The Moratorium on the entry of LMOs to Peru: analyzing how the government decided to defend our biodiversity

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Abstract

For a long time living modified organisms (LMOs) have been a source of concern and debate by governments, the industrial sector and consumers. As one of the most biologically diverse countries, Peru has not been a stranger to these problems, and the approach of this country has been through the establishment of a moratorium on certain uses of LMOs.

This research studies the aforementioned moratorium in order to determine whether the measure is consistent with the legal framework on biodiversity, especially with the Convention on Biological Diversity (CBD) and the Cartagena Protocol.

To this purpose we explain the characteristics of the moratorium in Peru, the arguments used to justify it and then analyze the moratorium based on the CBD and the Cartagena Protocol, particularly in relation to the precautionary principle. Furthermore, we investigate the progress that the Peruvian government has made so far in implementing the moratorium.

Finally, although the research is focused on Peru, the analysis of the successes, failures and observed risks is important for any country wishing to protect its biodiversity.

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The Moratorium on the entry of LMOs to Peru: analyzing how the government decided to defend our biodiversity¹

Introduction

On April 15, 2011 the government of Peru published the Supreme Decree No. 003-2011/AG – Biosafety Regulations on Development of Activities with Living Modified Organisms (LMOs) in the Agricultural or Forestry Sector and for Products Derived from LMOs in the Agricultural Sector. This regulation caused a fierce debate among different political parties and the gastronomic and industrial sectors since it was unknown how the entrance of transgenic products to Peru could affect both health and agriculture.

Due to those events, on December 9, 2011, Peru published the Law No. 29811, under which Supreme Decree No. 003-2011/AG was repealed. This Decree imposed a 10-year moratorium on the entry to Peru and production of genetically modified organisms to be released into the environment for breeding and cultivation purposes. This law was the result of strong pressure from the Peruvian media and the food sector to protect Peruvian biodiversity, while representatives of the industrial sector defended the use of transgenic seeds.

Therefore, the most important question that deserves a response is: Is this moratorium law consistent with the legal framework on biodiversity protection?

In this regard, we begin this article by describing the Peruvian Legal Framework of Biosafety, then we explain the rules that govern the moratorium, we analyze the arguments that were used to justify the moratorium, and later on we explore the moratorium and its relation to the precautionary principle in the CBD and the Cartagena Protocol. The article concludes with a brief review of the moratorium and the possibility that this is a barrier to trade.

I. The Peruvian International Legal Framework of Biosafety

While we recognize that many international instruments address directly or indirectly the issue of biosafety, we will focus on describing two of the most important and relevant to the investigation, the Convention on Biological Diversity and the Cartagena Protocol on Biosafety.

A) <u>The Convention on Biological Diversity</u>

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In November 1988, the United Nations Environment Programme (UNEP) convened the Ad Hoc Working Group of Experts on Biological Diversity to explore the need for an international convention on biological diversity. In May 1989, it established the Ad Hoc Working Group of Technical and Legal Experts to prepare an international legal instrument for the conservation and sustainable use of biological diversity. Its work culminated on 22 May 1992 with the Nairobi Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity (CBD). The Convention was opened for signature on 5 June 1992 at the United Nations Conference on Environment and Development (the Rio "Earth Summit"). The Convention entered into force on 29 December 1993, which was 90 days after the 30th ratification².

As can be seen in the objectives of the article 1, the Convention on Biological Diversity (CDB) is an international treaty that promotes the use of natural resources considering conservation, sustainability and equitable sharing of the benefits arising from their use.

"Article 1. Objectives

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding."

The importance of the Convention on Biological Diversity lies in the identification of probable adverse effects on health and the environment due to modern biotechnology, since it considers, for the first time, the sovereign right of States over their biological resources to exploit these under the regulations of their environmental policies.

"Article 3. Principle

States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction."

The Convention defines biological diversity as the variability between living organisms from any sources including, among others, terrestrial, marine and other aquatic ecosystems and the ecological complexes they are part of. Biological diversity also includes variability in and among species and ecosystems.

² Source: Convention on Biological Diversity. "History of the Convention" <u>http://www.cbd.int/history/default.shtml (15/04/2014)</u>

"Article 2. Use of Terms

For the purposes of this Convention:

Biological diversity means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems

(...)"

It should be noted that two important articles of this agreement, because they relate to the research, are Article 6 and Article 10, about general measures for conservation, and the sustainable use of components of Biological Diversity.

"Article 6. General Measures for Conservation and Sustainable Use

Each Contracting Party shall, in accordance with its particular conditions and capabilities:

(a) Develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity or adapt for this purpose existing strategies, plans or programmes which shall reflect, inter alia, the measures set out in this Convention relevant to the Contracting Party concerned; and

(b) Integrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies".

"Article 10. Sustainable Use of Components of Biological Diversity

Each Contracting Party shall, as far as possible and as appropriate:

(a) Integrate consideration of the conservation and sustainable use of biological resources into national decision-making;

(b) Adopt measures relating to the use of biological resources to avoid or minimize adverse impacts on biological diversity;

(c) Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements;

(d) Support local populations to develop and implement remedial action in degraded areas where biological diversity has been reduced; and

(e) Encourage cooperation between its governmental authorities and its private sector in developing methods for sustainable use of biological resources."

Finally, it is worth mentioning that Signatory Governments to the CBD are required to develop national strategies and action plans based on decisions taken by the Conference of the Parties (COP) and report back on implementation (Peru is a member of the Convention on Biological Diversity since 1993).

B) The Cartagena Protocol on Biosafety

Due to the complexity of modern biotechnology, the CDB stated the need to arrive at a future agreement on biosafety³. As a result, on 29 January 2000, the Conference of the Parties to the Convention on Biological Diversity adopted a supplementary agreement to the Convention known as the Cartagena Protocol on Biosafety (CPB)⁴. The CPB entered into force on 11 September 2003 and it was ratified by Peru in February 2004.

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international treaty governing the movements of living modified organisms (LMOs) resulting from modern biotechnology from one country to another, in other words, it defines the international rules countries will use to trade in these products.

"Article 1. Objective

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".

As can be seen, the Protocol contains reference to a precautionary approach and reaffirms the precaution language in Principle 15 of the Rio Declaration on Environment and Development⁵, which we will discuss later.

³ "Article 28. Adoption of Protocols

^{1.} The Contracting Parties shall cooperate in the formulation and adoption of protocols to this Convention.

^{2.} Protocols shall be adopted at a meeting of the Conference of the Parties.

^{3.} The text of any proposed protocol shall be communicated to the Contracting Parties by the Secretariat at least six months before such a meeting."

⁴ Source: Convention on Biological Diversity. "The Cartagena Protocol" <u>http://bch.cbd.int/protocol/background/ (11/03/2014)</u>

Like most treaties, the CPB establishes general rules as minimum requirements, focusing on transboundary movement of LMOs. The national legislation shall define the development of tools and the abilities to manage LMOs within their territories, as well as the creation of necessary institutional infrastructure. Therefore, the national measures to protect conservation, sustainability and the use of biological diversity may be stricter than the Protocol measures.

"Article 2 General Provisions

1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.

2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

3. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.

4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.

5. The Parties are encouraged to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health."

The CPB sets certain procedures to assess LMOs. It is necessary to create an Advanced Informed Agreement (AIA) and a Risk Assessment before such movement is made since possible risks of LMOs are not defined. The Protocol also contains provisions on Risk Management.

The Advanced Informed Agreement is a previous assessment of the Party of import to determine if a specific level of risk will be assumed from the information previously obtained. The imported product assessment will be made prior to the

⁵ The Rio Declaration: Principle 15 - the Precautionary Approach.

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

first transboundary movement of LMOs, and the decision about the product shall be made after a Risk Assessment.

The Risk Assessment establishes possible adverse effects on the conservation and sustainable use of biological diversity and adverse effects on human health, including the possibility of their occurrence and consequences.

"Article 7 Application of the Advance Informed Agreement Procedure

1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.

(...)

4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health."

"Article 15. Risk Assessment

1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

2. 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.

3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires."

"Article 16 Risk Management

1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.

2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.

3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.

4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its lifecycle or generation time before it is put to its intended use.

5. Parties shall cooperate with a view to:

(a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits."

Based on the Advanced Information Agreement and the Risk Assessment, a definite decision will be made on a total or conditioned approval of the LMO importation, or its prohibition. Furthermore, extra information or a longer term may be requested to make a decision.

LMOs are not judged equally in the Advanced Informed Agreement and Risk Assessment as it depends on the LMO uses, which may be, according to the CPB:

- <u>Intentional introduction into the environment</u>: the Advanced Informed Agreement shall apply prior to the first transboundary movement.
- <u>Direct use as food or feed or for processing</u>: each Party may make a prior decision regarding specific LMOs.
- <u>Contained use</u>: they are exempted of the AIA, provided that their contained use complies with national regulations.

Finally, the Protocol establishes a Biosafety Clearing-House to facilitate the exchange of information on LMOs and to assist countries in the implementation of the Protocol.

II. The Peruvian National Legal Framework of Biosafety

Contrary to what some may think, Peru has had a biosafety regimen for many years; however, we acknowledge its implementation and development have not been very successful.

A) <u>The Law 27104 and its Regulations: Prevention of Risks derived from</u> <u>Modern Biotechnology</u>

The Law 27104 on Prevention of Risks derived from the Use of Biotechnology was enacted in Peru in April 1999, prior to the Cartagena Protocol. This Law has a Regulation approved by Supreme Decree No. 108-2002-PCM of 2002.

These national rules regulate activities including research, production, introduction, handling, transport, storage, conservation, interchange, commercialization, contained use, and release of LMOs under controlled conditions. Furthermore, these regulations define the *Organismos Competentes Sectoriales* – OSC (Competent Sector Agencies) in our country. These agencies are in charge of elaborating sector regulations to establish mechanisms and procedures for LMO treatment in their applicable sectors:

- Agricultural sector: Instituto Nacional de Investigación Agraria INIA (National Agricultural Research Institute)
- Production sector: Vice-president of Fisheries of the *Ministerio de la Producción* (Ministry of Production).
- Health sector: *Dirección General de Salud Ambiental DIGESA* (General Bureau of Environmental Health)
- For its part, the *Ministerio de Ambiente* (Ministry of the Environment) is the inter-sectoral coordination institution in charge of the conservation and sustainable use of biological diversity.

Note that Law 27104 and its Regulations set the characteristics the risk assessment shall have: it must follow the AIA's procedures; the analysis of each case must be made separately and be based on information provided by the requestor, and the assessment shall be based on the precautionary principle.

This Law and its Regulation also point out that when the use of an LMO has been regulated or rejected by the competent authorities in a country, the request will be flatly denied, that is, its utilization will be prohibited within our country. LMOs that have not been approved in a different country will not be admitted because their use may imply a risk.

However, contrary to Cartagena Protocol's provisions, procedure differences for the end uses of LMOs have not been established.

B) The Supreme Decree 003-2011/AG

On April 15, 2011, the government of Peru published Supreme Decree No. 003-2011/AG – Biosafety Regulations on Development of Activities with Living Modified Organisms (LMOs) in the Agricultural or Forestry Sector and for Products Derived from LMOs in the Agricultural Sector. This rule included sector regulations that

established administrative procedures to allow those interested in activities with LMOs, in the agricultural or forestry sector, to submit applications and obtain the applicable licenses.

The Supreme Decree caused a broad reaction in the media, since it was seen as a mechanism of LMO free entrance to our country. After a long debate in the Congress, said Decree was repealed by Law 29811, which sets a moratorium of ten years on releasing LMOs into the environment for cultivation or breeding purposes.

Is it true that this Decree allowed LMOs to enter our country without any measures, assessment, or technical procedures? Even though the said Decree was not perfect, limitations set by Law 27104 regarding rejected, regulated or not proven LMOs in other countries prevented the free entry of these products into our country. This limitation stated that the applicant shall notify any application for the use of an LMO submitted abroad as well as the stage of said application or applications, specifying if they are in process or have been regulated or rejected.

Without prejudice to the foregoing, note that the repealed Supreme Decree 003-2011/AG did not include agricultural diversification and source areas that are currently considered in Law 29811; neither did it specify the validity period of registries of genetically modified products.

III. Provisions of Law 29811 and its Regulation on the Moratorium

This Law aims at national capacity improvement, infrastructure development and generating baselines for native biodiversity to allow an appropriate assessment of LMO release activities on the environment. It should be noted that, as per these Regulations, an LMO is any living organism having a new combination of genetic material obtained from the use of modern biotechnology⁶.

Additionally, the Regulation established that the baselines are systematized and analyzed information showing the current situation of native biodiversity (including genetic biodiversity of native species) that may be affected by LMOs and their use. The baseline generated will consider native species as a priority, then naturalized species and, finally, new alien species or those recently introduced.

The Law sets out that the minimum information contained in the baselines shall consist in lists and distribution maps of:

a) LMOs in international business;

⁶ The Regulations of Law 29811 states that modern biotechnology refers to in-vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cell and organelles; or fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and does not include techniques used in traditional breeding and selection.

- b) Native varieties and local breeds having LMO forms in the market, including related wild species;
- c) Crops and breeds having genetically modified forms in the market;
- d) Fungi and soil bacteria from breeding grounds that may be affected by the use of herbicides, fungicides and other chemicals;
- e) Insects as pests (target) and not as pests (no target), especially lepidoptera and coleoptera, related to crops with LMO forms in the market;
- f) Forest species potentially affected by introduced LMOs;
- g) Native fish and other hydrobiological species that may be displaced by genetically modified fish or affected by the excessive use of herbicides, fungicides and other chemicals;
- h) Rural lands with organic certification;
- i) Areas with high levels of agrodiversity; and
- j) Areas with wild relatives of cultivated species that may be affected by LMOs.

In light of this, what the Law 29811 specifically states is that Living Modified Organisms (LMOs) cannot enter Peru or be produced for agricultural⁷ or breeding⁸ purposes for 10 years so they cannot be released into the environment. Under the Regulations of this Law, releasing into the environment means an intentional or accidental introduction of an LMO to an external environment.

The law states that the following are excluded from the moratorium:

 LMOs for research purposes, provided that they are used in contained spaces such as buildings or facilities where LMOs are handled and controlled by specific measures that effectively limit their contact with the environment and their impact on the medium.

⁷ The Regulations define cultivation as the provision of necessary conditions and caring to ex situ wild or cultivated plants as a means of goods or services to satisfy human need. Cultivation includes each lifecycle stage and takes into account the plant's manipulation, fertilization and health, and, if necessary, their selection, cross-breeding and propagation. Cultivation may be carried out intensively or extensively in open or close spaces located in natural or artificial environments and may gather two or more species in the same area.

⁸ The Regulations define breeding as the provision of necessary conditions and care to tame or keep wild animals as a means of goods and services to satisfy human needs. Breeding includes each lifecycle stage and the animal's manipulation, feed, health, and, if necessary, selection, mating and reproduction. Breeding may be carried out intensively, semi-extensively, or extensively in open or close spaces located in natural or artificial environments and may gather two or more species (mixed breeding) in the same area.

- LMOs used as pharmaceuticals or veterinary products subject to International Treaties of which Peru is part and to special laws.
- LMOs or their imported by-products intended for direct use as food or feed or for processing.

Living Modified Organisms excluded from this moratorium shall be subject to risk analyses previous to use authorization and the application of measures for risk assessment, management, and communication. Note that, under no circumstances c a n the authorized use be replaced by agricultural or breeding use.

All genetic material entering the national territory, except that included in the exceptions to the moratorium, shall provide evidence that it is not an LMO. If the analyzed material turns out to be an LMO, the competent authority shall seize and destroy such material and impose applicable sanctions (fines).

One of the main authorities is the *Ministerio del Ambiente* (Ministry of the Environment)⁹ according to Law 29811, which is responsible for capacity building to fulfill the biosafety requirements and the mechanisms for protecting and promoting native biodiversity. In particular, it is in charge of generating baselines about biodiversity potentially affected by the LMO release as well as determining the environmental land use planning to ensure the preservation of biodiversity.

Finally, the Ministry is also responsible for overseeing and implementing centers of origin and diversification and, in coordination with the *Consejo Nacional de Ciencia, Tecnología e Innovación Tecnológica – Concytec* (National Council for Science, Technology, and Technological Innovation)¹⁰, is responsible for promoting capacity-building in science and technology at the national institutions in charge of disseminating the techniques used by modern biotechnology and biosafety in view of contributing to the suppliers' and consumers' decision-making with regard to LMOs, and promoting biotechnology based on native genetic resources to achieve its conservation and competitive development.

The other main authority regarding LMOs is the *Comisión Multisectorial de Asesoramiento* (Multi-sectoral Advisory Commission), created under Law 29811. This Commission is in charge of the capacity building and instrument development to enable the appropriate management of modern biotechnology, biosafety, and bioethics, elaborating technical sheets and proposals. This Commission is

⁹ The Ministry of the Environment belongs to the Cabinet of Peru, created on May 14, 2008 as the administrative authority of the national environmental sector, which is managed at local, regional and national government levels. Source: <u>http://www.minam.gob.pe/english/html/index.html</u> (01/02/2013)

¹⁰ CONCYTEC is the entity responsible for directing, promoting, coordinating, monitoring and evaluating the actions of the State in the science, technology and technological innovation fields. It is part of the *Presidencia del Consejo de Ministros* (Office of the President of the Council of Ministers). Source: <u>http://portal.concytec.gob.pe/index.php/concytec/quienes-somos/vision-y-mision.html</u>(05/02/2013)

composed of several Ministries as well as technical agencies and representatives of private organizations¹¹.

Other important institutions in charge of monitoring and implementing policies for the conservation of centers of origin as well as controlling cross-border trade are: *Ministerio de Agricultura* (Ministry of Agriculture)¹², *Ministerio de Salud* (Ministry of Health)13, *Ministerio de la Producción* (Ministry of Production)¹⁴, *Ministerio Público* (Office of the Attorney General)¹⁵, and Regional and Local Governments¹⁶. According to the Regulations, center of origin means the geographical area where a cultivated or wild species obtains its first distinctive characteristics and shares its distribution range with other closely related species. Center of diversification is also mentioned; this is a geographical area with great in situ genetic diversity (intraspecific and interspecific diversity).

To comply with the aims of Law 29811, the Regulations have set the creation of several Special Programs and Projects, specifically:

 Program for the Knowledge and Conservation of Native Genetic Resources with Biosafety purposes: This generates baselines regarding native biodiversity

¹² The Ministry of Agriculture is a ministry of the Cabinet of Peru, in charge of the agricultural sector. Source: <u>http://www.minag.gob.pe/portal/(10/02/2013)</u>

¹³ The Ministry of Health is a ministry of the Cabinet of Peru, responsible for the healthcare sector. Source: <u>http://www.minsa.gob.pe/(11/02/2013)</u>

¹⁴ The Ministry of Production is a ministry of the Cabinet of Peru, in charge of formulating, executing and supervising all levels of production (industry, manufacturing, and fishing). Source: <u>http://www.produce.gob.pe/#(11/02/2013)</u>

¹⁵ This is an independent constitutional body, with the primary mission of defending the legality and human rights. Source: <u>http://www.mpfn.gob.pe/home (12/02/2013)</u>

¹¹ The Regulations specify that the Commission is composed of *Ministerio de Ambiente* (Ministry of the Environment), CONCYTEC, *Presidencia del Consejo de Ministros* (the Office of the President of the Council of Ministers), *Ministerio de Agricultura* (Ministry of Agriculture), *Ministerio de Relaciones Exteriores* (Ministry of Foreign Affairs), *Ministerio de Comercio Exterior y Turismo* (Ministry of Foreign Trade and Tourism), *Ministerio de la Producción* (Ministry of Production), *Organismo de Evaluación y Fiscalización Ambiental* – OEFA (Environmental Assessment and Control Agency), *Instituto Nacional de Defensa de la Competencia y Protección a la Propiedad* – INDECOPI (National Institute for the Defense of Competition and Intellectual Property), *Asamblea Nacional de Gobiernos Regionales* – ANRG (National Board of Regional Governments), *Asociación de Municipalidades del Perú* - AMPE (Peruvian Association of Municipalities), *Asamblea Nacional de Rectores* – ANR (National Board of University Presidents), *Convención Nacional de Instituciones Empresariales Privadas* (National Confederation of Private Business Associations) and representatives of non-governmental organizations dedicated to managing modern biotechnology, biosafety, and bioethics.

¹⁶ The Regional Government organizes and manages each of the twenty-five regions in Peru. It has political, economic, and administrative autonomy. The Local Government is composed of Municipalities, which are the public institutions responsible for the management of the provinces, their districts and towns of Peru.

potentially affected by LMOs and their use. This way, an appropriate risk assessment will be ensured in each case when the moratorium period expires.

- Program for Biotechnology and Competitive Development: This promotes biotechnology based on native genetic resources in order to achieve their conservation and competitive development in financial, social, and scientific aspects. It identifies biotechnology applications on a multisectoral level and assesses their appropriateness and ability to resolve particular issues in national productive processes or in service creation.
- Special Project for the Development of Technological and Scientific Abilities used in Modern Biotechnology regarding Biosafety: This promotes the development of technological and scientific abilities of national institutions. It provides technical/scientific training to develop human abilities regarding research, biotechnological improvement, and innovation.

IV. The arguments in Peru to justify the moratorium

In general, the following benefits and concerns are usually indicated by the specialist for Genetically Modified Organisms (GMO).

Benefits¹⁷:

<u>Crop improvement</u>: for example, improved resistance to disease and reduced maturation time.

Animal improvement: for example, accelerated growth and disease resistance.

<u>To the Environment</u>: for example, GMOs need less pesticide, and may help in the conservation of soil and water.

<u>To Society</u>: for example, GMOs may help to produce more food for growing populations.

Concerns¹⁸

¹⁷ Source:

BALBOA, María Gabriela.

^{2012 &}quot;Legal Framework to Secure the Benefits while Controlling the Risks of Genetically Modified Foods: A Comparison of the Cartagena Protocol and Three National Approaches" .Temple Journal of Science, Technology & Environmental Law. p.2-3

<u>Health safety</u>: for example, the impact of GMOs on allergies and antibiotic resistance.

<u>Potential environmental impacts</u>: for example, the loss of flora and fauna biodiversity.

<u>Intellectual Property issues:</u> for example, the risk of having world food production dominated by a few companies and biopiracy.

<u>Ethics</u>: interfering with nature by mixing genes among species can be seen as an ethical dilemma because it violates the natural development of organisms.

<u>Labeling:</u> There is a controversy regarding the need to label GMO products. On the one hand, it is argued that it is necessary to respect the consumer's right to be informed and to choose but, on the other hand, there is the position that states that while products are not harmful, there is no need to label, as this can unjustifiably affect consumption.

In Peru, after the Supreme Decree 003-2011/AG enacting, many politicians and gastronomic sector representatives spoke against the entrance of LMOs into Peru. This led to the Law being repealed and the enacting of Law 29811 which set the moratorium. The main arguments presented are summarized as follows:

- <u>Biodiversity</u>: The recent country brand advertises Peru as a country offering different and unique experiences not found in other countries. Biodiversity is one of the aspects that make the country unique and it may be affected by the entrance of LMOs¹⁹.
- <u>Productivity</u>: Due to the great Peruvian biodiversity, LMOs are not necessary to improve the country's productivity. More organic crops²⁰ shall be produced instead²¹.
- <u>Risk to environment</u>: When the transgenic material is in the field, sooner or later it will be transported to other close species and crops by means of

¹⁹ These and similar declarations were made by several chefs, Gaston Acurio being one of them. Source: ACURIO, Gastón

^{2011 &}quot;Hay que evaluar cuánto afectan los transgénicos a la Marca Perú". El Comercio. Lima, June 8.(13/04/2013) <u>http://elcomercio.pe/actualidad/774143/noticia-gaston-hay-que-evaluar-cuanto-afectan-transgenicos-marca-peru</u>

²⁰Organic products are made from all-natural crops, receiving neither pesticides nor chemical fertilizers, but are treated in some cases with organic fertilizers.

²¹ These declarations were given by several members of the gastronomic sector and by the Viceminister of the *Ministerio de Cultura* (Ministry of Culture). Source: ACURIO, Gastón and others

^{2011 &}quot;La biodiversidad de nuestro país no requiere de transgénicos". El Comercio. Lima, May 13.(13/05/2013) <u>http://elcomercio.pe/gastronomia/756763/noticia-cocineros-biodiversidad-nuestro-</u> pais-no-requiere-transgenicos

pollen taken by the wind and insects, with a wide range of consequences, particularly, weeds resistant to herbicides²².

Were these arguments supported or were they just based on irrational fears and political interests?

<u>Biodiversity:</u> If biological diversity is the variability in genes, species, and ecosystems, as well as all ecologic processes necessary for all forms of life, then it is correct to say that Peru has a wide biological diversity, even though there is no detailed information about it.

As stated in our National Strategy on Biological Diversity²³, Peru has 84 life zones and 17 transitional zones of 104 in the world, 8 biogeographic provinces and 3 big river basins. It has a great variety of flora, approximately 25000 species (10% of the planet's total), where 30% are endemic. It is the fifth country in number of species; it is the first in number of plant species with known properties and used by population (4400 species) and also the first in the number of native cultivated species (128 species).

With regard to fauna, Peru is in the first place in varieties of fish (10% of the planet's total), the second in birds (1736 species), the third in amphibians (332 species), the third in mammals (460 species), and the fifth in reptiles (365 species). Also, it is one of the most important countries with endemic species with, at least, 6288 (5528 of flora and 760 of fauna).

It has a wide genetic diversity: it has the first place in varieties of potatoes (150 wild species), chili, corn (36 species), Andean grains, tubers, and Andean roots. It has 4400 species of native plants with known uses, mainly those with nutritional (782), medical (1300), and ornamental properties (1600).

It has five domestic forms: alpaca, domestic form of vicuña (Lama vicugna); Ilama, domestic form of guanaco (Lama guanicoe); cuy, domestic form of poronccoy (Cavia tschudii), Criollo duck, domestic form of Amazon duck (Cairina moschata), and cochinilla (dactilopius coccus).

In financial terms, Peruvian biological diversity is the basis of the national economy: 99% of fisheries depend on hydrobiological resources, at least 65% of agricultural production is based on native genetic resources, 95% of livestock

 ²³ Peru: National Strategy on Biological Diversity. Available on: Consejo Nacional del Ambiente (CONAM)
 2001 "Perú: Estrategia Nacional Sobre Diversidad Biológica". Lima. (09/05/2013) http://www.sernanp.gob.pe/sernanp/archivos/biblioteca/publicaciones/DOC VARIOS/ENDB.pdf

²² This declaration was given by Patricia Majluf, Director of the *Centro para la Sostenibilidad Ambiental de la Universidad peruana Cayetano Heredia* (Center for Environmental Sustainability of the Peruvian University Cayetano Heredia), for El Comercio. Source: MAJLUF, Patricia

^{2011 &}quot;La biodiversidad de nuestro país no requiere de transgénicos". El Comercio. Lima, July 10. (20/04/2013) <u>http://elcomercio.pe/politica/850282/noticia-transgenicos-sobre-mesa-gracias-alan-garcia_1</u>

consumes native natural grasses, and 99% of forest industry consumes forests and native species.

Furthermore, our country promotes a country brand that aims at making our diversity known, including biodiversity ("There is a Peru for each and everyone")²⁴.

One of the problems is that our biodiversity is still quite unknown in our country. For example, only recently, thanks to the joint efforts of a Peruvian-Canadian cooperation project, was it possible to identify 509 varieties of native potatoes²⁵.

As can be deduced, without knowing our biodiversity well it is very difficult to determine which products (genetically modified or not) might be liable to affect it.

The second problem, related to the first, is that all LMOs do not have the same effects, therefore, it is possible that a specific LMO does have an impact on some element of our biodiversity but, at the same time, another LMO is completely harmless.

<u>Productivity</u>: Stating that it is not necessary to increase our productivity via LMOs due to our great diversity is really difficult to confirm, because we do not know the maximum benefits of our biodiversity exploitation in the future. Added to this, there is little current and available information about organic production in Peru.

Notwithstanding the foregoing, some data shows the following:

- The most important products with Organic Certification in Peru are: coffee, cotton, cotton fiber and textiles; fresh vegetables and fruits, such as mango, banana, grapes and papaya; native and exotic fruit; Andean tubers and grains like quinoa, amaranth, yacon and maca; sesame; olives and olive oil; palm, citrus aurantifolia, tomatoes and tomato paste, Brazil nuts, honey, essential oils, a wide range of natural colorants and different herbs with aromatic and medicinal use²⁶.
- In 2006 the certified national organic production was 240 174 ha, while, in 2012 the area was 256 838.42 ha²⁷.

²⁵ Source:

Radio Programas del Perú (RPP)

²⁶ Source:

²⁷ Sources:

²⁴ Source: PROMPERU. "La marca país". <u>http://www.peru.info/#brand (</u>21/01/2013)

^{2014. &}quot;Investigadores de Canadá y Perú clasifican 509 tipos de papas nativas". May 23, 2014. <u>http://www.rpp.com.pe/2014-05-23-investigadores-de-canada-y-peru-clasifican-509-tipos-de-papas-nativas-noticia 694495.html</u>(14/10/2014)

MIRANDA LEYVA, Juan Francisco. "Cultivos Orgánicos en el Perú". https://es.scribd.com/doc/916657/Cultivos-Organicos-en-el-Peru (14/01/2014)

• Peru is one of the leading exporting countries of organic products in Latin America and globally it ranks around fifth, generally behind China, Brazil and Chile²⁸.

One big problem is that 81% of agricultural land in the country, especially in the highlands, is less than five hectares in size and that limits the competitiveness of small producers to, for example, address demand for quinoa (the Andean countries produce no more than 100,000 tonnes annually)²⁹.

Although Peru is positioning itself slowly in organic production, we have not found any scientific study dedicated to examining the possibility of relying solely on these crops for domestic consumption and exportation.

<u>Risk to environment</u>: It is true that wind and insects may transport transgenic material to an area where that material is not wanted. The fear of this crop contamination tends to focus on the possibility of the modified seed becoming an uncontrollable weed.

In this respect, although each situation must be taken independently, the case of herbicide tolerant canola in Canada can be taken as an example. In this case, although one of the initial concerns was an uncontrollable development of herbicide tolerant canola, according to a 2010 study, most surveys dismissed this concern as 62% reported no difference in controlling for volunteer GM canola than for regular canola, and only 8% indicated that they viewed volunteer GM canola to be one of the top five weeds they need to control³⁰.

Servicio Nacional de Sanidad Agraria (SENASA) 2007 "Situación de la Producción Orgánica Nacional al Año 2006". Lima. (15/03/2013) http://www.senasa.gob.pe/RepositorioAPS/0/3/JER/POR_INFORMACION_ESTADISTICA/INFORM ACION%20ESTADISTICA/SITUACION%20DE%20LA%20P.O.%202006%20fg.pdf

Servicio Nacional de Sanidad Agraria (SENASA) 2012 "Situación de la Producción Orgánica Nacional al Año 2006". Lima. (15/03/2013) http://www.senasa.gob.pe/RepositorioAPS/0/3/JER/POR_INFORMACION_ESTADISTICA/Situaci% C3%B3n%20de%20la%20Producci%C3%B3n%20Org%C3%A1nica%20Nacional%202012.pdf

²⁸ Inforegión. "Productos orgánicos de Perú entre los 5 mejores del mundo". September 23, 2012. <u>http://www.inforegion.pe/portada/142566/productos-organicos-de-peru-entre-los-5-mejores-del-mundo/</u> (21/06/2014)

²⁹ This declaration was given by Antonio Brack, former Minister of Environment in Peru, for ConexionEsan.com. Source:

BRACK, Antonio

2013 "La apuesta por los productos orgánicos". Conexionesan.com. Lima, June 27 <u>http://www.esan.edu.pe/conexion/actualidad/2013/06/27/apuesta-productos-organicos/</u> (20/10/2014)

³⁰ Source:

SMYTH, Stuart and others.

2010 "Assessing The Economic And Ecological Impacts Of Herbicide Tolerant Canola In Western Canada". University of Saskatchewan and University of Ottawa.

In addition, a moratorium in our country would not necessarily prevent contamination of crops. We cannot ignore that several neighboring countries (for example, Argentina and Brazil) have allowed, in some way, the entrance or production of LMOs within their national boundaries. This way, LMOs from these countries may enter into ours, even if they are prohibited in Peru.

In conclusion, although the reasons given to justify the moratorium were not unreasonable, they were based on intuition, as there is little information about our biodiversity, organic production and environmental effects of introducing LMOs.

V. <u>The moratorium and the precautionary principle in the CBD and</u> <u>Cartagena Protocol</u>

A) <u>The precautionary principle</u>

This principle gained worldwide recognition in the Rio Declaration on Environment and Development in 1992, that resulted from The United Nations Conference on Environment and Development. Specifically, Principle 15 of the Rio Declaration provides:

"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

The analysis of the precautionary principle involves a great challenge. Not only because of the lack of uniformity in its application, but also by the different ways of understanding it. Even in identifying its key elements, the doctrine is not uniform³¹. Nevertheless, in an attempt to point out its elements simply, we have³²: a) the threat of harm, b) the lack of scientific evidence and, c) the need and duty to act.

³¹ Source:

HICKEY, James E., Jr. and Vern R. WALKER,

1995 "Refining the Precautionary Principle in international Environmental Law". Va. Envtl. L. J. 3 pp. 424-425.

³² Sources:

TICKNER Joel and Carolyn RAFFENSPERGER.

"The Precautionary Principle in Action". Science & Environmental Health Network. https://www.google.com.pe/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&cad=rja&uact=8&ved=0 CDIQFjAC&url=http%3A%2F%2Fwww.sehn.org%2Frtfdocs%2Fhandbookrtf.rtf&ei=8htJVPz7J47MggTXsIGgBQ&usg=AFQjCNGhYSuafxLg65Isqs5-Xx2VABIZiA (22/03/2014)

http://www.canolacouncil.org/media/504427/assessing the economic and ecological impacts of herbicide_tolerant_canola_in_western_canada.pdf (20/09/2014)

i. Threat of Harm

There is no consensus on the level of damage required to activate the precautionary principle³³, some formulations of this principle require that the injury is severe and irreversible (as in The Rio Declaration). On the other hand, the Cartagena Protocol requires "imminent harm" and "adverse effects" to trigger this principle.

ii. Uncertainty

The Rio Declaration refers to "lack of full scientific certainty" and many definitions in other international instruments are vague about how much certainty must be demonstrated regarding a product or activity's safety³⁴. For example the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) refers to cases where scientific evidence is "insufficient."

In general, uncertainty may refer to situations in which there is no strong evidence of safety or benefits of the product or the activity. It also refers to evidence that is incomplete or not available³⁵.

iii. Necessity and duty to act

There is no consensus on which measure is applicable for each activity, but there are a variety of possible actions that could be taken to deal with possible harmful effects. These include: doing nothing; merely considering action; performing further research to improve understanding; in the case of a product, performing pre-

HOLDWAY, Aaron.

"Reducing Uncertainty: The Need to Clarify the Key Elements of the Precautionary Principle". Consilience- The Journal of Sustainable Development. http://www.consiliencejournal.org/index.php/consilience/article/viewFile/5/4 (22/03/2014)

³³ Source:

VANDERZWAAG, David

1999 "The Precautionary Principle in Environmental Law and Policy: Elusive Rhetoric and First Embraces" J. Envtl. L. & Prac. p. 359.

"Reducing Uncertainty: The Need to Clarify the Key Elements of the Precautionary Principle. Consilience- The Journal of Sustainable Development". http://www.consiliencejournal.org/index.php/consilience/article/viewFile/5/4 (22/03/2014)

³⁵ Source:

MCINTYRE, Owen and Thomas MOSEDALE

1997 "The Precautionary Principle as a Norm of Customary International Law" J. Envtl. L. 221 P. 222.

³⁴ Source: HOLDWAY, Aaron.

market testing; warning people of the possible harm caused by the product or activity (in the case of products, this could include labelling); monitoring the product or activity to look for evidence of possible harm; taking measures to reduce the impact of the possible harm (for example, by preventing exposure to it); placing strict regulations on the product or activity; placing a moratorium on the product or activity; phasing out the product or activity; and placing an outright ban on the product or activity³⁶.

B) In the Convention on Biological Diversity (CBD)

Like other environmental agreements, the CBD contains the "precautionary approach" but it doesn't mention precaution by name. In this regard, the preamble of the Convention states that "where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat". This version of the precautionary principle is similar to the statements in the Rio Declaration.

C) In the Cartagena Protocol

This instrument also contains a "precautionary approach" in the preamble: "reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development".

The Protocol also reflects precautionary decision-making in Article 1 (Objective), in Articles 10 (Decision procedure) and 11 (Procedure for living modified organisms intended for direct use as food, feed, or for processing), and in Annex III paragraph 4 (Risk assessment)

"Article 10. Decision Procedure

(...)

6. 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 the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects."

"Article 11. Procedure for Living Modified Organisms Intended for Direct Use as Food or Feed, Or For Processing

³⁶ Source: HOLDWAY, Aaron.

[&]quot;Reducing Uncertainty: The Need to Clarify the Key Elements of the Precautionary Principle. Consilience- The Journal of Sustainable Development". http://www.consiliencejournal.org/index.php/consilience/article/viewFile/5/4 (22/03/2014)

(...)

8.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 organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects."

"Annex III Risk Assessment (...) General Principles (...) 4. Lack of scientific knowl necessarily be interpreted as i

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk."

During the negotiations of this Protocol the use of the wording "precautionary principle" was blocked by the US and some other governments. The dispute was based on the fact that the precautionary principle is not yet recognized as an internationally recognized principle of law. The US and supporting governments did not want the Biosafety Protocol negotiations to set a precedent and recognize the Precautionary Principle as a principle³⁷.

D) <u>The establishment of a moratorium and the precautionary principle</u>

Applying the key elements that we have identified to the establishment of a moratorium, we believe that:

Regarding the Threat of Harm:

Due to the complexity and still lack of certainty about the effects of GMOs on human health and biodiversity, these organisms are candidates for the application of this principle.³⁸ Thus, at least potentially, the effects of these products could be severe and irreversible³⁹.

³⁷ Source:

Terje Traavik and Lim Li Ching (eds).

^{2007 &}quot;Biosafety First. Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms". Tapir Academic Press. Chapter 30,p3

Regarding the uncertainty:

The level of uncertainty is in dispute because "current knowledge is not sufficient to be able to draw scientifically (...) trusted conclusions about potential environmental effects of transgenic animals or their safe and effective management"⁴⁰. In this regard, science "has not fully responded to concerns about long-term environmental impacts and possible spillover effects to wild plant varieties".⁴¹

Added to the above, also because of the complexity of ecosystems, costs and the difficulty in monitoring GMOs (that could take years to show its effects)⁴² it is possible to say that GMOs comply with this element.

Regarding the necessity and duty to act

Although there is no consensus on which measure is applicable for each activity⁴³, the precautionary GMO regulation requires that governments act t o reverse the burden of proof on proponents of an activity to demonstrate that GM will not have negative effects on human health or the environment⁴⁴. Another measure proposed includes monetary deposits in advance of any activity that may endanger the environment, environmental impacts⁴⁵ and the

2001 "The Prometheus Principle: Using the Precautionary Principle to Harmonize the Regulation of Genetically Modified Organisms" J. Global Legal Studies.. p 256

³⁹ Ibid

⁴⁰ Source:
 KNUDSEN, Guy.
 2011 "Impacts of Agricultural GMOs on Wildlands: A New Frontier of Biotech Litigation". 26 Natural Res. & Env't 13.

⁴¹Source: UNITED NATIONS. 2011 "The World Economic and Social Survey 2011. The Great Green Technological Transformation". Doc ST/ESA/333. <u>http://www.un.org/en/development/desa/policy/wess/wess_current/2011wess.pdf</u> (16/09/2014)

⁴² Ibid

⁴³ Source:

SUNSTEIN, Cass.

2003 "Beyond the Precautionary Principle". Harvard Law School. p. 1003-1005.

44 Ibid

⁴⁵ Source:

VANDERZWAAG, David and Susanna D. FULLER, and Ransom A. MYERS.

development of a system of liability and compensation as is proposed in article 27 of the Cartagena Protocol.

We consider that it is appropriate to establish a moratorium to assess the effects on our biodiversity of LMOs released into the environment. Because every environment has a unique ecosystem, which implies that biosafety studies are difficult to generalize, we think that biosafety standards for health and environmental impact may require specific testing for the environment where the LMO will be introduced⁴⁶.

For this reason, even though the Cartagena Protocol does not include the establishment of a moratorium to protect biodiversity, its Article 2 does allow stricter measures, provided that they are not opposed to the objectives and provisions of the Protocol. We believe that by itself, the existence of a moratorium does not violate the Cartagena Protocol; since the Protocol itself allows stricter measures, and, from our point of view, a temporary measure, such as a moratorium, would be stricter than an assessment of each case^{47 48}.

VI. <u>A different problem: the perspective of commerce.</u>

Norms of precaution present particular difficulties because in a trade agreement dispute settlement proceeding they appear to be pretexts for protectionism. Thus, even considering that the moratorium, by itself, does not violate the Cartagena Protocol, there may be problems in relation to trade, which we will mention briefly.

2002 "Canada and the Precautionary Principle/Approach in Ocean and Coastal Management: Wading and Wandering in Tricky Currents" Ottawa Law Review p. 119.

⁴⁶ Source:

Bao-Rong Lu.

2008 "Transgene Escape from GM Crops and Potential Biosafety Consequences: An Environmental Perspective". Collection of Biosafety Reviews 66, Vol. 4.. p96-97 http://www.icgeb.org/~bsafesrv/pdffiles/Bao-Rong.pdf (14/08/2014)

⁴⁷ According to local news, the Executive Secretary of the Convention on Biological Diversity (CBD), Ahmed Djoghlaf, has sent a letter to the Peruvian government, noting that the moratorium is not incompatible with the CBD and the Cartagena Protocol. Unfortunately, the full content of the letter was not made public. Source:

PERU.COM

2011. "ONU desmiente a gobierno en cuanto a transgénicos"

http://peru.com/2011/07/19/actualidad/otras-noticias/onu-desmiente-gobierno-cuanto-transgenicosnoticia-12468 (22/02/2014)

⁴⁸ It is believed by some Peruvian specialists that the moratorium could be violating the Cartagena Protocol on Biosafety of Biotechnology since the Protocol establishes a regulation for each case based on strong scientific arguments. Source:

Colectivo Semillas de Diversidad

2011 Comment on November 28. "Perú será demandado por imponer moratoria a transgénicos" <u>http://semillasdediversidad.blogspot.com/2011/11/peru-sera-demandado-por-imponer.html</u> (05/03/2013) a) <u>The WTO Agreement on the Application of Sanitary and Phytosanitary</u> <u>Measures (SPS Agreement)</u>

As can be seen in its preamble, the SPS Agreement governs measures applied to protect the life or health of humans, animals, or plants from pests, disease-causing organisms, additives, contaminants, and toxins⁴⁹. Therefore, the agreement governs both food safety measures and agricultural quarantines.

The WTO SPS Agreement has a different purpose from the CBD and the Cartagena Protocol because it is not an environmental agreement; its objective is not to protect the environment or biodiversity but to reduce trade barriers and to eliminate discriminatory treatment in international trade⁵⁰.

The core of the SPS text is a series of science-based disciplines. An SPS measure that is not based on international standards must be supported by "a scientific justification" (Article 3.3). A challenged measure must be "based on scientific principles" (Article 2.2), must not be "maintained without sufficient scientific evidence" (Article 2.2), and the regulatory process leading to the measure must "take into account available scientific evidence" (Article 5.2). A central feature of the SPS Agreement, found in Article 5.1, is a requirement for a risk assessment, and the principal operative test in the agreement is the need for the measure to be "based on" that risk assessment. The SPS Agreement consequently codifies requirements for an approach to regulation roughly commensurate with the risk assessment/risk management duality.⁵¹

Even though the word "precaution" does not appear in the text of the SPS Agreement, Article 5.7 of the SPS Agreement incorporates policies similar to those underlying precautionary approaches:

⁴⁹ Preamble:

(...)

⁵⁰ Source:

Terje Traavik and Lim Li Ching (eds).

2007 "Biosafety First. Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms". Tapir Academic Press. Chapter 30..p5--6

⁵¹ Source:

WIRTH, David.

[&]quot;*Reaffirming* that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade.

^{2013 &}quot;Conference on Agriculture and Food Systems: September 28, 2012: The World Trade Organization Dispute Con-cerning Genetically Modified Organisms: Precaution Meets International Trade Law". Vermont Law Review. P7

"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."

Related to this, it is important to note that the Cartagena Protocol says little regarding its interpretation alongside other international trade agreements, including those under the WTO (the preamble states that the protocol is to be mutually supportive, not subordinate to other international agreements)⁵².

For a better understanding of the relation between the precautionary approach and de SPS agreement, especially in the context of a moratorium, it is worth mentioning the EC – Biotech case.

The *EC-Measures Affecting the Approval and Marketing of Biotech Products* dispute (*EC--Biotech*): in this case, the US, Canada, and Argentina accused the EU of having imposed a de facto moratorium on the commercialization of GMOs, maintained between 1999 and 2003 by "undue delay" in the approval procedure (the EC scheme required prior governmental authorization before a GMO may be placed on the market.). The complainants claimed that the European Member States either never performed the risk assessments on GMOs or dismissed the positive results of risk assessments. Thus, according to the complainants, the European behavior violated Article 5.1 of the SPS Agreement, which requires that SPS measures be based on scientific risk assessment. In the absence of such an assessment, the European delay amounted to a non-necessary and non-science-based restrictive measure to trade⁵³.

The European Communities argued that the safeguard measures on the import of certain GMOs were adopted by six EC member states (Austria, France, Germany, Greece, Italy, and Luxembourg) but, the case of inconsistency was to be examined under Article 5.7 of the SPS Agreement instead of Article 5.1, the former contemplating the case of insufficient scientific evidence and better reflecting the precautionary principle⁵⁴.

⁵² Source:

SMITS, Darren and Sean ZABOROSKI.

^{2001 &}quot;Trade and Genetically Modified Foods: GMOs: Chumps or Champs of International Trade?" University of Manitoba Law School. Asper Review of International Business and Trade Law.

⁵³ Source:

VECCHIONE, Elisa.

^{2012 &}quot;Is It Possible to Provide Evidence of Insufficient Evidence? The Precautionary Principle at the WTO". The University of Chicago. Chicago Journal of International Law.p.3-4

The WTO Dispute Settlement Body issued its ruling on the complaints, on the one hand faulting the EC for "undue delay" in approving GMO products for a four-year period ending in 2003 and, on the other, accusing a number of EC member states of maintaining unjustified bans on genetically modified products already found safe by the European scientific committees. Indeed, the justification of the six European states that scientific results were not "convincing" and needed further evaluation before they would allow the import of these products was not upheld by the Panel, which found no GMO case where scientific evidence was insufficient to perform an adequate risk assessment⁵⁵. In other words, the Panel concluded that the EC member state safeguard measures violated the SPS Agreement because they were not based on risk assessments and hence could be presumed to be maintained without sufficient scientific evidence.

It is important to mention that the United States has signed but not ratified the Biodiversity Convention, and Argentina and Canada have signed the Biosafety Protocol but not yet ratified it. Therefore, none were parties of these agreements which were inapplicable to the dispute.

b) The Peruvian moratorium: its duration and implementation

While the moratorium may not be a violation of the CBD and the Cartagena Protocol, there is reasonable concern regarding the possibility of trading being affected with this measure⁵⁶.

There are certain aspects which could indicate that this measure is a barrier to trade:

The duration

After reviewing the general provisions of the Law 29811 and the bills prior to this norm⁵⁷, we can see that no one had a clear idea of how long the moratorium period should be, as some bills suggested three years, and others proposed 10 or 15 years. Worse, in none of the bills, nor in the general provisions, was scientific analysis conducted to determine how long the moratorium needed to be in order to meet

⁵⁷Source:

⁵⁵ Ibid.

⁵⁶ Notwithstanding the above, there are some elements of the moratorium law that allow it to be considered as not posing an obstacle to trading:

[•] The moratorium applies to both importations and national development; therefore, there is no intention to support the national industry.

[•] The moratorium does not apply either to the importation of inputs or food and/or feed, or for searching or pharmaceuticals production purposes, since a very wide restriction on LMOs could be considered as a hidden restriction to trading.

[•] Transgenic by-products may be imported, provided that they will not be released into the environment for agricultural or breeding purposes.

CONGRESO DE LA REPÚBLICA DEL PERÚ <u>http://www2.congreso.gob.pe/Sicr/TraDocEstProc/Expvirt_2011.nsf/sicr/tradocestproc/Expvirt_2011</u> <u>.nsf/Agenda/D7A39736FAD87DD0052578E10082177D?opendocument</u> (11/09/2014)

their goals. In fact, the Law was almost subject to Executive Power regulation due to, among other reasons, concern about the moratorium period being too long⁵⁸.

It is very bad that the moratorium period was established without scientific analysis, because it means we do not have good arguments to defend ourselves if our country is denounced for acts that create barriers to trade.

The implementation

- The baselines: There is a reasonable concern regarding the possibility of trading being affected with this measure, since the way provisions of Law 29811 will be applied is uncertain. For example, it is unknown what the specific content of the baselines will be and if they will be considered as an excuse to reject any LMO when the 10-year term ends⁵⁹.
- The progress of the implementation: One of the problems we may face, even if the moratorium itself and its period are considered legal, is its slow and deficient implementation.

In general, the Peruvian government is usually slow in implementing the rules, especially those involving research⁶⁰ and major changes⁶¹.

⁵⁸Source:

⁵⁹ Source:

FERNÁNDEZ-NORTHCOTE, Enrique N.

2011 Análisis de la Ley que establece la moratoria al ingreso y producción de organismos vivos modificados al territorio nacional por un periodo de 10 años. Lima <u>http://www.perubiotec.org/PDFs/Analisis Moratoria %20EN Fernandez-Northcote.pdf</u>(16/04/2013)

⁶⁰For example, in 2007, a report about so-called illegal crops of transgenic seeds in the north part of Peru was released. The news aroused many debates regarding the methodology of the studies, and in 2010, the agricultural authorities released a report stating that said crops were not illegal. In 2011, this report was questioned by the Ministry of the Environment; so the existence of the crops is uncertain up to now. Sources:

UCEDA, Ricardo

2010 ""Mitogenesis. Falta de información, creencias increíbles, miedo a Monsanto: semillas del atraso tecnológico peruano en biotecnología" http://www.poder360.com/article_detail.php?id_article=4129&pag=1(13/02/2013)

Instituto Nacional de Innovación Agraria (INIA)

2010 "Informe Técnico. Verificación de la presencia de cultivos de maíz transgénico en el valle de Barranca" (20/07/2013)

http://pe.biosafetyclearinghouse.net/actividades/2010/presentaciones/informe_t%C3%A9cnico.pdf

MAJLUF, Patricia

^{2011 &}quot;La biodiversidad de nuestro país no requiere de transgénicos". El Comercio. Lima, July 10. <u>http://elcomercio.pe/politica/850282/noticia-transgenicos-sobre-mesa-gracias-alan-garcia_1</u> (20/04/2013)

To date, progress in the implementation of the Law 29811 has been very limited:

- A Multi-sectoral Advisory Commission was implemented through the appointment of its members⁶².
- Guidelines to select and designate official laboratories to identify LMOs were set and approved; however, said labs have not been selected yet⁶³.
- A law that sets the list of restricted products and a list of restricted products subject to control and sampling in the points of entry was published, but its application depends on the approval of the procedure, which is still being planned⁶⁴.
- The classification of infractions and the sanctions and fines scales for violating the moratorium has not been defined yet⁶⁵, neither has the Guide for

Instituto Nacional de Innovación Agraria (INIA)

2011 "Oficio No. 190" http://pe.biosafetyclearinghouse.net/casobarranca/respiniasobreinfminam.pdf (20/07/2013)

Ministerio de Ambiente (MINAM)

2011 "Oficio No. 12" <u>http://pe.biosafetyclearinghouse.net/casobarranca/infminamresulovmbarranca.pdf</u> (20/07/2013)

⁶¹ The best example of the slowness of the government in these issues is that, a Law on biosafety was enacted in 1999; however, after more than 11 years, the Regulations for its application have not been enacted yet.

⁶² Source:

Centro de Intercambio de Información sobre Bioseguridad del Perú (CIISB) 2013 Implementación de la Ley 29811. http://pe.biosafetyclearinghouse.net/imp_ley29811.shtml (25/08/2013)

⁶³Sources:
Centro de Intercambio de Información sobre Bioseguridad del Perú (CIISB)
2013 Implementación de la Ley 29811.
http://pe.biosafetyclearinghouse.net/imp_ley29811.shtml(25/08/2013)

Ministerio de Ambiente (MINAM)

2013 "Minam inicia proceso de selección de laboratorios de detección de organismos vivos modificados"

http://www.minam.gob.pe/index.php?option=com_content&view=article&id=2504:minam -iniciaproceso-de-seleccion-de-laboratorios-de-deteccion-de-organismos-vivosmodificados&catid=1:noticias&Itemid=21(20/07/2013)

⁶⁴ Source:

Centro de Intercambio de Información sobre Bioseguridad del Perú (CIISB) 2013 Implementación de la Ley 29811. http://pe.biosafetyclearinghouse.net/imp_ley29811.shtml(25/08/2013) the sampling of imported seeds to detect LMOs nor the Guide to the qualitative detection of LMOs (there are only bills on these topics)⁶⁶.

- The Committee Technical Standards on Biosafety of LMO has generated some technical standards on methods of analysis for the detection of GMOs and derived products, as well as technical standards for LMOs and their biosafety⁶⁷.
- The following is still under development⁶⁸: The Multi-sectoral Plan for monitoring and early warning detection of LMO in the fields; the Guide on sampling and qualitative detection of transgenic ornamental fish; the Guide on sampling and detection of LMOs in crop fields; studies for the baseline of native species to understand the diversity of species, varieties and breeds that have commercial transgenic events (first studies are on corn, cotton, potato and tomato).

There are several explanations of why the implementation is delayed⁶⁹.

First, since the adoption of Law No. 29811 Act in December 2011, it took almost a year to adopt the rules due to the different positions of the responsible entities regarding the law. This meant a delay in the start of implementation actions.

Second, there are problems of coordination between the agencies responsible, because some of them do not accord the issue the necessary priority. This is reflected in the fact that some entities do not include, in their annual budget, a separate line item for financing actions related to the implementation.

Also, the restructuring of the Ministry of Agriculture and the National Fish Health Service have made more difficult the implementation of the regulation that applies to them.

Finally, it appears that the Multi-sectoral Advisory Commission does not have a strong role yet.

⁶⁶ Source:

Centro de Intercambio de Información sobre Bioseguridad del Perú (CIISB) 2013 Normas publicadas para Consulta Pública http://pe.biosafetyclearinghouse.net/consultas_publicas.shtml(25/08/2013)

⁶⁷ Ministerio del Ambiente. "Primer Informe Anual al Congreso de la República sobre los avances y resultados en el marco de la implementación de la Ley N° 29811". 2011 – 2013. <u>http://pe.biosafetyclearinghouse.net/moratoria/cma/info_congreso_final.pdf___(01/09/2014)</u>

68 Ibid.

69 Ibid.

⁶⁵ Source :

Centro de Intercambio de Información sobre Bioseguridad del Perú (CIISB) 2013 Normas publicadas para Consulta Pública http://pe.biosafetyclearinghouse.net/consultas_publicas.shtml(25/08/2013)

Conclusion

The reasons for establishing the moratorium in Peru were not based on irrational motives or simply political interests, however although there seems to be abundant biodiversity in our country, we do not yet have a detailed knowledge of it, including its economic potential and vulnerability to LMOs. In this regard, we believe this mechanism is beneficial, since it will allow the identification of our biodiversity as well as the development of the institutions in charge of searching the effects of transgenic products.

From the legal aspect, although the Cartagena Protocol does not include the establishment of a moratorium, given that the Protocol allows for more stringent measures than those provided for the protocol, we believe that the moratorium is lawful and consistent with the precautionary principle.

Notwithstanding the above, taking into account the SPS Agreement, the moratorium could be considered a barrier to trade because its period of duration is extensive and was established without scientific justification and; implementation, so far, is rather slow and it is possible that it could take longer than 10 years.