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The Precautionary Principle and the Protection of Biological Diversity

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Abstract: Trade in safe and healthy foods is essential for businesses, authorities and consumers throughout the world. When drafting food policies, states should ensure that they provide protection for people's lives and health, as well as saving social and economic interests on a national and international level. Over the last few decades, scientific developments and technological innovations have enabled us to achieve extraordinary successes in our mastery of technology with a view to improving our quality of life. In this context, biotechnology has opened up a wealth of solutions to problems in sectors such as healthcare, industry, agriculture and the environment. Perhaps the greatest challenge facing humankind is to achieve sustained global economic growth while ensuring environmental protection and conservation and food security for future generations. Environmental policy is today one of the most important social challenges for public authorities and economic agents. It is a very sensitive issue in public opinion as it directly affects well-being and health. The precautionary principle, for its part, arises as a consequence of seeking to protect the environment and human health against certain activities characterized by scientific uncertainty about their possible consequences. The precautionary principle is conceived as the axiom on which environmental policy is based. The most characteristic feature of this principle is that it can be the basis for decisions to derogate from a legal regime that would in principle be applicable. In my research for this manuscript, I have carried out an exhaustive analysis of the precautionary principle in the area of biodiversity, with specific regard to LMOs. To do so, it was necessary to examine the legal, theoretical and jurisprudential aspects of the topic on several levels. This study is divided into three sections. The first offers a legal approach to the precautionary principle, in which the essential elements are analyzed. The second section is devoted to analyzing the precautionary principle in the area of International Agreements. This study would be complete analyzing the risk, damage and scientific uncertainty. The new challenges facing the international community in the area of encouraging fair and equitable participation in the profits obtained from the use of genetic resources are discussed, in the light of the Nagoya Protocol, and a new Protocol concerned with international liability, the Nagoya-Kuala Lumpur Protocol. These Protocols are of great interest, as they provide greater legal security and transparency in the area of LMOs.

Keywords: Environment, Precautionary Principle, Food Security, Living Modified Organisms

1. Introduction

Environmental concern began after World War II with a number of conventional instruments for the protection of fresh and sea waters, for example, the Protocol signed by France, Belgium and Luxembourg for the protection of boundary waters on April 8, 1950, and the Conventions to combat pollution of the Moselle River on October 27, 1956, of Lake Geneva on November 16, 1962, and of the Rhine River on April 29, 1963 [1].

At the end of the 1960s, in the face of scientific alarm, the most intense reactions of public opinion led to a more generalized awareness of the dangers. "This current of opinion was undoubtedly a phenomenon without precedent in history, becoming a philosophical current on the conception of the world that implied new individual and social values in reaction to the deterioration of the biosphere" [2]. These criticisms arose in Germany because certain chemical pollutants, in low concentrations, could have negative consequences for human health since there were uncertainties as to the effect of such substances [3]. Thus, the *"Vorsorgeprinzip"* or precautionary principle gradually

emerged in German policy [4].

In a report prepared for the UK Royal Commission on Environmental Pollution, von Moltke said that the concept of precaution was first enunciated by the German government in 1976, when it mentioned that environmental policy:

> *"...is not fully accomplished by warding off imminent hazards and the elimination of damage which has occurred. Precautionary environmental policy requires furthermore that natural resources are protected and demands on them made with care....is not being fully complied with by preventing imminent dangers and eliminating the damage that has occurred. Precautionary environmental policy also requires that natural resources be protected, and that care be demanded of them"* [5].

The precautionary principle was initially introduced in sector-specific regulations, such as the German Chemicals Act (*Chemikaliengesetz* 1980) or the Atomic Energy Act (*Atomgesetz* 1985) [6].

Starting with German law, the precautionary principle was extended in several international regulations. In 1968, for example, the Council of Europe adopted two texts, the first declared by an international organization in the field of the environment. These were the Declaration on Combating Air Pollution (adopted as a Resolution by the Committee of Ministers on March 8, 1968) and the European Water Charter (adopted on May 6, 1968).

2. International Instruments for the Protection of the Environment

2.1. Background on Environmental Concerns

Awareness of the dangers threatening the environment has varied between industrialized and developing countries. However, despite these differences, in 1968, African heads of state signed the Convention on the Conservation of Nature and Natural Resources. The article 2 states that: *"States (...) undertake to adopt the necessary measures to ensure the conservation, utilization and development of soil, water, flora and fauna, based on scientific principles and taking into consideration the principal interests of the people"*. This Convention replaced the London Convention of 1933, signed mainly between colonizing countries [7].

This international agreement deals with the conservation and utilization of the environment, i.e. soil, water, flora and fauna. In addition, it sets out some general principles of environmental protection such as the conservation of flora and fauna, where it establishes the creation of reserves and adopts rules on hunting and protection measures for certain species.

That same year, the United Nations General Assembly (UNGA) promoted, through Resolution 2398 (XXIII) of December 3, 1968, a major environmental meeting to be held in Stockholm in 1972 [8]. This Conference, known as the "United Nations Conference on the Human Environment of June 16, 1972, highlighted the differences between developing and industrialized countries, the former fearing that the environment would be invoked as another obstacle to their development [9]. In 1969, for example, the Report of Maha Thray Sithu U Thant (third Secretary of the UN 1961-1971) entitled "Man and his Environment" was published. In it, he highlighted man's inadequate attitude towards his environment, pointing out that, should this process continue, life on Earth would be threatened.

This international summit constitutes an important milestone in international environmental law, because for the first time, an international forum focused its attention on the environment as a comprehensive concept of a global and systematic defense of nature on a worldwide scale, overcoming the sectoral and regional vision of environmental problems.

The most positive outcome of the Conference was the Declaration of Principles for the Preservation and Improvement of the Human Environment, also known as the "Stockholm Declaration" [10], which addressed the major environmental issues affecting the human environment at the global level.

It is important to emphasize that international treaties, in a broad sense, are agreements between subjects of public international law that are mandatory, binding and with coercive potential to create, modify or extinguish a legal relationship between them. International declarations, on the other hand, are mere recommendations.

This Declaration promoted important advances in the legal protection of the environment, as evidenced by Principle 2, which states that "the Earth's natural resources, including air, water, land, flora and fauna, should be preserved for the benefit of present and future generations through careful planning or guidance as appropriate". It also explicitly recognized that man has the responsibility to preserve and manage the heritage of wild flora and fauna and their habitat (Principle 4). For its part, Principle 21 establishes the precautionary principle, considering that:

> *"In accordance with the Charter of the United Nations and the principles of international law, States have the sovereign right to exploit their own resources pursuant to their own environmental policies and the obligation 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".*

Subsequently, the UNGA established in 1983 a World Commission on the Human Environment and Development, which was chaired by Norwegian Prime Minister Gro Harlem Brundtland. The objectives of this Commission were to re-examine the most urgent problems of environment and development, to propose new directions for international cooperation, and to raise the level of commitment to achieve these goals by individuals, institutions and governments [11]. The report presented by the Commission, known as the "Brundtland Report," coined the concept of sustainable development [12]. This term refers to the rational use of the natural resources of a place, taking care that they are not impoverished and that future generations can make use of them.

The Brundtland Report highlighted the environmental problems that threaten our survival and made important proposals for the future, including the need for governments and regional and international institutions to support a new model of economic development that can be harmonized with the preservation of the environment, in order to guarantee the quality of life of both present and future generations. The aim is to achieve sustainable or lasting development, which the Report defines as development that meets the needs of the present without compromising the ability of future generations to meet their own needs.

Although the concept of sustainable development arises from concern for the environment, its essence is not eminently environmental, but rather seeks to overcome the vision of the environment as an aspect independent of human activity that must be preserved. It is conceived, therefore, as a programmatic aspiration for the future that generates the responsibility of not endangering the environment [13].

It is important to note that the term "sustainable development" was later taken up in Principle 3 of the Rio Declaration on Environment and Development (1992), which defines it as development that meets the needs of present generations without compromising the ability of future generations to meet their own needs.

The concept of sustainable development was not a new idea. What was new was the articulation of these ideas in the context of a global, industrial and information society. It was novel, moreover, because it incorporated the idea that inaction can have great consequences.

2.2. Widespread Acceptance of the Precautionary Principlein Environmental Matters

The precautionary principle quickly moved from marine environmental fora and agreements to environmental policy discussions at a broader level. The Governing Council of the United Nations Environment Programme adopted this concept in 1990 with respect to hazardous waste policies. In addition, it noted the adoption of the environmental protection and enhancement approach to precautionary measures and made an appeal:

> *"...to Governments and appropriate international forums, taking economic cost into consideration alternative clean production methods -including raw materials selection, product substitution, and clean production technologies and processes- as a means of implementing a precautionary approach in order to promote production systems that minimize or eliminate the generation of hazardous wastes and optimize use of raw materials, water and energy, for example through recycling."* [14]

In the same year, the Ministerial Conference on Environment of the Economic and Social Commission for Asia and the Pacific (ESCAP) adopted a Declaration on Sound and Sustainable Development stating that:

> *"...in order to achieve sustainable development, policies must be based on the precautionary principle."* [15]

Subsequently, the United Nations General Assembly convened the United Nations Conference on Environment and Development (UNCED), also known as the "Earth Summit" or "Rio Summit", through its resolution 228 of December 22, 1989. The preparatory work for the Summit took place within a Committee that held four series of meetings between 1990 and 1992: Nairobi, Geneva and New York. From the outset, it was agreed that decisions would be adopted by consensus. [16]

The Earth Summit was held in Rio de Janeiro in June 1992 and adopted three important agreements. The first was the Rio Declaration on Environment and Development, which is a set of principles defining the rights and duties of states. The second was Agenda 21, a global action program to promote sustainable development[1]. And the third, the Declaration on Principles for a Global Consensus on the Management, Conservation and Sustainable Development of All Types of Forests [17]. The 1992 Declaration of Principles for Sustainable Forest Management deals with sustainable forest management and, although not legally binding, represented the first global consensus on forest protection.

In addition, two legally binding instruments were opened for signature: the United Nations Framework Convention on Climate Change and the Convention on Biological Diversity.

The Rio Declaration establishes the criteria for making the demands of development compatible with those of environmental protection [16]. Principle 15 of this Declaration enshrines the precautionary principle by stating that:

> *"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 and irreversible damage, the lack of absolute scientific certainty of cost-effective measures to prevent environmental degradation."*

Thus, we see how the precautionary principle serves as a guide for the development and application of international environmental law in cases where there is no scientific certainty [18].

Subsequently, this legal principle was included in the preamble of the 1993 Convention on Biological Diversity, considering that "...where there is a threat of substantial reduction or loss of biological diversity, lack of unequivocal scientific evidence should not be invoked as a reason for postponing measures to avoid or minimize such a threat".

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[1] Agenda 21 is a global action plan covering aspects of sustainable development, including pollution of the atmosphere, air and water, the fight against deforestation, desertification and loss of agricultural land, etc. It also establishes development patterns that are a burden on the environment, such as poverty, the external debt of developing countries and population pressure. This Program is organized into four sections, namely, the social and economic dimensions, conservation and management of resources for development, the role of economic and social groups, and the means of implementation. In addition, it provides valuable and practical information on all aspects of environmental protection, including the conservation of biological diversity. It also mentions the precautionary principle in its section II, on the conservation and management of resources for development, noting that a strategy of precaution and prevention, rather than reaction, will be more useful in preventing degradation of the marine environment. Chapter 17.21 of Agenda 21.

Thus, we can see how these examples illustrate that the concept of precaution constitutes a new parameter in the different international legal instruments and in their environmental action.

2.3. Convention on Biological Diversity

a. Background of the Convention on Biological Diversity

At the 1992 United Nations Conference on Environment and Development, two legally binding agreements of great environmental importance were signed: the United Nations Framework Convention on Climate Change and the Convention on Biological Diversity, the latter being the first global agreement focused on the conservation and sustainable use of biodiversity.

Prior to the entry into force of the Convention on Biological Diversity, international environmental instruments did not specifically guarantee biodiversity conservation. The sectoral and regional nature of the treaties for the conservation of species and ecosystems led to significant gaps. The international treaties were too narrow in scope, focusing their efforts on the protection of certain types of habitats[2], the protection of certain types of species [3] and the regulation of certain types of threats to endangered species[4].

Likewise, although there were conservation agreements for specific objects, these were limited to certain parts of the planet, so that there were regions that remained outside the protection granted by the treaty[5].

The Convention on Biological Diversity is the first comprehensive global agreement that addresses all aspects of biological diversity: genetic resources, species and ecosystems: the conservation of biological diversity, the sustainable use of the components of biological diversity, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources are among the objectives of the Convention. This Convention was adopted at the United Nations Environment Programme (UNEP) Conference on March 24, 1992 and entered into force on December 29, 1993. [19]

b. Legal regime of the Convention on Biological Diversity.

The CBD defines a program to reconcile the economic development of States with the need to preserve all elements of biological diversity. Notwithstanding state sovereignty in the exploitation of its own resources and the responsibility of the state to ensure that activities carried out under its jurisdiction or control do not damage the environment of other states, it must be emphasized that issues related to biodiversity protection transcend national boundaries and therefore go beyond the national sphere.

The Convention addresses the biodiversity of the world's major habitat types, such as forests, agricultural land, dry and sub-humid lands, oceans and coastal areas, inland waters, mountains and islands. Also other cross-cutting issues, such as protected areas, access and benefit sharing, or incentives. In order to implement the CBD, the EU launched its own biodiversity strategy in February 1998, a plan with general measures to promote the conservation and sustainable use of biological diversity. The Cardiff Process was launched in 1998 and provides a mechanism for the integration of environmental considerations into key sectors of EU policy. Each of the Directorate Generals has an integration correspondent and specialized environmental units.

The scope of the CBD includes all aspects of biological biodiversity, which is defined in Article 2 as:

> *"The variability among living things from all sources, including, inter alia, terrestrial, marine and aquatic ecosystems and the ecological complexes of which they are part; it includes diversity within species, between species and of ecosystems."*

As can be seen, the CBD starts from a broad concept of biodiversity that could be classified into three levels. The first level is the diversity of ecosystems. The second is diversity among species, also called species diversity. And the third level is diversity within species, also known as genetic diversity. The Convention does not provide a concept of ecosystem diversity, but it has been defined by some authors as the variety of habitats, biotic communities and ecological processes in the biosphere, as well as the diversity within ecosystems themselves. [20]

The CBD is also seen as a framework convention that creates a global structure to promote international cooperation and to assist national implementation. Its Article 6 emphasizes the development of national biodiversity strategies and action plans as the basis for each country's obligations and provides that each Contracting Party shall, in accordance with its particular conditions and capabilities, develop national strategies, plans or programs for the conservation and sustainable use of biological diversity.

However, in accordance with the mandate of Article 19.3 of the CBD, the Parties were to consider the adoption of a protocol with the objective of regulating the transfer, handling and use of any living modified organism (LMO)[6].

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[2] To mention a few: The Convention on Wetlands of International Importance, especially as Waterfowl Habitat (Ramsar Convention, Iran, February 2, 1971) and the Convention for the Protection of the World Cultural and Natural Heritage (Paris, November 16, 1971).

[3] For example, Convention on the Conservation of Migratory Species of Wild Animals (Bonn Convention of June 23, 1979).

[4] Convention on International Trade in Endangered Species of Wild Fauna and Flora (Washington, March 3, 1973).

[5] For example, the Agreement on the Conservation of Nature and Natural Resources, concluded at the Association of Southeast Asian Nations (Kuala Lumpur, July 9, 1985) and the Protocol for the Protection and Development of the Marine Environment and the Wider Caribbean Region (Kingston, January 18, 1990).

[6] During the second meeting of the Conference of the Parties to the CBD, held in Indonesia in 1995, an Ad Hoc Working Group, known as the *Board Supports Working Group* (BSWG-5), was approved by Decision II/5. (Decision II/5, UNEP/CBD/COP/2/19). This Working Group was tasked with developing a Protocol on Biosafety, which was to take into account the principles enshrined in the Rio Declaration, in particular the precautionary principle. Furthermore, this protocol would not go beyond the scope of the Convention, nor would it derogate from or duplicate any other international legal instrument. The Group, meeting in Cartagena in 1999, submitted a draft protocol to the Conference of the Parties (UNEP/CBD/ExCOP/1/2, Appendix 1). However, the States Parties failed to

The final negotiation took place in Montreal on January 29, 2000, where the "Cartagena Protocol on Biosafety" was adopted and entered into force on September 11, 2003.

2.4. Cartagena Protocol on Biosafety

The Cartagena Protocol promotes biotechnology as a safe way to raise food production levels while ensuring that food is sustainable and environmentally beneficial.

The Protocol establishes, for the first time, a comprehensive regulatory system to ensure the safe transfer, handling and use of LMOs subject to transboundary movements. It allows governments to indicate whether or not they are willing to accept imports of agricultural products that include LMOs by communicating their decision to the international community through the Biosafety Clearing-House[7].

This international instrument deals primarily with LMOs that are to be introduced into the environment, such as seeds, trees or fish, and certain genetically modified agricultural products, such as corn and grains used for food, feed or processing.

The Cartagena Protocol aims to ensure an adequate level of protection of human health throughout the entire process of the use of LMOs, i.e. in their transfer, handling and use, as their use may have adverse effects on the conservation and sustainable use of biological diversity[8].

Thus, we can see how the Cartagena Protocol promotes biosafety by establishing practical rules and procedures for the transfer, handling and use of LMOs, with special attention to regulating the movement of these organisms across international borders.

a. Scope of application of the Cartagena Protocol.

Determining the scope of the Cartagena Protocol was problematic during its negotiation. The meeting discussed whether the Protocol should cover any activity related to LMOs or whether it would only be limited to transboundary movements and, if so, would include import, handling and use activities. Article 4 of the Protocol thus provides that it will apply "to the transboundary movement, transit, handling and use of all LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health".

It should be noted that the Cartagena Protocol uses the nomenclature LMO (living modified organism) and not GMO (genetically modified organism). This is due to the fact that during the negotiations it became clear that the term LMO should be used to include both traditional biotechnology and modern biotechnology, since both could have adverse effects on the conservation and use of biodiversity[9]. For this reason, Article 3 defines LMOs as follows:

> *"Any living organism that possesses a novel combination of genetic material that has been obtained through modern biotechnology."* [21]

LMOs can be classified into two groups. The first is intended for deliberate introduction into the environment, such as seeds. The second group consists of all those LMOs that can be used directly as food or feed or for processing, such as genetically modified vegetables. This second group is known as LMO-FFPs *(Living modified organisms for food, feed and processing)*.

This classification of LMOs is important when it comes to adopting standards of protection against their use. For example, with regard to LMO-FFPs, Article 11 of the Cartagena Protocol establishes a multilateral information exchange mechanism, entrusted to the Biosafety Clearing-House[10].

In addition to the control and reporting mechanism, the Protocol establishes four exceptions in which international trade in LMOs is not subject to the control and reporting mechanism. These are transboundary movements of LMOs of pharmaceutical products (Art. 5); LMOs in transit and those destined for contained use (Art. 6)[11]; and transboundary movement of LMOs that do not pose a risk to biological diversity and human health (Art. 7.4).

Finally, with regard to the definition of the subjective scope of application of the Protocol, it should be noted that the States that have ratified it are obviously bound as soon as it enters into force. However, it should be recalled that States Parties are allowed to enter into bilateral, regional and multilateral agreements concerning the international

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reach agreement on the text and adjourned the meeting (Decision EM-I/1, UNEP/CBD/ExCOP/1/3, Annex 1). Nevertheless, discussions were held with a view to assessing whether there was political will to resume negotiations until, in fact, the Vienna meeting in 1999 and the Montreal meeting the following year.

[7] The Clearinghouse is a mechanism established to facilitate the exchange of information and experiences on this species of organisms.

[8] If a Contracting Party fails to act in accordance with the objective of the Protocol, the Conference of the Parties may consider and approve institutional mechanisms for cooperation to promote compliance (Art. 34). In this regard, the Protocol determines which powers must be exercised to comply with its objective. Specifically, Art. 2.4 establishes that a State may take more protective measures than those described in the Protocol. Article 14(1) sets out the right of Parties to negotiate separate agreements on the transboundary movement of LMOs, while Article 24 regulates relations with non-Parties. Although these provisions do not contain a direct reference to Article 1 of the Protocol, the phrase "consistent with the objective and provisions of this Protocol" indicates that the objective set out in that Article must be respected in exercising the relevant rights and carrying out the relevant activities. It should be recalled that under international law, Article 18 of the 1969 Vienna Convention on the Law of Treaties, a State that has signed a treaty but has not yet ratified it is under an obligation not to act in a manner contrary to the objective of the Convention.

[9] Therefore, for the purposes of this research work, from now on the term genetically modified organism (GMO) or transgenic organism will be understood as a synonym for living modified organism (LMO), as it is better known by international doctrine.

[10] The Party of import must request data from the Biosafety Clearing-House on new LMO-FFPs that may be subject to international trade and, if it wishes, may subject such imports to domestic regulation. Thus, this Article explicitly allows Parties to subject the first import of LMO-FFPs to prior risk assessment and approval.

[11] Contained use is defined as "any operation, carried out within a room, facility or other physical structure, involving the handling of LMOs controlled by specific measures that effectively limit their contact with, or effects on, the external environment" (Art. 3(b) of the Cartagena Protocol).

transboundary movement of LMOs, provided that they meet two conditions. The first is that such agreements must be consistent with the objective of the Protocol. Second, they must not constitute a reduction in the level of protection established by the Protocol[12]. In addition, States Parties are allowed to enter into bilateral, regional or multilateral agreements with other non-Parties regarding transboundary movements of LMOs (Art. 24). The aim is to encourage non-Parties to adhere to the Protocol and thus provide relevant information on LMOs released or introduced into or transported out of their territories.

The Protocol thus allows the States Parties to gradually extend the subjective scope of application of the Protocol under certain conditions that are not excessively burdensome for the States.

b. The precautionary principle in the Cartagena Protocol.

The precautionary principle is reflected in the Cartagena Protocol from its first sentence in Article 1, stating 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 (...)".

Likewise, Articles 10.6 and 11.8 regulate the application of the principle as a condition for the import of LMOs. Article 10.6 of the Cartagena Protocol provides that:

"...lack of scientific certainty due to insufficient relevant scientific information or 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 the Party of import, in order to avoid or minimize such potential adverse effects, from taking a decision, as appropriate, regarding the import of the LMO in question..."

Article 11.8 establishes that:

"...lack of scientific certainty due to insufficient relevant information and knowledge about the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity shall not prevent that Party, in order to avoid or minimize such potential adverse effects, from taking a decision, as appropriate, regarding the import of that living modified organism..."

As we can see, both provisions specify that the lack of scientific certainty about the extent of the potential adverse effects of a LMO on biodiversity shall not prevent the Party of import from taking a decision, as appropriate, regarding the import of such LMOs.

In general, these provisions also address the situation where, having carried out a risk assessment in accordance with Article 15 of the Protocol, the importing Party may conclude, taking into account risks to human health, that uncertainty persists as to the potential adverse effects of LMOs on the conservation and sustainable use of biological diversity. In sum, the Cartagena Protocol marks the application of the precautionary principle, as it establishes concrete measures on a case-by-case basis to address the uncertain risk and thus achieve more effective preservation of the environment.

Finally, we should mention that Article 27 of the Cartagena Protocol established that the Parties, at their first meeting, should initiate a process regarding the elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of LMOs, and seek to complete that process within four years. This first meeting was held in February 2004 in Kuala Lumpur [22]. The last meeting, held on 15 October 2010, adopted the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety and entered into force on March 5, 2018.

c. Towards a compensation regime: the Nagoya-Kuala Lumpur Protocol.

The objective of this Protocol is to contribute to the conservation and sustainable use of biological diversity, taking into account risks to human health, and providing international rules and procedures in the field of liability and redress in relation to LMOs (Art. 1).

The new Supplementary Protocol provides international rules and procedures in the field of liability and redress in relation to damage to biological diversity resulting from LMOs[13]. As in the precursor agreement, the Cartagena Protocol, the adoption of this Protocol has a dual function. On the one hand, it prevents the creation of environmental damage, and, on the other hand, it provides confidence-building measures for the development and application of modern biotechnology. In doing so, it prepares an environment conducive to maximizing the benefits of LMOs by providing rules for compensation or response measures in the event that damage to biodiversity occurs or is likely to occur.

In 2018, Antonio Guterres, UN Secretary General, emphasized that natural areas are a prerequisite for ensuring our future and that of future generations, and that agricultural activities represent a means of subsistence and contribute to feeding millions of people in the world. He also mentioned that the States Parties to the Convention on Biological Diversity have begun work on a new action plan to ensure that biodiversity is preserved in the best possible way by 2050.

For her part, Cristiana Paşca Palmer, executive secretary of the CBD, stressed that biodiversity is at the core of the 2030 Agenda for Sustainable Development, as its deterioration encompasses other challenges, such as climate change, water, food insecurity and public health.

[12] These agreements must be notified to the other Parties through the Biosafety Clearing House (Art. 14 of the Cartagena Protocol).

[13] The meeting of the Parties to the Protocol adopted 17 other decisions. Among these were the adoption of a 10-year Strategic Plan for the implementation of the Protocol, a program of work on public awareness, education and participation in relation to LMOs, and additional guidelines on risk assessment and risk management.

3. Precautionary Principle: A Cross-cutting Principle of International Environmental law

The precautionary principle focuses on the uncertain effects of human activity and stresses the need to take into consideration possible and future damage. This principle is a basic criterion governing environmental action, according to which any substance, organism or technology must demonstrate its compatibility with the environment and public health before being authorized for production and use. It requires, therefore, that legislators, before adopting any decision authorizing the use of new technologies, be clear and certain about the possible harmful consequences of such technologies on human health and the environment.

The distinguishing feature of the precautionary concept is not that it dictates specific regulatory measures, i.e., measures that can be used for enforcement. The distinguishing feature is the form and timing of the measures to be adopted [23].

The precautionary concept assumes that science does not always provide the necessary knowledge to protect the environment effectively. Furthermore, it anticipates that financial resources may be allocated inefficiently if action is taken only after there is scientific certainty about proven harmful effects. [24]

We can point out that there are three essential elements in the criteria mentioned above. The first is a change of approach in trying to determine the level of pollution that the environment can assimilate, making use of new technologies that eliminate or at least reduce the entry of pollutants into the environment. This is a policy based on the minimization and containment of environmentally harmful substances.

The second element is the environmental impact assessment. This assessment implies that environmental policy is not to determine the harmful environmental effects that may follow an activity. Rather, it attempts to ascertain any possible negative effects before the activity occurs and thus, take action to avoid any negative effects.

The third is the need for rational economics within precautionary policy. This is a different concept from the traditional cost-benefit one, which determines that in the long run economic calculation methods are used to try to assimilate the cost of possible damage to the environment.

Therefore, the precautionary principle presupposes the following criteria: 1) the application of clean production methods, best available technology and best environmental practices; 2) general methods of environmental and economic assessment to be used in making decisions to improve the quality of the environment; 3) stimulating scientific and economic research that contributes to a better understanding of the long-term options available; and 4) administrative, legal and technical procedures for this principle to be applied; 4) administrative, legal and technical procedures for this principle to be applied. [25]

From a legal point of view, the most important facet of the precautionary principle is that positive action to protect the environment may be necessary prior to scientific proof that the damage has been proportionate. In such cases, the innovative element is the use of corrective measures. Indeed, the essence of the precautionary principle is that once the risk has been identified, the lack of scientific evidence cannot be used as a reason for not taking any action.

This suggests that the risk threshold has become easier to cross. From a legal perspective, it would imply that once the risk exists, then we enter the scientific uncertainty function against the potential polluter and not, as in the past, that preventive action was used once the harm had been determined.

Boisson de Chazournes states that precaution is a principle to address some of the environmental public health problems of contemporary society. He also emphasizes that four constituent elements can be extracted from the international legal instruments on environmental matters that incorporate the precautionary principle: risk, harm, scientific uncertainty and differentiated capabilities [26], which we will see below.

3.1. The Risk

This is the defining characteristic of precaution. Risk is a more or less foreseeable potential hazard that may cause harm. Therefore, by its very nature, it is uncertain. Precaution has developed in international law by taking into account a new category of risk, ecological risk [27]. In order to take a structural approach to risk, four related aspects should be borne in mind: risk assessment, risk control, risk management and risk communication in connection with the use of LMOs.

a. Risk assessment.

Risk assessment is a necessary tool for decision making and policy definition used in risk management. Risk assessment involves identifying the adverse consequences of a technology or activity and the assessment of whether those consequences will occur. A proper assessment should be based on available scientific evidence to identify and weigh the potential adverse effects of LMOs on the conservation and sustainable use of biological diversity, taking into account risks to human health (Art. 15 of the Cartagena Protocol).

In international law, risk assessment for human and animal life and health has been incorporated, at the global level, in the WTO Agreement on Sanitary and Phytosanitary Measures. On the other hand, at the regional level, especially in the European Union (EU), it has been incorporated through Regulation 178/2002/EC of the European Parliament and of the Council, which established the general principles and requirements of food law, of January 28, 2002. It should be noted that the Court of First Instance of the EU (CFI) has ruled on this issue in the case of *Pfizer Animal Health v. Council* (Case T-13/99), recognizing that risk assessment must be considered as a precondition for the application of the precautionary principle. The CFI noted that:

> *"...with regard to the application of the precautionary principle, which by definition occurs in a context of*

scientific uncertainty, the risk assessment is not required to provide the Community institutions with conclusive scientific evidence of the reality of the risk and the seriousness of the potential harmful effects if the risk were to materialize." [28]

However, the EU Court also specified that a hypothetical conception of risk cannot constitute a valid motivation for a preventive measure. It added:

"*On the contrary, it follows from the interpretation of the precautionary principle by the Community court that a preventive measure can only be adopted when the risk, the existence and extent of which have not been 'fully' demonstrated by conclusive scientific data, is nevertheless sufficiently documented in the light of the scientific data available at the time the measure is adopted".* [29]

After recalling that the purpose of risk assessment is to evaluate the likelihood that a given product or process will have adverse effects on human health and the degree of severity of those potential effects, the CFI concluded that a scientific risk assessment is a prerequisite for the adoption of any preventive measure. [30]

The interest of this judgment is evident, since it contains the jurisprudential line that can be considered of general application and that enshrines the need to carry out a risk assessment as a *sine qua non* condition for adopting measures justified by the precautionary principle. [31]

b. Risk control.

Risk control should be used once the potentially dangerous effects of a phenomenon have been identified and the risk of which cannot be exactly established by science. Hence, the first step in the use of the precautionary principle is a scientific evaluation of the various degrees of uncertainty. This honest judgment of science will allow the appropriate decision to be made to determine what level of risk is acceptable to a society. The process by which decisions are made should be transparent and involve all interested parties, i.e. scientists, the public, organizations, companies, etc.

c. Risk management.

Risk management, on the other hand, is characterized by weighing the risks and benefits associated with an activity and selecting an action strategy that modifies the levels of risk to which individuals or the population are subjected.

Thus, we can see how the precautionary principle contains an inter-temporal dimension in the sense that it goes beyond the problems associated with short- or medium-term risks, since it also refers to long-term risks, which could even affect the well-being of future generations. It is also based on the "lack of scientific certainty" and must also be limited to risks not of any nature but to "serious and irreversible" risks. [32]

d. Risk communication.

Finally, a structural approach to risk requires risk communication. Risk communication is understood as the interactive exchange of information and opinions on risks between risk assessors and risk managers, consumers and interested parties[14].

In the European Union, Article 3.13 of Regulation 178/2002/EC defined risk communication as "the interactive exchange, throughout the risk analysis process, of information and opinions regarding hazard and risk factors, risk-related factors and risk perceptions between risk assessors and risk managers, consumers, feed and food businesses, the scientific community and other interested parties, including the explanation of risk assessment results and the rationale for risk management decisions".

3.2. Damage

The second element of the precautionary principle is damage. The definition of damage to the environment concerns two different categories, depending on whether the damaged environment affects the health and property of individuals or the natural environment as such [33]. In the first case, damage to the environment would be included in the category of the so-called personal, patrimonial or economic damage, i.e. damage to the health and physical integrity of persons, such as, for example, asthma caused by atmospheric pollution, and damage to the property of persons and to the exercise of their economic activities, for example, fishing. In the second case, damage to the environment would be included in what the doctrine has called pure ecological damage, which is alien to any personal, patrimonial or economic connotation.

3.3. Scientific Uncertainty

The third element of the precautionary principle is scientific uncertainty about the harmful consequences of an act or product. In this sense, the precautionary principle is characterized by being applied in the face of the insufficient contribution of science to know precisely and indubitably the existence or not of the potential danger or risk of a given activity. Uncertainty has been defined as "the imperfection in knowledge about the state or processes of nature". [34]

Uncertainty is a *sine qua non* condition for the application, and indeed for the legitimacy, of the precautionary principle. Uncertainty, moreover, represents the difference between precaution and prevention. The prevention model must constantly rely on science and its expertise, which can provide certain degrees of objectivity as to the risks to which one is exposed. The scope of precautionary measures must be based on a minimum of knowledge based on scientific results that present a certain degree of consistency.

The precautionary principle does not confuse the need for environmental protection with the industrial activity of States, since States have, in accordance with Principle 2 of the Rio Declaration, the sovereign right to exploit their own resources according to their environmental and development policies. [35]

At the regional level, the CFI expressed its opinion on

[14] Definition adopted by the 22nd Session of the *Codex Alimentarius Commission*, Geneva 23-28 June 1997.

scientific uncertainty in its *Artegodan* judgment (joined cases T-74/00 and others) [36]. This case discussed the prohibition of the use of certain drugs that acted on the central nervous system, generating a feeling of satiety, and were therefore used to combat obesity [37]. In March 2000, the European Commission adopted three decisions to withdraw marketing authorizations for medicinal products for human use. The Commission ordered the Member States to withdraw the national marketing authorizations provided for in Art. 3 of Council Directive 65/65/EEC of 26 January 1965. The Court concluded that "when there is scientific uncertainty as to the safety of the drug, the competent authority must evaluate the drug in accordance with the precautionary principle". [38]

3.4. Differentiated Capabilities

The fourth characteristic element of the precautionary principle is differentiated capacity. This element implies that States with different levels of development cannot be subject to the same requirements with regard to the application of precautionary measures. [39]

If the capabilities of a State are taken into consideration, a link can be established between the precautionary principle and a proportionate approach in the light of that State's status. States at different levels of development may not be subject to the same requirements with regard to the application of precautionary measures. As far as the assessment of risk and harm is concerned, States do not have access to the same techniques, which means that the content as well as the reliability of the results will necessarily vary from one State to another. Proportionality is determined in this context in terms of capabilities, i.e. the human, financial, economic and technical means at the disposal of each State to understand a risk and manage it better. [40]

4. Conclusion

The conservation of biological diversity should not be seen as an activity isolated from the other activities of States and international organizations; in fact, the conservation and sustainable use of biological diversity has numerous aspects and interrelations with other fields. There is currently a generalized movement towards greater acceptance and practice of the precautionary principle, which has developed from a simple novel approach to environmental protection to a principle that guides behavior in international and national regulations, as evidenced by the agreement of the United Nations in the Rio de Janeiro Declaration on Environment and Development.

The precautionary principle is a principle aimed at preventing risks that are closely linked to uncertainty. Its diffusion in environmental policies in recent decades has been due to the concurrence of two factors in particular. On the one hand, attention must be paid to the characteristics of environmental policy and of the historical, social and ecological reality that such policy intends to face at this time. On the other hand, attention should be paid to the risks associated with LMOs.

In environmental matters it is difficult to find remedies for environmental damage and in many cases the damage is simply irreversible. Even where it is remediable, the cost of repair or rehabilitation is often prohibitive. For this reason, the precautionary principle has become a pillar of international environmental law, since it includes the use of special techniques aimed at controlling, as far as possible, the harmful consequences of an action or product. Thus, recourse to the precautionary principle presupposes, on the one hand, the identification of the possible negative effects resulting from a phenomenon, a product or a process. On the other hand, it implies the evaluation of the risk of a given activity, either because of insufficient data or because the nature of the data makes it impossible to draw a precise conclusion as to the existence or non-existence of the hazard in question.

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