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International Efforts to Protect Biosafety

Baqir Musa Saeed[1], Kadhim Khudair Mohammed[2]

Abstract

Living modified organisms, with their multiple aspects, especially those related to their production, health and environmental risks to biosafety, the increasing rates of cross-border transmission, and the means of protection against them, are among the most prominent issues that have received and continue to receive a great deal of international attention in the last two decades. The impact of human activity and the development of scientific techniques on the environment and natural resources, and the importance of this topic. This research will discuss the international protection of biosafety "a legal study under the Cartagena Protocol of 2000" and because the talk about biosafety extends to the extent of this topic, our study has been defined within the scope of the Protocol Cartagena for the purpose of clarifying the extent of its effectiveness in providing protection for bio-safety, as well as for a better understanding of this topic, which is one of the emerging issues in environmental life that has enjoyed and still enjoys great importance in the contemporary international community, especially with the increasing rates of production of living modified organisms.

Keywords: *Biosafety, genetically modified organisms, trans boundary movement of genetically modified organisms, international protection of biosafety*

First: Research topic

The biotechnology that the developed world has experienced has produced great results in various fields, especially in the applications of genetic engineering (or as it is called modified, transgenic), which is a new term that means that humans can exchange genetic material between completely different races and types of organisms, and this modification results in great benefits. On the scientific and medical levels, as well as on the quality of the product, but at the same time it has concerns, warnings, and many side effects on biodiversity and human health, and then the problem of not taking into account biosafety arises when trading these genetically modified organisms or transporting them across borders without controls and without providing the necessary levels of safety. In order to avoid these risks and provide biosafety, the need arose to find international legal protection for biosafety from the damage that could be caused by living modified organisms. The international response began by adopting the Cartagena Protocol (2000) on biosafety of the Convention on Biological Diversity, which established international legal rules to provide protection. For biosafety, its importance lies in the fact that it is the first international agreement that provides a detailed legal framework for biosafety and transboundary transfers of living modified organisms, as well as ensuring an appropriate level of protection and safety in the field of transport, circulation and use of living modified organisms. It has also established mechanisms to ensure the implementation of its provisions and the fulfillment of its obligations. (Rahayu, 2023)

[1] University of Babylon / College of Law, law.baqer.saeed@uobabylon.edu.iq
[2] University of Babylon / College of Law, Khdum.Swedy@uobylon.edu.iq

Second: The importance of research and its problem

The importance of this research lies in the fact that it includes recent studies that deal with biosafety under the Cartagena Protocol (2000) on biosafety, to demonstrate the effectiveness of the protocol in providing protection for biosafety, and its importance also appears to be that it raises the level of public awareness among members of communities regarding the risks that can occur. Caused by living modified organisms because there is no point in legislating when legal awareness among segments of society about it is weak. The problem of the research is to know the extent of the effectiveness of the Cartagena Protocol (2000) in providing international protection for biological safety from the use of biotechnology to change the species of living organisms, and whether it was able to achieve a balance between the benefit that developed countries obtain from the use of modern technology in changing the species of living organisms, And the damage it poses to biodiversity and human health. (Suleman et al., 2023)

Third: The goal and methodology of the research

The research aims to explain the details of the international legal system for protecting biosafety, and to point out its strengths and weaknesses, in order to provide some contributions that have a role in developing that protection, even by alerting public awareness to the risks that result from living modified organisms. Our study (International Protection of Biosafety - A Legal Study Under the 2000 Cartagena Protocol) will be an analytical study because it relied on the analytical approach to the provisions and principles of the Cartagena Protocol in order to extract the foundations and rules of protecting biosafety from the dangers of living modified organisms. (Schäfers, 2022)

Fourth: Research plan

We will study this topic through three sections. In the first, we review the definition of the Cartagena Protocol by studying the stages of concluding the Protocol and the scope of its application. In the second section, we talk about the provisions of the Cartagena Protocol. The third section is devoted to dealing with implementation and compliance within the framework of the Cartagena Protocol.

The first topic

Introduction to the Cartagena Protocol

The Cartagena Protocol of 2000 is the first legal reference for everything related to the protection of biosafety at the international level, which prompts us to study the problem of biosafety by taking note of this protocol by examining the stages of concluding a protocol. This is what will be discussed in detail in the first requirement. As for the second requirement It will be devoted to addressing the substantive and temporal scope of application of the Protocol. (Jajang, 2023)

Tthe first requirement

Abram concluded the Cartagena Protocol

The United Nations Conference on Environment and Development in 1992, held in Rio de Janeiro, began seriously thinking about finding a solution to the problem of living modified organisms. At this meeting, more than 178 governments adopted Agenda 21, which approved a new world order based on international cooperation between countries. Developed and developing countries (1) This system included a chapter on "Environmentally Sound Management of Biotechnology", and at the same meeting the Convention on Biological Diversity was opened for signature (2) and one of the main objectives addressed by the Convention is biosafety, that is, the need to protect human health and the environment from the effects Potentially harmful effects of modern biotechnology products.

It is recognized that biotechnology has great potential to promote human well-being and sound management of the environment. The Convention on Biological Diversity clearly recognizes these dual aspects of biotechnology and includes provisions to promote both biotechnology and the development of procedures to ensure its safety, for example Article 16/1 and Article 1/ 19.2, calls for access and transfer of technology, including biotechnology relevant to the conservation and sustainable use of biological diversity, while Articles G and Article 3/19 seek to ensure the development of appropriate measures to enhance the safety of biotechnology in the context of the overall objective of the Convention, namely to reduce all Potential threats to the sustainable use of biodiversity, including risks to human health (3). The content of Article 3/19 of the Convention on Biological Diversity is controversial, as opinions differed about the need for internationally agreed rules on biosafety. During the negotiation of the Convention on Biological Diversity, the discussion focused on two points. The first is the organization that makes the development of a protocol on biosafety mandatory, and the second point. The text of the article does not explicitly call for a protocol, but rather asks the parties to consider the need for a protocol, and the second opinion was preferred (4). In 1994, at the first meeting of the Conference of the Parties to the Convention on Biological Diversity in Nassau, Bahamas, it was announced that a meeting would be held to consider the need for Protocol on Biosafety and its Methods. Accordingly, a group of experts met in Cairo in May 1995, followed by a meeting of the Ad Hoc Open-ended Expert Group on Biosafety (i.e. open to all Parties to the Convention on Biological Diversity and observers) in Madrid in July 1995, the vast majority of Delegations attending the Madrid meeting developed a protocol on biosafety that would have adverse effects on the conservation and sustainable use of biological diversity (5). Negotiations on the regulation of biotechnology were fraught with a compromise between ensuring sustainable uses of biotechnology on the one hand, and environmental and health concerns on the other. At its second meeting in 1995 in Jakarta, the Conference of the Parties discussed the report submitted by an open-ended group of experts, and the Parties stressed the need to provide International measures on biosafety are a capable and effective framework for developing international cooperation aimed at ensuring safety in biotechnology by assessing and managing risks effectively for the transfer, handling and use of any living modified organism resulting from modern biotechnology that may have negative environmental impacts that could affect the conservation of diversity. and its sustainable use, and the Conference of the Parties decided to establish an ad hoc open-ended working group within the framework of the Conference of the Parties, composed of representatives, including experts, appointed by Governments and regional economic integration organizations, with the mandate to define key concepts and terminology, and to consider prior informed consent procedures, with emphasis In particular on the transboundary movement of any living modified organisms arising from modern technology, which may have adverse effects on the conservation and sustainable use of biological diversity (6). At the third meeting of the Conference of the Parties, the report submitted by the working group that met in Aarhus/Denmark in The period from July 22 to 26, 1996, and the parties asked the working group to hold two meetings, the first in 1997, and a sufficient number of meetings in 1998 to enable the working group to complete its work. During these meetings, the Miami group, led by the United States, demanded that genetically modified organisms (genetically modified organisms) be treated like any other substance, subject to The law of the World Trade Organization, and strongly opposed the precautionary principle, supporting its opinion on the lack of sufficient information about the effects of living modified organisms, and called on European countries to treat living modified organisms in special treatment, which would allow them to refuse the display of living modified organisms based on the precautionary principle due to their citizens' fear of the effects of those organisms in particular. In the field of agriculture and nutrition (8). At the fourth meeting, the Conference of the Parties decided to hold two meetings, one of which was the Ad Hoc Open-ended Working Group on Biosafety, and another extraordinary meeting of the Conference of the Parties in February 1999 at the headquarters of the Secretariat of the Convention on Biological Diversity in

Montreal/Canada. The extraordinary meeting would address the adoption of a protocol on biosafety, and decided that The Secretariat receives proposals from Governments regarding the provisions to be included in the Protocol, which will enable the Ad Hoc Open-ended Working Group to consider these proposals during its meeting in August 1999, and decided to open the Protocol for signature at the United Nations headquarters in New York, within a period not exceeding Three months from the date of its adoption by the Conference of the Parties (9). At the extraordinary meeting of the Conference of the Parties held in 2000, which was attended by many environmental non-governmental organizations, representatives of the industrial sector and many journalists, and after intense negotiations, it was agreed with difficulty to adopt the Cartagena Protocol (1/28/2000(10)) and in accordance with the provisions of Article 37 the Protocol entered into force. It entered into force on September 11, 2003, and on August 15, 2003, 106 members of the European Community ratified the Protocol (11). Although there are international instruments concerned with the issue of biosafety, the Cartagena Protocol plays a fundamental role in addressing the main issues related to living modified organisms and represents the culmination of the most important international debate on issues related to this issue (12).

The Second Requirement

Scope of Application of the Cartagena Protocol

In this requirement, we will try to know the objective and temporal scope of the application of the Cartagena Protocol in order to know the cases covered by the Protocol.

First Branch

Substantive Scope of the Cartagena Protocol

The scope of application of the 2000 Cartagena Protocol was one of the major stakes for the opposing parties. Some people preferred to limit the application of the Protocol to living modified organisms intended for introduction into the environment. According to this opinion, this Protocol should only be applied to seeds, as they may pose a potential threat to the environment, especially to biological diversity and health. As for the other direction, it is preferable to expand the scope of application of the Protocol to include agricultural products that contain living modified organisms and used in human and animal nutrition, whether directly or after conversion. Rather, it extends to apply to living modified organisms used in pharmacy and medicine, and the open-ended working group reached compromise solutions between the two directions. The Cartagena Protocol used the phrase (living modified organisms) instead of the conventional phrase usually used in this field by specialists, which is (genetically modified organisms) (13). The Cartagena Protocol defined living modified organisms as "any living organism that possesses a new combination of genetic material obtained through the use of modern biotechnology." (14) As for a living organism, the Protocol defined it as "any biological organism capable of transferring or multiplying genetic material, including: These include sterile organisms, viruses, and virus-like organisms (15)

The use of the term "living" for genetically modified organisms has made the Protocol apply only to biologically active products, such as seeds and agricultural products modified for the purpose of human and animal nutrition, and non-agricultural products intended for human or animal nutrition, such as live fish. As for materials derived from the previous materials, such as flour and oils, these materials are known to not They multiply biologically and genetic material cannot be transferred, so they are excluded from the scope of application of the Protocol (16). This is what the Protocol confirmed through the text of Article (4), which states: "The Protocol applies to the transboundary movement, transit, handling and

use of all living modified organisms that may "Have adverse effects on the conservation and sustainable use of biological diversity, taking into account the risk to human health" (17). Also, under Article 5, living modified organisms that are considered pharmaceutical substances for humans and are covered by other relevant international agreements or organizations are excluded from the scope of application of the Protocol.

Second Branch

Date range of the Cartagena Protocol

Article 37 of the Protocol stipulates that the Protocol shall enter into force on the ninetieth day from the date of deposit of the twentieth instrument of ratification. The Protocol shall enter into force for each State or political or economic integration organization on the ninetieth day from the date on which such State or political or economic integration organization deposits its instrument of ratification or Acceptance, formal confirmation, approval or accession (18). It is clear to us from the above article that the Cartagena Protocol has immediate effect in application, like any other international treaty, as it does not stipulate the principle of non-retroactivity of treaties, and this applies with the general rule (non-retroactivity of treaties), meaning that the concluded treaty does not apply to the facts that were concluded. In the past, the states parties to it are only bound by it from the date of its entry into force, but as an exception to the rule, the effects of any international treaty can apply to include facts that occurred in the past, provided that this is stipulated in the treaty, explicitly or implicitly (19). With reference to the Cartagena Protocol, it was not We find that it has been stipulated that it applies retroactively or implicitly.

The Second Topic

Provisions of the Cartagena Protocol

The Cartagena Protocol came with a set of legal provisions that were agreed upon between the parties, which as a whole aim to create effective protection for biosafety from the risks that can be posed by living modified organisms. Addressing this issue requires presenting the general legal obligations related to living modified organisms in the first requirement, and then we explain Special legal obligations relating to the transboundary movement of living modified organisms in the second requirement.

The First Requirement

General Legal Obligations Relating to Living Modified Organisms.

The Cartagena Protocol established a set of general legal obligations related to living modified organisms. These obligations are as follows:

First Branch

The Parties' Commitment to Prevent or Reduce Risks

The principle of prevention or minimization means that countries must conduct studies on assessing the environmental impact of any project before authorizing its establishment, as well as on new environmental impacts of already existing projects, and they must take, whether individually or collectively, in accordance with the findings of these studies, all measures And the necessary measures to prevent or reduce harmful environmental impacts (20). The origin of this principle in international law goes back to the arbitration ruling issued in 1941 in the Trail Smelting Plant case between Canada and the United States regarding Canada's responsibility for the damages that occurred in the United States as a result of air pollution. From a smelter located in Canada (21).

This commitment is contained in Article 2/2 of the Cartagena Protocol, which stipulates that "Parties shall ensure that a method is followed for the development, handling, transfer, use, transfer and release of any living modified organisms that prevents or reduces risks to biological diversity, taking into account risks to human health as well."

We note from this text that this commitment refers to the main objective of concluding the Cartagena Protocol stipulated in Article 1, which is the conservation and sustainable use of biological diversity, taking into account risks to human health, by stipulating that activities that include living modified organisms must be carried out "in a manner that prevents or reduces risks", Article 2 relates directly to the need for ex-ante risk assessment, and this reflects the precautionary approach, which is widely recognized in modern international law, which stresses that legal rules should be designed to prevent harm from occurring rather than From trying to repair the damage after it occurs, and Article 2/2 specifies the methods through which the damage is prevented or reduced, which are development, handling, transport, use, conversion and release. These terms were not defined in Article (3) of the Protocol, and accordingly they must be understood in terms of their meaning, According to the context of the subject and purpose of the Protocol (22), it must be mentioned that the principle of prohibition contained in the Protocol, in addition to being an agreement text contained in an international legal instrument, is considered a customary rule, and accordingly, introducing genetic modification to organisms is an activity It is capable of causing damage to biological diversity and human health, and thus this activity contradicts this principle. If such damage occurs, international responsibility falls on the responsible state, even if we assume the absence of the agreement text, because it did not take special measures to confront the risks and damage arising from genetically modified organisms. These rules are not limited to parties to the Protocol, but rather extend to non-parties. They are general rules that bind all countries, whether they are parties to the Cartagena Protocol or non-parties (23).

Second Branch

Commitment to the Principle of the Preventive Approach

The enormous scientific and technological revolution that the world is witnessing makes man unable to predict the occurrence of many disasters that cause great and indescribable damage to the environment, and in most cases he is unable to provide certain evidence about the future damage of human activities to the environment (24). Therefore, there has become a necessity. To take preventive measures in anticipation of the occurrence of such potential damage. Hence, the preventive approach is more relevant and effective in preserving and protecting the environment than the approach based on action when pollution occurs. The application of this principle is based on the assumption that scientific uncertainty cannot be used as an excuse to refrain from taking measures. necessary to protect the environment, and this reflects the burden of proof and places it on those who claim that this activity is not destructive (25).

Within the framework of the Cartagena Protocol, living modified organisms are considered one of the most appropriate areas for applying a preventive approach, due to the risks they pose to biological diversity and human health, as the currently available information has not completely excluded the impact of living modified organisms on biological diversity, human health, and the environment, such as causing cancer and kidney failure. Therefore, the principle of the preventive approach was accepted by many European countries and non-governmental organizations, and the Miami Group refused to include it in the body of the protocol, and agreed to include it in the preamble, considering that this allows countries to refuse to import living modified organisms contained in agricultural products or intended for feeding or processing, which gives practical content. And my application of the principle, which is what European countries were demanding (26)

The Cartagena Protocol stipulates reliance on the precautionary principle to achieve biosafety and employing it in an attempt to achieve complete protection against potential threats to biological diversity and human health, as this was stated in the preamble and body of the Cartagena Protocol. As for the preamble to the Protocol, it stipulates that, emphasizing the precautionary approach contained in Principle 15 of The Rio Declaration on Environment and Development" with reference to the Rio Declaration of Rescue states that "In order to protect the environment, States shall widely adopt a preventive approach, according to their capabilities, and in the event of the emergence of risks of serious and irreversible harm, the lack of full scientific certainty shall not be used as a reason." To postpone cost-effective measures to prevent environmental degradation."

As for the text, we find the text of Article 6/10 of the Cartagena Protocol was consistent with what was stated in the Rio Declaration of 1992, as it stated: "The lack of scientific certainty as a result of insufficient information and relevant scientific knowledge regarding the severity of potential harmful effects resulting from a living organism." Focusing on the conservation and sustainable use of biological diversity in the Party of import, while also taking into account risks to human health, does not prevent that Party from taking a decision, as appropriate, on the import of the living modified organism concerned, as referred to in paragraph 3 above, with a view to avoiding or minimizing impacts potentially harmful."

In the same sense, Article 8/11 stipulates that there is a lack of scientific certainty as a result of insufficient information and relevant scientific knowledge regarding the severity of potential harmful effects resulting from a living modified organism, stipulating the conservation and sustainability of the use of biological diversity in the Party of import, taking into account the risks to human health. Also, that shall not prevent a Party from taking a decision, as appropriate, regarding the import of the living modified organism concerned, as referred to in paragraph 3 above with a view to avoiding or minimizing potential adverse effects." One of the applications of this principle is the decisions taken by some European countries to ban the import of all forms of living modified organisms, including agricultural crops, on the basis of a preventive approach, as the countries with the largest agricultural production in the European Union banned their import, namely (France, Australia, Germany, Greece). These countries reported There are many reasons for this ban, the most important of which are doubts about its benefits, and doubts about its health and environmental risks (27).

Third Branch

Commitment to Identifying Living Modified Organisms

The issue of identifying living modified organisms is considered one of the issues that almost failed in the negotiations that took place at the special session of the Conference of the Parties in Montreal 2000 due to the conflicting position between America and the European Union, because America considers that identifying living modified organisms has no practical benefit, justifying its position by allowing the display of These materials are on the market, which means that they do not have harmful effects. In addition, the identification process is costly from an economic standpoint. As for the European Union, it stuck to its position in the face of the American rejection and demanded respect for consumers' freedom of choice and respect for health and environmental security requirements. European countries demanded that the identification process not concern Living modified organisms - germs, animals and plants - but extends to include even agricultural and food products, in line with the laws of the European Union, which require the identification of food products, seeds and products used as animal feed, which noted that these texts are of no use if they do not become international (28). Create a type Cartagena Protocol. To reconcile the two conflicting positions, it states: "Each Party shall take the necessary measures to ensure the handling, packaging and transport of living modified organisms subject to

intended transboundary movement within the scope of this Protocol under safe conditions, taking into account appropriate international rules and standards to avoid adverse effects on the conservation and sustainable use of the diversity." "Biological, taking into account the risks to human health as well." (29) It is clear from the text above that it obligated the parties to determine the identity of living modified organisms intended for use directly as food, feed, or for processing. At the same time, the Protocol allowed countries importing the organisms to request additional information about the identity of these organisms. It also obligated States to confirm the nature of the product, confirm the presence or absence of living modified organisms, and postponed a decision on determining the detailed requirements for this purpose, including their identity and any unique specific characteristics, no later than two years after the date of entry into force of the Protocol. The Conference of the Parties was mandated to do so, as Text: "Each Party shall take measures to require accompanying documents to clearly specify, for living modified organisms intended for direct use as food or feed, or for processing, that they may contain" living modified organisms that are not intended for intentional introduction into the environment, in addition to a contact point for further information, The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including identification and any specific unique characteristics, no later than two years after the date of entry into force of this Protocol" (30).

The second requirement

Special Legal Obligations Relating to The Transboundary Movement of Living Modified Organisms

The Cartagena Protocol allows the movement of living modified organisms in cases where there is no harm to biological diversity or risks to human health, in accordance with certain standards and obligations. To regulate the transfer of living modified organisms, the Cartagena Protocol imposed legal obligations related to the intended, unintentional, and illegal transfer of living modified organisms.

First Branch

Obligations Relating to the Intended Transboundary Movement of Living Modified Organisms

On the basis of the principle of prior informed agreement, the Cartagena Protocol imposes strict requirements regarding the intended transboundary movement of living modified organisms. These requirements or restrictions form the core of the Protocol's control system, which allows a State, on the basis of the precautionary principle, to oppose the import of a living modified organism in the absence of sufficient knowledge of the consequences. This applies to biological diversity, taking into account health and socio-economic considerations (31) and is based on three basic stages:

The first stage: Notification: The provisions of the first paragraph of Article (8) emphasized this obligation, which falls on the exporting party, that is, the country from which the movement of living modified organisms began. This obligation is for the exporting party to undertake, through its national law, or request from the exporter (often A (private) entity must submit a written notification to the competent national authority of the importing party before carrying out the intended cross-border transfer of any living modified organism. The notification includes, as a minimum, the information specified in Annex I, which is the name and address of the exporter and importer, their contact details, and their name and identity. Living modified organisms, as well as the local classification of the biosafety level of the living modified organism, if it exists in the exporting country. The notification must include the date or intended dates of transboundary movement, if known, the taxonomic status, common name, points of collection or acquisition, and characteristics of the recipient organism or predecessor organisms. related to biosafety, centers of origin and centers of genetic diversity of the recipient organism

and ancestral organisms if known, taxonomic status and common name, points of collection or acquisition, and characteristics of the donor organisms related to biosafety (32).

We should ask the following question: Does the prior informed consent procedure apply to every cross-border movement of a living modified organism or to the first cross-border movement?

During the negotiation of the Protocol, there was some debate about whether the prior informed consent procedure should apply to every transboundary movement of a living modified organism to a Party or to the first transboundary movement of a designated organism to an importing Party, Article 1/7 appears to resolve this problem, as it states that PIC applies only to the first intended transboundary movement of living modified organisms into the environment of the importing Party. However, in light of Article 1/7, it may be somewhat unclear whether PIC It will be required every time a particular object is imported into a party for the first time from a "new" export party, or whether it only applies the first time a particular object is imported into an import party from any party - and then, assuming the import The first is permitted. The same LMO should be allowed to be imported under the same conditions from all Parties. The former interpretation can be supported by a close reading of the definition of "transboundary movement" in Article 3/k which indicates that this term means movement of an LMO from one Party to another. In this definition, the term "single party" in Article 3/K refers to a specific party – so every time a new exporting party engages in a transaction with an importing party it is considered the "first" cross-border movement (33).

The second stage: Acknowledgment of receipt of the notification: The second stage of the prior informed consent procedure is the acknowledgment of receipt of the notification, as after receiving the notification from the exporter, the importing party has an obligation, which is to acknowledge to the exporter in writing that it has received the notification, and this response must be within ninety days from The importing party receives the notification from the exporter, and the declaration addressed to the exporter specifies the date of receipt of the notification, and the information the notification contains contained in Article 8 of the Protocol, which we previously talked about in the first stage. It also specifies whether the local regulatory framework applies to the transport of living modified organisms or Procedures stipulated in Article (10) of the Protocol. If the importing party chooses the local regulatory framework to apply to the export of living modified organisms, this framework must be compatible with the provisions of the Protocol.

The meaning of the phrase "in accordance with this Protocol" was not specified and is not subject to any specific oversight mechanism in the Protocol. It would have been more appropriate for the international legislator to use the phrase "in accordance with the objective of this Protocol," as is the case in Articles 4/11, 1/14 and 11/24, and it seems that setting the condition of consistency with the provisions of the Protocol places more stringent restrictions on the party than consistency with the goal of the Protocol. In general, the failure of the importing party to acknowledge receipt of the notification within the specified time period does not constitute approval for the intended cross-border movement (34).

The third stage: Decision-making procedure: The final stage of the advance informed agreement procedure is the decision taken by the competent national authority of the importing party. Under the provisions of Article 10 of the Protocol, the decisions taken by the importing party must be in accordance with Article 15 and Annex III of the Protocol, and by reference Article (15) stipulates that decisions must be based on risk assessments carried out in a scientifically sound manner, that is, an assessment of the potential harmful effects of living modified organisms on the preservation and sustainability of biological diversity and risks to human health. Risk assessment is a dynamic process that takes into account new developments and the progress of science. Conducting appropriate risk assessments will ensure that the benefits of DNA technology remain available (35). Annex III of the

Protocol sets out principles and methodologies on how to conduct a risk assessment. The main principles are: as follows :-

- Risk assessment must be conducted in a scientifically sound and transparent manner.

- Lack of scientific knowledge or scientific consensus should not necessarily be interpreted to indicate a particular level of risk, no risk, or acceptable risk.

-Risks should be considered in the context of risks posed by unmodified recipients or parental organizations

- Risks must be assessed on a case-by-case basis (36)

The general risk assessment methodology described in Annex III of the Protocol begins with the identification of a potential hazard (eg a particular characteristic of an LMO), and the risk is assessed through a combined assessment of the likelihood of adverse effects and the consequences if such effects occur, similar to the principles and methodology for risk assessment set out in The Protocol replaces those of traditional risk assessment frameworks (37)

In the event of a lack of information about the risks of living modified organisms, the importing country can request the exporting country to conduct analyzes and studies on the potential risks, provided that the exporting country bears the costs spent in obtaining information regarding these risks, and the exporting and importing countries can bear them together (38). The exporting State may, within ninety days from receipt of the notification, notify the notifier in writing of the intended cross-border transport proceeding or at least ninety days after the notification without written approval. In the event that the importing State provides written approval, the importing party shall, within 270 days from the date of receipt of the notification By informing the notifier and the Biosafety Clearing-House of his decision, and the decision is either to approve the import with or without conditions, or to prohibit the import, or to request additional information, or to inform the notifier that the period specified in this paragraph may be extended by a specific period of time, but the extension period is not specified. In the event that the importing country agrees to the transfer of living modified organisms without conditions, it must state in its decision the reasons that motivate it to accept without conditions, and the reason for the decision appears likely. The reasons given for making a decision are likely to be important in the event that the notifier wishes to appeal the decision (or the conditions associated with it). (39) under any domestic procedures available in the Party of importation, will also be important if the notifier subsequently requests a review of the decision, and the failure of the importing Party to communicate its decision within 270 days of receipt of the notification does not explain its approval of the intended transboundary movement (39).

Notably, importing countries can ban imports due to a lack of scientific certainty. This ban may continue until the importing country considers that it has gained scientific certainty regarding the impact of the products in question on biodiversity and human health. However, since the importing country is not required to seek The information necessary to reach this certainty, the trade restrictive measure may remain in force indefinitely (40), but it should be noted that the intended ban measure is not intended to impose a risk assessment as is the case with advance informed agreement, but rather to prevent the marketing of living modified organisms and thus can Considering the measures taken by a state party to this Protocol unilaterally to ban the import of living modified organisms as an arbitrary and unjustified restrictive measure.

In this regard, we pose the following question: Are the decisions taken regarding procedures for transporting living organisms across borders final?

The decisions taken by the importing party are not final, but rather it has the right to review them in the light of new scientific information about the potential harmful effects on the preservation of biodiversity and human health. In this case, the importing party must, within 30 days, inform the notifier of its decision, as well as inform the Biosafety Clearing-House. It explains the reasons for making the decision, and at the same time the Cartagena Protocol gives the exporting party the right to ask the importing party to reconsider its decision in the event that a change in circumstances appears to have occurred that affects the results of the risk assessment on the basis of which a decision to export was made, or if new scientific and technical information becomes available that it affects the decision. Biodiversity and human health. The importing party must respond in writing to such a request within ninety days, and explain the reasons for making the decision (41).

Second Branch

Obligations Relating to Unintentional Transboundary Movements of Living Modified Organisms

While much of the Protocol is concerned with the intended transboundary movement of living modified organisms, living modified organisms can also unintentionally cross national borders, and Article 3/16 requires each Party to take appropriate measures to prevent unintended transboundary movements of living modified organisms, including This requires a risk assessment to be conducted before the first release of living modified organisms. Article 17 addresses issues related to cooperation between States and preventive measures in the event of such unintended transboundary movements of living modified organisms. The Cartagena Protocol does not define unintended movement, but Article 17 recognizes that Living modified organisms may spread across national borders, posing potential risks to biodiversity and human health within the jurisdiction of other States, and in order to avoid such risks, Article 17 contains a series of obligations that primarily address the duty to notify and consult in the event of unintended movements. Transboundary transfer of living modified organisms. Under Article 17, parties must become aware of the occurrence of an unintended transfer of living modified organisms within their jurisdiction that is likely to have harmful effects on biodiversity and human health. Parties have an obligation to take appropriate measures to address the risks of states that are likely to be affected by the transfer. Unintended, as well as notifications to the Clearinghouse and competent international organizations, such as the United Nations Environment Program or the Food and Agriculture Organization, for example, as well as relevant regional organizations. This notification includes information about the estimated quantities and characteristics of the living modified organisms, and information about the conditions of release. The living modified organism, the estimated date of release, information on its potential impacts on the conservation and sustainable use of biodiversity, its health risks and risk management measures, and any other information concerning the living modified organism that is the subject of an unintended transfer and, presumably, notification must be made in a written form. However, If the parties agree to this, through bilateral or regional arrangements, they can also benefit from other more appropriate modalities and means of communication (42). Parties of origin of unintended transboundary movements of living modified organisms do not fulfill their obligations merely by notifying other states. Rather, prevention and cooperation obligations require states to provide any assistance to reduce any significant adverse effects on biodiversity and human health, and to request immediate consultations to agree on any applicable emergency measures. Obviously, the Party where the incident occurred is obliged to provide consultations simultaneously with the notification. If more than one State is potentially affected, joint consultations between all States concerned may be more practical, to enable them to determine appropriate responses and take the necessary measures, including Emergency measures to reduce impacts on biodiversity and human health. (43)

Third Branch

Obligations Relating to Illicit Transboundary Movements of Living Modified Organisms

Article 25 addresses the situation where transboundary movements of living modified organisms are in conflict with national regulations implementing the Protocol, and in essence Article 25 requires each Party to adopt domestic measures to prevent and (if appropriate punish) transboundary movements of living modified organisms in conflict with Its national measures to implement the Protocol consider such transboundary movements to be illegal. Allows a Party affected by an illicit transboundary movement of living modified organisms to request that the Party of origin dispose of the LMO concerned at its own expense. Requires Parties to exchange information through the Safety Clearing-House On illegal transboundary movements of living modified organisms, the question remains what is the legal status if a transboundary movement of living modified organisms takes place under the jurisdiction of a Party in direct violation of the provisions of the Prior Informed Agreement Protocol, but the Party concerned does not take measures Domestic on this issue? The Protocol did not address this situation, and the reference to domestic measures here means that the Protocol will not necessarily provide a global standard for what constitutes an illegal cross-border movement. The higher the standards set by a Party's implementing legislation, the more types of conduct it classifies as Illegal cross-border movement. It is likely that the same conduct associated with the movement of an object may be considered illegal in one Party but legal in another, and therefore, it is important to take into account the specific national legislation of the Party of import, the Party of export and any Party of transit in relation to each cross-border movement. It would be better for the parties to the Cartagena Protocol to draft an integrated legal text that considers the illicit transfer of living modified organisms to be a criminal act, as did the Basel Convention, which stipulates in Article 3/4 that "the Parties consider the illicit trade in hazardous wastes or other wastes to be a criminal act."

The Third Topic

Implementation and compliance under the Cartagena Protocol

In this section, we will address the mechanisms for implementing the provisions of the Protocol in the first requirement, while the second requirement will be devoted to addressing compliance within the framework of the Cartagena Protocol.

The First Requirement

Mechanisms for Implementing the Provisions of the Protocol

The Cartagena Protocol included mechanisms to ensure the implementation of the provisions it brought in. Without these mechanisms, there is no point in making provisions that remain just ink on paper. These mechanisms are represented by the following.

First Branch

The Obligation of States Parties to The Protocol to Take Internal Implementation Measures

National implementation is the way in which major principles and commitments negotiated at the international level are translated into actual practice at the domestic level. What happens to such negotiated commitments depends on how treaties or other agreements are implemented within the signatory countries. Implementing the agreements involves In practice there is often a complex process of shaping and modifying domestic policy to conform to international standards, in addition to the added complexity of coordinating activities between many governments that implement different policies in parallel. But international environmental agreements are not intended to restrict governments only, they

are also supposed to affect a wide range. The behavior of actors whose behavior does not change simply because governments adopt an international obligation, and implementation includes countless government actions, such as issuing and implementing new regulations and laws (44). Therefore, the Protocol under Article 1/2 imposes on states parties that each party must take Legal, administrative and other appropriate measures to implement its obligations under this Protocol. These laws include administrative regulations related to the implementation of the Protocol and national legislation to implement its provisions. Failure to do so will result in the state violating its obligations being subject to international responsibility, as the Vienna Convention on the Law of Treaties of 1969 has confirmed this. The principle stipulates that "every treaty in force is binding on its parties and they must implement it in good faith," as implementation in good faith obliges the parties to refrain from doing anything that might prevent the achievement of the purpose of the agreement (45). It is worth noting that since the adoption of the Cartagena Protocol, there has been a noticeable increase in countries that have National biosafety frameworks. In 2002, the Global Environment Facility adopted an initial strategy with some measures to be taken. This strategy was followed in June 2001 by a United Nations Environment Program (UNEP)-Global Environment Facility project in the amount of US$39 million to help 100 developing countries Establishment of national biosafety frameworks By 2007, more than 130 countries had developed or were in the process of developing their own national biosafety frameworks with support from the Global Environment Facility. By May 2012, 121 countries had completed most parts of the national biosafety framework69 and the frameworks could be said to have Biosafety is partially or fully present in most States Parties to the Protocol. There is a need to harmonize these biosafety frameworks to ensure the safe handling of GMOs during cross-border transport in different regions of the world (46).

Second Branch

Information Sharing and Biosafety Clearing-House

Article 20 provides for the establishment of the Biosafety Clearing-House, which is an information exchange mechanism to assist Parties in implementing the Protocol. It was established as part of the clearing-house mechanism established under the Convention on Biological Diversity. The Biosafety Clearing-House is a repository of information and a central tool for implementing the Protocol. Many provisions of the Protocol require Parties to submit information to the Biosafety Clearing-House, which has a special role in exchanging information on living modified organisms intended for direct use as food or feed or for processing. The Clearing-House uses electronic and other systems to exchange information relevant to the Protocol, as well as It will provide access to other international biosafety clearing-house mechanisms. The clearing-house is being developed in phases, starting with a pilot phase that aims to collect basic information and explore mechanisms for establishing and operating the biosafety clearing-house. This pilot phase is underway. After the protocol enters into force, it will be based on Parties to the pilot phase experiences" to decide at their first meeting how the Biosafety Clearing-House would operate (47).

Given the central role of the Biosafety Clearing-House in implementing the provisions of the Protocol, the availability, accuracy and accessibility of relevant information through the Biosafety Clearing-House will be crucial. In addition to practical considerations, one question that may arise is to what extent Oversight and verification of information provided through the Biosafety Clearing-House?

Another question arises about who should perform this function - for example, the Secretariat, or any other body. Article 20, in its paragraphs, addresses a number of issues. It establishes the Biosafety Clearing-House, and describes the main objectives and functions of the Biosafety Clearing-House, in relation to the objectives Its main objective is to facilitate the exchange of scientific, technical,

environmental and legal information and expertise in the field of living modified organisms, and one of its objectives is to help the parties implement the Protocol, taking into account the special needs of developing countries, especially the least developed countries, including small island developing states, countries whose economies are in stages of transition, as well as countries Which represent centers of origin and centers of genetic diversity. (48)

Accordingly, the effective operation of the Biosafety Clearing-House depends on the active participation of developed countries, developing countries, and Parties with economies in transition, in providing developed countries with technological resources in developing countries and Parties with economies in transition, and this is considered a basic and important pillar in designing The Biosafety Clearing-House will stimulate the necessary efforts to develop information-sharing mechanisms within the Biosafety Clearing-House that do not rely on the Internet. The operation of the Biosafety Clearing-House will also depend on the resources and training provided to Parties from developing countries and Parties with economies in transition. Entering into force of the Protocol, the Secretariat organized regional workshops on the Biosafety Clearing-House, and Article 11 addresses the special role of the Biosafety Clearing-House in relation to modified living modified organisms, feed or processing (49)

As for the main functions of the Biosafety Clearing-House, they are defined in paragraph 2, which specifies the information that must be made available to the Biosafety Clearing-House and facilitates access to the information it provides related to the implementation of the Protocol. It stipulates that the Conference of the Parties/Meeting of the Parties shall decide how the Safety Clearing-House will operate. biology and keep its work under review

Third Branch

Capacity Buildings

The concept of capacity building means: strengthening the human resources and institutional capacities of States Parties, especially developing countries, to implement the provisions of the Protocol (50). For example, developing countries do not have the capacity to conduct risk assessment and manage the risks of living modified organisms, or to monitor living modified organisms once they are released into the environment. Therefore, the Protocol requested the parties to cooperate among themselves to develop and strengthen human resources and institutional capacities in the field of biosafety, especially in biotechnology, to implement the provisions of the Protocol in these countries. This cooperation and development is carried out through global, regional, non-regional and national institutions and organizations, as well as the involvement of the private sector, and includes building... Capabilities Scientific and technical training on the sound and safe management of biotechnology, as well as cooperation in using risk assessment and management for biosafety purposes, as well as improving technological and institutional capabilities in the field of biosafety (51)

Accordingly, at the first meeting of the Ad Hoc Open-ended International Committee for the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, a number of tools and mechanisms were prepared to facilitate capacity-building efforts among Parties. These tools and mechanisms include:

1-An action plan for capacity building 2- A coordination mechanism and 3- A set of indicators to evaluate the implementation of the action plan and 4- A list of biosafety experts. Capacity building was one of the priority items on the agenda of the first meeting of the Intergovernmental Committee on the Cartagena Protocol on Biosafety, and in At that meeting, it was decided to convene an expert meeting to prepare proposals on the implementation of the capacity-building provisions of the Protocol, and the Secretariat, in order to assist the expert meeting in its consideration of this issue, prepared a questionnaire

to help identify needs in the area of capacity-building, and the expert meeting prepared a proposal for an action plan on capacity-building and approved The Committee then decided upon it at its second meeting. At its third meeting, the Committee worked on draft procedures for a coordination mechanism for capacity-building initiatives and interim guidelines for a list of experts. At its third meeting, the Committee also considered an initial set of indicators to monitor the implementation of the action plan. The Fifth Meeting of the Parties to the Protocol considered Status report on the implementation of the Action Plan, and the Parties to the Protocol decided that the Parties at their sixth meeting would undertake a further comprehensive review of the Action Plan. The objective of the Action Plan is to facilitate and support the development and strengthening of capacities to ratify and implement the Protocol effectively at the national, subregional, regional and global levels, including Including providing financial, technical and technological support to developing countries, including countries with economies in transition, the Action Plan provides a general strategic framework to guide and facilitate the identification of countries' needs and priorities, as well as procedures and mechanisms for implementing and financing capacity-building at all levels (52).

Fourth Branch

Raising Awareness

Public awareness, education and participation are essential elements for the effective implementation of the Protocol. It is important for the public to know and understand issues and processes related to living modified organisms and to have access to relevant information in order to make informed choices and actions, and to be able to participate effectively in decision-making processes. Likewise, public participation in the decision-making process is crucial to facilitate transparency and accountability, and to enhance public support for decisions taken regarding living modified organisms. Article 23 requires States Parties to the Protocol, individually and in cooperation with other States and international bodies, to promote and facilitate public awareness, education and participation, including access to information, regarding the safe transport, handling and use of living modified organisms. It also requires Parties to consult with the public in decision-making process, to announce the final decision taken and to inform the public of means of accessing the Biosafety Clearing-House (53).

The Second Requirements

Compliance under the Cartagena Protocol

Effective implementation of the provisions of the Cartagena Protocol requires the establishment of special mechanisms to ensure that parties comply with its provisions, procedures for reporting compliance, as well as taking appropriate measures in the event of non-compliance, and this is what we address as follows.

First Branch

Compliance Mechanism Under the Cartagena Protocol

As the number of multilateral environmental agreements has increased over the years, the international community has increasingly turned its attention towards ensuring that states comply with their international environmental obligations. The issue of compliance was an important area of focus during the preparatory process for the subsequent United Nations Conference on Environment and Development (UNCED), in April. 1993 European environment ministers adopted at a meeting in Lucerne a declaration urging contracting parties to environmental agreements in the area covered by the United Nations Economic Commission for Europe (UN-ECE) to cooperate within the relevant governing bodies of those agreements to work to establish compliance systems to address issues of non-

compliance with treaty obligations Since then, the international community has demonstrated its concern in negotiations on environmental agreements and in various initiatives to further improve existing mechanisms and processes regarding compliance, implementation and enforcement of multilateral environmental agreements (54).

The Protocol did not stipulate the measures and procedures to be taken in the event of non-compliance by the parties. It referred the issue and definition of these procedures to the Conference of the Parties at its first regular meeting (55). At its first meeting, the parties began discussing this issue in order to reach an agreement on the measures that could be taken. In the event of a breach of the provisions of the Protocol, the Intergovernmental Committee for the Cartagena Protocol has established compliance procedures and mechanisms, and a Compliance Committee was established during the first meeting of the Conference of the Parties in 2004. The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol agreed that if a State Party discloses difficulties in compliance, The Compliance Committee makes recommendations to the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on assistance measures for that Party (56).

As for mechanisms, we mentioned that an institutional mechanism was established during the first meeting called (the Compliance Committee). The committee consists of 15 members nominated by the parties and elected by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety on the basis of three members from each of the five regional groups of the United Nations, and it was stipulated that Members of the Committee shall have recognized competence in the field of biosafety or other relevant fields, including legal or technical expertise, and shall act objectively and in a personal capacity. Members shall be elected by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety for a term of four years, a full term. At its first meeting, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety shall elect five members, one from each region, for a half-term and ten members for a full term, and each time thereafter, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety shall elect members Renewed for a full term to replace those whose membership terms have expired. Members may not serve more than two consecutive terms. The secretariat is responsible for organizing the committee's meetings, which are held twice a year unless otherwise stipulated.

In order to promote compliance and address cases of non-compliance, the Committee shall, under the general guidance of the Conference of the Parties, undertake the following functions: identify the specific circumstances and possible causes of individual cases of non-compliance referred to it, consider information submitted to it in relation to matters relating to compliance and cases of non-compliance, provide advice and/or assistance, as appropriate, to the Party concerned on compliance-related matters with a view to assisting it in complying with its obligations under the Protocol, reviewing general issues relating to Parties' compliance with their obligations under the Protocol, taking into account information provided in national reports submitted in accordance with Article 33 of the Protocol as well as through the Chamber Exchange biosafety information, take measures, as appropriate, or make recommendations to the Conference of the Parties serving as the meeting of the Parties to the Protocol, and perform any other functions as may be assigned by the Conference of the Parties serving as the meeting of the Parties to the Protocol (57).

Second Branch

Compliance Reporting Procedures

The Committee shall receive through the Secretariat any data relating to compliance from any Party affected or likely to be affected in relation to another Party, and the Secretariat shall, within a period of fifteen days of receiving the submitted reports, transmit a copy of the reports to the Party whose

compliance with a particular provision of the Protocol is in dispute. As soon as the secretariat receives the response and information from this party whose compliance is questionable, the secretariat sends the response and information to the Committee, and the party that received a report regarding its compliance with the provisions of the Protocol is responsible for responding and resorting to the Committee for assistance if necessary. It is also the responsibility of the party that received the necessary information regarding its compliance with the provisions of the Protocol. compliance with the provisions of the Protocol, preferably within three months, and in any event not later than six months, and this period of time begins to be calculated from the date of receipt of the request as approved by the Secretariat, and in the event that the Secretariat does not receive any response or information from the Party Meaning within six months as referred to above, it shall refer the submission to the Committee for its consideration, and the Party, on which a report is submitted or which submits a report, has the right to participate in the deliberations of the Committee, and the Committee shall consider the information received and may request new information from the Party on which it is submitted. Submit statements of non-compliance by another party, or from the clearinghouse, or from relevant international organizations. The secretariat may take advice from biosafety experts in this regard, and the committee's work is required to be confidential (58).

Third Branch

Measures to Enhance Compliance and Address Instances of Non-Compliance

The Committee may take one or more of the following measures with a view to promoting compliance and addressing cases of non-compliance, taking into account the ability of the Party concerned, in particular developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, to comply, and factors such as the cause, type, degree and frequency of non-compliance.

The committee will take one of the following measures:

1. Providing advice or assistance to the concerned party.
2. Make recommendations to the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol on the provision of financial and technical assistance, technology transfer, training and other capacity-building measures.
3. To request or assist, as appropriate, the Party concerned to develop a compliance action plan in relation to achieving compliance with the Protocol within a time frame agreed upon between the Committee and the Party concerned.
4. Invite the party concerned to submit progress reports to the Committee on its efforts to comply with its obligations under the Protocol.
5. Report to the CMP on efforts undertaken by Parties in the event of non-compliance to return to compliance and maintain this as an agenda item for the Committee until it is appropriately resolved, and the CMP may, based on the Committee's recommendations, take into account the capacity of the Party Meaning, particularly developing country Parties, may take one or more of the following measures:

- Providing financial and technical assistance, technology transfer, training and other capacity building measures.
- To request the Executive Secretary to publish cases of non-compliance in the Biosafety Clearing-House.
- In cases of repeated non-compliance, take such measures as may be decided by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its third meeting, and thereafter in accordance with Article 35 of the Protocol (59).

Conclusion

We can make the following among the most important conclusions and proposals drawn from this study:

First: conclusions

1- The Protocol is characterized by its lack of comprehensiveness, as it excludes from its scope of application living modified organisms that are considered pharmaceutical substances for humans and are regulated by other international agreements or organizations. Also, the use of the word "living" for living modified organisms makes the Protocol only apply to biologically active products such as seeds and agricultural products modified for the purpose of Human and animal nutrition and non-agricultural products intended for human or animal nutrition, such as live fish. As for materials derived from the previous materials, such as flour and oils, it is known that these materials do not multiply biologically and cannot be transported.

2- The Cartagena Protocol allows the movement of living modified organisms in cases where there is no harm to biological diversity or risks to human health, in accordance with certain standards and obligations. To regulate the transfer of living modified organisms, it required taking into account the principle of prior informed agreement, which created strict requirements related to the intended transboundary movement of organisms. The living modified organism, and these requirements or restrictions form the core of the protocol's control system.

3- The Cartagena Protocol created mechanisms to guarantee the implementation of the provisions it brought in. Without these mechanisms, there is no point in establishing provisions that remain a hostage on paper. Among these mechanisms is what ensures that the parties take national measures to implement their obligations, including information sharing and the Biosafety Clearinghouse. Including capacity building and raising awareness

Second: Recommendations

1- Expanding the objective scope of the Cartagena Protocol to include living modified organisms that are considered pharmaceutical materials for humans, and thus subjecting this type of waste to the legal regulation established by the Cartagena Protocol.

2- Work to encourage countries to join the Cartagena Protocol to ensure the participation of the largest number of countries in it, especially industrially developed countries, which is necessary within the scope of protection, as any agreement is meaningless without the participation of active and influential countries.

3- Formulating an integrated legal text that considers the illicit transfer of living modified organisms to be a criminal act, as did the Basel Convention, which stipulates in Article 3/4 that "The Parties consider the illicit trade in hazardous wastes or other wastes to be a criminal act."

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