cost-effective measures that would prevent threats of serious or irreversible damage. But a strong version of the precautionary principle that allows different types of measures to regulate all kind of risks without solid scientific evidence and without taking into account the cost-benefit of the measures and the new risks created by these measures undermines the EU legal system and leads to arbitrary and incoherent decisions.

The general idea of caution is based upon a rule of common sense which is at the same time an ethical and legal principle employed to deal with hazardous situations: "Be cautious, do no harm". However, the precautionary principle goes further than caution, because it contains other ethical and political values that are deeply rooted in "green" thinking, such as worrying about future generations, the concern for uncertain risks, or the absolute precedence of health and the environment over economic interests. Nevertheless, there are political options that can undermine the foundational values of a legal system, such as fundamental rights, legal certainty, the rule of law, or the prohibition of arbitrariness.

How GMO Administrative Regulations affect the private Balance between Seller and Buyer

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Although there are a lot of scholarly articles on GMO, it is hard to find any texts on private law issues. Legal doctrine has focused its analysis mainly on public policy issues. But the production and commerce of GMO takes place between private parties, so it generates private law problems that have to be settled. This article will show how the different GMO public policy approaches in different countries or how the change of this policy in one country affects the private relationship between seller and buyer in an international contract of sale of GM food and feed. We will show how the ignorance of the public health or environmental national regulations on food, feed and GMO affects the contractual relationship between seller and buyer in international sale of these commodities in favour of the seller. We conclude the convenience to spread the knowledge of certain international public standards, such as the Codex Alimentarius, in order to balance the positions of international sellers and buyers.

I. Introduction

Litigation between private parties in cases related with GMO is neither frequent in national nor in international scopes yet. We can find only one case related with GM food in international sale of goods contracts, and few national cases, mostly from USA, Canada and United Kingdom, related with another private law questions such as of agricultural contracts,[1] patents,[2] trademark,[3] antitrust,[4] insurance,[5] false advertising,[6] labelling,[7] and environmental liability.[8] Nevertheless, scarce case law does not mean that we can not foresee the possible legal solutions for actual problems in the GMO trade by applying statutes and case law about general food and feed international private trade.

II. The contract of international sale of GM goods

In international trading of food and feed protectionist measures adopted to protect human or animal health or to protect the environment are common. When countries adopt restrictive measures to imports, such the one adopted with GMO in the European Union, there are instruments of International Public Law that try to remedy their consequences by means agreed by the countries inside

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1 Such as spraying pesticides (Roundup), Voesenek v. Runne. Manitoba Court of Queen's Bench. Portage la Prairie Centre. Hamilton J. July 17, 2001.

2 It is frequent the farmer's infringement of patent license by saving seeds. Among others: MONSANTO v. McFARLING, UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT. 488 F.3d 973; 2007 U.S. App. LEXIS 12099; 82 U.S.P.Q.2D (BNA) 1942. May 24, 2007, Decided. MONSANTO, et al. vs. TRIVETTE. Case No. 4:07CV343 CDP. UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI, EASTERN DIVISION. 2007 U.S. Dist. LEXIS 33798. May 8, 2007, Decided. May 8, 2007, Filed. MONSANTO v. SCRUGGS. UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF MISSISSIPPI, WESTERN DIVISION. 342 F. Supp. 2d 584; 2004 U.S. Dist. LEXIS 26650. June 14, 2004, Decided. July 6, 2004, Filed. GMO cotton and soybean. MONSANTO v. SWANN. UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI, EASTERN DIVISION. 308 F. Supp. 2d 937; 2003 U.S. Dist. LEXIS 5338. January 8, 2003, Decided. January 8, 2003, Filed. GM cotton and soybean. This infringement is considered inclusive if the saving of seeds was because o adventitious contamination: Infringement of GMO patent, in Monsanto v. Percy Schmeiser, Supreme Court of Canada. May 21,2004.
More frequent are the patent claim litigations:
MONSANTO v. BAYER, UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT. 514 F.3d 1229; 2008 U.S. App. LEXIS 1409. January 25, 2008, Decided. Patent of GMO corn with that expressed Bacillus thuringiensis. SYNGENTA v. MONSANTO et al. UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT. 231 Fed. Appx. 954; 2007 U.S. App. LEXIS 10496. May 3, 2007, Decided. GMO corn that produces insecticidal protein. Invention invalid for obviousness. ADANG and KEMP, v. FISCHHOFF and ROGERS, UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT. 286 F.3d 1346; 2002 U.S. App. LEXIS 7220; 62 U.S.P.Q.2D (BNA) 1504. April 10, 2002, Decided. Insect resistant tomato plants. Etc.

3 MONSANTO v. HILL. UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI, EASTERN DIVISION. 2005 U.S. Dist. LEXIS 43765. March 28, 2005, Decided. March 28, 2005, Filed. Breach of Roundup soybean and Yieldgard corn trademarks.

4 Normally courts do not consider tying contracts as anticompetitive: MONSANTO v. MCFARLING. UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT. 363 F.3d 1336; 2004 U.S. App. LEXIS 6968; 70 U.S.P.Q.2D (BNA) 1481; 2004-1 Trade Cas. (CCH) P74,358. April 9, 2004, Decided. Roundup and corn seeds tying contract is not prohibited, and the prohibition of saving seeds is valid since the patent gives right to the patentee over all the future generations derived from that seeds.
Agreements to eliminate competitors have not been proven. SCHOENBAUM, et al. vs. DUPONT DE NEMOURS et al., Case No. 4:05CV01108 ERW. UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI, EASTERN DIVISION. 2008 U.S. Dist. LEXIS 24630. March 27, 2008, Decided. March 27, 2008, Filed. Antitrust in markets of corn and soybean GM herbicide resistant seeds.
Although the evidence is difficult: SAMPLE, et al., vs. MONSANTO. UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI, EASTERN DIVISION. 218 F.R.D. 644; 2003 U.S. Dist. LEXIS 17352; 2003-2 Trade Cas. (CCH) P74,171. September 30, 2003, Decided. Anticompetitive behavior (in Roundup soybean and Yieldgard corn) was not enough proved. Adventitious contamination was not proved. Impossibility to sale to Europe is speculative. But sometimes the courts consider sufficient evidences: MCINTOSH, et al. vs. MONSANTO, et al. Case No. 4:01CV65 RWS. UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI, EASTERN DIVISION. 462 F. Supp. 2d 1025; 2006 U.S. Dist. LEXIS 84323; 2006-2 Trade Cas. (CCH) P75, 522. November 20, 2006, Decided. November 20, 2006, Filed. In a summary judgment the court considered that GMO companies reached to anticompetitive agreements to eliminate competition in the soybean seeds market. LARSEN, et al. vs. PIONEER HI-BRED., UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF IOWA, CENTRAL DIVISION. 2007 U.S. Dist. LEXIS 83505. November 9, 2007, Decided. November 9, 2007, Filed. Anti-competitive agreements to artificially raise the price of Roundup Ready soybeans and unreasonably restrain trade.

5 CGU INTERNATIONAL INSURANCE PLC v ASTRAZENECA INSURANCE CO LTD. COURT OF APPEAL. [2006] EWCA Civ 1340; [2007] 1 All ER (Comm) 501; [2007] 1 Lloyd's Rep 142. 16 October 2006. English reinsurers of Starlink scandal were released from paying by a judge decision that overruled an arbitral majority award. Insurance policy does not cover patents infringement claims by Monsanto because it was not foreseeable in 1996. RALPH, ET AL. v. PIPKIN, ET AL. COURT OF APPEALS OF TENNESSEE, AT JACKSON. 183 S.W.3d 362; 2005 Tenn. App. LEXIS 287. February 17, 2005, Session. May 17, 2005, Filed

6 Monsanto V. Syngenta. United States District Court For The District Of Delaware. 2006 U.S. Dist. Lexis 54534. August 4, 2006, Decided.

7 International Dairy Foods Association v. Amestoy. 92 F. 3d 67 (2nd Cir. 1996). Commercial freedom of speech is preponderant to consumer's right to be informed through labeling of the content of rBST (recombinant Bovine Somatotropin) in the milk. (The court permits voluntary labeling of rBST). Alliance For Bio-Integrity, Et Al., v. Donna Shalala, Et Al., (United States District Court For The District Of Columbia. 116 F. Supp. 2d 166; 2000 U.S. Dist. Lexis 18866. September 29, 2000, Decided. September 29, 2000, Filed). The Court considers that FDA can refuse to mandate compulsory labeling of GM food if it interprets the FDC Act in a reasonable manner.

8 Claims of extracontractual liability of GMO industries are frequently dismissed because of insufficient evidences: Extracontractual liability caused by GM related pesticides. H & H Lockrey Farms 1997 Ltd. v. Hayter. Ontario Superior Court of Justice London, Ontario. G.P. Killeen J. Heard: December 12, 14, 15 and 16, 2005. Judgment: January 3, 2006. Hoffman v. Monsanto Canada Inc. Saskatchewan Court of Appeal. Cameron, Gerwing, and Sherstobitoff JJ.A. Heard: December 11, 2006. Judgment: May 2, 2007. GEERTSON FARMS., et al. v. JOHANNS, et al. UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA. 439 F. Supp. 2d 1012; 2006 U.S. Dist. LEXIS 53931. July 26, 2006, Decided. July 26, 2006, Filed. Geertson attacks the EPA's modification of tolerance level of glyphosate in alfalfa hay for human consumption without considering the risk for endangered species, what will permit GM alfalfa hay resistant to Roundup. It was dismissed. R (on the application of Friends of the Earth) v U. K. Food Standards Agency. QUEEN'S BENCH DIVISION (ADMINISTRATIVE COURT)[2007] All ER (D) 300 (Feb) 23 FEBRUARY 2007. The Court refused any responsibility of the Public Agency in a case of adventitious contamination of rice. R v Secretary of the State for the Environment, Transport and the Regions and another, ex parte Watson. COURT OF APPEAL (CIVIL DIVISION). The Times 31 August 1998, (Transcript: Smith Bernal). 21 JULY 1998. Organic farmer fails in seeking destruction of legal trial GM maize before it flowers. R v Secretary of State for the Environment, and Transport and Regions and the Ministry of Agriculture, Fisheries and Food, ex parte Watson. QUEEN'S BENCH DIVISION (CROWN OFFICE LIST). CO/2393/98, (Transcript: Smith Bernal). 10 JULY 1998. Public authorities' permission for GM corn to flower can not be disputed when there is scientific support of no risk of cross pollination.
The level of proof sometimes is reached: CENTER FOR FOOD SAFETY; et al. vs. JOHANNS, Secretary, U.S. Department of Agriculture; et al. UNITED STATES DISTRICT COURT FOR THE DISTRICT OF HAWAII. 451 F. Supp. 2d 1165; 2006 U.S. Dist. LEXIS 62981; 64 ERC (BNA) 1650. August 31, 2006, Decided. GM corn and sugarcane with vaccines plantations were approved violating US environmental law. IN RE GENETICALLY MODIFIED RICE LITIGATION. (Rice farmers vs. Bayer CropScience LP) Case No. 4:06MD1811 CDP ALL CASES. UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI, EASTERN DIVISION. 2008 U.S. Dist. LEXIS 49670. June 27, 2008, Decided. June 27, 2008, Filed. Rice farmers seek damages because GM rice contaminated the food supply.

the WTO, multilateral treaties (EU, NAFTA, MERCOSUR) or in Bilateral Investment Treaties. States deal with these questions inside the WTO and the Cartagena Protocol.[9] The process to determine who is going to bear with the consequences of these measures is slow from a private commercial point of view, where prices are so volatile and deliveries are measured in days. Furthermore, only some of these instruments permit private operators of commerce of food and feed to claim for damages against the State that takes these restrictive measures, and even in these cases, the arbitration awards that decide the question take years.[10]

From a practical point of view, private parties should include in the provisions of the contract of sale which part is going to carry the burden of these restrictions: What happens if these restrictions were ignored both by the seller and the buyer or which party will suffer a change in the regulations of the country of destination.

International sales of commodities can be agreed between members of an international association of a particular food or feed trade.[11] These associations use model contracts that may address this problem, or may not.[12]

If these problems are not dealt with in the model contract, parties can agree (or the strong party can impose) a clause that covers the problematic issue, for example, by excluding or limiting any seller's liability.[13] It is true that, from a public law perspective, liability can not be excluded neither in strict liability regimes concerning trade of GMO nor in "in fault" regimes, in spite that such issues falling under this regimes rarely happen.[14] Nevertheless, from a private law point of view, liability can be excluded in any case: if the party that has been contractually exempted of any liability is submitted to a public law penalty, this will be contractually assumed by the other party.

What international case law on international sale of commodities shows is that many contracts do not address the problem of the ignorance or the change of the buyer's country or the regulations of the country of destination. This is particularly evident in the commerce for food and feed, where litigation is mainly focused on this question.[15] GMO trade is especially affected since we can find different levels of regulations: more permissive in USA, Canada and Argentina (exporter countries) and more restrictive in the European Union or Japan.

When the contract does not clearly solve the problem of the consequences of these restrictions to the parties, this gap has to be fulfilled by one national law, ordinarily the law of the strongest party during the negotiations. If both parties have similar bargaining force and they are in one international association with model contracts, the law expressly referred to in the contract and signed by the parties will be applied.[16] If there was no specific clause about the law governing the contract, the tra-

9 WTO Dispute Panel issued a report on September 29th 2006, proposing solutions to the complaints of USA, Canada and Argentina, alleged on May 14, 2003 against the EU moratorium on GM products since October 1998. The conflict was finally solved by agreement of the parties, in January 2008. Cfr. http:// www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm

10 One example is NAFTA. Chapter 11 of NAFTA Treaty permits claims of private investors against any of the NAFTA States. One example is the case of Canadian Cattlemen v. United States, 28 January 2008. In this case, the Canadian Associations claimed for damages caused by the US ban on Beef imports from Canada after the discovery of one case of BSE (mad cow disease). The Arbitral Tribunal dismissed the claim for lack of Jurisdiction because the Canadian Cattlemen Association had not made any investments and were not seeking to make any investments in the territory of the United States. http://www.kluwerarbitration.com/arbitration/Newsletter.aspx?month=april2008

11 For example, North American Export Grain Association (NAEGA), or Grain And Feed Trade Association (GAFTA) Model Contracts.

12 Clause 18 of GAFTA Model Contract No. 100 addresses the problem of the export ban or restriction in seller's country of export by allowing the seller's cancellation of the contract sending notification to the buyer without delay. On the other hand, the same model contract does not solve the problem of a ban or restriction in the country of destiny of the commodities.

13 Total exclusion of liability of the seller can be dangerous in certain countries where this clause of the contract can be considered abusive and void. It is more usual that seller limits its liability for breach of contract to a certain amount of damages, never exceeding the price agreed in the contract.

14 See Díaz, P., Anadón, P., (2008). "International principles on offences under food law and legal uncertainty. Liability and State responsibility". European Food and Feed Law Review 3 (4), 232–245. As general rule, misbehaviours involving ultra hazardous, high risk activities entails the application of strict liability rules; in actions in fault of duty of care or due diligence, the application of negligence rules would be advisable.

15 It is relatively frequent that the party who want to change the terms of a contract because, for instance, a change of the price of the commodity, or a change in the public regulations of its country tries to elude this burden by alleging that the contract of sale has never existed (because a lack during its formation), or that it has already been mainly performed, or by avoiding the contract alleging that it has been fundamentally breached by the other party. In this sense, the change of the pubic regulations will have a straight effect in the performance of the international sales contract of commodities.

16 GAFTA Model Contracts apply United Kingdom law. Other associations apply. NAFTA Model Contracts apply the Law of the State of New York. National Agricultural Commodities Marketing Association (NACMA) the Law of New South Wales.

ditional solution was filling the gaps of the contracts by using the rules of International Private Law (a complex system of conflicts of norms the results of which were almost unforeseeable). In all these cases, the national private law applicable to the contract will be known by the strongest party, or may be, it will be applied the law of a country different than any parties' country.

These solutions to the filling of the gaps are completely unforeseeable, and create legal uncertainty, which becomes a real barrier in international trade. For this reason the UNCITRAL decided to unify the private law of contracts of international sale of goods. The fruit of its work is the Vienna Convention on International Sale of Goods (CISG), a self executing treaty with substantive content affecting the formation of the contract of sale, rights and obligations of the seller and the buyer, and an international uniform system of remedies in the case of breach of the contract.

CISG is in force in more than 70 countries,[17] representing the 70 % of the trade of the world. CISG has been ratified by China, Singapore, Japan, South Korea, Egypt and almost every country in the Americas, Europe and Oceania.

In general, CISG will be applied if seller and buyer have their place of business in countries that have ratified CISG (article 1 CISG) or if both parties voluntarily include an opt-in clause. Nevertheless, the application of CISG is not universal because there are some important countries that have not ratified this convention yet (Brazil, United Kingdom, South Africa and India), and because, pursuant to article 6 CISG, parties can exclude the application of the CISG to a particular contract, by expressly including an opt-out clause.[18] These CISG opt-out clauses are important in GMO trade, because they are to be applied in the model contracts of the USA associations of grain exporters.

Our commentary will be limited to contracts governed by CISG, given the new trend of accepting CISG by important food and feed exporters associations[19] and the UNCTAD and WTO recommend the application of the CISG to international sale of commodities.[20]

We will focus our study in the main problems faced by exporters and importers in the GMOs trade:

- Which one of these has to carry with the burden of the risk if there is an internal element, such a lack of knowledge of the customs or public health regulations by one of the parties.
- Or an external element, such as a modification of these rules during the formation or the application of the contract.
- Retention of the GM goods by the custom officers, due to infringement of the aforementioned regulations due to a cross-contamination of non GMOs with GMOs.
- The consequences of the GMO adventitious contamination of non GMO commodities in bulk contracts and
- The consequences of the flaws of labelling of the delivered goods.

CISG interpretation has to be autonomous, without considering any domestic trade, and must take into account decisions of arbitrators, judges and tribunals of any nation, in order to achieve the purpose of the international interpretation, pursuant to article 7 CISG.[21] Given the lack of case law about GM products we will analogically use case law and doctrine regarding food and feed international commerce.

III. Consequences of the lack of knowledge of the customs or public health regulations by one of the parties

When a party breaches the contract of sale, it is usual the breacher's allegation of a lack of formation of the contract or a reasonable excuse for the breach. In the food and feed trade, and, specifically,

17 http://www.uncitral.org/uncitral/en/uncitral_texts/sale_goods/1980CISG_status.html

18 All GAFTA Model Contracts, NAAEGA Model Contract No. 2 and NACMA Model Contract No. 1 expressly exclude CISG.

19 Model Contract of Australian associations have deleted the opt-out clause from their contract, thus allowing the CISG application: Model Contract of the Chamber of Commerce of West Australia, and NACMA Model Contracts No. 2, 3 and 4 (June 2008 version). Civil Law countries do not exclude CISG: INCOGRAIN (Syndicat de Paris du commerce et des industries des grains, produits du sol et dérivés) Model Contracts. the private law analysis to the application of one law.

20 INTERNATIONAL TRADE CENTER (UNCTAD/WTO)., International Sale of Perishable Goods. Model Contract and Users' Guide., Geneva 1999. Clause 14. It includes the UNIDROIT Principles of International Commercial Contracts, the most successful instrument of the new Lex Mercatoria.

21 A. Martinez Cañellas, Interpretación e integración de la Convención de Viena sobre compraventa internacional de mercaderías. Granada. Comares, 2004.

in GMO trade, the lack of knowledge of the food and feed regulations or the changes in them has been frequently alleged by parties in private dispute settlements.

In some national laws, this lack of knowledge may justify the absence of the contract because of an error in its formation. In the CISG the ignorance of the public regulations by the seller does not affect the formation of the contract. The principle of *favor convention is* recognized in CISG both by case law and scholarly texts allows mandatory rules of one specific country to be applied without necessarily voiding the contract. Neither buyer's nor seller's ignorance of the mandatory rules of the other party's country affects the formation of the contract. Consequently, this contract will be validly concluded when the essential terms of offer and acceptance are agreed by the parties.

The most frequent case in the CISG case law about food and feed is the seller's ignorance of the regulations of the country where the buyer wants to resell the goods, and, as a consequence, the rejection of these goods by the public health or the customs authorities of the country of destination. It is not so strange, since most of the international trade is speculative[22] and public regulations stem frequently from different public health considerations, ideological convictions, and traditional rules of conduct that greatly differ from country to country.

The question discussed in these cases is if the goods delivered by the seller are in conformity with the contract or not (because of lack of quality), considering article 35 CISG,[23] albeit they are not in conformity with the mandatory regulations of the buyer's country or the country of destination of the goods if different.

According to articles 35.1.a and b. CISG, conformity of the goods exists if they are fit for the purposes for which goods of the same description would ordinarily can be used, or fit for any particular purpose expressly or impliedly made known to the seller at the time of the conclusion of the contract.

In the international food trade the purpose of the buyer is not the consumption of the goods but the resale of them. In the case of foodstuffs intended for human consumption, resaleability includes that the goods are unobjectionable as to health, i.e., at least not hazardous to human health, which is determined by public regulations.[24] In case of feedstuffs, the resaleability consists in the unobjectionability as to animal and human health. In the case of GMO, these must be unobjectionable as to health and as to the environment.

In these cases, case law has considered that there is no breach of the contract by delivering goods that are not in conformity to the health regulations of the country where the resale is expected:

– if these regulations are different to the regulations of the seller's country,[25] (if they were the same, it would be a breach of the contract)[26],
– the seller could not reasonably know these regulations (for example, there will be a breach of the contract by delivering goods forbidden in the *Codex Alimentarius* because the seller could easily know this, in this sense *Codex Alimentarius*

22 Singapore is the 6th country in volume of international sale operations.

23 Article 35 CISG:
(1) The seller must deliver goods which are of the quantity, quality and description required by the contract and which are contained or packaged in the manner required by the contract.
(2) Except where the parties have agreed otherwise, the goods do not conform with the contract unless they:
(a) are fit for the purposes for which goods of the same description would ordinarily be used; (b) are fit for any particular purpose expressly or impliedly made known to the seller at the time of the conclusion of the contract, except where the circumstances show that the buyer did not rely, or that it was unreasonable for him to rely, on the seller's skill and judgment; (c) possess the qualities of goods which the seller has held out to the buyer as a sample or model; (d) are contained or packaged in the manner usual for such goods or, where there is no such manner, in a manner adequate to preserve and protect the goods.
(3) The seller is not liable under subparagraphs (a) to (d) of the preceding paragraph for any lack of conformity of the goods if at the time of the conclusion of the contract the buyer knew or could not have been unaware of such lack of conformity.

24 Bundesgerichtshof. 2 March 2005. http://cisgw3.law.pace.edu/cases/050302g1.html Dioxine in frozen pork meat to Bosnia.

25 Bundesgerichtshof. 8 March 1995. http://cisgw3.law.pace.edu/cases/950308g3.html Cadmium in New Zealand's Mussels to Germany. In this case, the regulation was not mandatory but strongly recommended. INCITRAL Digest of article 35. AP Granada. 2 March 2000. http://turan.uc3m.es/uc3m/dpto/PR/dppr03/cisg/sespan15.htm Frozen hen and chicken legs to Ukraine (infringement slaughtering technology). On the contrary Landgericht Darmstadt. 22 December 1992. http://cisgw3.law.pace.edu/cases/921222g1.html Argentinian beef to Germany. Federal District Court of Louisiana. 17 May 1997. Medical Marketing Int'l, Inc. v. Internazionale Medico Scientifica, S.r.l., http://www.cisg.law.pace.edu/cisg/wais/db/cases2/990517u1.html where an arbitration tribunal and an American district court unquestioningly presupposed the applicability of the importing country's (USA) safety regulations. Cámara Nacional de Apelaciones en lo Comercial Sala C. 31 October 1995, Bedial, S. A. v. Paul Müggenburg & Co. GmbH, UNILEX = CLOUT No. 191 http://turan.uc3m.es/uc3m/dpto/PR/dppr03/cisg/sargen9.htm

26 Cour d'Appel Grenoble, 13 September 1995. http://cisgw3.law.pace.edu/cases/950913f1.html sweetened red wine into France. Witz, Witz/Wolter, the over-sweetening was also not permitted under the law of the exporting country (Italy). Bundesgerichtshof. 2 March 2005. http://cisgw3.law.pace.edu/cases/050302g1.html Dioxine in frozen pork meat to Bosnia.

can be considered as an international use of commerce from a international private law perspective and pursuant to article 9 CISG can be included as an implied part of the contract of sale),[27] and
– the goods were saleable in another country (if there were the same rules all around the world, then an infringement of the human or animal health or environmental rules would become a cause of non conformity).[28]

Although the buyer's country regulations ban the import of GM goods, the seller would have delivered conforming goods, and the buyer is obliged to take reception of them. The buyer will be able to resell the same goods in another country (including the seller's country).

If the seller has delivered conformity goods and the buyer refuses (or it is impossible for him) the reception of the goods, the seller has the duty to mitigate the damages (article 77 CISG) by making a substitutive purchase in another country and claiming for the difference between the price agreed with the seller and the price obtained in the substitutive purchase.

Of course, the liability of the buyer in failing to disclosure has the limit of the knowledge of these rules (*v. gr.* the prohibition of GMO trade in EU countries) that the seller knew or ought to have known.[29]

Consequently, if the buyer does not want the seller's country public regulations to be considered as the standard of human or animal health or environmental protection standard, he would do better:
– to communicate to the seller which buyer's countries norms are (for instance, prohibition of GMO if the sale is going to be delivered in a country that forbids the GMO object of the contract of sale), during the negotiations or in the contract[30] or in previous commercial relationships with the same seller,[31]
– to exonerate himself expressly in the contract of any liability derived from any violation of these mandatory regulations (*v. gr.* including a DDP *Incoterm*),[32]
– albeit there is no necessity for this communication if these regulations have become international usage.[33]

The burden of the consequences of the limitation of import of goods (such as GMO products) for the buyer is increased by the usual inclusion (imposition) of sellers' standard terms in the contract of sale of grains. Standard terms usually impose limitation of the seller's liability.[34]

IV. Modification of the public regulations on food and feed after the conclusion of the contract and transfer of risk

In order to reduce the costs imposed on the buyer and to reduce uncertainty and litigation, the unification of food law is interesting for international pri-

27 Hof's Gravenhage. 23 April 2003. Rynpoort v. Meneba http://cisgw3.law.pace.edu/cases/030423n1.html (Wheat-flour with potasium bromate) to Mozambique.

28 Oberlandesgericht Hamburg. 14 December 1994. http://cisgw3.law.pace.edu/cases/941214g1.html Cobalt sulphate case of South Africa.

29 Schlechtriem, "Uniform Sales Law in the Decisions of the Bundesgerichtshof", in Commentary on CISG issues considered by the Bundesgerichtshof, presented in "50 Years of the Bundesgerichtshof".

30 Oberster Gerichtshof (Austria). 25 January 2006. http://cisgw3.law.pace.edu/cases/060125a3.html Frozen pork liver to Serbia.

31 Landgericht Ellwangen. 21 August 1995. http://cisgw3.law. pace.edu/cases/950821g2.html Ethylen oxyd in paprika to Germany.

32 This is not usual. In internacional trade of grains (included GMO) parties agreed in CIF or FOB contracts.

33 Oberster Gerichtshof (Austria). 27 February 2003. http://cisgw3.law.pace.edu/cases/030227a3.html Frozen fish case to Latvia.

34 In case of non conformity of the plants. The seller would be liable only "if it had been grossly negligent in ignoring the lack of conformity, and anyway only up to a sum corresponding to the price". GAFTA Contract No. 100. Hoge Raad. 28 January 2005. http://www.unilex.info/case.cfm?pid=1&do=case&id=1012&step=Abstract. Gran Canaria Tomato plants to Belgium. Bacteria and infection of other plants. Appellationsgericht Canton Basel-Stadt. 33/2002/SAS. 22 August 2003. http://cisgw3.law.pace.edu/cases/030822s1.html Belgium Soyprotein products (vegetarian schnitzel) to Switzerland. It was mentioned in the attachments to the contract that the product had to be free from genetically modified organisms (GMO) but the seller included a limitation of liability up to "the invoiced value of the original transaction". The tribunal stated: "although exemption clauses are generally not reconcilable with a warranty, as the simultaneous existence of both agreements is impossible from a legal point of view. This, however, only applies to the unlimited contracting-out of guarantees, while a restricted exemption appears indeed to be possible (Giger, Berner Kommentar, para 21 on Art. 199 Obligationenrecht). Thus – despite the warranty of freedom from GMO – it was still permissible in the present case to limit the liability for delivery of defective goods in such a way that, although the buyer can avoid the contract, it does not have any further rights to additional damages."

vate traders and the wide and effective (in time and content) communication of these rules to the trading operators. These intensive communications can convert these regulations into international usage, as far as they are assumed by the operators and, as a consequence, an implied part of the contract (article 9 CISG), even if they are not assumed in every country.

The liability of the buyer in the contract does not predict the consequences of the violation of public regulations of the country of destination is of particular importance in cases where these regulations are modified (including the modification of the thresholds) not only during the precontractual negotiations, but specifically once the contract has been concluded.

The resolution of disputes in these cases should follow the same rules: the seller is not under obligation to know public authority regulations on consumption of goods of the buyer's country of destination,[35] and will be liable only if these new (not the derogated ones) regulations of the buyer's destination country are the same as in seller's country.

The buyer can communicate the modification of the public rules of the country of destination, but this communication will not release him from any contract liability (or the payment of the price) since these "new particular purpose" of the goods will be communicated after the conclusion of the contract.

Since jurisprudence considers this problem a question of lack of conformity (a flaw in the quality of the goods because they are not more usable for their ordinary purpose, pursuant to article 35.2.b), this will exist even if the public regulations of the buyer's country or the country of destination are passed after the time of transfer of risk to the buyer (articles 36, 66 to 69 and 70 CISG), albeit the non conformity had not yet been discovered (but already physically existed before although the goods would have been in conformity according the previous regulations).[36] If the seller has not known or ought not have known the regulations of the buyer's country or the country of destination, then the goods will conform if they are resaleable (what for food and feed means at least not harmful to animal and human health, which is determined by public law provisions) according to the seller's country regulation.[37]

As we have seen, the ignorance or the modification of the public regulations or thresholds of acceptance of GMO in the buyer's country will usually be suffered by the buyer. But the buyer can elude the risk of the modification of the rules:

- by including in the contract a DDP Incoterm or other similar clause that obliges the seller to carry all the export and import documentary obligations.
- by including in the contract a clause requiring the seller to obtain public certificates of the country of destination for its products. This objective requirement must be obtained by the seller and the failure to fulfil this obligation will be a fundamental breach of the contract, no matter if the regulations have been modified by the public authority between the moment of the conclusion of the contract and the moment of its performance.
- by establishing in the contract a place of delivery inside the buyer's country.[38] In this case, the buyer has to suffer the risk of the modification of the rules of buyer's country but the seller will breach his obligation of delivering the goods in time, because the public authorities at the frontier of the buyer's country would have adopted preventive or precautionary measures of seizure of the goods,[39] including cases where the measures are adopted by mere suspicion of contamination that render the food unsaleable.[40]

35 Bundesgerichtshof, 2 March 2005. http://cisgw3.law.pace.edu/cases/050302g1.html Dioxine in frozen pork meat to Bosnia.

36 Bundesgerichtshof, 2 March 2005. http://cisgw3.law.pace.edu/cases/050302g1.html Dioxine in frozen pork meat to Bosnia. This irrelevancy of the articles of transfer of risk is true only when the measures of the public authority are related to the nature and characteristics of the goods. In cases when the goods themselves are not relevant to justify the public authority action (for instance, the UN embargo to Yugoslavia), the problem of transfer of risk becomes relevant. Budapest Arbitration. 10 December 1996. http://cisgw3.law.pace.edu/cases/961210h1.html UN embargo. Caviar case to Hungary. In this case, the risk was passed to the buyer in the seller's premises, and the UN embargo took place later.

37 Bundesgerichthof, 2 March 2005. http://cisgw3.law.pace.edu/cases/050302g1.html Dioxine in frozen pork meat to Bosnia.

38 This is not usual in international sales of GMO grains since the great majority of the contracts include a CIF or a FOB Incoterm. Both Inconterms establish that the delivery will take place once the goods have passed the ship's rail of the carrier, before arriving to the buyer's country.

39 The same will happen if the goods are seized in the free zone of the country of transit of the goods before the goods have been delivered to the buyer. Preventive measures are adopted when there is a risk of hazard that can be quantified in probabilistic terms. Precautionary measures are adopted when this risk can no be temporary quantified but it exists, and they will be subject to review. The difference between the legal concepts of "prevention" and "precaution" is clearly stated in Recuerda, Miguel Á. "Dangerous Interpretations of the Precautionary Principle and the Foundational Values of the European Union Food Law: Risk Versus Risk", Journal of Food Law and Policy, Vol. 4, No. 1, 2008.

V. Public Authorities ban on importing goods as an exemption to performance

We have seen that the buyer will suffer the modification of the regulations of its public authorities if these regulations are different than the ones of the seller's country. He can only transfer the burden of such a modification by including, explicitly or implicitly, a specific clause in the contract or stating a place of delivery beyond the frontier of the buyer's country. When the buyer does so, the seller will carry the consequences of any ban or quarantine on importation of goods, and will be liable because of its breach of the contract by not delivering goods on time in accordance with the contract. These consequences can temporarily be avoided by the seller by alleging the exemption of article 79 CISG,[41] which allows the suspension of the performance of the contract if it is caused by an impediment beyond the defaulting party's control, and this party could not reasonably be expected to have taken the impediment into account at the time of the conclusion of the contract or to have avoided or overcome it or its consequences. An administrative ban on imports of GMO can be a cause of suspension of performance since it does not depend on the defaulting party and it is usually unexpected (but not always, sometimes public authorities communicate a future ban with anticipation and sometimes the seller knows the change in public regulations before concluding the contract).[42]

In order to consider this ban on importing as an excuse to perform, it has to be the only cause of lack of performance by the seller, as well, because if there is a breach of the contract not caused by the ban (such as a delay previous to the ban),[43] or that would had happened anyway if the ban had not existed, then the ban will not excuse this breach.[44] The party in breach will be also responsible for impediments when he could have prevented them but failed to do so.[45]

The delivery of reasonable substitutive goods is included in the prevention of damages derived from the impediment,[46] or selling the goods in a substitutive purchase to another country, mitigating the damages (article 77 CISG). This can hardly happen in cases where the public administration adopts seizure measures because it will usually be unreasonable to urge the seller so a big effort in changing labels, costs of reloading, identifying port docking space and refrigerator container availability in a so reduced time.[47]

Pursuant to article 79 CISG, in the case that the impediment can be considered as an excuse, the seller (the party in breach), has to give notice to the buyer of this impediment and its effect in his ability to perform, and this notice has to arrive in a reasonable time to the other party. In the case the impedi-

40 Bundesgerichtshof, 2 March 2005. http://cisgw3.law.pace.edu/cases/050302g1.html Dioxine in frozen pork meat to Bosnia.

41 Article 79 CISG:
(1) A party is not liable for a failure to perform any of his obligations if he proves that the failure was due to an impediment beyond his control and that he could not reasonably be expected to have taken the impediment into account at the time of the conclusion of the contract or to have avoided or overcome it or its consequences.
(2) If the party's failure is due to the failure by a third person whom he has engaged to perform the whole or a part of the contract, that party is exempt from liability only if: (a) he is exempt under the preceding paragraph; and (b) the person whom he has so engaged would be so exempt if the provisions of that paragraph were applied to him.
(3) The exemption provided by this article has effect for the period during which the impediment exists.
(4) The party who fails to perform must give notice to the other party of the impediment and its effect on his ability to perform. If the notice is not received by the other party within a reasonable time after the party who fails to perform knew or ought to have known of the impediment, he is liable for damages resulting from such non-receipt.
(5) Nothing in this article prevents either party from exercising any right other than to claim damages under this Convention.

42 Rechtsbank's-Hertogebosch, 2 October 1998. Malaysia Dairy Industries v. Dairex Holland. http://cisgw3.law.pace.edu/cases/981002n1.html Powdered milk to Singapore.

43 American Arbitration Association. 23 October 2007. Macromex v. Globex. Frozen chicken parts to Romania. http://cisgw3.law.pace.edu/cases/071023a5.html Budapest Arbitration. 10 December 1996. http://cisgw3.law.pace.edu/cases/961210h1.html UN embargo. Caviar case to Hungary. In this case, the risk was passed to the buyer in the seller's premises, and the embargo took place later.

44 Tallon, "article 79" in Bianca/Bonell. Milano., 1987., "A change in circumstances will not be taken into account if it occurred during a delay in performance of the person alleging application of the doctrine" due to the good faith requirements of the CISG, and that when "the impediment occurs during the delay, its causality for the breach of contract is given only if it had an effect in the case of delivery within the period prescribed'." Cheng Wei Liu, Force Majeure: Perspectives from the CISG, UNIDROIT Principles, PECL and Case Law, § 4 (2d ed. Apr. 2005).

45 Bundesgerichtshof, 24 march 1999. Vine Wax to Austria. http://cisgw3.law.pace.edu/cases/990324g1.html

46 Secretariat Commentary 1978. CIETAC. 30 November 1997. http://cisgw3.law.pace.edu/cases/971130c1.html Canned Hunan Oranges.

47 Nevertheless, if another seller has done so, the tribunal can decide that these efforts were reasonable. American Arbitration Association. 23 October 2007. Macromex v. Globex. Frozen chicken parts to Romania. http://cisgw3.law.pace.edu/cases/071023a5.html

ment is a ban of import, is reasonable for the buyer to know this prohibition, what can be discussed is if the seller affected by the impediment will lose the exemption if there is a delay in this notice or no notice at all.

Finally, the seller (the party in breach) will have only a temporary justification not to perform, until the administrative measures that impede the performance disappear and if the passing of the timespan will not be considered as a fundamental breach.

If the suspension of the delivery due to public authorities seizure is as long as to deprive the buyer of what he expected in the contract, for example a delivery in an agreed time, or the delivery becomes impossible, because the destruction of the goods, the buyer will be able to avoid the contract.

If the seizure is temporal, but the goods can not be delivered in the buyer's country, the seller will be liable of breach of the contract, but he will be free of selling the same goods in another country.

VI. Consequences of the limitations or ban on importation of GMO

One of the most problematic factual problems in GMO commerce is the public limitation of imports in several countries, and the absolute ban on imports in the European Union. We have already studied the international public trade law conflicts that these limitations have created between GMO producing countries and countries that prohibit GMO imports. Here we will analyse the consequences of these limitations in private trading of this type of commodities. The main problems are derived from the possible contamination of the non GM goods with GM seeds and grain commodities, the problems of the inspection of these goods, and problems related with the traceability and the labelling of these products. In addition, the entry into force of new legal provisions in the European Union allowing Member states to provide for legal responses in cases of serious breaches related to trade and release of GMO entails an enforcement of the ban in cases of unlawful infringements of the restrictive UE legislation on the issue, which shall be assessed in the future.[48]

1. Adventitious contamination

One of the big problems related with GMO is the adventitious contamination of GM in non GM grain sales in bulk. Although sowing and harvesting of GM products are activities very much controlled by farmers (because of environmental public regulations and industrial property reasons), their storage, transportation and manipulation are frequently not so stringently controlled. It is not unusual to find non GMO commodities mixed with low percentages of GMO. It is normal, because the carrier is not obliged to carry only GM products. In fact, it is impossible to avoid and it has been very difficult to measure. This is the reason why in the Cartagena Protocol it was decided to force the operators in international trade of GM seed to mention in their documentation if the bulk "may contain" GMO. Private grain producers associations such as GAFTA have included in the contracts these "may contain" clause, excluding the seller of any responsibility derived from this adventitious contamination of GMO. This "may contain" is not a *carte blanche* to sellers. They have to control the levels of GMO contamination of the bulks because of the public environmental and health regulations (Japan allows a 5 % of adventitious contamination, Switzerland 1 %, European Union 0,9 %) that can have public sanctions (seizure) or private sanctions (a public seizure can generate private breach of contract for late delivery, including a fundamental breach, that allows the injured party to void the contract,[49] a destruction of the goods by the public authority will create a breach of the contract).[50]

48 At this respect, the recent adoption of the Directive 2008/99/EC (UE No L 328 o/ 6.12.008) allows Member states of the European Union to provide for criminal penalties when serious infringements of community law on the protection of environment arise, without prejudice to other systems of liability for environmental damage under Community law or national law. Offences listed at Annex A to the Directive included any unlawful conduct related: a) the contained use of genetically modified micro-organisms covered by Directive 90/219/EEC and b) the deliberated release into the environment [trade and marketing] under Directive 2001/18/EC. (See also note 14).

49 Appellationsgericht Canton Basel-Stadt. 33/2002/SAS. 22 August 2003. http://cisgw3.law.pace.edu/cases/030822s1.html Belgium Soyprotein products (vegetarian schnitzel) to Switzerland.

50 In cases of contamination public authorities can impose destruction (normally in case of rotten products mixed with agreed products). United States Court of Appeals, Seventh Circuit. Chicago Prime Packers, Inc. v. Northam Food Trading Co. No. 04-255. 23 May 2005. http://cisgw3.law.pace.edu/cases/050523u1.html Rotten pork ribs to Canada.

The control is needed because of the contract clauses that may limit the adventitious contamination to levels that can differ from the public regulations.[51] Mentioning GMO in the contract is relevant. If a product has been delivered with an element, and nothing is said about this element in the contract (and there are some specifications about other elements), case law assumes that the buyer did not consider the presence of this element in the goods as an important element whose presence could justify a fundamental breach.[52] The violation of these clauses has only contractual consequences (it will be a breach of contract and it may justify the voidance of the whole contract if it is impossible to separate GM seed from non GM seed).

In these cases, the buyer position is usually more difficult because sellers impose standard terms with limitation of their liability up to the price and only in cases of gross negligence in ignoring the lack of conformity.[53] The buyer has also the burden of proof of the lack of conformity according to Article 38 CISG (although inspection has become easier, cheaper and quick it has to be performed and paid for by the buyer) and he has to give notice to the seller of the lack of conformity by exceeding the agreed limits in a reasonable time, pursuant to Article 39 (of days, given the possibility of the easy and rapid inspection).[54] In any case, the seller can not rely on Arts 38 and 39 CISG, pursuant to Art 40 CISG, when the seller could not be unaware of the defect, because it was a result of his intentional behaviour,[55] mixing the goods with unsuitable goods. The problem for the buyer is bigger when insurance policies exclude such a risk of adventitious contamination.

In fact, although some levels of prohibition of adventitious contamination may seem to have been agreed in the contract, there may be more obstacles for the buyer, since the seller usually can try to challenge if the limits were really agreed in the contract. This defence is reasonable when these limits were included in standard terms of the buyer's offer and the seller sends his acceptance to the buyer with his own standard terms which include a different minimum percentage of GMO adventitious contamination. In these cases, there will be a problem of battle of forms solved by the "last shot rule" according to article 19 CISG, and the levels of last sent term are to be applied, which implies the buyer's convenience to answer the acceptance of the seller with another communication of buyer's minimum levels of contamination. But if the minimum levels are considered by the parties as a substantial element of the contract, what is usual in non GMO trade, the contract would have not been concluded because there would be no agreement on an essential term, or, if applying the *lex mercatoria* principle of *favor contractus,* the contract can be considered concluded but considering the "knock out rule"[56] generating only the nullity of the limit contamination clause, what, in generally, will be better for the seller.

Finally, if the contract clearly includes a limitation of GMO adventitious contamination clause, the seller can also discuss the moment when this contamination has been occurred. Frequently, it is a

51 Appellationsgericht Canton Basel-Stadt. 33/2002/SAS. 22 August 2003. http://cisgw3.law.pace.edu/cases/030822s1.html Belgium Soyprotein products (vegetarian schnitzel) to Switzerland. It was mentioned in the attachments to the contract that the product had to be free from genetically modified organisms (GMO). The court of first instance considered that only the use of genetically modified enzyme or other additives was reserved, as their use could not be avoided, but the use of GMO soyprotein could be avoided. And seller expressly declared to the buyer that the soy products were tested by SGS and absolutely free from GMO soy. The Laboratory for Food Chemistry at the University of Berne ordered by buyer and the Cantonal Laboratory of the Sanitary Department of Canton Basel-Stadt ordered by the court of first instance proved the existence of GMO (0,1 to 1 %). It was below the mandatory limit of 1 % imposed 3 years after the contract by Swiss regulations, nevertheless it was a breach of the contract.

52 CIETAC Arbitration proceeding. 9 January 1993. http://cisgw3.law.pace.edu/cases/930109c1.html erucic acid in Linseed cakes to New Zealand.

53 In standard terms: GAFTA Contract No. 100. Hoge Raad. 28 January 2005. http://www.unilex.info/case.cfm?pid=1&do=case&id=1012&step=Abstract. Gran Canaria Tomato plants to Belgium. Bacteria and infection to other plants. Or by means of the placement of oral orders followed by invoices containing sales terms or additional terms included in a subsequent written confirmation (included for example on the top of each individual box) unless timely objected to. United States District Court, Western District Washington, at Tacoma. Barbara Berry, S.A. de C.V. v. Ken M. Spooner Farms, Inc. No. C05-5538FDB. 13 April 2006. http://cisgw3.law.pace.edu/cases/060413u1.html Raspberry roots to Mexico.

54 Oberlandesgericht Karlsruhe. 8 February 2006. http://cisgw3.law.pace.edu/cases/060208g1.html wheat with vomitoxine and lead to Hungary. GAFTA rules. Lack of proof of the buyer. 38 and 39 CISG.

55 Landgericht Trier. 7 HO 78/95. 12 October 1995. http://cisgw3.law.pace.edu/cases/951012g1.html Wine blended with water to Germany. Only when the seller is the producer. Oberlandesgericht Zweibrücken 26.7.2002 – 2 U 27/01 (http://cisgw3.law.pace.edu/cases/020726g1.html) Wine blended with water to Germany.

56 Bundesgerichtshof, 9 January 2002. http://cisgw3.law.pace.edu/cases/020109g1.html Rancid powdered milk to Algeria and Aruba.

result of the transportation that the goods are not conform, because the adventitious contamination takes place in the same transport.[57] The dispute will be governed by the contract clause that governs the transfer of the risk, normally an Incoterm, and if there is not a specific clause, by Articles 66 to 70 CISG. The most frequent Incoterms are FOB and CIF and consider that the risk transfers to the buyer when the goods pass the ship's rail in the moment *of the handing* over to the transportation company in the port of origin. Article 67 CISG states that the transfer of the risk to the buyer will take place when the goods are handed over to the carrier in the place agreed in the contract.[58] In these cases, the buyer has the burden of proof that this contamination occurred before the moment of the transfer of the risk (which for GMO is feasible, because other risky moments of adventitious contamination are the sowing, harvesting and storage of the non GM seeds, which usually occur before the transfer of the risk).[59]

2. Problems related with the inspection of the goods

Public limitations and contracts of sale demand inspections. The buyer is obliged to inspect the goods and communicate any lack of conformity of the goods in a reasonable time pursuant articles 38 and 39 CISG, unless otherwise agreed.

Inspections are of two types and have different purposes: public inspection in order to guarantee the environment and the public health of the food and feed,[60] and private inspections in order to control the performance of the contract, the techniques for sampling and testing are usually agreed in the contract.[61]

CISG does not refer to public inspections but to private inspection of the buyer, which does not follow the same strict rules of public inspections. For this reason, inspection of the public authorities does not exclude private inspection of the goods pursuant article 38 CISG.[62] This article demands immediateness of the private inspections but not necessarily an expert inspection, so non expert examination of random samples may be sufficient.[63] Private certification of the seller stating that the goods have already been inspected or the obtaining of a certificate of inspection issued by a public veterinarian authority that holds that the goods are safe to be imported does not absolve the buyer from inspecting the same goods.[64]

In some cases we can find different private inspections with different results (in different moments), in these cases, the conformity will be determined according to the inspection agreed in the contract,[65] if no agreement of this was made, the moment of transfer of risk will be decisive to

57 Court of Cassation 23 January 1996. http://cisgw3.law.pace.edu/cases/960123f1.html wine turned into vinegar to France.

58 Article 67
(1) If the contract of sale involves carriage of the goods and the seller is not bound to hand them over at a particular place, the risk passes to the buyer when the goods are handed over to the first carrier for transmission to the buyer in accordance with the contract of sale. If the seller is bound to hand the goods over to a carrier at a particular place, the risk does not pass to the buyer until the goods are handed over to the carrier at that place. The fact that the seller is authorized to retain documents controlling the disposition of the goods does not affect the passage of the risk
(2) Nevertheless, the risk does not pass to the buyer until the goods are clearly identified to the contract, whether by markings on the goods, by shipping documents, by notice given to the buyer or otherwise.

59 Saskatchewan Organic Directorate v. Monsanto and Aventis; Monsanto v. Percy Schmeiser (Supreme Court of Canada). ORGANIC STANDARD SOIL ASSOCIATION. "Seeds of Doubt. North American Farmer's Experiences of GM Crops", in http://www.soilassociation.org/seedsofdoubt p 47–55.

60 Cour d' appelle de Paris. 10 February 1999. http://cisgw3.law.pace.edu/cases/990210f1.html Horse meat with trichinosis to France. Réseau National de Santé Publique et la Direction Générale de l'Alimentation proofs.

61 GAFTA or NACMA have specific rules of private sampling and inspection. Schiedsgericht der Börse für landwirtschaftliche Produkte in Wien S. 2/97. 10 December 1997. Barley to Poland. SGS GmbH (Austria Control Co.) Österreichisches Getränke Institut. Polish Institute PISiPAR. Laboratorium der Zentralinspektion für Standardisierung. Challenge of SGS inspection certificate (clause in the contract). These private rules of inspection use to be complete. Only in one case an inspection has been rejected by the tribunals because it did not follow the national domestic rules of procedure in CIETAC, 26 October 1993. http://cisgw3.law.pace.edu/cases/931026c1.html Frozen beef case.

62 Oberlandesgericht Thüringen. 26 may 1998. http://cisgw3.law.pace.edu/cases/980526g1.html Live trouts to Germany.

63 Oberlandesgericht Thüringen. 26 may 1998. http://cisgw3.law.pace.edu/cases/980526g1.html Live trouts to Germany.

64 Oberlandesgericht Thüringen. 26 may 1998. http://cisgw3.law.pace.edu/cases/980526g1.html Live trouts to Germany. Nevertheless, the good faith principle may give the buyer an excuse to preserve his remedies for lack of conformity of the goods if the certificate was issued by the seller or by an independent inspector appointed by the seller. Appellationsgericht Canton Basel-Stadt. 33/2002/SAS. 22 August 2003. http://cisgw3.law.pace.edu/cases/030822s1.html Belgium Soyprotein products (vegetarian schnitzel) to Switzerland.

65 United States District Court for the Eastern District of Louisiana. Civ. A. 02-1185. Comercializadora Portimex S.A. de C.V. v. Zen-Noh Grain Corporation. 7 June 2005. http://cisgw3.law.pace.edu/cases/050607u1.html Zearalenone in sorghum to Mexico.

determine who will suffer from the absence of conformity of the goods, because the different results are frequently caused by defective transportation.[66]

Public inspection is not necessarily decisive. The important inspection in private disputes used to be the private one. But in some cases the official authorities' inspection (both at places of origin and destination) can detect hidden flaws of the goods[67] and has been considered decisive by the tribunals if there was a clause in the contract that demanded a public authority inspection[68] and its subsequent certification[69] to consider the goods as conformed or if there is a private[70] inspection and notice of the defects in a reasonable time after the public inspection.

In some cases public inspection is entrusted to private companies,[71] but they are still public and their validity depends on the provisions of the contract.

GMO only can be inspected if there are samples and with very specific techniques, and the buyer is expected to use them, unless otherwise agreed.[72] At the beginning GMO testing was expensive and the possibilities to test for the absence of GMO were limited,[73] but these difficulties did not excuse any fundamental breach.[74] Nowadays the techniques of detecting GMO are easy, not expensive and very fast. In any case, the seller can not rely on Arts 38 and 39 CISG, if he could not be unaware of the defect, because it was a result of his intentional behavior, pursuant to Art. 40 CISG.[75]

Articles 38 and 39 CISG obliges the buyer to inspect the goods immediately and to give notice of any lack of conformity in a reasonable time. In the case that the goods are livestock, this inspection must be done at once or at least on the very next day, and the notice must be given shortly thereafter.[76] A delay in this examination can cause deterioration in the livestock in the absence of food and water, make it too thin and not appropriate to be slaughtered immediately. The Seller is not responsible if public inspections do not respect this timing, once he has delivered the goods in time and to the place.[77]

Once the inspection has been done by the buyer, if there is any lack of conformity, he has to give notice of it in a reasonable time, what has to be undertaken regarding infected commodities has to be completed in a period so as short as practicable,

66 United States District Court for the Eastern District of Louisiana. Civ. A. 02-1185. Comercializadora Portimex S.A. de C.V. v. Zen-Noh Grain Corporation. 7 June 2005. http://cisgw3.law.pace.edu/cases/050607u1.html Different Zearalenone measures in sorghum to Mexico can be caused by the increase of Zearalenone in certain temperature or humidity conditions.

67 Oberlandesgericht Zweibrücken 26.7.2002 – 2 U 27/01 http://cisgw3.law.pace.edu/cases/020726g1.html Wine blended with water to Germany. Ver primera instancia AP Pontevedra 19 December 2007 http://turan.uc3m.es/uc3m/dpto/PR/dppr03/cisg/sespan70.htm Frozen seafood to Spain.

68 AP Pontevedra. 3 October 2002. http://cisgw3.law.pace.edu/cases/021003s4.html Parasited haddock to Jordan. A negative result of the inspection of the public authority of the port of destination was explicitly considered a cause of avoidance of the contract because a contract clause stated that in the event the Jordanian authorities established the existence of defects in the microbiology of the goods, the seller would assume full responsibility. The court stated that the question if parasites were not microbes was not relevant since the goods were not merchantable in Jordan as they were not suitable for human consumption, regardless of the name given to the defect, as the goods were not in a good state according to Jordanian authorities.

69 ICC Arbitration Case No. 9773 of 1999. http://cisgw3.law.pace.edu/cases/999773i1.html Infected hulled buckwheat to Poland. Parties agreed the phytosanitary control by Chinese authorities and only demanded in contract the issue of the Chinese phytosanitary authorities. Private inspection of conformity was different.

70 AP Barcelona. 12 September 2001. http://cisgw3.law.pace.edu/cases/010912s4.html frozen octopus to Egypt.

71 AP Barcelona. 12 September 2001. http://cisgw3.law.pace.edu/cases/010912s4.html frozen octopus to Egypt.

72 In other commodities as wine, case law states that in "case of sale of wine, unless there are some particular reasons to do so, the buyer is not bound to have the wine examined with respect to possible water additions, since this kind of examination is not included among the ones generally undertaken in the wine branch". Landgericht Trier. 7 HO 78/95. 12 October 1995. http://cisgw3.law.pace.edu/cases/951012g1.html Wine blended with water to Germany.

73 Appellationsgericht Canton Basel-Stadt. 33/2002/SAS. 22 August 2003. http://cisgw3.law.pace.edu/cases/030822s1.html Belgium Soyprotein products (vegetarian schnitzel) to Switzerland. Soy from harvest 1996. GMO

74 Appellationsgericht Canton Basel-Stadt. 33/2002/SAS. 22 August 2003. http://cisgw3.law.pace.edu/cases/030822s1.html Belgium Soyprotein products (vegetarian schnitzel) to Switzerland. GMO

75 Landgericht Trier. 7 HO 78/95. 12 October 1995. http://cisgw3.law.pace.edu/cases/951012g1.html Wine blended with water to Germany. Only when the seller is the producer. Oberlandesgericht Zweibrücken 26.7.2002 – 2 U 27/01 http://cisgw3.law.pace.edu/cases/020726g1.html Wine blended with water to Germany.

76 Oberlandesgericht Schleswig. 22 August 2002. http://cisgw3.law.pace.edu/cases/020822g2.html Sheep to be slaughtered in Denmark. On the contrary, AP Cuenca 31 January 2005. http://cisgw3.law.pace.edu/cases/050131s4.html calves to Spain. Considers 20 to 25 days as a reasonable period to communicate de lack of conformity of the calves (although the examination was made by the veterinary in two days after the delivery).

77 A normal delay (two months) in the examination of skin care products with vitamin A decreased the content of vitamin below the minimum agreed level and buyer rejected reception of the goods and packing and labeling. Helsinki Court of Appeal. 30 June 1998. Skin care products to Finland.

for reasons of public policy, to allow the seller to prevent the spread of the infection.[78]

The cost of storage charges during the inspection are to be paid in conformity with the contract. If there is no provision in the contract, the buyer will be responsible of their payment if the risk has been transferred. If the charges have been provoked by a refusal of the goods reception by the buyer, articles 85 to 88 CISG will apply, and the buyer will be responsible unless he proves the lack of conformity of the goods and its communication to the seller in a reasonable time pursuant to articles 38 and 39 CISG. If there is a limitation up to the price or value of the invoice, the seller will never be obliged to pay the costs of inspection nor storage of the goods.[79]

As a result of the official control inspections at entry point, competent authorities are entitled to adopt all the necessary measures intended to enforce the health and consumers protection legislation[80]. Sometimes the custom authorities destroy the goods according to its regulations of import and export of commodities.[81] Neither the buyer nor the seller can consider the possibility of reselling the goods to another country any longer. In these cases, there will not always be a non conformity of the delivery of the goods. Its existence will depend on the private examination by the buyer, if it has been possible or it is not unusual in the particular trade.[82] If it possibly had been the case before destruction that the goods were not conform, then a notice has to be sent immediately to the seller (to avoid the problem of impossibility of a second examination by the seller). If it has not been possible, the buyer can be affected because he will not examine and will lose his rights to allege the non conformity, unless we can consider custom offices examination to be equivalent to buyer's inspection, which has to be customary in commerce or to be included in the contract.

3. Importance of traceability for dealers

The importance of the traceability of the GM products is essential to reduce the amount of damage arising from a breach of contract or from a violation of a mandatory regulation. Traceability will be advisable for the seller. It will prevent him claiming damages for the total amount of delivered goods in cases of a minimal in quantity but fundamental in quality non conformity of the goods.[83] Traceability of the goods is also advisable for the buyer, because it can reduce the effects of a public seizure or destruction of the goods.

From a contractual point of view, traceability of the goods can be demanded by the buyer. The seller is not supposed to determine parts of the goods delivered. It is not included in the obligation of mitigation of damages of Art 77 CISG unless it is customary use of commerce in that particular trade. When trading

78 AP La Coruña. 21 June 2002. http://turan.uc3m.es/uc3m/dpto/PR/dppr03/cisg/sespan19.htm Rainbow trout eggs to Spain. The buyer sent the goods for inspection in 28 April 1998, the inspection could be done in two weeks (7 days incubation of virus plus 2 to 7 days for diagnosis).

79 Appellationsgericht Canton Basel-Stadt. 33/2002/SAS. 22 August 2003. http://cisgw3.law.pace.edu/cases/030822s1.html Belgium Soyprotein products (vegetarian schnitzel) to Switzerland. GMO

80 At European Union level, article 54.2 of Regulation (EC) 882/2004 establishes a list of measures that Member states can adopt to ensure enforcement of food and feed legislation, including also cautionary measures (a) the imposition of sanitation procedures or any other action deemed necessary to ensure the safety of feed or food or compliance with feed or food law, animal health or animal welfare rules; (b) the restriction or prohibition of the placing on the market, import or export of feed, food or animals; (c) monitoring and, if necessary, ordering the recall, withdrawal and/or destruction of feed or food; (d) the authorisation to use feed or food for purposes other than those for which they were originally intended; (e) the suspension of operation or closure of all or part of the business concerned for an appropriate period of time; (f) the suspension or withdrawal of the establishment's approval; (g) the measures referred to in Article 19 on consignments from third countries"

81 Higher People's Court [Appellate Court] of Shandong Province. 10 September 2004. WS China Import GmbH v. Longkou Guangyuan Food Company http://cisgw3.law.pace.edu/cases/040910c1.html rotten fruits to Germany. Lack of packaging and mixing of the fruits. Cleaning, storage and destroying fees. Seller could not ignore the mixing of the goods, so buyer is released o fits obligation of notice of the lack of conformity.

82 Landgericht Trier. 7 HO 78/95. 12 October 1995. http://cisgw3.law.pace.edu/cases/951012g1.html and Oberlandesgericht Zweibrücken 26.7.2002 – 2 U 27/01 http://cisgw3.law.pace.edu/cases/020726g1.html. Wine blended with water to Germany in both cases.

83 Appellationsgericht Canton Basel-Stadt. 33/2002/SAS. 22 August 2003. http://cisgw3.law.pace.edu/cases/030822s1.html Belgium Soyprotein products (vegetarian schnitzel) to Switzerland. GMO. Although the seller alleged the reduction of damages to the parts of the goods, in which traces of genetically modified corn were actually found, and could be regarded as unusable. The tribunal considered that it could not be considered as such parts only samples that were taken, but also the rest of the goods because of a possible contamination of the remainder of the goods (precautionary principle). The buyer was neither expected to examine the entire goods (because it was not reasonable expensive in time and money), nor could it have been expected to process the unexamined goods and sell them with the risk of being reaccused of the forbidden distribution of genetically modified organisms. For this reason, the buyer is allowed to avoid the contract in its entirety, although as a consequence thereof, the book value of all goods delivered will apply as the maximum amount of liability.

seeds and grain in bulks, traceability of GMO is not an international standard, nor a reasonable implied obligation because of its difficulty.[84]

4. Labelling

Labelling of the goods is important, particularly in cases that the commodities are destined for the consumers. The possibility of the products being labelled is an important element of the conformity of the sale of food and feed. Labelling can be mandatory or voluntary. If voluntary, there can be public or private controllers of the labels. If the goods bought by the buyer do not fulfill the requirements of these authorities, then the label will not be granted, and the market value of the goods will be reduced or even the sale of the goods can be forbidden in the country of destination.

The problem in these cases is that there are too different controls: a control made by the public or private controller and the control of the buyer. The former usually takes more time than the immedite time for examination and a reasonable short timespan for notice of the lack of conformity of the goods, demanded to the buyer, pursuant to article 38 and 39 CISG and its case law. This problem is solved by including a clause in the contract demanding the controller certification at the moment of delivery.[87]

Sometimes the requirements of the controller are included by the buyer in the contract explicitly or implicitly (for example by giving to the seller a sample of the package or the label,[88] or giving to the seller the data that have to be included in the tag)[89]. Thus, the delivery of the goods in a package or without the labelling agreed in the contract is a breach of the obligation of the delivery of goods in conformity with the contract (Article 35.2.c CISG).

The inclusion of the labelling and packaging requirements in the contract can be explicit or implicit. It is implicit when it is not explicitly stated by the parties during the negotiations nor in the contract terms, but common practice between the parties has been established. For example, if seller and buyer are in a business relationship, the seller has to interpret the contract (pursuant to article 8.1 CISG) according to the prior relations and ought to know that the buyer buys the goods to be resold in a particular country, so the goods have to be packaged and labelled according to the manner required in the country of destination.[90]

If this packaging or labelling is not explicitly or implicitly agreed in the contract, then the uses of the particular commerce of the goods will be applied. But the buyer has to clearly specify the requirement in the contract or clearly prove the existence of this particular commercial practice. And he will have the duty to inspect the correctness of the packaging and labelling at the very moment of the delivery of the goods[91] and to mitigate the loss, for example, by adding stickers as labels. If he fails in doing so, then he will bear the non conformity of the delivery of the goods.[92]

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84 GAFTA and US Wheat Association.

85 Higher People's Court of Shadong Province. 27 June 2005. (Norway Royal Supreme Seafoods v. China Rizhao Ocean Food Company et al.) http://cisgw3.law.pace.edu/cases/050627c1.html Frozen lobster tails mincemeat to Norway. It is not a case of labeling. The time for notice was seven days after the buyer receives the goods by providing the inspection report issued by an authorized organization (SGS Norge Company).

86 Oberlandesgericht München. 13 November 2002. http://cisgw3.law.pace.edu/cases/021113g1.html Organic Barley to Belgium. Refusal by the Supervising authority of the Belgian Ministry of Agriculture to qualify the barley as "organic" (Council Regulation EEC No. 2092/91). The buyer could not process and sell it to the ultimate customer. The organic origin is proven by certificates accompanying the goods issued by companies admitted for certification.

87 On the contrary, 30 days from delivery were considered as reasonable time in the sense of articles 38 and 39 CISG in Cour d' Appel de Grenoble, Chambre Commerciale. 13 September 1995. http://cisgw3.law.pace.edu/cases/950913f1.html Italian cheese to France without label of composition and expiration date in the wrapping. A 30 days term to notice of lack of conformity use to be expressly agreed in some types of international sale contracts (polyesther), but this is not necessarily a general use of commerce. As an example, the contract discussed in CIETAC 19 June 2003. http://cisgw3.law.pace.edu/cases/030619c1.html PTA to China.

88 COMPROMEX. 30 November 1998. Dulces Luisi c. Seoul International. http://cisgw3.law.pace.edu/cases/981130m1.html Sweets to Korea. The Mexican enterprise packaged the goods according to the instructions of the Korean companies but the Korean custom officers seized the goods because the label stated a caducity date of two years and the public regulations stated a time limit of one year for sweets.

89 CIETAC. 25 September 1998. Alaska fish oil, lecithin, shark cartilage and intelligence quotient supplement for children to China.

90 Cour d'Appel de Grenoble, Chambre Commerciale. 13 September 1995. http://cisgw3.law.pace.edu/cases/950913f1.html Italian cheese to France without label of composition and date of peremtion in the wrapping.

91 Rechtbank Rotterdam. 20 January 2000. http://cisgw3.law.pace.edu/cases/000120n1.html unsuitable packaged Argentinian cherries to Netherlands.

92 Landgericht Hamburg. 31 January 2001. http://cisgw3.law.pace.edu/cases/010131g1.html frozen pork ribs and apple blinies to Germany in inappropriate packaging (not transparent when it is use of commerce) and labelling.

Usually, the lack or the improper labelling is not a justified cause of fundamental breach of the contract.[93] It only makes the goods less marketable and it can be easily remedied by sticking a tag label in the package. It will be a fundamental breach only if the parties agreed to consider the improper labelling as an essential lack of conformity or if it was labelled contrary to the requirements demanded by the buyer and the wrong labelling impedes the international marketability of the goods although that is not necessarily the case due to (the way in which customs series work[94] or) how the Lex mercatoria has been evolving recently concerning trade of goods or series that fall under the umbrella of some multilateral environmental agreements.[95] But it will be not a fundamental breach the fact that if the public health authorities of buyer's country did not deliver the mandatory certificate or the official label to make the goods saleable in the country of destination. This is a reasonable solution because the goods may be still fit for their purpose so they can be sold in another country or be labelled properly in time.

Once again the position of the buyer is weaker than the seller's position: if he wants to argue that the lack of labelling is to be considered a fundamental breach, he has to prove not only that the labelling is inappropriate (according to the contract,[96] or to the public regulations of the seller's country or the ones of the buyer's country if they were the same as the seller's country, or were communicated to the seller before the conclusion of the contract or were an international commercial practice) which is relatively easy,[97] but also that the inappropriate label has caused him a substantial detriment,[98] foreseeable by the seller (Article 25 CISG), which will be harder. On the other hand, the buyer's refusal to take delivery of the goods can be considered a fundamental breach of contract.

VII. Conclusions

The ignorance of the public health or national environmental regulations on food, feed and GMO affects the contractual relationship between seller and buyer in international sales of these commodities in favour of the seller. Unless otherwise agreed, or unless the buyer communicates his country regulations before the conclusion of the contract, the seller's country regulatory standards will be applied. In order to balance the positions of seller and buyer

93 CIETAC. 25 September 1998. Alaska fish oil, lecithin, shark cartilague and intelligence quotient supplement for children to China. Labels in English, goods are not necessary not conformed.

94 Decisions of administrative courts concerning the damage caused to goods by the delay in the health and environmental inspections at the EU socalled "border inspections posts" have stated that the Administration should be immune to liability claims due to the amplitude of the reasonableness test. Any damage based in the existence of any error in the certificates, labels or papers, that triggers special inspection procedures, cannot be attributed to the custom services but to the exporter or importer-depending on their contractual arrangements. See e.g. decisions on June and July 2009 by the Spanish Council of State. The recent Council Regulation (EC) No 1005/2008 of 29 September 2009, establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated – IUU fisheries –, even allows, in article 7.3, the administration, after 14 days, to dispose of the fishery products awaiting final import permit (due to the defects on the paper certificates), without any right to compensation to the importer or exporter.

95 This special "public order" value of some basic principles concerning "non-LMD" or "non-GMO" labelling, that may affect the validity of contract clauses or even of contract themselves, or that could shift – toward a fundamental breach of contract – the interpretation of silence in the contract could be applicable at least in circumstances where national law makes of the GMO labelling a question of what for example Marsha A. Echols, has called the "marketing order" (see Marsha A. Echols, "Expressing the Value of Agrodiversity and its Know-how in International Sales", in 48 Howard Law Journal 431, 446ff., 2004), or when the parties to the contract have a very clear understanding that they are engaging in relationships within the context of what Joseph A. Miller has called private "Non-GMO contracts" (see Joseph A. Miller, "Contracting in Agriculture: Potential Problems", in 8 Drake Journal of Agricultural Law 57, 82ff., 2003). In general this is a trend applicable to many other State or self-imposed "ius cogens" rules by coeporations which conduct their usual business of international transactions in areas where international environmental law has set clear-cut principles that all nations should observe, or even where the market has adopted "Beyond Compliance" standards as the usual diligence standard in that market. See, for all, Enrique Alonso García, Introduction to International Environmental Law: Handbook with Cases and Materials foe American Lawyers (Friends of Thoreau-IUEN-URJC University Press, 2d ed., 2009), Ch 9, pgs 9–1 ff. and the selected bibliography listed in pgs 9–38 ff.

96 If both buyer and seller have adopted a common code of conduct or belong to an association that has adopted a code of conduct that, for example, demands certain requirements to trade with GMO in order to get am specific label, then this code of conduct will be applied to their relationship as a part of the contract.

97 The incorrect earmarks or chips or lack of both of the livestock delivered to be slaughtered could be a lack of conformity, if the buyer had given notice in a reasonable time and proved that this flaw is prevent it to be slaughtered. In this case, the buyer failed in this proof in Oberlandesgerichthof Schleswig. 22 august 2002. http://cisgw3.law.pace.edu/cases/020822g2.html Sheep to be slaughtered in Denmark.

98 Not only a direct loss, but also indirect losses such as losses of subsidies and payment of fines because the infringement of mandatory labeling. AP Madrid. 8 May 2003. http://cisgw3.law.pace.edu/cases/030508s4.html packaged bovine meat to Netherlands.

it is advisable to spread the knowledge of certain international public standards of food safety[99], such as the *Codex Alimentarius*, among international private trade operators, particularly associations of exporters and importers. This balance can be restored only if these common international common standards are accepted by the private parties in the contracts (for example, by including a clause with reference to theise standards in the model contracts of the international traders associations) or only if these standards become international commercial practice.

The modification of national public regulations once the contract has been concluded creates more legal uncertainty, suffered also by the buyer (importer) more than by the seller. In this case, the balance between seller and buyer is impossible to achieve until international common standards overrule the national public regulations.

The same has to be concluded with reference to the problems derived from the contamination of the non GM goods with GM seeds and bulk grain or commodities, the problems of the inspection of these goods, and problems related with the traceability and the labelling of these products. The buyer will have always the weaker position: he has to inspect in a brief time the possible contamination of the goods, or the flaws of the labels, at his expenses, because neither public nor seller's inspection will be sufficient unless otherwise agreed. Fortunately, in private inspection matters, international associations have developed international standards. It would be convenient to develop international standards in labelling and acceptance of GMO, as well. But it seems impossible, since labeling of the food and GMO acceptance is a question directly related to the consumer's right to choose what he believes is more convenient. These consumer's decisions are influenced by scientific communications and by cultural[100] and religious motives that are hard to harmonize. Perhaps these motives will change once confronted with the increasing necessity of attending to global needs of food.[101] If these different consumers' perceptions do not change, we will face not only restrictions of free trade, but also a new wave of processing food industry relocation, since GMO producers, in order to avoid the problems derived from the minimal GMO contamination percentage standards, will no longer import food and feed in bulks, instead they will process the food and feed in the country of harvest and will export only processed and packaged products.

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99 See, Recuerda Girela, M.A. (2006), Seguridad Alimentaria y Nuevos Alimentos. Régimen Jurídico-Administrativo. Thomson-Aranzadi.

100 Sahlins, Marshall. Cultural and Practical Reason. 1976. On the contrary, some authors consider that food decisions are made solely on the basis of material factors. Harris, Marvin. Cultural Materialism: The Struggle for a Science of Culture 1979. Both cited in Hutt, Peter Burton/Merril, Richard A./Gossman, Lewis A. Food and Drug Law. Cases and Materials. Foundation Press. Thomson West. 2007. p. 91.

101 Food security concerns may overcome food safety reticences, which currently impose restrictions to internacional GMO international commerce. About the legal concepts "food security", "food safety" and the "right to food" cfr. Recuerda, Miguel Á. "Food Safety: Science, Politics and the Law", European Food and Feed Law Review, n. 1, 2006.

GMOs and Resolution of Conflicts Under the WTO

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The use of different standards and approaches for the assessment, management and communication of risk analysis in general, and in particular in foodstuffs, has important trade consequences. That is so noticeable that an organization outside the field of regulating food safety, the World Trade Organization (WTO), has become the most important (pseudo) standardization organization in the field through the implementation of its Agreement on Sanitary and Phytosanitary (SPS) measures. This paper will analyze how trade regulations are dealing with these issues and how these effects are borne by the States, private companies and ultimately normal citizens. This paper will first introduce the general framework of international trade to focus, after that, on the regulation on food safety within the WTO and to conclude with an analysis of the GMO dispute and its effects.

I. A brief history of the international trade framework: from GATT to WTO

1. Introduction

The General Agreement on Trade and Tariffs (GATT) was approved in 1947, as a provisional agreement until the establishment of the International Trade Organization (that never came into force), to promote the liberalization of international trade. The success of the GATT agreement is based on the establishment of a pseudo-organizational structure, which included the development, through customary law, of its well known and controversial dispute settlement procedure, and on its leading role as the international forum on trade expressed through several rounds of negotiations[1] (presently embarked in the 9th Round of negotiation: the Doha Round[2]).

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1 The GATT entered into force through the approval of the Protocol of Provisional Application (Australia, Belgium, Canada, United States, France, The Netherlands, Luxemburg and the United Kingdom), which lasted almost 50 years. See 55 UNTS 308 (1947); John Howard Jackson, The World Trading System: Law and Policy of International Economic Relations, 38 (1997) MIT Press; Marc Hansen, The GATT Protocol of Provisional Application: A Dying Grandfather?, 27 Columbian Journal of Transnational Law 263 (1989).

2 Stefan Griller, At the Crossroads: The World Trading System and the Doha Round. Springer (2008).

2. GATT main provisions

To achieve its main objective the GATT agreement rests on the principles of transparency and non-discrimination. The latter is reflected through the Most Favored Nation[3] and the National Treatment[4] provisions. These two non discriminatory principles guarantee the non-discrimination of "like products"[5] of different countries at the customs level, and, once they have entered the country, the non discrimination of the imported goods before national "like products".

Although the preferences and habits of the consumers are included in the "tax adjustment at the border" test[6] applied by the different panels in their reports, reality shows that all the panels have focused their analysis in the more objective criteria (such as the tariff classification of the product, its physical features or its final use)[7] probably to avoid the complexity of having to value more subjective appreciations that were located too far away from them.

Another important pillar of GATT is based on the prohibition of quantitative restrictions8 (though the agricultural sector has been historically one of the main exceptions, and now one of the main obstacles to conclude the present Doha Round) and the non-tariff measures.

Apart from the important list of rights and obligations, GATT-1947 would have never been approved without the inclusion of a list containing exceptions that show the areas that are more sensitive for the States, areas where States do not want to lose or restrain their sovereignty and powers. Article XX is the expression of the limits of international free trade and the general rights and obligations contained in the GATT. The importance of risk analysis and food safety9 is covered by Article XX.b) which allows States, according also to the requirements of the Chapeau of article XX, to adopt measures "necessary to protect human, animal or plant life or health". In any case to compensate this deviation of the rights and obligations to the agreement, the Contracting Party invoking the exception bears the burden of proof.

When a developing country invokes Article XX (b), the necessity test and the "reasonably available" alternatives must be looked at in the light of the actual possibilities available to developing countries, and in particular their economic cost and technical complexity in relation to the scarcity of financial and technical resources characteristic of such countries.

3. Negotiation rounds

As has been noted previously, the success and consolidation of the GATT agreement as the main international forum on international trade is directly connected with the development and results of its different Rounds of negotiation. GATT 1947 went through 8 different Rounds of negotiation (the eighth, the Uruguay Round, was the one approving the World Trade Organization).

The first five rounds were devoted almost exclusively to the reduction of tariffs with the negotiation of different lists that reflected the concessions of each Contracting Party regarding the reduction of tariffs.[10] The sixth round – the Kennedy Round – was the first one that approved a side code, the Antidumping Code of 1967, showing a new trend towards the regulation and abatement of non-tariff measures.[11] The following Rounds – Tokyo and Uruguay Rounds – just confirmed that expansion.[12] The Tokyo Round negotiated and approved 9 special agreements (Codes) and 4 understandings.

The Uruguay Round was able not only to expand to new fields, such as services or intellectual prop-

3 Article I, GATT-19947 (available at http://www.wto.org/english/docs_e/legal_e/legal_e.htm).

4 Article III, GATT-1947 (supra note 1).

5 To see a complete list of the cases that have dealt with the interpretation of like products see the footnote 58 in page 33 of the Appellate Body report on European Communities – measures affecting asbestos and asbestos-containing products (WT/DS135/AB/R).

6 Julian Wong, Are Biotech Crops and Conventional Crops Like Products? An Analysis under GATT. Duke Law and Technology Review 27 (2003).

7 Supra note 4.

8 Article XI, GATT-1947 (supra note 1).

9 See, on the legal concept of food safety and risk analysis, Miguel Á. Recuerda, Seguridad Alimentaria y Nuevos Alimentos. Régimen jurídico-administrativo. Thomson-Aranzadi, 2006.

10 Miguel Angel Díaz Mier, Del GATT a la Organización Mundial de Comercio. 115 Editorial Síntesis SA, (1996).

11 This side Code was problematic for the US Congress and a new one had to be approved in the following Round (Tokyo Round) in 1979. JACKSON (supra note 1), p. 72–74.

12 That vis expansiva has been deeply analyzed in a special number of The American Journal of International Law, Vol. 96, no. 1 (January 2002), in particular Joel P. Trachtman (2001) Institutional Linkage: Trascending "Trade and …".

erty rights, but also to create a single package, where a Contracting Party has to accept the whole package to become a Member (with the exception of the plurilateral trade agreements of Annex 4), ending the legal uncertainty created by the "pick and choose" situation of the side Codes of the Tokyo Round. The 1st of January 1995 the WTO started its operations and the 31st of December of that year GATT 1947 ended its application. The agreement on "Sanitary and Phytosanitary" (SPS) measures and the agreement on "Technical Barriers to Trade" (TBT) are included as part of the Multilateral Agreements on Trade in Goods of Annex 1A.

The WTO also introduced a new and more sophisticated Dispute Settlement Understanding with the inclusion of a new Dispute Settlement Body. The system relies on the same basis of the panels' reports but with a more automatic procedure for the adoption of the reports and with the possibility of appealing those reports to a second instance, the newly created Appellate Body. The system only foresees the solution of disputes between Contracting Parties (States), not allowing the participation of private companies or individuals as claimants.

II. The WTO regulation on food safety

1. Introduction

Although, there are other international institutions that deal with public health and food safety issues, for example the FAO through its *Codex Alimentarius* Commission, the WTO is the only organization providing for a set of legally binding obligations for its Members when they develop their own food safety regulations. Most of these rules are contained within the SPS agreement.

Any Contracting Party, under GATT-1947, could establish a sanitary or phytosanitary measure against the rights and obligations of the GATT agreement invoking the exceptions of article XX, in particular article XX.b). According to GATT's practice, most SPS measures would be under that exception as long as the policy measures fell within the protection of public health and were deemed necessary to fulfill the policy objectives. Of the course the measures had to be applied in a non-discriminatory manner (on imported as well as on domestic goods). So, until 1995, under GATT-1947 any sanitary or phytosanitary measure that was considered necessary and reasonable and it was not applied in a discriminatory manner, would have been covered by the exception of article XX.b). This exception left an important degree of flexibility to the Contracting Parties to exercise its sovereignty in a field that it is considered very sensitive for the states.

The increasing use of non-tariff barriers[13] in the latter part of the application of GATT-1947 led the negotiators during the Uruguay Round to the belief that the principle of non-discrimination, as the basis for the introduction of this kind of measures, was not sufficient to address this specific policy issue, and that scientific evidence should be also required. Under these premises the Contracting Parties negotiated a set of rules that would have to be followed when introducing or applying their own regulations for food safety. In that sense the SPS agreement is clearly, as it will be explained later, an extension or development of the exceptions covered by article XX.b) of the GATT agreement.

2. SPS agreement basic rights and obligations

The SPS agreement applies to "all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade" (article I).[14] Members have the right to take SPS measures "necessary to protect human, animal or plant life or health" (article 2.1) though the objective of the agreement, as expressed in article 1, is exactly the opposite, to limit that right to guarantee that it is not used as an excuse to restrict trade.[15] From article 1 it is clear

13 Peter Ward, Sanitary and Phytosanitary Measures at the WTO: Balancing Biological Risk and Commercial Interest, 7 Asper Review of International Business and Trade Law 101(2007). This author points out that the number of food imports into the US that were subject to non-tariff barriers raised from 57 % in 1966 to 90 % in 1986.

14 The definition of sanitary and phytosanitary measure is included in Annex A: "Any measure applied: a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms; (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs; (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests."

15 Nick Covelli, Viktor Hohots, "The Health Regulation of Biotech Foods Under the WTO Agreements", 6 Journal of International Economic Law 778 (2003).

once more that WTO is a trade focus organization and that its main objective is not the protection of public health or consumers but the elimination of barriers to trade in the form of sanitary and phytosanitary measures.

The idea of the development and limitation of article XX.b) in the case of sanitary and phytosanitary measures is clearly stated in the SPS agreement in the repetition of that text in different provisions. Article 2.1 refers to the specific exception of article XX.b) as a right of the Members to adopt such measures. However, article 2.2 conditions that right and the introduction of those measures "only to the extent necessary", which makes reference to the already known test of necessity which was also applied by the panels in the observance of the exceptions of article XX. The necessity test is also accompanied with the proportionality test included in article 5.6, which states that "Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary and phytosanitary protection, taking into account technical and economic feasibility".

The application of the non-discrimination principle is reinforced in the SPS agreement with the inclusion of the text of the Chapeau of GATT's article XX, which is fully covered under article 2.3. The terms and tests of the Chapeau of article XX are also included in article 5.5, which specifically refers to the avoidance by a Member of arbitrary or unjustifiable distinctions, in the determination of the appropriate level of sanitary or phytosanitary protection and in different situations, "if such distinctions result in discrimination or a disguised restriction on international trade".

The repetition of the provisions contained in article XX is balanced with the establishment of the presumption that measures in conformity with the SPS agreement are in accordance with the obligations of the Members under the provisions of GATT 1994, in particular with the exception of article XX.b).[16]

3. Scientific basis and international standards

The central pillar of the SPS agreement is the addition – to the existing non-discrimination, necessity and proportionality tests – of the sound science as the basis for the adoption and maintenance of sanitary and phytosanitary measures[17]. Article 2.2 states that Members shall ensure that any sanitary and phytosanitary measure they adopt "is based on scientific principles and is not maintained without sufficient scientific evidence".

For the application and recognition of the sound science, Members must apply international standards the only exception to that rule , being the existence of "a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate" (article 3.3).

To reinforce the application of international standards the SPS concedes a presumption of consistency with the SPS and the GATT agreements of those measures adopted following international standards. In particular, the SPS refers to those standards established by the *Codex Alimentarius* Commission, the International Office of Epizootics and the International Plant Protection Convention.[18] Through this technique WTO makes binding standards that previously were considered and negotiated as voluntary, which has had an important impact on these organizations.

The work of the *Codex Alimentarius* Commission has experienced an important politicization since the entry into force of the SPS. As TRACHTMAN and ALEMANNO have pointed out, the presumption of conformity introduced by the SPS makes these organizations "quasi legislators".[19] Since 1995 the approval of a new standard within those organizations means conformity of that standard with the SPS and, therefore, many countries have now a political interest in the approval of its own standards, for instance in the *Codex Alimentarius*, to avoid the defence of its measures under SPS. This politicization of the Commission makes it more dif-

16 Article 2.4.

17 See, Miguel Á. Recuerda, "Food Safety: Science, Politics and the Law", 1 European Food and Feed Law Review (2006).

18 Joanne Scott, "International Trade and Environmental Governance: Relating Rules (and Standards) in the EU and the WTO", 15 European Journal of International Law 324–325 (2004).

19 Joel P. Trachtman and G. Marceu, The Technical Barriers to Trade Agreement, the SPS and GATT. A General Map of the WTO Law of Domestic Regulation of Goods, Journal of World Trade 5, (2002). Joel P. Trachtman, The World Trading System, the International Legal System and Multilevel Choice, 12 European Law Journal 480, (2006). Alberto Alemanno, Trade in Food: Regulatory and Judicial Approaches in the EC and the WTO, 263 Cameron May (2007).

ficult for Members to agree on the setting up of new standards, and many of the ones finally approved are now approved by majority vote and not by consensus, weakening the scientific authority of the Commission and its standards.[20] This has produced two direct effects. The first one is the prevention of the adoption of scientifically controversial standards. The second is a higher degree of controversy in those standards not approved by consensus. A good example of the latter is the long and heated debates on the approval of beef hormones standards, and after its approval the establishment of a dispute between the United States and the EC (panel) within the WTO that led to the famous beef hormones case.[21]

4. Mutual recognition and equivalence

Equivalence is a complement, where there are no international standards, or an alternative to harmonization. According to article 4.1 "Members shall accept the sanitary or phytosanitary measures of other Members as equivalent (...) if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection". This clause provides the Members with a large degree of flexibility, "which allows countries to allocate scarce resources efficiently rather than identically"[22]. Indeed, to encourage reporting of equivalence protocols, the WTO adopted specific notification procedures in 2001.[23]

5. Risk assessment

Directly connected with the obligation imposed in article 2.2 are the risk assessment provisions included in article 5, which determines that all the SPS measures adopted by a Member have to be based on an assessment, "as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations".

Risk assessment is defined in Annex A of the SPS where it differentiates two types of risk. The first would be related with quarantine measures established to stop the entry or spread of a pest or disease. In that case the risk assessment should be made on the likelihood of that situation. The second would be related to measures adopted to limit or avoid the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs. In this case the risk assessment would focus on the potential for adverse effects on human or animal health.[24]

According to the Appellate Body "the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effect on human health in the real world where people live and work and die."[25] This is actually to highlight that the purpose of the measure has to be the identification of specific risks and that "theoretical risks" are not the kind of risk to be assumed under article 5.1.[26] This means that hypothetical risks are to be excluded from the risk assessment process, therefore leaving aside in most of the cases the practical application of the precautionary principle.[27]

In order to develop such risk assessment, Members shall take into account "available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other

20 Alemanno (supra note 19), 267.

21 For more detailed information on the issue of the politicization of the Codex Commission see Frode Veggeland and Svein Ole Borgen, Changing the Codex: The Role of International Institutions (2002). Available at http://www.nilf.no/Publikasjoner/Notater/En/2002/N200216Hele.pdf.

22 David Orden and Donna Roberts, Food Regulation and Trade under the WTO: Ten Years in Perspective, 37 Agricultural Economics 111, (2007).

23 Available at http://www.wto.org/english/tratop_e/sps_e/format_equivalence_e.doc.

24 Nick Covelli, Viktor Hohots (supra note 15), 780

25 EC-Hormones Appellate Body Report, European Communities – Measures Concerning Meat and Meat Products (Hormones), WT/DS26, 48/AB/R (Jan. 16, 1998), para 187.

26 EC-Hormones Appellate Body Report (supra note 22), para 123–125. On the legal concept of risk see, Miguel A. Recuerda (2006) "Risk and reason in the European Union Law", 5, European Food and Feed Law Review.

27 See Miguel A. Recuerda (2008) "Dangerous interpretations of the precautionary principle and the foundational values of European Union Food Law: Risk versus Risk", 4 Journal of Food Law and Policy.

treatment".[28] In regard to this list the Appellate Body has stated that "there is nothing to indicate that the listing factors that *may be* taken into account in a risk assessment of article 5.2 was intended to be a closed list" [29] (emphasis added). That statement could induce the thinking that other factors, not only objective and neutral as those presented in the list of article 5.2, could also be weighted when adopting a SPS measure. Contrary to that interpretation the Appellate Body has tightened the connection between science and the SPS measure, requesting an "objective and rational relationship"[30] between the measure and the scientific evidence. That "rational relationship" is to be determined "on a case by case basis and will depend upon the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence".[31]

From the previous paragraphs and the reports of the Appellate Body it is possible to conclude that risk assessment must examine probability as well as potential of the risk. The reference to possible risks is not enough and even the probability assessment must be sufficiently specific to the problem and the measure proposed. "It is not enough that substances be demonstrably nasty in general terms. They must be demonstrably nasty when used in the specific circumstances contemplated by the protective measure in question."[32]

If risk analysis is composed, as it has been explained previously, by three different elements (risk assessment, risk management and risk communication), risk management is missing in the risk analysis procedure established in the SPS agreement. A possible interpretation of that silence could be that the SPS did not want to be perceived as very intrusive regulating something that it belongs to the national level and that it is so connected with the decision-making procedure of each country, and therefore the signal was to preserve as much as possible national sovereignty. Such an interpretation can only be defended on formal grounds, because in real terms the Appellate Body has clearly denied that possibility.

Firstly, the Appellate Body has explicitly rejected the differentiation between risk assessment and risk management made by a panel stating that "Article 5 and Annex A of the *SPS Agreement* speak of 'risk assessment' only and that the term 'risk management' is not to be found either in Article 5 or in any other provision of the *SPS Agreement*. *(...)*The fundamental rule of treaty interpretation requires a treaty interpreter to read and interpret the words actually used by the agreement under examination, and not words which the interpreter may feel should have been used."[33] Secondly, imposing the requirement, which is an interpretation of the Appellate Body not directly found in the SPS agreement, of the "objective and rational relationship" between the SPS measure and the scientific evidence.[34] This interpretation has preempted the possibility of incorporating other legitimate factors, far from science (safety does not derive exclusively from scientific evaluations) but directly connected with the protection of public and human health in a society, in the risk management procedure.

The final obligation of the risk analysis process reiterates the main objective of the entire SPS agreement reaffirming that SPS Members have the obligation of ensuring that SPS measures "are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility" (article 5.6).[35]

Another important element that is missing, or at least underdeveloped within this framework, is the economic assessment of regulations, a movement towards the incorporation of cost-benefit analysis of the SPS measures.[36]

All in all, the clear view from the SPS provisions is that the scientific element would ensure that

28 Article 5.2.

29 EC-Hormones (supra note 23), para 187.

30 EC-Hormones (supra note 23), para 189 and also Japan-Agricultural products (WT/DS76/AB/R), para 82.

31 Japan- Agricultural Products (WT/DS76/AB/R), para 84.

32 Joanne Scott, The WTO Agreement on Sanitary and Phytosanitary Measures : a Commentary. 137, Oxford University Press, 2007.

33 EC-Hormones (supra note 23), para 181.

34 Japan- Agricultural products (WT/DS76/AB/R), para 82.

35 The test of the least restrictive measure is developed in a footnote of the SPS agreement that explains that "a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade." Those conditions are cumulative so all must be present to consider the measure to be valid under the SPS agreement.

36 David Orden and Donna Roberts, Food Regulation and Trade under the WTO: Ten Years in Perspective, 37 Agricultural Economics 111, (2007).

SPS measures address a real and objective health risk and are not protectionist measures disguised as health regulations or unnecessarily restrictive health regulations.

6. Provisional measures

The only exception to the rigorous scientific conditions established in articles 2.2 and 5 is established under article 5.7. This article allows the adoption of provisional SPS measures in cases of insufficient scientific evidence. In any case those provisional measures have to be based on the available pertinent information, so the strong connection between the SPS measures and its scientific basis is also required in the adoption of these provisional measures.[37] Moreover, the acceptance of the measure as provisional is conditioned to the adoption of the appropriate actions to get, within a reasonable period of time, more complete information to review those provisional measures.

In the reference to this provision as the possible application of the precautionary principle within the SPS agreement, the Appellate Body has noted four principles regarding the relationship of the precautionary principle and the SPS agreement. These principles recognize some elements of precaution that must be present when judging SPS measures, though always respecting the obligations contained in the SPS agreement.[38]

7. Notification and transparency requirements

WTO, and in particular the SPS agreement, has been successful in promoting symmetry of information about regulations and standards among its Members through its notification process under the terms of the SPS article 7 and Annex B. Under these provisions all Members have the obligation of notifying and publishing (make them available to other Members) all[39] its sanitary and phytosanitary measures and to establish an enquiry point, which is "responsible for the provision of answers to all reasonable questions from interested Members as well as for the provision of relevant documents". Hence, this requirement is not simply a mere notification process but it is a truly communication element within the risk analysis.[40]

According to ORDEN and ROBERTS over the first 10 years of operation of the SPS agreement (1995-2004), WTO Members submitted more than 5.350 SPS notifications. Those notifications have produced 330 complaints before the SPS Committee.41 These figures show the importance of this instrument and the low rate of complaints in comparison with the number of measures notified. The rate of complaints is even lower if one observes the number of measures that have ended up in the establishment of a panel or it has gone through the appellate body.

III. Food Safety Disputes

1. Introduction

If the procedure of notification and the transparency requirements of Annex B are not enough to clarify or solve the concerns and comments raised by a Member, then the Member still can use the Dispute Settlement procedure of the WTO. The number of the disputes involving the SPS agreement is really small in comparison with the number of measures that have been notified. However small the number, these cases have attracted a great deal of public and political attention, due to the matter itself and to the opposite views and interests at stake, that they play a critical role, not only in defining the scope of SPS/WTO rules and obligations, but also in defining a large share of the present public opinion about the entire WTO system.

Between 1995 and 2006 there have been 41 formal requests for consultations about food regulations that could be in conflict with the SPS agree-

37 "An overly broad and flexible interpretation of that obligation would render Article 5.7 meaningless". Japan-agricultural products, para 80)

38 EC-Hormones (supra note 23), para 124.

39 There is a footnote in Annex B of the SPS agreement that specifically mentions that "Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally" and also this clarification of broad interpretation has been also made by the panel on Japan-Agricultural products stating that "nowhere does the wording of this paragraph require such measures to be mandatory or legally enforceable" (WT/DS76/R para 8.111).

40 There is a comprehensive document, called "How to Apply the Transparency Provisions of the SPS agreement" that can be retrieved from the WTO webpage at www.wto.org/english/tratop_e/sps_e/spshand_e.doc.

41 David Orden and Donna Roberts, Food Regulation and Trade under the WTO: Ten Years in Perspective, 37 Agricultural Economics 109, (2007).

ment. Only 10 ended up in a panel report and of those only 6 were referred to the Appellate Body. All the cases referred to the Appellate Body (EC-Hormones, Australia-Salmon, Japan-Agricultural products and Japan-Apples)[42] have been ruled against the defendant of the measure.[43] Although the case recently ruled by a panel report on GMOs products will not be appealed, that case due to its relevance should be added to the previous list as it was partially ruled against the defendant of the measure, in this case the EC.

While under GATT article XX.b) exception is the Contracting Party that invokes the exception the one that bears the entire burden of proof, under the SPS is the complaining Party who bears the initial burden of proof, showing a *prima facie* case of inconsistency with SPS, although after that initial moment the Contracting Party that has established the measure is the one that bears the burden of proof.

2. Standard of review

The standard of review is not only a question of judicial procedure but it is especially relevant when there is such a strong connection between the scientific evidence and the SPS measures. When the interpretation of the application of the SPS Agreement has been constructed in such a narrow way connected just in one direction (the "rational and objective relationship" between the scientific evidence and the SPS measures) to what degree the panel or the appellate body is entitled to review the scientific information becomes a crucial part of the outcome.

One of the major improvements that the WTO system has operated in comparison with the previous GATT system has been within the dispute settlement procedure. WTO includes in its single package a specific annex for the Dispute Settlement Understanding (annex 2). The procedure gains, in general, a more judicial and automatic character, from two main features: the panel reports are adopted unless there is consensus against them and the possibility of the appellate review with the establishment of a permanent Appellate Body. It is important to give the reminder that the Dispute Settlement procedure in the entire WTO system only refers to Members (states or regional markets, like the EC) but not to individuals or private companies.[44]

In spite of the existence of this Dispute Settlement Understanding, the issue of the standard of review is not clear, article 11 being the only reference in the entire text.[45] However, the previous "objective assessment" does not offer a specific standard of review. That term could comprise, as ALEMANNO points out, from "total deference" to a "*de novo review*", affecting of course the final outcome of any dispute.[46]

The EC tried to convince, unsuccessfully, the Appellate Body in the hormones case that the correct standard of review to be applied by the panels was the one established in article 17.6 (i) of the Antidumping agreement. The Appellate Body, after denying any connection of that article regarding the SPS agreement, reiterated that the "applicable standard is neither *de novo review*, nor "total deference", but rather the "objective assessment of the facts".[47]

The EC-Hormones case was a missed opportunity for the Appellate Body for defining the appropriate standard of review for SPS measures with the typical ambiguity of this body. On the one hand the Appellate Body seems to be the first to acknowledge that the panels are "poorly suited" to undertake a *de novo review*, but on the other hand claims that "total deference to the findings of national authorities" could not ensure an "objective assessment" as foreseen by article 11".[48]

With this degree of uncertainty it is up to each panel and to the Appellate Body, on a case by case basis, to decide the standard of review necessary to ensure an "objective assessment" of the matter.

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42 EC-Hormones (WT/DS26/AB/R, WT/DS48/AB/R), Australia-Salmon (WT/DS18/AB/R), Japan-Agricultural products (WT/DS76/AB/R) and Japan-Apples (WT/DS245/AB/R).

43 David Orden and Donna Roberts, "Food Regulation and Trade under the WTO: Ten Years in Perspective", 37 Agricultural Economics 112, (2007).

44 The new Dispute Settlement system established with the WTO introduced the possibility for the panels to request or even receive unsolicited amicus curiae briefs submitted by individuals, private entities or NGOs. See Lester, Simon/Mercurio, Bryan/Davies, Arwell/Leitner, Kara, World Trade Law. Texts, Materials and Commentary, Oxford and Portland (Oregon). 2008, p. 198.

45 Article 11 provides that a panel must make "an objective assessment of the matter before it, including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements, and make such other findings as will assist the DSB in making the recommendations or in giving the rulings provided for in the covered agreements".

46 Alemanno (supra note 16), 333.

47 EC-Hormones (supra note 22), para 116–117.

48 EC-Hormones (supra note 22), para 117.

The specific cases where SPS measures have been at stake, in particular those interpreted by the Appellate Body, have widened the standard of review of the panels in the review of SPS measures. If initially the Appellate Body in the EC-Hormones case recognized that the panels had to consider the evidence presented "and make factual findings on the basis of that evidence"49, during the latest case (Japan-Apples) any deference to the defendant risk analysis has been eliminated.50 The "rational relationship"51 test combined with this standard of review makes that the panels have to "review the scientific evidence before it, reach a conclusion on the meaning of the evidence, and then determine whether the evidence is sufficient to justify the measure".52

This interpretation leads to the application of a standard of review very close to a *de novo review* and to the establishment of thresholds to the scientific evidence. This standard of review seems extremely intrusive, especially taking into account the tight relationship constructed between the scientific evidence and the SPS measures. The degree of flexibility allowed to the Members in incorporating other factors within the risk management procedure is non-existent.

Some authors have clearly pointed out the risks related with the assumption by panel reports and the Appellate Body in SPS issues of a standard of review very close to a *de novo review*. GUZMAN, for instance, highlights the fact that "panels and the Appellate Body are more likely to make mistakes in this area than in others, and because the costs of mistakes in SPS cases will tend to be larger than in other trade disputes". This author concludes that the no deference to the choice made by the defendant Member will normally mean the establishment of two trade barriers instead of one.[53]

3. EC-Biotech products

In 2003 the United States, Canada and Argentina requested the establishment of a panel, within the Dispute Settlement Body, against the EC in regard the application of a *de facto moratorium* (between 1999 and August 2003)[54] on the approval of agricultural products obtained by modern biotechnology as restricting the imports of those countries. The arguments put forward by the complainants in this case were that the general operation and application by the European Communities of its regime for approval of biotech products[55] and the safeguard measures adopted by some EC Member States prohibiting or restricting the marketing of biotech products were incompatible with the SPS, the GATT 1994, the Agreement on Agriculture and the Agreement on Technical Barriers to Trade (TBT).[56] The EC defended its measures under the application of the precautionary principle, a principle, according to the EC, that should be taken into account when applying the rules and procedures of the SPS agreement, in particular regarding Genetically Modified Organisms (GMOs). The political character and the high level of controversy of this dispute were confirmed by the number of countries (15) that reserved their rights to participate as third parties in the work of the panel.[57]

On the other hand, on September 11th 2003, the Cartagena Protocol on Biosafety came into force. This Protocol, which has been developed under the Convention on Biological Diversity (CBD), has as its main objective the protection of human health and biodiversity from the possible adverse effects of the transboundary movements of Living Modified Organisms (LMOs). The major difference between the Protocol and the SPS agreement is the amount of scientific evidence of the negative effects on the environment or human health that an importing

49 EC-Hormones (supra note 22), para 137.

50 Japan-Apples (WT/DS245/AB/R), para 165-166.

51 See panel report on Japan-Agricultural Products (WT/DS76/R), para 8.28 and 8.42.

52 Andrew T. Guzman, "Food Fears: Health and Safety at the WTO", 45 Virginia Journal of International Law Fall 10 (2004).

53 Ibid.

54 This de facto moratorium was forced by the declaration, in 1999, of the so called "Group of Five" (Denmark, Italy, Greece, France and Luxembourg), which denied the approval of new GMOs (for food or feed) at the European level until the adoption of rules on labeling and traceability. The moratorium came to an end with the introduction of stricter rules on labeling and traceability (Regulations (EC) No. 1829/2003 and 1830/2003) and in real terms the 19th of May 2004 with the authorization of a new GMO [sweet maize (Bt11)]. During that time the European Commission did not challenge any of the safeguard measures adopted by several Member States. For more information about the enactment of this new legislation see Simon Baughen, "International Trade and the Protection of the Environment", 73-77, Routledge-Cavendish, 2007.

55 In this case the norms at stake were the Regulation (EC) No. 258/97 and the Directive 2001/18/EC.

56 WT/2919/23 request for the establishment of a panel presented by the US.

57 WT/291/24, WT/292/18, WT/293/18.

state has to produce to justify a restriction in the commercialization of GMOs.[58] The Cartagena Protocol is mainly based on the application of the precautionary principle[59], which means that most of the measures adopted by the EC could apparently be justified under the Protocol.[60] The Cartagena Protocol has 156 Parties[61], though none of the complainants of the case are parties to this Protocol.

With several months of delay the panel issued its 1300 pages report (leaving aside the annexes) on November 21st 2006. In its report the panel concluded that the EC applied *de facto moratoria*[62] over the approval of biotech products between June 1999 and August 2003 (these dates are relevant because the panel could ignore the entry into force of the Cartagena Protocol). The panel considered that the EC had acted inconsistently with its obligations under the SPS agreement, in particular, under Annex C(1)(a), first sentence and article 8, because of the undue delays that the moratorium produced in the European process of approval of products.[63] That was the only inconsistency the panel determined regarding the general system of approval implemented by the EC.[64]

In its analysis of the safeguard measures established by some EC Member States, the panel concluded that those measures were inconsistent with articles 5.1 and 2.2 of the SPS agreement, due to the fact that those measures were not based on a risk analysis as defined in the SPS agreement, and therefore they could lead, as it was in the case, to the adoption of decisions without the sufficient scientific evidence.[65] The national safeguard measures could not be maintained on the basis of the provisional measures of article 5.7, because the safeguards were applied to GMOs already approved at EC level, and therefore it was difficult to maintain the "insufficient scientific evidence" for GMOs that had already fulfilled a thorough risk assessment at the EC level. This is one of the most interesting issues at stake in this dispute because those measures could be apparently justified under the Cartagena Protocol. The problem the panel was facing was the narrow way established by the SPS measures, in particular the scientific evidence and the rational relationship between the SPS measures and the scientific evidence, and the subsequent interpretation of the Appellate Body that on those provisions is where the sensitive balance reached during the negotiations of the SPS agreement between the expansion of international trade and the protection of life and health of humans, animals and plants lies. At this point the discussion has to turn to the possibility of a Member establishing a higher level of protection, which is allowed under article 3.3 of the SPS agreement, if there is scientific justification. There it would be the main difference, because the application of the precautionary principle would justify a measure without absolute scientific certainty, whereas that possibility is not envisaged under the SPS agreement.

The EC argued that it had applied international customary law, which actually had been crystallized in the Cartagena Protocol. The main idea expressed by the EC was that the principles contained in the Cartagena Protocol were already part, even before the entry into force of the Protocol, of the international customary law and therefore it complemented the rules of the WTO. The legal basis to sustain that idea was article 31(3) of the Vienna Convention on the Law of the Treaties that clearly states that the interpretation of the Treaties has to take

58 Patrick Vallely, "Tension between the Cartagena Protocol and the WTO: The Significance of Recent WTO Developments in an Ongoing Debate", 5 Chicago Journal of International Law 369, (2004).

59 The explicit mention to the precautionary approach goes from the preamble to different articles of the Protocol itself (such as articles 1, 10.6, 11.8)

60 Since the entry into force of the Cartagena there has not been any Party that has challenged any measures adopted by other Parties.

61 As June 22nd 2009. Information retrieved from www.cbd.int/biosafety/parties/list.shtml. s

62 In the early 90s several EU countries raised concerns regarding the existing legal framework for GM-products in the EC. As a result, the EC started revising its GM-legislation. Regulation (EC) No. 258/97 was adopted in 1997, but it was only at the Environment Council of June 24/25, 1999, that the Member States reached a political agreement on the amendment of Directive 90/220. However, Denmark, Greece, France, Italy and Luxembourg declared that the compromise did not adequately respond to concerns on environmental and health risks, and stated that they would "take steps to have any new authorisation for growing and placing on the market suspended" pending the adoption of "full draft rules ensuring labelling and traceability of GMOs and GMO-derived products." The new Directive was adopted in 2001, but additional legislation on labelling and traceability, as well as on GM-food and feed, was not in place until late 2003. The last GMO was adopted in October 1998. Daniel Wüger, ASIL INSIGHT March 8, 2006 (VOL. 10, ISSUE 5): Biotech Products WTO Panel Report (infra note 61).

63 WT/DS291/R, WT/DS292/R, WT/DS293/R, para 7.1570.

64 The panel did not consider that the EC had breached its obligations under articles 5.5, 5.6 and 2.3 of the SPS agreement, against the claims of the United States, Argentina and Canada.

65 WT/DS291/R, WT/DS292/R, WT/DS293/R, para 7.3399.

into account any other relevant rules of international law applicable in the relations between the parties.[66] In this sense the panel interpreted that "the rules of international law to be taken into account in interpreting the WTO agreements at issue in this dispute are those which are applicable in the relations between the WTO Members".[67] Indeed the panel concluded that "requiring that a treaty be interpreted in the light of other rules of international law which bind the States parties to the treaty ensures or enhances the consistency of the rules of international law applicable to these States and thus contributes to avoiding conflicts between the relevant rules".[68]

The panel established that to take into consideration a rule in the interpretation and application of the WTO rules and norms, that rule must be admitted by all the WTO Members (not only the Members involved in a dispute but all the WTO Members). This interpretation is not only extremely controversial[69] but also it could be interpreted as going against the rulings that the Appellate Body has made in previous cases.[70] That line of interpretation followed by the panel seems to avoid the situation where a WTO Member is suddenly bound by a rule to which has not expressed its consent through its ratification.[71] The panel in this case clearly tried to maintain the strict line marked in the SPS measures, in particular keeping scientific evidence and science as the clear line determined by the SPS agreement to avoid SPS measures that could distort international trade.

This interpretation leads to the paradox that whereas the SPS agreement gives the presumption of conformity to voluntary standards approved some of them by simple majority. it is unable to even acknowledge the existence of an international binding agreement that has been negotiated after the entry into force of the WTO, which applies more specifically to the transboundary movement of GMOs and that could be relevant to the dispute. With this interpretation a voluntary standard with less support would override an international binding agreement with a broader universal participation. Indeed this approach seems to favour in an unbalanced way the position of the United States.

Despite the very unfortunate interpretation of the panel, it seems that they have managed, through a *pseudo* political decision, to content all the Members involved, at least from the signal of the non appeal of the dispute. The EC does not have big problems with the panel report regarding its own measures due to the approval of its new Regulations[72] in 2003 (none of these new Regulations were challenged in this dispute). Indeed, the solution adopted by the EC to accommodate the public perception there has been resulted from the introduction of strict labelling requirements for GMOs. Although it is beyond the scope of this paper and it is difficult to foresee the result of a WTO panel regarding labelling and traceability of GMOs it is important to make a very general preliminary comment. First, it is argued that the labelling of products that contain GMOs could be in compliance with the SPS and TBT agreements, in particular, taking into account the progress made in the last Meeting of the Parties of the Cartagena Protocol regarding the issue of documentation accompanying a shipment, progress that moves steadily from the initial "may contain" towards the clear identification (by 2012) of all the GMOs present in a shipment[73]. Secondly, the economic benefits of the measure are also argued. The most problematic part of the EC regulations would be its application not only to products that contain GMOs but of those that have been "produced from" GMOs. Those kinds of products are not covered by the scope of the Cartagena Protocol and it would be difficult for them to pass

66 Regarding the application of article 31 of the Vienna Convention see Jose Alvarez and Robert Howse, "From Politics to Technocracy-and Back Again: The Fate of the Multilateral Trading Regime", 96 American Journal of International Law 110 (2000).

67 Panel Report EC-biotech products, para 7.68 (WT/291-293/R) (www.wto.org/english/tratop_e/dispu_e/cases_e/ds293_e.htm).

68 Panel Report EC-biotech products, para 7.70 (WT/291-293/R) (www.wto.org/english/tratop_e/dispu_e/cases_e/ds293_e.htm).

69 The interpretation of the panel regarding article 31(3) of the Vienna Convention has been widely criticized, mainly by the International Law Commission, because it makes almost impossible to find a multilateral context in which to take into account other multilateral agreements. For more information see Vallely (supra note 52), p. 377.

70 In the Shrimp-Turtle case (Appellate Body Report WT/DS58/AB/R) the AB applied the Convention on International Trade in Endangered Species of Wild Fauna and Flora or the Convention on International Trade the Law of the Sea (UNCLOS) to interpret different concepts when one of the parties to that dispute (the US) was not even a party to the latter Convention.

71 Mark Wu, "Small States, Big Veto: Customary International Law in the WTO After EC-Biotech", 32 Yale Journal of International Law 264–265 (2007).

72 Regulation (EC) No. 1829/2003; Regulation (EC) No. 1830/2003; Directive 2001/18/EC; Regulation (EC) No. 1946/2003.

73 During the 3rd Meeting of the Parties in 2006, the Parties of the Cartagena Protocol decided to interpret the expression "may contain" in a progressive way towards the clear identification of all the GMOs contained in a shipment to be used as food or feed or for processing (Decision BS III/10). (www.cbd.int).

the different test of the SPS and TBT agreements.[74] Nevertheless, for the time being these Regulations remain unchallenged by any Member before the Dispute Settlement Body of the WTO.

4. Implementation of the report

The implementation of the panel report is also controversial. The EC originally affirmed not to have problems with the implementation of the panel report and it requested an initial period of time of one year to make the appropriate adjustments (the difficult part was to fulfill the duties regarding the national safeguards and the withdrawal of those measures in certain Member States) to the proper implementation of the recommendations. After that deadline the EC has requested different extensions of that period, extensions that were granted by two of the Parties to the dispute (Canada and Argentina), but that were not that simple to agree with the United States. In early 2008 the United States requested authorization from the Dispute Settlement Body to suspend concessions and other obligations with respect its dispute on biotech products with the EC.[75]

Even before the submission of the final report by the panel the EC was trying to remove and get into compliance the most controversial safeguard measures adopted by some EC Member States. In 2003 the Commission, after the approval of the new regulations, requested the 8 Member States that were applying national safeguard provisions to submit complete information on those measures. After evaluating the new information the European Food Safety Authority (EFSA) concluded that the previous risk assessments were still valid. Meanwhile some of the national safeguard measures were rendered pointless as the specific GMOs were no longer commercialized. The European Commission increased pressure on the more problematic countries (Austria and Hungary) but all its proposals to end those national safeguard measures were rejected by the European Parliament and the EC Council of Environment.[76] Today, these safeguard measures are no longer in force, since the European Court of Justice has considered them unjustified exceptions to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms.[77]

The last report of the EC before the Dispute Settlement Body, presented on June 13th 2008, showed progress regarding the elimination of certain prohibitions in the EU countries that were using the safeguards. During that meeting the present food crisis was used by the US to underscore the potential of GMOs for addressing these problems worldwide.[78]

It is important to note that only few countries in the EC were applying the contested safeguard measures and that actually only two of them (Austria and Hungary) maintain this kind of measures limited to very specific strains of GMOs. The rest of the procedure of evaluation and approval of the EC regarding GMOs was considered in line with the SPS agreement.

Is it worth having two trade barriers (the United States is establishing retaliatory measures) instead of one (and in a small number of countries, not in the entire EU) than to allow those markets to adapt to their own internal legitimate concerns (what they will do anyway because of the nature of the European market itself)?

IV. Other instruments from regional markets

It is beyond the scope and intention of this paper to cover in detail other instruments within regional or bilateral trade agreements. However, the present situation of slow progress or blockage of the negotiations of the Doha Round have meant that some countries (like US), while trying to resolve the problems of the negotiation within the WTO, have focused in the development of bilateral free trade agreements to make real progress through a more pragmatic and simpler approach.

74 For a closer preliminary look to the labeling and traceability requirements and its compatibility with the WTO see Joanne Scott (supra note 28) 233–242.

75 At the time of writing this paper the question of the suspension of concessions was still an open question.

76 Simon Baughen, "International Trade and the Protection of the Environment", 78–79 Routledge-Cavendish, 2007.

77 Judgment of the European Court of Justice (Third Chamber), 13 September 2007 in Joined Cases C-439/05 P and C-454/05 P. Appeals under Article 56 of the Statute of the Court of Justice, brought on 7 and 16 December 2005, Case Land Oberösterreich, and Republic of Austria, versus Commission of the European Communities.

78 http://www.wto.org/english/news_e/news08_e/dsb_24june08_e.htm.

At the regional level it is not necessary to mention, within the EU, the important judiciary bodies that allow individuals to bring their claims, under certain procedures, to the European Court of Justice. Other regional models, not so well developed institutionally speaking, like the North American Free Trade Agreement (NAFTA) and bilateral trade agreements, are also allowing under specific dispute settlement mechanisms, the presence of individuals and private companies as claimants against measures established by States. This is the case of the provisions of the chapter XI referring to foreign investment (articles 1115 to 1138). Although, there have been some cases related with public health and environmental issues[79], the measures that have been analyzed here (importing measures) are more difficult to create a dispute of this kind, though there has been already one case that has dealt with this type of controversy though it was rejected.[80]

V. Conclusions

Before the entry into force in 1995 of the WTO system, a Member of GATT-1947 could apply "measures necessary to protect human, animal or plant life or health", invoking the exception covered in article XX.b), as long as it was in conformity with the non-discrimination, necessity and proportionality tests. The SPS agreement has developed that specific exception applying the same tests with a stronger system based on science. The regulatory freedom of a Member establishing SPS measures it is limited to an "objective and rational relationship" between the scientific evidence and the SPS measures and taking into account that those measures should be the least trade restrictive ones.

The use and application of certain international standards as a presumption of validity within the SPS and the GATT agreements have eased the process though at the same time have had controversial effects over those standards, in particular with the politicization of the scientific organizations.

The notification process established under the SPS agreement has been also a valuable element to avoid conflicts and to search for common grounds before the SPS measures are approved and implemented by each Member.

The most controversial part of the SPS agreement is actually what is not directly regulated under its provisions, the risk management procedure. The reduction of the risk analysis process to a narrow risk assessment procedure, where hypothetical and long term risks can hardly be incorporated (leaving aside the application of the precautionary principle) and with a tight connection between the SPS measures and the scientific evidence, does not allow any room for the consideration of other legitimate factors that can be far from science. As long as those factors reflect the preferences and priorities of the country and not protectionist reasons, the measures adopted according to those factors should be respected. Not to do so increases, as it has been analyzed through the different disputes (in particular the EC-biotech products case), the trade tensions at the international level while jeopardizing public support regarding WTO[81]. This kind of disputes before WTO, though few, have put into question the practical limits of science in regulatory convergence.

79 Patricia Isela Hansen, "Dispute Settlement in the NAFTA and Beyond", 40 Texas International Law Journal 420, 2005.

80 Canadian Cattlemen v. United Status, NAFTA Tribunal Dismissed the Case for lack of Jurisdiction because the Claimants, all Canadian Nationals, had not made any investments and were not seeking to make any investments in the territory of the United States.

81 In general the WTO panel decisions on cases in which multilateral environmental agreements and decisions of international environmental regimes have been adjudicated are rejected by the majority of legal scholars as biased and contrary to basic principles of international environmental law. See Enrique Alonso García, Introduction to Environmental Law. Friends of Thoreau-IVEN-URJC, 2009.