Genetically Modified

Precautionary Principle and
Consumers' Rights in Peru

ISABEL LAPEÑA

Genetically Modified.
Precautionary Principle and
Consumers Rights in Peru

Isabel Lapeña García

Towards the Implementation of a Biosafety Regime in Peru: applying the Precautionary Principle, Consumers´ Rights and Liability Project.

Sociedad Peruana de Derecho Ambiental
Prolongación Arenales Nº 437, San Isidro Perú
Teléfonos: (511) 421 1394 422 27 20 / Fax: (511) 442 4365
postmast@spda.org.pe
www.spda.org.pe

With the support of:

Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) GmbH
Programme Implementing the Biodiversity Convention"*
P.O. Box 5180; 65726 Eschborn; Germany
Tel.: +49 (6196) 79-1359
Fax: +49 (6196) 79-801359
http://www.gtz.de/biodiv

Comissioned by German Federal Ministry for Economic Cooperation and Development (BMZ).

The views expressed in this publication do not necessarily reflect those of the BMZ or GTZ.

First Editon March 2006

Cover design Marco Velásquez F.

Printed in Peru

ISBN 9972-792-53-6

The Peruvian Society for Environmental Law would like to thank Deutsche Gesellschaft Zusammenarbeit (GTZ) and the German Federal Ministry for Economic Cooperation and Development (BMZ) for its support to the project "Towards the Implementation of a Biosafety Regime in Peru: Applying the Precautionary Principle, Consumers' Rights and Liability", under which this publication has been made possible.

The author would like to thank Manuel Ruiz Müller for the comments made to this document.

Also many thanks to all those who have contributed with their experience and by sharing information, for better understanding the subject matter of this study.

INDEX

PROLOGUE

During the last twenty years, modern biotechnology has produced a real revolution in science. New medicines, new therapies, new food and new industrial products - enzymes, bioremedies, cosmetics, etc.- are all contributing to changing consumer patterns, research tendencies and human well being.

With all its recognized potential, biotechnology and its resulting products are part of a growing national and international political and legal discussion mainly addressing how to guarantee minimum levels of security, guarantees to human and animal health and environmental protection.

This discussion and the need to prevent risky and dangerous situations with regard to biotechnology and its products, has resulted in a series of national and international norms, protocols and codes of conduct on biosafety and the recent adoption of the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*.

Peru has been an active participant in these discussions and has developed a national biosafety framework. Debates have included different actors of civil society (indigenous communities and consumer associations) in order to stimulate the generation of ideas and proposals on how to face the biotechnology challenge and introduction of its products into markets and the environment.

In this context, this investigation is one of the first national efforts to try to systematize and organize a political and legal debate on biosafety, around three key issues: the Precautionary Principle, the role of consumers' rights and legal liability.

Isabel Lapeña in a clear and simple language, analyzes these different variables in the midst of a growing concern over the positive and negative impacts resulting from the application of biotechnology and the generation and introduction of its products. Though not a Legal Treaty on Biosafety, Ms. Lapeña has managed to clearly identify the critical issues of the discussion, allowing and helping the reader understand their implications and consequences.

On the other hand, this investigation does have a political/legal orientation, but can be easily understood by those who are basically informed on the matter.

We are sure that due to this effort and from its dissemination, new and specific research initiatives will emerge in relation to the different issues identified throughout the document. It will be a valuable input for those seeking to develop public policies on biosafety.

Manuel Ruiz Müller
Director of the Program
on International Affairs and Biodiversity
SPDA

I. INTRODUCTION

The Convention on Biological Diversity (1993) defines biotechnology as *"…any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use"*[1]. Biotechnology[2] is an area in science that not only implies crossing barriers between species, but also the lines dividing organisms. This may have adverse affects on future generations of such species or organisms. This technology allows the generation of what is known as living modified organisms (LMOs) or genetically modified organisms (GMO's) which are, for purposes of this paper, equivalent concepts.[3] In view of this, the term biosafety is being used to describe policies and procedures that need to be adopted in order to ensure the environmentally safe application of modern biotechnology.

This term becomes more relevant when taking into account the growing interest of countries to obtain benefits from the application of modern science to medicine, the environment, to agriculture and food security. This calls for the need to prevent that the adoption of technologies implies long term risks for communities' health and the environment. Thus, biosafety would include a series of measures, policies and procedures to reduce the possible risks from the transfer, management, use and release of LMOs to the environment, biological diversity, human health and socio-economic structure.

This investigation is not about the benefits and risks which are generally attributed to modern biotechnology. Nevertheless, it is important to mention the different elements relevant for the development of a policy on biosafety in Peru and which may be considered in the application of modern biotechnology in the country.

In this sense, admittedly, the debate has been centred on the struggle to defend the benefits or risks of biotechnology from a purely technical point of view, without acknowledging the existence of social and socio-economic factors which are not fully understood in all their dimensions. This has meant obviating in the debate the coexistence and participation of other kinds of knowledge, such as traditional

---

1 Convention on Biological Diversity, Article 2.

2 This study is referred to modern biotechnology or genetic engineering, understanding under this concept the application of: a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection. Zaid A. et al. (2001) *Glossary of Biotechnology for Food and Agriculture. A revised and augmented edition of the Glossary of biotechnology and genetic engineering.* FAO Research and Technology Paper. Rome, Italy. 2001 http://www.fao.org/biotech/find-formalpha-n.asp

3 LMOs are a subset within GMOs. Throughout this document the acronym LMO will be used as in the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, and as adopted in national legislation. Other regimes, such as European Union Legislation use the acronym GMOs.

knowledge of communities, and the necessary agricultural and socioeconomic research to address these knowledge gaps.

In this context, it is very different to discuss the significance of this new technology in a developed country where its impacts are measured by its repercussions on societies with access to a variety of products; which are accessible for the economy of the average citizen; and which are generally produced in a secure, plentiful and diverse manner; where farmers have experience with technology and access to capital and technological instruments; where public and private research exists to assist the evolutionary needs of agriculture and a well developed regulatory system and medium informed consumers exist. To try and understand the impact of these same technologies, in a society that does not produce enough to feed its communities; where one or two products control the diet; where farmers lack the basic infrastructure for transport, storage and access to markets; where farmers do not have a budget or access to credit in order to invest in technology; where farmers have limited capacity to assume new risks; with limited private research and scarce budgets for public research; where the capacity to manage the risks associated with such technology is limited and public participation and awareness incipient,[4] is a totally different story.

Although the debate is dominated by values from developed countries, and in general does not include the concerns, perspectives and experiences of countries with other distinct features, -including environmental and physical agricultural structure, and regulatory experiences and policies-, the mentioned issues are as significant as those related to benefits and risks of modern biotechnology in general. In the development and regulation processes, above all, the characteristics of the country where a technology is to be applied, as well as the social priorities it seeks to satisfy must be understood.

On the other hand, it is essential to provide with a sincere answer to a series of concerns when addressing the challenges of modern biotechnology and to question the existence of capacities at different levels. It would be particularly interesting to determine the degree of public research and budgets for a country to undertake research in a modern biotechnology which seeks to confront the specific needs of local farmers; concentrating on seeds and local products, basing this research in its coexistence with that of conventional improvement. Elements to also be evaluated would be: the presence of public infrastructure to accompany such technology in terms of education and distribution; the regulatory capacity to ensure a safe and healthy product for consumers; the existence of a regulatory system to govern the imports, development, trials and use of LMOs and legal and scientific control and monitoring which would allow for the ideal implementation of such regulatory systems.

[4] Feeding the world. A look at biotechnology and world hunger. Pew Initiative on Food and Biotechnology. March 2004.

The language of precaution is reflected in some of the previous dimensions. However, this language (which was introduced internationally before the Rio Declaration of 1992, but which refers to it explicitly in Principle 15) is still not wholly understood especially in its translation to practical management and policy tools by decision-makers. Proof of this is the political tensions at the international level and the difficulty of its full comprehension and application at the national level.

In light of the above, there is the need to respond to the rights consumers have to demand that a chemical product, a crop or a technology be tested before being delivered for common use. If there was evidence suggesting there could be possible negative effects on humans, the environment or culture, any country or society would have the right to avoid the risk. A key element to have in mind is the level of social acceptability of a determined risk.

This study attempts to reflect on the issues outlined and help decision-makers and public in general, nationally and internationally, understand the basic concepts of the debate regarding biosafety and its application to modern biotechnology.

Finally, biosafety is itself a broad concept and its study in Peru implies extending it to other significant issues. Its link to the protection of intellectual property rights; the relevance of the flow of genes in a centre of origin of biological and agricultural biodiversity, as well as access to genetic resources and fair distribution of the benefits derived from their use, among other matters should not be overlooked. All are issues with their own distinct features and should be subject of more profound studies.

II. REGULATORY AND INSTITUTIONAL FRAMEWORK ON BIOSAFETY IN PERU

A developing regulatory framework since 1999 and a proposed institutional framework recognizing the responsibilities of different biosafety sectors, reflects that there is the desire in the country to acknowledge the growing concern regarding the potential benefits of biotechnology and the need to regulate and reduce possible threats. Special emphasis is made regarding this point, given the need to consider the country's specific characteristics, its condition as a megadiverse country and centre of origin and diversity of a variety of domesticated biological resources of great importance for food security of communities and the world's population.

2.1. Regulatory Framework

Genetic manipulation by means of modern biotechnology is acquiring great importance and major dimensions at an international level, where most debates and regulatory discussions are taking place. The main international instrument regarding biosafety is the *Cartagena Protocol on Biosafety* (CPB). This agreement was recently ratified by Peru and entered into force in July.[5] The CPB is a development of the Convention on Biological Diversity,[6] also ratified by Peru,[7] and its main objective is to regulate transboundary movements, transit, handling and use of all living modified

[5] Legislative Resolution No. 28170 of February 15th ratifies the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*. The Protocol entered into force in Peru on July 13th 2004.

[6] Article 19 of the Convention on Biological Diversity regarding the Handling of Biotechnology and Distribution of its Benefits provides that *"1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties. 2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms. 3. The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organisms resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity. 4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced"*.

[7] Legislative Resolution No. 26181 of April 30th 1993; in force since September 7th 1993.

organisms that may have possible adverse effects on the conservation of biological diversity and human well-being.[8]

Nevertheless, the biodiversity legal framework does not navigate isolated; its implementation is indirectly affected by other parallel legal systems. Given the link between biodiversity regimes and foreign trade issues, the World Trade Organization (WTO) of which Peru is also a member, is also of relevance.[9] Three central World Trade Oorganization agreements, the *Agreement on Technical Barriers to Trade* (TBT), the *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS) and the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS) have implications on the application of biosafety norms.

As a party of the WTO, Peru is obliged by a series of provisions which promote international trade. If Peru does not comply, the country may be subject of legal action under the *Dispute Settlement Mechanism* and *Appellate Body* of the WTO. Similarly, Peru is also negotiating bilateral Free Trade Agreements with, among other countries, the USA[10] and Thailand, which may also have a bearing on biosafety issues.

Peru is also part of the *Codex Alimentarius Commission* that was created jointly in 1963 by the *United Nations Organization for Food and Agriculture* (FAO) and the *World Health Organization* (WHO). Codex Alimentarius is one of the main commissions responsible for the development of international food standards. Food standards are linked to the introduction of LMOs in the food chain, which is the object of debates and negotiations through the *Ad hoc Intergovernmental Group on Food Derived from Biotechnology* and the *Codex Committee on Labelling Food.*

The difficulty to find a consensus for the establishment of a harmonized international regime on LMOs, has led the Codex Alimentarius Commission, during its Twenty-Eighth Session celebrated in July 2005, to agree to the constitution of an *Ad Hoc*

[8] The scope of the Protocol is restricted to "living organism" which means *"any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids*" -Article 3(h)-. Within the scope of the Protocol, the following are included: seeds, cereals, fruits, vegetables, live animals, non-pasteurized cheeses that contain LMOs, microbes and vaccines. In contrast, the following would be excluded: products resulting (derivates) from LMOs such as flour, bread, oils, fruit juices, soy sauce, which although they are manufactured using modified genetic material, are not capable of replicating the genetic material. However, the Peruvian national legal framework indirectly broadens its scope of application to LMOs and their derived products.

[9] Legislative Resolution No. 26407 of December 18th 1994, in which Peru declares its adherence to the World Trade Organization; in force since January 1st 1995.

[10] The institutional complexity linked to modern biotechnology development leads to a disperse treatment of the issue in the different bilateral treaties. Negotiations on agriculture, investment and intellectual property rights will have its consequences to be seen in the future on biosafety regimes in the country. Nevertheless, it is believed that the FTA with the USA will imply the entry of LMOs into the country. These may include transgenic rice, corn, soy, cotton and feed for animals.

Intergovernmental Task Force on Foods derived from Biotechnology which must present the Commission its final report by 2009.[11]

Finally, consumer protection from products resulting from modern biotechnology is the least developed aspect at the international level. There are only two non binding instruments, the *United Nations Guidelines for Consumer Protection* of 1985[12] which is presently under revision and the *Code of Ethics for International Food Trade*[13] of *Codex Alimentarius* of the same year.

At the regional level, the analysis of the regulatory framework on biosafety focuses on the Andean Community (AC) which is applicable in Peru. Decision 345 *on a Common Regime on the Protection of the Rights of Breeders of New Plant Varieties* of October 21st 1993, takes into account provisions of the Convention on Biological Diversity and in its Third Transitory Provision instructs Member Countries[14] to ratify before December 31st, 1994 a *Common Regime on Access to Genetic Resources and guaranteeing biosafety in the Subregion*. Although it was decided to address both matters separately and a Decision on access to genetic resources was passed, to date there are still no regulations to cover biosafety. Hence, countries of the Andean Community have proceeded to independently create their own regimes.

Additionally, the R*egional Biodiversity Strategy for the Tropical Andean Countries*[15] provides for the development of biotechnology and parallel biosafety mechanisms in some of its lines of action. Line of Action 7, within Objective I, emphasizes the value of establishing joint biosafety policies and actions on biotechnology within the AC. As a result, the following is anticipated:

- the adoption of joint mechanisms and procedures to control the trade in, and transboundary movements of LMOs and LMO products and derivatives, through the creation of scientific capacities for risk assessment;
- the identification and adoption of labeling guidelines and principles to determine liabilities and compensations for LMO related damage;
- the need to systematize and disseminate experiences gained through the use of LMO trials, establish joint biosafety policies and actions and strengthen the capacities of countries adopting the CPB.

Objective IV includes Line of Action 14, on the development of priority research on conservation, sustainable use, technological innovation and biotechnology. This action recognizes the need to develop technologies for Andean crops and species, in order to add value and access markets with improved benefits. This action will balance

[11] The preliminary version of the report from these sessions may be found at: http://www.codexalimentarius.net/web/index_en.jsp.

[12] http://www.un.org/esa/sustdev/sdissues/consumption/english.pdf

[13] CAC/RCP 20-1979, Rev. 1 (1985) http://www.codexalimentarius.net

[14] Colombia, Venezuela, Ecuador, Bolivia and Peru form the Andean Community of Nations.

[15] Approved by Decision 523 on July 7th 2002.

the current tendency in which research efforts undertaken by transnational companies are centered on "commodities" such as soybean, corn and wheat.

Lastly, the Strategy emphasizes the need to establish investment funds for subregional projects which allow the strengthening and development of research capacities of Andean Community scientists.

At the national level, Peru through its different normative instruments and policies has declared itself in favor of the need to promote biotechnology but protecting human health, the environment and biological diversity. Thus, after ratifying the Convention on Biological Diversity in April 1993, a series of significant laws have been promulgated covering conservation, sustainable use of biological diversity and biosafety.

Different laws and regulations clearly indicate the need to promote biotechnology research. Among these is Law No. 26839 of July 8th 1997, on *Conservation and Sustainable Use of Biological Diversity* which in Article 25 establishes that *"the State with the participation of the private sector, promotes: a) the development of scientific research, access, generation and transfer of appropriate technologies, including biotechnology"*. In Article 26 *"it declares a priority and national interest, scientific research in: c) knowledge, conservation and industrial and medicinal application of genetic resources through modern and traditional biotechnology"*.

At the same time, there is the need to provide the country with parallel biosafety policies. Article 30 of Law 26839 establishes that *"the research, development, production, liberation, introduction and transit of all genetically modified organisms throughout national territory must develop security mechanisms to reduce threats to the environment and human health"*, and Article 29 includes, as part of the limitations to access genetic resources or their derived products, biosafety regulations.

An essential policy framework addressing the country's priorities on conservation and sustainable use of biological diversity is the National Strategy on Biological Diversity, ratified after a participative process, through DS 102-2001-PCM, which includes in the Second Strategic Line relative to *"integrating sustainable use of biological diversity in the management of natural resources"*, Strategic Objective 2.9 named *Biosafety*.

Strategic Objective 2.9 proposes a series of actions:

- creating a *National Biodiversity Program* in accordance with the Cartagena Protocol, with a special emphasis on agricultural and nutritional aspects;
- establishing a *National Biotechnology System* to promote research on native species, promote criteria, safeguards and safety indicators, to develop and revalue traditional knowledge regarding selective use of biological diversity;
- developing research and educational programs to minimize the risks to the environment and human health;
- implementing existing laws and regulations; and
- guaranteeing an adequate legislation and securing the control, prevention and risk evaluation mechanisms, as well as the development of national capacity and regional networks to identify and anticipate the import of living modified organisms into national territory.

In Strategic Objective 3.3 - in the Third Strategic Line regarding *"establishing special measures for the conservation and restoration of biological diversity in the light of external processes"*- the National Biodiversity Strategy expressly regulates the control of LMOs. It determines that *"living modified organisms represent "hidden" risks, as it is very difficult to anticipate the manifestation of genes that may harm biological diversity"* and includes the following actions:

- periodically inform the users of this technology of the risks and benefits involved in LMO activities;
- strengthen plans to prevent the import of living modified organisms which are a risk to human health, the environment and biological diversity; and
- promote private and public sectors participation in the eradication of living modified organisms which are a risk to human health, the environment and biological diversity.

To summarize, Peru has been one of the first countries in Latin America to establish a system that regulates safety in the use of biotechnology. Unlike other countries that have defined biosafety issues in a broader and more indirect manner through legislation on pesticides and toxic chemicals in food or others based on voluntary regulations, Peru has chosen to create a specific binding regime which includes a Law and implementing regulation. This is the *Ley de prevención de riesgos derivados del uso de la biotecnología* (Law to prevent risks derived from the use of biotechnology), Law No. 27104 from January 4th 1999 and its Regulation adopted through by Supreme Decree No. 108-2002-PCM (the Regulation).

Law 27104 defines its scope of application to *"research, production, introduction, handling, transport, packing, conservation, exchange, commercialization, confined use and liberation activities with LMOs, under controlled conditions"*. However, the Regulation of the Law indirectly broadens the scope to LMOs and their derived products. This situation is being questioned in discussions of the Coordinating Committee of the National Biosafety Framework and is generating considerable legal uncertainty.

This regulatory framework is quite comprehensive as it covers the complete spectrum of uses of LMOs: from research, field trials to commercialization. However, the design of the legal framework is an ongoing process which seeks to create an institutional and procedural structure, and is far from being complete. At present, norms that specifically define the competences and responsibilities of the different sectors and authorities are being developed. Hence, issues such as segregation of LMOs; creation of traceability mechanisms; regulation of coexisting LMO crops which are not; labeling systems and the design of a liability regime, will be subject of further work in the future, as discussions mature and similar issues are clarified at the international level.

On the other hand, the ratification by Peru of the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity* (CPB)[16] may lead to future modifications in national legislation which was developed before ratification, in order to ensure national and international coherency of the biosafety regulatory framework.

Finally, it must be pointed out that the biosafety system has not managed to permeate sectorial legislation. The reference to transgenic organisms in seed legislation is very brief; it simply refers to a biosafety authority for supervision and authorization.[17] Law No. 27322, *Ley Marco de Sanidad Agraria* (the Law of Agriculture Sanitation) is also not very extensive; it provides in Article 30 that *"the introduction, investigation, handling, production, transit, packaging, release, conservation, commercialization, use and management of Living Modified Organisms and their products thereof, for the agricultural and livestock industry, will be subject to phytosanitary and zoosanitary measures adopted by the National Agriculture Authority (…)".*

From the perspective of consumers' protection, the *Texto Unico Ordenado del Decreto Legislativo 716, Ley de Protección al Consumidor* (Law for the Protection of Consumers), related to the general regime of consumers protection in the country, contains no information referring to transgenic foods.

2.2. Institutional Framework

The Regulation of the Biosafety Law establishes the country's institutional biosafety framework. This regulation places the biosafety institutional framework on three main pillars: it distributes competences to sectorial bodies; it establishes counseling bodies on biotechnology safety and coordinates these through an intersectorial organism.

The biosafety legal framework does not seek to create new institutions and organisms but, rather, strengthens existing bodies under the coordination of an intersectorial organism and relying on the support and advice from technical groups formed by different authorities, academics from universities and other invited experts.

Article 6 of the Regulation establishes as Competent Sectorial Organisms, the *Instituto Nacional de Investigación y Extensión Agraria* (INIEA, National Institute of Extension and Agricultural Research), the *Vice Ministry of Fisheries* and the *Dirección General de Salud Ambiental* (DIGESA, National Direction of Environmental Health) of the Ministry of Health.

[16] The text of the Convention on Biological Diversity and the text of the Cartagena Protocol on Biosafety can be found at http://www.biodiv.org

[17] *Ley 27262, Ley General de Semillas* (General Seed Law), published in the Official Gazette El Peruano on May 13th 2000 and Decreto Supremo 040-2001-AG, which ratifies the Law; published in the Official Gazette El Peruano on July 9th 2001del 2001.

Among the duties of the Competent Sectorial Organisms are the following:

- receive applications and authorize, modify, suspend or refuse the register of institutions interested in carrying out LMO activities, providing they comply with the requirements to introduce, use and commercialize LMOs, their derivatives and products thereof;
- create an identification system of third independent parties in charge of carrying out risk assessments of LMOs and related procedures and conditions;
- implement a National Monitoring Program for activities carried out with LMOs in the country;
- undertake inspections and, if necessary, order close down of facilities;
- and canalyze accusations on possible adverse effects caused by the use and management of LMOs and disseminate information on possible risks and benefits derived thereof.

This distribution of competences presents two main problems. Firstly, the National Institute of Extension and Agricultural Research (INIEA) would become a judge and an interested party at the same time. That is, as an institution dedicated to modern biotechnology research in the agricultural sector and as the organism responsible for authorizing and supervising modern biotechnology. Such a circumstance affects the neutrality and objectivity needed in the decision of whether to authorize the register of persons or activities related to LMOs in the agricultural sector, especially those undertaken by INIEA itself.

Secondly, the proposed system will need the development of important coordination mechanisms among authorities. Mainly among the National Service for Agrarian Sanitation (SENASA) in charge of supervising the production, certification and commercialization of seeds and maintaining the registry of seeds and pesticides and the National Institute of Extension and Agricultural Research (INIEA) who is competent in creating the registry on LMO activities in the agricultural sector.

The Competent Sectorial Organisms will be supported by Sectorial Technical Groups (GTS) formed by experts in the sector, in order to comply with the duties mentioned above. The Sectorial Technical Groups of the agricultural sector include the National Institute of Extension and Agricultural Research (INIEA), the National Institute for Natural Resources (INRENA), the National Service for Agrarian Sanitation (SENASA), the Peruvian Institute for Amazonia Research) and university representatives.

In the fisheries sector, the Sectorial Technical Groups include IMARPE (Institute of the Sea of Peru), ITP (Technical Fisheries Institute), Peruvian Institute for Amazonia Research (IIAP) and universities related to the sector.

Finally, for the health sector, the National Directorate of Environmental Health (DIGESA), the National Institute of Health (INS) and university representatives, will play this role.

All these Technical Sectorial Groups (TSG) have the crucial duty of carrying out assessments of the risks derived from activities developed with LMOs, and issuing technical reports which authorize or deny the import of LMOs.

The *Comisión Nacional de Diversidad Biológica* (CONABID, National Biodiversity Commission), a participative and representative organism of the different sectors and civil society, will act as the advisory body for counseling and coordinating on biosafety issues.

Ideally, the National Directorate of Environmental Health (DIGESA) should participate transversally in the Sectorial Technical Groups of all three sectors given all have a linkage to human health related issues [18].

Finally, the *Consejo Nacional del Ambiente* (CONAM, National Environmental Council) acts as the intersectorial coordinating organism. CONAM is the *Biosafety Clearing House* compiling and disseminating information from the Competent Sectorial Organisms. In its organic structure within the *Biodiversity and Biosafety Unit*, a Biosafety Area has been created to centralize the information as a focal point. At present, CONAM is in the capacity of receiving and sending information related to decision making and has established a data base with national experts.

[18] This statement is based on a presentation by Ing. Dora Pariona (representative of SENASA) during a consultancy on "Regulations for development of activities involving LMOs and derived products", which took place on August 31st 2004 under the PNUD-GEF National Biosafety Framework Perú Project

III. APPLICATION OF THE PRECAUTIONARY PRINCIPLE

In order for the Precautionary Principle to be incorporated into the decision-making processes on activities related to LMOs, it is of great consequence to understand its meaning; the basis for its application; its legal consequences and possible actions its use may require in practice.

3.1. Content of the Precautionary Principle

In general, the Precautionary Principle responds to the idea that it costs more to repair damage than to prevent it. Therefore, this principle calls for action, for the adoption of a positive decision even in situations where there is a scientific uncertainty surrounding potential threats to the environment and human health.

In this sense, it is clearly an *ex ante* measure to prevent damage which may occur on the environment and human health. As some authors have suggested, it is a principle which helps the decision making process to distinguish between moderate ignorance of normal damage, from profound ignorance of severe potential damage[19].

The basis for applying the Precautionary Principle would be the presence of a situation, substance or conduct, which implies a threat to the environment and human health in a serious and irreversible manner, with the possibility of the risk being materialized. Implicit to this situation is the existent scientific uncertainty in relation to the nature and extension of the threat, and on the concretion or not of the risk in specific damage. That is, a situation of uncertainty related to the magnitude and the probability of damage occurring.

It is often argued that societies have always lived with different types of risks which have been confronted and managed through prevention measures and mitigation, with more or less of an understanding of the consequences and probabilities of the effects and risks. The Precautionary Principle responds to the need to face growing concern in society of a "new generation" of risks, which, to a considerable degree, are linked to the same novelty of emerging technologies.

This way, when facing these new technologies, as is the case of LMOs that allow a higher intervention in nature and imply the introduction of permanent changes for future generations, we find they lack a history[20] (in the context of other risks that are a part of everyday life). Society finds itself unable to describe and anticipate the possible consequences and cannot predict with confidence the probability of the

[19] Stone, Christopher (2001), "Is there a precautionary principle"? Environmental Law Reporter, Volume Year XXXI, July 2001.

[20] Ibid.

impacts nor their long term magnitude nor their effectiveness or the costs involved in the future from their mitigation.

In the light of scientific uncertainty, when assessing the risks of determined human actions, the only option for decision-makers, based on the assessment by experts and valuation of different alternatives, is to determine if the risks are socially acceptable and define the course of action to take under these circumstances.

As expressed previously, the key objective of the Precautionary Principle is to operate within the limits of science at the time of predicting and managing the potential serious and irreversible risks of activities. Regardless of this objective and above all, the Precautionary Principle implies the transfer of responsibility from scientists to decision-makers. The responsibility of the decision to accept a determined level of risk will fall on the policy-makers. At the same time, this means the elimination of all temptation by decision-makers to delegate the responsibility of their policies to scientists.

In relation to the uniformity present in solutions science usually offers, the legitimacy of the decision to accept a determined risk will depend on a specific social context. These days, science can provide information on the existence of a determined level of risk -between margins of error- but cannot define what level of risk is socially acceptable. This will be defined and shaped by circumstances such as culture, economy, degree of awareness of citizens and the interests to be protected of social groups and countries[21]

Almost certainly, the Precautionary Principle is a question of common sense and should be easy to understand and admit. The problem arises when it is time to define the level of acceptability of the risk -the risks society is prepared to tolerate- and the level of benefits we are to receive in exchange of accepting the risks. The discrepancies emerge mainly when those who receive the benefits in society, are different from those who suffer the damage and cost of an activity.

Part of the doctrine states that the application of the Precautionary Principle should imply various fundamental elements:

- the existence of a threat of risks;
- that the damage be serious and irreversible;
- scientific uncertainty on the nature and severity of the results of such a threat;
- an obligation for policy decision-makers;

[21] Boutilon, Sonia (2002), "The Precautionary Principle: Development of an International Standard". Michigan Journal of International Law. Winter 2002. University of Michigan Law School.

- the commitment to grant the health of the community and the environment, "the benefit of the doubt" when under potential damage, uncertain but possible;
- the possibility of admitting informed public participation in the determination of options to be chosen;[22]
- the formulation of possible alternatives;
- and the need for transparency when using scientific and technological information in the analysis of available alternatives.[23]

3.2. Regulatory provisions related to the Precautionary Principle

As mentioned previously, the Precautionary Principle in Peru is regulated by Law No. 27104 and its implementing regulation. It is appropriate to refer to national legislation in the first place, as these norms were enacted before the ratification of the CPB. Furthermore, national rules need to be interpreted in the light of principles included in the CPB.

Article 10 of Law No. 27104 establishes the following:

> "*The State, through its competent organisms, shall evaluate the negative impacts to human health, the environment and biological diversity, from the deliberate release of a determined LMO and unauthorized release and use if possible threats were found, provided the measure is technically justifiable and does not constitute a technical obstacle or restriction to trade".*

Similarly, the Cartagena Protocol on Biosafety[24] provides in Article 1, that:

> "*In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements*"

[22] The Precautionary Principle in Wildlife Conservation. Summary of the Workshop on "The Precautionary Principle in Wildlife Conservation" Lauterpacht International Law Centre. University of Cambridge 6-7 July 2000. Africa Resources Trust, IUCN/SSC Wildlife Trade Programme, IUCN Environmental Law Centre, and TRAFFIC International. www.traffic.org/briefings/precautionary.html. During the workshop, attention was drawn to the need and value of recognizing nonscientific forms of knowledge. This is mainly knowledge of indigenous and local communities, who as part of the assessment process, may have information regarding threats to biodiversity, not necessarily included as part of scientific evidence.

[23] O'Brien Mary, (2000) "Making better environmental decisions: An alternative to risk assessment". MIT Press. Cambridge. 2000.

[24] For a comparative study of the Precautionary Principle in the CPB see Katz, Deborah (2001). "The Mismatch between the Biosafety Protocol and the Precautionary Principle". *Georgetown International Environmental Law Review.* Summer, 2001. Georgetown University.

In turn, the Rio Declaration on Environment and Development defines Principle 15 as follows:

> *"Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".*

In relation to LMOs intended for direct use as food or feed or for processing, Article 11 of the CPB establishes that:

> *"Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organisms intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects".*

Article 10 of the Protocol expresses similar terms in relation to LMOs intended for deliberate release into the environment (for example, seeds).

Finally, it is also interesting to highlight the formulation of the Principle in Decision 391 *on a Common Regime on Access to Genetic Resources:*

> *"The Member Countries may adopt measures aimed to impeding genetic erosion or the degradation of the environment and of the natural resources. If the danger of serious and irreversible damage exists, the lack of scientific certainty should not be used as a reason for postponing the adoption of effective measures.*
>
> *The principle of precaution should be applied in accordance with the provisions in the Chapter on Liberalization Program of the Cartagena Agreement and other applicable rules and regulations of the body of law of this Agreement".*

3.3. Foundations for the application of the Precautionary Principle

Frequently there is the temptation to invoke the Precautionary Principle in opposition to what is known as *sound science* or solid scientific knowledge, as if they were irreconcilable concepts. However, these are not polarized variables. Science inevitably finds limitations and, at the same time, decision-makers when dictating policies, must take into account a plurality of legal, social, political dimensions, as well as available at the time scientific and technological knowledge.

It should also be considered that there exist other sources of knowledge of equal importance and not normally included in the concept of *sound science* mostly referred to the formal/academic/scientific one. In Peru the knowledge that campesino communities have on agriculture and biodiversity management has led to the creation, use and preservation of an immense variability of crop genetic resources, kept as a legacy of their culture to successive generations and of global value for human food security and future breeding.

3.3.1. Risk assessment

In general, it can be proposed there are two variables that lead to the application of the Precautionary Principle:

a) the existence of scientific uncertainty or insufficient or inconclusive scientific information, and
b) the possible existence of 'serious or irreversible damage" (Principle 15 of the Rio Declaration), or "possible adverse effects" (Articles 10 and 11 of the CPB), or, as established in Law No. 27104, the possibility of existing "threats of negative impacts for human health, the environment and biological diversity", which are incompatible with the level or protection desired.

In this sense, this is a situation where the existence of possible severe impacts derived from a phenomenon, product or process have been identified, and where scientific evaluation does not allow with certainty and precision the determination of the existing risk.

Therefore, the Precautionary Principle is relevant only when there is a potential risk. These are situations where the risk cannot be totally demonstrated or quantified, nor can its effects be completely defined due to insufficient scientific information.

This means that before the Precautionary Principle is invoked, the identification of any possible negative effects must take place as should a risk assessment. The risk assessment must be based on available information and express, if possible, the degree of probability that the damage will occur, its seriousness and magnitude, as well as the reliability of existing information and the importance given to any unresolved scientific gaps or inconsistencies.

In this sense, risk assessments have different components such as the identification of dangers and their characterization in qualitative and quantitative terms; the existing probabilities that the danger will materialize and the characterization of the risk in terms of probability, frequency and severity of the adverse impacts on human health or the environment.

The limits of scientific knowledge can be evidenced in each of the mentioned phases. Also, scientific uncertainty in relation to the identification of the risk can occur due to the lack of information and of unanimity or existing discrepancies of scientific interpretation.

Nevertheless, the CPB establishes limitations in this respect. In Annex III, Section 4, it provides that "*lack of scientific information or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk".* To some, this indicates a clear limitation to the application of the Principle in the CPB. Scientific uncertainty cannot be used on its own as a reason to postpone an action and, at the same time, is not a reason that justifies the adoption of an action or response. Consequently, the only clear requirement for the application of the Precautionary

Principle is that the risk assessment take place *ex ante* and the countries base their policy decisions in accordance and consistent with the results of such an assessment.[25] This could imply a relation between the CPB and the regulatory framework of the World Trade Organization , as will be addressed further below.

On the other hand, the CPB offers a framework to carry out analysis of the risks in accordance to a number of principles established in Annex III. Section 3 provides that "*risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations".*

With this, it invokes criteria of *sound science* and refers to directives and codes accepted internationally; particularly when relating to LMOs intended for human consumption it would be referring to parameters established in the Codex Alimentarius.[26]

At the national level, Law No. 27104 establishes that the risk assessment take place "*analyzing case by case, separately, following technical and scientific procedures provided by competent international organisms*". Likewise, the Regulation establishes that the risk assessment be carried out following procedures from the Competent Sectorial Organisms, based on an exhaustive examination of the information provided by the applicant and taking into account the criteria of the characteristics of the LMO to be released, the proposed LMO activity and the potential recipient environment of the LMO (Article 33).

Regarding health issues, different sanitary regimes and instruments should be applied to analyze the risks to human health of LMOs. The main objective in this case would be to minimize the risks from LMOs themselves or their derived products. Ideally, this would mean an analysis along the food chain. An area related to this would be LMOs intended for feed and food sanitary measures in this context. At present, the tendency is not to make distinctions when relating to LMOs for food or feed, provided the latter end up being present in the human food chain.

[25] Boutillon, Sonia (2002) "The Precautionary Principle: Development of an International Standard". *Michigan Journal of International Law*. Winter 2002. University of Michigan Law School.

[26] Although the Codex is open to all governments, there are only a few developing countries that monitor and are a part of the decision making process in this organism. This situation has been subject of strong criticisms and of a recent declaration by the Commission in its Session No. 27 on the need to increase the participation of least developed countries.
http://www.fao.org/newsroom/en/news/2004/46967/index.html.
On the limited presence of the interests of developing countries at the time of defining policies and international standards, in different negotiation forums, see Mackenzie, Ruth and Netwell, Peter (2004) "Globalization and the international governance of modern biotechnology: promoting food security?". In *Globalization and Poverty*. April 2004. http://www.gapresearch.org/

This way, the risk assessment of LMOs intended for food or feed would be centered on an analysis of their innocuousness. This means research on any direct effects on health (toxicity); tendencies to cause an allergic reaction (allergenicity); specific components suspected to have nutritional or toxic properties; stability of the gene inserted; nutritional effects associated to genetic modification and any undesired effect caused by genetic modification.

The analysis is based on the characteristics of the inserted gene, of the organism obtained and its application and uses. The risk in the context of innocuousness refers to the danger (biological, chemical or physical agent or property of a food, capable of provoking a harmful effect on health) and the probability that the event/damage may occur.

At present, one of the major problems is the absence of a harmonized regime to undertake risk assessments at an international level. In different international forums answers are being sought to this problem by creating a plurality of directives. Although these norms are *soft law* in nature and non binding, their weight must not be underestimated as a reference during controversies within the WTO. That is the case of the Codex Alimentarious Commission guidelines and standards related to food safety; the International Plant Protection Convention (IIPC) for plant health and the World Organization for Animal Health (OIE) for animal health. These three international standard-setting bodies are been recognized in the World Trade Organization *Agreement on the Application of Sanitary and Phitosanitary Standards* (SPS).

Recently, the *Directives of the Interim Commission of Phytosanitary Measures* of the *International Plant Protection Convention* (IPPC) were adopted. These Directives will contribute to the harmonization of the methods used by countries in their risk assessments to avoid the damage LMOs may cause in the area of plants. In short, this norm will attempt to reduce the risks to plants from releasing LMOs and generating new plants with weed features, capable of damaging crops and vegetable ecosystems.[27]

In relation with the *World Organization for Animal Health* (OIE), its last meeting celebrated in May 2005 proposed the creation of an Ad Hoc Group on Biotechnology and the elaboration of guidelines and standards for: research and use of vaccines for animals produced through biotechnology; animal health risks linked to cloning; exclusion of unapproved animals and products from the livestock population and segregation from the feed and food supply; and animals that have been genetically engineered to produce medicines or chemicals.

[27] International Standards for Phytosanitary Measures. Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms ISPM no. 11. Secretariat of the International Plant Protection Convention. FAO. Rome, April 2004. Annexes 2 and 3 of the document are especially important. http://www.fao.org/newsroom/es/news/2004/43684/

Under the *Codex Alimentarius*, uniform principles have tried to be identified when carrying out risk assessment in the area of food safety.[28] The *Ad Hoc Intergovernmental Group on Foods Derived from Biotechnology* has been conducting different projects on the issue: *Principles for the risk analysis of foods derived from modern technology*; *Guidelines for food safety assessment of foods derived from recombinant-DNA plants*; and *Guidelines for food safety assessment of foods produced using recombinant-DNA microorganisms*.[29]

3.3.2. Socio-economic considerations

The CPB also establishes that risk assessment should consider the specific circumstances of a country whose environment will receive a LMO. It is critically important to consider Annex III, section 6 which provides: "*risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organisms concerned, its intended use and the likely potential receiving environment*".

These aspirations were equally reflected in different parts of the Protocol recognizing "*the crucial importance to humankind of centers of origin and centers of genetic diversity*" (Preamble of the CPB). Furthermore, with regards to the decision-making process for LMOs intended for direct use as food or feed, or for processing, Annex II establishes in the required information that "*g) the centers of origin and centers of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitat where the organisms may persist or proliferate*".

However, once the risk assessment has been undertaken, and during the risk management phase, the regulatory organism can take into account other considerations (different to the mere impacts on human health and the environment) such as socio-economic, cultural, religious, consumer interests or ethical factors, to the effect of approving or refusing a LMO activity. Article 26 of the CPB offers the possibility to base the decision-making process on socio-economic considerations.

Following Aarti Gupta 2001,[30] the objective of including this article in the CPB is existing fears by developing countries of finding themselves in the context of progressive globalization, submitted to pressures and new dependency relationships from technologically, more advanced countries or multinational companies, and in the context of expanding the intellectual property regimes in relation to the market of transgenic seeds and the possible consequences on the communities' lifestyle. In view of this, developing countries demanded during the negotiation process of the CPB, that consideration of socio-economic measures were included in the decision-making and Advanced Informed Agreement procedure.

[28] For Codex and the risk assessment see: http://www.fao.org/docrep/003/x735s/x7354s10.htm#comm3

[29] For the Intergovernmental Group and their reference documents see: http://www.fao.org/es/esn/food/risk_botech_taskforce_es.stm

[30] Gupta, Aarti (2001). "Advanced Informed Agreement: A shared basis for governing trade in Genetically Modified Organisms?". Indiana Journal of Global Legal Studies. 2001.

These aspirations were finally reflected in Article 26 of the CPB:

> *"The Parties, in reaching a decision on import under this Protocol or under its domestic measure implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity especially with regard to the value of biological diversity to indigenous and local communities".*

The attempt is to try and put into evidence that many of the consequences from the import of LMOs to a determined country may not be reflected in the risk assessments, restricted only to human health and environmental aspects. These other areas are related to the need to preserve certain traditional lifestyles and agro-biodiversity practices which are critical for countries, like Peru, with a great cultural and agro-biodiversity richness and of great value to local communities food sovereignty.

Nevertheless, the aspirations of developing countries were confronted by those of the *Organization for Economic Cooperation and Development* (OECD) and *Global Industry Coalition* who believed that the introduction of socio-economic considerations would lead to the establishment of unacceptable barriers for international trade. This block advocated invoking only scientific justifications.

The conciliatory solution chosen by the CPB was that socio-economic considerations be linked to the possible loss of biological diversity and subject to the countries international obligations, which leaves the implementation of the principle under considerable ambiguity.

However, part of the doctrine on biosafety, states that a problem in the area of biosafety that is purely normative is being "technified". What is required are considerations from diverse social groups on the acceptability of risks and assessment of different values such as equity, justice, capacity to choose, which should be added to the language of technical analysis of damage and risks.

This is critical for developing countries where the technical capacity on which to base policy decisions is limited and where socio-economic priorities predominate. In this sense, these reasons should not be extracted from the debate when undertaking a risk evaluation by a country. These reasons would be justified by the need of the country to choose in light of possible social and economic transformations. Therefore, part of the doctrine advocates in favor of not only a scientific risk assessment, but also a social assessment.[31]

[31] Peru is part of the Group of Like-Minded Megadiverse Countries which was constituted in Cancun, on February 18th 2002. At its second meeting on November 29th 2002, the Group issued the Cuzco Declaration on Access to Genetic Resources, Traditional Knowledge and Intellectual Property Rights establishing "the need to promote bioprospecting and biosafety in a manner consistent with sustainable use of biological resources, in accordance with national laws and policies and to prevent biopiracy and illegal access to genetic resources and traditional knowledge".

Probably, the most comprehensive project on this matter has been the *Code of Conduct on Biotechnology as it relates to Genetic Resources for Food and Agriculture* developed by FAO. One of its eight objectives establishes the need to help assess and minimize possible adverse socio-economic impacts biotechnology might have on agriculture and the food industry, in small communities and economies in developing countries (Article 1.6). It also highlights appropriate technologies, including technologies which are: technically viable; generate tangible benefits to users; environmentally safe and are socially, economically and culturally acceptable (Article 3).

Additionally, the Code determines that international governments and organizations must, as part of their technology assessment procedure, monitor the possible socio-economic impacts of biotechnology.

On the other hand, this aspect is closely linked to what is understood by the World Trade Organization at the time of interpreting the Precautionary Principle and, more specifically, to the possibility of allowing "relevant economic factors" to be taken into account in the risk analysis (Article 5.3 of the *Agreement on the Application of Sanitary and Phytosanitary Measures,* SPS). In Chapter IV of this study this issue is covered with more detail.

3.4. Specific implications of the Precautionary Principle

The concept of biosafety in itself derives from the need to control the effects and dangers that may be produced by modern biotechnology and guarantee an adequate level of protection. Similarly, the Precautionary Principle is based on an "a priori" consideration of LMOs as being unsafe products. This has two fundamental legal implications: first, the person who introduces this new technology must show that it is not damaging for the environment and second, the recipient of the technology must be provided with all the information necessary to give his prior consent.

3.4.1. Reversal of the burden of proof

Policy makers and legislators have taken a step further in terms of caution, in the sense that LMOs be considered unsafe until otherwise proved and have transferred the burden of proof from the regulator (who attempts to rule an activity as potentially dangerous) to the party who attempts to continue or perform an activity, claiming its innocuousness or safety.

In this sense, a manifestation of the Precautionary Principle consists in reverting the responsibility at the time of disclosing the relevant scientific information, to the party undertaking the potentially dangerous activity.

The problem that immediately arises is: where is the level of safety to be approved or admitted established? In this situation, absolute absence of risks (what is known as "zero risk") or proving total safety in an activity is deemed to be impossible. Therefore, the level of safety refers to a demand for scientific evidence of damages which are considered serious or irreversible and not so much to the existence of

evidence regarding the safety of the activity. This means the need to carry out scientific assessments rigorously and determining through this the absence of evidence of possible damages.[32]

In this sense, "zero risk" does not exist, but what Kriebel *et al.* (2001) have expressed as "*the absence of evidence of harm is not the same thing as evidence of absence of harm*"[33] has been equally admitted. That is, it is not the same to say that there is no existing proof that damage exists, as to say that there is proof that these damages do not exist. The Precautionary Principle will require proof indicating that these do not exist.

The issue of "absence of damage" is also linked to a different question: what is the admissible level of damage? This means, where is the threshold or the limit to consider the damage socially admissible placed? The answer will depend on the context and priorities of a determined society or country.[34]

Law No. 27104 refers to "negative impacts to human health, the environment and biological diversity"; the CPB refers to adverse effects on conservation and sustainable use of biological diversity; however, Principle 15 of the Declaration of Rio requires that the damage be "serious or irreversible" in nature.

---

[32] Scott, Dayna Nadine (2003) Shifting the Burden of Proof: The Precautionary Principle and its Potential for the "Democratization" of Risk. Doctoral Candidate, Osgoode Hall Law School. Law Commission of Canada, Legal Dimensions Initiative.

[33] D Kriebe *et al.* (2001) "The Precautionary Principle in Environmental Science" 109 Environmental Health Perspectives pp. 873.

[34] Abouchar, Juli The "Precautionary Principle in Canada: the First Decade", 32 Environmental Law Report 11407. The author presents a study on the application of the Precautionary Principle in the Jurisprudence of Canada and establishes that the criteria's adopted to determine what is considered "serious and irreversible damage" are different. Therefore, the *Canadian Environmental Protection Act* -ratified in September 14, 1999 and in force since March 31, 2000- provides in Article 64, that the threshold for "serious" damage is crossed over when a possible immediate impact or long term impact on the environment or biological diversity exists or may exist; when there is a potential damage to the environment on which life depends or possible damage to life or health in Canada. The mere classification of a substance as inherently toxic is equivalent to the presence of possible serious damage. As provided for in this Article, the Jurisprudence in Canada has provided that "serious damage" under which the Precautionary Principle may be invoked occurs when:

a) there are existing threats to drinking water;
b) there is the possibility of drinking water being contaminated from the exposure to cancerigenic substances;
c) there are threats to vulnerable species;
d) there are existing substances that can be toxic or can become toxic;
e) there are activities that may have long term effects on the environment;
f) they involve marine contamination, and
g) there is the use of pesticides in living areas or near bodies of water.

In the context of the CPB and with reference to LMO transboundary movements, the burden of proof concerning the safety of a product lies on the exporter, who is required to undertake a risk assessment. This means that the burden of proof falls upon those who have more information on the innocuousness of their products.

This principle is clearly stated in relation to LMO transboundary movements intended for intentional introduction into the environment.[35] However, the CPB leaves national legislation to develop specific regulations related to LMOs destined for direct use for food or feed, or for processing.

In this sense, regarding the former, Article 15 of the CPB regulates the burden of proof by establishing that "*The party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment*". Furthermore, paragraph three of the same Article establishes that "*The cost of risk assessment shall be borne by the notifier if the Party of import so requires*".

In the case of transboundary movements of LMO intended for food, feed or for processing, where a similar procedure was not provided for, the user, a consumers' association or public authorities could demonstrate the nature of the danger and level or risk posed by a product or process. In this case, the burden of proof will be more flexible and could be transferred at any moment to the producer, manufacturer or importer. In these circumstances, a general principle would not be in place with regards to the burden of proof and it would need to be invoked on a case by case basis. Under the Peruvian legal framework, Law No. 27104 adopts an extreme position (due perhaps to the implicit acknowledge of a lack of capacities in the country) when it prohibits the use of a LMO if it has been subject to observations or refused by the competent authorities in another country, or in the case it has not been tested in another country and, therefore, a potential risk exists from its use. However, this provision is omitted in the Regulation which, in general, provides that the import or production of LMOs or derived products be undertaken once the natural or legal person carrying out LMO activities and the LMO and derived products have both been registered before the Competent Sectorial Organisms.

In relation to the register of LMOs and derived products, the Regulation establishes that it will apply for each LMO and its proposed use (Article 18). It also requires that the application be presented together with documentation that is required by internal regulations of each Competent Sectorial Organism. Once the application has been received, the authority will proceed to carry out the risk assessment, and charge the applicant with the costs.

[35] The CPB divides LMOs into three classes for the purpose of being regulated differently: a) those intended for intentional introduction into the environment; b) those intended for direct use as food or feed, or for processing; c) LMOs in transit or destined for contained use. The CPB establishes stricter requirements for the importer and for the exporter of LMOs to be released into the environment, including seeds, plants and live fish.

The risk assessment shall be undertaken based on an exhaustive assessment of the information provided by the applicant, taking into account as provided in Article 33:

- the characteristics of the LMO to be released: the receiving organism, insert or specific trait to be introduced, the centre of origin or diversity and the transformation protocol;
- the proposed LMO activity: if it is for confined use, intentional release or introduction into the market, including the scale provided and waste management procedures;
- the possible receiving environment of the LMO, its derivatives and products thereof and the interactions with it.

3.4.2. Advanced Informed Agreement

For some authors, prior informed consent of the States encapsules the paradigm of the relationship between the Precautionary Principle and the participation principle as enshrined in Principle 10 of the Declaration of Rio. These find their most visible form in CPB prescriptions related to Advanced Informed Agreement.

At the centre of the issue lies the requirement of exchange of information between the possible exporter and authorities which will allow or reject the entrance of the product into the country. Under this, the exporter would be obliged to provide the importer documentation related to the origin of the product, biotechnological techniques used for its production, uses for which it is destined, risk assessment reports and methods for the safety regarding its management, storage, transport and use.

Such a procedure is addressed by the CPB for LMOs intended for intentional release into the environment, such as seeds, live fish, microorganisms and other organisms and which are destined to grow with possibilities of transmitting their modified genes to future generations.

The Advanced Informed Agreement implies the need for an application permit before the first LMO transboundary movement. It obliges the exporting Party to notify the importing State in writing or guarantee the notification by submitting the documentation to the authority of the importing Party before the transboundary movement. The importing Party has a period to acknowledge receipt of the notification and a period not exceeding 270 days to communicate its decision whether to approve or prohibit the import, request additional information or extend the decision period. This decision will be submitted to the exporter and Biosafety Clearing House. Thus, the only way in which a transboundary movement can take place is with the consent of the importing State.

In principle, excluded from the Advanced Informed Agreement are: LMOs intended

for direct use for food or feed, or for processing, LMOs in transit to third countries, LMOs destined to contained use,[36] some pharmaceutical products destined for humans and those LMOs the Conference of Parties declares are not a risk to the environment or human health. However, the CPB delegates to national legislation the regulation of these situations. This means national regulations can broaden the application of the Advanced Informed Agreement to these specific cases.

Nevertheless, with regards to LMOs intended for direct use for food or feed, or for processing, as in the case of trade of basic agricultural products or *commodities* (for example, bulk shipments of corn or soybeans destined to be used for food and not as seeds to obtain new crops, which figure as the most important category of LMOs in international trade), the CPB establishes two minimum requirements: a) the importing country should inform the existence of the product to the Parties, notifying the Biosafety Clearing House; and b) carry out a risk assessment, as provided for by parameters specified in CPB Annex III, within a period of 270 days.

This means that while in the case of the Advanced Informed Agreement, the CPB places the responsibility of notifying the intention to export LMOs on the export Party; in the second situation, the obligation to develop and communicate the regulatory norms in a proactive way are responsibility of the importing State. The immediate consequence is the need to develop as soon as possible, measures to implement these regulatory systems.

At the national level, Law No. 27104 creates an all embracing regime regarding the application of the Advanced Informed Agreement procedure. The procedure is also required for LMOs intended for food, feed, or for processing, which implies to transfer the mentioned responsibility to the export Party in all the cases.

This is the direct consequence of Law No. 27104 not discriminating in the treatment of LMOs with regard to their destined use, given Article 3 defines the scope of the Law to include "*activities of research, production, introduction, handling, transport, storage, conservation, exchange, commercialization, contained use and liberation of LMOs, under controlled conditions*".

On the other hand, Article 13 of the Law determines in relation to risk assessment, that this will be undertaken as provided for by the Prior Informed Consent procedure, to the effect that the person intending to introduce a LMO into the country, and *"carry out any of the activities mentioned in Article 3 of the Law, should previously present an application to the Competent Sectorial Organism*" (Article 16).

In the same token, the Regulation does not make distinctions. All LMOs and derived products require their previous registration accompanied by all documentation and

[36] "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment". -CPB Article 3(b)-

the corresponding risk assessment. Once the documentation has been revised, the Competent Sectorial Organism will adopt one of the following decisions:

a) *"the register of the LMO, given its minimum risk to human health, the environment and biological diversity in the activity to be carried out with the LMO";*
b) *the register of the LMO, under a risk management system, until it is determined it will not cause negative impacts to human health, the environment and biological diversity;*
c) *not registering the LMO, given its harmful effects on human health, the environment and biological diversity"* (Article 19).

Accordingly, LMOs entering the country without having previously presented a registration certificate to the Competent Sectorial Organism will be rejected and reembarked or confiscated and subsequently destroyed (Article 26 of the Regulation). LMO activities will also not be allowed by legal or natural persons who have not been registered at the Competent Sectorial Organisms (Article 23 of the Regulation).

The CPB establishes that the information provided by the exporter is followed by an obligation by the recipient, to protect the confidentiality of the information. Nevertheless, this demand is conditioned by confidentiality standards determined in national legislations. In other words, the information to be provided by the exporter will be subject to decisions by the governments or national parliaments on access to information by the public.

Finally, Article 11, paragraph 5 should not be overlooked, in which "*A Party may adopt a decision on the import of modified organisms intended for direct use as food or feed, or for processing in accordance to their national regulatory framework compatible with the objective of the actual Protocol*". This could involve the importing State prohibiting the entry of a LMO product, provided it also prohibits its national production.

3.4.3. Export documentation

The CPB demands certain documentation for exports. In the case of LMOs destined for release into the environment, the documentation should clearly indicate that the dispatch involves LMOs. It should specify the identity, features and characteristics of the relevant LMOs, requirements for handling, packing, transport, safe use, a contact point to collect information and the importer's and exporter's names and address. The documentation should also indicate that the dispatch is in accordance with the CPB.

The CPB also establishes the obligation to label LMOs destined for contained use as food or feed, or for processing. This requirement is to be applied after two years of the Protocol entering into force. This way, the dispatch of *commodities* containing or which might contain LMOs for direct use for food or feed, or for processing, should be identified as such in the accompanying documentation. Such requirements, according to the doctrine, would oblige exporters to segregate commodities which are LMOs from those which are not, or label all exports as "may contain" LMOs for direct use for food or feed, or for processing. According to some positions, the effect may be an

increase in competition and a drop in prices.

3.5. What actions can be adopted when applying the Precautionary Principle?

Once the risk assessment has been undertaken and all considerations have been taken into account, the risk management phase begins by adopting measures to eliminate or minimize identified risks to an acceptable level of risk. The risk management phase takes place at the decision-making level and is undertaken by the regulating entity. It will take into account the risk assessment results along with other factors, and determine if the application for the LMO activity should be approved or denied.

At this point, the decision-maker must define whether the risk to be assumed is acceptable by a determined society in relation to other benefits and costs. This is a policy, non technical decision.

Although all regulatory provisions related to the Precautionary Principle are based on assumptions that have been evaluated, all are equally ambiguous at the time of defining the measures or type of specific actions decision-makers should adopt to apply this principle in practice. The reason for this omission may be due to the fact that risk management measures will be adopted differently, on a case by case basis.

3.5.1. Possible actions

For the majority of the doctrine, legal interpretations and experiences in the application of the Precautionary Principle in countries, indicate that the actions to be taken consist of a decision to do, or not to do or undertake intermediate measures such as imposing labelling requirements or enhancing research.[37]

Thus, in the *Communication from the European Commission on the Precautionary Principle* dated February 2nd, 2000, where a common interpretative criteria is determined with relation to the Principle within the European Community,[38] it is proposed that the application of the Precautionary Principle does not necessarily imply the final adoption of instruments designed to produce legal effects which are open to a future legal review. On the contrary, the possibility is open for a wide range of options which may vary from environmental impact studies; the continuation and enhancing of research; the reevaluation of policies adopted in a context of uncertainty or even in

[37] This was the interpretation adopted, for example, by the European Court of Justice in the case of the "mad cow" illness or BSE illness, where the symptoms were known, but not the causes of contamination. It is estimated that the lack of scientific certainty on the cause-effect relation is not enough of a motive to lift the ban on the trade of cattle; the transitory character of the decisions adopted with respect to the European Commission are recognized and an appeal is made to continue research to support future decisions.

[38] Commission of the European Communities. (2000) *Communication from the Commission on the Precautionary Principle*. Brussels. 02.02.2000. COM (2000) 1.

the decision to inform the public of possible adverse effects from a process or product. Nevertheless, what remains clear is that decisions adopted will be exclusively national in nature and restricted to national jurisdictions.[39]

Similarly, some authors have included among the measures to be adopted, the recognition of liability and compensation mechanisms; the creation of capacities in emergency plans; independent monitoring and adoption of minimum limits of safety. Jurisprudence in Canada[40] equally recognizes that the Precautionary Principle may result in forbidding the activity or a series of actions which include that the proponent of the activity: adopts additional measures to protect the environment; carries out an assessment of available alternatives; demonstrates reliably the absence of possible threats; establishes mechanisms to monitor the activity or undertakes an assessment of the cumulative effects.

Decision-makers should also consider, together with the results of scientific evaluations, what the possible costs from inaction or adoption of a determined measure may signify in the future. Principle 15 of the Declaration of Rio seems to refer to this criteria, when it determines that the costs-benefits of the measures to be adopted must be taken into account.

Given the coexistence of the Principle with others of relevance, such as the capacity of developing countries, intergenerational equity and intragenerational equity, the doctrine determines that the cost-benefit analysis should be undertaken in the context of such principles, taking them into account and pondering possible long term effects. In this case, the cost of severe and irreversible damage which may materialize in the future as a consequence of a determined activity or a lack of action should be also added to the actual cost of a determined activity.

On the other hand, cost-benefit analysis also reflects consideration of possible benefits from carrying out an activity and potential risks from omitting or preventing the activity. Therefore, what is required is a search for the balance between benefits and costs of a specific activity at the time of justifying its acceptance or refusal.

In this regard, some authors have criticized that the application of the Precautionary Principle, in the context of the CPB, starts on the basis of negative assumptions associated to risks derived from modern biotechnology. This approach omits a

[39] This has been proposed by the doctrine as a difficulty in the application of the Precautionary Principle when facing problems of global nature, such as global warming or transboundary contamination. Boutillon, Sonia (2002) "The Precautionary Principle: Development of an International Standard". *Michigan Journal of International Law*. Winter 2002. University of Michigan Law School.

[40] Abouchar, Juli Teh "Precautionary Principle in Canada: The First Decade". *Environmental Law Report* 32.

balance by not considering the possible benefits that the application of genetic engineering may produce. These authors propose that the admission of LMOs should be based on due consideration of risks and potential benefits.[41]

The CPB does not mention the actions that would be triggered by the implementation of the Precautionary Principle. Articles 10 and 11 of the CPB do not provide concrete criteria for the action, nor describe a specific action which would be the result of its application. They simply limit their content to establishing that the Party may "*adopt a decision, as appropriate"*.

Nevertheless, the result of applying the Precautionary Principle in the context of the CPB will be reflected in the decision of the importing country to accept or refuse the import of LMOs, once the information from the exporters has been evaluated. In this sense, the importing country may refuse the import of genetically modified foods on the basis of the Precautionary Principle. In the context of food safety, such measures could result in the establishment of traceability measures, labeling and monitoring, vigilance systems and a liability regime.

3.5.2. Ruling principles

When identifying the criteria which are to rule the previous actions, Law No. 27104 provides that "*the measure be technically justifiable*", which seems to imply that a decision be founded on a solid scientific basis or "sound science" and that "*it does not constitute a technical obstacle or restriction to trade*" (Article 10). This interpretation seeks to alleviate concerns about the application of the Principle resulting in a barrier to free trade and with this, save *ab initio* any existing concerns. This also reflects neoliberal economic measures installed in all the fields of economic activity in the country during the decade of the 90s.

On this particular issue, the general principles included in the *Communication from the Commission of the European Union* are of special interest. It is widely considered that these should guide the actions of European states when applying the Precautionary Principle. In the first place, it determines that all decisions should take into account the different concurrent interests in the decision-making process as early as possible. Therefore, all Parties should be involved, if possible, in the assessment of different existing alternatives for *risk management*, once the results of the risk analysis and scientific assessment have been produced, and that the process be as transparent as possible. Participation will generate legitimacy to the measures adopted and allow for consideration of any social concerns regarding the levels of environmental and human health protection desired.

During the decision-making process, the principles of proportionality, non-discrimination, consistency, examination of the benefits and costs of the action or

[41] Katz, Dleborah (2001). "The Mismatch between the Biosafety Protocol and the Precautionary Principle". *Georgetown International Environmental Law Review*. Summer, 2001. Georgetown University.

lack of action and examination of scientific advances should be taken into account. Thus, this reflects that measures proposed should be proportional to the adequate level of protection required, without becoming disproportional or attempting zero risk situations. In this sense, situations may arise where a total prohibition might not be a proportionate answer with regard to a potential risk; but there may be other situations where this may be the only possible option.

At the same time, comparable situations should not be treated differently and different situations should not be treated in the same way. In addition, geographical discrimination does not fit into the application of measures, which could lead to arbitrary decisions. Measures should be consistent with others adopted in similar, previous circumstances.

Furthermore, an examination should be undertaken on the cost-benefit of the measures adopted or of impacts in the long and short term. This examination of the pros and cons of the action or inaction should not be reduced to the economic analysis of the cost-benefits, but include consideration of other non-economic aspects such as effectiveness of the available alternatives or socio-economic variables, including priorities and social acceptability of a proposed measure. In this regard, a determined society might be prepared to pay a higher cost for the protection of certain interests such as the environment or health.

Finally, the decision could be adopted temporarily, and be the subject of reevaluation in the light of scientific advances taking place. Such measures could be agreed provisionally while the relevant data or scientific information remains incomplete, imprecise or inconclusive or while the acceptance of a determined risk is considered dangerous for society.

Article 12 of the CPB relates to the provisional measures adopted in the application of the Precautionary Principle. To these effects, Article 12 provides that the importing Party may at any moment and on the basis of new scientific information, revise and modify the decision of an intended transboundary movement. Equally, the exporter may request the importer a revision of the decision adopted if he considers there has been a change in the circumstances which might influence in the result of the risk assessment on which the decision was based or if new scientific information becomes available.

IV. THE PRECAUTIONARY PRINCIPLE IN THE CONTEXT OF THE WORLD TRADE ORGANIZATION

Peru is as much a part of the CBD as of the World Trade Organization (WTO). Given this situation, the application of certain provisions of the CBD, particularly the CPB that further develops them, could lead according to some opinions, to accusations before the Appellate Body of the WTO, for creating barriers to trade. This issue has been the subject of a series of studies which highlight a "major weight" or greater enforcement possibilities of Treaties signed under the WTO, given their compliance is guaranteed through the appellate bodies and dispute settlements of the organization. The need to coordinate the application of socio-economic considerations of Article 26 of the CPB with "international obligations" refers to this context.

International trade relations are based on a series of common principles recognized by the international community which provide a framework when applying criteria on risk management. The first of these principles is that measures adopted be necessary and proportional to the risks identified. Together with this call for necessity and proportionality, they should be technically or scientifically justified.

These principles are also linked to other principles, mainly on international trade. One of these is non-discrimination, which implies that identical situations not be treated differently. This way, LMOs from a foreign country must not be treated differently from nationally produced LMOs.

The FAO *International Convention for the Protection of Plants* incorporates all principles related to the application of risk management criteria for the control of pests and the illness of plants. The Convention, of which Peru is a member since July 1st 1975, provides that phytosanitary measures to be adopted meet a series of minimum requirements: they must not be discriminatory; must be "needed" according to phytosanitary criteria; must be "proportionate"; "technically justifiable"; consistent with the risk of pests; represent "the least restrictive available measures" to trade and imply a minimum restriction to the displacement of people, basic products and means of transport.[42]

These principles run parallel to those specified in the WTO *Agreement on the Application of Sanitary and Phytosanitary Measures*[43] (SPS) that urges the FAO Convention to set international requirements so measures can be harmonized and not used as unjustified barriers to trade. As mentioned in Paragraph 3.3.1, in April 2004, through the *FAO Guidelines of the Interim Commission of Phytosanitary Measures*, standards have sought to be established to harmonize the methods used by countries in their risk

---

42 International Convention for the Protection of Plants. New text revised and approved by FAO Conference in Session No. 29, November 1977. Articles VI and VII. See: http://www.ippe.int/IPP/Es/pdfs/spippc.pdf. Ratified by Peru under Decreto Supremo No. 063-99-RE; published in the Official Gazette El Peruano.

43 See: http://www.wto.org/english/docs_s/docs_s.htm.

analysis and, therefore, to avoid damage LMOs may cause to vegetables and plant health, in a way that these do not generate a barrier to trade.

Under the WTO, and within the *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS), the legitimate right of governments to adopt sanitary and physosanitary measures needed for the protection of plants, animals and human health, including the resulting risks of LMOs is recognized. In the exercise of these rights, the SPS provides that all sanitary and phytosanitary measures established nationally in relation to the safety of plants, animals and human health, be scientifically justified and based on international standards, with the objective of avoiding unacceptable restrictions to trade.

Article 5.7 of the SPS Agreement regulates the Precautionary Principle (which should be interpreted in accordance to Article 2.2 of the same Agreement) and determines that member countries who adopt sanitary and phytosanitary measures (that implicate restrictions to exports from third countries), make sure these are based on scientific knowledge, will not be maintained absence sufficient scientific proof.
Article 5.7 provides:

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

An interesting interpretation of this principle was made recently by the Appellate Body of the WTO in the "*Apple case*"[44], in a dispute between the United States and Japan on certain quarantine restrictions imposed by Japan, based on the application of the Precautionary Principle and due considerations of vegetable sanitation.[45]

The WTO Appellate Body ruled against Japan arguing that the measure adopted by this country was imposed without enough scientific evidence and was not based on a risk assessment analysis. The Appellate Body also determined that for the Precautionary Principle to be applied, four essential conditions must concur. The absence of one would mean countries cannot adopt precautionary measures as provided by the SPS Article 5.7. The four conditions referred to are the following:

a) measures shall be adopted in relation to a situation where the relevant scientific knowledge is insufficient;

[44] Japan-Measures Affecting the Importation of Apples, WT/DS245/AB/R

[45] McGivern, Brendan (2004) "No Change of Heart on the Precautionary Principle: The WTO Apple Dispute". *Bridges.* ICTSD. Year 8. No. 2. February 2004.

b) measures shall be adopted on the basis of available scientific information;
c) the member country adopting the measure is obliged to investigate or seek to obtain additional information needed for a more objective risk analysis;
d) the member country must revise the sanitary and phytosanitary measures in a reasonable period of time.

With relation to the understanding of "a reasonable period of time", the Appellate Body determines that this will be defined on a case by case basis, and depend on specific circumstances, including the difficulty to obtain additional information needed for the revision, and the characteristics of sanitary and phytosanitary measures adopted.

In the case of the above mentioned dispute, the Appellate Body judged that Japan used precautionary criteria improperly, not applying it to circumstances of scientific uncertainty as alleged by Japan, but to insufficient scientific evidence, and that it was Japan´s obligation to present such scientific evidence. It was expressed that the application of Article 5.7 was based "*not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence*".

Therefore, the Appellate Body considered that sanitary and phytosanitary measures should be based on a risk assessment appropriate for the circumstance and should be specifically focalized on the alleged risk. In this case, Japan carried out a generic risk assessment and not a specific evaluation targeted at the introduction of pests in apples. It was determined that the risk assessment not be carried out to justify *ex post facto* decisions, or to serve as a basis for preconceived visions and policy decisions already adopted.

The repercussion in relation to the compatibility of applying the Precautionary Principle in the different and coinciding scopes of the CPB and SPS are considerable. First, Article 5.7 of the SPS does not require the existence of serious or irreversible damage, which is coherent with the Treaty's' spirit by virtue of which each State may discretionally determine the appropriate level of protection, provided it is objectively justified. This was expressed by the Appellate Body in the *Beef Hormones Case,*[46] this is, the right of each member country to choose higher levels of protection than those established by international standards if required and that the Treaty does not impose an acceptable specific level of risk.

Nevertheless, other than *sound science,* no other reasons are recognized when applying precaution criteria or sanitary and physosanitary measures which restrict trade.

Secondly, it is also asserted that States lack discretion when evaluating and selecting scientific evidence. They would not be in a position to allege judgements based on cost-benefit analysis. Thirdly, "the benefit of the doubt" would not apply but rather

[46] Report of the Appellate Body, European Communities-Measures concerning meat and meat products, WT/DS26/AB/R and WT/DS48/AB/R (Jan 16, 1998). See: http://www.wto.org

"*the objective assessment of the evidence*. Fourth, risk assessment should take place prior to the adoption of any precautionary sanitary and physonatary measures, or any policy decisions by a country, and not to justify a decision already adopted. Fifth, burden of proof should not be placed on the export country but on the country that alleges measures to be imposed to prevent damages.

Finally, the SPS Agreement only takes into account socio-economic considerations in a limited range of "relevant economic factors" to be considered in the risk analysis. This includes: "*the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks"* (SPS Article 5.3).

Therefore, the focus is socio-economic considerations related to loss that may potentially originate from sanitary or physosanitary related damages. Issues related to environmental damage or referred to human health are not considered at any moment, including those referred to social acceptability and public opinion based on cultural or ethnical values. It is at this point where most of the conflicts may arise when interpreting this principle at the WTO forums and where collisions may occur between different regulatory systems.

On safety and food sanitation matters, the SPS remits to relevant standards, recommendations and directives adopted at the international level. The measures and criteria used by countries will be evaluated based on scientific evidence and countries will be informed when they involve unjustified trade restrictions.

When comparing the CPB and SPS on the application of the Precautionary Principle, there are quite a few differences that lead to conclude that the CPB complements the regulations contained in SPS:

- the SPS does not define precisely what risk assessment implies, while the CPB provides details in Annex II;
- the SPS does not refer to risk management, only to risk assessment. The CPB establishes that both practices are necessary and, that while the second refers to obtaining data, the former refers to the construction of a regulatory regime based on the data (Articles 15 and 16);
- the CPB allows Parties to take socio-economic considerations into account during decision-making, while the SPS keeps silent on the matter;
  the CPB is specific with relation to the process of review of a decisions in light of the appearance of new evidence (Article 12). The SPS is ambiguous at the time of determining what measures to adopt in situation of uncertainty;
- and the CPB places the burden of proof on the export Party, while the SPS does not specify anything on the matter.[47]

[47] Burgiel, Stas and Cosbey, Aaron (2001) "The Cartagena Protocol on Biosafety: An Analysis of Results", *IISD Briefing Note*. HSD 2000. Alberta, Canada. See: http://www.iisd.ca

The problem is, to what extent is the Precautionary Principle as interpreted by the SPS, applicable to developing countries, mainly Peru? Such a principle emphasizes undertaking risk assessments based on scientific evidence. However, one should ask whether all WTO members have the same technological capacity and the capacity for scientific evaluation. As mentioned in the next section, Peru confronts a considerable challenge to guarantee capacity to carry out the relevant risk assessments. Without access to technology and with limited scientific capacity, it is difficult for Peru to exercise the privileges the SPS offers.

In view of this, one would have to keep in mind principles such as "common but differentiated responsibilities" recognized by international environmental law - Principle 7 of the 1992 *Rio Declaration on Environment and Development*-.This principle, within the WTO, would be translated into the principle of "special and differentiated treatment", but has not yet been effectively implemented.

The question which remains to be answered is: what happens if a country with minimum scientific evidence decides to prohibit the import of a LMO product, claiming it has the authority to do so under the provisions of Article 11 of the CPB, which relates to the Precautionary Principle?.

V. APPLICATION OF THE PRECAUTIONARY PRINCIPLE IN PERU: WHAT ARE THE NATIONAL CAPACITIES TO ASSESS, MANAGE AND CONTROL RISKS?

The entry into force of the CPB will affect the trade of transgenic products and place responsibilities affecting not only export countries but also importers, who must implement regulatory systems, create capacities on biosafety and risk assessment, identify experts to counsel public authorities on scientific-technical aspects, and at the same time, create a platform for participation and public information. Compliance of international obligations by Peru in the area will depend to a great extent on the development of these aspects.

At the moment, Peru lacks the capacities to carry out risk assessments. The units responsible for the implementation of the biosafety framework have not been designated. This means it is not possible to process any applications to evaluate or commercialize LMOs in the country. There is no assigned budget and few possibilities of including budgetary previsions in the near future. Furthermore, these units also lack sufficient technical personnel to carry out risk assessments.

These limitations increase in the face of public officials being continuously reassigned to other posts, making it difficult to create "expertise" on the matter. The technical and regulatory authorities which will be assigned competences at the national level do not follow-up on discussions at the international level; on the contrary, they are displaced by people who are not familiar with agreed commitments.

Due to these deficiencies, the Regulation leaves the possibility open for risk assessments to be carried out by laboratories or companies accredited by the designed Technical Sectorial Groups (TSG) in agriculture, fisheries or health.[48] Nevertheless, this does not exempt public authorities from the obligation to revise and undertake an effective control of the risk assessments carried out by such companies.

In this circumstance, a procedure is in place where the applicants for the authorization of field trials or releases for commercialization, present the regulatory authority with their data and trials, which must examine these and verify their consistence and scientific basis, and on the basis of its own analysis, approve or refuse them. The information would be provided by companies and the authorities should have the capacity and adequate public laboratories to contrast the information. However, it could be possible that the authorities are not in the condition to do so, or that state laboratories are non existent. With this, legal compliance is left to the good will of interested companies.

[48] The Technical Sectorial Groups are formed by different authorities, academics from universities and other invited experts to support and advice the Competent Sectorial Organisms in charge of authorizing the register of LMOs activities. See Paragraph 2.2 of the present document.

Identical limitations are observed in relation to the capacity of the Competent Sectorial Organisms to control LMO transboundary movements. At present, there is no control at the entry point, by health and fisheries sectorial organisms. In the first case, when a transformed product enters the country, the sanitary control carried out by the National Direction of Environmental Health (DIGESA) is merely documentary[49] The product enters the country once all the documentation is approved, -which includes a trial by an accredited laboratory-. *In situ* controls extracting samples to be analysed in laboratories are never carried out. The same happens to hydrobiological resources for aquaculture, which only enter the country when they have a formal concession contract for aquaculture exploitation without any other requirement or form of control. In this case the control is made by delegation, through the customs authority.

In the case of seeds, live animals or propagative material in the field of agriculture and livestock, feed and products of first transformation, the National Service for Agrarian Sanitation (SENASA) undertakes, under limited conditions and scarce human resources, a phytosanitary and zoosanitary control at the different entry points of the country. These are 28 control points in coordination with the customs offices.[50] The Ministry of Agriculture responsible for controlling their innocuousness is hardly fulfilling its role. Its limitations are also obvious when carrying out risk management, that is, the follow-up and inspection of activities.

If such is the situation, it is difficult to conceive that authorities will have the capacity to analyze and control whether LMOs[51] are entering the country in the short and long term. A major concern refers to the lack of capacities in relation to hydrobiological resources related LMOs, given their potential risk to the environment.
To date no labelling requirements have been developed in relation to importing LMO in the country. This means that there is a possibility of LMO products being introduced in the country without any notice.

At the moment, the capacity to guarantee a segregation and traceability system which responds to documentation and labelling obligations for the export of LMOs does not exist. This may be of concern in the light of the impossibility to comply with new European Union norms on traceability and labelling.

The capacity for risk management also needs a special comment. The CPB establishes that each country should administrate and control the risks which may be identified

[49] Control is undertaken in accordance with Decreto Supremo No. 007-98-SA, by which the *Reglamento sobre vigilancia y control sanitario de alimentos y bebidas* (Regulation on vigilance and sanitary control of food and beverages) is approved; published in the Official Gazette El Peruano, November 25th, 1998.

[50] Applications for the import of LMOs presented to SENASA after October 28th, 2002, are in suspense.

[51] It is believed that at present LMOs such as corn, soy, tomatoes and vegetable seeds, among others, are entering the country without control. Fernandez-Northcote (2004) *Progresos realizados en el MNB-PERU. Proyecto CON/AM/UNEP-GEF* (GFL/2716-02-4577).

through a risk assessment. The basic elements for an efficient risk management should include vigilance systems, research programs, technical training and improved internal coordination among the organisms and governmental services.

The Regulation provides that the applicant propose measures to be adopted in risk management and these should be evaluated and approved by the Competent Sectorial Organisms (Article 43). It also establishes periodic revisions of the proposed developing activity and areas or installations where these activities are to take place. It also demands compliance with the Internal Norms for Biotechnology Safety, according to the activity being undertaken, using international standards as a reference.

Lastly, the Competent Sectorial Organism has the capacity to order emergency plans and declare the country or affected area in a state of biological emergency.

With relation to the monitoring or risk management phase, the Peruvian normative only recognizes the Competent Sectorial Organisms competences and does not establish liability for the applicant of the LMO activity. In this sense, the obligation for the applicant to exercise all actions which would lead to minimizing the risks (informing authorities on the development of the activity, periodic reports and communicating authorities on any pernicious event or accident) is omitted.

In relation to national capacities in risk management and monitoring, Competent Sectorial Organisms do not have a decentralized representation in many parts of the country; this implies that many of its monitoring functions would be realized with difficulty. However, monitoring acquires great significance when considering the introduction of GMOs in areas defined as hotspots of biodiversity or zones regarded as centres of crop diversity.

VI. FROM A CONSUMERS PERSPECTIVE

6.1 Previous considerations

The Food and Ethics Council[52] prepared a matrix to work on key issues in order to understand how different actors of the food chain adopt their decisions in relation to modern biotechnology. The aim is to enumerate three basic principles which may inform decision-making: the principle of wellbeing (health, prosperity), the principle of autonomy -freedom to vote- and principle of justice (equity). This shows that each of the actors of the food chain adopts decisions applying these principles but for completely different reasons and interests.

For actors involved in the food industry, the principle of wellbeing would assist the need to obtain benefits, as well as satisfactory working conditions; autonomy would be reflected in the liberty to manoeuvre or to act appropriately and justice would be reflected by the existence of equitable laws and practices. For the consumer or common citizen, wellbeing would be reflected in security or food sanitation and quality of life; autonomy would be reflected in the democratic capacity to vote and justice or equity in the availability of food in an economically accessible way.

The development of the next chapter takes into consideration these different perspectives and their impact on public policies.

6.1.1. Change of tendencies in the food chain

Decision-makers are used to focusing the food issue in developing countries from the point of view of food security and the problems of undernourishment. These concerns are still valid but at the same time, and parallely, are beginning to coexist with other types of factors, due to growth of urban centers, the migration of rural communities to larger cities, which Peru is quite aware of.[53] For example, this circumstance has led developing countries to witness nutritional changes in their populations and to the coexistence of malnutrition problems and others which are more typical of the developed countries, such as obesity.[54]

Countries' changes in food policy tendencies, including developing countries, are reflected in the following box and are therefore necessary in order to understand the new role of the consumers.

---

52 Food and Ethics Council (2003) *Engineering Nutrition GM crops for Global Justice?* P. 6 See: http://www.foodethicscouncil.org

53 At present, Peru is going through an accelerated urbanizing process which determines that the majority of the population lives in urban areas -approximately 72%-. By 2015, the total should have reached 82%. *Estrategia Nacional de Seguridad Alimentaria 2004 -2015*, Annexe B. The strategy mentioned has been approved by Supreme Decree No. 066.2004-PCM; published in the Official Gazette El Peruano on September 8th, 2004.

54 In Peru, 35% of women at the fertile age have overweight problems and 9% obesity problems

	Old Food Policy	New Food Policy
Population	Principalmente rural	Principalmente urbana
Trabajo Rural	Mainly rural	Mainly urban
Rural Work	Mainly in agriculture	Mainly in fields other than agriculture
Actors in the food market	Seed traders	Food companies
Chain distributors	Small range	Long range and distribution
Preparation of customary food	Cooked at home	Prepared out of home, precooked foods
Common products	Basic foods and grains without specific names	Processed food; brand foods; more animal products in the diet
Packing	Low	High
Sale of food products	Markets, small food shops	Supermarkets
Matters on food sanitation	Intoxication due to pesticides on field workers; Toxins associated to deficient storage	Pesticide residues in food; Adulteration; Biosanitation in processed foods (salmonella, listeriosis)
Nutritional problems	Undernourishement	Chronic diet illnesses (obesity, heart diseases, diabetes)
Nutritional issues	Calories, micro nutrients	Fats, sugar, salt
Food insecurity	Peasants	Poor in the urban and rural areas
Vulnerability elements in food at the national level	Atmospheric changes and other problems related to production	Income problems that cause poverty and undernousrishment
Vulnerability elements in food at the level of homes	Intoxication due to pesticides on field workers; Toxins associated to deficient storage	Pesticide residues in food; Adulteration; Biosanitation in processed foods (salmonella, listeriosis)
Forums on food policies	Ministers of Agriculture, Social Assistance and Health	Ministers of Trade and Industry, of Finance; consumers; food activist groups and NGOs
Matters on food policy	Agricultural technology, parastatel reforms, supplementary foods	Competitiveness and search of profits from the value chain; industrial structure in the distribution sector; future markets; waste management; marketing; health education; and food sanitation
International institutions	FAO, WFP, UNICEF, WTO,	FAO, UNIDO, WHO, WTO[55]

These changes in the food system generate pressures during different phases of the food chain as those exercised on small farmers and subsistence peasants, on consumers and social food culture. They also evolve towards the concentration of power along the food chain in the hands of bigger companies, multinational companies and supermarket chains during production, manufacturing, distribution and marketing.

Changes in the food system therefore mean that new actors have entered to play a primary role. This hardly means that the power of decision is concentrated in farmers. In fact, at present they have the least capacity for making or influencing decisions in the food system, but rather refer to the protagonism of other actors within the system. These include food research centres, food processors, manufacturers, distributors, governments agencies and intermediaries. In this sense, the food chain cannot be conceived lineally (production-consumption) but rather, as the result of an interaction of multiple economic and political actors.

This is clearly reflected at the level of public authorities, where food has passed from being a problem of the Ministries of Agriculture and Health, to being a subject of trade, economics and environment, included in the agendas of international trade negotiations.

From a consumer's perspective, this translates into an increasing disconnection with the origin of food production, which may lead to a further imbalance in the information required at the time of making a food and consumption related decision. Given there are so many actors in the system, the information which gets to the consumer is the result of multiple interventions. This disconnection increases in the light of new technologies such as biotechnology, which leads to the concentration of more information and power in certain actors to the detriment of others.

In parallel, consumers concerns on the food they consume respond to a series of complex changes in the daily life of individuals. The concerns over nutritional value, price, toxicity, appearance, preparation needs, effects on the environment, etc. become evident when discussing peoples' food preferences. At the same time, although food is a nutritional factor closely related to the needs of individuals in an isolated manner (therefore all analysis from this point of view develops within consumers' concerns as an isolated subject) consumers also have a social role and are immersed in a context of social and cultural relations.

[55] Source: Maxwell, S. and Slater, R. (2003) "Food Policy Old and New" in *Odi Briefing Paper,* November 2003, www.odi.org.uk
FAO: Food and Agriculture Organization of the United Nations; WFP: United Nations World Food Programme; UNICEF: United Nations Children Funds; WHO: World Health Organization; CGIAR: Consultive Group on International Agricultural Research; UNIDO: United Nationals Industrial Development Organization; WTO: World Trade Organization.

Thus, consumers also decide bearing into account collective factors: social, cultural or environmental. A collective sentiment tied to the existence or not of a gastronomic culture may exist. In this sense, food is culturally defined. For example, a medium diet of a country's community may be primarily based on a series of products derived from ancestral practices. This is the case of potatoes, corn and chillies in a country like Peru. These crops have more importance and meaning than their merely nutritional value. However, nutritional options are also a part of social relations.

In this sense, consumers' preferences move around a wide range of interests, from economical, social, ethical, ecological, and cultural, to scientific. This contrasts with the interests of experts and other actors of the food chain who focus either on scientific considerations or are more closely linked to commercial or industrial interests.

In the context of modern biotechnology, the questions posed by society are very different to those set forth by science. They both focus on risks but in a different manner: while science responds to risk assessment mechanisms, society has broader concerns. Part of modern biotechnology's fate and potential will depend on the public's acceptance. To achieve this, it is imperative to attend to their concerns and make them an active participant in decisions that directly affect them.

6.1.2. What is transgenic food?

The biggest development in genetic engineering on food has been produced in the creation of foods of plant origin. The modification of plants and basic agricultural products or *commodities* has been centred on improving characteristics related to the production process, (insect resistance, herbicide tolerance or illness resistance) altering their properties for the processing phases, transport, shelf life (for example, delay during the growing process); altering their nutritional value (for example, rice with a greater content of Vitamin A) or facilitating their industrial process. These modified plants may be used directly as food, (for example, delayed tomato ripening) or may be elaborated as raw material to produce food for human consumption (for example, soy oil) or feed.[56]

[56] Transgenic crops are very concentrated geographically in terms of type of crops and characteristics. According to data of the year 2004, transgenic soy bean would be represented by 60% of the cultivated transgenic area worldwide; following would be corn, with 23%, cotton with 11% of the world total and colza with 6%. Nearly all transgenic crops have been manipulated to replace widely used chemical substances (*Bacillus thuringiensis*) and herbicides (glyphosate or gluphosinate). Nearly 72% have been manipulated to resist herbicides such as glyphosate or gluphosinate; 19% of the world transgenic crops are Bt (*Bacillus thuringiensis*) varieties -mainly corn- and the rest have been manipulated to produce a toxin against insects and to have both Bt and glyphosate characteristics. United States (59%), Argentina (20%), Canada (6%), Brasil (6%), China (5%), and Paraguay (2%) represent 98% of the surface planted with transgenics in 2004. Data obtained from James, C. (2004) "Preview: Global Status of Commercialized Biotech/GM crops:2004". *ISAAA Briefs* No. 32 ISAAA Ithaca, NY http://www.isaaa.org

Likewise, some foods are manufactured using chemical substances, for example, enzymes which produce genetically modified microorganisms. This process has been used mainly to produce chesses, beer, and transgenic yeast for bread-making. Although these products are obtained through "biotechnological methods", for some authors these are not exactly biotechnological foods. Advances in the fields of food production from animal origin are less frequent. An example would be modifications on fish like transgenic salmon, in order to alter some features such as size. Another would refer to the bovine growth hormone injected into milk producing cattle to increase their production capacity.

Lately, genetic engineering in plants and animals is taking place for purposes other than food, like the production of useful biological substances to create medicines.[56]

6.1.3. Transgenics in the food chain: what is the problem?

Two study areas are addressed when trying to summarize the concern of scientists with regards to biotechnology: the environment and health. From the perspective of possible damages to the environment, scientists centre their attention on the study of various risk factors: that transgenic plants, as a consequence of the introduction of foreign transgens, acquire the properties of weeds, modifying their ecological habits and invading agroecosystems; possibility of genetic flow or genetic contamination of native plants (landraces), non-modified domesticated plants or wild relatives; undesired effects on beneficial organisms, altering the dynamics of populations, the environment and ecosystems where they are introduced; development of resistances to traits introduced; development of resistance of herbicides to weeds; homogenization and simplification of the farming systems and genetic erosion, among others.

In relation to human health, scientists concerns are focused on analyzing possible problems which may originate with regards to the innocuousness, toxicity and allergenecity of LMOs used for food or food ingredients. In concrete: the possibility of the inserted transgene having in itself an adverse effect; that the inserted transgene codify toxic proteins for humans; implications in the alteration of resistance patterns to antibiotics of the intestinal flora or human respiratory tract as a consequence of gene markers resistant to antibiotics, with the subsequent development of resistance to orally administered antibiotics; implications in the increase of toxins, antinutrients and allergenic proteins; transgenes inserted codify proteins that may cause an allergic reaction in some consumers, among other potential risks.[58]

Monsanto covers 80% of the market of transgenic plants, followed by Aventis with 7%, Syngenta (before Novartis) with 5%, BASF with 5% and DuPont with 3%. These companies also produce 60% of all pesticides and 23% of commercial seeds. Data extracted from http://www.nodo50.org/worldwatch

[57] The information is based on a document prepared by Rosina Bonomi with the help of Juan Izquierdo for the distance training course of FAO "Understanding Biotechnology in Food and Agriculture" (2002).

[58] Ibid.

From a consumer's perspective, other elements can be added to the debate, including the prevailing idea that the consumer does not receive any benefits from biotechnological products now on the market, yet assumes the risks. There are only a few cases in which modern biotechnology has served to improve foods in order to meet consumer's needs.

At present, LMO traits identified aiming towards consumer's interests/preferences have been identified, among others, in the following cases: increase of antioxidants in tomatoes and broccoli; enhancing the flavour in peppers, increasing vitamin A in rice and canola; increasing the proteins in potatoes, sweet potatoes and rice and reducing the allergen substances in soy beans and wheat. Only in the first case, the increase of antioxidants in tomatoes is at the commercialization stage. The other cases are subject to field and laboratory trials.[59] On the other hand, these products have not been on the market long enough in order to carry out long term assessments of impacts.

As a consequence, criticism that has risen from consumer's organizations point towards questioning biotechnological advances, in terms of whether they are directed towards creating benefits and covering farmers needs or, more restrictively, only assisting the priorities of certain industries or biotechnological companies, without considering consumers' interests or priorities. The objective of new technologies has been to create needs more than satisfying the existing ones and, once again, there has been no effort to guarantee the innocuousness of food. In the light of this, consumers have the right to be informed and choose whether they want to take certain risks.[60]

6.1.4. In a context of food insecurity[61]

The questions that derive from the dissemination of LMO products through distribution chains tend to become mixed with the questions related to the possible use of modern biotechnology to ensure food security.

Although this issue deserves in itself a separate study, it is convenient to make a reference in this document due to its quantitative value (affected population) and qualitative (nutritional quality) relevance to food security issues in Peru.

[59] Food Ethics Council (2003) *Engineering Nutrition, GM Crops for Global Justice*? Pp.9. See http://www.foodethicscouncil.org

[60] Shallat, Lezak (2000) *Los alimentos transgenicos en boca de todos?* Consumers International. Regional Office for Latin America and the Caribbean, See: www.consumidoresint.cl

[61] In accordance to Article 1 of Decreto Supremo No. 118-2002-PCM by which the C*omisión Multisectorial de Seguridad Alimentaria* (Multisectorial Food Security Commission) is created, food security is understood as *"the material and economical access by all people at all times to enough, adequate, innocuous and nutritional food, in order to satisfy their nutritional needs and lead a healthy life, without running the risks of loosing access. This definition implies the concepts of availability, access, use and stability in the supply of food"*. At the same time, the vulnerability or risk of food insecurity is defined as *"group of factors which determines the inclination to suffer from food insecurity when food production is interrupted by the failure of provision systems"*.

Regardless of the previous observations with relation to the dynamic changes existing in food systems, it must not be overlooked that in Peru, the majority of rural populations practice a subsistence type of agriculture thereby consuming what they produce. This reflects a context of farmers being unaffected by market requirements, directing their produce towards their own consumption.

Many farmers live on local food crops that are not widely commercialized, except for exchange or small scale commercialization in local markets and generating products that hardly ever reach national markets. The crop varieties used are local; frequently with no distinction between crops or seeds aimed to production or consumption; with management practices based on saving seeds from one year to another and exchanging them among farmer communities and in seed fairs. Often, crops are not commercially homogeneous and variable. Rather, they manage diversity and crop variability in order to confront environmental, climate and market risks so to guarantee provisions of food and ensure a minimum production during difficult conditions.

In this context, for many farmers, access to land, water, seeds and tools is the basis for food security. The total dependency on markets for their income or food is too much of a risk and hardly considered. When talking about technical opportunities, these should be evaluated in a wide socio-cultural context to determine if they offer possibilities for the poor.

In Peru, subsistence farming is small scale. Its significance in the agrarian structure of the country is not contemptible when considering that agricultural units are 3.1 hectares in extension on average. Farmers have low possibilities of creating associations among themselves. They have low technological advances. They also have limited education opportunities, limited management skills and poor access to commercial and agricultural information.[62]

Likewise, a subsistence farmer is by definition, a minimizer of risks: his disadvantage in certain factors such as lacking capital and information, the impossibility to acquire technology and seeds, insecurity in the possession of land, impossibility to use agro-chemicals and extreme climate conditions, leads him naturally to seek food security through specific agricultural practices. Such practices inherited through generations, promote the development of a great variety of crops adapted to different microclimate conditions and scarce land and imply adaptation processes of plants into different environments and ecological niches with the objective of reducing risks and facing the vulnerability in which they live.

[62] MINCETUR (2004) *Perú. Plan Estratégico Nacional Exportador (2003-2013). Plan Operativo Exportador del Sector Agropecuario-Agroindustrial.* April 2004. MINCETUR. See: Http://www.mincetur.gob.pe/COMERCIO/OTROS/bid/consultorias.htm

This way of managing risks has lead to Peru being a centre of diversity with a great richness of species and genetic diversity of crops together with the ancestral campesino knowledge and culture that accompanies and supports them. Agrobiodiversity production, contributes to approximately 90% of the food supply of local communities.[63]

At the same time, the concentration of this agrobiodiversity coincides geographically with the poorest areas in the country. However, it is important to differentiate between poverty and undernourishment situations.

In relation to undernourishment, the data provided in the *Estrategia Nacional de Seguridad Alimentaria 2004-2015* (National Food Security Strategy) [64] identifies cereals (wheat and rice) as the main source of protein and energy in Peru. In the case of wheat, the energy availability *per capita* depends on 30% of imports. This data contrast with the minor importance given to native crops and rich in proteins traditional products (such as quinoa, kiwicha, tarwi, among others), mainly a consequence of the succesive erroneous agriculture and food aid programmes in the country. On the contrary, hydrobiological products destined for direct human consumption account incomprehensibly, given the hydrobiological wealth of Peru, for only 7% of the total resources extracted and contribute with only 10% of the total protein consumed by the Peruvian population.

In 2002, it was estimated that nationally, 35.8% of homes had a caloric deficit of 29.4% in urban areas and 47.7% in rural areas.

In terms of poverty quantification, of the 26.6 million people living in Peru (according to 2001 statistics) 20.4% live in the extreme poverty and 30.4% in poverty, the great majority concentrated in rural areas (78.35%).[65]

Given these numbers, it may be asked if they are the result of a lack of productivity in agricultural practices or, on the contrary, they are the result of a variety of circumstances of different social, economical, cultural and political nature. A number of studies on poverty carried out in Peru are inclined to suggest that the dimension of poverty in the country is not purely economic, but rather multidimensional and

63 Flores, Salvador (2003) "Potencial de la agro-biodiversidad en el Perú". En: *El Medio Ambiente en el Perú Año 2002*. Instituto Cuánto, Lima, Perú, 2003.

64 Approved by Supreme Decree No. 066-2004-PCM; published in the Official Gazette El Peruano, September 8th, 2004.

65 According to the *Plan Nacional para la Superacion de la Pobreza* (National Plan for Poverty Reduction) 2004-2006, rural poverty has a more structural feature than urban poverty. In relative terms, 77.1% of the rural population is poor and 50.3% is extremely poor, according to data of the year 2002. The *Plan Nacional para la Superacion de la Pobreza* was approved by Supreme Decree No. 064-2004-PCM, published in the Official Gazette El Peruano of 8th September 2004.

implies aspects related to the vulnerability of people, their quality of life, access to opportunities, risk exposure by some social segments, among others.[66]

Therefore, the poor find themselves in a vulnerable situation, facing higher risks which they cannot easily confront nor protect themselves from. This vulnerability derives from lack of incomes, poor living conditions, violence, social exclusion, not understanding their rights and rules of the game, lack to access to credit, lack of education and healthcare, among others. This means they are in a situation of extreme disadvantage in the face of external pressures which may worsen their poverty situation.

To the effect, it is convenient to quote the economist Iris Roca Rey, who established the following in her study on *"Why and how to listen to opinions of the poor?"*:

> *"According to Pizarro (2001), the new development patterns implemented in developing countries have led the ways of production, institutions and values to have a strong impact on those in communities with smaller incomes. The incapacity of these groups is reflected in them not being able to obtain any advantages from these changes, known as "social vulnerability" (Ibid., pp.7-8). This phenomenon has generated more insecurity when facing new risks brought by the capitalist system, inducing them to make decisions which at the same time unchain consequences, damaging their possibilities for development (World Bank 1999ª.9").*[67]

In short, with regards to poverty and its relationship with the agricultural system the question to ask is how the autosubsistence agrarian system has been affected by a continuous lack of representation and inexistence in national agricultural and trade policies and by limited institutional support necessary to broaden the scenario of capacities and opportunities. In what way has this agricultural system been affected particularly by the general given weaknesses of agriculture in Peru: by the lack of agricultural research expressed in a deficient public system of conventional plant breeding; infrastructure, quality systems and sanitation deficiencies; lack of financial support; weak associations and unions; lack of management culture, excess of small

66 Following the *Estrategia Nacional de Seguridad Alimentaria* 2004-2015, some determining factors of food insecurity would include limited access to basic education; limited access, coverage and quality of integral health care and to the nutrition of pregnant woman and their babies; disarticulated food assistance of other social services; limited access to basic sanitation services, basic housing and healthy environments; limited access to specific benefits for vulnerable individuals/families due to TB, AIDS, malaria; limited capacity of response in emergency situations and disarticulation between the demand of social services and local offer of poor jobs and low incomes in the majority of households. In relation to weaknesses in the agricultural system, the study of Martin Valdivia and Miguel Robles (2002) "Alternativas para la pequeña agricultura en el Perú". *Un Análisis y Propuestas. Contribuciones al debate sobre políticas publicas*. No. 5. January 2002 is particularly interesting. See: www.grade.org.pe

67 Roca Rey, Iris (2003) "Por que y cómo escuchar la opinión de los pobres"? In Vásquez, Enrique and Winkelried, Diego (Eds) (2003) *Buscando el bienestar de los pobres. Cuán lejos estamos?* Universidad del Pacifico, Centro de Investigación. Lima, Perú. pp.29.

farms; lack of added value chains; technological segmentation,[68] legal uncertainty in land rights, among others.

In this sense, it is indispensable to make an effort and understand how the introduction of new technologies, practices of monoculture, homogenization and creation of genetically uniform commercial varieties, might affect and impact the autosupply of rural communities. It is essential to carefully identify the risks these new external inputs may place on agrobiodiversity. It is also central to determine whether these would have repercussions in the increase of vulnerability and food dependency of these communities. This implies security in quantitative terms and also in qualitative terms, with regard to the quality of food and its nutritional values.

In order to respond to this analysis, it would be interesting to evaluate the effects of the Green Revolution on the improvement of rural communities' quality of life. This analysis should be followed by an identification of the differences that modern biotechnology would imply in the consideration of risk in relation with conventional breeding and its repercussions in the agricultural management and autosupply of campesinos.

It could be argued that risk management procedures imported from developed countries are not ready to be applied in the context of countries with undernourishment problems and subsistence economies.[69] There does not exist to date, an appropriate study of the possible social and economical consequences on the lifestyles of small farmers, the impacts on traditional agricultural systems that LMOs may have in certain areas of Peru. Given this limited knowledge of socio-economic consequences, the Precautionary Principle referred to in Article 26 of the CPB could be applied.

On the other hand, new questions emerge regarding long term potential harm: who will be responsible? Who will be responsible for the consequences which may derive from possible genetic contamination affecting small farmers? And who will be responsible for the possible consequences or damage to rural economy?

With all these questions, it is essential to develop mechanisms in order to evaluate social acceptability by small farmers of these new technologies. Also, to determine the risks for these communities from the import of LMOs, mainly those destined for intentional introduction into the environment (i.e. seeds).

[68] According to the *Censo Agropecuario* of 1994 (Agriculture and Livestock Census of 1994), 92% of all agriculture and livestock farmers do not use any type of mechanized machines or tools in their work. There are ten thousand tractors and only 17% of all farmers use improved seeds or seedlings, according to data extracted from the *Informe sobre Desarrollo Humano. Peru 2002. Aprovechando las potencialidades*. PNUD-PERU, pp.4. Lima, Peru, 2002.

[69] EFB Task Group on Public Perceptions of Biotechnology (1999) *Ethical Aspects of Agricultural Biotechnology.* Cambridge Biomedical Consultants. The Hague, Holland. See: www.agbios.com

In the same token, the individual acceptability by small farmers of the risks would depend on the way in which each country faces risk management and their governments capability to develop transparent and balanced policies taking into account different coexisting interests, including those of large biotechnological companies, consumers' and small and big farmers.

However, and contrary to calls for participation, the common denominator in public policies has been the application of measures from "top to bottom" as a means to improve the quality of life and of food security in communities, without previously asking any questions. As a consequence, such policies rarely include the points of view and priorities of communities whose conditions of life are to be improved. In reality, this exact practice seems to repeat itself in the case of improved seeds being introduced through modern biotechnology.

Such an omission in many cases leads to other equally feasible alternatives and options being left out, as well as other interests and priorities. Likewise, the strong influence of companies and different actors of the food chain in determining what is convenient to guarantee food security can lead to communities not having a voice when defining policies of which they are supposedly the main beneficiaries[70] As the economist Enrique Vasquez comments, in interventions coming from the State and from private agents, the poor have always been simple spectators in this "*mercado de ayuda a los pobres*" or "*market to support the poor*".[71]

Regarding this, it would be imperative to articulate the needs and priorities of communities into regulatory and policy measures for the future instead of imposing pre- determined lifestyles. Their interests and needs[72] should be kept in mind when defining problems and assessing possible solutions. Governments can then focalize their policies appropriately and plan public spending in agricultural investigation for example.[73]

[70] Tom Wakeford and Michel Pimbert (2003). "Power-Reversals in Biotechnology: Experiments in Democratization" Democratising Biotechnology: Genetically Modified Crops in Developing Countries. Briefing Series. Briefing 13, Brighton, UK: Institute of Development Studies. See: www.ids.ac.uk/biotech

[71] Vasquez, Enrique y Winkelried, Diego (Eds) (2003) *Buscando el bienestar de los pobres. Cuán lejos estamos?*. Universidad del Pacifico. Centro de Investigación. Lima, Perú. pp.8.

[72] The result of surveys carried by HOPE elaborated in 1998 and 1999 by CIUP, with the support of IDRC, on a group of extremely poor homes in the departments of Lima, Cusco, Cajamarca and Loreto were very interesting. Families located in the rural areas perceived as their main need the improvement of their homes and their second priority the lack of work opportunities and food. Families located in the urban areas, perceived as their first priority the lack of work opportunities and their second problem the lack of an income. Data from Roca Rey, Iris (2003) "Por que y como escuchar la opinión de los pobres"? In Vásquez, Enrique and Winkelried, Diego (Eds) (2003) *Buscando el bienestar de los pobres. Cuan lejos estamos?* Universidad del Pacifico. Centro de Investigación. Lima, Perú. pp. 33.

[73] Food Ethics Council (2003) *Engineering Nutrition. GM crops for global justice?* See: www.foodethicscouncil.org

Finally, the insertion of new technologies should be accompanied by previous technical and educational development at the rural level. The main concern is that new technologies developed by big corporations may overlap and indiscriminately dominate technologies already inserted in the rural world, displacing sound technologies and not providing extensio services nor technical education needed for its management.

6.2. Public perception: what concerns does society have regarding modern biotechnology?

The debate concerning modern biotechnology has been centred on continuous misunderstandings between different actors involved. The concerns society and scientists have about modern biotechnology are different, as are their answers and solutions to problems posed by biotechnology.

From a scientist's point of view, the problem lies in the lack of understanding of scientific issues. The solutions come as a result of better education on the issue, from presenting the issues in terms accessible to the common citizen -in a way that the benefits of the new technology is perceived- and from the need to improve the communication on the risks and favour an adequate perception of these. The solution rests therefore, mainly in creating educational mechanisms and adequate communication.[74]

For the common citizen however, the issue is not purely scientific. It is political and ethical: linked to the conception that people have regarding nature, and the use, benefits and moral acceptability of modern biotechnology.

6.2.1. Different myths on what society believes

Many studies have been carried out in relation to the public perception of LMOs, with the objective of designing communication strategies. A common denominator of these studies is a general failure in adequately understanding society's demands and concerns. Therefore, what is interesting is highlighting the ideas scientists and decision-makers have in relation to what civil society knows about LMOs.

There are certain myths repeated over and over at different forums on this issue and which should be mentioned. The following are some of the most common assumptions made by the scientific community and decision-makers:

- the main cause of the problem is that most people are unaware of scientific issues;
- people adopt radical postures in favour or against LMOs;

[74] An example of this view can be found in: Alberts, B.M. & J.B. Labov 2003. *The future of biotechnology depends on quality science education*. Electronic J. Biotechnology 6(3) www.ejbiotechnology.info/content/vo16/issue3/editorial.html

- consumers' accept LMOs related to medicine but not to food or agriculture;
- consumers' want products to be labelled and therefore exercise their rights of free choice;
- people believe LMOs are not natural;
- society demands zero risks, when they are not reasonable nor possible;
- modern biotechnology risks are magnified and others from conventional agriculture are not taken into account, such as the use of pesticides;
- opposing LMOs is due to other reasons of ethical, political and emotional character;
- public opinion is victim of a sensationalist media and campaigns and equivocal information from radical environmental NGOs.

Although society in general is not aware of genetic handling at the scientific and technical levels, this lack of awareness is not what explains the answer or concerns in view of technology. The surveys and focus groups activities undertaken in the United States and Europe clearly contradict these assumptions.[75] On the contrary, results tend to focus the concerns of the public on other considerations which determine acceptability of LMOs, such as:

- why do we need LMOs and what are the benefits?;
- who are to benefit from their use?;
- who does the risk fall on?;
- who decides their development and how are decisions adopted?;
- why are citizens not properly informed of their use in foods before they enter the markets?;
- why are citizens not allowed the free choice of whether to consume LMO products or not or buy the products?;
- do public authorities have enough power and resources to face the interests of big companies who develop these products?;
- do public authorities have the capacity to effectively implement control and supervision?;
- will the risks be evaluated seriously? By who? How?;
- have long term effects been taken into account? How?;
- how have uncertainties and areas with absence of complete scientific knowledgebeen taken into account when adopting decisions?;
- what emergency measures exist in the event of unanticipated impacts or damage?;
- who will be responsible in the case of undesirable impacts? What repair mechanisms have been anticipated?;

[75] We are referring to PABE studies undertaken in Europe in 1998-1999 in relation to *"Public Attitudes to Agricultural Biotechnologies in Europe"* and those conducted in the United States by the FDA in 2000, both contained in the very interesting article by Claire Marris (2003) *Issues Concerning Public Awareness and Attitudes Towards Genetically Modified Bananas and Tropical Fruits* presented at the Third Session of the FAO Intergovernmental Group on Bananas and on Tropical Fruits celebrated in Spain in December, 2003. CCP:BA/TF 03/CRS.13 November 2003. See: www.fao.org.

In view of the above, scientists tend to assume that citizens need to have specialized knowledge on genetic modification techniques, in a way that this knowledge almost instantly translates into the elimination of irrational fears and in more favourable attitudes which would derive into less opposition to such technologies. However, the conception of "top to bottom" professional attitude is erroneous, when considering the basis of public concerns.

At the core of these concerns, are citizens' appraisal in relation to how public authorities have acted in the past and the capacities they have regarding the development and control of technological innovations and risks. Such behaviours and capacities shall be repeated in relation to LMOs and related issues.

In this context, confidence in institutions is a key factor as evidenced in Europe in relation with different cases of intoxication and the "mad cow" crisis. The consequence is that the centre of the problem does not consist of improving communication strategies, but in making changes in institutional practices, which generate greater transparency in the decision-making processes and in the admission of capacities (or lack of them), at the time of managing uncertainties and risk assessment results, or risk assessments themselves.

There is no doubt that much of the success of this new technology will depend on its acceptance by civil society, mainly by consumers'. Therefore, most of the answers should be treated in a wide policy, socio-economic and ethical context and in contributing with more information, participation and transparency.

Although most of the studies carried out in relation to public perception have taken place in the United States and European Union (main markets of food import) a survey was undertaken by *Environics International* in the year 2000, in 35 countries where more than 35,000 people where interviewed regarding the quote: "*the benefits of biotechnology outweigh the risks*"-. Peru was one of the countries surveyed where 58% agreed on the quote, 26% showed unconformity and 16% were not sure.[76]

Nevertheless, the results of such a survey could be put into question as they contrast with the present reality, where within the Peruvian society there is an absolute unawareness, knowledge and education on this particular matter. As an example, during the last few years, the subject has been absent from the media and political debates; it is not on the agendas of the agricultural associations nor representative organizations of peasant and indigenous communities, nor agricultural unions such as food producers or restaurants, or in the policies of supermarket chains or businesses.

[76] Hoban, Thomas (2004) "Public Attitudes towards Agricultural Biotechnology". *ESA Working Paper* No. 04-09. May 2004. FAO Agricultural and Development Economics Division. In relation to other Latin American countries, 62% in Mexico, 44% in Argentina, 55% in Brazil, 47% in Chile, 66% in Colombia and 64% in Venezuela, agreed to the quote. See: www.fao.org/es/esa.

6.2.2. Different uses, different preferences

In the study and in relation to the total of countries surveyed, differences are pointed out in people's acceptance of different biotechnology uses. There is more public approval in relation to the use of biotechnology for the development of new medicines (85%); for environmental uses such as cleaning oil residues (73%) or for the production of recycled plastic (74%); for the production of seeds with nutritional improvement (68%) or for the production of pesticide resistant seeds that need less chemicals (71%). However, the approval declines when trying to improve animal productivity (35%) and even more so when trying to develop genetically modified animals to produce healthier meat (55%) or cloning animals for medical research (42%). The survey concludes that ethical implications exist in the debate and therefore the need to include other subjects to the purely scientific discourse.

6.3. Biosafety and public participation

The need to provide a scenario which shows different perspectives of actors linked to the food chain and give a voice to the majority of small farmers in the design of policies affecting them would help clarify the application of the Precautionary Principle in terms of public participation.

As demonstrated, under the Precautionary Principle lies a conflict of "authority". While some allege that policy decisions be based exclusively on *sound science*, others also propose due consideration to moral, ethical and democratic variables. The latter, however, poses a problem when facing ordinary policy thinking frames (which, for example, normally ignore other sources of knowledge such as local or indigenous communities traditional knowledge) and given it is normally easier for decision-makers to directly base their decisions on scientific information than to adopt a more *holistic* vision of the problems.

Nevertheless, if something is clear from invoking the Precautionary Principle, it is the recognition of it being a process where decisions should be adopted, not from a monocentric perspective but taking into consideration a plurality of visions, realities and interests. In this sense, the democratic ideals would require that decisions affecting peoples health, among other aspects, be adopted allowing their full participation.

At the same time, recognizing existing limits in scientific certainty and displaying social values which are implicit when carrying out a scientific risk assessment may lead to greater participation by different actors in processes affecting their lifestyles and open the debate between civil society and the scientific community.

6.3.1. Participation in decision-making

In this sense, any process that does not respond to such demands of public participation may be in danger of affecting legitimacy and credibility and, subsequently, not being able to be solidly grounded.

Public participation in biosafety national frameworks should take place during the processes of regulatory development, implementation and monitoring. In short, the CPB in Article 23 on "*Public Awareness and Participation*" opens different roads for public participation as well as the possibility to access information from the *Biosafety Clearing House*. Article 23 calls Parties to try and ensure access to information on LMOs, that Parties consult the public in the decision-making process regarding LMOs and make the results of such decisions available to the public.

Although these consultations are subject to what is provided by national legislation, Article 23 suggests it is a legal obligation, therefore, the reference to national laws should be understood as a reference to consultation modalities. Thus, the way to ensure public participation would, to a great extent, depend on the available resources, existing cultural policies, civil society's demands and level of public participation commitments. Therefore, the tools adopted for public participation depend on the circumstances of each country.

Public participation in Peru has been based on a "top to bottom" approach. That is, the creation of formal participation spaces has been based on State initiatives, rather than originating from initiatives of citizens themselves.

In some countries the pressure by farmers[77] or consumers through public demonstrations has forced initiatives for policy decisions on issues related to biosafety and, as a consequence, the adoption of biosafety regulatory frameworks. In Peru, these processes have not taken place mainly due to civil society limited awareness and information on the matter.

Of the three phases of design, implementation and monitoring of policies, Peru has only been active in the phase of designing policies by creating a consultation and exchange of information system through formal participation instruments. This is the case of the National Technical Biosafety Working Group, as a committee of experts supporting the *Consejo Nacional del Ambiente* (CONAM, National Environmental Council) and formed by different representatives of civil society and public administration. This group (whose mandate has already concluded) tried to find a consensus in relation to policies to be designed and basically paved the way to the existing normative on biosafety in the country, including the proposal by Congress to ratify the CPB.

[77] For example, in Latin America one of the biggest battles on transgenic issues has taken place in Brazil, led by the *Instituto Brasileno de Defensa del Consumidor* (IDEC) who filed a legal demand against *Monsanto* which concluded with the Federal Court forcing the company to present environmental impact studies before starting to grow and commercialize transgenic soy bean. Lately, consumers' associations have managed to withdraw a publicity campaign by Monsanto considering it to be misleading publicity in relation to transgenic foods. See: www.idec.org.br

At present, participation in the design of policies has been transferred to the National Committee for the Management of the Biosafety Framework,[78] created to undertake activities of the *Proyecto UNEP-GEF sobre Desarrollo de Marcos Nacionales de Bioseguridad* (GEF project to develop national biosafety frameworks). This Committee was created to develop the specific legal and institutional frameworks needed to implement the CPB. It was formed by eight representatives from different public organisms such as the Viceministry of Fishery, National Institute of Extension and Agricultural Research (INIEA), National Direction of Environmental Health (DIGESA), Peruvian Institute for Amazonia Research (IIAP), National Service for Agrarian Sanitation (SENASA), the National Council for Science, Technology and Innovation (CONCYTEC) and the National Environmental Council (CONAM); by a representative from the School of Biologists; a representative from the academia (University Agraria La Molina), a representative from the trade unions (National Society of Industries) and a representative of NGOs (Sociedad Peruana de Derecho Ambiental).

As this formal mechanism of participation was subject to the existence or a mere project and not permanent in nature, its objectives of representativeness and transparency have progressively been diminished and its contribution absent in the adoption of biosafety policies and national negotiation positions.

Unfortunately, the mentioned National Committee nor other participatory platforms ever consider to have representation from consumers' associations nor small farmers. In relation to this, Peru ratified on January 16th, 2003, the *FAO International Treaty on Plant Genetic Resources for Food and Agriculture* which entered into force the 29th of June 2004.[79] Article 5.2 of the Treaty establishes that Contracting Parties shall as appropriate, take steps to minimize or if possible eliminate threats to plant genetic resources for food and agriculture.

Article 9 of the Treaty regulates for the first time, Farmers' Rights. After recognizing the enormous contribution that local and indigenous communities and farmers of all regions of the world, particularly those in centres of origin and crop diversity have made to the conservation and development of plant genetic resources, Article 9 establishes "*the right [of farmers] to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture*". Therefore it is deemed essential in the future to include these sectors in the debate on biosafety frameworks, facilitating their access to existing information.

[78] On the criticism of pressure and celerity demanded on developing countries for the development of their regulatory frameworks on biosafety, which have taken countries' years to execute and are necessary for the entrance into force of the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity* see: Glover, Dominic (2003) "Public Participation in national biotechnology policy and biosafety regulation". *IDS Working Paper* 198 www.ids.ac.uk.

[79] Ratified by Supreme Decree No. 012-2003-RE; published in the Official Gazette El Peruano, January 27th, 2003.

Another participatory organism is the National Biodiversity Commission (CONABID), which acts as an advisory and coordination entity for biodiversity matters, providing assistance to Sectorial Competent Organisms and proposing national biosafety policy to CONAM. CONABID[80] is a participative and interdisciplinary entity where representatives of the public, private and academic sectors, NGOs and indigenous communities interact. Although its possibilities as a participatory mechanism, this Commission has not been very proactive during the last years in the proposal nor discussion of policies related to biodiversity nor biosafety policies to be adopted in the country, due perhaps to its decisions lack of repercussion in such policies.

Parallel to this formal participation through specific organisms, biosafety norms allow communities to participate in the processes by presenting observations during thirty days after presenting an application to release LMOs and before the risk assessment by the Competent Sectorial Organism are completed. However, the norm does not establish how the competent authorities will respond to consultations and observations.

Finally, for effective participation to take place, mechanisms must be foreseen in order for information to be shared transparently. The exchange of information and public awareness is necessary to allow issues to be considered and opinions to be formed.

This perspective is foreseen in national legislation. The very recently Ley General del Ambiente (General Environmental Law),[81] among its guiding principles, provides in its Article 2 "On the right to access to information" that *"Every person has the right to accede to adequate and opportune public information on policies, norms, measures, and activities that could affect, directly or indirectly the environment, without any need to justify such interest or requirement of information.*

Every person is obliged to adequately and opportunely provide to public authorities with the information that these would require for an effective environmental management, according to Law".

This article is extensively developed in Chapter 4 of the Law, and particularly in its Article 41 *On access to environmental information*, that establishes that "*According to the right to accede adequately and opportunely to public information over the environment and its component and its implications on health, every public organism, or private legal persons that provide for public services, will facilitate access to this information, to any person that requires it, without any distinction and subject exclusively to what the law provides for".* Equally, on Article 42 it establishes several measures to be adopted by public authorities for this right to be materialized, such as the obligation to establish public mechanisms for the provision of information, direct and free access to information, and quality review measures for the environmental information provided.

80 It is regulated under Titulo VIII of the Reglamento de la Ley sobre Conservacion y Aprovechamiento Sostenible de la Diversidad Biologica (Biodiversity Regulation), D.S. No. 068-2001-PCM (20/06/2001).

81 Law No. 28611 published in the Official Gazette El Peruano, on October 15th, 12005.

In the same token, Law No. 26842, the General Health Law,[82] in its Preliminary Title, Paragraph XIV, states that "*Information on health is of public interest. Each person is obliged to provide the Health Authority information required by law. What the State holds is in the public domain, with the exceptions established by the law".* Article 5 establishes the right of each person to be duly informed by the Health Authority on any health matters, particularly proper diets and the promotion of healthy lifestyles.

6.3.2. Access to information

During the past years, a transparency culture has been sought within Peruvian State agencies. A change of attitude by public officials and public authorities has been pursued with the issuance of different norms in order to guarantee access to information held by public entities. Although such a right has been developed in some sectorial norms, it has also been addressed in a comprehensive manner through specific regulations.

These norms are Law 27806, Law on Transparency, and Access to Public Information,[83] the Regulation of the Law[84] and Law No. 26301, which regulates the habeas data procedure.[85]

More specifically, the right of citizens to have access to public information in the hands of any public entity is foreseen. Information requested from a public entity may be referred to the one either produced by it or to the information under its control, being generated by another entity or private company. The public authority should offer the information during a period not exceeding seven working days, which may be extended for an additional five days and the person should only have to pay the costs of reproducing the information.

Exceptions to access public information include those related to commercial, industrial and technological secrets (Article 17.2 of Law No. 27806). These are considered a part of "trade secrets" susceptible to being economically exploited and which could refer to the production or commercialization process of goods or services or any knowledge obtained as a result of a scientific or technical research processes.[86]

82 *Ley No. 26842, Ley General de Salud,* Published in the Official Gazette El Peruano dated July 20th 1997.

83 Decreto Supremo No. 043-2003-PCM; published in the Official Gazette El Peruano, dated April 24th, 2003.

84 Decreto Supremo No. 072-2003-PCM, published in the Official Gazette El Peruano, dated August 7th, 2003.

85 Published in the Official Gazette El Peruano, dated May 3rd, 1994.

86 Defensoria del Pueblo (2003) *El Acceso a la Información Publica. No a la cultura del secreto.* Defensoria del Pueblo. 2003. Lima, Perú.

Finally, the 1993 Peruvian Constitution, in Article 200, includes the possibility for a person to defend his right to access to information, creating an action that represents a constitutional guarantee called *habeas data* against any act or omission from a public authority, public official or any person who interferes with the constitutional rights to obtain information.[87]

Although legislation in Peru regarding biosafety does not specify nor further develop access to information provisions, it could be argued that access to information may take place in three different ways: publicity on the registration application; publicity on the final administrative Resolution for the approval or refusal of the application and the existence of a Public Register in each Competent Sectorial Organism.

In relation to publicity of registration of the application, Law 27104 determines that once the application is accepted, the Competent Sectorial Organism will publish a summary of the information in a newspaper of national circulation, in order for anyone to provide information related to the specific LMO and for its inclusion in the risk assessment (Article 20). In the same sense, Article 35 of the Regulation provides that the "*Competent Sectorial Organism in coordination with the applicant, publish a summary of information on the application and provide a period of thirty working days subsequent to the publication date, for any legal or natural person to present any observations related to the LMO application*".

This provision is a clear indication of how access to information relates to participation in decision-making. However, it is not clear if at the time of observations, one may have access only to the summary of the application published or if this also includes access to any other documentation included, the risk assessment and resulting risk management plans. It seems this last option is the logical consequence, taking into account that Article 36 determines "*once the period to present any observations on the summary of information has expired, the Competent Sectorial Organism will finalize the risk assessments, issuing their decision no later than 120 subsequent working days*". No mention is made to the minimum content of the summary, or whether one should have access to the Registry of applications to introduce LMOs (where each case will be followed individually) as provided in Article 25.

Equally, the Administrative Resolution authorizing or refusing the application should be published in a written newspaper of national circulation (Article 22 of Law 27104 and Article 40 of the Regulation). In both cases, the costs of the publications will be covered by the applicant of the LMO activity, as provided in Article 22 of the Regulation, which expressly determines that "*the costs of publishing the summary of information as well as the costs to register will be covered by the interested party*".

[87] In accordance with Law 26301 which regulates the *habeas data* procedure, the action is presented to a civil judge in the place of residence or where files or similar documents are located. For this action to proceed, the plaintiff must request the authority that possesses such information, through a notary public, at least fifteen working days in advance.

Apart from this, the system determines that each Competent Sectorial Organism implement a Public Registry of LMOs, their derivatives or products thereof; of legal or natural persons interested in carrying out activities with these and any approvals, refusals and cancellations which may occur. As these are public registers, they should be open for consultations by civil society (Article 7 of the Regulation). This is fundamental considering that the release of LMOs is made case by case and that there should be a phase to consolidate such information at the national level and which the public can directly access.

In this sense, it would be desirable for the National Environmental Council (CONAM) as the Biosafety Clearing House focal point to centralize all relevant information on LMOs into one register providing the public with easy access. It would also be important if the application to release LMOs is published in the local media or on publicity panels of Municipalities[88] of areas where the activity will take place and the application is notified to local authorities and members of the National Biodiversity Commission (CONADIB), in order for them to present their observations.

Besides the information mentioned above, it would have been convenient to also be made public the date of the beginning of the activity, its objective as well as information in relation to monitoring activities, aspects which have not been specified in current norms.

Finally, attending to certain circumstances (including type of LMO, proposed use, characteristics of the environment which may be affected, level of existing experience in relation to risks to the environment and human health, if it is a first release into the environment or new location, or first time LMOs are introduced in the market, etc.), participation should be extended and new communication mechanisms be created between different committees, for example, the National Agrobiodiversity Working Group, the Coordination of Conservation *In-Situ* Project, specialized institutions and different actors involved[89].

With regard to this, a function of the Competent Sectorial Organism under the Regulation is the dissemination of information on risks and benefits derived from the

[88] The UNEP International Technical Guidelines for Safety on Biotechnology adopted in 1995 recommends in Annex 7, different ways to promote participation of civil society, which includes informing local communities through public hearings and the local media, as well as dialogue between the public, universities, academic centers and companies. Http://www.biosafetyprotocol.be/UNEPGuid/Contents.html.

[89] In regards to their reference to access to information, public participation in decision-making and access to justice in relation to genetically modified organisms, it is of interest the Guidelines that have been adopted by countries of the *Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters* (Aarhus Convention) in October 2002. Type of information to be presented to the authorities regarding LMO matters is proposed. See: http://www.unece.org/env/pp/gmo.htm.

use and management of LMOs and participation of civil society (Article 7 s). CONAM is the organism in charge of consolidating all the national and international information generated on the matter (Article 5 a).

6.3.3. Confidentiality

Another critical aspect is to what extent the applicant may withhold information he considers "commercially sensible" and avoid it being disseminated among the public. In order to prevent the possibility of a person's right to access information being denied, the CPB has provided different minimum conditions under which exceptions to the right to information cannot be invoked. Article 21 specifies information which cannot be considered confidential and cannot affect a person's right to information: the identification of the operator; general description of the LMO; a summary of the risk assessment and methods and contingency plans in the case of an emergency.

Law No. 27104 regulates the issue similarly, although it adds the obligation to put at a persons disposal, information on the area where the activity is to take place. Article 24 provides that "*confidentiality on the identification of the holder or person responsible of the project, objective and place where the activity is to be carried out, systems and emergency measures and control, or the assessment of the risks to human health, the environment and biological diversity shall not be granted*".

Likewise, the interested person should expressly request confidentiality of information *"which may be used unfairly"*, and accompany this with proof he may have (Article 23 of the Law). He may also resort to the Competent Sectorial Organism when confidential information is considered non-confidential (Article 48 of the Regulation). The Competent Sectorial Organisms have the competence to withhold the files with confidential information and any information which is not confidential will be derived to CONAM, the intersectorial organism.

It is important to note that although such provisions on public participation have been created under the framework of biosafety, the tools and their use will greatly depend on the context in which they will be applied and the culture of the country when addressing issues such as transparency, accountability or the communities requirement for authorities to be responsible, and democracy in general.[90]

Finally, there is the understanding that the mere existence of provisions on public participation should imply a translation into immediate participation. However, clear mechanisms will have to be developed for this to take place. Even the best provisions on public participation may never be implemented if the public does not have the capacity to participate in an effective manner.

[90] Glover, Dominic (2003) "Public Participation in National Biotechnology Policy and Biosafety Regulation". *IDS Working Paper* 198. See: www.id.ac.uk.

6.4. Labelling

The labelling of LMOs or LMO derived products is a sub-area within the concept of access to information. Labelling constitutes a mechanism developed within biosafety policies and food safety whose main objective is to offer consumers' information related to the LMO or LMO derived product already being used or to be utilized. Consumers in this case include actors in the food chain such as farmers, providers or retailers and people in general.

6.4.1. Consumers' rights

To the classic rights to health and food security, new rights related to consumers' are being the subject of defence. These rights have emerged in parallel to modifications in the food chain and progressive disconnection and separation of the final consumer with centers of origin and food production as the right to be informed and, consequently, elect and adopt informed decisions.

6.4.1.1. Right to information

The development of a labelling policy is based on the premise that the consumer has the right to know what he is buying and, consequently, consuming or eating. The greatest source of information to this respect can be found on the products labels. Based on information provided on the products labels, consumers may adopt a better and more informed decision when exercising their rights to choose between products on the market. This capacity to choose may be motivated by reasons of economical, health, religious, ethical and moral nature or by other needs. This circumstance helps labelling become a market mechanism which may contribute to the acceptance or not of a determined product or technology used for producing a certain product.

Another function of labelling is its role as a mechanism to protect consumers from deceptive practices that might appear on the market. Therefore, labelling assures consumers that the information offered on a product is true and that the consumer is getting what he is offered.

Finally, a reference should be made to the education function a label plays. Food safety and environmental protection may be the object of promotion through labelling practices, for example, when information is offered by proper labelling.

The tendency at present is towards the labelling of LMOs and LMO derived products, at national and international[91] levels.

[91] In the Thirty third meeting of Codex Alimentarious Committee on Food Labelling (CCFL) celebrated in May 2005 in Malaysia, 30 out f 55 country delegations spoke in support of creating GM labelling standards. At present, all countries member of the European Union, Australia, New Zealand, Japan, Korea, China and Brazil, Russia, among others, establish LMO labelling as mandatory.

Consumers' movements and surveys have resulted in the demand for information in this sense.[92]

Maintaining a position in favour of labelling LMOs and LMO derived products gives the idea they are different to other normal food products or which are produced by conventional methods. Arguments in favour are based on food safety reasons, providing consumers with information that might affect their health and the possibility that the information on labels help identify the origin of the problem that may arise. Finally, the establishment of a labelling system would also help address liability issues.

Reference is made for example, to toxicity and allergenicity cases or an accidental change in the level of nutrients in foods that have been genetically modified and may lead to dangerous situations for consumers' health. Cases such as genes transferred from Brazil nuts to soy beans, which breeders never imagined, would imply a transfer in the conditions of allergencity. In this particular case, lack of labelling put consumers' health in danger and contributed to the difficulty of detecting the problem.

The issue is even more complex, considering that processes of modern biotechnology are generating vegetable and animal products for purposes other than for human consumption. Traceability when using this technology and need for labelling indicating the processes under which products have been obtained is more urgently required according to this view, given that at present, modern biotechnology is being used to produce vegetable and animal products for pharmaceutical purposes. Thus, corn seeds for example, are medicines, vaccines against hepatitis, male contraceptives, industrial chemicals, vaccines for animals.

How can cases in which genetic contamination has taken place be detected, when the processes these vegetables or animals have been objected to are not evidenced? How to ensure these will not become an unintentional part of the food chain?[93] Those

[92] Including USA, where the consumption of transgenic products is extended, there is a 95%-98% demand for the requirement of labelling transgenic foods. Data extracted from Jean Halloran, Symposium: Remarks on Regulating Genetically Modified Foods: Is Mandatory Labelling the Answer?, 10 Richmond Journal Law and Technology. 12 (2003). See: http://law.richmond.edu/jolt/v10i2/article12pdf

[93] A case in point, is the contamination of Starlink genetically modified corn destined to feed, not apt for human consumption, which was mixed with corn for human consumption and became a part of transformed products for human consumption. Similar situations have occurred in the United States in relation to *pharma crops* or seeds destined for pharmaceuticals, particularly regarding genetically modified corn to create medicines for treating viruses in pigs. On the history of the food crisis in the USA and issue of labelling: Kirby, Sarah (2001) "Generically Modified Foods: More Reasons to Label Than Not". *Drake Journal for Agricultural Law.* Fall 2001 and Kathleen Hart, Symposium, Symposium: Remarks on Regulating Genetically Modified Foods: Is Mandatory Labelling the Answer?, 10 Richmond Journal Law and Technology. 6 (2003). See: http://law.richmond.edu/jolt/y10i2/article6pdf.

supporting this position understand that labelling products would help address issues which should be at the expense of those introducing the new technology.

However, there is also a position against labelling being compulsory and in favour of it being voluntary, based on the fact that by providing consumers with more information does not necessarily mean they will become more informed. This may simply help exacerbate sensibilities against the consumption of these products. It is said that transgenic foods are no different to conventional products. The requirement to label would therefore imply the existence of separate and segregate mechanisms for products along the food chain, which would not only be uncompetitive and inefficient for companies, but sometimes impossible to undertake. This would also imply new costs which would fall on consumers. Then, the obvious question is whether the consumer is willing to assume the costs.

Apart from this, there is an interest in "negative labelling": some producers might be interested in indicating their products are free of LMOs, in order to distinguish them from those genetically modified.[94] Along the food chain there might be the case of accidentally mixing products with and without LMOs. Assessments would need to be made to establish a minimum presence of LMOs when considering a product to be "genetically modified". In the light of this, various questions need to be answered at the national level: to what point are products considered to be free of LMOs? and what threshold value should be set for LMOs, starting from when a product would be considered a LMO?

Other related questions may be added such as: what is the objective scope labelling should cover? These questions increase the complexity of the subject and have been answered in different ways by regulatory systems. They mainly focus on questioning whether there is the need to include labelling on second generation products such as meat from animals fed with transgenic soy beans and corn, or in the case of soft drinks containing fructose produced with the aid of enzymes, made from genetically modified microorganisms.

6.4.1.2. Right to choose

Based on information provided, consumers have the right to choose their food products. There may be other reasons than those related to food sanitation for a person to exercise his right. The consumer may choose whether to buy a product or not based on religious, moral, lifestyle, taste and cultural beliefs or merely opinion.

[94] In Europe for example, a product is considered genetically modified when it has a 0.9% presence of LMOs. A recent agreement signed by Mexico, Canada and USA, in October 2003, establishes rules for the labelling of genetically modified products between the three countries and determines that LMO labelling would be directed only to distributors not consumers, labelling is not required in the case of transport which might have accidentally given way to products containing LMOs and sets a 5% threshold for a LMO labelled product. This policy is being defended by USA when negotiating bilateral trade agreements with different countries around the world. Brazil has established a threshold of 1% for LMO labelling.

Thus, independently from expressing that inserting genes of human origin into foods does not imply an outstanding fact regarding food safety, given the majority of human genes are similar to those of other species, according to cultural and religious beliefs, many consumers may consider consuming these products cannibalism and be against it.

Therefore it is essential for these concerns to have a space when determining policies. In this sense, consumers' should have the autonomy to choose the food they consume. An agent is autonomous when he can take action based on his values. Respecting his autonomy would therefore imply contributing with sufficient information to allow him to decide what action is suitable according to his values, beliefs and lifestyle. Labelling would therefore respond to the protection of autonomy and consumers capacity to choose, when providing information during the purchase or consumption of certain foods.[95]

6.4.2. A controversy at the international level

Labelling is becoming one of the most complex issues in international debates, and as a consequence there is no consensus regarding international rules. Labelling rules for LMOs and foods in general, are being the subject of negotiation in the Codex Alimentarius Commission. In the area of biosafety, the CPB provides in Article 18 an obligation of Parties in relation to identifying LMOs subject to transboundary movements. In both cases, when products are the subject of exchange at the international level, their regimes coexist with those of the World Trade Organization.

6.4.2.1. Labelling in the World Trade Organization

The *Agreement on Technical Barriers to Trade* (TBT)[96] of the WTO governs labelling in relation to international traded products. The TBT is relevant in relation to labelling LMOs and LMO derived products. This Agreement is applied to technical and standard regulation requirements of packing, handling, identification and labelling, in order to guarantee that these norms do not become a barrier to trade and are applied in accordance with principles of "need" and "proportionality".

Paragraph 6 of the Preamble of the TBT provides: "*no country should be prevented from taking measures necessary to ensure the quality of its export, or for the protection of human, animal or plant life or health of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade, and are otherwise in accordance with the provisions of this Agreement*".

95 EFB Task Group on Public Perceptions of Biotechnology (1999) *Ethical Aspects of Agricultural Biotechnology*. Cambridge Biomedical Consultants. The Hague, Holland. See: www.agbios.com.

96 For the text of the Treaty see: http://www.wto.org.

All products including industrial and agricultural products shall be subject to the provisions of this Agreement (Article 1.3) and shall not be applied in regards to sanitary and physosanitary rules of the *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS, Article 1.5). In this sense, the SPS determines whether biotechnological products imply a risk to human health or the environment. Therefore, the TBT would only be applied in relation to labelling products as a LMO, following general rules of international trade.

In particular, imported products shall be granted national treatment like products of national origin (Article 2.1); technical regulations will not generate unnecessary obstacles to international trade and shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account the risks non-fulfilment of this objective would create (Article 2.2) These legitimate objectives are, *inter alia*: national security requirements; the prevention of deceptive trade practices; protection of human health or safety, animal or plant life or health or the environment

6.4.2.2. Labelling in the Codex Alimentarius Commission

Apart from the above, under the Codex Alimentarius Commission, particularly, under the Codex Committee on Food Labelling, an international debate on issues related to labelling foods derived from modern biotechnology is taking place. The work of this Committee is to basically set standards and harmonize regulations in relation to labelling food derived from modern biotechnology in order to minimize any effects these may have in the international markets of these products.

While the Codex standards are of voluntary nature, the Codex Alimentarious Commission is recognised by the *Agreement on the Application of Sanitary and Phitosanitary Standards* (SPS) as the international organization responsible for standard-setting related to food safety. It means that WTO Members will have to base the adoption of measures related to human and plant health on Codex´s standards, guidelines or recommendations.

The Codex Commission in 1999 adopted a draft on *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods* referring to LMOs, which is presently under a review process. They have also developed a number of drafts on guidelines and directives which have nevertheless, not been approved due to their controversial nature. This lack of consensus has led to discrepancies to be transferred to other forums closely linked to this, as the WTO.

This controversy is at present becoming intense in the context of the *"Proposed Draft Guidelines for the Labelling Foods Obtained through Certain Techniques of Genetic Modification/Genetic Engineering.* The discrepancies in the Committee are evidence of existing different and polarized regulatory perspectives: while some members are in favour of only allowing for labelling of those biotech foods that are substantially different in terms of composition, nutritional value, or allergenic content to conventional counterparts; other Codex members defend the use of process-based

labels, so that would allow for labelling of biotech foods not only in relation to the mentioned case, but also when the products are composed or containing GMOs, or produced from but no longer containing GMOs.[97]

In this regard, it is important to make a short review of the different regimes which are the subject of controversy (mainly those defended by the USA before the European Union), as it allows to establish certain boundaries to concepts and analyze different alternatives presented when adopting regulatory decisions and policies.

The European regulatory regime has a precedent in the food crisis suffered during the 90s in some countries of the European Union. Cases such as the mad cow crisis or Bovine Spongiform Encephalopathy -BSE- in the United Kingdom and subsequently transferred to Europe; chicken meat intoxicated with dioxins in Belgium or aphtose fever, put into evidence an inadequate and non-existent communication with consumers on the risks, which generated consumers to mistrust any changes introduced in the food chain. Even worse, this produced a total lack of confidence in the regulatory agencies and their capacity to take care of consumers' interests, which would enter to compete with other lobbies from the food industry and farmers and cattle associations when decision making processes.

Although this crisis was not originated by genetically modified foods, the publics' acceptability was influenced by this context. As a result, the *Eurobarometer Survey* of December 2001 resulted in that 56% of European citizens expressed that transgenic foods were dangerous, 70% did not want this type of food and only 14% trusted the national regulatory agencies to tell the truth about biotechnology.[98]

This situation led the EU in 1998 to impose a de facto moratorium for the approval of new LMOs, which was lifted in 2004 and substituted by a stricter regulation on

97 Report of the Thirty -third Session of the Codex Committee on Food Labelling celebrated in Kota Kinabalu, Malaysia, 9-13 May 2005 is referred as ALINORM 05/28/22. In this meeting, and due to difficulties in obtaining an agreement on the issue, the Committee agreed to restructure the Draft Guidelines to work on a double labelling regime: one for mandatory laelling provisions relevant to changes in nutrient content, product composition, end use and the other for optional labelling provisions linked to labelling of method of production. Http://www.codexalimentarius.net

98 Even in 2005 when asked on the quote "Public authorities in the European Union view the health of consumers as being more important than the profit of producers", a 47% disagreed, 39% agreed, and 14 % did not know. When asked about the most trusted sources to inform them about a serious food risk, Europeans would most trust consumer groups (32%), their doctor or physician (also 32%), scientists (30%) public authorities (22%), Media (17%), Food Manufacturers (6%) and Farmers (%). Special Eurobarometer 238. "Risk Issues". February 2006.
http://europa.eu.int/comm/public_opinion/archives/ebs/ebs_238_en.pdf
In the mentioned 2005 Eurobarometer when European citizens were asked to what extent they are worried about genetically modified products in food or drinks, 25% of EU citizens answered "very worried" and 37% answered "fairly worried".

labelling and traceability[99] of foods. In accordance with the new European normative[100](which entered into force in all European countries in April 2004) all foods with derived LMO ingredients must be labelled, whether or not they have detectable levels of DNA or proteins from the original LMO in the final product. Only an accidental presence of 0.9% LMO in foods will be allowed; any percentage above 0.9% must be labelled as a GMO.[101] The new regulation will also impose GMO labelling for animal food consumption, following the same principles as for human food consumption.

However, labelling is not required for products such as meat, milk or eggs obtained from animals fed with GMOs or treated with genetically modified medicines. Also, products such as cheese or beer frequently produced with the help of enzymes originating from genetically modified microorganisms do not need to be labelled.
The regime also requires a traceability system "from farm to table" in order for all industries involved in the production, storing, transport or processing of GMO derived products to have a follow-up history of the product and maintain a registry for at least five years.

This system is clearly a confrontation with the existing system established in the USA in relation to LMO labelling, to the point that the USA has been filing suit against the European Union before the WTO alleging their regulations to be discriminatory and generating unjustified trade barriers.

The American regulatory system assigns competences to the Food and Drug Administration (FDA), which operates based on the principle that transgenic products should be subject to the similar norms on labelling for other products. The evaluation is undertaken on the final product and not during the process. Therefore, food safety is more important than the process. Some foods obtained through genetic manipulation will have to be labelled, not because of the production process but because of nutritional and allergenicity reasons, the same as any product obtained conventionally. As a consequence, special labelling is not required if the product is basically the same as a conventional one, (principle of substantial equivalence) considering its composition, nutritional quality or safety in its consumption.

The regulatory system is based on what is called the principle of substantial equivalence and places an emphasis on the final products (without further analysis of

99 Traceability is understood by the follow-up of an LMO product from the farm to the table, through the complete process of distribution, processing and manufacturing of the final product.

100 Regulation 1830/2003 in relation to traceability and labelling of genetically modified organisms and traceability of food and feed produced from these and Regulation 1829/2003 on genetically modified food and feed.

101 Ecological agriculture according to the European normative will not allow the presence of GMOs. Article 6.1 of the European Normative 2092/91/EEC on Ecological Agriculture.

the production processes and technologies). Labelling is voluntary. The possibility of negative labelling is foreseen in order for companies to voluntarily indicate on their labels that a product does not contain transgenic ingredients.[102]

In addition, criticisms on the new European system are centred on high costs, lack of efficiency and competitiveness of companies, given obligations on traceability and the labelling system and the obstacles this might imply on trade, mainly for those developing countries that lack compliance mechanisms.

In parallel, the American system has also been subject to a series of debates motivated by food contamination cases. Although the producer of foods, as much through conventional methods as biotechnological methods, has the legal obligation to guarantee their innocuousness for consumers', in the case of LMOs a special or distinctive risk assessment has not been required. This has implied in practice, leaving the pre-market risk assessment to the wilfulness of companies, with resulting cases of transgenic food contamination.

There have been some cases of food for human consumption being contaminated by GMOs destined for industrial uses, for the treatment of animal illnesses or destined for medicinal uses. This has lately been called genetically modified pharma crops, plants and animals to produce vaccines and medicines. Detection of contamination has occurred at the post-market stage when the contaminated product was already on the market.[103]

Two different experiences on the treatment of labelling and right for consumers' to be informed and choose have resulted from this situation. While the Food and Drug Administration (FDA) considers that the right to be informed does not justify labelling based on processes, the EU recognizes consumers' rights to information and labelling as a tool for informed decision-making.

These experiences put in evidence the difficulty to obtain common international norms on basic definitions, levels of tolerance and detection methods. Therefore, there is a growing concern that the proliferation of standards gives way to the creation of trade barriers, and finally, implies more confusion among the final consumers. The lack of harmonization of norms and whether they are accepted or not by consumers, constitute elements which future global trade of transgenic foods will depend on.

[102] However, an approved guideline on voluntary labelling does not yet exist.

[103] On background, applications and contamination found in the USA in relation with these types of crops and the concerns at the regulatory level and the public's perception, the *Center for Science in the Public Interest* offers an interesting report. http://www.espinet.org/new/index.html.

6.4.2.3. Labelling in the Article 18 of the Cartagena Protocol on Biosafety

The CPB does not refer to the issue of labelling strictly from a consumers perspective. Article 18 refers mainly to the identification requirements of LMOs in documentation attached to transboundary movements. Therefore, the norms related to labelling are directed mainly to operators taking care of the transport, customs authorities and authorities responsible for sanitary and phytosanitary regulatory measures, including risk management mechanisms during transport phase.
However, the fact that Articles 11 and 18.2 a) address LMOs destined for direct use as food or feed or for processing, implies this is an issue that affects and protects consumers' indirectly.

Therefore, under the first paragraph of Article 18, each Party shall adopt necessary measures to require that living modified organisms that are subject to intentional transboundary movements are handled, package and transported under conditions of safety, taking into account relevant international rules and standards.

Each Party shall:

- clearly identify living modified organisms that are intended for direct use as food or feed, or for processing, "that may contain" living modified organisms and are "not intended for intentional introduction into the environment", as well as a contact point for further information;
- the Conference of the Parties serving as the meeting of the Parties to this protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than a two year period;
- clearly identify living modified organisms that are destined for contained use, specifying any requirements for the safe handling, contact point for further information and data on the individual or institution whom the LMOs are consigned;
- identify living modified organisms intended for intentional introduction into the environment of the Party of import; identifying their identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and safe use; the contact point for further information; identification of the importer/exporter and declaration that the movement is in conformity with the requirement of this Protocol applicable to the exporter.

The shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport in consultation with other relevant international bodies (Article 18.3).

The first meeting of the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol (COP-MOP1) took place in Kuala Lumpur, Malaysia during February 2004. As a result of the meeting, a system for the identification, handling, packaging and transport of LMOs was established. According to the new

system, transporting LMOs destined for direct introduction to the environment such as seeds and fish should be clearly identified as "destined for confined use". The exporter should make the contact points for further information more explicit in case of any emergency, identifying the type of risk of LMOs and the way it should be used.

During handling and transport, the LMOs intended for direct use for food or feed, or for processing should be labelled with the common, scientific or commercial names of the organisms and with the transformation event code, equally identifying the type of risk they imply. Exporters should specify contact details and manner in which the LMOs should be used.

Among the issues that were not resolved at the COP-MOP-1, is the percentage or threshold of genetic material that might be considered to be determinant of a product as free of LMOs during transport and inclusion of additional documentation. Such matters were again object of discussions in the COP-MOP-2 celebrated in Montreal during 30 May- 3 June 2006 without reaching an agreement.[104]

6.4.3. Framework for transgenic foods and labelling in Peru

At present, the biosafety legal framework in force in Peru does not contemplate any provisions related to creating mechanisms to detect LMOs and their presence in foods, nor includes norms in relation to segregating conventional products, nor labelling of genetically modified foods. In relation to this, there are no requirements to label LMOs or LMO derived products with the objective of providing information for consumers. Furthermore, no mention to the institution with competences on LMOs is made nor are these issue included among the competences assigned to the Competent Sectorial Organisms.

Neither is reference made to specific norms regarding the identification of the transboundary movement of LMOs. The only requirement considered in this regard is Article 53 of the Regulation that provides "*the international transit of any LMO be carried out in closed and taped containers previously authorized by the corresponding Competent Sectorial Organism*".

There is no special consideration of labelling LMO products or LMO derived products or issues of segregation, in sectorial legislation. Chapter II of the *Regulation on Vigilance and Sanitary Control of Foods and Beverages*[105] (regulating the labelling of foods and beverages for commercialization), does not contain references to LMOs and only provides in Article 8, "*that the vigilance on matters of labelling and publicity of foods and beverages is in charge of the National Institute for the Protection of Competition and Intellectual Property (INDECOPI)".*

[104] The official report of the COP- MOP-1 is referred as UNEP/CBD/BS/COP-MOP/1/15. The official report of the COP-MOP-2 is referred as UNEP/CBD/BS/COP-MOP/2/15

[105] Decreto Supremo No. 007-98-SA approved the *Reglamento sobre Vigilancia y Control Sanitario de Alimentos y Bebidas*, published in the Official Gazette El Peruano, September 25th 1998.

It has been under the framework of INDECOPI that norms related to labelling products in general and for the treatment of LMOs and LMO derived products has taken place and where a *Technical Normalization Committee on LMOs Biosafety* (*Comite Tecnico de Normalizacion de Bioseguridad en OVMs*) has been created to develop technical norms for the commercialization of such products.

Legislative Decree 716, *Law for the Protection of Consumers*[106] establishes in Article 15, that the provider has the obligation to truthfully indicate all information on products and services "*destined for food and health of individuals, extending their obligation to inform on their ingredients and components*".

It also provides that "*all information or presentation misleading consumers in relation to their nature, origin, fabrication method, components, uses, volume, weight, measurements, prices, way of use, characteristics, properties, suitability, quantity, quality or any other data or services offered*" is prohibited.

Nevertheless, these norms respond to a general labelling policy and do not address specific features of labelling LMOs or LMO derived products. The new Law 28103 provides that all manufactured industrial products commercialized in Peru need to be labelled.[107] This Law entered into force on November 30th, 2004, but is silent in relation to LMOs. This may be due to the lack of understanding regarding the implications which a policy on labelling LMOs might have in the country in relation to capacities, costs and rights.

6.5. Consumers' in Peru

It is safe to argue that consumers in Peru have very limited capacities to exercise their rights in the light of these new emerging challenges.

At present, there are approximately ten organizations of consumers, the most important one named *Asociación Peruana de Consumidores y Usuarios* (ASPEC) largely present in the media and dedicated to consumer matters at the national level.[108] All associations are based in the capital, Lima.

The limited representation of consumer movements at the national level might be linked to the notion that consumers are persons living in industrial and urban societies. Thus, the consumer would be reflecting the affluence of money in society, continued consumption and development of market economies. In this sense, the

[106] Decreto Supremo 039-2000-ITINCI which approved the *Texto Unico Ordenado del Decreto Legislativo 716 Ley de Protección al Consumidor*, published in the Official Gazette El Peruano, December 11th,2000.

[107] *Ley No. 28103, Ley que establece la obligación de rotular los productos industriales manufacturados que son comercializados en el Perú.* Published in the Official Gazette El Peruano, November 21st, 2003. The entry into force was suspended until November 30th 2004.

[108] Nearly all reports before the Comisión de Protección al Consumidor have been presented by this Association.

term "consumer" would limit its scope to only one aspect (somewhat passive) of human life, mainly the ability to use money to consume good and services. This would imply an external dependency, where consumers have money to spend but are incapable of self-satisfying basic needs, relying on external agents.[109]

To this conception of consumer as a final component in the production-consumption chain, a Peruvian reality should be incorporated where individuals and their families are multifunctional in that they can intervene in different stages of the food chain, by growing, harvesting, processing and cooking the food they consume.

In this sense, in regards to consumers in Peru, it is necessary to observe the dynamics of consumption relations, in which some grey areas exist, with asymmetry of information issues addressed by consumer protection normative. However, this normative refers only to the last link of the chain or final consumer of products and services, but not to other individuals with equally weak positions in the food chain.

Some grey areas also exist, when the status of provider and consumer are simultaneously present. Under this situation of mixed uses, goods are used indistinctively for personal joy or to develop a commercial activity.

This has lead the concept of "consumers" to be widely extended in some cases to small and medium size companies conceptually pertaining to the category of providers, yet finding themselves in situations of final consumers, where the circumstance of asymmetry of information is verified .

However, in terms of the Law for the Protection of Consumers, providers who access or use goods for their own activities such as producing, extracting, industrializing or transforming intermediate or final goods are not considered consumers or users. Those adding products to the productive chain or an economical process or for the development of economical activities are excluded.[110]

This is a crucial issue as it implies that small farmers are excluded from protection mechanisms contemplated under the legislation on consumers, and therefore closing the path for them to defend their interests before the Commission for the Protection of Consumers *(Comision de Proteccion al Consumidor),* which depends of the National Institute for the Defense of Competence and Protection of Intellectual Property (INDECOPI). This circumstance may put small farmers in a disadvantage, not able to access such defense mechanisms, for example in the case of purchasing LMO seeds and in the case such seeds do not respond to the advantages offered by the seller. In these situations, farmers will find themselves in the need to claim compensation to the Judiciary, with the economical burdens and delays the Judiciary implies in the solutions of conflict.

[109] Tansey, Geoff and Worsley, Tony (1995) *The Food System. A Guide.* Earthscan Publications Limited, London.

[110] Espinoza, Juan (2003) "Sobre los alcances del concepto de consumidor". *Cuadernos Jurisprudenciales.* Numero 26. Agosto 2003. Gaceta Jurídica, Lima, Perú.

Among the rights recognized to consumers, Article 5 of the Law for the Protection of Consumers recognizes the following:

- the right to be efficiently protected against products and services which under normal or predictable conditions, represent a risk or danger to health or physical safety;
- the right to receive from providers all the necessary information to adopt a decision or choose based on adequate information;
- the right to access a variety of products and services; the right to be protected against restrictive commercial practices or those implying misinformation or the wrong information on products and services; and
- the right to the reparation of any damage or harm caused as a consequence of acquiring goods and services offered on the market or from their use and consumption.

Among the provider's obligations, the Law determines that they are responsible for the capability and quality of products and services, authenticity of their brands and legends they exhibit, variety of commercial publicity and content indicated on the packaging of the product (Article 8).

It also determines that products offered to consumers must not bear a risk which is not notified or is unjustified for consumers' health (Article 9). In the case of products which are subsequently detected to have risks which were anticipated, the provider is under the obligation of adopting reasonable measures to eliminate or reduce the risks, such as notifying the competent authorities, withdrawing the products from the market and informing consumers (Article 10).

As there is no explicit norm that requires for the labelling of LMOs or the obligation to inform on foods genetically modified, any accusation that could be made by the consumer in relation to a product containing LMOs, due to their allergenicity, for example, should be covered under Article 9 of the Law.

During the time the Law has been in force, there have been approximately 20 claims by consumer associations in relation to issue of food labelling. A claim must be made in writing, previously paying a fee of 32.00 Nuevos Soles (equivalent to US$10). The Resolution issued by the Commission for the Protection of Consumers may be the subject to an appeal before the Tribunal for the Defense of Competition and Intellectual Property (Competition Defense Section) of INDECOPI, prior to paying a fee of 320.00 Nuevos Soles (equivalent to US$100). All records are made public and copies may be obtained.

The Tribunal has evaluated cases involving lack of information and also labelling providing wrong information which may lead to errors. The Tribunal has declared its resolutions "*that providers are obliged to display all the relevant information for consumers to make the adequate decisions for consumption*".[111]

A problem observed on consumer protection provisions and vigilance and safety control of foods and beverages regulation (DS No.007-98-SA), is the absence of a detailed regime on sanctions and penalties which include corrective measures and those that imply some type of liability in favor of those affected.

To date, there is no law to protect consumers in the context of the Andean Community. The Andean Community could become an appropriate forum to address common issues by establishing a regional policy on biosafety and labelling.

[111] Resolution No. 0259-2004/TDC-INDECOPI. In this Resolution a beverage company is accused for not mentioning on the label that the beverage contained caffeine and the Tribunal determined "the characteristics of the beverage are erroneous, leading consumers to adopt a decision which might affect their interests".

VII. SOME REFLEXIONS ON LIABILITY

The Precautionary Principle responds to the need to adopt *ex ante* measures. The systems on liability try to respond to situations where the damage is occurring or has already occurred. *Ex ante* measures are those where regulatory mandates prescribe the obligation to prevent the damage. E*x post* measures on the other hand leave it to the producer of risks to find out, carrying out their own cost-benefit analysis which would be the most adequate conduct. This is similar to the *laissez faire* principle where the market is presumed to be the most appropriate means for distinguishing ways to avoid losses generated by a free market-.

Ex ante mechanisms imply more caution in the sense of avoiding possible risks beforehand, but as proposed by some authors, this may contribute to a greater regulation and "bureaucracy". In this sense, applying the Precautionary Principle would imply finding an expansion of *ex ante* measures and accepting the risks from creating a more rigid regulation instead of accepting costly future damages.

At the same time, the confidence in *ex ante* measures has increased as opposed to the weaknesses of *ex post* measures in a determined context. National and international regimes on liability are still subject to testing and considerable uncertainty.

Decision-makers are inclined to adopt *ex post* or subsequent solutions for the damage instead of choosing precaution policies, when the actor responsible for the damage may:

a) be identified
b) be easily denounced before the tribunals
c) prove his liability and
d) be forced to repair the damage through the legal system.

In the light of new risks modern biotechnology may imply, many of these elements are put into question. In these cases, the sources of risks have consequences that are becoming more extensive and permanent, not focalized on specific issues. There is an increasing interaction among different sources of risks and agents which create risks and damage, whose interconnection remains uncertain. This makes it difficult to prove who is responsible for the damage.

This difficulty increases when trying to identify the damaged party and refer to the common goods. At the same time, the issue becomes complicated among States when trying to define the competent jurisdiction in transboundary conflicts (imagine what would happen in the case of the Amazon). Finally, the issue would become unmanageable if the areas bearing the damage where common areas where the State or those damaged are not easily identified, as in the case of common pool resourcees. In these situations, to obtain an indemnification by the party who caused the damage is not guaranteed.

An additional issue refers to the failure of *ex post* measures to adequately respond to considerations of a distributive character. Certain situations exist where the damages may be impossible to compensate. Therefore, an option may be defended in the context of cost-benefit analysis even though this same option may imply damages not accounted for or which cannot be compensated, in which cases *ex ante* measures would have to be considered.

Likewise, all decisions imply winners and losers. In the past, in all technologies previously introduced, the owner and beneficiary of the technology was responsible for any adverse effects. This does not necessarily happen with decisions linked to modern biotechnology. Although a decision on the issue might benefit certain farmers who focus on intensive agriculture based on export commodities; this same decision might be harmful for other small farmers, Andean farmers or farmers dedicated to organic farming. In this case, given the circumstance under which damages may occur, it would be convenient to determine who will bear responsibility.

Finally, the issue is found to be linked to the capacity of response of the legal and administrative systems in the light of a demand to compensate and repair for the damage. This is linked to the effectiveness and cost of the administrative and legal procedures available.

The level of uncertainties leads to consider the need to adopt more precautionary attitudes. What can be concluded throughout this study is that the relation of precautionary policies with liability regimes could reflect a triple dimension. Firstly, the mere existence of a liability system can act as a prevention mechanism. This way, the establishment of a liability and redress regime will complement the biosafety regulatory regime, by increasing the security regarding products launched into the market. Secondly, the creation of a liability regime can be through a prevention mandate policy, that is, regulatory authorities can choose to admit a determined LMO activity but subject to liability conditions and redress measures (once the results of the risk assessments are considered). Finally, the more complete and effective the liability mechanisms are, so they offer guarantees for compensation by promoters of an activity, the more open and flexible the prevention policies will be.

7.1. In the context of the Cartagena Protocol on Biosafety

In the context of LMO transboundary movements, Article 8.2 of the CPB provides that "*the Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter*". This provision seems to indicate that the export Party is responsible for developing a framework of sanctions, when the exporter misinforms or produces erroneous information in relation to his products.

In relation to the definition of an international liability regime, Article 27 of the CPB related to liability and redress specifically addresses this issue. During the negotiations of the Cartagena Protocol, the issues on liability and redress gave way to various discussions between import and export countries, developed and developing: who is liable, what must be considered as damage, should the liability be objective or

conditioned to the negligence of those causing the damage, among others. Discrepancies gave way to Article 27 on liability and redress in the Protocol but with a merely compromising and enabling content, leaving for future negotiations the agreement of its substantive content.

Therefore Article 27 calls the first meeting of the Conference of Parties to this Protocol, to adopt a process in relation to international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of LMOs, setting a period of four years to complete this process taking due account of the ongoing international processes.

The COP-MOP 1 which took place in Kuala Lumpur established a working group on liability and redress to analyze and identify the boundaries which will be required in the design of international rules. The group considered among others, the issues on definition, nature, scope of damage, valuation of the damage to biodiversity and human health and analyzed how international regimes on liability matters can be applicable. The Group will have a report and proposal of a liability regime by the year 2008, when the next MOP will adopt a decision.

Nevertheless, there are various issues which must be resolved in the negotiation of the international liability regime, among these are:

- The concept of "damage" resulting from LMO transboundary movements. How should this concept be defined or valued. Due consideration should be given to whether it only refers to damage resulting from the transport from one point to another or to a wider context including all activities which fall under the scope of the Protocol as handling, transport, packaging and use of LMOs. Also what should be taken into account is whether it refers to damage caused to biological diversity, life and human health, to property, the environment or socio-economic damage.
- Determining who is responsible: to who is the liability for damage resulting from transboundary movements transferred. No doubt this is the key question for the regime. Different options exist to be considered: the exporting State; importing State, exporting company; importing company; person in the best position to prevent the damage; the person easily identified and financially capable of covering the damage.
- Who has the right to present claims from resulting damages?
- Type of liability: if any kind of liability is required, will it be objective or faulty; if the existence of a concrete result will be enough or the need to prove the negligence of those responsible.
- Circumstances to take into account for the exemption of liabilities: interference of third parties, etc.
- Temporary limits to liability: temporary jurisdiction where the claim can be filed.
- Monetary limits to the liability. In this sense, the obligation to impose financial guarantees and security mechanisms for companies involved in L M O

transboundary movements. Determination of the States liability. In short, definition of it main role and subsidiary role on liability.

7.2. National regime on liability[112]

The liability regime applicable would be that provided in different civil, legal and administrative regimes.

7.2.1. Administrative liability

As mentioned before, a sectorial administrative liability regime has not been developed in relation to the exercise of activities related to LMOs. Such a regime would need to be the subject of future regulations. However, the National Direction of Environmental Health (DIGESA) would be responsible for imposing penalties and sanctions related to LMO derived products destined for direct human consumption, including products derived from hydrobiological LMOs; the Vice Ministry of Fisheries of activities related to LMOs of hydrobiological origin, excluding derived products, and the National Institute of Extension and Agricultural Research (INIEA) of activities with LMOs related to plants and live animals and derived products and feed.

In the agricultural sector, there will be the need to coordinate with the existing liability regime on sanitary and phytosanitary measures established in order to prevent the introduction and dissemination of plagues and illnesses affecting the national agricultural production and those related to agricultural safety. The National Service for Agrarian Sanitation (SENASA) would be responsible for overseeing the imposition of penalties and sanctions.

The regimes established on consumer protection and environmental conservation matters should be added to these. In relation to the first, the Law for Consumers Protection establishes that the Commission for the Protection of Consumers is the competent administrative organ to acknowledge infractions and impose corresponding administrative sanctions. To this effect, there is the possibility of imposing an administrative sanction of up to a maximum of 100 Unidades Impositivas Tributarias (special units) (at present, 1UIT is equivalent to 3,200 New Soles) which could be added to corrective measures such as the confiscation and destruction of merchandise, temporal closure of an establishment, publication of informative or rectifying warnings, repositioning and repair of products, among others. Graduating such sanctions would be based on the seriousness of the fault, the resulting damage, benefits obtained by the provider, conduct of the transgressor during the procedure and any effect these may have on markets, among others (Seventh Title).

[112] The development of this paragraph is based on information contained in the Manual de Legislación Ambiental (Environmental Legislation Manual). SPDA. Lima, Peru. 2005.

Under environmental legislation, Article 136 of the Ley General del Ambiente (General Environmental Law)[113] develops a general regime of administrative sanctions from fines and activity prohibitions or restrictions, total or partial closures of establishments, confiscations, imposing compensatory obligations, suspension or cancellation of licenses, permits or concessions. In principle, these sanctions are to be applied by the sectorial authority to all violations of the rules contained in the Code and its provisions. If there is no competent authority to sanction, CONAM would be called to sanction instead.

Every person without restriction is legitimize to interpose before sectorial auhtorities a denounce against an administrative environmental infraction.

7.2.2. Civil liability

The extra-contractual civil responsibility seeks to legally respond to the need to identify those economically responsible for the damage that occurs from a given situation. In this respect, Article 1969 of the Peruvian Civil Code in force since 1984, provides that "*Someone who causes damage by fault or fraud to another person has the obligation to indemnify that person. The author bears the burden of providing absence of fault or guilt*". In this case, the economic burden from the damage falls upon the accused party, that is, for acting in an imprudent manner, with inexperience, negligently or with the intention to harm. If the damage is caused without intention, guilt or fault, there will not be the obligation to indemnify. However, proof of acting in a prudent and diligent manner falls on the perpetrator. Article 1969 of the Código Civil frees the victim from accrediting the fault or fraud but does not free him from the need to demonstrate the relation between the event which occurred and damage it caused.

Article 1970 establishes the obligation to repair the damage caused by a dangerous or riskful action or from exercising a dangerous activity. This theory is based on the principle that if a person knowingly benefits from the development of a riskful activity or from the use of goods equally riskful and dangerous, he should assume the costs from the harm caused.

Most of the time victims do not turn to this type of option, making civil indemnification in Peru, more theoretical than practical. Among others, the following can be emphasized:

a) indemnities set by judges and tribunals do not relate to the value of the goods damaged.
b) the responsibilities from damages are usually associated to those related to life, the body and person; in a lesser degree to the heritage of people and even lesser degree to health and aspects related to the environment.
c) a market of insurances on liability by third parties has not been developed and, as a consequence, the social demand for insurances directed towards creating the need to include the environment as an interest to be secured does not exist.

[113] Law No. 28611 published in the Official Gazette El Peruano, October 15th, 2005..

d) trials are too long and costly for the majority of people and the service of lawyers.
e) there is little knowledge on techniques to quantify the indirect services offered by natural resources to determine the compensatory and indemnity amounts.

7.2.3. Criminal liability

The problem here is that penal liability of legal entities is not recognized. However, in the case of LMO related offenses, legal entities would be identified as generally committing these. Article 105 of the Código Penal (Penal Code) -Decreto Legislativo 635, of April 8th 1991- includes references to "accessory consequences applicable to legal entities" in cases where the damage is committed during the exercise of an activity by a legal entity or using their organization to favor themselves or as a cover up.

Penalties included in the Article 105 are:

a) temporary or definitive closure of the establishment or premises.
b) liquidation of the society, association, foundation, cooperative or committee.
c) suspending activities of the society, association, foundation, cooperative or committee for no longer than two years.
d) prohibiting activities by a society, foundation, association, cooperative or committees who have carried these out by committing, favoring or covering up an offense. In these cases, the ban may be definite or temporary not exceeding five years. When one of these measures is applied, the judge will order the competent authority to intervene the legal entity in order to safeguard workers rights. On the other hand one must take into account rules contained in the *Capítulo Unico* of Title XIII of the Criminal Code on crimes against natural resources and the environment. Related to this, Article 305 imposes a prison penalty of no more than four years and less than two years and three hundred and sixty five to seven hundred and thirty penalty-days when the damage or alternation occurred acquires a catastrophic character; when the agent has carried out the activity secretly or when the contaminating action seriously affects natural resources which are the basis of the economical activities.

At the same time, Article 306 establishes liability of the public official who grants a license to operate any industrial activity or who favors the granting of the license to operate without observing the requirements of the rules and regulations on environmental protection. As seen previously, normative prescriptions on responsibility do exist in national legislation in relation to products put on the markets by companies.

Various complex issues emerge under the definition of liability in the case of transgenic foods. As an example, one should ask if a person who has suffered from an allergy due to the consumption of LMOs, could file a demand and follow the same process assuming the intoxication was from any other product. Under what criteria would responsibility be set: would there need to be the existence of negligence in order to declare a responsibility or would an objective responsibility be enough?

Could a company be made responsible from the lack of information and warnings on labels? Who would be responsible: the company or public entity that authorized the product after proving there were no existing risks? On whom would the burden of proof fall: should the consumer prove the relationship by chance or is it the company who should demonstrate that the cause-effect relationship does not exist?.

There is even more difficulty to identify those responsible in the case of existing genetic contamination. Given the case, would it be possible to make the companies who sold LMO seeds responsible from the events of gene flow?[114] Or would the farmers who use those seeds be responsible?.

[114] For an analysis on what meant to the Aventis Company the issue of costs of civil liability in the case on genetic contamination of StarLink corn in USA in 2000, consult Donald Uchtmann, *Symposium: Liability Issues: Lessons From Starlink*, 10 RICH. J.I. & TECH.22(2003), See: http://law.richmond.edu/jolt/v10i2/article22pdf.

VIII. CONCLUSIONS

1. The potential biotechnology offers for the world of agriculture and food is commonly accepted. There are many benefits which will appear in the future with the development of modern biotechnology applied to improving the nutritional quality of products and creating new seed varieties. Nevertheless, the existence of risks this may imply on human health and the environment and need to develop parallel biosafety mechanisms is equally recognized. There is little disagreement over the development of this technology implying risks and that science should progress towards a better understanding of this issue in the future. Therefore, the argument proposed by FAO which provides that modern biotechnology may be a strong instrument when integrated with other technologies, is used to resolve concrete problems, is accessible for those who must use them and is accompanied by a biosafety system is again being confirmed.

2. The mission of regulatory public authorities is to avoid damage which emerges from modern biotechnology. This objective comes from the liberal objective that the State is the only entity legitimized to restrict individual freedom, including the freedom to use or sell a new technology, if the actions of a determined individual may damage third parties. Putting this principle into practice may be complicated in the face of situations where it might not be possible to predict exactly what type of risks are faced, the type of damage and to whom.

3. There is equally a general consensus in the sense that carrying out risk assessments based on solid scientific evidence, is the only objective method to determine their probability and magnitude and their impacts on the health of the communities and the environment. Nevertheless, the existence of other economic and social interests, priorities of society, that are not normally included in risk assessments and which should equally be incorporated in the decision-making process, are also an aspect to consider. Thus, science can and should inform the decision-making processes but not take possession of them.

4. In this sense, it is critical when adopting decisions, to take into account concrete social and economic realities where new technologies are to be applied. In Peru for example, it would be critical to study the effects from the development of modern biotechnology on the vulnerability of small farmers; its influence on subsisting economies, on agro-biodiversity and rural economy in general. And these could eventually implicate an increase of risks, putting farmers under a long term disadvantage. In this social evaluation, the final addressees should be asked about their acceptance of the risks new technologies may implicate and balance them to compare their potential benefits. There would be the need to establish the necessary participation and consultation mechanisms, to focus such issues as close as possible to the users of these technologies and consider their degree of autonomy in this respect. It is equally important to study how new technologies will affect traditional knowledge and practices of peasant

communities, and how the necessary correlative education and training for its management will be accounted for.

5. At this respect, we are attending to two parallel processes taking place. On one hand, new technologies will depend in the future on their acceptability by consumers and users. On the other hand, the desire of these stakeholders does not define to date, the modern biotechnology research agendas nor the policies and regulations which, in the end, are destined to affect them.

6. Furthermore, relevant changes are taking place along the food chain which have given way for new actors with a role in the management of markets and information. These actors are not the farmers or consumers, but those located in the centre of the agricultural and food research, food processors, manufacturers, distribution agents and intermediaries, among others. The developments in biotechnology are added to this dynamic which makes consumers to become disconnected and distant from the centres adopting food related decisions. Lately, these have contributed to deepening an asymmetry of information situation. The result is a situation in which the consumer finds it very difficult to exercise his autonomy when adopting food related decisions.

7. To the classic rights of citizens to health and food safety, new rights in their condition of consumers are being the subject of defense: the right to be informed of products consumed and choose among possible alternatives, attending to a multiplicity of interests of individual, economical, cultural, environmental and social character. Respecting this autonomy translates into opening a wider spectrum of public debate on biotechnology, considering the questions asked by society in the light of these, taking into account their priorities and values. It also implies the provision of enough information to allow consumers to decide which action is best for their lifestyle.

8. The Precautionary Principle implies making consumers participate in policies and decision-making on modern biotechnology and biosafety; the right to obtain information and right to choose among available alternatives. Equally, the application of such a principle means that the promoters of such technologies will have to provide any information and bear its economic costs. Respecting this autonomy will depend on the acceptability and social success of new technologies and confidence in the regulatory institutions in the future.

9. On the other hand, it is essential to guarantee such autonomy through the design of an adequate liability system. Therefore, this issue should be linked to others which indirectly refer to the debate on the acceptability of modern biotechnology. New study areas such as the impact of unfair competition laws to prevent monopolistic practices in the seed and agricultural biotechnology sectors, as well as the clarification of issues on responsibility and compensation for damages, should be the subject of research.

Thus, there should be a better understanding of the corporative responsibilities - as the addressees of biosafety regulations will be the companies themselves- and, in parallel, identify the responsibilities of public authorities and final users.

10. The acceptance of modern biotechnology should also be understood in an institutional context. It is fundamental for this decision to be followed by national capacities accompanying such technologies in terms of education, research, regulatory capacity to ensure environmental and sanitary safety for consumers, a regulatory system to govern the import and development of LMO activities and their control and monitoring.

11. At present, the decision-making capacity at the policy and regulatory levels in Peru is limited, on one hand due to the need to implement the Cartagena Protocol requirements and, on the other hand, to the imperative to comply with obligations and commitments of the country in the World Trade Organization and in the context of bilateral trade agreements. The *freedom to operate* is confined to the parameters determined by such forums.

12. In terms of regulations, Peru is still far from having the infrastructure, budget and personnel to establish a biosafety framework, which supports an integrated evaluation and risk management system. It is therefore urgent to strengthen local scientific capacity in relation to LMOs, enhance human resources and infrastructure and develop communication, information and public consultation mechanisms. Although there is a positive national attitude towards developing a biosafety normative framework, this cannot induce citizens to believe that such technologies are being applied with guarantees and under secure conditions in the country. The mere existence of a normative does not necessarily mean there is a political determination to implement it. Such legislation should be accompanied by resources and mechanisms necessary for it to become effective in practice. Otherwise, the biosafety system in the country will simply be an empty eggshell.

BIBLIOGRAPHY

Abouchar, Juli Teh, Precautionary Principle in Canada: The First Decade. 32 *Environmental Law Report* 11407.

Audley, John J. *et al.*(2003) *La Promesa y la Realidad del TLCAN, lecciones de México para el hemisferio.* Canergie Endowment for International Peace. 2003.

Boutilon, Sonia (2002) "The Precautionary Principle: Development of an International Standard*".* In: *Michigan Journal of International Law*. Winter 2002. University of Michigan Law School. 2002.

Burgiel, Stas and Aaron Cosby (2000) "The Cartagena Protocol an Biosafety: An analysis of results". In: *IISD Briefing Note*. IISD Alberta. 2000.

Commission of the European Communities.(2000) *Communication from the Commission on the precautionary principle*. Brussels.02.02.2000. COM (2000) 1.

Defensoría del Pueblo (2003) *El Acceso a la Información Pública. No a la cultura del secreto*. Defensoría del Pueblo. Lima. Peru. 2003

EFB Task Group on Public Perceptions of Biotechnology (1999) *Ethical Aspects of Agricultural Biotechnology.* Cambridge Biomedical Consultants. The Hague. Netherlands. 1999. www.agbios.com

Espinoza, Juan (2003) "Sobre los alcances del concepto de consumidor". En *Cuadernos Jurisprudenciales*. No. 26. Agosto 2003.Gaceta Jurídica. Lima, Peru. 2003

Fernandez-Northcote (2004) Progresos realizados en el MNB-PERU. Proyecto CONAM/UNEP-GEF (GFL/2716-02-4577).

Flores, Salvador (2003) "Potenciales de la agrobiodiversidad en el Perú". En: *El Medio Ambiente en el Perú Año 2002*. Instituto Cuanto. Lima, Peru. 2003.

Food and Ethics Council (2003) *Engineering Nutrition. GM crops for global justice?* www.foodethicscouncil.org

Glover, Dominic (2003) "Public Participation in national biotechnology policy and biosafety regulation". *IDS Working Paper* 198 www.ids.ac.uk

Gupta, Aarti (2001) Advance Informed Agreement: A Shared basis for governing trade in genetically Modified Organisms?. In: Indiana Journal of Global Legal Studies. 2001.

Hart, Kathleen (2003) Symposium: Remarks on Regulating Genetically Modified Foods: Is Mandatory Labelling the Answer?, 10 *Richmond Journal Law & Technology*. 6 (2003).

Hoban, Thomas (2004) "Public Attitudes towards Agricultural Biotechnology". *ESA Working Paper* No. 04-09. May 2004. Agricultural and Development Economics Division. FAO

Katz, Deborah (2001) "The Mismatch between the Biosafety Protocol and the Precautionary Principle". *Georgetown International Environmental Law Review*. Summer, 2001. Georgetown University.

Kirby, Sarah (2001) "Genetically Modified Foods: More Reasons to Label Than Not". In: *Drake Journal of Agricultural law*. Fall 2001.

Kriebel, D. *et al.* (2001) "The Precautionary Principle in Environmental Science" In: 109 *Environmental Health Perspectives.*

Mackenzie, Ruth and Peter Netwell, (2004) "Globalisation and the international governance of modern biotechnology: promoting food security?". In: *Globalisation and poverty*. April 2004.

Marris, Claire (2003) *Issues Concerning Public Awareness and Attitudes Towards Genetically Modified Bananas and Tropical Fruits*. Third Session of the FAO Intergovernmental Group on Bananas and on Tropical Fruits. Spain. December 2003.

Maxwell, S. and R. Slater (2003) "Food Policy Old and New". In *Odi Briefing Paper*. November 2003.

McGivern, Brendan (2004) "No Change of Heart on the Precautionary Principle: The WTO´Apples Dispute". In: *Bridges*. ICTSD. Year 8. No.2. February 2004.

O'Brien, Mary (2000) Making better environmental decisions: An alternative to risk assessment. *MIT Press*. Cambridge. 2000.

Pew Initiative on Food and Biotechnology. (2004) *Feeding the world. A look at biotechnology and world hunger*. Pew Initiative on Food and Biotechnology. March 2004.

PNUD (2002) *Informe sobre Desarrollo Humano. Perú 2002. Aprovechando las potencialidades*. PNUD-PERU, Lima, Peru. 2002.

Scott, Dayna Nadine (2003) *Shifting the Burden of Proof: The Precautionary Principle and its Potential for the "Democratization" of Risk*. Doctoral Candidate, Osgoode Hall Law School. Law Commission of Canada. Legal Dimensions Initiative.

Secretariat of the International Plant Protection Convention. FAO International Standards for Phytosanitary Measures. *Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms* ISPM No. 11, Roma, April 2004.

Shallat, Lezak (2000), *¿Los alimentos transgénicos en boca de todos?* Consumers International. Oficina Regional para America Latina y el Caribe.

Snow, A. A. *et al.* (2004) ESA Position Paper submitted to the ESA Governing Board. ESA Public Affairs Office. February, 2004.

SPDA (2005) *Manual de Legislación Ambiental*. SPDA. Lima, Peru. 2005.

Stone, Christopher (2001) "Is There a Precautionary Principle?". In: *Environmental Law Reporter*. Volume Year XXXI. July 2001.

Tansey, Geoff and Tony Worsley (1995) *The Food System. A Guide*. Earthscan Publications Limited. London. UK. 1995.

The Precautionary Principle in Wildlife Conservation. Summary of the workshop on "The Precautionary Principle in Wildlife Conservation "Lauterpacht International Law Centre University of Cambridge 6-7 July 2000. Africa Resources Trust, IUCN/SSC Wildlife Trade Programme, IUCN Environmental Law Centre, and TRAFFIC International.www.traffic.org/briefings/precautionary.html.

Uchtmann, Donald (2003) *Symposium: Liability Issues: Lessons From Starlink*, 10 RICH. J.L. & TECH. 22 (2003). http://law.richmond.edu/jolt/v10i2/article22.pdf.

Vásquez, Enrique and Diego Winkelried, Diego (Eds.) (2003), *Buscando el bienestar de los pobres. ¿Cuán lejos estamos?*. Universidad del Pacífico. Centro de Investigación. Lima, Perú. 2003.

Valdivia, Martin and Miguel Robles (2002), "Alternativas para la pequeña agricultura en el Perú". In *Análisis y Propuestas. Contribuciones al debate sobre políticas públicas*. No. 5. Enero 2002. www.grade.org.pe

Wakeford, Tom and Michel Pimbert (2003) "Power-Reversals in Biotechnology: Experiments in Democratization" *Democratising Biotechnology: Genetically Modified Crops in Developing Countries. Briefing Series*. Briefing 13, Brighton, UK: Institute of Development Studies.

Zaid A. et al. (2001) *Glossary of Biotechnology for Food and Agriculture. A revised and augmented edition of the Glossary of biotechnology and genetic engineering*. FAO Research and Technology Paper. Rome, Italy. 2001 http://www.fao.org/biotech/find-formalpha-n.asp