Articles

Lack of Sherpas for a GMO Escape Route in the EU

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A. Introduction

The foodborne disease and other incidents of food contamination, such as the dioxins crisis, have tested the internal market of the European Union (EU) in relation to the free movement of goods.[1] The protective measures adopted under the safeguard clause obliged EU Member States to act in co-ordination with the European Commission and, in fact, to modify elements of their food chain structure. Certainly the agrofood safety crisis of the 1990s and the review of European food law have resulted in a system in which the European Food Safety Authority (EFSA) plays a key role.

In this context, the conflict over Genetically Modified Organisms (GMOs) constitutes a challenge for EU policymakers. In the words of EC President Barroso, the challenge will need "sherpas" like in an expedition to climb the Himalayas in order to be adequately resolved,[2] but the European Court of Justice (ECJ) has recently added that some transparency will be also welcomed.[3]

In 2001, Chevassus-au-Louis proposed three strategies to be adopted by European governments and EU institutions on biotechnology. Option A represented starting a

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[1] In Rome, member states agreed to a common market supported by several pillars, initially adopting the free movement of goods and other production factors, and later adopting the Single European Act (SEA) to reach an internal market by revising the concept common market into the single market. Looking for a stronger common market and a more efficient economic integration, the Maastricht and Amsterdam Treaties have added relevant rules to get the Internal Market throughout two basic and complementary principles: free movement of goods and free competence. Harmonisation of national laws, the third dimension of the internal market, is the pathway of execution of both principles. JEAN-MARC FAVRET, DROIT COMMUNAUTAIRE DU MARCHÉ INTÉRIEUR 17 (Gaulino ed., 2000) In the context of the strategy of internal market implementation, the European Commission develops very important tasks, basically, in terms of prevention and sanction, promoting the co-operation between national authorities, notification of national technical rules, and derogatory measures. P.P. CRAIG & GRAINNE DE BÚRCA, EU LAW 548 (2d ed. 1998)

[2] Peter O'Donnell & Jennifer Rankin, *Barroso Lacks Sherpas for GM Escape Route*, EUROPEAN VOICE, June 26, 2008, at 1.

[3] Case T-42/05, Williams v. Comm'n, 2008 E.C.R. 1-6308, *available at* http://curia.europa.eu/jcms/jcms/Jo1_6308/curia.

process of generalization and banalization of GMO coordinated with the execution of commitments in transparency and good governance in decisions related to authorizations and product labelling. Option B consisted of stating a durable prohibition and exclusion of GMO (crop, crop and import, foods and others) and a definition of non-GM products (threshold of presence, technical aspects, obligation of means or obligation of results). Option C was focused on the public and proactive investment in GMO in order to grant the acceptable and possible co-existence of GMO crops and non-GMO crops allowing a better adaptability to the wide range of existing interests and the uncertainties of the future.[4]

Currently, the debate is ongoing and none of these options have been clearly developed. In physics, we can say that *inertia* has replaced *synergy* on this issue due to several factors: first, although the EU process is stopped de facto after the difficulties of the Treaty of Lisbon, options and strategies should be developed concerning the GMO because the EU system, consisting of prior authorizations and compulsory labelling, has produced problems between the EU and the US and the essential mistrust of European consumers is the main reason for the cautions adopted by EU legislation; second, EU Institutions should assure the freedom of movement in the internal market and the possibility of maintaining high standards of health and environmental protection. The precautionary principle interacts with the principles of freedom of investigation, information and participation, and with the ethical analysis of research activities. Third, the GMO regulatory approaches analysed are inspired by different perceptions of risk. Therefore, the precautionary principle, as a legal instrument to prevent and manage such risk, constitutes the pillar of a large list of consequences with new legal concepts such as traceability; and fourth, EU territory is an attractive market for GMO exporting countries and GM seed companies. Internal harmonisation of the EU is not working on this issue in spite of the fact that EC institutions and lobbies have made great efforts. For instance, there is a long backlog of GMO applications following the modification of GMO legislation.

In this article, after analysing the interaction between GMO risk and precautionary principle, we will focus on key elements of the EU system in order to conclude that traceability, labelling and coexistence must be considered the keywords of the EU GMO system. In addition, we will propose that transparency and simpler and better proceedings should be also powered by EU institutions.

[4] Bernard Chevassus-au-louis, *OMG et Agriculture: options pour l'action publique*, LA DOCUMENTATION FRANÇAISE (2001).

B. Risk and GMO

I. GMO Represents a Multidimensional Risk

As it is known nowadays, biotechnology is associated with conflict, often because there is a controversial perception of risk assessment, management and communication in terms of social, economic, health and environmental risks.

Though scientists have been using GM techniques for twenty years, biotechnology related to agriculture and food is now a source of permanent dispute between citizens, NGOs, governments, and so on. According to Guerra Daneri, one of the important aspects of the new biotechnical agriculture is that it implies an assumption of risks of unknown magnitude, and it affects legally protected goods and rights such as biodiversity and consumer health.[5]

If we consider that genetic modification is merely a technique, there should be no problems assessing GM products. Lee concludes that the very understanding of agricultural biotechnology as a trade issue rather than a social, distributional or environmental one is problematic.[6]

However, there is a vast spectrum of scientific, social, ethical and religious parameters which immediately connect the issue of biotechnology in the food sector to risk. The risk is therefore multidimensional in the so-called Food Society.[7]

1. Social Dimension

If one of the main goals of Food Law is to assure social stability in relation to the legal system and to keep the citizens' confidence through the legal framework and its institutions, the social dimension of the GMO conflict needs revision.[8] In this sense, many authors have noted that if the social dimension of the problem is not analysed, the approach to the GMO conflict is not complete.[9]

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[5] Ernesto Guerra Daneri, *Aspectos jurídicos de la responsabilidad en la agricultura transgénica*, RIVISTA DE DIRITTO AGRARIO, April/June 2000 at 207.

[6] MARIA LEE, EU REGULATIONS IN GMO: LAW DECISION-MAKING FOR A NEW TECHNOLOGY 190 (2008).

[7] STEPHANIE MAHIEU, LE DROIT DE LA SOCIETE DE L'ALIMENTATION 409 (2007).

[8] *Id*. at 407.

[9] At this point, Zarrilli considers that, given the lack of scientific evidence of the actual or potential impact of agricultural biotechnology on human and animal health and on the environment, the debate on GMOs continues to be vocal and emotional. *See* Simonetta Zarrilli, *International Trade in GMOs and GM products: National and Multilateral Legal Frameworks*, 29 POL'Y ISSUES IN INT'L TRADE & COMMODITIES, STUDIES SERIES, 2 (2005). Slovic points out that "Danger is real, risk is socially constructed." *See* PAUL SLOVIC, TRUST, EMOTION, SEX, POLITICS AND SCIENCE:

When a "scientific fact" becomes an issue for society, science is no longer purely science, but starts to incorporate elements of opinion. No matter what the nature of these elements (i.e., moral, cultural, political or economic), they become as important as the scientific viewpoint on reality. So, as well as making better use of an impartial and transparent science advisory process, when they make their decisions, policymakers are supposed to consider other kinds of "rationalities" besides scientific rationality, since these different "rationalities" are expressed in public debates and represent the point of view of the social actors concerned with the issue. In practical terms, this includes recognising as valid the different ways the public assess risks arising as a result of new scientific and technological applications, even if they do not follow scientific rationality and they are merely social representations.[10]

Scientists and consumers have different approaches to evaluating risk associated with food products, which is because each actor within the food supply chain provides diverse and not homogeneous risk perception. As the risk perception should be measured case by case, it is difficult to define options and strategies *erga omnes*. In any case, it is clear that a major role must be given to "more insulated officials who are in a better position to judge whether risks are real."[11]

2. Public Health and Environmental Dimension

The emotional debate continues around the deficiency of the legal instruments to protect citizens from environmental and sanitary GMO risks and especially to protect producers from GMO cross-border dissemination or transfers. As a global public health problem, the potential risk associated with a food product is based on scientific criteria, so the risk assessment of GMO should be carried out from the perspective of both health and the environment. Years ago the main objective of a Public Health Policy was focused on the quality and safety of food supply. Nowadays, a healthier food and an optimal nutrition is also a crucial concern.

SURVEYING THE RISK-ASSESSMENT BATTLEFIELD IN THE PERCEPTION OF RISK 390 (2000). Consequently, in order to define the "risk" associated with biotechnology, we should also take into account public opinion. This is a critical point, since public debate does not normally follow the same rules as scientific discussion. Once the item is explained to the public, the scientific facts are opened to a great number of different social agents. *See* Robert F. Durant & Jerome S. Legge, Jr., *Public Opinion, Risk Perceptions, and Genetically Modified Food Regulatory Policy: Reassessing the Calculus of Dissent among European Citizens,* 6 EUROPEAN UNION POLITICS 181, 197 (2005). Public opinion covers, as has been mentioned above, environmental, ethical and religious factors. Experience and education are key points to understand the perception of risks associated with biotechnological products. *See* Mercedes Sánchez & Ramo Barrena, *El consumidor ante los alimentos de nueva generación: alimentos funcionales y alimentos transgénicos*, 204 ESTUDIOS AGROSOCIALES Y PESQUEROS 95 (2004).

[10] Andrea Lorenzet & Federico Neresini , *Science, risk and social representation*, 82 THE IPTS REPORT (2004).

[11] CASS R. SUNSTEIN, LAWS OF FEAR: BEYOND THE PRECAUTIONARY PRINCIPLE 126 (2005).

As for the sanitary risk, the risk assessment has become an integral part of the EU's decision-making process in relation to food.[12] Inserted in the EU legal framework, the precautionary principle and the traceability rules are the basis to cover risk assessment along the supply chain. So far, no health risk has been detected in relation to GMO, although zero risk does not exist[13] and usually there is a lack of proof of direct causal links.[14] Nowadays, the evolution of the problem has gone through the concepts of "reasonable certainty of no harm" and "negligible risk."

II. EU Precautionary Principle

The precautionary principle can be developed in two dimensions, as Mellado said. On the one hand, there is a positive dimension of the principle since it works as an engine for research into certitude about risks. On the other, the negative dimension consists of legitimating certain bans or prohibitions because of the assessed risks.[15]

Therefore, one of the main points of debate is the interpretation of the precautionary principle. Although different definitions of the precautionary principle exist, the following is considered by the authors a more canonical one: "When an activity raises threats of

[12] In EU food law, Article 6 of Regulation EC number 178/2002 says that in order to achieve the general objective of a high level of protection of human health and life, "food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure. . . ." Therefore, risk assessment shall be based on "the available scientific evidence and undertaken in an independent, objective and transparent manner" and risk management "shall take into account the results of risk assessment", and, in particular, the opinions of the EFSA (European Food Safety Authority), other factors legitimate to the matter under consideration and the precautionary principle "where the conditions laid down in Article 7(1) are relevant, in order to achieve the general objectives of food law established in Article 5". Commission Regulation 178/2002, art. 6, 2002 O.J. (L 31) 8.

[13] In relation to GMO, among other factors, the health risk is assessed in terms of toxicity, allergies and other pathological elements. However, it is known that allergic reactions to tacos made from "Star Link" GM corn in the USA have been detected. *See* Colin Carter & Allen Smith, Univ. of California, Dept. of Agricultural and Resource Economics, *The Market Effect of a Food Scare: The Case of GM StarLink Corn*, Paper No. 04/012, 2004). It is also true that there is the lengthy question of genetic transfer to bacterial and antibiotic resistance, and it is obviously difficult to prove that there are no long-term effects.

[14] *See* Theofanis Christofourou, *The Regulation of Genetically Modified Organisms in the European Union: The Interplay of Science, Law and Politics*, 41 COMMON MKT. L. REV. 637, 709 (2003); Theofanis Christofourou, *The Precautionary Principle in European Community Law and Science*, *in* PRECAUTION, ENVIRONMENTAL SCIENCE AND PREVENTIVE PUBLIC POLICY 243 (J.A. Tickner ed., 2003).

[15] LUIS MELLADO RUIZ, BIOSEGURIDAD Y DERECHO: LA ADMINISTRACIÓN ANTE LOS RIESGOS DE LA TECNOLOGÍA DE LA VIDA 145 (2004).

harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."[16]

In EU law, the Maastricht Treaty has included in article 130 R-Environmental Policy a reference to the precautionary principle. Some regulations have reproduced it (Regulation EEC 315/1993, Directive 93/43/ECC, etc.) and the ECJ has confirmed its application to human health with the available scientific evidence.[17]

The Green Paper, adopted by the Santer Commission in 1997, has separated assessment, management and risk communication and explained the concept of negligible risk and of precautionary principle.[18] In 2000, the European Commission produced a Communication aiming to "outline the Commission's approach to using the precautionary principle; establish Commission guidelines for applying it; build a common understanding of how to assess, appraise, manage and communicate risks that science is not yet able to evaluate fully; and avoid unwarranted recourse to the precautionary principle, as a disguised form of protectionism." Therefore this principle is considered a key element in the analysis of risk and its management in the EU.[19]

Concerning the EU GMO system, the ECJ's extensive interpretation has been included by EU legislators, for instance, in Number 8, Articles 1 and 4.1 and Annex IIB of Directive 2001/18 on GMO; and Article 7 of Regulation 178/2002, which determines as follows:

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[16] German legal scientists have configured the *Vorsongeprinzip* as the necessary intervention of public administration, although scientific evidence may not be certified. In the USA, the Delaney clause of section 409 of the 1958 Federal Food, Drug and Cosmetic Act included a zero risk concept: "the Secretary of the Food and Drug Administration shall not approve for use in food any chemical additive found to induce cancer in man, or, after tests, found to induce cancer in animals". Principle 15 of Rio Declaration 1992 and Cartagena Protocol has fixed the precautionary principle in the context of environmental policies. *See* Peter Montague, *The Precautionary Principle*, RACHEL'S ENVIRONMENT AND HEALTH WEEKLY, Feb. 19, 1998.

[17] The application of the precautionary principle in matters concerning human health has been declared by ECJ, among others, in Case C-180/96, United Kingdom v. Commission, 1998 E.C.R. I-02265, and T-33/99, Pfizer Animal Health v. Council, 2002 E.C.R. II-3305. In particular, we must highlight the simultaneous application of the precautionary principle and proportionality by the ECJ in United Kingdom v. Commission and Great Britain's beef embargo by resolution of 12 July, 1996.

[18] *The General Principles of Food Law in the European Union*, COM (1997) 176 (April 30, 1997).

[19] In the Communication, the European Commission states that "The precautionary principle is not defined in the Treaty, which prescribes it only once - to protect the environment. But in practice, its scope is much wider, and specifically where preliminary objective scientific evaluation, indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen for the Community." *Communication on the Precautionary Principle*, COM (2000) 1 final (Feb. 2, 2000).

> 1. In 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.

The EU has added that measures adopted on this basis shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, keeping in mind 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.

Besides a European Food Authority, the EC designed a programme of legislative measures consolidating the principles of food safety such as responsibility of feed manufacturers, risk analysis and application of the precautionary principle.[20] After the adoption of Regulation EC num. 178/2002, the ECJ has returned to the precautionary principle in light of the need for the Community legislature to take account of this principle when it adopts, in the context of the policy on the internal market, measures intended to protect human health.[21]

Therefore, the precautionary principle plays a crucial role in the EU GMO system because GMOs have been considered a distinct class of biological entities requiring specific regulatory attention.[22]

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[20] General principles and new requirements of food law are contained in Regulation 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the EFSA and laying down the procedures in matters of food safety. *See* Commission Regulation, *supra* note 12. The EFSA is in charge of scientific risk assessment and has no powers of risk management. Risk management is the power of public authorities, as is risk communication.

[21] For instance, ECJ has confirmed the validity of several articles of Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. Joined Cases C-154/04 & C-155/04, The Queen ex parte Alliance for Natural Health v. Secretary of State for Health and National Assembly of Wales, 2005 E.C.R. 1-06451.

[22] Javier Lezaun, *Creating a New Object of Government: Making Genetically Modified Organisms Traceable*, 36 SOC. STUD. SCI. 500 (2006).

Concerning EU GMO product approval procedure, as it will be described later on, the point was that the precautionary principle seeks a "zero risk" that transfers a kind of *probatio diabolica* to the person who, looking for authorization has to prove the safety or the lack of harm of each individual product. The authorised products are also subject to *a posteriori* control as part of the ex-post risk assessment.

Gonzalez Vaque has noted that the precautionary principle should be applicable by way of substituting the resulting obligation—negligible risk—for an obligation of "employing the *state of the art* means for," because a lack of knowledge does not mean lack of risk.[23] In that context, the measures in applying the precautionary principle should be transitory, proportional and passive, like the authorization procedures for GMO products.

From a global outlook, it is relevant that the United States government supports precautionary approaches to risk management but stops recognizing a universal precautionary principle.[24]

C. A Conflict of Legal Frameworks

I. Brief Reference to International Context

The US and EU have different approaches to the GMO issue and these differences have consequences in both economic terms and in the WTO and the United Nations' context. The differences between the two sides of the Atlantic concerning scientific and ethical matters are deep, and consequently, the respective legal backgrounds reveal a different political assessment of the effects of GMOs on health and the environment, and the subjective approach of the techniques used to carry out these assessments.[25]

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[23] González Vaque, *El TJCE confirma su jurisprudencia relativa al principio de precaución: la Sentencia "Monsanto agricultura Italia SpA y otros*, 6 UNIÓN EUROPEA ARANZADI 5, 5–15 (2004).

[24] US policy-makers have expressed that "there are two major perils associated with an extreme approach to precaution. One is that technological innovation will be stifled, and we all recognize that innovation has played a major role in economic progress throughout the world. A second peril, more subtle, is that public health and the environment would be harmed as the energies of regulators and the regulated community would be diverted from known or plausible hazards to speculative and ill-founded ones." John D. Graham, The Heritage Foundation Washington, D.C., *The Perils of the Precautionary Principle: Lessons from the American and European Experience*, REGULATORY FORUM, Oct. 20, 2003, *available at* http://www.whitehouse.gov/omb/inforeg/speeches/031020graham.pdf. The deepest objection to the precautionary principle is methodological: the precautionary principle focuses on risks in isolation. Sunstein categorizes it among approaches to environmental protection that are "unhelpful, sometimes, even, ludicrous". The legitimacy of the precautionary principle will be undermined if it comes to apply to just any fear that people happen to have in regard to new technologies. SUNSTEIN, *supra* note 11, at 55, 100, 120. Nevertheless, some authors have supported a precautionary principle interpretation more connected to the European one. Lisa Heizerling, *Climate Change, Human Health, and the Post-Cautionary Principle*, 96 GEO. L.J. 445 (2008).

[25] *See* Compés López & Guillem Carrau, *Regulation of GMOs: The Commercial Conflict Between the United States and the European Union*, 3 NEW MEDIT 3, 3–10 (2002).

The key element of the conflict is that the US considers that GMO products are substantially equivalent to the non-GMO products and the EU does not share this view. This approach has led to a more notable expansion of GMOs in the USA than in the EU, as is well known.[26]

Since the late 1980s, the EU has introduced different pieces of legislation aimed at treating GMOs as an object of specific regulation. By treating transgenic organisms as a regulatory category, the EU has effectively abandoned the principle of "substantial equivalence" between genetically engineered organisms and their conventional counterparts.[27] That principle had been stated in the initial international agreements on the governance of biotechnology products (Organisation for Economic Co-operation and Development -OECD, 1993) and still characterizes North-American regulatory regimes.[28]

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[26] The US is the world's primary producer of genetically modified agricultural products and has not committed to the Cartagena Protocol**.** One of the principal reasons for US leadership in GMOs is the flexibility of their regulation. The regulatory procedures for the approval of GMOs in the EU differ significantly from those of exporting third-party countries, including differences in the time for processing authorisation dossiers. The time it takes for GMO authorisations to be completed in the EU is over 2½ years, as opposed to a US average of fifteen months. The growth of this technique in the second half of the 90s has been so spectacular that, at the present time, a very high percentage of its production of maize, soya or cotton is already organic. The first GM product on the world market was a variety of herbicide-resistant soya exported from the US to Europe and Australia during 1996 Following the 2007 International Service for the Acquisition of Agri-biotech Applications (ISAAA) information, in 2006, the first year of the second decade of commercialization of biotech crops 2006–2015, the global area of biotech crops continued to grow for the tenth consecutive year at a sustained double-digit growth rate of 13%, or 12 million hectares, reaching 102 million hectares. GMO producers are 10.3 million people in 22 States and, nowadays, 29 countries have authorised the imports of GMO as food. The value is US$6.15 billion; more or less 16 per cent of the global crop market. The US is the primary producer, followed by Argentina, Brazil, Canada, India and China. In this context, Spain continues to lead the European continent, planting 60,000 hectares in 2006. Clive James, *Global Status of Commercialized Biotech/GM Crops: 2006*, ISAAA BRIEF 35-2006: HIGHLIGHTS (2006), http://www.isaaa.org/resources/publications/briefs/35/highlights/default.html. Critics have expressed concern that the ISAAA makes outrageous claims, inflates its figures and ignores negatives. For instance, the report emphasises that 10.3 million farmers grew GM crops in 2006, but this is just 0.7% of farmers world-wide. And just 600,000 farmers grew 85% of all GM crops on industrial farms in North and South America. Small third world farmers are abused and misused as fodder for ISAAA's PR.

[27] *See* Patrycja Dabrowska, *Risk, Precaution and the Internal Market: Who Won the Day in the Recent Monsanto Judgement of ECJ on GM foods*, 5 GERM. L.J. 151 (2004).

[28] In 1992, as a general rule, the USA considered that transgenic food did not need a particular regulation separate from the standards of food commercialization. *Statements of Policy: Foods Derived from New Plant varieties*, 52 Fed. Reg. 22984 (U.S. Food and Drug Administration, May 29, 1992). This position is based on the affirmation of the Science National Academy, which considers that the transgenic products have the same risks that a conventional one. The basic institutional structure for regulation of all biotechnology products in the US is the "Coordinated Framework for Regulation of Biotechnology" established in 1986. *See* GianCarlo Moschini, Iowa State Univ., Working Paper No. 06-WP 429, 2006, *Pharmaceutical and Industrial Traits in GM crops: Co-existence with Conventional Agriculture*, 8, *available at* http://www.card.iastate.edu (last visited Sept. 12, 2007). The US federal agencies working jointly on the approval of GMOs, are APHIS (Animal and Plant Health Inspection Service), the EPA (Environmental Protection Agency) and the FDA (Food and Drug Administration). By mandate of the National Institute of Health (NIH), a Biosecurity Committee evaluates every genetic improvement's project before

First, we have pointed out that the WTO has been one of the controversial contexts. As it is known, the WTO system should assure both the freedom of movement and the possibility for countries to maintain high standards of health and environmental protection.[29] Domestic trade rules should be assessed in light of GATT 94 and the Sanitary and Phytosanitary Measures Agreement (SPS) and the Trade Barriers to Trade Agreement (TBT) agreements, and even the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement when taking into account the reasons for the patentability of biotechnological innovations.[30]

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its launch and it is able to recommend that a project is not developed. These agencies are those responsible in the main for the environment and consumer health protection. On the one hand, when an application is presented, APHIS should deliver authorizations in order to: be able to use some facilities (greenhouses) to develop the cultivation; carry out trials in fields; transport seeds from the greenhouse to the trial fields; and to determine the status of "not regulated" that allows cultivation, use and marketing of the product. The process lasts approximately ten months. On the other, the EPA is responsible for authorizing release in the environment and authorizing pesticides obtained by means of genetic manipulation and plants modified to have pesticide characteristics. In particular, the EPA should authorize the following acts: trials in exploitations over 10 acres; establishing tolerance thresholds (maximum limits of modified proteins in food from the plant); registering products for commercial use. Finally, the FDA, as the agency responsible for the security of all foods, advises and supervises companies in the GMOs' development phase. The advice process is voluntary, but the requirements are compulsory, and all the companies involved tend to keep on it. Labelling is also ruled by the general principle that products obtained by means of genetic manipulation are not different the conventional products (they are "substantially equivalent", according to the concept coined by the OECD and the WHO) and, because of this, they are regulated by identical norms. The FDA only requires specific labelling of GM content when the product carries with it some element of risk (an allergic reaction, for example) or if its nutritional characteristics or composition are significantly different from its equivalent conventional one; in this case, the difference should be indicated on the label. This regulation, however, may change in the near future. Food scandals, like the one unleashed by the appearance of GMOs in certain foods of the Taco Bell chain of restaurants, have opened a debate on the segregation of GMOs from conventional foods in the North American food chain. In this sense, certain opinion groups have made Congress admit legislation establishing a compulsory pre-marketing test for GMOs, which ought to be carried out by the FDA, a GMO product labelling and an obligation for biotechnological companies to assume responsibility for problems derived from their products. In this line, the FDA has presented in February of this year a proposal that determines the mandatory communication of foods coming from biotechnology, prior to their commercialization, with the purpose of highlighting its coherence with the FFDCA. Concerning co-existence, US regulation in this area at present presumes a zero tolerance level in the food supply. Moschini considers that for first-generation GM products co-existence does not carry health or environmental risks because the health and environmental safety of GM products is assessed prior to approval. The additional risk of second generation products points out that the coexistence of traditional agriculture with crops transformed to express pharmaceutical and industrial traits will, in his opinion, take quite a different form than the first generation of GM products in the US.

[29] *See* Lukasz A. Gruszczynski, *Science in the Process of Risk Regulation under the WTO Agreement on Sanitary and Phytosanitary Measures*, 7 GERM. L. J. 371 (2006).

[30] The difficulties of admitting the patentability of microorganisms were solved by the US Supreme Court on June 16th 1980 in Diamond v. Chakrabarty because the microorganism was an invention of the laboratory and not of nature. *See* Diamond v. Chakrabarty, 447 U.S. 303 (1980). In particular, the Court declared that living organisms which are products of human ingenuity are patentable. *See id*. In the EU, Directive 98/44, on the legal protection of biotechnological inventions, has stated the common provisions for patentability of biotech inventions by EU Law. Council Directive 98/44, 1998 O.J. (L 213) 13, 13–21. For Romero, this exposes the main elements of the EU

In 2006, the resolution of the GMO dispute in the WTO arena determined that the SPS Agreement is not compatible with GMO de facto moratoria and safeguard measures without previous risk assessments adopted by the EU and several of its Member States. Nevertheless, the GMO conflict has not reached the level of debate of meat hormone or banana affairs, where the EU was also condemned by the WTO

Second, the other field of conflicts is in the UN context. The UN has promoted the adoption of the Cartagena Protocol, whose main objective is to ensure that the trade of living modified organisms (LMOs) is carried out safely. As the WTO has discretely, and the US has openly pointed out, the pre-eminence of the multilateral system of trade against an environmental agreement is not a good basis for the Protocol's success.[31] The point is that the US view of the GMO conflict is not completely compatible with the Cartagena Protocol's terms. Nevertheless, there are doubts about the prevalence of the Protocol against WTO rules and relatively few countries have committed themselves to the Cartagena Protocol. In addition, there is not a clear definition of what a scientific reasonable doubt is, so precautionary principle is hardly applicable.[32]

II. EU Law

1. Evolution of the GMO' Legal Framework

In the EU, as Mahieu has highlighted,[33] aiming to protect their citizenship and intellectual property rights, Member States have supported complex legislation covering GMO when it has been identified that the EU level is better suited to regulate the matter.

On the one hand, the reticent position of a significant part of public opinion has contributed to the authorities' adoption of an exigent legislation in order to avoid potential risks. The EU's political position stems not from the opinion of the scientific community but the feelings of the majority of European citizens, probably in the face of the perceived risk of this technology, considered as a source of threats. Out of the commercial interests, EU politicians are backing consumers and their interests.

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evolution in the context of the Munich Convention. *See* Romero Fernández, *La patentabilidad de las invenciones biotecnológicas*, 5829 LA LEY : REVISTA JURÍDICA ESPAÑOLA DE DOCTRINA, JURISPRUDENCIA Y BIBLIOGRAFÍA 1, 3 (2003), *available at* http://www.epo.org/patents/law/legal-texts/html/epc/1973/e/ma1.html.

[31] To date, 142 instruments of ratification or accession have been deposited with the UN Secretary-General from the following Parties to the Convention on Biological Diversity. *See* Convention on Biological Diversity, http://www.cbd.int/biosafety/default.shtml.

[32] *See* Cara Fuentes, *Riesgo y Derecho comunitario: modificaciones genéticas en el ámbito de lo agrícola*, 33 ACTUALIDAD ADMINISTRATIVA 963 (2000).

[33] *See* Mahieu, *supra* note 7, at 415.

On the other, the influence of the WTO has been apparent in the development of the EU's regime on GMOs.[34]

As we have already pointed out, rather than dealing with transgenic organisms as, in principle and in the absence of proof to the contrary, equivalent to "conventional" or "natural" ones, the EU has chosen to consider GMOs as a prima facie object of governance: a distinct class of biological entities requiring specific regulatory attention.[35]

EU law regulates a "case by case" authorization process, applying the precautionary principle, in order to make decisions on the basis of risk assessment, scientific criteria, the introduction of emergency and surveillance programmes, and so on. The process also respects a "step by step" principle that implies, for instance, no authorization for GMO marketing if there is no previous authorization for voluntary dissemination and no authorization for GMO voluntary dissemination if there is not previous authorization for confined experiments in a laboratory. Internal market and consumer and environmental protection are alternately the basis of EU GMO law.[36]

From an outside perspective, the European position on GMO appears fairly homogenous. During the late 1990s, the EU as a whole seemed to have shifted to a more restrictive policy. A closer look, however, reveals profound differences from country to country. What appears to be "the" European stance is the result of a complicated balancing of different countries' changing views and interests through the European institutions, which themselves add another political layer. In particular, the EC, in its attempt to harmonize diverging positions, has a dual role as both an integrator and a key player. Within attempts to harmonize, Member States have always differed in their impact on the overall "European" position.[37]

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[34] *See* Joanne Scott, *European Regulation of GMOs and the WTO*, 9 COLUM. J. EUR. L. 213 (2003).

[35] *See* Alberto Germano, *Corso di diritto agrolimentare*, G. GIAPPICHELLI EDITORE 94 (2007).

[36] Related to the legal basis, some debates have been finally solved by ECJ concerning the legal basis of the so-called Biotech Directive. Malcolm MacLaren, *Patently Unsatisfactory? Community Legislative Competence and the ECJ Biotech Decision*, 2 GERM. L.J. 18 (2001).

[37] It should be highlighted that, for a long time, those who have exercised prominent influence on biotechnology policy were France, the UK, and (in part) Germany, but also smaller countries such as Denmark and the Netherlands. Austria, in contrast, was hardly visible in terms of political influence, although in retrospect, the Austrian policy seems to anticipate early elements of what was to come later in other European countries *See* Helge Torgensen, *Austria and the Transatlantic Agricultural Biotechnology Divide*, 24 Sci. Comm. 174 (2002). The ministers of the new partners participated for the first time at the Environment Council of Ministers of June 2004, and on the agenda was the debate about the controversial point of commercialisation of another strain of GM maize, NK603. On the one hand, Cyprus, Hungary, Latvia, Malta and Lithuania were against the authorisation of GM maize NK603; on the other, the Czech Republic, Poland and Estonia were in favour and Slovakia and Slovenia abstained. Following the scheme of the transitional voting system, applied at the Council of Ministers until

There has been a *moratorium* in the execution of Directive 90/220/EEC as it was not efficient to assure the citizenship confidence. It started in 1998, when France, Denmark, Greece, Italy and Luxembourg declared a voluntary blockade of GMO commercialisation's applications, and it finished in 2004.[38]

Representatives of the industry and Administration in the US have expressed, more than once, their worries about the delay and the cost their companies incur in obtaining authorizations to market their GM products in the EU. They have considered that this procedure was a technical barrier to the trade in the terms of the WTO rules and it has already negatively affected their exports.[39] This criticism has been expressed more forcefully because of the EU's compulsory 2000 labelling rules and 2003 traceability Regulations, because in the US GMO labelling is voluntary.[40]

As we have already mentioned, since these positions did not change on the substantial points, the controversy over the different ways of regulating GMOs was settled in the WTO. On 13 May 2003, the US and Canada requested consultations at WTO Dispute Settlement Procedure with the EC. Three months later, the EC announced its intention to implement the recommendations of the Dispute Settlement Body (DSB) of the WTO.

Ultimately, in May 2004, the *moratorium* finished when the EU Council of Ministers was shown divided because of the Commission's decision related to GM maize Bt11 for human consumption. Moreover, EU enlargement has introduced new agents with different roles in the biotechnology debate.

Later on, the already mentioned WTO panel report circulated in November 2006. The resolution of the GMO conflict in the WTO arena has determined that the SPS Agreement is not compatible with GMO *de facto moratoria* and safeguard measures without previous

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October 2004, the majority was against the authorisation and commercialisation (16 in favour/15 against/6 abstentions). *See also* Dabrowska, *supra* note 27.

[38] In the Council of Ministers of 24th and 25th June 1999, the French, Greek, Italian, Luxembourg and Danish delegations passed a declaration deciding to block any new commercialization application whilst the system did not warrant transparency and perfect traceability. Therefore, a moratorium was actually decided and revision process of the system began. From October 1991, when the Directive came into force until July 2000, 18 authorizations were approved, with 14 pending, with no authorization from 1998. In fact, no product had been authorized until March 2003.

[39] The most relevant affairs have been Novartis maize and Monsanto soya. *See* David Kelch, Mark Simone & Madell, *Biotechnology in Agriculture Confronts Agreements in the WTO*, WTO/WRS/98/44 (Dec. 1998).

[40] U.S. Food and Drug Administration, Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering (2001) (draft released for comment), http://www.fda.gov/OHRMS/DOCKETS/98fr/001598gd.pdf.

risk assessments adopted by the EU and several of its Member States. The panel report concludes that the EC applied a general *de facto moratorium* on the approval of biotechnological products and the approval procedures concerning twenty-four specific GM products, in violation of the SPS Agreement, and that nine national safeguard measures introduced by Austria, Greece, France, Germany, Italy and Luxembourg were not based on risk assessment.[41]

In that context, we can conclude that the European Commission and the European Court of Justice contributed to the end of the *moratorium*.

Related to the role played by the EC, it is also accepted that the *facto moratorium* expired with the reform of Directive 2001/18/EC, with the entry in force of the Regulations 1829/2003, 1830/2003 and 1946/2003, and the recommendation of the European Commission on coexistence and its activity against Member States that were failing to fulfil obligations or granting the effectiveness of the harmonisation measures. Besides, the EC has sent to ten Member States a letter of "mise en demeure" because of they had not implemented Directive EC/2001/18 in time and, in some cases, proceedings were brought by the EC pursuant to Article 228 EC to ECJ.[42]

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[41] The US, Canada and the European Union have agreed that the reasonable period of time for the EU to implement the recommendations expires on 21 November 2007. *See* WT/DS291/35, June 26, 2007.

[42] First, the European Community has adopted Regulation EC 1829/2003 on genetically modified food and feed; Regulation EC 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, amending Directive 2001/18/EC; Regulation EC 65/2004, of January 14th 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms; and Commission Recommendation 2004/787/EC of October 4th 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 1830/2003 . Secondly, at execution level, to be precise, twelve GMO dossiers have been authorised in EU up until June 2007 (maize NK603, maize MON863, maize 1507, maize MON 863 x MON 810, carnation 123.2.38, rape GT73, rape MS8, RF3 and MS8 x RF3, maize Bt11, maize NK603, maize MON 863, maize GA21 and maize 1507). Thirdly, the European Commission has sent to ten Member States a letter of "mise en demeure" because of they had not implemented Directive EC/2001/18 in time. *See* Case C-419/03, Comm'n v. France, 2004 E.C.R. The European Commission has claimed that the French Republic failed to comply with the judgment of the Court of July 15th, 2004 and the Court ordered France to pay a lump sum for failing to comply swiftly with the 2004 Judgement of the Court establishing its failure to fulfil obligations concerning GMOs. *See* Case C-121-07, Comm'n v. France, 2008 E.C.R. Recently, the ECJ has dismissed an appeal of Austria and its Land Oberösterreich seeking to have set aside the Judgment in Joined Cases T-366/03 & T-235/04, Land Oberösterreich and Austria v Comm'n, 2005 E.C.R. 4005, by which the Court of First Instance dismissed their actions seeking the annulment of Commission Decision 2003/653/EC of September 2nd, 2003, relating to national provisions on banning the use of genetically modified organisms in the region of Upper Austria notified by the Republic of Austria pursuant to Article 95(5) of the EC Treaty. *See* Joined Cases C-439/05 P & C-454/05 P, Land Oberösterreich and Austria v. Commission, 2007 E.C.R. *See also* Commission Recommendation on Guidelines for the Development of Strategies and Best Practices to Ensure the Co-Existence of Genetically Modified (GM) Crops with Conventional and Organic Farming, DG AGRI Report (2003), *available at* http://ec.europa.eu/agriculture/publi/reports/coexistence2/guide_en.pdf.

ECJ Judgements have also been a crucial factor in this matter. In September 2003, the ECJ provided, in the *Monsanto case* concerning the possibility of a Member State adopting provisional bans of GMO marketing, a wide definition of substantial equivalence and reemphasized the need for risk assessment activities before adopting provisional measures based on the precautionary principle.[43]

Some criticisms have also been expressed regarding the Regulations EC num. 1829/2003 and 1830/2003 and their compatibility with WTO agreements. In particular, the use of traceability as a risk management tool has been considered unacceptable and against the agreement on SPS measures and the TBT Agreement. International handlers of agricultural commodities and grain-exporting countries have led the opposition to the EU traceability regime for biotechnology. These critics argue that such a high level of scrutiny is simply unworkable in a world of massive trade flows, where agricultural and food products are routinely mixed together and shipped in bulk across borders, and where essential economies of scale are generated precisely by ignoring genetic distinctions between organisms and commingling transgenic and conventional products.[44]

In terms of policy assessment, in 2007, the Commission carried out a mid-term review of the strategy, based on an in-depth assessment of the progress made since 2002.[45]

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[43] *See* Vaque, *supra* note 23, at 9. González Vaque says that this means that the compulsory labelling would be justified if the GM product were substantially equivalent to the conventional product. If the products were "alike" or "similar", obligation would not be justified, because the only difference would reside in a characteristic of the productive process—the transgenic techniques—that does not influence the appreciable characteristics of the final product or its safety, and this would also suppose a treatment discrimination that is not accepted by the Agreement. Therefore, if it is not possible to demonstrate that the products are different or that the transgenic is not safe, then the products are "similar", and it the compulsory label is not justified—although the voluntary one is—nor any other measure restricting imports. *See* Case C-236/01, Monsanto Agricoltura Italia, 2003 E.C.R. II-8105; Case C-296/01, Comm'n v. France, 2003 E.C.R. I-13909 and Joined Cases C-439/05 P & C-454/05P, Land Oberösterreich and Austria v. Comm'n, 2004 E.C.R. I-07141. Related to ECJ resolutions, among others, *see also* EFIC Judgement of May 10th, joined cases T-366/03 & T-235/04 Land Oberösterreich and Austria v. Comm'n, 2005 E.C.R. II-4005; Case C-132/03 Ministero della Salute v Codacons and Federconsumatori 2005 E.C.R. I-4167; Case C-456/03 Comm'n v Italy 2005 E.C.R. I-5335. Related to this approach, Dabrowska considered that in the *Monsanto* case "the Court has perhaps sought to prevent Member States supporting the moratorium on all GM products from using the safeguard clause for purely political reasons." In her view, this Judgment is the first case in which the Court has directly invoked the precautionary principle regarding Member States' power to adopt a provisional prohibition on the marketing of GMO-derived novel foods. *See* Dabrowska, *supra* note 26, at 4 and 7; *but see* Thijs Etty & Han Somsen, *Case C-236/01: Monsanto Agricoltura Italia SPA and others vs. Presidenza del Consiglio dei Ministeri and others*, 13 EUR. ENVTL. L. REV. 14 (2004).

[44] *See* Lezaun, *supra* note 22, at 500.

[45] *See Communication from the Commission to the Council, the EP, the European Economic and Social Committee and the Committee of Regions on the Mid Term Review of the Strategy on Life Sciences and Biotechnology*, at 441, COM (2007) 175 final (Oct. 4, 2007).

Following a request of the European Parliament, the European Commission is carrying out an assessment of modern biotechnology and an evaluation of its consequences, opportunities and challenges for Europe in terms of economic, social and environmental aspects. With this aim, the "Bio4EU" study has been produced by the Joint Research Centre (JRC) to constitute the primary input to the reflection on the role of Life Sciences and Biotechnology in the renewed Lisbon Agenda and which provides evidence of the wide impact of biotechnologies on Europe's industries.[46]

Since 2008, after some ECJ resolutions, it has been clearly stated by the ECJ that transparency and good governance principles must be applied to EU GMO law,[47] and the European Commission has provided a report to the Council and the European Parliament concerning Regulation EC 1830/2003.[48]

As stated earlier, although EU process is stopped *de facto* after the difficulties of the Treaty of Lisbon, some developments have still been occurring in the European Commission. In May 2009, there was a general orientation debate to review Europe's biotechnology regulations.[49]

2. Elements of the EU GMO Legal System

We can say that the regulation of the GMO in the EU is a synthesis of the economic, safety and social challenges of controlling the "biotech risk" associated with food and it is also a statement about the future and choices of the EU.

Assessment, management and communication of the risk are the common elements to explain the principles and the objectives—and also the limits—of the regulator's art for GMO contained use, voluntary dissemination and marketing.[50]

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[46] *See Consequences, Opportunities and Challenges of Modern Biotechnology for Europe* (April 20, 2007), *available at* http://bio4eu.jrc.ec.europa.eu/documents/eur22728en.pdf; *Economic Impacts of Genetically Modified Crops on the Agri-Food Sector* (Commission of the European Communities, Working Document No. Rev.2 DG AGRI, 2000).

[47] *See* Case C-552/07, Commune de Sausheim v. Pierre Azelvandre, 2009 E.C.R. 00000; Case T-42/05, Williams v. Comm'n, 2008 E.C.R.

[48] *See Report on the implementation of Regulation EC 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC*, COM (2008) 560 final (Sept. 17, 2008).

[49] EUR. VOICE, May 8, 2008, at 8.

[50] *See* MAHIEU, *supra* note 7, at 400.

The regulation of biotechnology has a performative character, in the sense that a particular distinction between "natural" and "artificial" organisms, institutes new categories and gives those categories a precise technical and legal meaning. This crucial generative character of regulation is even more apparent with the latest addition to the European regulatory scheme: the establishment of an infrastructure capable of ensuring the "full traceability" of GMOs; the creation of a set of administrative practices and detection instruments able to track GMOs throughout the food production system, "from the farm to the table."[51]

As we have already pointed out, EU rules reflect a particular view that GMOs, due to their novelty, generate scientific uncertainty and therefore represent a potential danger that will appear in the future. This justifies that, based on the precautionary principle, a prior and complete assessment of the environmental and health risks must be carried out.

To summarize, EU agro-biotechnology is essentially regulated, first, by Directive 2001/18 on GMO voluntary dissemination and commercialization of GMO products not intended for human consumption. The Directive provides a complex approval procedure and regulates a wide range of matters such as public information, sanitary and environmental risk evaluation, labelling and traceability, the composition of standing committees, Commission reports, etc. Regarding Directive 2001/18, it must be pointed out that, after its revision, the new provision established deadlines to decide a GMO authorization. The procedure was redefined: the phase's limits are quite well defined, majority of votes will take the approval decisions, and several changes have been operated in traceability, labelling and environmental responsibility. Particularly, the approval process allows each Member State to determine its thresholds, its analysis methods and the products to evaluate. Besides, a simplified procedure has been established for novel foods derived from GMOs that do not

[51] Historically, the EU Food Safety system may be understood in the context of the Common Market and the goals of the Common Agriculture Policy (CAP). The objectives of the CAP are the following: ensure availability of supply; increase productivity; stabilize markets; reasonable prices; and fair standard of living for farmers. Nowadays, the CAP reforms and the internal market strategy are the keys to explain the EU Food Safety. Certainly, the agro food safety crisis on the 90's and the review of the European food law has developed a system where the European Food Safety Authority (EFSA) plays a key role. Aiming for a higher level of consumer protection, the European Commission's White Paper on a Common Food Safety Strategy was the new approach to the food sector known "from farm to the table" that assures traceability throughout the food chain and states a Rapid Alert System for Food and Feed (RASFF). The EU integrated approach to food safety aims to assure a high level of food safety, animal health, animal welfare and plant health within the European Union through coherent farm-to-table measures and adequate monitoring, while ensuring the effective functioning of the internal market. The European Commission continues the enforcement of its mission to determine legislative and other actions: to assure effective control systems and evaluate compliance with EU standards in the food safety and quality, animal health, animal welfare, animal nutrition and plant health sectors within the EU and in third countries in relation to their exports to the EU; to manage international relations with third countries and international organisations concerning food safety, animal health, animal welfare, animal nutrition and plant health; to manage relations with the European Food Safety Authority (EFSA) and ensure science-based risk management. PAUL NIHOUL & STEPHANIE MAHIEU, *LA SÉCURITÉ ALIMENTAIRE ET LA RÉGLEMENTATION DES OGM: PERSPECTIVES NATIONALE, EUROPÉENNE ET INTERNATIONALE* 182 (2005); Lezaun, *supra* note 22, at 502.

contain transgenic material and offer a substantial equivalence with the existent foods in terms of composition, nutritional value, and metabolism, use to which they are dedicated and level of unwanted substances. In these cases, the product can be marketed in the EU notifying to the European Commission with a justification of this equivalence emitted by the competent authority of a Member State. Second, Regulation EC 1829/2003 is focused on the marketing of GMO food, Regulation EC 1830/2003 on traceability and labelling, and Regulation EC 641/2004 on GM identifiers.[52]

In terms of "soft law", the EC has lodged a recommendation in order to allow the co-existence of GM and conventional crops, conferring powers to Member States, through the subsidiarity principle, to establish distances to be kept between one type of crop and another, avoiding cross-contamination problems and protecting producers of non-GM goods.[53]

Therefore the European Community has produced, on the one hand, a group of horizontal rules concerning the contained use of GMO, their road and rail transportation, and so on. These norms cover GMO activities independently of the GMO product (plants, animals, medication, industrial products, etc.) and are normally adopted as Directives or Decisions. On the other hand, EC has developed vertical rules for specific GM products, such as the Novel Food Regulation, the GM Seed Directive, and labelling regulations. Some problems

[52] Mahieu has explained that the applicants for a GMO authorization whose products are not going to feed humans or animals will be concerned only by Directive 2001/18/EC and the applicants for a GMO authorization whose products are intended to feed humans or animals will be subjected to the Regulation EC 1829/2003/EC. Mahieu has stated that the applicants can introduce files by both administrative ways and, indeed, many of the applicants use both procedures. MAHIEU, *supra* note 7, at 455, 456.

[53] The European Commission has invited Member States to act at the domestic level in order to regulate compensations for damages due to cross border contamination. *See* Commission Recommendation 556 of March 5th, 2003. However, it would be inexact to state the evolution of Member States' decisions without a mention of some restrictive administrations. *EU Policy in Biotechnology*, DG ENVI (2006), *available at* http://ec.europa.eu/environment/biotechnology/pdf/eu_policy_biotechnology.pdf. At the EU level, the GMO legal framework is not acceptable for Member States or local and regional authorities. Particularly, there has been a reply to the EC Recommendation. In November 2003, a group of "GM-free regions" was created and now comprises 164 European regions. For instance, in France, close to 38 million people live in areas whose local authorities have declared their opposition to GMOs. For instance, in Italy, the Act 5 2005 about co-existence has produced constitutional problems, since the division of powers between National and Regional Administrations has not made it possible. Corte Costituzionale [Constitutional Court] 150 (2006); Corte Costituzionale [Constitutional Court] 116 (2006). In that context, the goal of the EU is the harmonization of national laws. Taking into account commercial goals, the harmonization will be more efficient if the National Administration is the body empowered to regulate coexistence. The main issue, therefore, is to know how national and regional systems are coordinated and the degree of collaboration between the different bodies and institutions of each administration. Always based on the identity of traditional production and regional peculiarities, these authorities are against the homogenization and expansion of GM crops because it is not compatible with respect for ethnographic heritage. None of these regional governments have forbidden GM crops, but have conferred powers to farmers for the creation of non-GM areas establishing a special administrative authorisation to those producers interested in the use of GM seeds. 10 EUR. VOICE 30, 20 (2004).

are created by the absence of any connection between the horizontal and vertical rules. For instance, while Directive 2001/18 covers GM products and products containing GM ingredients, it does not cover products obtained from GMO but that do not contain them. Another example is that the protective measures in Regulation EC 2309/93 and the Novel Food Regulation reach further than the scope of Directive 2001/18.

The deliberate release authorization process is similar to the marketing one but not as controversial at the EU level, as it is the national administration that bears the responsibility of the procedure and the EC participation is not substantial (Part B of Directive 2001/18/EC). Academics have criticized the Directive because it does not contain a definition of what deliberate release is and there is a common position that identifies deliberate release as the one for investigation purposes.[54]

As it has been said, the more polemical element of the legal framework is the authorization process for GMO marketing, which covers commercialization and donations (Part C of Directive 2001/18/EC and Regulation EC n 1829/2003).

From an Internal Market point of view, this procedure is complicated and involves Member States and European Commission authorities. Before approval can be given, a compulsory assessment of the human health, animal welfare and environmental aspects of each case must be carried out (Annexes II and III of Directive 2001/18/EC). The company intending to market a GMO should lodge an application for commercialisation and choose the Member State properly, since a report about environmental risk assessment must be sent to the Member State's authorities where the product is proposed to be first commercialised. If the assessment report is positive, the Member State's administration will then prepare a summary of the documentation to send to the EC, which will forward it to other Member States within thirty days.

The procedure can last up to eighteen months and first contemplates assessment reports of the national authority of the country where the application is filed and, second, assessments of the rest of the EU Member States.

If the application is rejected on the basis of the assessment report, the company could try introducing the file in another Member State.[55]

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[54] RUIZ, *supra* note 15, at 289.

[55] For instance, in German law, the authorization must be conferred when, according to the state of the art, damage expected for health and environment is justified in order to comply with marketing goals. GenTG (*Gesetz zur Reglung der Gentechnik*) [Law Regulating Genetic Engineering] ¶ 16(2) (1993) (F.R.G.). The justifiability clause has been criticised by Mir Puigpelat because the rule legitimates some kind of damage, which is always expected in medicines (side effects listed in the prospectus) but not in food. ORIOL MIR PUIGPELAT, TRANSGÉNICOS Y DERECHO : LA NUEVA REGULACIÓN DE LOS ORGANISMOS MODIFICADOS GENÉTICAMENTE 205 (2004).

It is worth mentioning that a country can suspend approval temporarily if it considers that risks exist, in which case approval should be given by means of a decision made by the European Commission. Problems can arise if the EU confers authorisation where Member States have emitted a negative evaluation report. Are Member States enforced to authorise against their own criteria? Or can Member States add conditions to the EU authorisation? Some of these problems have already been solved by the European Court of Justice, such as when the ECJ stated that the French Government must follow the EU authorisation and, furthermore, confer authorisation.[56]

Following the process, if any objection is stated, the authorization procedure goes on inside the EC, which must consult the European Food Safety Authority about the objections and elaborate upon a decision proposal. This proposal is examined by an experts' Committee that will adopt a position by qualified majority. If there is no qualified majority at the Committee, the Council of Minister must take a decision about the application by qualified majority and, if it does not occur, the final adoption is passed through the EC.

Therefore, the operation of this procedure has not been satisfactory for any of the parts.

According to the labelling system, the presence of a GMO in a product should be communicated to consumers through labelling, with the exception of accidental presence not up to 0.9% of GMO authorised or 0.5% of non-authorised products with a positive scientific assessment. Nevertheless, the pretension of some green groups, which ask for a compulsory labelling to products obtained by genetic manipulation, seems also to be inconsistent with the TBT Agreement. One of the points still open in EU Law consists of the possibility for Member States to introduce labelling requirements for the rest of the commercialisation chain once the product is on the market. Ethical labelling or other modalities are also issues to be analysed.

In this context, the administrative intervention is also surveillance, control and sanction, which are in connection with the concept of traceability. Once the activity has been authorised by public administration, it can be assumed that persons working or dealing with GMO will report periodically on their activities and will adopt self-control measures. In any case, public administration still has responsibilities after authorisation is conferred (Articles 8.1.a and c, 13.6 and 20.2 of Directive 2001/18).

[56] As Germany, France, Luxembourg, Portugal and Austria have done in Novartis BT grain case. First and foremost, it should be stressed that a political agreement at the European Council could have the power to silence the technical objections laid down by Member States' competent authorities. Mellado has a critical view of the European phase of the process, considering that risk assessment and risk management should not be matters of transaction. MELLADO, *supra* note 15, at 174.

The company will always be in charge of notifying any change about the information provided during the authorisation process in order to respect the precautionary principle.[57]

If, as a result of inspection activities, new elements of risk are identified, administrations will adopt all required measures to minimise the risk or to eliminate its consequences. Furthermore administrations will propose new conditions for the authorisation of the activity and, if necessary, will declare the suspension or the end of activities. Central Administrations will communicate this to the public, the EC and other Member States.[58]

The interpretation of article 23 of Directive 2001/18, which contains a safeguard clause, legitimates Member States, before and after the conclusion of the EU phase of the authorisation process,[59] to ban or limit the commercialisation or use in its territory of an authorised GMO.[60]

As we have already established, the issues of coexistence measures and seed thresholds, which are closely linked with approval and cultivation of GMOs, remain partially unresolved. Pollen flow between adjacent fields is a natural phenomenon and due to the labelling requirements for GM food and feed, this may have economic implications for farmers who want to produce non-GM plants intended for food.

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[57] Case C-6/99, Greenpeace et al., 2000 E.R.C. 1-1651.

[58] *See* Council Directive 01/18, arts. 4.5, 8.2, 19.4, 20.3 and 23, 2001 (EC).

[59] *See* Greenpeace et al., *supra* note 57, describing the interpretation of Article 13.2 of Council Directive 90/220/EEC, 1990 O.J. (L 117), on the deliberate release into the environment of genetically modified organisms, as amended by Commission Directive 97/35/EC, 1997 O.J. (L 31) adapting to technical progress for the second time Council Directive 90/220.

[60] The safeguard clause was invoked on nine separate occasions under Directive 90/220/EEC, three times by Austria, twice by France, and once each by Germany, Luxembourg, Greece and the United Kingdom. The scientific evidence provided by these Member States as justification for their measures was submitted to the Scientific Committee(s) of the EU for opinion. In all of these cases, the Committee(s) deemed that there was no new evidence justifying overturning the original authorisation decision. In spite of the repeal of Directive 90/220/EEC, eight of the nine bans remained in place (the UK withdrew its ban) and were considered under the safeguard provision (Article 23) of Directive 2001/18/EC. The GMOs in question (Bt 176, T25 and MON 810 maize, Ms1xRf1 and Topas 19/2 oilseed rape) had been authorised under Directive 90/220 for all uses (including cultivation) with the exception of Topas 19/2 (import and processing). The Commission examined the additional information provided by certain Member States, which was also reviewed by EFSA. In addition, in January 2005, Hungary invoked the safeguard clause in order to prohibit the cultivation of MON 810 in its territory. In June 2005, the Environment Council reached a qualified majority against eight proposals to lift the eight bans invoked by five Member States. As a result, DG for the Environment consulted EFSA again in order to obtain an updated opinion. The Commission now has three options, namely to submit either the same or amended proposals back to the Council or to submit proposals for adoption through co-decision, on the basis of EFSA's awaited opinion. *See* EU Policy, *supra* note 53.

Finally, Regulation EC 1829/2003 is focused on the marketing of GMO or food with GMO components or ingredients. The procedure begins with the application to the National Authority where the product is going to be commercialized with the information required by Annexes III and IV of Directive 2001/18/EC. The national administrations forward the information to the EFSA, which is going to adopt a risk assessment report in a 6 month period. The EFSA report and the application are sent to the EC and the Member States' authorities and they are also publicized. In three months, EC will introduce a proposal of the Decision to the EFSA Scientific Committee that, once accepted, is communicated to the applicant.

D. Keypoints of the Challenge for EU Policy Makers and Legislators

The GMO issue constitutes a goal for EU policy makers and that the huge challenge can be described as an expedition to climb the Himalayas. Due to the evolution of the matter, not only sherpas were needed but some transparency would also be welcomed.

As Lee highlights rules on labelling, coexistence, liability and intellectual property are a crucial part of the regulatory settlement for GMOs, influencing the relationship between the biotechnology industry and those it affects. The legal and political framework need not preclude the consideration of the full range of issues provoked by GMO.[61]

Therefore, labelling and traceability will grant a peaceful commercial relationship with the US and a desirable coexistence of GMO crops with free-GMO ones.

I. Labelling

Labelling is considered the key element for future developments in GMO conflict. In the WTO arena, labelling provisions, which are adopted to offer information to the consumer about characteristics of the product that cannot be known before acquiring the product, are regulated by the TBT Agreement, unless its end is to protect the health of the consumers, in which case the pertinent agreement is the SPS.

Although this can be challenged, the norms on GMO labelling should be compatible with the TBT Agreement. Contrary to the SPS Agreement, the TBT Agreement forces member countries to follow international standards, except when these are inappropriate. In the case in hand, such standards do not exist, although the Codex, and their committee on food labelling, has begun the process to create norms or international recommendations related to foods obtained by genetic manipulation.[62]

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[61] LEE *supra* note 6, at 245.

[62] CODEX ALIMENTARIUS COMMISSION, PRINCIPLES FOR THE RISK ANALYSIS OF FOODS DERIVED FROM MODERN BIOTECHNOLOGY, GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS, AND GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS PRODUCED USING RECOMBINANT-DNA MICROORGANISMS (2003);

Relating to labelling, the evolution of European rules has been slow and complex. Slow, because authorizations were being given from 1990 (Directive 90/220) and compulsory labelling was not introduced in some cases until 1997(Regulation 258/97 on novel foods). Complex, first because labelling was regulated based on the principle of "substantial equivalence" (Regulation 258/97), later on, a specific label was establish for Monsanto soya and Novartis maize (Regulation 1139/98); and finally, labelling has been determined as compulsory when transgenic material is present over a certain threshold (Regulation 49/2000).[63]

Directive 2001/18/CE enlarges the regulatory field, without having the last word, since not every situation has been covered. Consequently, the performance of the EU can be criticized without forgiving the difficulty of solving these problems. It is a fact that, as a consequence of these misbalanced legal developments, transgenic products have arrived to the EU food chain without regulated labelling.[64]

Regarding the labelling of certain foods and feeding ingredients, the indication of the presence of genetically modified contents is not obligatory when each one of them contains less than 1 percent of genetically modified material (corn or soya or other materials approved by Regulation 258/97) and their presence is accidental (Regulation EC 44/2000, of January 10th 2000, modifying Regulation EC 1139/98, that enforced a special label when transgenic DNA or proteins were detected).

Foodstuffs that contain genetically modified additives and flavours or those produced from GMO should be labelled as such (Regulation EC 50/2000 of 10th January 2000). Some European countries add their own requirements on labelling. The label "GM free" it is not regulated, so that is the reason why its use is controversial.

In summary, the presence (or not) of transgenic material can be considered a difference, just like other product properties. The European rule is based on the principle of detection of proteins and transgenic DNA (Deoxyribonucleic acid). It forces labelling when the presence of genetically modified ingredients is superior to 1%, meaning that it can be proven that the product has a composition different to its equivalent non-GM one. However, the controversy on labelling is not just a legal matter, but rather has an economic dimension: compulsory labelling based on this technique would force producers

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CODEX AD HOC INTERGOVERNMENTAL TASK FORCE ON FOOD DERIVED FROM BIOTECHNOLOGY, ELABORATION OF STANDARDS, GUIDELINES OR OTHER PRINCIPLES FOR FOODS DERIVED FROM BIOTECHNOLOGY (1997).

[63] DABROWSKA, *supra* note 27.

[64] Specific dispositions exist for the forest material of reproduction and for the vineyard, for medical products for human and veterinary use, workers' protection and transport. Plants authorised before 1997 were not subjected to compulsory labelling (one soya, one maize and two rapeseed plants).

to separate their transgenic production from 'traditional' production, and to assure the traceability of the product, implying an exhaustive documental pursuit of the productive process. The European Commission has estimated that this would increase production costs between 6 and 17%.[65]

Therefore, those companies whose products contain GMOs but that could not be identified as such in a conventional inspection, because of the disappearance of the transgenic material along the way, would have no incentive to label them in a voluntary way, creating high enforcement costs. The main reason is that the cost they would incur would not be compensated by the perceived price, which would be even inferior to that of the equivalent product given the negative image of GMOs in some countries.

The European Commission has recognised that:

> Industrial associations and exporters from third countries continue to argue that, for instance, the Regulation EC 1930/2003 introduces excessive administrative burdens. It restricts the export of GMOs to the European Union, and forces European operators to use high priced conventional products. They consider the labelling thresholds as arbitrary choices and claim that labelling products produced from GMOs, where no GM material can be detected, places an unfair burden on operators in the food and feed sector to verify compliance of refined material.[66]

The European Commission has communicated that some Member States and stakeholders also pointed to the need for labelling thresholds for the presence of GMOs in seeds. The Commission is currently carrying out an impact assessment to examine this issue.[67]

In conclusion, all these factors concerning GMO labelling should be taken into account by the so-called European Commission GMO "sherpas" but the real challenge is considering citizens as technological citizens rather than mere consumers.

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[65] Commission of the European Communities, *Traceability and Labelling of GMO and Products Containing GM*, Working Document ENVI/620/2000, 2000).

[66] *See supra* note 42.

[67] *SeeEC Report*, *supra* note 48.

II. Communication and Transparency

In the *Communication from the Commission on the mid term-review of the Life Sciences and Biotechnology strategy*[68] the EC has declared that "[a]lthough GMOs represent only a small part of biotechnology, public perception often sees this as the main application. The gap between public perception and the agreed legal framework on GMOs has to be addressed."

A claimed good governance—making the process open and being seen to listen to citizens' concerns—and, of course, achieving good results in terms of containing and managing risks, are goals of the EU Authorities.

The level of clear communication is not too high. On the one hand, perhaps the absence of the "Bové phenomenon" like in France has led to a lack of an open debate about GMO issues in other Member States. Therefore, there is neither a political discussion nor a proper execution of the participation principle, nor even domestic parliamentary debates. On the other, as there is a permanent dispute between transmitters and recipients (producers, consumers, industries, governments, media, etc.) and an unclear selection of the information containing the risk message, European consumers usually receive a lot of scientific debate about the assessment of risks to the environment and health posed by biotechnology. Moreover, European consumers have suffered in relatively few years several crises regarding of the food supply chain, such as BSE (Bovine Spongiform Encephalopathies), dioxins and avian influenza (bird flu). While those crises are present in consumers' memories, just legislation alone to control risk is not the answer to risk communication, because the concerns of the public are not necessarily the same as those of science.[69]

After risk perception, one of the major issues arising in risk management is communication.[70] It has been concluded by some authors that reinforcing the trust of

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[68] *Communication from the Commission on the Mid-Term—Review of the Life Sciences and Biotechnology Strategy*, 7 COM (2007) 175 final, and *Strategy for Europe on Life Sciences and Biotechnology,* COM 27 final (2002).

[69] After a period of decline in optimism about biotechnology, the 2005 Euro-barometer showed an increase in optimism since 1999 (52% say biotechnology will improve their life), and an overall support for many biotech applications (such as gene therapy, biofuel and bioplastics). It also shows that knowledge about biotechnology and genetics, although improved, remains limited. However, 58% of respondents oppose GM food while 42% do not. The Euro-barometer also confirmed that there were major differences in acceptance levels between Member States, in that 50% or more say they would buy GM food if it were healthier, if it contained less pesticide residues, or if were more environmentally friendly. *See* Europeans and Biotechnology in 2005: Patterns and Trends (2006), *available at* http://www.ec.europa.eu/research/press/2006/pdf/pr1906_eb_64_3_final_report-may2006_en.pdf.

[70] Richard Shepherd & Lassen Frewer, *Risk Communication*, *in* TENNANT, D.R.: FOOD CHEMICAL RISK ANALYSIS 399, 407 (1997).

citizens in the risk assessment and risk management processes will clearly make the task easier.[71]

Concerning public access to GMO documents, after the resolution of the *Williams case,*[72] the ECJ has confirmed the citizens' right to consult the EC files concerning the elaboration of Directive 2001/18/EC in the legal framework provided by Regulation EC 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, as we have already pointed out.

Regulation EC 1049/2001 defines the principles, conditions and limits governing the right of access to documents of those institutions which is provided for in Article 255 EC. In *Williams v. Commission*, the applicant asked for annulment of the Commission's decision partially refusing the applicant access to certain preparatory documents dealing with the legislation on GMO. In this case, the Commission clearly stated that the exception on which the refusal of access was based was that relating to the protection of the decision-making process but the ECJ Fifth chamber declared that there "is no further need to rule on the lawfulness of the Commission's decision . . . partially refusing Ms Rhiannon Williams access to certain preparatory documents in respect of the legislation on genetically-modified organisms in so far as it may include an implied refusal of access to preparatory documents from the Commission's Directorate-General (DG) for Trade relating to the adoption of Directive 2001/18/EC . . . ." and annulled the restrictive Commission decision.

In the other recent case already noted, the *Azelvandre ca*se,[73] the ECJ declared that Member States cannot invoke a public order exception so as to prevent the disclosure of the location of release of GMO. The declaration has been produced in accordance with Directive 2001/18/EC and in the context of a dispute between the Commune de Sausheim and Mr Azelvandre concerning the refusal to disclose to Mr Azelvandre prefectural correspondence and planting records relating to deliberate test releases of GMO.

Therefore, ECJ considers that confidential information notified to the Commission and to the competent authority or exchanged in accordance with the directive, and also information liable to harm a competitive position and protecting intellectual property rights, cannot be disclosed. Furthermore, the competent authority decides, after consulting the notifier, what information must be kept confidential in light of the "verifiable justification" given by the notifier. So the information relating to the location of the release can in no case be kept confidential. In those circumstances, considerations

[71] Ben Duncan, *Public Perception and Efficient Risk Communication*, IPTS REPORT 82 (2004).

[72] *See* Williams, *supra* note 42.

[73] *Id.*

relating to the protection of public order and other secrets protected by law cannot constitute reasons capable of restricting access to the information listed by the directive, including in particular that relating to the location of release.

At the end, we consider that the efforts of the European Institutions and Member States to compass their works in order to improve the EU GMO legal framework must be also focused on increasing the levels of transparency and the quality of their communication skills.

III. Traceability

Traceability, as a general principle of food law, has become an increasingly typical response to modern outbreaks provoked by the mobility of products. In Europe, the first time traceability appeared as a legally mandated obligation was the reorganization of the blood donor system in France in the early 1990s, following the scandal of HIV-contaminated blood banks. Similarly, the first example of an EU-wide system of food traceability is not the GMO scheme described in this paper, but the infrastructure created since the late 1990s to track cattle and beef products in the aftermath of the BSE crisis. In all of these cases, traceability represents an effort to control the effects of outbreaks and to make opaque networks of production governable, by tracing the trajectories of the entities that travel along them.[74]

Concerning GMO, Mir Puigpelat highlights the useful mechanism of traceability.[75] Traceability is granted by a code (a unique identification) that is transmitted through the food supply chain. It can be assumed that if operators and administration can follow the GM product throughout the whole food chain, public authorities will consider this an effective control of GMO risk.[76]

The majority of Member States have found that the effect of traceability rules on labelling and informed choice is positive, because they facilitate official controls, risk management and the functioning of the entire system. The effect on imports is also reckoned to depend on the product and is particularly important where exporters from third countries submit little information about the presence of GMOs. However, it should be noted that the traceability rules of the Regulation make no distinction between EU products and imports from third countries. So the challenges concerning the availability of documentation

[74] Lezaun, *supra* note 22, at 521.

[75] Puigpelat, *supra* note 53, at 224.

[76] The StarLink case is a clear example of the need for appropriate rules for authorisation and traceability of a GMO (Declaration of European Union Trade Directorate, *available at* http://europa.eu.int/comm/trade/goods/agri/pr130503_en.htm).

remain the same for EU and third country operators. Traceability rules have an overall positive influence on public opinion on food safety, and a favourable impact on the marketing of non-GM products due to the persisting negative perception of GM products held by consumers.[77]

As the European Commission has said, most Member States regard unique identifiers as useful tools for identifying and labelling genetically modified products and report no serious problems. Overall they reported limited but positive experience with regard to the implementation of Regulation EC 65/2004 and the use of unique identifiers. However, a few Member States pointed to the fact that unique identifiers are not always included in the documentation accompanying the products—in which case traceability is not reliable and business operators must endeavour to get these codes by requesting additional information from the suppliers. Moreover, several Member States reported problems with the limited resources available and the resultant reduction in inspections and controls.[78]

IV. Coexistence

In relation to environmental risks, genetic transfer does not allow coexistence with traditional agriculture due to several factors such as dispersion, cross-contamination, soil quality, etc.[79]

Coexistence is also considered one of the critical points of the EU GMO system. Stated by a Recommendation, it should be reconsidered by legislators in order to determine the rule in a *hard law* instrument.

In our opinion, an EC Recommendation could be considered as an insufficient instrument in order to harmonise the regulation of GMO coexistence throughout Member States. In addition, the GM-free zones are controversial initiatives that should be interpreted in a technical and political light, as most of the zones are part of regions with plain powers on the matter.

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[77] *Report on theImplementation of Regulation EC 1830/2003*, *supra* note 48, at 4.

[78] *Id.* at 6.

[79] Without decreasing health and safety risks, a certain environmental risk has been detected, where GMO seeds are employed, associated with changes in biomass. MAHIEU, *supra* note 7, at 405. In relation to the risk communication, US judgements and European authorities have considered some risks relating to plant varieties resistant to antibiotics as unacceptable, and "communication risk strategy has failed or there is certain contradiction between the risk assessment's conclusions and the European authorities' acts." Escajedo San Epifanio, *Los retos de la regulación jurídica de los cultivos transgénicos: su investigación, cultivo y comercialización*, 7 REVISTA ARANZADI DE DERECHO AMBIENTAL 115 (2005).

V. Simpler and Better Proceedings

Simpler and better proceedings for GMO issues can be obtained by reducing administrative burdens.[80] This concept means the choice of the legal option more adequate in order to satisfy these requirements of public health and environment so a previous well-performed risk evaluation will facilitate to select the best option of prevention and control.[81]

It would be worth examining whether there are ways of accelerating the EU authorisation procedure without compromising the high standards and validity of the risk assessment. Furthermore, we should look at possible approaches to how to deal with imports containing minute or just detectable traces of GMOs that are fully approved in exporting countries according to internationally agreed standards. In this regard, the discussions at the level of Codex are important and should be pursued.[82]

At this point, it is important to know what role is going to be played by the EFSA,[83] as the Authority can carry out scientific assessment on any matter that may have a direct or indirect effect on the safety of the food supply, including matters relating to animal health, animal welfare and plant health.[84]

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[80] *A Strategic Review of Better Regulation in the European Union*, COM (2006) 689, *available at* http://europa.eu/legislation_summaries/institutional_affairs/decisionmaking_process/l10103_en.htm.

[81] RUIZ, *supra* note 15, at 133.

[82] *Economic Impact of Unapproved GMOs on EU Feed Imports and Livestock Production,* 7 (2007) COM, *available at* http://ec.europa.eu/agriculture/envir/index_es.htm#gmo.

[83] As the EC points out, the enforcement of EFSA's mission determines legislative and other actions, including the assurance of effective control systems, evaluation of compliance with EU standards in the food safety and quality, animal health, animal welfare, animal nutrition and plant health sectors within the EU and in third countries in relation to their exports to the EU, management of international relations with third countries and international organisations concerning food safety, animal health, animal welfare, animal nutrition and plant health, management of relations with the EFSA, and insurance of science-based risk management. The EFSA collects information and analyses new scientific developments so it can identify and assess any potential risks to the food chain. In the context of the debate of independent agencies and food safety, we find the two different European and North American models. In the EU institutional structure, the agencies have contributed to the execution of specific EU programmes in order to promote social dialogue and the internal market or to protect consumer safety. Despite the diversity of denominations and activities of EU agencies, they have similar basic organizations of board, executive director and scientific or technical committees. They also have in common the intervention (intervention or exclusion?) from the European Court of Auditors and the European Commission. Financial revenues are generally from subsidies and taxes. In the EU, agencies form a kind of network with other national and European administrations as a model of collaboration (Art. 10 of the Treaty) and show the relevance of administrative law and the concept of delegation of powers to third bodies in EU law. Recuerda Girela & Miguel Angel, SEGURIDAD ALIMENTARIA Y NUEVOS ALIMENTOS: RÉGIMEN JURÍDICO-ADMINISTRATIVO 102 (2006).

[84] Bénédicte Nicolini, *Les risques alimentaires liés au conditionnement des vins,* RAPPORT ANNUEL ICV 3 (2000).

In addition, it will be a healthy experience, in administrative terms, to evaluate the complete proceedings concerning GMO, as it has been done in 2007 with Regulation EC 1830/2003, in the framework of the Action Programme aimed at reducing administrative burdens on businesses in the EU.[85]

E. Conclusions

At this time, it would be unrealistic to expect Brussels to take clear political decisions on the GMO matter, but the legal framework in force should be improved in order to provide a better response to GMO issues. We have concluded that a revision is required on some elements of the EU GMO legal system.

Labelling, traceability, communication, coexistence and simpler legislation are, a priori, cardinal points of the compass of the so-called European Commission "sherpas" on this matter.

As the social dimension of the GMO risk is really appreciated by the Council of Ministers, it will also be relevant to have a though in European Commission about reforming the composition of Scientific Committees of EFSA to include sociologists, lawyers, etc. The presence of representatives of social sciences could enricht the reports of the Committees.

Concerning labelling, it is important to keep in mind that some Member States and stakeholders also pointed to the need for labelling thresholds for the presence of GMOs in seeds. It seems to be convenient any rule on this issue at EU level to satisfy the traceability principle. Although the majority of Member States reported that overall controls and official inspections are carried out without serious problems, transgenic products have

[85] On 23 March 2005, the European Council requested "the Commission and the Council to consider a common methodology for measuring administrative burdens with the aim of reaching an agreement by the end of 2005." On 16 March 2005 the Commission's Communication on Better Regulation proposed to start work on a limited number of administrative burden reduction proposals that were likely to generate significant benefits through minor changes in the underlying legislation. "A quick harvest of these 'low hanging fruits' would be tangible evidence of the commitment of the European Institutions to this agenda and would allow significant results to be achieved at an early stage." It is proposed that these low-hanging fruits be identified in the early 2007 Action Programme following consultation on this Commission working paper, while duly taking into account planned and ongoing policy review processes. *An EU Common Methodology for Assessing Administrative Costs Imposed by Legislation*, COM (2005) 518 and Staff Working Paper, *Annex to the 2005 Communication on Better Regulation for Growth and Jobs in the European Union, Minimizing Administrative Costs Imposed by Legislation, Detailed Outline of a Possible EU Net Administrative Cost Model* 175 SEC 12 (2005). In the second strategy review, the European Commission focused, among others, on Regulation 1830/2003 GMOs, in regard to traceability rules that require operators to have in place a system to hold information for 5 years in the priority area of Food Law. The information obligation has been categorized in the following items: provision of information about the presence of GMOs in products; keeping information available about the presence of GMOs in products and the identity of suppliers and receivers; and labelling of pre-packaged products and non-pre-packaged products. *Reducing Administrative Burdens in the European Union 2007 Progress Report and 2008 Outlook*, at 35, COM (2008) 13.

arrived to the EU food chain without regulated labelling. In that context, traceability requires a more effective control by national administrations. The European Commission has communicated that several Member States reported problems with the limited resources available, and the resultant reduction in inspections and controls. It has been highlighted that a few Member States pointed to the fact that unique identifiers are not always included in the documentation accompanying the products.

Furthermore, it is already time to produce an EC Regulation containing co-existence rules with no more 'soft law' in order to avoid future conflicts and to respect the self-declared GM-free regions and their producers in terms of protecting traditional production methods and regional peculiarities.

Finally, simpler and better proceedings can be obtained from the reduction of administrative burdens, as we have exposed. There is also a need to complete legislation regarding compulsory risk communication and risk management. Moreover, the European Commission is not doing their best with respect to communication and transparency. As the ECJ has stated, the European Commission is called upon to offer the consumer more precise information about the health and environmental risks associated with GMO and, in particular, about the internal dossiers of GMO approvals.