Socio-Economic Considerations of Living modified Organisms and Impacts on Trade: Evolution of Environmental Disputes at the World Trade Organization

Leonardo Munhoz
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Elisabeth Haub School of Law at Pace University

Leonardo Munhoz

SOCIO-ECONOMIC CONSIDERATIONS OF GMOS AND IMPACTS ON TRADE
EVOLUTION OF ENVIRONMENTAL DISPUTES AT THE WORLD TRADE ORGANIZATION

2023
ABSTRACT

The Convention on Biological Diversity (CBD) is the most important international treaty concerning the conservation of biodiversity and the Cartagena Protocol is a specific instrument to regulate biosafety measures for Living Modified Organisms ("LMOs") or commonly referred as a Genetically Modified Organism ("GMO") In this Protocol, apart from mandatory environmental and health risk assessments, the Parties can also voluntarily adopt socio and economic considerations ("SECs") arising from LMOs, as stated in article 26.

However, the definition of SECs is still under negotiation, therefore it does not currently have a definite concept and meaning. Also, the last Conference of the Parties proposed to expand SECs by adding extra cultural, traditional, religious and ethical considerations, resulting in an even broader and possibly non-measurable requirement.

As for trade, the World Trade Organization (WTO) rules, especially the General Agreement on Tariffs and Trade, the Technical Barriers to Trade Agreement and the Agreement on the Application of Sanitary and Phytosanitary Measures, do have exemptions for stricter standards based on environmental concerns and protection. Although each one is used for a different trade purpose (i.e., bans, tariffs and sanitary measures), they share some common characteristics: science-based and precise language. Hence, as they currently stand in the CBD, it is unclear whether the SECs are aligned with the WTO rules, possibly leading to future trade disagreements if enforced, especially through domestic biosafety laws. In this respect, several countries already have regulations that include provisions to adopt SECs if desired.
This study assesses whether the WTO rules and private standards apply and are in accordance with SEC requirements on biosafety regulations. For that, firstly, it is essential to determine if the trade rules and language cover socio and economic concerns or if these concerns only apply to environmental and health impacts per se. Also, this study analyzes whether the COP/MOP decisions to the expansion of SECs by adding cultural, traditional, religious and ethical criteria are helpful or will only cause more incompatibility and enlarge the gap between the CBD and the WTO.

In this regard, this study also investigates whether the WTO panels and the Appellate Body, as important actors in pacifying international trade conflicts with their history of jurisprudence, can provide some guidance to answer these questions or perhaps other dispute settlement bodies of International Law can be more responsive regarding environmental and social concerns. This study also indicates how Environmental Law Principles are evolving as sources of International Law.

As a consequence, it will become clearer if and how SECs can be an enforceable requirement for biotechnology, improving the lives of farmers and local communities, and just not an arbitrary trade measure used by countries as a new tool for green protectionism, without fulfilling CBD’s goals or society’s needs for more sustainable practices.

Keywords: Socio-economic considerations; Cartagena Protocol, World Trade Organization; Biosafety; Biodiversity; International Law; Genetically Modified Organisms
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# ACRONYMS

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ATHEG</td>
<td>Ad Hoc Technical Expert Groups</td>
</tr>
<tr>
<td>SPS</td>
<td>Agreement on the Application of Sanitary and Phytosanitary Measures</td>
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<tr>
<td>COP</td>
<td>Conference of the Parties</td>
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<td>CBD</td>
<td>Convention on Biological Diversity</td>
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<td>DSB</td>
<td>Dispute Settlement Body</td>
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<td>EU</td>
<td>European Union</td>
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<td>GATT</td>
<td>General Agreement on Tariffs and Trade</td>
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<td>GMO</td>
<td>Genetically Modified Organism</td>
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<tr>
<td>ICJ</td>
<td>International Court of Justice</td>
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<td>LMO</td>
<td>Living Modified Organism</td>
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<td>MOP</td>
<td>Meeting of the Parties</td>
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<td>MFN</td>
<td>Most Favoured Nation</td>
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<td>MEA</td>
<td>Multilateral Environmental Agreements</td>
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<td>NGO</td>
<td>Non-Governmental Organizations</td>
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<tr>
<td>DSU</td>
<td>Procedures Governing the Settlement of Disputes</td>
</tr>
<tr>
<td>SEC</td>
<td>Socioeconomic Considerations</td>
</tr>
<tr>
<td>SBSTTA</td>
<td>Subsidiary Body on Technical and Scientific Technological Advice</td>
</tr>
<tr>
<td>TBT</td>
<td>Technical Barriers to Trade Agreement</td>
</tr>
<tr>
<td>TPRB</td>
<td>Trade Policy Review Body</td>
</tr>
<tr>
<td>TPRM</td>
<td>Trade Policy Review Mechanism</td>
</tr>
<tr>
<td>UNEP</td>
<td>United Nations Environment Programme</td>
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<tr>
<td>WTO</td>
<td>World Trade Organization</td>
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INTRODUCTION

Suppose an important economic global player such as the European Union decides to ban all imported living modified organisms (hereinafter “LMOs”) from its common market based on the argument that it is uncertain whether those products socially and economically contribute to a better livelihood for local farmers and communities.

On the one hand, this measure would surely affect big LMOs and commodity exporters such as the United States, Brazil, Canada, Argentina and Australia, possibly leading to unprecedented litigation at the World Trade Organization (WTO) and impacting world trade. On the other hand, this legal uncertainty could also impair a positive new type of approval assessment for LMOs, which takes into account not only the impacts on human health and the environment but also the social and economic outcomes of biotechnologies, thus missing an opportunity to attest LMOs as a tool with the potential to benefit local communities and small farmers.

The hypothetical case mentioned above, regarding the trade aspects, actually happened in the European Communities Biotech Products WTO case (EC – Biotech).1 The difference between them is that the real Biotech case did not address the social and economic considerations of LMOs, but their broad impacts on human health and the environment, ending up in a dispute settlement. Therefore, WTO dispute bodies have never fully discussed the interactions of environmental concerns created by LMOs with trade regulations, therefore, all the questions about this subject remain unanswered. (hereinafter "SECs") ensures an adequate level of protection when it comes

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1 European Communities — Measures Affecting the Approval and Marketing of Biotech Products.
to LMOs and prevents adverse impacts on biodiversity. The Cartagena Protocol, Nagoya Protocol\textsuperscript{2} and the recent Nagoya Kuala Lumpur Supplementary Protocol\textsuperscript{3} ("CBD") is the most important international treaty concerning the conservation of biological diversity, sustainable use of resources, and equitable sharing of benefits.

Regarding the Cartagena Protocol, several topics were discussed in the past Conference of the Parties. Among them, the most pressing and complex topic are the SECs arising from LMOs, stated in article 26 of the Protocol:

\begin{quote}
\textbf{The Parties, in deciding on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially concerning the value of biological diversity to indigenous and local communities.}
\end{quote}

However, SECs have not been officially defined yet. Thus, at the 8\textsuperscript{th} Session of the Meeting of the Parties (MOP8), a proposed definition for SECs, encompassing not only social and economic factors, but also cultural, traditional, religious and ethical aspects,\textsuperscript{4} started to be negotiated. This proposal as it is presents the following problem: it is extremely broad, as it adds subjective and non-measurable criteria such as cultural, traditional, religious and ethical aspects.

\begin{itemize}
\item \textsuperscript{2} This Protocol aims to the fair and equitable sharing of the benefits arising from the use of genetic resources.
\item \textsuperscript{3} This Protocol regulates liability and forms of redress under the Cartagena Protocol on Biosafety.
\item \textsuperscript{4} “Socio-economic considerations in the context of Article 26 of the Cartagena Protocol may, depending on the national or regional circumstances and on national measures implementing the Protocol, cover economic, social, cultural/traditional/religious/ethical aspects, as well as health and ecological aspects, if they are not already covered by risk assessment procedures under Article 15 of the Protocol.”
\end{itemize}
From the perspective of international trade regulations, the absence of a definition and the risk of adopting broad criteria can be extremely troublesome, since SECs might eventually become a sustainable requirement for commercial relations.

In this regard, the WTO, initially with the General Agreement on Tariffs and Trade ("GATT"), through article XX, allows general exemptions for some demands on international trade.

Although the environmental exemption for the GATT exists, it cannot be arbitrary. This is a problem for SECs as, due to their undetermined concept, it is not clear whether the social impacts of LMOs can be regarded as environmental impacts per se or just an arbitrary and discriminatory measure, conflicting with the WTO’s free trade principles.

In addition, this link between the social component and its environmental impact on trade is not clear in the Technical Barriers to Trade Agreement ("TBT"), which allows the Parties to create barriers if they have legitimate objectives, such as preserving human safety and the environment, but it requires scientific/technical justification.

As to the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS"), the language regarding the possibility of taking into account economic factors during sanitary risk assessments is more explicit, hence a possible breach to include future SEC standards. However,

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5 2.2. Such legitimate objectives are, inter alia: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, inter alia: available scientific and technical information, related processing technology or intended end-uses of products.
6 See TBT Annex 1.1.
7 5.3: In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as...
it is uncertain whether it applies to SECs not only due to their unclear concept, as previously mentioned, but also due to the use and interpretation of the precautionary principle.\(^8\)

Thus, incorporating this indefinite subjective definition of SECs into the precise science-based context of the WTO may be a matter of disagreement if the Parties to the Protocol adopt this requirement, and this may be concern for the countries.\(^9\)

The SECs provoke a deeper background discussion regarding the new context of globalization and trade, with increasing environmental and social concerns and preferences for sustainable consumption. Citizens nowadays doubt the role of the international community. They wonder if the United Nations Multilateral Environmental Agreements ("MEAs") and the Parties to the MEAs can assure a better environment and social justice for all by enabling international and national rules to tackle today’s problems effectively.

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\(^8\) In theory, article 5.7 of the SPS Agreement conflict with articles 11.8 and 10.6 of the Cartagena Protocol. See EC-Hormones, WTO. Also see Henckels Caroline, GMOs in the WTO: A Critique of the Panel’s Legal Reasoning in EC-Biotech, Legal Studies Paper No 253, p. 302, Melbourne Law School. Available at: http://ssrn.com/abstract=949262

\(^9\) Brazil has stressed these doubts and risks on commerce. At the last MOP9, Brazil argued that trade regulation interlinkages with SECs had to be better addressed. Thus, Decision CBD/CP/MOP/9/14 states: [N]othing contained in the voluntary “Guidance on the Assessment of Socio-Economic Considerations in the Context of Article 26 of the Cartagena Protocol on Biosafety” can be interpreted or used to support non-tariff barriers to trade, or to justify breaches of international human rights law obligations, in particular of the rights of indigenous peoples and local communities. Although Decision CBD/CP/MOP/9/14 briefly raised awareness of these problems, especially the risk of a conflict between WTO rules and principles with SEC requirements, this vague connection of trade with the social component as a type of environmental protection, apart from some shallow discussions in the WTO Committee on Trade and Environment, is unprecedented in international trade law and environmental law. See UNEP-UNCTAD Capacity Building Task Force on Trade and Environment and Development and IFOAM-FAO-UNCTAD International Task Force on Harmonization and Equivalence in Organic Agriculture.
As to this rulemaking, according to the theory of legal positivism, a new rule requires the proper authority to enact it by following the correct procedure and hierarchy, regardless of its content or purpose. For the SECs, this can be formally done by the Parties to an MEA (e.g., CBD), in the case of international law, and by the legislative branch of a government, in the case of national laws.\(^\text{10}\)

However, as some critics of hard legal positivism argue, by accounting for procedural and validity elements without considering morality, that future SEC regulations may be enacted in a formally valid way but not necessarily result in environmental protection and social justice. Instead, they might be arbitrary and discriminatory if used by some countries merely as a protectionist instrument. This would result in unjust laws detached from social reality, not fulfilling their main, original purpose established in CBD goals.\(^\text{11}\)

According to legal realists, the judge and the interpretation of the law through cases are essential, because jurisprudence is a chance to link and adapt the rule to society's demands. Regarding SECs, apart from criticisms, some lessons from legal realism might be useful, because the WTO and, if appropriate, other international dispute settlement bodies, can use their decisions to clarify concepts of new international or national regulations to provide certainty. This, in theory, can help to ensure fair trade with environmental protection and social justice, overcoming attempts at green protectionism initiatives.\(^\text{12}\)

\(^{10}\) See Immanuel Kant, Critique of Practical Reason.

\(^{11}\) Legal Positivism advocates that there is a separation between law and morality. However, some positivists, such as Hart, believe that positivism needs to have a minimum of Natural Law, which is the need of morality and justice as a rulemaking purpose. See H.L.A., Hart, The Concept of Law, oxford, 1961, p. 189/195.

\(^{12}\) See L.L. Fuller, American Legal Realism, University of Pennsylvania Law Review, vol 82, No.5, 1934.
Nonetheless, as for the role of the WTO dispute settlement system and bodies, guided by the procedures of the Dispute Settlement Understanding, there is an ongoing discussion about the extent to which both the WTO Panels and the Appellate Body can use other non-WTO treaties, especially of environmental content, like the CBD and the Cartagena Protocol, to interpret WTO regulations in their decisions.

Therefore, as SECs are currently conceptually vague and the chance to include subjective criteria into their definition and their interaction with other international trade rules may potentially generate legal disagreement, this study assesses how the WTO can address SEC requirements in biosafety regulations.

For that, firstly, it is essential to determine if trade rules and language cover socio and economic concerns or if these concerns only apply to environmental and health impacts per se. Also, this study analyzes whether the COP/MOP decisions for the expansion of SECs with cultural, traditional, religious and ethical criteria is actually helpful or will only add more incompatibility and enlarge the gap between the CBD and the WTO.

Furthermore, it investigates whether the WTO Panels and the Appellate Body, as important dispute settlement actors, can provide guidance to answer these questions or perhaps other bodies and regimes of International Law can be more responsive regarding environmental and social concerns since the WTO might have been deciding cases on a narrow rather than normative basis and
attaching more importance to Customary International Law than to non-WTO treaties of environmental content.\textsuperscript{13}

As a consequence, it will become clearer if and how SECs can be an enforceable requirement for biotechnology, improving the lives of farmers and local communities, and not just an arbitrary trade measure used by countries as a new tool for green protectionism, without fulfilling CBD’s goals or society’s needs for more sustainable practices.

This assessment is relevant, especially for exporting countries. For instance, as Brazil is one of the largest producers of agricultural commodities and its main products, such as soy and cotton, are LMOs, these are pressing issues.

In this regard, although the Brazilian Biosafety Law\textsuperscript{14} mirrors the Cartagena Protocol risk assessment procedure,\textsuperscript{15} considering SECs in the approval of an LMO is not a general rule, but an exception.\textsuperscript{16} In other words, the Brazilian procedure for the approval of LMOs is not currently prepared to apply SEC requirements on a daily basis.

Also, for example, should Brazil decide to enforce SECs as a basic mandatory national requirement along with health tests, or if it becomes a private standard for supply chains, it is questionable

\textsuperscript{13} Pauwelyn, J. (2001). The Role of Public International Law in the WTO: How Far Can We Go? American Journal of International Law, 95(3).


\textsuperscript{15} See Cartagena Protocol, Annex 3.

\textsuperscript{16} Lei No 11.105 de 24 de março de 2005. Diário Oficial da União [D.O.U.] de 25.03.2005 (Braz.): Article 8 The National Biosecurity Council (CNBS) shall be created, linked to the Presidency of the Republic, as the highest assessment body of the President of the Republic for the formulation and implementation of the National Biosecurity Policy – (PNB).II – Analyze, at the request of CTNBio, requests to authorize GMOs and their derivatives for commercial use, with regard to the desirability, suitability in social and economic terms, and the national interest.
whether countries and the WTO would be prepared to enforce such obligations, both legally and operationally. Currently, Brazil is not the only country that has a domestic biosafety regulation allowing the use of SECs as a requirement, as other countries, including Argentina, the European Union and Indonesia also do.

Additionally, if all the issues previously raised are clarified and SECs are well applied in domestic regulations, biotechnologies of LMOs can actually contribute socially and economically to local communities.

As for the general structure of this study, it is divided into four main parts. Chapter 1 explores the CBD and the Cartagena Protocol, including the origin, agenda and purpose of SECs. It analyzes a possible definition of SECs and whether it is already being used in domestic legislations and real cases. Lastly, it investigates SECs in biosafety regulations in the context of International Law.

Chapter 2 assesses WTO rules, such as GATT, TBT and SPS, to determine whether and how each of these regulations better apply to SEC standards, using both the stricter definition of SECs (i.e., only socio-economic considerations) and the broader proposal discussed in the last COP/MOPs (i.e., ethical, religious and cultural considerations). In addition, it is essential to check possible overlaps or gaps between WTO rules and the Cartagena Protocol regarding the interpretation of environmental protection legal provisions of non-WTO rules, especially the precautionary principle in risk assessments of LMO approval procedures.

17 See Resolución nº656/92, SAGyP.
19 See Regulation 21 of 2005.
Chapter 3 analyzes how the WTO Dispute Settlement Body, including the Panels and the Appellate Body, decides environmental cases. This will imply assessing International Law rules of interpretation, such as the Vienna Convention on the Laws of Treaties, in order to find out whether they can assist the WTO in cases of indeterminacy, and the International Court of Justice (ICJ) cases assessing indeterminacy in International Law.

Chapter 4 thoroughly analyzes leading cases with more similarities with a possible SEC trade requirement. In this respect, EC – Seal discussing public morals and EC – Biotech discussing LMOs and the Precautionary Principle with sanitary measures can help to clarify by analogy how the WTO would address environmental and social concerns of LMOs and whether the WTO Panels and the Appellate Body are prepared to fully address new forms of environmental concerns in trade dispute settlements.

Chapter 5 lists all the main findings of this study and discusses whether and how a SEC measure can be drafted and applied successfully, not being regarded as a protectionist and discriminatory trade restriction.
CHAPTER 1

1. The Socio-Economic Considerations of Living Modified Organisms

1.1. The Convention on Biological Diversity (CBD)

The United Nations Convention on Biological Diversity (CBD) had its origin in the growing concern to better protect biodiversity, which until 1980 lacked a specific international instrument. As a response, in 1988 and in 1989, the United Nations Environment Programme (UNEP) assembled an Ad Hoc Working Group of Experts on Biological Diversity\(^{20}\) and an Ad Hoc Working Group of Technical and Legal Experts\(^{21}\) with the goal of exploring the need for an international convention addressing biodiversity, especially its conservation and sustainable use, and preparing a legal instrument for this purpose.

Hence, in 1992, the Ad Hoc Working Groups presented at Nairobi Conference\(^{22}\) the Agreed Text of the Convention on Biological Diversity. The document was later opened for signature at the United Nations Conference on Environment and Development (the Rio "Earth Summit"). It received 168 signatures and entered into force on December 29, 1993.

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\(^{22}\) See UNEP/Bio. Div/Conf/1.
As a result, the CBD was the first International Treaty to fully and broadly address the preservation of biodiversity as a whole and not only migration species.\textsuperscript{23} The convention established the following main objectives: (i) the conservation of biological diversity, (ii) the sustainable use of its components and (iii) fair and equitable sharing of the benefits arising out of the utilization of genetic resources.\textsuperscript{24}

To fulfill these objectives and operate successfully, the CDB branches out into other Protocols and has an administrative system and decision-making process by which the Convention is organized and negotiated by the Parties.

\textbf{1.1.1 CBD Protocols}

As for the goal of conservation of biological diversity and the sustainable use of its components, for a while, the CBD was sufficient to address all pressing issues. However, over time and, especially, with the development of biotechnologies, new specific legal instruments became necessary, therefore the CBD established in articles 28\textsuperscript{25} and 29\textsuperscript{26} the possibility of adopting Protocols in order to supplement the Convention’s text.

\textsuperscript{24} Convention on Biological Diversity, article 1.
\textsuperscript{25} “1. The Contracting Parties shall cooperate in the formulation and adoption of protocols to this Convention. 2. Protocols shall be adopted at a meeting of the Conference of the Parties. 3. The text of any proposed protocol shall be communicated to the Contracting Parties by the Secretariat at least six months before such a meeting.”
\textsuperscript{26} “1. Amendments to this Convention may be proposed by any Contracting Party. Amendments to any protocol may be proposed by any Party to that protocol. 2. Amendments to this Convention shall be adopted at a meeting of the Conference of the Parties. Amendments to any protocol shall be adopted at a meeting of the Parties to the Protocol in question. The text of any proposed amendment to this Convention or to any protocol, except as may otherwise be provided in such protocol, shall be communicated to the Parties to the instrument in question by the secretariat at least six months before the meeting at which it is proposed for adoption. The secretariat shall also communicate proposed amendments to the signatories to this Convention for information. 3. The Parties shall make every effort to reach an agreement on any proposed amendment to this Convention or to any protocol by consensus. If all efforts at consensus have been exhausted, and no agreement reached, the amendment shall as a last resort be adopted by a two-thirds majority vote of the Parties to the instrument in question present and voting at the meeting and shall be submitted by
As to the connection between the CBD and its Protocols, the Convention establishes that any
decision taken under a protocol must only generate effects to the Parties for that specific Protocol,
not affecting the Parties to the CBD or other Protocols.27

Thus, on January 29, 2000, the Parties adopted the Cartagena Protocol on Biosafety, which entered
into force in 2003. It is worth mentioning that this Protocol was already planned in article 1928 of
the CDB, given the growing importance of biotechnologies in the future. Therefore, the Protocol
has the exclusive objective of protecting biological diversity from the potential risks posed by the
transboundary movement and handling of living modified organisms ("LMOs")29 resulting from
modern biotechnology.

In order to enable protection against possible harms caused by the development of new LMOs, the
Protocol established, in article 15, a mandatory risk assessment that must be carried out by all
signatory Parties. Essentially, this assessment has the purpose of attesting whether a new LMO
poses any threat to human health and biodiversity, and it must be performed in a scientific manner:

the Depositary to all Parties for ratification, acceptance or approval. 4. Ratification, acceptance or approval of
amendments shall be notified to the Depositary in writing. Amendments adopted in accordance with paragraph 3
above shall enter into force among Parties having accepted them on the ninetieth day after the deposit of instruments
of ratification, acceptance, or approval by at least two-thirds of the Contracting Parties to this Convention or of the
Parties to the protocol concerned, except as may otherwise be provided in such protocol. Thereafter the amendments
shall enter into force for any other Party on the ninetieth day after that Party deposits its instrument of ratification,
acceptance, or approval of the amendments. 5. For the purposes of this Article, "Parties present and voting" means
Parties present and casting an affirmative or negative vote.”
27 Convention on Biological Diversity, article 32.
28 “Handling of Biotechnology and Distribution of Its Benefits: […]3. The Parties shall consider the need for and
modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in
the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may
have an adverse effect on the conservation and sustainable use of biological diversity. […]”
29 The Protocol defines the term “living modified organism” as “any living organism that possesses a novel
combination of genetic material obtained through the use of modern biotechnology” (See Cartagena Protocol article
3, (g)).
15.1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.\(^\text{30}\)

The methodology that the risk assessment should follow is described in Annex III of the Protocol, where the Parties agree that, since LMO threats may be unknown, lack of scientific knowledge should not necessarily indicate a specific level of risk, absence of risk or an acceptable level of risk. Instead, the assessment must always be conducted on a case-by-case basis, requesting further studies and information on issues, and applying risk management and strategies.

Since the Protocol is a binding international treaty, all Parties must follow this risk assessment procedure. For instance, Brazil’s Biosafety law\(^\text{31}\) exactly mirrors Annex III of the Protocol, and even virtually copy the wording of article 9 of the Protocol. As the Protocol has 173\(^\text{32}\) Parties so far, the methodology for producing and handling LMOs is practically a global uniform standard.

Later, in 2010, the Nagoya Protocol came out as a response to achieve the CBD objective regarding fair and equitable sharing of the benefits arising out of the utilization of genetic resources. Lastly, the latest one, the Kuala Lumpur Supplementary Protocol (hereinafter "Supplementary Protocol"), has the purpose of addressing the redressability of the damages caused by illegal transboundary moments of LMOs.

\(^{30}\) Cartagena Protocol, article 15.


\(^{32}\) Until July 2020.
1.1.2. Structure of the CBD

The CBD also sets forth the administrative system and decision-making process\(^{33}\) which the Parties should follow to negotiate. In this administrative system, a Secretariat was created to organize and manage the Conference of the Parties, fulfill the roles assigned by the parties, such as reporting to and coordinating with other relevant international bodies and bodies within the CBD itself.\(^{34}\)

With regard to the decision-making process, the Conference of the Parties ("COP") is the meeting where all signatory Parties convene and negotiate the main decisions to be taken in the scope of the convention. Thus, the COP has the authority to review scientific, technical and technological advice and assessments; consider and adopt protocols, amendments and annexes; create subsidiary bodies; provide advice on scientific programs and international cooperation.\(^{35}\) Regarding the protocol meetings, they are defined as Meeting of the Parties ("MOP"), instead of COP, and have specific decisions within their scope.

In order to facilitate the Parties’ work for the COP, given the wide array of topics, the CBD also relies on the Subsidiary Body on Technical and Scientific Technological Advice ("SBSTTA"), which consists of preparatory meetings prior to every COP. The SBSTTA is essential because it provides the Parties with timely technical recommendations on several COP matters. In other words, the SBSTTA "digests" all negotiations in advance, optimizing COP discussions. The SBSTTA can share specific technical knowledge since its members are government

\(^{33}\) See UNEP/CBD/COP/DEC/VIII/10.

\(^{34}\) Convention on Biological Diversity, article 24.

\(^{35}\) Id. supra, article 21.
representatives competent in a specific relevant field of expertise.\textsuperscript{36} Usually, there are two SBSTTA meetings prior to every COP. These meetings result in recommendations that assist the Parties on the COP negotiations for every topic of the agenda.

Also, the Parties can also create Ad Hoc Technical Expert Groups ("AHTEG"). AHTEGs are not expressively stated in the CBD, but rather on a COP Decision concerning rules of procedure.\textsuperscript{37} The AHTEG includes individuals with expertise in a specific field. It is created with a determined mandate given by the Parties to discuss a specific topic or matter on the CBD agenda which may be taken into account in the SBSTTA and in the COP.

Finally, to assist these ongoing discussions, online forums can be held. Online forums are an open digital platform allowing everyone to participate. This is positive because it enables the general public to engage in the debates, hence the strong participation of Non-Governmental Organizations ("NGOs") enriching the discussions with different perspectives on the same problem.

Simplifying this CBD decision-making process structure into a scheme, it would look like the following:

\textsuperscript{36} Convention on Biological Diversity, article 25.
\textsuperscript{37} UNEP/CBD/COP/DEC/VIII/10, articles 24, 24 and 26.
The CBD structure is relevant since it guides not only how topics are negotiated, but especially how they are created and become part of the agenda. As for socio-economic considerations, this is important because it helps to comprehend the ongoing discussions and what to expect from future COP decisions regarding the development of this topic.

1.2. Socio-Economic Considerations (SECs)

Given that the Cartagena Protocol exclusively addresses the implications of LMO handling and transboundary movement in biodiversity and human health, as explained previously, it focuses intensively on procedures that ensure the safety of biotechnologies.

As previously explained, article 15 makes it mandatory to assess the risks from the approval of new LMOs, by following the procedures and standards of Annex III in order to provide protection against the impacts on biodiversity and human health. However, in addition to the risk assessment, article 26 allows the voluntary application of socio-economic considerations arising from LMOs:

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

According to the Protocol:

- SECs as to impacts on biodiversity must necessarily originate exclusively from LMOs (element of causation and damage);
- SEC requirements must be a voluntary instrument of the Protocol that can be adopted by a Party;
- SEC requirements must respect other international treaties (which is stated in the preamble of the Cartagena Protocol38).

Despite that, these brief aspects can be concluded from the Protocol and some issues are raised regarding this provision:

- SECs have never been officially defined, which until today raises questions and uncertainty about their implementation;
- The connection between SECs as a voluntary instrument of article 26 with the mandatory risk assessment of article 15;
- The methodology to be applied in these assessments and the need to perform ex ante and ex post studies (i.e., prior and after the approval or importation).

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38 “Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements.”
In this regard, SECs, as a topic, originated at the second MOP\(^39\) of the Protocol, in which the Parties submitted studies to initiate the discussion of article 26. At MOP4,\(^40\) the Parties assessed these studies and decided that more work was necessary. Hence, at MOP6,\(^41\) an AHTEG, specifically for SECs ("AHTEG SEC"), was created to analyze the studies and produce a report\(^42\) for MOP7.

Thereafter, at MOP7, the Parties extended the AHTEG SEC mandate,\(^43\) determining that its analysis should also include: (i) a proposal for a SEC definition and (ii) the outline of a Guidance to fulfill objective 17 of the Strategic Plan for the Cartagena Protocol on Biosafety for the Period 2011–2020.\(^44\) (Annex 1)

Finally, at MOP8, as requested, the AHTEG SEC issued\(^45\) the document "Revised Framework for Conceptual\(^46\) Clarity," proposing an outline for the SEC voluntary Guidance entitled "Guidance on the Assessment of Socio-Economic Considerations in the Context of Article 26 of the Cartagena Protocol on Biosafety" (hereinafter "SEC Guidance"), as well as the following possible definition for SEC (Annex 1):

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\(^{39}\) Decision BS-II/12.
\(^{40}\) Decision BS-IV/16.
\(^{41}\) Decision BS-VI/13.
\(^{42}\) UNEP/CBD/BS/AHTEG-SEC/1/3.
\(^{43}\) Decision BS-VII/13.
\(^{44}\) Id. supra at Elements of a Framework for Conceptual Clarity on Socio-Economic Considerations.
\(^{45}\) Due to lack of funding, it could not convene a face-to-face meeting as established in its mandate, AHTEG choosing to hold an online meeting instead to discuss a definition proposal, which is a procedural mistake (the must convene a face-to-face meeting — see UNEP/CBD/COP/DEC/VIII/10, paragraph 23). Thus, in October 2017, the AHTEG SEC eventually had to convene a face-to-face meeting, officially validating the definition proposal and an outline for the Guidance, as formal recommendations for the Parties at MOP09, with the document “Guidance on the Assessment of Socio-Economic Considerations in the Context of Article 26 of the Cartagena Protocol on Biosafety.”
\(^{46}\) UNEP/CBD/BS/COP-MOP/8/13.
Socio-economic considerations in the context of Article 26 of the Cartagena Protocol may, depending on the national or regional circumstances and on national measures implementing the Protocol, cover economic, social, cultural/traditional/religious/ethical aspects, as well as health and ecological aspects, if they are not already covered by risk assessment procedures under Article 15 of the Protocol.  

This proposed definition can be problematic because it is extremely broad and adds subjective and non-mensurable criteria such as cultural, traditional, religious and ethical aspects. Consequently, the Parties only "took note" of the document and did not officially endorse the proposed definition to be used for now.

As for the SEC voluntary Guidance, the group of experts tried to better explain what each one of the aspects of the proposed SEC definition means (i.e., social, cultural/traditional/religious/ethical), and prepared a draft methodology for future assessments, which is divided it into three steps: Scoping; Assessment; and Evaluations.

The interesting part here is the AHTEG SEC suggesting what social, economic, ecological, cultural, traditional, religious and ethical aspects of a SEC analysis would be:

![Figure 2 Stage B: Assessment and evaluation of SEC.](image)

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47 Decision BS-VII/13 at *Elements of a Framework for Conceptual Clarity on Socio-Economic Considerations.*

48 Guidance on the Assessment of Socio-Economic Considerations in the Context of Article 26 of the Cartagena Protocol on Biosafety.
In other words, the Expert Group only gives one example of each, leaving it open for further interpretation. Specifically, in the case of cultural, traditional, religious and ethical aspects, which necessarily adds subjectiveness to the text, the only example given is "effects on seed saving and exchange practices," hence not solving the problem at all and requesting Parties to submit information about preliminary experiences concerning SECs and the use of the voluntary Guidance\(^49\) applied to their national legislation.

Also, the SEC guidance does not establish a connection between the voluntary SEC analysis of article 26 with the mandatory risk assessment of article 15, let alone a specific methodology which these assessments can follow. In other words, whether SEC studies occur as part of the risk assessments or separately/independently.

This uncertainty is visible on the 6\(^{th}\) principle for the assessment of SECs stated in the Guidance:

6. The assessment of socio-economic considerations and the risk assessment may be conducted concurrently, consecutively or in an integrated manner, as applicable. Planning and conducting a risk assessment and an assessment of socio-economic considerations may be complementary and both may contribute to the decision-making process.\(^50\)

This issue is extremely important because if a methodology of assessment puts SECs as part of the risk assessment rather than as an independent analysis, although SECs are voluntary according to the Cartagena Protocol, this may gain mandatory implications, hence the confusion of a voluntary domestic standard with a mandatory international obligation, potentially impacting trade.

\(^{49}\) Notification 2019-031.

\(^{50}\) CBD/CP/MOP/9/10 – Annex.
Lastly, another issue identified in the proposed Voluntary SEC Guidance is that the document does not define the necessity to perform both ex ante and ex post SEC analyses, that is, to assess both before and after LMO approval scenarios, leaving it open for the national biosafety regulations of each Party. The lack of an ex-post study can hinder further confirmation of the possible benefits or harms of biotechnologies.

In this sense, it is important to stress in recent COP15, Parties only took note of this issue, hence not adopting any definition and postponing even more this lack of concept for SEC.\textsuperscript{51}

1.2.1. Parties’ SEC Regulatory Experiences

Currently, only a small group of countries can somehow include SEC analyses as part of their biosafety procedures on LMO approvals, as demonstrated in the research study of Falck-Zepeda:

\textsuperscript{51} CBD/CP/MOP/10/L.6
<table>
<thead>
<tr>
<th>Country</th>
<th>CBD/CPB&lt;sup&gt;a&lt;/sup&gt;</th>
<th>CFT/CO&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Language of relevant text considering socio-economic considerations</th>
<th>Relevant law and regulations for socio-economic considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Decision on the convenience of the commercialization the genetically modified material over its impact on markets, in charge of the National Market Directorate, so as to avoid potential negative impacts on Argentinean exports.</td>
<td>Resolution n° 656/92 of SAGPyP and Resolutions n°39/03 and n°57/03 SAGPyP</td>
</tr>
<tr>
<td>Brazil</td>
<td>Y/Y</td>
<td>Y/Y</td>
<td>Article 48. Paragraph 1. The National Biosafety Council—CNBS shall: II—analyze, upon request by CTNBio, in the convenience, socio-economic opportunity and national interest, requests to grant license on the commercial use of GMO and GMO derivatives.</td>
<td>Decree NO. 5,591, of November 23, 2005</td>
</tr>
<tr>
<td>Honduras</td>
<td>Y/Y</td>
<td>Y/Y</td>
<td>Socio-economic considerations will be conducted through partial studies that should include different social and economic impacts.</td>
<td>Honduras draft policy</td>
</tr>
<tr>
<td>Kenya</td>
<td>Y/Y</td>
<td>Y/N</td>
<td>“In reaching a final decision, the Authority shall take into account ... (a) socio-economic consideration arising from the impact of the GMO on the environment.”</td>
<td>Kenya draft policy</td>
</tr>
<tr>
<td>Uganda</td>
<td>Y/Y</td>
<td>Y/N</td>
<td>“No approval shall be given unless the GMO will not have adverse socio-economic impacts.”</td>
<td>Uganda draft regulations of 2006</td>
</tr>
<tr>
<td>Nigeria</td>
<td>Y/Y</td>
<td>N/N</td>
<td>The decision-making procedures shall take into consideration risk assessment, which involves scientific, socio-economic, cultural and ethical considerations.</td>
<td>Nigeria National Biosafety Framework, 2005</td>
</tr>
<tr>
<td>R.S. Africa</td>
<td>Y/Y</td>
<td>Y/Y</td>
<td>“The Council may in performing its function in terms of sub regulation (8), consider the socio-economic impact that the introduction of a genetically modified organism may have on a community living in the vicinity of such introduction.”</td>
<td>GMO Act 1997 (Act No. 15 of 1997)</td>
</tr>
<tr>
<td>Philippines</td>
<td>Y/Y</td>
<td>Y/Y</td>
<td>“Socio-economic, cultural and ethical considerations. Impacts on small farmers, indigenous people, women, small and medium enterprises, and the domestic scientific community to be taken in to account.”</td>
<td>Executive Order 514 (EO514)</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Y/Y</td>
<td>Y/Y</td>
<td>“The utilization of GEAP originating from both domestic and foreign products must pay attention to and take into consideration the religious, ethical, socio-cultural and esthetical norms.”</td>
<td>Regulation 21 of 2005</td>
</tr>
<tr>
<td>India</td>
<td>Y/Y</td>
<td>Y/Y</td>
<td>India’s biosafety system provides for evaluation of the economic benefits of LMOs through systematic evaluation of agronomic performance.</td>
<td>Not included or mandated by the Environmental Act or Biosafety Guidelines</td>
</tr>
<tr>
<td>United States</td>
<td>N/N</td>
<td>Y/Y</td>
<td>Voluntary/additional information</td>
<td>None</td>
</tr>
<tr>
<td>Canada</td>
<td>Y/N</td>
<td>Y/Y</td>
<td>Voluntary/additional information</td>
<td>None</td>
</tr>
<tr>
<td>EU</td>
<td>Y/Y</td>
<td>Y/Y</td>
<td>European Commission requires preparing a report on the socio-economic impact of GM crops every three years. Definition of socio-economic considerations is unclear in current legislation and associated guidelines, no provision for a risk-benefit analysis.</td>
<td>None</td>
</tr>
</tbody>
</table>

Note. Compilation by author from National Biosafety Frameworks, laws and regulations posted at the Biosafety Clearinghouse (Convention on Biological Diversity, 2006).

<sup>a</sup> CBD/CPB=Party to the Convention on Biological Diversity/Cartagena Protocol on Biosafety

<sup>b</sup> CFT=Conducted confined field trials, CO=Has made approval for commercialization

<sup>a,b</sup> Y=Yes, N=No

Figure 3: Current National Socio-Economic Norms.

It can be noticed that most of the countries listed only use socio and economic aspects as criteria, with a few exceptions, such as Nigeria and Philippines, which also include cultural, traditional,
religious and ethical aspects as the broad SEC definition proposal currently being negotiated at the CBD.

This fact can be attested by the Parties that submitted their reactions towards the use of a possible voluntary SEC Guidance proposed by the AHTEG SEC. Likewise, through the online forum, some countries shared their views about the interlinkage between a voluntary SEC analysis and the mandatory risk assessment of article 15 of the Cartagena Protocol.

a) Brazil

Brazil’s national legislation on Biosafety — Federal Law 11105/2005 and Federal Decree 5591/2005 — mirrors the Cartagena Protocol risk assessment procedure and takes SECs into account in the approval of LMOs, hence not as a general rule, but an exception, demanding a complex and bureaucratic system.

Article 8 The National Biosecurity Council (CNBS) shall be created, linked to the Presidency of the Republic, as the highest assessment body of the President of the Republic for the formulation and implementation of the National Biosecurity Policy – (PNB).

II – analyze, at the request of CTNBio, requests to release GMOs and their derivatives for commercial use, concerning the desirability, suitability in social and economic terms, and the national interest.

In other words, the Brazilian procedure for the approval of LMOs is not currently prepared to apply SEC requirements on a daily basis. This was even confirmed in the Brazilian submission regarding preliminary experiences with the SEC Guidance requested by the AHTEG SEC, in which Brazil

claims that although its law allows the use of SECs, the country has never used it in the approval of any LMO and consequently does not have anything to contribute regarding methodology.

In addition, Brazil stresses that some aspects of the voluntary Guidance outline go beyond and are not limited to the exclusive socio-considerations of LMO impacts as stated in article 26 of the Cartagena Protocol.57

b) United States

Although not a Party to the Convention, much less to the Cartagena Protocol, the United States (US) submitted information as an observer, claiming that due to the lack of an official definition for SECs, applying the voluntary Guidance is extremely difficult, as each Party might have different interpretations and, consequently, distinct assessment methodologies.

The US also stated that the Voluntary SEC Guidance does not clarify the interlinkages between risk assessment of article 15 with the voluntary SEC analysis of article 26.58 This is key because as this link is not clear, there can be binding implications to what was supposed to be a voluntary instrument of the Protocol.

c) European Union

57 Brazil submission: “Brazil considers that some aspects of the voluntary Guidance go beyond the scope of article 26, since they are not limited to the impact of living modified organisms (LMOs) in the conservation and sustainable use of biodiversity and raise the importance of non-scientific aspects in the evaluation of the LMOs.” Available at: http://bch.cbd.int/onlineconferences/portal_art26/Submissions2019.shtml

58 United States submission: “The steps outlined in the ‘overall assessment process’ should be tailored to be focused on decisions related to the import of LMOs, in line with Article 26.” Available at: http://bch.cbd.int/onlineconferences/portal_art26/Submissions2019.shtml
Although it has a regulatory framework aiming at a high level of environmental and human health protection against the impacts of LMOs,\(^{59}\) the European Union (EU) informed the AHTEG SEC that it does not have any experience using SECs as a standard for LMO approval. To better understand the issue, in 2013, the European GMO Socio-Economic Bureau (ESEB) was established with the purpose of organizing and gathering data about SEC implications, having issued two main reports on the subject in 2015\(^{60}\) and 2016.\(^{61}\) Despite the positive initiative of compiling topics relevant to SEC guidelines and indicators etc., the reports showed no evidence of impacts in the European Union due to lack of data. So far, it is inconclusive.\(^{62}\)

d) **South Africa**

South Africa responded that its national legislation on biosafety (the Genetically Modified Organisms Act No 15 of 1997\(^{63}\)) does include SECs. Moreover, South Africa explains that, according to its national law, SECs can refer:

\[
\ldots \text{to all impacts (i.e., those resulting from the "development, production, use, application and release of a genetically modified organism." In contrast, Article 23 of the Cartagena Protocol refers to 'indirect' effects (i.e., those arising from impacts on the conservation and sustainable use of biological diversity).}^{64}\n\]

\(^{59}\) Directives 2001/18/EC, 2009/41/EC and 2015/412

\(^{60}\) Framework for the socio-economic analysis of the cultivation of genetically modified (GM) crops. Available at: http://publications.jrc.ec.europa.eu/repository/bitstream/JRC95572/ipts%20jrc95572%20%28online%29.pdf


\(^{62}\) United States submission on page 21: “However, the main constraint concerns the lack of data to conduct the analyses. Surveys of farmers, industry and consumers are necessary to assess the majority of topics. Fewer topics can be analyzed by compiling secondary data from existing sources”. Available at http://bch.cbd.int/onlineconferences/portal_art26/Submissions2019.shtml

\(^{63}\) Available at http://ext wrplgs1.fao.org/docs/pdf/saf37570.pdf

\(^{64}\) The South African submission is probably using the wrong article. The right article would be 26 of the Cartagena Protocol, instead of article 23. Available at: http://bch.cbd.int/onlineconferences/portal_art26/Submissions2019.shtml

\(^{65}\) *Id.* supra.
Therefore, the country affirms that its law is much broader than the wording used in the Cartagena Protocol, assessing both positive and negative SEC outcomes of LMOs. In other words, the biosafety law requires analyzing *ex ante* (prior to the release and approval) benefits such as improved yield, greater economic returns, improved food security and risks like job losses, reduced food security, both human and animal health. However, South Africa does not follow up on an *ex post* SEC assessment, which may compromise a complete verification of SEC outcomes.

Regarding the voluntary SEC Guidance proposed by the AHTEG SEC, South Africa criticizes the document based on the same reason other Parties did: lack of clarity. South Africa stresses that the Guidance does not clarify when a SEC analysis is triggered, resulting in decision-making delays or even a barrier for other Parties.

e) Nigeria

Among the Parties that responded to the AHTEG SEC, Nigeria is an exception regarding SEC regulations. Differently from the other countries and even from the Voluntary SEC Guidance proposed by the AHTEG SEC, Nigeria has a more complete and clear regulation on the issue.

Initially, the Nigerian Law — National Biosafety Management Act of 201566 — states that SEC studies must be conducted with risk assessment and not as an independent study, if decided by the biosafety national authority:

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66 Available at: http://extwprlegs1.fao.org/docs/pdf/nig162641.pdf
24. (3) Any person, institution or body that submits an application under this section for the commercial release of a genetically modified organism must ensure that the application addresses the socio-economic considerations set out in the Third Schedule to this Act.67

SECs are also clearly stated as a parameter for risk assessments:

Risk Assessment Parameters
The user or applicant in respect of genetically modified organisms shall carry out an assessment prior to use or release of genetically modified organisms or products as regards the risks to human, animal health, biological diversity, the environment and the socio-economic welfare of societies and its assessments shall take the following parameters into consideration including any other parameter seemed to be relevant in the circumstances).68

Because SECs are part of the risk assessment methodology in the Nigerian Law, consequently, it is a mandatory instrument, not a voluntary one.

Another interesting point in the Nigerian biosafety regulation, which both the Parties to the Protocol and the AHTEG SEC have been struggling with, are the factors defining SECs. Nigeria regulation clearly lists which socio-economic impacts should be investigated:

Socio-economic consideration
79. Anticipated changes in the existing social and economic patterns resulting from the introduction of the genetically modified organism or products.
80. Possible treats to biological diversity, traditional crops or other products and in particular, farmers' varieties and sustainable agriculture.
81. Impacts likely to be posed by the possibility of substituting traditional crops, products and indigenous technologies through modern biotechnology outside of their agroclimatic zones.
82. Anticipated social and economic costs due to loss of genetic diversity, employment, market opportunities and in general, means of livelihood of the communities likely to be affected by the introduction of the genetically modified organisms or products.
83. Possible countries and communities to be affected in terms of disruptions to their social and economic welfare.
84. Possible effects which are contrary to the social, cultural, ethical and religious values of communities arising from the use of release of the genetically modified organism or the product.69

67 National Biosafety Management Act of 2015, 24 (3).
68 Id. supra, page 27.
69 Id. supra, page 30.
Among them, it is worth noting that Nigeria uses the broad concept of SECs, encompassing cultural ethical and religious factors, similar to the one proposed by the AHTEG as a possible definition for SECs in the Cartagena Protocol.

In its submission, Nigeria also informs that its SEC analysis gathers data from both prior and after the importation approval of new LMOs (i.e., *ex ante* and *ex post*), which so far has neither been addressed by most Parties to the Protocol with SECs in their biosafety laws nor by the AHTEG SEC in its proposed Voluntary SEC Guidance.

From this part of this study, it can be concluded that not all countries have a regulatory framework allowing SEC analysis. The group of countries that have SECs as a possibility within their legislations have never really applied this instrument and, therefore, totally lack practical experience.

Another point raised by some counties, such as the US, South Africa and Brazil, is the absence of clarity concerning the connection between voluntary SEC analysis and the mandatory risk assessment of article 15. The US and Brazil reaffirm that those are separate instruments of the Protocol and that any methodology used for a SEC guidance must necessarily exclude any connections with risk assessment.

On the other hand, Nigeria is an exception, having a legislation that does not only list the factors to be investigated in a SEC analysis, but also where SECs are part of the risk assessment, therefore a mandatory instrument.
However, none of the Parties, not even Nigeria, officially submitted information detailing real cases in which SECs were used and how they were used if, in fact, LMOs can improve or not the livelihood of small farmers and local communities.

1.2.2. Existing SEC Assessment Cases of Biotechnologies

Given the Parties’ lack of practical experience regarding SEC analysis of the possible impacts of LMOs and the uncertainties presented by the AHTEG’s proposed Voluntary SEC Guidance, observing real cases of non-transgenic (i.e., "non-LMOs") biotechnologies may be useful to answer some of the issues discussed previously.

The Food and Agriculture Organization of the United Nations (FAO) has been analyzing some cases of socio-economic impacts of non-LMO biotechnologies in developing countries in order to find out whether biotechnologies can be beneficial.\textsuperscript{70} The FAO case study presents some criteria and processes for a better assessment of SECs, advising that a SEC study should be conducted aiming to two main scopes: micro and macro sector levels.

The micro level is the most traditional way of analyzing technologies on farms. This can be done by assessing farm and household productivity, such as yield, unit cost of production, income and labor data. The macro level analysis consists of observing the implications of a biotechnology on

\textsuperscript{70} Andrea Sonnino, Zephaniah Dhlamini, Fabio Maria Santucci, Patrizio Warren, Food and Agriculture Organization of the United Nations (FAO) study Socio-Economic Impacts of Non-Transgenic Biotechnologies in Developing Countries – The case of plant micropropagation in Africa. Rome 2009. Available at: http://www.fao.org/3/i0340e/i0340e00.htm
the supply and demand of a certain commodity for producers and consumers, market prices, and
the overall welfare of the new technology.

The FAO study also discusses the importance of both *ex ante* and *ex post* analyses, which is called
"impact pathway."\(^7\) Assessing before and after scenarios is important because it allows to identify
the link between outputs, outcomes and potential impacts of the biotechnology in question, hence
a comparative observation attesting the advantages and disadvantages — a full analysis.

This SEC assessment process can be simplified with the following table:

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\(^7\) Steffen, A. Report on the peer review of the paper “The socio-economic Impacts of Plant Micropopagation
<table>
<thead>
<tr>
<th>Level</th>
<th>Scope</th>
<th>Impact evaluated</th>
<th>Indicators used</th>
<th>Time frame</th>
<th>Approach/model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micro</td>
<td>Farm (family village)</td>
<td>Agronomic</td>
<td>Yield, cost of production factors</td>
<td><em>ex ante</em></td>
<td>Effects on production function</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Workload, family income, health of workers, additional time</td>
<td><em>ex ante</em></td>
<td>Household approach</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Socio-economic</td>
<td></td>
<td><em>ex post</em></td>
<td></td>
</tr>
<tr>
<td>Sector</td>
<td>Market of a single product in a single country</td>
<td>Economic</td>
<td>BCR</td>
<td><em>ex ante</em></td>
<td>Dynamic Research Evaluation for Management (DREAM)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Internal rate of return</td>
<td></td>
<td>Scenario analysis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aggregate economic welfare analysis (single market partial equilibrium models)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Net present value</td>
<td><em>ex post</em></td>
<td>Economic surplus models</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Distribution of benefits between operators of the production chain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Macro</td>
<td>Market of many products in a single country</td>
<td>Economic</td>
<td>International price of products</td>
<td><em>ex ante</em></td>
<td>Partial equilibrium models (few commodities)</td>
</tr>
<tr>
<td></td>
<td>Market of a single product in many countries</td>
<td></td>
<td>Distribution of benefits between regions or countries (adopters/non-adopters)</td>
<td><em>ex ante</em></td>
<td>Computable general equilibrium (CGE) models (across commodities and sectors)</td>
</tr>
<tr>
<td></td>
<td>Multicommodity market in many countries</td>
<td></td>
<td>Distribution of benefits between society categories</td>
<td><em>ex post</em></td>
<td>(DREAM) multimarket analysis</td>
</tr>
</tbody>
</table>

Figure 4: Common approaches for assessing the impact of biotechnology applications.
It is interesting that FAO links better income with better human health. This factor strengthens the theory that SEC analysis should be part of the mandatory risk assessment.  

Using this SEC assessment process, FAO analyzed some real cases of non-LMO biotechnologies in Africa. Also, it is relevant to observe some data gathered by Brazil regarding 20 years of LMOs used in its agriculture.

a) Sweetpotato SEC Case in Zimbabwe

Since its independence, Zimbabwe's economy has been heavily dependent on agriculture. However, the production system of agricultural commodities is divided between agribusiness corporations and small farmers: a dualism that the government has been trying to mitigate. In order to modernize its agriculture and reduce the gap created by this dual system, especially by improving the lives of small farmers, Zimbabwe developed a project with sweet potato called the "Sweetpotato Project," which was carried out from 1996 to 2003, with the purpose of increasing local farmers' income.

Sweet potato is a challenging crop, as the plant is easily susceptible to pests and accounts for 14% of Zimbabwe’s GDP. In order to reduce this loss, plant micropropagation is a tissue culture technique that may be useful. The "Sweetpotato Project" took place in the Chigodora region,

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72 Andrea Sonnino, Zephaniah Dhlamini, Fabio Maria Santucci, Patrizio Warren, Food and Agriculture Organization of the United Nations (FAO) study Socio-Economic Impacts of Non-Transgenic Biotechnologies in Developing Countries – The case of plant micropropagation in Africa. Rome 2009, page 11. Available at: https://www.fao.org/3/i0340e/i0340e00.htm
73 Id. supra, page 37.
involving 54 villages with a population of 7,800 people and its data was analyzed to confirm whether biotechnologies can have a positive social economic impact.

The study confirmed that, with the new technology, despite bigger costs of implementation, local farmers eventually increased their net profit, by introducing new varieties with safer home cultivation/multiplication and less plant diseases:

<table>
<thead>
<tr>
<th>Item</th>
<th>2001</th>
<th>2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue from tubers</td>
<td>381</td>
<td></td>
</tr>
<tr>
<td>Revenue from vines</td>
<td>152</td>
<td>73</td>
</tr>
<tr>
<td>Total revenue</td>
<td>152</td>
<td>454</td>
</tr>
<tr>
<td>Cash cost</td>
<td>63</td>
<td>212</td>
</tr>
<tr>
<td>Net profit</td>
<td>89</td>
<td>242</td>
</tr>
<tr>
<td>BCR</td>
<td>1.71</td>
<td>1.87</td>
</tr>
</tbody>
</table>

Table 1: Benefits and costs (USD) in the Hwedza district.
Source: Andrea Sonnino, Zephaniah Dhlamini, Fabio Maria Santucci, Patrizio Warren, Food and Agriculture Organization of the United Nations (FAO) study Socio-Economic Impacts of Non-Transgenic Biotechnologies in Developing Countries – The case of plant micropropagation in Africa. Rome 2009, page 42. Available at: https://www.fao.org/3/i0340e/i0340e00.htm

The study also acknowledges that, as a consequence of using biotechnology, local farmers were able to diversify their diet, have better food security, increase their capacity of investing in the business and even expand to other agricultural activities, purchase more equipment, pay school fees, and be less subject to vulnerability factors such as droughts.

Findings from Chigodora Ward substantially validate this hypothesis. In this postproject scenario, 97 percent of the farmers has adopted micropropagated sweetpotatoes. The majority of farmers recognizes that these new varieties produce higher yields and are more palatable and more profitable than local varieties. Before the project, sweetpotato was basically a garden crop, but now it has become one of the most important crops grown for household consumption and for selling by 44 and 39 percent of farmers, respectively.\(^7^4\)

\(^7^4\) Andrea Sonnino, Zephaniah Dhlamini, Fabio Maria Santucci, Patrizio Warren, Food and Agriculture Organization of the United Nations (FAO) study Socio-Economic Impacts of Non-Transgenic Biotechnologies in Developing Countries – The case of plant micropropagation in Africa. Rome 2009, page 46. Available at: https://www.fao.org/3/i0340e/i0340e00.htm
This case is important because it is an example that, if socio-economic assessment is performed focusing on objective productivity and economic criteria, it is feasible and, in theory, could also be used for LMOs, finally attesting if this type of technology can improve the lives of farmers and communities.

b) Banana SEC Case in Uganda

Like Zimbabwe, Uganda also had an experience assessing the social and economic impacts of micropropagation biotechnology in the lives of local banana farmers.

The research took place in Bamunanika subcounty, located halfway between Kampala and Luwero, with around 25,000 people, of whom 88% lived in rural areas, according to the National Census.

Micropropagated banana was used from 2001 to 2005. However, unlike the Zimbabwe sweetpotato case, the Uganda case was more selective with the identification of adopters of the new biotechnology. In this case, only 76 farmers had the potential to undertake the new opportunity, as they had land, labor, and some know-how, from a total of 210 farmers in the region (i.e., 134 were excluded).

As to the micropopagated banana costs and benefits, adopters responded they indeed had gains, mainly consisting of higher yield, faster growth and a more palatable fruit compared with indigenous cultivars.
Table 2: Advantages of the best micropropagated plants compared with indigenous cultivars (76 adopters).

<table>
<thead>
<tr>
<th>Perceived Advantage</th>
<th>No.</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Higher yields</td>
<td>60</td>
<td>78</td>
</tr>
<tr>
<td>Faster plant growth</td>
<td>45</td>
<td>60</td>
</tr>
<tr>
<td>More palatable fruit</td>
<td>41</td>
<td>54</td>
</tr>
<tr>
<td>Rapid multiplication</td>
<td>16</td>
<td>21</td>
</tr>
<tr>
<td>Resistance to pests</td>
<td>14</td>
<td>18</td>
</tr>
<tr>
<td>Demanding less inputs</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Demanding less work</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

As consequence, this affected their daily lives by allowing a fruit surplus and more cash flow. The money earned with the banana surplus could be used to purchase other food groups such as sugar, meat, salt and tea (i.e., a more diverse diet), pay for health care, education, and improve house furniture and facilities. As in the Zimbabwe sweetpotato case, biotechnology can enable a better lifestyle.

However, due to the more selective criteria of eligibility to become an adopter of the micropropagated banana project, the study did not achieve the same range as the Zimbabwe case, attesting that biotechnology can require an initial investment that some small farmers might not have, being excluded from it.

c) 20 Years of SEC Data in Brazil

Brazil has always been a strong agricultural commodity producer, with a significant rate of use of transgenics, which started in 1998, 72 currently approved LMOs. Brazil’s biggest transgenic
products are cotton (94% of the national production), maize, and soy (92% of the national production), with approximately 50 million hectares of transgenic crops in 2017.\textsuperscript{75}

According to an independent study performed by Centro de Informações de Biotecnologia (CIB), a private non-profit association founded in 2002 to promote and disseminate Biotechnology and Innovation, mainly in Portugal and in Portuguese-speaking countries,\textsuperscript{76} the use of LMOs in crops improves efficiency by requiring less land. Specifically in the case of soy, there was an increase of 287% in production, demanding 170% more lands from 1998 to 2017. For maize, which is an older commodity of the Brazilian agriculture, in the same timeframe, the increase in production was 75%, demanding only 18% more areas. In addition, the study also found a smaller use of pesticides, resulting in fewer GHG emissions.

As for social and economic impacts resulting from the use of LMOs, the study also found a profit and income increase for farmers.

<table>
<thead>
<tr>
<th>Financial Impacts on Farmers (20 years, cumulative)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variables</td>
</tr>
<tr>
<td>Grain production increase (million tons)</td>
</tr>
<tr>
<td>Total income increase (billion BRL)</td>
</tr>
<tr>
<td>Total profit increase (billion BRL)</td>
</tr>
</tbody>
</table>

Table 3: Financial Impacts on Farmers (20 years, cumulative) (Translated by the author).

\textsuperscript{75} 20 anos de transgênicos: impactos ambientais, econômicos e sociais no Brasil, Conselho de Informações sobre Biotecnologia, Agroconsult, 2018. p. 8.
\textsuperscript{76} See https://cibpt.org/missao/
According to the same study, the financial gains from the use of LMOs go beyond the farm’s gates, since LMOs can also generate better income for the whole economy. LMOs are an industry that creates direct and indirect jobs, consequently increasing a country’s GDP.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Brazil</th>
<th>Soy</th>
<th>Maize</th>
<th>Cotton</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wealth growth (billion BRL)</td>
<td>45.3</td>
<td>9.1</td>
<td>35.8</td>
<td>0.4</td>
</tr>
<tr>
<td>GDP contribution (billion BRL)</td>
<td>2.8</td>
<td>1.6</td>
<td>1.2</td>
<td>0.1</td>
</tr>
<tr>
<td>Tax contribution (million BRL)</td>
<td>731</td>
<td>200</td>
<td>526</td>
<td>5</td>
</tr>
<tr>
<td>Trade balance contribution (million tons)</td>
<td>16.7</td>
<td>2.6</td>
<td>14.1</td>
<td>0.03</td>
</tr>
<tr>
<td>Jobs created</td>
<td>49.281</td>
<td>27.295</td>
<td>21.044</td>
<td>943</td>
</tr>
<tr>
<td>Additional wages (billion BRL)</td>
<td>2.2</td>
<td>0.6</td>
<td>1.6</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Table 4: Brazil’s social and economic impacts of LMOs (20 years, cumulative) (Translated by the author).

Therefore, for Brazil, the use of LMOs in the past 20 years generated almost 50,000 jobs, 45 billion BRL in wealth and 2.2 billion BRL in extra wages.

To summarize this part of the study, based on the studies analyzed, LMOs can in fact generate better income and more wealth for farmers and the economy. However, the Brazil and the African cases were either inconclusive or not specific enough regarding the positive impacts on small communities, thus further studies would be necessary.

Additionally, SECs are a voluntary instrument from the Cartagena Protocol and binding to all signatory Parties, which have the prerogative to adopt it if appropriate. However, with the ongoing and unsolved CBD negotiations, SECs do not have a definition yet, much less a uniform methodology, leaving countries with total liberty on this issue, which can create asynchronies.
About the current national biosafety regulations, most countries only briefly touch on the subject and use SECs as an additional type of assessment for LMO approvals, adopting a stricter definition that does not cover the broad one proposed by the AHTEG SEC, with cultural, religious, and ethical aspects. The exceptions, in this case, are South Africa and Nigeria, which do not only use a broader definition but also put SECs as part of their risk assessment.

These unsettled questions can become potentially more problematic depending on how SECs will evolve in the context of International Law and their interaction with trade agreements under the scope of the WTO.
CHAPTER 2

2. Socio-Economic Considerations in Trade Regulations

As seen in the previous chapter, from an international trade regulation perspective, the absence of a SEC definition and the risk of adopting broad criteria can be extremely troublesome, as SECs can become a sustainable requirement for commercial relations demanded by any Party to the Protocol as part of LMO approval procedures.

This may raise concern and reactions, once it may eventually become a requirement with positive outcomes, but also a disguised restriction to international trade. Therefore, it is essential to assess trade rules and their interlinkages with SECs.

77 See US – Gasoline, p. 25: “Arbitrary discrimination', 'unjustifiable discrimination' and 'disguised restriction' on international trade may, accordingly, be read side-by-side; they impart meaning to one another. It is clear to us that 'disguised restriction' includes disguised discrimination in international trade. It is equally clear that concealed or unannounced restriction or discrimination in international trade does not exhaust the meaning of 'disguised restriction.' We consider that 'disguised restriction', whatever else it covers, may properly be read as embracing restrictions amounting to arbitrary or unjustifiable discrimination in international trade taken under the guise of a measure formally within the terms of an exception listed in Article XX. Put in a somewhat different manner, the kinds of considerations pertinent in deciding whether the application of a particular measure amounts to 'arbitrary or unjustifiable discrimination' may also be taken into account in determining the presence of a 'disguised restriction' on international trade. The fundamental theme is to be found in the purpose and object of avoiding abuse or illegitimate use of the exceptions to substantive rules available in Article XX." See also Brazil – Retreated Tyres, para. 239: " [T]he Panel conditioned a finding of a disguised restriction on international trade on the existence of significant imports of retreaded tires that would undermine the achievement of the objective of the Import Ban. We explained above why we believe that the Panel erred in finding that the MERCOSUR exemption would result in arbitrary or unjustifiable discrimination only if the imports of retreaded tires from MERCOSUR countries were to take place in such amounts that the achievement of the objective of the Import Ban would be significantly undermined. As the Panel's conclusion that the MERCOSUR exemption has not resulted in a disguised restriction on international trade was based on an interpretation that we have reversed, this finding cannot stand. Therefore, we also reverse the Panel's findings, in paragraphs 7.354 and 7.355 of the Panel Report, that "the MERCOSUR exemption … has not been shown to date to result in the [Import Ban] being applied in a manner that would constitute … a disguised restriction on international trade."
2.1. The World Trade Organization

A global trading system was designed in 1947, after World War II, with the General Agreement on Tariffs and Trade (GATT), a replacement for the frustrated International Trade Organization (ITO), launched in the Breton Woods Convention. Thus, despite not being an international organization as previously intended by countries, the GATT is an agreement signed by 23 countries on October 30, 1947, with the purpose of regulating/reducing tariffs and subsidies and setting principles that avoid discriminatory policies in trade relations to boost the world economy and pursue free trade.

The GATT provided the world with a regulatory trade framework from 1948 to 1994, where the number of signatory parties rose from 23 to 164, but in 1995, after the Marrakesh Round, the parties to the agreement finally decided to replace it with a formal international organization as initially intended with the failed International Trade Organization in 1947, so the World Trade Organization (WTO) was created. Therefore, unlike the GATT, the WTO is not just an international treaty, but an organization with its treaties, rules of procedures, and departments. However, despite being an organization, the WTO has kept the GATT, with its principles and main set of rules, continuing with the goal of pursuing free trade.
2.2. The WTO Structure

As the WTO was established as an international organization, it gained an administrative structure with its rules of procedure, which is stated in the Marrakesh Agreement Establishing the World Trade Organization, as described below.\footnote{Available at: https://www.wto.org/english/docs_e/legal_e/04-wto_e.htm}
Figure 5: WTO organization chart.
Source: https://www.wto.org/english/thewto_e/whatis_e/tif_e/org2_e.htm
As observed, the WTO is organized into councils and committees, including the Ministerial Conference,\textsuperscript{79} WTO’s highest authority, where the meeting of the parties convenes every two years to discuss and take decisions on all matters under any of the multilateral trade agreements (i.e., much like the Convention on Biological Diversity Conference of the Parties, COP). The General Council, composed by the Parties, conducts regular work, and reports to the Ministerial Conference, which is held in two different subsidiary bodies: the Dispute Settlement Body and the Trade Policy Review Body.\textsuperscript{80}

The Trade Policy Review Body (TPRB) is responsible for undertaking and reviewing domestic trade policies from a multilateral perspective. This is performed through the Trade Policy Review Mechanism (TPRM),\textsuperscript{81} an instrument allowing greater transparency for the parties to understand and get familiar with national provisions and investment regimes. Regarding domestic environmental trade policies, according to the WTO Environmental Database, requests to review and use the Trade Policy Review Mechanism have been increasing ever since its launch, targeting mostly energy and agricultural norms. Demands come mostly from the European Union, followed by China and the United States.\textsuperscript{82}

\textsuperscript{79} Marrakesh Agreement Establishing the World Trade Organization, article IV. Available at: https://www.wto.org/english/docs_e/legal_e/04-wto_e.htm
\textsuperscript{80} Id. supra, article IV.
\textsuperscript{81} This mechanism was officially created with the Uruguay Round and its objectives are stated in Annex III of the Marrakesh Agreement.
\textsuperscript{82} Environmental Database. Available at: https://edb.wto.org/tpr
However, due to its novelty in the trade regulation environment as seen in the previous chapter, SEC policies have not been required to go through the TPRM assessment yet.

The Dispute Settlement Body (DSB) certainly is one of the WTO’s most important bodies due to its authority to address trade disputes between the Parties in disagreements regarding trade measures and national policies, in which case it is required to interpret trade rules. It operates according to Annex 2 of the WTO Agreement, the "Understanding on Rules and Procedures Governing the Settlement Disputes,"83 which lists all rules of procedures to be adopted to settle conflicts.

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83 Understanding on Rules and Procedures Governing the Settlement of Disputes, article 1: “The rules and procedures of this Understanding shall apply to disputes brought pursuant to the consultation and dispute settlement provisions of the agreements listed in Appendix 1 to this Understanding (referred to in this Understanding as the "covered agreements"). The rules and procedures of this Understanding shall also apply to consultations and the settlement of disputes between Members concerning their rights and obligations under the provisions of the Agreement Establishing
In this regard, in the case of a conflict, initially, a Panel is convened to "[…] make an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements and make such other findings as will assist the DSB in making the recommendations or in giving the rulings provided for in the covered agreements […]." The panel is composed of qualified individuals with a term of reference and may eventually write a report with its decision.

Within 60 days after the Panel issues a report, the DSB can adopt it or the Party can request an appellate review from the Appellate Body, which is composed of seven members who must necessarily address legal issues and legal interpretations given by the Panel, having the authority to reverse the Panel's previous decision if appropriate. However, unlike the Panel's report, the decision reached by the Appellate Body is adopted by the DSB and the losing Party. Also, because the decisions of the Appellate Body must be adopted by other political organizations to be legally enforced, some scholars claim that this is not a full legal system, but a "quasi-judicial system."

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the World Trade Organization (referred to in this Understanding as the "WTO Agreement") and of this Understanding taken in isolation or combination with any other covered agreement.” Available at: https://www.wto.org/english/tratop_e/dispu_e/dsu_e.htm
84 Id. supra, article 11.
85 Id. supra, article 6.
86 Id. supra, article 7.1.
87 Id. supra, article 16.4.
In addition to the DSB and the TPRB, the General Council also has three specific councils: Trade in Goods, Trade in Services, and the Trade-Related Aspects of Intellectual Property Rights. The WTO also has several committees that discuss certain topics with a growing importance in the trade agenda.

2.3. WTO Free Trade Principles

To achieve economic liberalism, fair trade, and avoid discriminatory practices, since its creation, the GATT has been based on two main principles: the Most Favoured Nation (MFN) and the National Treatment clause.

In short, the MFN is a principle in article I stating that it cannot be any trade measure imposed by a party, which favors one country to the detriment of all the other signatory parties regarding a like product:

Article I. 1. With respect to customs, duties and charges of any kind imposed on or in connection with importation or exportation or imposed on the international transfer of payments for imports or exports, and with respect to the method of levying such duties and charges, and with respect to all rules and formalities in connection with importation and exportation, and with respect to all matters referred to in paragraphs 2 and 4 of Article III,* any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties.90

While the MFN focuses on trade practices aiming to potentially unfair differences between parties of the GATT, the National Treatment is stated in article III and avoids that national and domestic measures create privileges for national products to the detriment of foreign ones regarding a like product:

90 GATT, Article I.1.
Article III. 1. The contracting parties recognize that internal taxes and other internal charges, and laws, regulations, and requirements affecting the internal sale, offering for sale, purchase, transportation, distribution or use of products, and internal quantitative regulations requiring the mixture, processing, or use of products in specified amounts or proportions, should not be applied to imported or domestic products so as to afford protection to domestic production.*

[...]

4. The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use. The provisions of this paragraph shall not prevent the application of differential internal transportation charges which are based exclusively on the economic operation of the means of transport and not on the nationality of the product.91

The "like product" expression is a key element to enable the applicability of both MFN and National Treatment principles. It is present in articles I.1, II.2, III.2, III.4, VI.1, IX.1, XI.2(c), XIII.1, XVI.4 and XIX.1. The element of likeness allows a comparison between goods from national and foreign countries, consequently identifying discriminatory trade measures. But the GATT does not explain the definition of "like product." This understanding was only reached by the WTO jurisprudence, through the interpretation of the DSB with its Panels and Appellate Body. The WTO has relevant cases addressing the definition or understanding of "like product" and likeness. In United States — Certain Measures Affecting Imports of Poultry from China, the Panel report set four definite requirements to determine a like product:

7.425 The traditional approach for determining "likeness" has, in the main, consisted of employing four general criteria: 667 "(i) the properties, nature and quality of the products; (ii) the end-uses of the products; (iii) consumers' tastes and habits – more comprehensively termed consumers' perceptions and behaviour – in respect of the products; and (iv) the tariff classification of the products."

Additionally, in Japan — Alcoholic Beverages, 1996, the WTO Appellate Body explained that this concept is also flexible with an additional need of a case-by-case analysis:

91 * Id. supra, article III.4.
[...] there can be no one precise and absolute definition of what is "like". The concept of "likeness" is a relative one that evokes the image of an accordion. The accordion of "likeness" stretches and squeezes in different places as different provisions of the WTO Agreement are applied. The width of the accordion in any one of those places must be determined by the particular provision in which the term "like" is encountered as well as by the context and the circumstances that prevail in any given case to which that provision may apply. [...]93

In this decision, the WTO Appellate Body also reminded that this ruling had been issued in past disputes initiated with the Working Party on Border Tax Adjustments:

... the interpretation of the term should be examined on a case-by-case basis. This would allow a fair assessment in each case of the different elements that constitute a "similar" product. Some criteria were suggested for determining, on a case-by-case basis, whether a product is "similar": the product's end-uses in a given market; consumers' tastes and habits, which change from country to country; the product's properties, nature, and quality.94

However, regarding environmental concerns, the concept and understanding of likeness previously used were altered. In EC — Asbestos, the WTO Appellate Body had to address whether chrysotile asbestos fibers were like products with other types of glass and cellulose fibers. Although these fibers have the same end use (i.e., China Poultry test), in this case, since asbestos is toxic and carcinogenic, it generates different environmental and health impacts compared to glass and cellulose fibers, therefore those are not like products, which made the Appellate Body reverse the Panel’s decision: "This carcinogenicity, or toxicity, constitutes, as we see it, a defining aspect of the physical properties of chrysotile asbestos fibres."95

94 Id. Supra, p. 20. Also, at Report of the Working Party on Border Tax Adjustments, BISD 18S/97, para. 18
95 EC — Measures Affecting Asbestos and Products Containing Asbestos, p. 44. Available at: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/DS/135ABR.pdf&Open=True
The GATT is a cornerstone regulating and assuring free trade without discriminatory practices between countries and between domestic and foreign like products, reflected by articles I and III. To assess these situations, the concept of like product is crucial to allow comparison. However, when it comes to environmental and health concerns, the Appellate Body, with its jurisprudence, such as the EC Asbestos case, defines like products from a different perspective.

Additionally, the special treatment given to environmental concerns does not only apply to the definition of like products, but it is also clearly stated in the GATT wording, as an exception to the main rules of free trade of articles I and III, which will now be assessed.

2.4. WTO Environmental Exceptions and SECS

Even though it started with the GAAT in 1948, so far, The WTO has three main agreements which dictate most of the rules for trade policies and tariffs: the General Agreement on Tariffs and Trade (GATT), Technical Barriers to Trade Agreement and the Agreement on the Application of Sanitary and Phytosanitary Measures. All of them have the environment as an exception to the principles of free trade such as the Most Favoured Nation (MFN) and the National Treatment clauses.

2.4.1. General Agreement on Tariffs and Trade (GATT)

Within its complex text of 38 articles and respective provisions, GATT article XX addresses possible exceptions to the general rules assuring free trade; in other words, situations that justify a measure that would create differences between like products of different Parties.
Thus, article XX lists all the scenarios where these exceptions may be applied, among which provisions (b) and (g) specifically address human health and environmental protection:

Article XX: General Exceptions. Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

(b) necessary to protect human, animal, or plant life or health;
(g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption;

However, it is worth mentioning that when article XX was designed during the negotiations of the attempted International Trade Organization (ITO) at the London session of the Preparatory Committee, the Parties at that time already showed concerns regarding a possible abusive use of this prerogative, as it could be used to cover unfair trade measures:

"’to protect animal or plant life or health’ are misused for indirect protection. It is recommended to insert a clause which prohibits expressly [the use of] such measures [to] constitute an indirect protection …" ⁹⁶

Likewise, the same concern was expressed at the Technical Sub-committee of Committee II at London:

"In order to prevent abuse of the exceptions of Article 32 (i.e., article XX) … the following sentence should be inserted as an introduction: ‘The undertakings in Chapter IV of this Charter relating to import and export restrictions shall not be construed to prevent the adoption or enforcement by any Member of the following measures, provided that they are not applied in such a manner as to constitute a means of arbitrary discrimination between countries where the same conditions prevail, or a disguised restriction on international trade.’" ⁹⁷

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⁹⁶ 7EPCT/C.II/32 (Note of the Netherlands and the Belgo-Luxembourg Economic Union, 30 October 1946).
⁹⁷ 8EPCT/C.II/50, p. 7.
Therefore, the *chapeau* of article XX states that this exceptional discrimination cannot be arbitrary or unjustifiable, consequently adding limits regarding how the exceptions can be invoked.98

**A) Article XX Structure (Two-Tiered Test)**

The *chapeau* also sets an interpretation structure. Firstly, the trade measure must be assessed to determine whether it fits as an exception listed in the provisions, then it must be determined whether the measure is either arbitrary or unjustifiable, according to the *chapeau* — a two-tiered test. This order of analysis was further explained by the Appellate Body in United States — Gasoline; and in United States — Import Prohibition of Certain Shrimp and Shrimp Products, respectively. In United States — Gasoline, the Appellate Body developed the interpretation using the two-tiered test of article XX:

"[...] In order that the justifying protection of Article XX may be extended to it, the measure at issue must not only come under one or another of the particular exceptions — paragraphs (a) to (j) - listed under Article XX; it must also satisfy the requirements imposed by the opening clauses of Article XX. The analysis is, in other words, two-tiered: first, provisional justification by reason of characterization of the measure under XX(g); second, further appraisal of the same measure under the introductory clauses of Article XX."99

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98 Also see US – Gasoline, the Appellate Body Report, p. 22: “The chapeau by its express terms addresses, not so much the questioned measure or its specific contents as such, but rather the manner in which that measure is applied. It is, accordingly, important to underscore that the purpose and object of the introductory clauses of Article XX is generally the prevention of ‘abuse of the exceptions of [what was later to become] Article [XX].’ This insight drawn from the drafting history of Article XX is a valuable one. The chapeau is animated by the principle that while the exceptions of Article XX may be invoked as a matter of legal right, they should not be so applied as to frustrate or defeat the legal obligations of the holder of the right under the substantive rules of the General Agreement. If those exceptions are not to be abused or misused, in other words, the measures falling within the particular exceptions must be applied reasonably, with due regard both to the legal duties of the party claiming the exception and the legal rights of the other parties concerned.” Available at: https://docs.wto.org/dol2fe/SS/SS/2liner.aspx?filename=Q:/$/WT/DS/2ABR.pdf&Open=True

99 US — Gasoline, the Appellate Body Report, p. 22. Available at: https://docs.wto.org/dol2fe/SS/SS/2liner.aspx?filename=Q:/$/WT/DS/2ABR.pdf&Open=True
Thereafter, in United States — Import Prohibition of Certain Shrimp and Shrimp Products, the Appellate Body reaffirmed this test by reversing the Panel decision, which had not performed the two-tiered test previously:

"The sequence of steps indicated above in the analysis of a claim of justification under Article XX reflects, not inadvertence or random choice, but rather the fundamental structure and logic of Article XX. The Panel appears to suggest, albeit indirectly, that following the indicated sequence of steps, or the inverse thereof, does not make any difference. To the Panel, reversing the sequence set out in United States – Gasoline 'seems equally appropriate.' We do not agree. The task of interpreting the chapeau so as to prevent the abuse or misuse of the specific exemptions provided for in Article XX is rendered very difficult, if indeed it remains possible at all, where the interpreter (like the Panel in this case) has not first identified and examined the specific exception threatened with abuse. The standards established in the chapeau are, moreover, necessarily broad in scope and reach the prohibition of the application of a measure 'in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail' or 'a disguised restriction on international trade.' (emphasis added) When applied in a particular case, the actual contours and contents of these standards will vary as the kind of measure under examination varies."

Thus, to invoke article XX not only the measure in hand must fit into the criteria of the exceptions listed in the provisions, but also pass the scrutiny of the chapeau (i.e., not arbitrary and/or unjustifiable). In other words, the two-tiered test must be applied.

**B) Article XX Environmental Exceptions**

Concerning SECs, given their undetermined concept, the use of article XX can be challenging. As shown above, according to the two-tiered test, the measure must first be regarded as one of the exceptions stated in the provisions, which for environmental purposes would be provisions (b) and (g), then be assessed from the angle of the chapeau.

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100 The two-tiered test was reaffirmed again by the Appellate Body in Brazil — Retreaded Tyres case.
101 United States — Import Prohibition of Certain Shrimp and Shrimp Products, paras. 119–120. Available at: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/DS/58ABR.pdf&Open=True
102 GATT, Article XX, (b): “necessary to protect human, animal or plant life or health.”
103 GATT, article XX, (d): “relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption.”
Although SECs are a voluntary instrument of the Cartagena Protocol, with the ultimate goals of preserving biological diversity, the sustainable use of its components, and the fair and equitable sharing of its benefits, from a WTO regulation perspective, this is not clear. Based on the DSB jurisprudence, both provisions (b) and (g) have determined and restrictive concepts, which would not be appropriate for the social and economic impacts of transgenic products.

Regarding provision (b) aiming to protect human, animal, or plant life or health, the WTO’s jurisprudence already defined these terms. In Thailand — Restrictions on Importation of and Internal Taxes on Cigarettes, Thailand enabled a policy prohibiting imports of cigarettes due to risks to human health. The Panel found that Thailand was taking into account the recommendations of the World Health Organization to protect its public health, hence falling within article XX (b):

The Panel then defined the issues which arose under [Article XX(b)]. In agreement with the parties to the dispute and the expert from the WHO, the Panel accepted that smoking constituted a serious risk to human health and that consequently, measures designed to reduce the consumption of cigarettes fell within the scope of Article XX(b). The Panel noted that this provision allowed contracting parties to give priority to human health over trade liberalization; however, for a measure to be covered by Article XX(b) it had to be ‘necessary.’

However, for the Panel, Thailand failed to justify it as a "necessary" measure. The Panel found that Thailand could have used other less restrictive and more effective alternatives to import prohibition, for instance, reducing the quantity and ensuring the quality of the cigarettes sold in the country.

104 Thailand — Restrictions on Importation of and Internal Taxes on Cigarettes, para. 73.
105 See Id. Supra, para 76: “The Panel noted that the principal health objectives advanced by Thailand to justify its import restrictions were to protect the public from harmful ingredients in imported cigarettes, and to reduce the consumption of cigarettes in Thailand. The measures could thus be seen as intended to ensure the quality and reduce the quantity of cigarettes sold in Thailand.”
Therefore, WTO jurisprudence acknowledges that provision (b) is not only specifically designed to protect human health, but it also must be necessary for this purpose, having restrictive measures as the last option after checking other alternatives. In this regard, the DSB precedents had affirmed that a restrictive measure is necessary compared to "its possible alternatives, which may be less trade-restrictive while providing an equivalent contribution to the achievement of the objective pursued."\(^{106}\)

For provision (g), regarding the conservation of exhaustible natural resources, the DSB, in some disputes, clarified the meaning of these terms and how this exception can be applied. In Canada — Measures Affecting Exports of Unprocessed Herring and Salmon, in 1988, the Panel had to assess whether Canadian policies restricting the export of unprocessed salmon and herring was following article XX (g), i.e., whether the measure would protect a natural resource. The Panel examined Canada’s statistics and environmental programs for salmon, such as the Salmonid Enhancement Program, concluding that since Canada already had initiatives that could ensure the protection of this natural resource without imposing prohibitions, the trade policy in hand targeting only the unprocessed type of salmon products was not "primarily aiming"\(^{107}\) this goal.

\(^{106}\) Brazil — Retreated Tyres, Appellate Body Reports, para. 156. See also US — Gambling.

\(^{107}\) Canada — Measures Affecting Exports of Unprocessed Herring and Salmon, Panel Report para. 12: “The Panel concluded for these reasons that, while a trade measure did not have to be necessary or essential to the conservation of an exhaustible natural resource, it had to be primarily aimed at the conservation of an exhaustible natural resource to be considered as "relating to" conservation within the meaning of Article XX(g). The Panel, similarly, considered that the terms "in conjunction with" in Article XX(g) had to be interpreted in a way that ensures that the scope of possible actions under that provision corresponds to the purpose for which it was included in the General Agreement. A trade measure could therefore in the view of the Panel only be considered to be made effective "in conjunction with" production restrictions if it was primarily aimed at rendering effective these restrictions".
Determining whether the measure is primarily aimed to protect exhaustible natural resources was reaffirmed in United States — Import Prohibition of Certain Shrimp and Shrimp Products. In this case, the Panel also had to address the meaning of the term "exhaustible natural resource" regarding a measure imposed by the US. The Panel found that the term should not be limited to mineral or non-living resources, but also living and renewable natural resources subject to exhaustion. The Panel also stressed that this interpretation should always be in the light of new contemporary concerns of the communities of nations regarding environmental protection, hence a term that can be adjusted over time and with the evolution of environmental threats.

Finally, taking into account a broad SEC definition as proposed by the AHTEG SEC, which does not only include the socio and economic impacts of LMOs but also their religious, ethical, and

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108 United States — Import Prohibition of Certain Shrimp and Shrimp Products, para. 141: "In its general design and structure, therefore, Section 609 is not a simple, blanket prohibition of the importation of shrimp imposed without regard to the consequences (or lack thereof) of the mode of harvesting employed upon the incidental capture and mortality of sea turtles. Focusing on the design of the measure here at stake, it appears to us that Section 609, cum implementing guidelines, is not disproportionately wide in its scope and reach in relation to the policy objective of protection and conservation of sea turtle species. The means are, in principle, reasonably related to the ends. The means and ends relationship between Section 609 and the legitimate policy of conserving an exhaustible, and, in fact, endangered species, is observably a close and real one. In our view, therefore, Section 609 is a measure 'relating to' the conservation of an exhaustible natural resource within the meaning of Article XX(g) of the GATT 1994.

109 Id. Supra, para. 128: "Textually, Article XX(g) is not limited to the conservation of 'mineral' or 'non-living' natural resources. The complainants' principal argument is rooted in the notion that 'living' natural resources are 'renewable' and therefore cannot be 'exhaustible' natural resources. We do not believe that 'exhaustible' natural resources and 'renewable' natural resources are mutually exclusive. One lesson that modern biological sciences teach us is that living species, though in principle, capable of reproduction and, in that sense, 'renewable', are in certain circumstances indeed susceptible of depletion, exhaustion and extinction, frequently because of human activities. Living resources are just as 'finite' as petroleum, iron ore and other non-living resources."

110 Id. Supra, para. 129: "The words of Article XX(g), 'exhaustible natural resources', were actually crafted more than 50 years ago. They must be read by a treaty interpreter in the light of contemporary concerns of the community of nations about the protection and conservation of the environment. While Article XX was not modified in the Uruguay Round, the preamble attached to the WTO Agreement shows that the signatories to that Agreement were, in 1994, fully aware of the importance and legitimacy of environmental protection as a goal of national and international policy. The preamble of the WTO Agreement -- which informs not only the GATT 1994, but also the other covered agreements -- explicitly acknowledges 'the objective of sustainable development [...] From the perspective embodied in the preamble of the WTO Agreement, we note that the generic term 'natural resources' in Article XX(g) is not 'static' in its content or reference but is rather 'by definition, evolutionary'. It is, therefore, pertinent to note that modern international conventions and declarations make frequent references to natural resources as embracing both living and non-living resources."
traditional aspects, provision (a)\textsuperscript{111} of article XX should be analyzed, which is an exception exclusively aimed at protecting public morals and, from this perspective, religious, traditional, and ethical values and concerns could be regarded as a public moral.

Provision (a), like the others from article XX, was also designed to allow parties to protect common interests through exceptional circumstances and lift the general rules of non-arbitrary and unjustifiable discrimination. But unlike the environmental exceptions of provisions (b) and (g) that over time acquired definite concepts, the term "public moral" is also conceptually vague and has not been an object of thorough research,\textsuperscript{112} which made the Parties use it for a vast array of situations.

In this regard, the DSB has some precedents that can help clarify this issue. The most important case which mixes public morals with animal protection and welfare is the EC — Seal Products case. In this case, the European Union (EU) issued a regulation entitled EU Seal Regime\textsuperscript{113} addressing seal products, banning seal imports, and placing on the market seal products derived from "commercial" hunts, while allowing seal products from hunts to satisfy certain criteria related to the identity of the hunter and the hunting purpose, aiming to seal welfare.

Eventually, exporters of seal products, such as Canada and Norway, challenged this measure at the WTO. The EU argued that the measure was necessary to protect public morals as Europeans are

\textsuperscript{111} GATT, article XX, (a): “necessary to protect public morals;”
\textsuperscript{112} Katarina Jakobsson, The dilemma of the moral exception in the WTO, Faculty of Law, Stockholm University, 2013, p. 30.
\textsuperscript{113} The Panel considered that the Regulation (EC) No. 1007/2009 (i.e., “Basic Regulation”) and Commission Regulation (EU) No. 737/2010 (i.e., “Implementing Regulation”) as one named “EU Seal Regime”
concerned with seal welfare, thus an exception to provision XX (a). To achieve this objective, the EU Seal Regime demanded that all seal products imported should come from hunts conducted by Inuit communities. According to the EC Seal Regime, seal hunts must be performed by Inuit communities, as, traditionally, their subsistence is based on seals, therefore their hunting activities are of a smaller scale and more sustainable nature.

According to the DSB jurisprudence, initially, in China — Publications and Audiovisual Products, the term "public moral" corresponds to "a standard of right and wrong conduct maintained by or on behalf of a community or nation," taking into account that they are influenced by their social, cultural, ethical and religious values.114 Thereafter, in EC — Seal Products, the Appellate Body reaffirmed this ruling by stressing that the members must give scope to "public morals" based on their values, i.e., the concern with seal welfare.115

Therefore, regarding the application of exception (a), both the Panel and the Appellate Body concluded that the regulations forming the EU Seal Regime were an instrument to protect public morals in Europe. The Appellate Body reaffirmed the Panel’s finding, concerning the legislative

114 China — Publications and Audiovisual Products, Panel Reports, paras. 7.759 and 7.763: “[T]he term 'public morals' denotes standards of right and wrong conduct maintained by or on behalf of a community or nation.” […] ”The content and scope of the concept of 'public morals' can vary from Member to Member, as they are influenced by each Members' prevailing social, cultural, ethical and religious values…”

115 EC — Seal Products, Appellate Body Reports, para. 5.199: “[W]e also have difficulty accepting Canada's argument that, for the purposes of an analysis under Article XX(a), a panel is required to identify the exact content of the public morals standard at issue. The Panel accepted the definition of 'public morals' developed by the panel in US — Gambling, according to which 'the term 'public morals' denotes 'standards of right and wrong conduct maintained by or on behalf of a community or nation. The Panel also referred to the reasoning developed by the panel in US — Gambling that the content of public morals can be characterized by a degree of variation, and that, for this reason, Members should be given some scope to define and apply for themselves the concept of public morals according to their own systems and scales of values. Canada does not challenge these propositions on appeal. In addition, we note that, although Canada indirectly questions the existence of EU public moral concerns regarding seal welfare by contending that the Panel ought to have considered the similarity of animal welfare risks in both terrestrial wildlife hunts and seal hunts, Canada does not directly challenge the Panel's finding that there are public moral concerns in relation to seal welfare in the European Union.”
history and the existence of the EU’s public concern with seal welfare,\footnote{European Communities — Seal Products, Appellate Body report para. 5.139. The Panel concluded based on its examination of the text and legislative history of the EU Seal Regime, as well as other evidence about its design, structure, and operation, that the objective of the EU Seal Regime is "to address the moral concerns of the EU public with regard to the welfare of seals". The Panel elaborated that these concerns have two specific aspects: (i) "the incidence of inhumane killing of seals"; and (ii) "EU citizens' 'individual and collective participation as consumers in, and exposure to ('abetting'), the economic activity which sustains the market for' seal products derived from inhumane hunts."} thus demonstrating a clear objective of the EU Seal regime based on an EU ethical value:

The European Union submits that the 'moral concern with regard to the protection of animals' is regarded as a value of high importance in the European Union. We consider, and the parties do not dispute, that the protection of such public moral concerns is indeed an important value or interest.”\footnote{Id. supra, at Panel report, para. 7.632}

To analyze whether the measure is applicable as protection of public morals, the DSB must check two steps: if the concern exists in that society, such as in its legislative history, and if it falls in the scope of public morals, such as actions taken towards this goal.\footnote{Łukasz Gruszczynski, WTO PANEL REPORT (WT/DS400/R, WT/DS401/R OF 2013) AND APPELLATE BODY REPORT (WT/DS400/AB/R, WT/DS401/AB/R) IN EC – SEAL PRODUCTS CASE: PUBLIC MORALITY MEETS THE WORLD TRADE COURT, POLISH REVIEW OF INTERNATIONAL AND EUROPEAN LAW, 2014, Vol. 3, Issue 1-2: “According to the panel, the initial analysis of the public morals defense involves two steps: (i) whether the specific concern exists in the particular society, and (ii) whether such a concern falls within the scope of public morals.” The first element may be determined solely on the basis of the content of a contested measure, e.g. by looking at its preamble and legislative or regulatory history. It appears that there is no need for a public survey which would objectively confirm the existence of a specific moral or ethical conviction in a particular society. As regards the second element, it can be ascertained through reference to actions taken in the past to address specific moral issues, existing legislation, and international legal instruments applicable in the country(-ies) concerned. Again, the threshold here seems to be relatively low. See also Colombia – Textiles, Appellate Body Reports, paras. 5.67-5, where the Appellate Body conducts a two-step analysis to assess whether a measure is capable of protecting public morals: designed to protect public morals and necessary to protect public morals.}

Although the Appellate Body reversed the Panel’s finding concerning the two-tiered test, that is, although article XX subparagraph (a) applies to the case, the measure did not meet the criteria of the \textit{chapeau}, being discriminatory and arbitrary. For the Appellate Body, the differences between
traditional and commercial hunting and the outcomes from more humane seal hunting practices were not clear.

However, although the EC Seal Regime is regarded as discriminatory by the Appellate Body, this case is important because it shows that ethical values and public morals regarding animal protection can be accepted as a trade exception for the WTO.

C) Application of GATT Article XX for SEC Measures

As observed above, GATT environmental exceptions (a), (b), and (g) of article XX are extremely strict with very determined triggers to be used. Thus, applying SEC requirements of LMOs in these exceptions can be uncertain and unlikely to happen.

Concerning provision (b) for the protection of human, animal and plant life, the acknowledgment of SECs as this exception is limited. Especially in the Thailand — Cigarettes case, the DSB explained that this provision can be invoked not only when health risks are demonstrated, but also that the measure to address this protection must be necessary (i.e., no other option). For SECs, this is challenging because not only the SEC measure has to demonstrate its impacts on the health of the local community, but it also must be the only option available.

In this regard, in the FAO study with micropropagated banana and sweet potato in Uganda and Zimbabwe, there are some timid indicators that biotechnology, by providing better income, can
consequently provide better health conditions, however, this outcome is indirect and further studies must be performed to better understand this linkage.\textsuperscript{119}

Also, even if these indirect impacts on improving human health are attested, from the perspective of article XX, the use of SECs remains uncertain, as provision (b) requires a measure to be necessary as the last option and given the lack of practice and experience with SECs, it is difficult to imagine a SEC measure as the last option (i.e., no less restrictive alternative) to effectively protect human health.

As for provision (g) aiming to protect exhaustible natural resources, the use of SEC measures seems even more unlikely to occur. WTO DSB cases such as the Shrimp Turtle case have shown that the interpretation given to the term "exhaustible natural resources" applies only to mineral and renewable living natural resources, hence a measure focusing on socio and economic impacts of LMOs, even considering that better income can boost environmental protection, seems a significant stretch from the WTO interpretation, making SECs not meeting this criterion.

However, in the scenario of adopting a broad SEC definition as proposed by the AHTEG SEC, encompassing ethical, religious, and traditional aspects, applying article XX (a) to public morals might be possible. As observed in EC — Seal Products, both the Panel and the Appellate Body confirmed European ethical values for animal welfare as a public moral. Thus, SEC measures

\textsuperscript{119} See Andrea Sonnino, Zephaniah Dhlamini, Fabio Maria Santucci, Patrizio Warren, Food and Agriculture Organization of the United Nations (FAO) study Socio-Economic Impacts of Non-Transgenics Biotechnologies in Developing Countries – The case of plant micropropagation in Africa. Rome 2009. Available at: http://www.fao.org/3/i0340e/i0340e00.htm
based on socio, economic, religious, traditional, and ethical aspects (i.e., broad definition of SECs), according to the DSB precedents, could, in theory, be accepted as an exception to protect public morals.

2.4.2. Technical Barriers to Trade Agreement ("TBT")

The Technical Barriers to Trade Agreement ("TBT") is a WTO agreement with the purpose of ensuring that technical regulations, standards, testing, and certification procedures do not cause unnecessary obstacles to trade, thus furthering the GATT objectives previously explained.

To do this, article 2.1 of the TBT reaffirms the main GATT principles of National Treatment and Most-Favoured Nation (MFN):

2.1 Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country.

In this regard, Article 2.1 resembles the chapeau of GATT article XX. This similarity is reaffirmed in US – Tuna II (Mexico).

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120 The definition of technical specification is in Annex 1, article 1: “A specification contained in a document which lays down characteristics of a product such as levels of quality, performance, safety or dimensions. It may include, or deal exclusively with terminology, symbols, testing and test methods, packaging, marking or labelling requirements as they apply to a product.”

121 TBT Preamble.

122 US — Tuna II (Mexico) Appellate Body Reports, para 7.88: "[G]iven that the sixth recital of the preamble of the TBT Agreement serves as relevant context for understanding Article 2.1, and the language of that recital has important commonalities with the chapeau of Article XX of the GATT 1994, the jurisprudence under the chapeau of Article XX is not irrelevant to understanding the content of the second step of the 'treatment no less favourable' requirement under Article 2.1 of the TBT Agreement. Indeed, previous Appellate Body decisions concerning one provision of a covered agreement may shed light on a proper understanding of the scope and meaning of a different provision in another agreement where the same or similar language is used in both provisions, provided always that due account is taken of more immediate context, and of the function of each provision."
A) TBT and Environmental Exceptions

Like GATT, TBT also allows Parties to create exceptional technical barriers or regulations based on legitimate objectives, such as preserving human safety and the environment, which is stated in article 2.2:

2.2 Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, inter alia: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, inter alia: available scientific and technical information, related processing technology or intended end-uses of products.

Like GATT, the TBT exception also needs to be justified. In other words, the technical regulation must not only be aimed at protecting human, animal, plant health, and the environment, but also not be excessively trade-restrictive to achieve this target, considering the risks non-fulfillment would create. Hence, here is a connection between the first and second sentences of article 2.2.123

The DBS had explained how to assess this relationship between these two sentences of article 2.2. Firstly, to determine whether the regulation will achieve the objective pursued, as done in Australia — Tobacco Plain Packaging, the "underlying purpose" of the measure questioned must be

123 See US – COOL Appellate Body Reports, para. 369: "The first two sentences of Article 2.2 establish certain obligations with which WTO Members must comply when preparing, adopting, and applying technical regulations. In accordance with the first sentence, they must ensure that such preparation, adoption, and application is not done 'with a view to or with the effect of creating unnecessary obstacles to international trade'; and, in accordance with the second sentence, they must ensure that their technical regulations are 'not … more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create'. The words '[f]or this purpose' linking the first and second sentences suggest that the second sentence informs the scope and meaning of the obligation contained in the first sentence."
identified. According to the Panel of this case, a distinction must be drawn between the objective pursued from the level at which a Party aims to achieve this objective.  

In US — COOL, the objective of the measure concerns evidence relating to its text, design, structure and legislative history, thus it is clear that the measure was created to achieve that specific and legitimate goal. A legitimate goal in the context of article 2.2, based on the precedents, apart from those stated in the text (i.e., national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment.), is a non-exhaustive list of elements.

However, in US — Clove Cigarettes and in EC — Asbestos the DSB, it is argued that this non-exhaustive list must relate to an objective in which there is a "well known and life threatening" risk. Further on, in EC — Sardines, the Panel noted that this risk also refers to the protection of...
interests which are supported by relevant public policies and social norms, assessed from the perspective of the current society, consequently subject to evolution.

As for the requirement of article 2.2 that a regulation should not be more restrictive than necessary, there is a three-step assessment used in US — Tuna II (Mexico). The steps are:

(i) the degree of contribution made by the measure to the legitimate objective at issue;
(ii) the trade-restrictiveness of the measure;
(iii) the nature of the risks at issue and the gravity of consequences that would arise from non-fulfilment of the objective(s) pursued by the Member through the measure.

Regarding the first step, i.e., the degree of contribution made to achieve the objective, in Australia — Tobacco Plain Packaging, the Panel concluded that not only the quality of the actual impact of the measure must be observed (i.e., the design and structure of the measure with the respective results expected), but also its broader context and long-term effects, with quantitative projections.

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129 See Panel Report on EC – Sardines, para. 7.121.
130 See Panel Reports, US – COOL, para. 7.650: “In our view, whether an objective is legitimate cannot be determined in a vacuum, but must be assessed in the context of the world in which we live. Social norms must be accorded due weight in considering whether a particular objective pursued by a government can be considered legitimate. It seems to us, based on the evidence before us, that providing consumers with information on the origin of the products they purchase is in keeping with the requirements of current social norms in a considerable part of the WTO Membership.”
131 Australia — Tobacco Plain Packaging, Panel Report, para. 7.499: “[T]he relative weight to be attributed to specific evidence, including evidence relating to the design, structure and intended operation of the measures, on the one hand, and evidence relating to their application, on the other hand, will depend on the nature and quality of such evidence and its probative value for the question before us.
132 Id. supra, para. 7.506.
133 Id. supra, para. 7.938.
As for the second step regarding the trade-restrictiveness\textsuperscript{134} of the challenged measure, again based on Australia — Tobacco Plain Packaging case, the Panel found that the restrictiveness of a measure is shown on the circumstances of the given case, based on quantitative and qualitative evidence.\textsuperscript{135} This can be attested by the complainants demonstrating that the measure questioned alters the competition environment with limiting effects on international trade.\textsuperscript{136}

Finally, the third step, regarding the risk of non-fulfillment, concerns an analysis that should identify the consequences and gravity arising from the non-fulfillment of the challenged measure.\textsuperscript{137} This can determine whether the alternative measure can represent a greater risk. In US — Cloves Cigarettes, the Panel rejected Indonesia alternatives claiming that they would be a greater risk to young smoker’s health, consequently agreeing with the United States ban.\textsuperscript{138}

To conclude this part, although the DSB precedents address these issues and set a number of tests to determine whether a regulation meets article 2.2. criteria, these assessments are complex and

\begin{itemize}
\item \textsuperscript{134} According to the Appellate Body in US — Tuna II (Mexico), para. 319, the term “restriction” means: “[…] something that restricts someone or something, a limitation on action, a limiting condition or regulation […]”
\item \textsuperscript{135} Australia — Tobacco Plain Packaging, Panel Report, para. 7.1168: “[A]ppropriate evidence of such limiting effect will in particular be required in the case of a non-discriminatory internal measure. We do not consider, however, that this demonstration must be based on actual trade effects. Rather, it could in principle be based on a qualitative assessment, taking into account in particular the design and operation of the measures, or on a quantitative assessment of its actual trade effects, or both.”
\item \textsuperscript{136} \textit{Id.} supra, para. 7.1167.
\item \textsuperscript{137} US — COOL (Article 21.5 – Canada and Mexico), Appellate Body Reports, para. 5.217
\item \textsuperscript{138} US — Clove Cigarettes, Panel Report, para. 7.424: "In addition, each of the alternative measures suggested by Indonesia appears to involve a greater risk of non-fulfillment of the objective of reducing youth smoking, as compared with the outright ban currently in place. In analyzing the existence of alternative measures, we are required by the terms of Article 2.2 to take into account 'the risks that non-fulfillment would create'. Thus, Article 2.2 suggests that if an alternative means of achieving the objective of reducing youth smoking would involve greater 'risks of non-fulfillment', this may not be a legitimate alternative. This is consistent with the jurisprudence developed under Article XX(b) of the GATT 1994, pursuant to which the relevant question is, as explained above, whether there is one or more alternative measures that would make an 'equivalent' contribution to the achievement of the objective at the level sought. In our view, where an alternative measure would entail a greater risk of non-fulfillment of the objective, it would be difficult to find that it would make an 'equivalent' contribution to the achievement of the objective, at the level of protection sought."  
\end{itemize}
occur on a case-by-case analysis, which leads to individual results with a certain degree of unpredictability.

B) Application of TBT to SEC Regulations

A SEC regulation, in principle, could be within the scope of TBT. As demonstrated in previous precedents, although article 2.2 sets some exceptions (i.e., national security requirements; prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment), this list is not limited to these items. Article 2.2 could encompass life-threatening issues to public policy concerns. For SECs, this is relevant as this type of regulation considers the use of biotechnology to improve the livelihood of local communities and indigenous people, which can be part of national public policies.

In EC — Seals, both Panel and the Appellate Body had to indirectly address the economic impacts of seal hunting in indigenous communities’ lives. When deciding whether the European Seal Regime banning seal products from commercial hunting would better protect seals and ensure the traditional way of living of indigenous people, the WTO had to discuss if socio and economic issues of trade regulations can be covered by the TBT. Thus, theoretically, SECs can also be covered in the TBT.

However, despite this possibility, for SECs to be fully covered by the TBT, the regulation will have to activate further triggers of article 2.2, namely: (i) degree of contribution made by the measure to the legitimate objective, (ii) trade-restrictiveness of the measure, and (iii) consequences that would arise from non-fulfillment of the objective. In this regard, observing WTO precedents
discussing these requirements (i.e., Australia — Tobacco Plain Packaging), they depend on qualitative and quantitative evidence of the given case, thus a case-by-case analysis. As for the consequences that would arise from the non-fulfillment of the objective, according to US — Cloves Cigarettes, the alternatives proposed cannot be a greater risk to the regulation being challenged, which is a more certain and objective analysis.

Finally, a SEC regulation meeting these requirements may not only be complex but very unpredictable, since it is mostly a case-by-case assessment and, as demonstrated, SECs lack precedents and experiences. Therefore, although possible, it is currently difficult to foresee any SEC regulation being successfully covered by the TBT.

2.4.3. Agreement on the Application of Sanitary and Phytosanitary Measures

The Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS") entered into force in 1995 and dictates measures aiming at food safety, animal, human and plant safety, thus phytosanitary measures, which is defined in Annex A of SPS:

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

Like TBT and GATT, SPS does not allow a sanitary measure to be discriminatory and a disguised restriction on international trade. In other words, the sanitary measure to be applied cannot hinder the free trade principles (i.e., National Treatment) previously set in GATT. In this regard, SPS articles 2.3 and 3.2 reaffirm this concern, by mirroring GATT’s principles.
2.3. Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

3.2. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.

To avoid this discrimination and restriction to trade, article 5.6\textsuperscript{139} of SPS sets out that a measure should not be more trade restrictive than the necessary to achieve the appropriate level of sanitary protection. In this regard, to assess if article 5.6 is met (i.e., level of sanitary protection), the DSB established in the Australia — Salmon case a cumulative three-element test: (i) technical and economic feasibility, (ii) appropriate level of sanitary protection and (iii) less restrictive to trade than the SPS measure contested\textsuperscript{140}.

With regard to the technical and economic feasibility of an alternative measure, in case of a dispute, the WTO Panel should analyze if it is actually feasible in the real world, even if there is a risk of incorrect enforcement.\textsuperscript{141} For the element of appropriate level of sanitary protection, according to India — Agricultural Products, this is not the ultimate objective, but rather to identify whether a less trade-restrictive measure that would meet the appropriate level of protection is already available.\textsuperscript{142} Finally, for the element "less restrictive to trade than the SPS measure contested," in Australia — Salmon, the Panel concluded that all alternative measures for Canada to export salmon to Australia were significantly less restrictive than the practical prohibition imposed by Australia.

\textsuperscript{139} SPS, 5.6: “Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.”

\textsuperscript{140} Appellate Body Report, Australia — Salmon, para. 194.

\textsuperscript{141} Panel Report, Japan — Apples, para. 8.171.

\textsuperscript{142} Appellate Body Report, India — Agricultural Products, para. 5.223.
by denying the importation of heat-treated salmon. Therefore, the alternative measures must be less restrictive than the measure in dispute.\textsuperscript{143}

In order to ensure the sanitary levels of protection mentioned above, the SPS agreement is based on risk assessments as its main tool. The risk assessment uses scientific principles like scientific evidence, processes, methods of production, inspection, testing, as stated in article 5:

5.1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.

5.2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest — or disease — free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

In EC — Hormones, the Panel clarified that since a risk assessment is a process to establish the basis for a sanitary measure,\textsuperscript{144} for the SPS agreement, the scientific evidence is relevant. But, if there is no scientific evidence to attest a possible risk, the SPS agreement allows the adoption of temporary measures, as explained in article 5.7:

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

In other words, article 5.7 setting the possibility of imposing temporary measures based on the lack of scientific evidence could be an exemption of article 2.2. This question of whether article

\textsuperscript{143} Panel Report, Australia — Salmon, para. 8.182.
\textsuperscript{144} Appellate Body Report, EC — Hormones, para. 187.
5.7 is an exception or an autonomous right was already answered by the DSB. Initially, in Japan — Agricultural Products II, the Appellate Body found article 5.7 an exception to article 2.2. Nonetheless, the Panel of EC — Approval and Marketing of Biotech Products disagreed with the ruling rendered in Japan — Agricultural Products II and, instead, adopted the ruling from EC — Tariff Preferences and EC — Hormones, which considered article 5.7 as an autonomous right to be claimed. But the Panel stressed that this right is not absolute.

To claim the lack of scientific evidence to use a sanitary measure, some requirements must be met. Based on the Appellate Body decision in Japan — Agricultural Products II, to invoke the right of article 5.7, the Member must show four cumulative elements:

(i) imposed in respect of a situation where relevant scientific information is insufficient;
(ii) the measure was adopted based on the available information;
(iii) seeks to obtain additional information necessary for a more objective assessment;
(iv) periodically review the measure.

It must be stressed that the use of a sanitary measure to protect human, animal and plant life or health in the absence of scientific evidence and data, in a certain way, translates the Precautionary Principle. Among all WTO trade treaties, the SPS agreement is the one with the closest connection with this Environmental Principle.

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147 Id. supra, para. 7.2973.
In EC — Hormones, the Appellate Body recognizes that, although the Precautionary Principle is not expressively written in the SPS agreement, its signs can be found in article 5.7. However, the Precautionary Principle cannot override articles 5.1 and 5.2 of SPS; in other words, the principle cannot justify measures that are not following the free trade principles and must be based on some type of evidence. ¹⁴⁹

In this regard, EC — Approval and Marketing of Biotech Products is the WTO dispute case that most discussed and exposed this interlinkage. In this case, the Panel explained that a Party could apply the precautionary approach based on scientific uncertainty, however, some type of assessment or another method reasonably supported by an assessment must be adopted.¹⁵⁰ For this, the Panel reaffirmed that the precautionary Principle implicit in article 5.7 must respect the guidelines of article 5.1 (i.e., E C – Hormones ruling).¹⁵¹

Finally, in US /Canada — Continued Suspension, the Appellate Body reminded that the test of four cumulative elements of article 5.7 must take into account¹⁵² the existence of the Precautionary Principle implicit in the same provision.¹⁵³

¹⁴⁹ Appellate Body Report, EC — _Hormones, paras. 124 and 125: "[A] Panel charged with determining, for instance, whether "sufficient scientific evidence" exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g., life-terminating, damage to human health are concerned. ... [H]owever, the precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a Panel from the duty of applying the normal (i.e., customary international law) principles of treaty interpretation in reading the provisions of the SPS Agreement.”
¹⁵² SPS, article 5.7: “(i) imposed in respect of a situation where relevant scientific information is insufficient; (ii) the measure was adopted based on the available information; (iii) seeks to obtain additional information necessary for a more objective assessment; (iv) periodically review the measure.
Thus, the Precautionary Principle is implicit in article 5.7. of SPS, which allows the use of sanitary measures in the case of no scientific evidence, however, this provision is an autonomous right that is framed by article 5.1. Therefore, some limits are drawn for its application, such as the test of four cumulative elements.

A) Sanitary Measures and Economic Factors

It should be pointed out that unlike GATT and TBT that allow the use of trade exceptions to protect the environment and health, SPS innovates by also allowing a Party to consider economic factors when evaluating risks:

5.3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.

Due to this explicit language to consider economic factors in sanitary risk assessments, it might be possible to include future SEC standards.

Taking into account relevant economic factors in risk assessments was initially addressed in Russia — Pigs (EU), where the Panel emphasized that Members should consider economic factors as part of article 5.3. Therefore, this confirmed the possibility of performing assessments also from an economic perspective.
In addition, the Panel recognized that article 5.3 relates to articles 5.1\textsuperscript{154} and 5.7.\textsuperscript{155} The Panel in Russia — Pigs affirms that whereas article 5.7 is an autonomous right which could potentially flex the strictness of article 5.1, considering relevant economic factors (i.e., article 5.3) can occur both in situations where there is scientific relevance (article 5.1) and when there is no scientific evidence (article 5.7). Therefore, economic factors can be invoked in both situations.\textsuperscript{156}

When it comes to defining a "relevant economic factor", the Panel in EC — Approval and Marketing of Biotech Products argued that items (1) (c) and (d)\textsuperscript{157} of Annex A state that one of the purposes of a sanitary measure is to prevent or limit damages of pests, therefore, the economic factor, in that case, could be the financial impacts of diseases. However, the same Panel also affirmed that this definition cannot be restricted to this event, since the concept of "damage" is broad and could also include different types of harm resulting from a reduction of economic value, thus a flexible and open definition so far:

"The residual category of 'other damage' is potentially very broad. In our view, 'other damage' could include damage to property, including infrastructure (such as water intake systems, electrical power lines, etc.). In addition, we think 'other damage' could include economic damage (such as damage in terms of sales lost by farmers). The dictionary defines the term 'damage' as 'physical harm impairing the

\textsuperscript{154} SPS, article 5.1: "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations."

\textsuperscript{155} SPS, article 5.7: "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

\textsuperscript{156} Panel Report, Russia — Pigs (EU), para. 7.772: "[I]f a measure is adopted pursuant to Article 5.7 of the SPS Agreement, a Member does not have the obligation to base its provisional measure on an assessment of risk pursuant to Article 5.1. As a consequence, a Member in such situation will not have to take into account the relevant economic factors listed in Article 5.3 for the purposes of assessing the risk to animal or plant life and health. However, even when a Member has adopted a provisional SPS measure pursuant to Article 5.7, it will still have the obligation to take into account, in determining the measure it will apply to achieve its ALOP, the relevant economic factors listed in Article 5.3."

\textsuperscript{157} Article 1(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.
value, usefulness, or normal function of something' and 'unwelcome and detrimental effects', or 'a loss or harm resulting from injury to person, property, or reputation'. These definitions cover harm resulting in a reduction of economic value, adverse economic effects, or economic loss. Also, interpreting 'other damage' to include economic damage is consistent with the context of Annex A(1)(d). Article 5.3 of the SPS Agreement states that relevant 'economic factors' to be taken into account in a risk assessment include 'the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or a disease'. Thus, Article 5.3 shows that the SPS Agreement elsewhere uses the term 'damage' in an economic sense, and it does so in connection with damage from 'pests'. Thus, Article 5.3 contemplates a similar situation to that contemplated in Annex A(1)(d).

**B) Application of SPS to SEC Regulations**

Considering the SPS cases explained above, a SEC measure, in theory, could be regarded as part of a sanitary measure. But some issues must be stressed.

Initially, compared with GATT and TBT, SPS has a more explicit wording regarding economic factors as part of risk assessments, so it is more plausible to imagine SEC requirements being accepted within the SPS rules. The EC — Approval and Marketing of Biotech Products case showed that, although Annex A (1) (c) and (d) restricts economic damages to pests and diseases, the Panel clarified that since the meaning of "damage" is broad, economic factors must also include reduction of economic value of production caused by different types of harms. In this regard, the socio-economic impacts of transgenics on the lives and farming activities of local communities and indigenous people could be part of it.

Another related issue is the fact that even if economic factors are taken into account, those are part of a risk assessment to establish a sanitary measure which, according to SPS, aims at protecting human, animal and plant life/health. However, in the Cartagena Protocol, risk assessment and SECs are in different provisions, different instruments (i.e., articles 15 and 26). Discussions are

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159 See SPS Annex A (1) (a).
underway in the COP/MOPs to determine whether a SEC analysis should occur with or separately from risk assessments. It is also a question raised in the AHTEG proposed SEC Guidance:

6. The assessment of socio-economic considerations and the risk assessment may be conducted concurrently, consecutively or in an integrated manner, as applicable. Planning and conducting a risk assessment and an assessment of socio-economic considerations may be complementary and both may contribute to the decision-making process. 160

This uncertainty about independent or integrated instruments was a concern of both Brazil and the US in their respective submissions, since a risk assessment is mandatory whereas SECs are voluntary, and considering them integrated would make SECs also mandatory. Despite this conflict, imagining a scenario where a SEC analysis is performed along with a risk assessment, from a SPS perspective, which uses risk assessments to impose sanitary measures, is easier for SEC regulations to be within its scope.

Another issue for SEC policies to be within SPS is the uncertainty of whether their assessment has sufficient scientific evidence. In other words, if economic factors can be part of SPS measures with lack of scientific evidence (i.e., article 5.1 and 5.7). In this sense, since the SPS is a new standard, with an undefined definition and method of analysis, observing how the Precautionary Principle evolves in the context of International Law is relevant.

To conclude this part of the study, based on the cases described, among GATT, TBT and SPS, GATT exception of public morals from article XX and SPS provision 5.3 including relevant

160 GUIDANCE ON THE ASSESSMENT OF SOCIO-ECONOMIC CONSIDERATIONS IN THE CONTEXT OF ARTICLE 26 OF THE CARTAGENA PROTOCOL ON BIOSAFETY. Available at: https://www.cbd.int/doc/c/0215/0803/cb8d71c24d40c683e6dabf0a/cp-mop-09-10-en.pdf
economic factors in sanitary measures seem legal possibilities more plausible to encompass SEC regulations as non-discriminatory and non-arbitrary trade policies.

For the GATT public moral exception, the Seal case demonstrated it is possible to exceptionally restrict trade with a measure based on a collective concern, custom or moral of a society. More importantly, this precedent links this public moral with an environmental concern; in this situation, more humane seal hunting practices that ensure the livelihood of Inuit communities, since, for the Europeans, this is an ethical issue. Regarding future SEC policies, embracing a broader definition as being proposed by the AHTEG SEC with not only social and economic factors, but also religious, moral, and ethical ones, in theory, could facilitate the link between SEC and GATT’s article XX of public moral exception.

Concerning SPS, this is the only agreement that enables the use of economic factors when performing risk assessments of sanitary measures aiming at trade restrictions. This is positive, once it clearly states economic damages on human, animal and plant life or health caused by sanitary harm. In EC — Approval and Marketing of Biotech Products, the Panel clarified that the concept of damages should be assessed from a broader perspective — in other words, not limited to pests and diseases listed in Annex A, provision (1) (c) and (d), thus, SECs can also be regarded as a SPS measure.
CHAPTER 3

3. Socio-Economic Considerations and Gaps of WTO Regulations in the Context of International Law

In short, international law has three sources with binding effects called Hard Law, which are: treaties, customary law, and general principles of international law. These sources are listed in the International Court of Justice Statute, which is an international body that acts both as a legal advisory body and as a court for dispute settlements:

Article 38
1. The Court, whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply:
   a. international conventions, whether general or particular, establishing rules expressly recognized by the contesting states;
   b. international custom, as evidence of a general practice accepted as law;
   c. the general principles of law recognized by civilized nations;
   d. subject to the provisions of Article 59, judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.  

A treaty is a source of international law that is binding only upon its signatory Parties and follows the rules set by the Vienna Convention on the Law of Treaties ("Vienna Convention"). The Vienna Convention is crucial, as it does not only define what is a treaty, but also and, most importantly, how they should be interpreted:

Article 31 General rule of interpretation

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161 International Court of Justice Statute, article 38.
162 Vienna Convention on the Law of Treaties, article 2.1 (a): “‘treaty’ means an international agreement concluded between States in written form and governed by international law, whether embodied in a single instrument or in two or more related instruments and whatever its particular designation.”
1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.

2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes: (a) any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty; (b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty. 163

3. There shall be taken into account, together with the context: (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions; (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation; (c) any relevant rules of international law applicable in the relations between the parties.

4. A special meaning shall be given to a term if it is established that the parties so intended.

Customs on the other hand is a source of Hard Law that is binding upon all countries. This occurs because it is both a norm and a widely accepted practice by all States. 164 Similarly, the general principles are also binding upon all countries, since they are applied to fill the gap between treaties and customs, based on the use of domestic laws mostly accepted by several countries.

However, when it comes to Environmental International Law, most of the existing norms are treaties and their respective Protocols, like the CBD, the United Nations Framework Convention on Climate Change (UNFCCC) etc., which apply the principles of Environmental Law. The Environmental Law principles were first established on Environmental Declarations. Unlike the International Law sources described above, a Declaration, along with recommendations, resolutions are a non-binding instrument called Soft Law.

Soft Law can be described as a guidance/consent, which helps to define standards of good behavior expected from "well governed states." Despite not binding, Soft Law is extremely important for the International Law-making process, because it allows a more flexible option for States to

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164 See The Scotia, 14 Wall. 170, 187 (1871); The Paquete Habana, 175 US 677, 20 SCt. 290 (1900).
experiment new legal norms before becoming binding upon the international community. This is so relevant that, most of the times, especially regarding environmental issues, Soft Law eventually guides the creation of future treaties, thus directly influencing the adoption of Hard Law sources. For Pierre-Marie Dupy: "In any event, it is evident that a substantial part of "soft" law today, in an impressionistic way, describes part of the 'hard' law of tomorrow." This phenomenon is clearly seen in the development of environmental law principles within the scope of international law.

SECs are a voluntary provision stated in article 26 of the Cartagena Protocol that each signatory Party has the prerogative to adopt if it considers it is necessary for its national biosafety law, making it a binding standard, since the Protocol is a Treaty, thus a hard source of International Law.

In this regard, the previous chapters indicated not only the uncertainties regarding the lack of criterion and definition of SECs, but also a gap between trade regulations of the WTO and SEC policies. Neither of the three main WTO agreements (i.e., GATT, TBT and SPS) specify whether a SEC policy could be included in their provisions and regarded as a fair-trade measure or just discriminatory restriction to trade.

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Due to this lack of clarity in the agreements, the WTO precedents have a central role, therefore, it is important to assess how the DSB relates international law and other treaties with the trade regulation to support its decision-making process.

3.1. The Environmental Law Principles and the International Law

The concern with biodiversity and nature preservation was not an isolated movement at the CBD. It was part of a bigger context regarding new standards for environmental preservation that started in 1972 with the Declaration of the United Nations Conference on the Human Environment ("Stockholm Declaration") and later in 1987 with the Brundtland Report. In short, these documents lay the foundations for the current International Environmental Law by establishing the environment as a human right.

Principle 1 Man has the fundamental right to freedom, equality and adequate conditions of life, in an environment of a quality that permits a life of dignity and well-being, and he bears a solemn responsibility to protect and improve the environment for present and future generations. In this respect, policies promoting or perpetuating apartheid, racial segregation, discrimination, colonial and other forms of oppression and foreign domination stand condemned and must be eliminated.167

Then, in 1992, at the Rio "Earth Summit," along with the signing of the Convention on Biological Diversity, the Rio Declaration on Environment and Development ("Rio Declaration") was adopted. The goal of this Declaration was to continue the debate that started with the Stockholm Declaration and improve the international instruments for environmental protection. Thus, it supplemented the Stockholm wording by listing the principles of International Environmental Law in detail.

Those are:

- Right to life and healthy environment;\(^{168}\)
- State sovereignty;\(^{169}\)
- Right to development;\(^{170}\)
- Sustainable development;\(^{171}\)
- Common heritage of humankind;\(^{172}\)
- Obligation not to cause environmental harm;\(^{173}\)
- Intergenerational and intergenerational equity;\(^{174}\)
- Duty to assess environmental impacts;\(^{175}\)
- Right of public participation;\(^{176}\)
- Precautionary principle.\(^{177}\)

Among them, for the purposes of this work, it is extremely relevant to emphasize the Precautionary Principle. This principle is stated in the Rio Declaration with the following wording:

Principle 15 In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

\(^{168}\) Rio Declaration on Environment and Development, principle 1.

\(^{169}\) Id. supra, principle 2.

\(^{170}\) Id. supra, principle 3.

\(^{171}\) Id. supra, principle 4.

\(^{172}\) Id. supra, principle 8.

\(^{173}\) Id. supra, principle 2.

\(^{174}\) Id. supra, principle 3.

\(^{175}\) Id. supra, principle 17.

\(^{176}\) Id. supra, principle 10.

\(^{177}\) Id. supra, principle 15.
At a national level, the precautionary principle first appeared in the German Law in the 1970s as the *Vorsorgeprinzip*, which can be translated as the "foresight principle" and today is also present in several domestic legal systems. In Brazil\(^{178}\) and in France\(^{179}\), this principle is even established in their national Constitutions.

At an international level, the precautionary principle first appeared in the preamble of the 1985 Vienna Convention for the Protection of the Ozone Layer;\(^{180}\) later, at the 1987 Ministerial Declaration of the Second International Conference on the Protection of the North Sea; then in 1992 in the abovementioned Rio Declaration.

However, despite all these treaties mentioning somehow the Precautionary Principle, they do not fully define it. The clearest idea of this principle was written in the Rio Declaration, briefly proposing that decision-makers adopt precautionary measures in situations of scientific uncertainty that may harm human health and the environment. Note that this principle does not specifically set which precautionary measures must be taken, but suggests that actions should be cost-effective to avoid possible environmental damages, so it offers flexibility for governments in adopting the best

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178 Constituição Federal [C.F.] [Constitution] article 225, (Braz): "All have the right to an ecologically balanced environment, which is an asset of common use and essential to a healthy quality of life, and both the Government and the community shall have the duty to defend and preserve it for present and future generations. Paragraph 1. To ensure the effectiveness of this right, it is incumbent upon the Government to: […] V – control the production, sale and use of techniques, methods or substances which represent a risk to life, the quality of life and the environment;"

179 1958 Const. article 5 (France): "When the occurrence of any damage, albeit unpredictable in the current state of scientific knowledge, may seriously and irreversibly harm the environment, public authorities shall, with due respect for the principle of precaution and the areas within their jurisdiction, ensure the implementation of procedures for risk assessment and the adoption of temporary measures commensurate with the risk involved in order to deal with the occurrence of such damage."

180 Available at: https://ozone.unep.org/treaties/vienna-convention
option in hand for a specific situation. Therefore, it provides a framework for governments to create preventive measures and policies when scientific data is unavailable.181

Evidently, this can divide opinions. Some argue that this certainly helps to prevent health and environmental damages, by enforcing stricter mitigation and preventive measures regarding new technologies, products etc. Others argue that this principle may stall the development of new scientific breakthroughs.

Needless to say, the Precautionary Principle is part of the CBD, and is stated in its preamble: "Where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat."182

Moreover, the Precautionary Principle is the main core of the Cartagena Protocol, since, as previously mentioned, risk assessment is a mandatory instrument for Parties on approving LMOs and new biotechnologies, which is even crystallized into Annex III, section 3 of the Protocol. But, for an analysis of SECs, this issue does not have a definite understanding yet, because there is still a lack of consensus of whether SECs are a separate instrument or a part of the risk assessment of the Protocol, and this doubt also appears in national biosafety regulations.

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182 Preamble of the Convention on Biological Diversity.
Regarding this blurred line between SECs and risk assessment, with the use of the Precautionary Principle, from an International Law perspective, there is an ongoing discussion of whether the principles of Environmental Law are becoming custom or a general principle of international law. Consequently, this can influence how environmental treaties, such as the CBD, relate to other non-environmental norms, such as the WTO’s regulations.

On this issue, although the International Court of Justice (ICJ) precedents are not official sources of International Law, the Court can be a "progress developer of International Law" and an indicator of new state practices, which eventually can become custom. In this respect, there is already a developing thread of environmental precedents from the ICJ, which must be observed.

a) **Hungary v. Slovakia**

In Hungary/Slovakia ("Gabčíkovo-Nagymaros Project"), among several issues, the ICJ discussed whether the principle of sustainable development, present in both the Stockholm and Rio Declarations, can be regarded as a general principle of international law.

This litigation has its origins in 1977, when Hungary and the old Czechoslovakia (currently Slovakia) agreed, through a bilateral treaty (i.e., the Budapest Treaty), to build a dam on the Danube River. The dam had the purpose of increasing energy capacity and contributing to the economy of both countries, but it also represented an environmental threat. Therefore, in the treaty, both Parties agreed that the construction had to consider environmental protection concerns.

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183 Allain Pellet, Decisions of the ICJ as Sources of International Law?, page 41.
For this purpose, article 19 of the Budapest Treaty specifically addressed the environment, creating binding obligations to Hungary and Czechoslovakia by stating: "The Contracting Parties shall, through the means specified in the joint contractual plan, ensure compliance with the obligations for the protection of nature arising in connection with the construction and operation of the System of Locks."\(^{185}\)

The disagreement began when Hungary notified Slovakia of the unilateral termination of the Treaty, making Slovakia conclude the project alone and adding "Variant C," a river diversion system that drastically reduced water flow in the Danube. Hungary eventually filed a complaint against Slovakia with the ICJ based on the argument that Slovakia affected Hungary’s interest in the river and environment, calling it "state of ecological necessity."\(^{186}\)

In the analysis of the case, the Court acknowledged that environmental norms are part of international law, especially when reconciling environment with development conflicts (i.e., sustainable development). It was the first time that environmental concerns have been handled in an ICJ trial and discussed in an international litigation context:

140. The Court is mindful that, in the field of environmental protection, vigilance and prevention are required on account of the often-irreversible character of damage to the environment and of the limitations inherent in the very mechanism of reparation of this type of damage. Throughout the ages, mankind has, for economic and other reasons, constantly interfered with nature. In the past, this was often done without consideration of the effects upon the environment. Owing to new scientific insights and to a growing awareness of the risks for mankind - for present and future generations - of pursuit of such interventions at an unconsidered and unabated pace, new norms and standards have been developed, set forth in a great number of instruments during the last two decades.


\(^{186}\) Id. \textit{supra}, page 36.
Such new norms have to be taken into consideration, and such new standards given proper weight, not only when States contemplate new activities but also when continuing with activities begun in the past. This need to reconcile economic development with protection of the environment is aptly expressed in the concept of sustainable development.

For the purposes of the present case, this means that the Parties together should look afresh at the effects on the environment of the operation of the Gabčíkovo power plant. In particular they must find a satisfactory solution for the volume of water to be released into the old bed of the Danube and into the side-arms on both sides of the river.187

The ICJ, in its ruling, stressed that environmental concerns such as sustainable development have a growing importance and, because of that, the court is willing to accept new International Law principles. This fact is even clearer in the Vice President Judge Weeramantry’s opinion, especially when he states the importance of Soft Law sources, as the Rio Declaration, in making the environment the focus of attention amidst the international community and sustainable development as an accepted concern:

In 1992, the Rio Conference made it a central feature of its Declaration, and it has been a focus of attention in all questions relating to development in the developing countries. The principle of sustainable development is thus a part of modern international law by reason not only of its inescapable logical necessity but also by reason of its wide and general acceptance by the global community.188

b) Argentina v. Uruguay

With a similar issue, in Uruguay v. Argentina ("Argentina — Uruguay Pulp Mill decision"), the ICJ also had to address the use of environmental law principles, specifically the precautionary approach. In this case, Argentina filed a complaint with the ICJ against Uruguay alleging breach of the 1975 Statute of the Uruguay River,189 which is a bilateral treaty between the Parties setting forth the shared use of Uruguay River. The water dispute between Argentina and Uruguay started

188 Separate Opinion of Vice President Weeramantry, page 95. Available at: https://www.icj-cij.org/public/files/case-related/92/092-19970925-JUD-01-03-EN.pdf
in 2005 when two Uruguayan pulp mills were set up near Uruguay River, which could generate pollution.

Due to this fact, Argentina argued in the ICJ that Uruguay failed to report the construction of the pulp mills, thus breaching the 1975 Statute. The 1975 Statute clearly stated the obligation of both Parties to report operations that would alter or cause any influence on the river, once it is a shared water resource. The Statute also set forth that any failure to notify would imply a procedural breach. Finally, Argentina also claimed that the pulp mills would potentially cause water pollution. In this case, not causing pollution was also an obligation established in the 1975 Statute.

However, what is more relevant in this case is not how the ICJ addressed the use of environmental law principles in international law as it has done previously with Hungary v. Slovakia, but specifically the use of the precautionary approach. When Argentina filed a complaint regarding breach of the duty to inform of a facility that could cause pollution, and requested reversal of the burden of proof so Uruguay had to prove the pulp mills would not pollute, Argentina was claiming the precautionary approach:

160. Argentina contends that the 1975 Statute adopts an approach in terms of precaution whereby "the burden of proof will be placed on Uruguay for it to establish that the Orion (Botnia) mill will not cause significant damage to the environment". It also argues that the burden of proof should not be placed on

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190 See article 7 of the 1975 Statute: "Article 7. If one Party plans to construct new channels, substantially modify or alter existing ones or carry out any other works which are liable to affect navigation, the regime of the river or the quality of its waters, it shall notify the Commission, which shall determine on a preliminary basis and within a maximum period of 30 days whether the plan might cause significant damage to the other Party."

191 See article 41 of the 1975 Statute: "Article 41. Without prejudice to the functions assigned to the Commission in this respect, the Parties undertake: (a) To protect and preserve the aquatic environment and, in particular, to prevent its pollution, by prescribing appropriate rules and measures in accordance with applicable international agreements and in keeping, where relevant, with the guidelines and recommendations of international technical bodies."
Argentina alone as the Applicant, because, in its view, the 1975 Statute imposes an equal onus to persuade — for the one that the plant is innocuous and for the other that it is harmful.\textsuperscript{192}

In 2010, the ICJ ruled that Uruguay had indeed failed to inform Argentina of the construction of the pulp mill, as established in article 7 of the 1975 Statute. As for the environmental harms that the mills could cause, the ICJ ruled that Uruguay took the prevention measures requested by the Bilateral River Commission (CARU), hence not causing environmental damage.\textsuperscript{193} Regarding reversal of the burden of proof, despite emphasizing the importance of the precautionary approach, the Court did not fully enforce the reversal, stating that this should be an obligation of both Parties and that the 1975 Statute does not operate with this possibility.

164. Regarding the arguments put forward by Argentina on the reversal of the burden of proof and on the existence, vis-à-vis each Party, of an equal onus to prove under the 1975 Statute, the Court considers that while a precautionary approach may be relevant in the interpretation and application of the provisions of the Statute, it does not follow that it operates as a reversal of the burden of proof. The Court is also of the view that there is nothing in the 1975 Statute itself to indicate that it places the burden of proof equally on both Parties.\textsuperscript{194}

Regardless of this aspect of the ICJ decision by not applying the reversal, which is one of the main cores of the precautionary approach, the Court restated the importance of environmental protection and the environmental law principles, this time particularly citing precaution. This happened because more countries are including these concerns in their national legislation, so it is a possible new practice.

\textsuperscript{192} International Court of Justice, REPORTS OF JUDGMENTS, ADVISORY OPINIONS AND ORDERS, CASE CONCERNING PULP MILLS ON THE RIVER URUGUAY (ARGENTINA v. URUGUAY) JUDGMENT OF 20 APRIL 2010. Paragraph 160.

\textsuperscript{193} International Court of Justice, REPORTS OF JUDGMENTS, ADVISORY OPINIONS AND ORDERS, CASE CONCERNING PULP MILLS ON THE RIVER URUGUAY (ARGENTINA v. URUGUAY) JUDGMENT OF 20 APRIL 2010. Paragraph 189.

\textsuperscript{194} Id. supra in paragraph 164.
C) New Zealand v. France

In this case, New Zealand and Australia filed a complaint against France with the ICJ regarding French nuclear tests in the South Pacific and possible nuclear fallout in the atmosphere. This issue was discussed over the years since the 1970s; however, with France’s second round of test, the complainants argued that France should prove its test would not harm the environment, based on the Precautionary Principle (i.e., reversal of the burden of proof), and asked ICJ to check the status of this principle in the context of the International Law and eventually as a customary law.195

Unfortunately, the Court decided that New Zealand’s claims did not fall under the jurisdiction of ICJ due to procedural reasons, therefore it did not address the Precautionary Principle. Even though the Court did not discuss the merits regarding the Precautionary Principle, it reaffirmed the States’ obligations to preserve the environment.196 Additionally, dissenting votes specifically mentioned the importance of the environmental principle and its status in International Law, especially the vote cast by Judge Weeramantry.

196 REQUEST FOR AN EXAMINATION OF THE SITUATION IN ACCORDANCE WITH PARAGRAPH 63 OF THE COURT’S JUDGMENT OF 20 DECEMBER 1974 IN THE NUCLEAR TESTS (NEW ZEALAND v. FRANCE) CASE, para. 34: “Whereas during its oral statements New Zealand further contended that changes in the law were capable of affecting the basis of the 1974 Judgment, since the Court must have been aware at the time of the Judgment in 1974 of "the prospect of a significant forward surge in the evolution of standards and procedures" in the field of international environmental law; that such an evolution had indeed taken place both in customary international law and by virtue of the Noumea Convention; that, under current customary law, especially stringent controls applied to the marine environment, so that, in general, the introduction of radioactive material into the marine environment was forbidden; and that, specifically, "any introduction of radioactive material into the marine environment as a result of nuclear tests" was forbidden; that the standard of proof to which New Zealand should be subject in seeking to demonstrate that France was in breach of its obligations was a prima facie test; and that by virtue of the adoption into environmental law of the "Precautionary Principle", the burden of proof fell on a State wishing to engage in potentially damaging environmental conduct to show in advance that its activities would not cause contamination." Available at https://www.icj-cij.org/public/files/case-related/97/097-19950922-ORD-01-00-EN.pdf
In his vote, Judge Weeramantry stressed that, back in the 1970s, litigations underway could not rely on the knowledge available in 1995, thus further testing was necessary to confirm whether radioactivity could harm the atmosphere. In this regard, Judge Weeramantry explained the Intergenerational Principle, which addresses the right of future generations to a healthy environment and the Precautionary Principle, given the scientific uncertainty of the tests and the obligation of France to prove it would not cause harm based on the reversal of the burden of proof which the principle demands.

At the end, Judge Weeramantry stated that by only addressing procedural issues the Court missed a unique opportunity to tackle an important environmental and international law principle:

I regret that the Court has not availed itself of the opportunity to enquire more fully into this matter and of making a contribution to some of the seminal principles of the evolving corpus of international environmental law. The Court has too long been silent on these issues and, in the words of ancient wisdom, one may well ask "If not now, when?"

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197 DISSENTING OPINION OF JUDGE WEERAMANTRY, at page 74: “Having regard to the information furnished to the Court by New Zealand as summarized above, and in the absence of specific scientific material or impact assessment studies by France, the possibility of accident is another ground which goes to make out the prima facie case that New Zealand would be obliged to present. Available at https://www.icj-cij.org/public/files/case-related/97/097-19950922-ORD-01-05-EN.pdf

198 Id. supra, page 57: “New Zealand's complaint that its rights are affected does not relate only to the rights of people presently in existence. The rights of the people of New Zealand include the rights of unborn posterity. Those are rights which a nation is entitled, and indeed obliged, to protect. In considering whether New Zealand has made out a prima facie case of damage to its interests sufficient to bring the processes of this Court into operation in terms of paragraph 63, this is therefore an important aspect not to be ignored.”

199 Id. supra, page 64: “There are two ways of approaching this question. The first is to place the burden of proof fairly and squarely upon New Zealand, and to ask whether a prima facie case has been made out of the presence of such dangers as New Zealand complains of. The second approach is to apply the principle of environmental law under which, where environmental damage of any sort is threatened, the burden of proving that it will not produce the damaging consequences complained of is placed upon the author of that damage. In this view of the matter, the Court would hold that the environmental damage New Zealand complains of is prima facie established in the absence of proof by France that the proposed nuclear tests are environmentally safe. It will be noted in this connection that all the information bearing upon this matter is in the possession of the Respondent. The Applicant has only indirect or secondary information, but has endeavoured to place before the Court such information as it has been able, to the best of its ability, to marshal for the purposes of this application. The second approach is sufficiently well established in international law for the Court to act upon it. Yet, it is sufficient for present purposes to act upon the first approach, throwing the burden of proof upon New Zealand.”

200 Id. supra, page 78.
Thus, following the history of international precedents regarding environmental principles, there is a growing discussion, especially within ICJ dissenting votes, about starting to accept them not only as part of a Treaty, but also as a state practice, eventually becoming a custom or general principle of international law, especially the Precautionary Principle. Consequently, this could directly influence other non-environmental norms, such as those trade related.

Considering the above, could the WTO Dispute Settlement Body, with its panels and Appellate Body, use Environmental Principles or take them into consideration when deciding a trade conflict?

3.2. International Law and Environmental Principles in the WTO Dispute Settlement Body

The DSB as the WTO body responsible for settling trade disputes between WTO Parties, uses both trade regulations and international law. However, the relationship between them is complex.

International Law, unlike domestic Law, does not have hierarchy. National Laws usually have a structure based on a pyramid of hierarchy in which the Constitution is at the top of laws, decrees, and regulations, respectively.201 On the other hand, international laws do not have any hierarchy between them.

Public International Law is written by a decentralized system without a central legislator, which leads to question how these treaties and customs relate with each other and with national laws.

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201 See Hans Kelsen, Pure Theory of Law.
But, when it comes to WTO rules, this doubt is even stronger given the unique status of the WTO regulatory framework.\textsuperscript{202} According to Pauwelyn, although the WTO rules are a part of international law, these rules are "lex specialis" in comparison with general international law.

For the scholar, WTO rules are somehow different from other international law rules, as it regulates commerce and trade liberalization, therefore it has the prerogative to contract out other rules, however, it cannot contract out all international law rules because this can potentially impact several segments of the society and the Law.\textsuperscript{203} For Pauwelyn, the relationship between WTO rules and international law rules is classified into five categories:

- (i) WTO rules which can add to previously existing rights of international law;
- (ii) WTO rules that contract out of general international law;
- (iii) WTO rules which confirm preexisting rules of international law;
- (iv) Non-WTO rules that already existed when the WTO treaty was concluded;
- (v) Non-WTO rules created after the WTO treaty. (This category applies to the Cartagena Protocol)\textsuperscript{204}

In these categories, there is a "trap" regarding categories (ii) and (iii), as one may wonder if confirming preexisting rules of international law in the WTO can be proof of contracting out other rules. According to the Permanent Court of International Justice (PCIJ) and the International Court, an omission in a trade agreement cannot exclude other treaties.

\textsuperscript{203} Id. supra, page 539.
\textsuperscript{204} Id. supra, page 540.
This line of thinking can be observed in the 1971 South Africa Advisory Opinion, where the Court clearly stated that: "[…] The silence of a treaty as to the existence of such right cannot be interpreted as implying the exclusion of a right which has its source outside of the treaty, in general international law […]". Pauwelyn states that this shows a favor towards continuity or against conflict in a way that if a treaty does not contract out of a preexisting rule, that rule continues to exist.

3.2.1 Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) and Evolutionary Interpretation

Within WTO rules, the one that most displays this fact is article 3.2 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), which says:

The dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. The Members recognize that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements.

Briefly, the DSU is a set of procedural rules guiding how the WTO Dispute Settlement Body should carry a Panel or an Appellate Body when deciding a case. Specifically, article 3.2 implies


that the DSB Panels and Appellate Body will use customary rules of interpretation to clarify their decisions regarding trade agreements and disputes.

Because not all WTO members are Parties to the Vienna Convention on the Law of Treaties (hereinafter "Vienna Convention"), the DSU opted to refer to customary rules of interpretation as an alternative of the Vienna Convention articles 31 to 33, which sets the rules of interpretation of international law.

The Vienna Convention has a major importance for International Law, as it establishes rules for interpreting agreements and their respective duration, modification, and termination. In this respect, article 31 is essential, as it is the main provision addressing rules of interpretation:

Article 31 General rule of interpretation 1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose. 2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes: (a) any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty; (b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty. 3. There shall be taken into account, together with the context: 12 (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions; (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation; (c) any relevant rules of international law applicable in the relations between the parties. 4. A special meaning shall be given to a term if it is established that the parties so intended.

This provision also reveals that interpretation is guided by evolution. In other words, how new concerns, terms, and definitions evolve over time, acquire new meaning and, consequently, have the capacity to alter the interpretation of a treaty. The evolutionary interpretation of a treaty has been debated not only by scholars, but also in ICJ cases, since the Vienna Convention is not clear about this concept and when this occurs.
The notion of contemporaneity plays a central role in clarifying this issue, because it denotes that a treaty must be interpreted in accordance with the intention of the parties at the time of its conclusion.\textsuperscript{207} This Principle has long been accepted by the academia, for Gerald Fitzmaurice: "[…\] the terms of a treaty must be interpreted according to the meaning which they possessed, or which would have been attributed to them, and in the light of current linguistic usage, at the time when the treaty was originally concluded."\textsuperscript{208}

Despite article 31 not clearly stating these principles of change of interpretation, the ICJ had contemplated this in its history of jurisprudence due to having to tackle these issues and creating a legal guide on how to apply them.

First, with the Namibia case, the ICJ had to decide in the 1970s whether South Africa could continue its presence in Namibia, such as since 1919 because of World War I in European colonies in Africa. The South African presence in Namibian territory had been condemned by the Security Council with its Resolution 276 (1970),\textsuperscript{209} however, South Africa claimed Article 22 of the Covenant of the League of Nations,\textsuperscript{210} which guaranteed that some nations could administer others


\textsuperscript{209} "[…] declares that the continued presence of the South African authorities in Namibia is illegal and that consequently all acts taken by the Government of South Africa on behalf of or concerning Namibia after the termination of the Mandate are illegal and invalid."

\textsuperscript{210} "ARTICLE 22: To those colonies and territories which as a consequence of the late war have ceased to be under the sovereignty of the States which formerly governed them and which are inhabited by peoples not yet able to stand by themselves under the strenuous conditions of the modern world, there should be applied the principle that the well-being and development of such peoples form a sacred trust of civilisation and that securities for the performance of this trust should be embodied in this Covenant. […]". Available at: https://avalon.law.yale.edu/20th_century/leagcov.asp;\textasciitilde;\textasciitilde;text=ARTICLE%2022.&text=Certain%20communities%20formerly%20belonging%20to%20are%20able%20to%20stand%20alone.
after losing colonial powers with the end of World War I, a fact that happened in Namibia as former German colony being assisted by South Africa. In other words, to be assisted, some nations had a "sacred trust" from others.

However, 50 years later, the presence of South Africa lost its purpose, since Namibia became a fully independent country, requiring a new interpretation of this treaty. Thus, the ICJ tackled this dispute by applying the evolutionary interpretation, especially regarding the concept of "sacred trust." By using the principle of contemporaneity, the court ruled that sacred trust constituted a moral idea and not a legal right, hence South African presence was illegal.

53. … Mindful as it is of the primary necessity of interpreting an instrument in accordance with the intentions of the parties at the time of its conclusion, the Court is bound to take into account the fact that the concepts embodied in Article 22 of the Covenant — "the strenuous conditions of the modern world" and "the well-being and development" of the peoples concerned — were not static, but were by definition evolutionary, as also, therefore, was the concept of the "sacred trust". The parties to the Covenant must consequently be deemed to have accepted them as such. That is why, viewing the institutions of 1919, the Court must take into consideration the changes which have occurred in the supervening half-century, and its interpretation cannot remain unaffected by the subsequent development of law, through the Charter of the United Nations and by way of customary law. Moreover, an international instrument has to be interpreted and applied within the framework of the entire legal system prevailing at the time of the interpretation. In the domain to which the present proceedings relate, the last fifty years, as indicated above, have brought important developments. These developments leave little doubt that the ultimate objective of the sacred trust was the self-determination and independence of the peoples concerned.211

It is important to stress that, in this case, the ICJ applied the evolutionary interpretation by default, unlike some other cases, where the ICJ had to set a guide to clarify this issue. In the Aegean Sea case and in the Dispute regarding Navigational and Related Rights, the ICJ set an assessment system simplifying when and how to use the evolutionary interpretation.

The Aegean Sea Continental Shelf case involved a dispute over the continental shelf boundary between Turkey and Greece. Greece claimed it owned the area based on the General Act for the Pacific Settlement of International Disputes (i.e., adopted in 1928), in which it did not define the concept of "continental shelf" and that this uncertainty was frozen in time. The Court disagreed with this rationale stating the meaning of "territorial status" should evolve with the Law.212 Thus, in contrast with the Namibia case, here the court intentionally used the evolutionary interpretation.

As for the Dispute regarding Navigational and Related Rights, the ICJ finally formulated a general rule determining when the evolution intention must be presumed; in other words, the evolutive intent is an obligation, not just an option.213

In this case, the court decided that Nicaragua did not have the right to demand visas or any other requirement of Costa Rican vessels to navigate the San Juan River which, based on the 1958 Treaty, such Nicaraguan requirements were possible. Therefore, the Court changed the interpretation of the 1958 Treaty between these two nations regarding the use and navigation of the river. In other words, the Court used the evolutionary interpretation.

In order to use a presumed evolutionary interpretation, the ICJ set a two-step test:

(1) First, the parties have used ‘generic terms’ (in which case the parties have ‘necessarily […] been aware that the meaning of the terms was likely to evolve over time’), and
(2) the treaty ‘has been entered into for a very long time or is ‘of continuing duration’.

212 Aegean Sea Continental Shelf (Greece v. Turkey), I.C.J. Reports, 1978, para. 77.
214 Id. supra, para. 19.
These three cases represent a set of precedents where the Court applied evolutionary interpretation through different systems depending on the terms being analyzed (i.e., taxonomy of terms). First, in Namibia, the problem of not updating the understanding of an old agreement was so explicit that the Court automatically applied evolutionary interpretation (i.e., default). As for the Aegean Sea case and the Dispute regarding Navigational and Related Rights, the evolutionary interpretation was not so clear, thus the Court had to better assess the issues and craft a test in which the evolutive intent could be established after a thorough comprehensive evaluation (i.e., non-value driven evolving terms).

Regarding the WTO, the Appellate Body confirmed Vienna Convention articles 31 to 33 and its rules of interpretation as customary law.215 For example, in US — Gasoline, the Appellate Body confirmed that the general rule of interpretation contained in Article 31 of the Vienna Convention has the status of customary or general international law:

The 'general rule of interpretation' set out above has been relied upon by all of the participants and third participants, although not always in relation to the same issue. That general rule of interpretation has attained the status of a rule of customary or general international law.19 As such, it forms part of the 'customary rules of interpretation of public international law' which the Appellate Body has been directed, by Article 3(2) of the DSU, to apply in seeking to clarify the provisions of the General Agreement and the other 'covered agreements' of the Marrakesh Agreement Establishing the World Trade Organization (the 'WTO Agreement'). That direction reflects a measure of recognition that the General Agreement is not to be read in clinical isolation from public international law.216

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Therefore, when assessing a dispute, both the Panels and the Appellate Body must consider not only the agreement in hand but also the customary rules of interpretation.

In Korea — Measures Affecting Government Procurement, the Panel confirmed the importance of the customary rules of interpretation and explained its relationship with WTO agreements for economic relations:

We take note that Article 3.2 of the DSU requires that we seek within the context of a particular dispute to clarify the existing provisions of the WTO agreements in accordance with customary rules of interpretation of public international law. However, the relationship of the WTO Agreements to customary international law is broader than this. Customary international law applies generally to the economic relations between the WTO Members. Such international law applies to the extent that the WTO treaty agreements do not 'contract out' from it. To put it another way, to the extent there is no conflict or inconsistency, or an expression in a covered WTO agreement that implies differently, we are of the view that the customary rules of international law apply to the WTO treaties and to the process of treaty formation under the WTO.217

[...] We should also note that we can see no basis here for an a contrario implication that rules of international law other than rules of interpretation do not apply. The language of 3.2 in this regard applies to a specific problem that had arisen under the GATT to the effect that, among other things, reliance on negotiating history was being utilized in a manner arguably inconsistent with the requirements of the rules of treaty interpretation of customary international law.218

In this paragraph, the Panel emphasized that article 3.2 of the DSU applies not only to rules related to interpretation of treaties, but all other international law. However, the Panel limited this reference only to customary law per se, not encompassing a broader scope regarding other sources of international law such as general principles of international law.219

Additionally, concerning the customary rules of interpretation, article 3.2 of the DSU also demands it to be done while providing security and predictability to the multilateral trading system. In Japan

217 Panel Report, Korea – Procurement, para. 7.96.
218 Panel Report, Korea – Procurement, fn 753.
– Alcoholic Beverages II, the Appellate Body clarified that all WTO rules being interpreted must be reliable, comprehensible, and enforceable, but not so rigid or inflexible in a way that would not allow adaptations to the for future flow of real facts, which are always changing:

WTO rules are reliable, comprehensible and enforceable. WTO rules are not so rigid or so inflexible as not to leave room for reasoned judgements in confronting the endless and ever-changing ebb and flow of real facts in real cases in the real world. They will serve the multilateral trading system best if they are interpreted with that in mind. In that way, we will achieve the 'security and predictability' sought for the multilateral trading system by the Members of the WTO through the establishment of the dispute settlement system.220

The DSB shows its concern about allowing WTO rules to evolve along with current issues and with modernity, just like in the ICJ. In this regard, in US – Shrimp, seen in the last Chapter, the Appellate Body had to decide whether the meaning of "exhaustible resource" is not confined to non-living resources, with the purpose of being accepted as a GATT exception from article XX (g). In this respect, the Appellate Body, in a certain way, followed the ICJ rationale in the sense that the terms and their respective content cannot remain static over time.

From the perspective embodied in the preamble of the WTO Agreement, we note that the generic term 'natural resources' in Article XX(g) is not 'static' in its content or reference but is rather 'by definition, evolutionary […]

[…] Given the recent acknowledgement by the international community of the importance of concerted bilateral or multilateral action to protect living natural resources, and recalling the explicit recognition by WTO Members of the objective of sustainable development in the preamble of the WTO Agreement, we believe it is too late in the day to suppose that Article XX(g) of the GATT 1994 may be read as referring only to the conservation of exhaustible mineral or other non-living natural resources. Moreover, two adopted GATT 1947 panel reports previously found fish to be an 'exhaustible natural resource' within the meaning of Article XX(g). We hold that, in line with the principle of effectiveness in treaty interpretation, measures to conserve exhaustible natural resources, whether living or non-living, may fall within Article XX(g).221

Hence, the DSB concluded that given new environmental concerns developed over time, the definition of "exhaustible resource" must include both living and non-living resources. With this

221 Appellate Body Report, US – Shrimp, paras. 130–131
case, evolutionary interpretation of treaties also applies to environmental trade issues within the DSB procedural rules.

3.3. WTO Precedents as Instruments to Change International Law and its Interpretation

Given the fact that the WTO DSB, through its decision, does not only create mandatory obligations to the Parties, but also alters current definitions and understandings due to evolutionary interpretations, there is a fiercer debate regarding how the WTO can change International Law, especially Environmental International Law.

In this regard, it is essential to assess the legal schools of thoughts such as Natural Theory, Positivism and Realism. These schools discuss how laws are created, based on human’s will, morality, and ethics, and the extent to which judicial decisions can evolve laws.

In short, Natural Law Theory defends that laws are created from the human idea of right or wrong. It is inherent in human morality and behavior, hence inevitable, separating it from ethics itself – "a legal embodiment of morality." Naturalists use not only the law, but moral values to answer questions or fill gaps created by the legal system.

On the other hand, Positivism claims that rules are crafted by a competent authority having little regard for morality, for Positivism morality and law do not necessarily share the same connection. Hence the Separability Theory.

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223 Id. supra, page 3.
Depending on the scholar, the separability between law and morality stated by Positivism can occur in a hard or soft version – Exclusionary and Inclusionary Positivism. As for Exclusionary Positivism, Joseph Raz denies any connection between law and morality, reducing laws to a system which only includes authorities creating, issuing, and interpreting norms. For him, morality is an independent value which can but should not be used for the enforcement of the law.

Regarding Inclusionary Positivism, for H. L. A. Hart, despite law and morality being different, they constantly merge: "[...] the simple contention that it is in no sense a necessary truth that laws reproduce or satisfy certain demands of morality, though in fact they have often done so." Therefore, for him, Positivism has an unavoidable minimum of Natural Law. This happens due to the necessity to live in society and follow social rules (i.e., notion of right and wrong).

However, an issue that arises with Positivism is when the law is silent. There are situations when the law is not clear or gives conflicting orders, especially when there is a doubt regarding the gap between rule and morality. This can be described as indeterminacy.

Dworkin, a Positivism critic, claimed that Positivism cannot offer any solution for indeterminate disputes. To support his opinion, he cites Riggs v. Palmer, a New York appellate court case in

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224 Hart, Concept of Law p. 181–182.
225 See Chambers, Jonathan Brett, "Legal Positivism: An Analysis" (2011). Undergraduate Honors Capstone Projects. 79. P 10: “[…] Hartian Positivism relies heavily upon social practices, customs and traditions to determine law. Primary rules (referred to by Hart as rules of the first type) are designed to regulate the actions of individuals (coercion). While primary rules are necessary in the maintenance of a lawful society, a society must not subsist on them alone. Because law is based on social facts, and social practices change and evolve, it must reflect social norms in any given lawful society. These changes are made through secondary rules. Secondary rules serve basic needs of the legal system. They recognize, change, and enact (adjudication) the law.”
which a 16-year-old male defendant, Riggs, murdered his grandfather, Palmer, by poison, for being the residuary legatee of his will. Here, the conflict between law and morality is extremely clear.

By exclusively following property law and the will, the defendant was entitled to his grandfather’s estate. As mentioned by Dworkin: "the court began its reasoning with this admission: 'it is quite true that statutes regulating the making, proof and effect of wills, and the devolution of property, if literally construed, and if their force and effect can in no way and under no circumstances be controlled or modified, give this property to the murderer."227 On the other hand, considering moral values, it was more adequate to annul the will or exclude Riggs from it, as requested by the Plaintiffs, Palmer’s other two children.

On this dilemma used by Dworkin to criticize Positivism, Hart responded that indeterminacy is a component of legality, and the proper issue here would be what degree of indeterminacy is acceptable:

Even if laws could be framed that could settle in advance all possible questions that could arise about their meaning, to adopt such laws would often war with other aims which law should cherish. A margin of uncertainty should be tolerated, and indeed welcomed in the case of many legal rules, so that an informed judicial decision can be made when the composition of an unforeseen case is known and the issues at stake in its decision can be identified and so rationally settled.228

Hart stresses that uncertainty should be tolerated, and judicial decision could be used to work out solutions addressing rule gaps. For Hart, the judge should "act as a conscientious legislator […] by deciding according to his own beliefs and values,"229 as there are cases where the law is so

227 Dworkin, Taking Rights Seriously, p. 23.
228 Hart, Concept of Law, p. 252.
229 Id. supra, p. 273.
incomplete or silent, that it is impossible to know its purpose or expectations, therefore the judge cannot be unjust concerning its "ex post fact law making."

Despite the differences between Legal theories such as Natural Law and Positivism, as well as the differences within Positivism itself, the central fact that binds this whole discussion unto indeterminacy is the lack of clarity provided by some laws.

The same indeterminacy phenomenon also happens at the WTO and in trade rules. Within the scope of the WTO, indeterminacy can be attributed to:

- **Linguistics:** As seen in the previous chapters, the WTO’s rules such as GATT, SPS and TBT are most often confusing and unclear, requiring judicial interpretation. This fact is so explicit that the DSB constantly used its history of precedents to help understand the terms stated in the statutes. When it comes to environmental dispute, this issue is even bigger.\(^{230}\)
- **Lacunae:** When a norm does not cover a specific situation.\(^{231}\)
- **Conflict:** When a norm conflicts with another. In the WTO this can happen more often, such as a WTO rule conflict with a non-WTO rule or agreement.\(^{232}\) Concerning environmental issues, this can be noticed in the main claim of this study (i.e., Biosafety protocols and socioeconomic criteria being considered in trade law?)

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\(^{231}\) See Steinberg, “Judicial Lawmaking at the WTO”, 252.

\(^{232}\) Jan Neumann, Die Koordination des WTO-Rechts mit anderen völkerrechtlichen Ordnungen (Berlin: Duncker & Humblot, 2002).
These types of indeterminacy can occur alone or simultaneously. How does the DSB behave when addressing it, especially in environmental dispute cases?

The main purpose of this question is to assess the extent to which the WTO is contributing to the evolutionary interpretation of its norms, when faced with indeterminacy, to consider modern environmental concerns (i.e., new moral values). Again, observing some specific WTO precedents is necessary.

Although it has been briefly mentioned in this study, it is now relevant to analyze United States – Import Prohibition of Certain Shrimp and Shrimp Products in depth. This is an emblematic indeterminacy case, as it includes environmental/animal welfare concerns covered with moral values and GATT provisions unable provide a clear and straight response.

3.3.1. US – Import Prohibition of Certain Shrimp and Shrimp Products — Leading Case for the WTO to Address Indeterminacy in Environmental Issues

US – Import Prohibition of Certain Shrimp and Shrimp Products is a case where the WTO was provoked in 1997 by India, Malaysia, Pakistan and Thailand to assess whether a United States import ban regarding commercial fishing technology was in accordance with trade rules.
This ban (i.e., Section 609 (b) (1) enacted in 1991) consisted of the United States accepting only shrimp imports from countries certified with this technology, which allowed catching harvested shrimp without endangering turtles (i.e., Turtle Excluder Devices — TED).

It is worth noting that the US ban was introduced in the context of the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES), which was even used by the US in its defense. The CITES is a Multilateral Environmental Agreement (MEA) that entered into force in 1975 with the purpose of ensuring that international trade would not threaten the survival of animal and plant species (listed in its Annex I).

The complainants claimed the ban of Section 609 was not in accordance with the GATT rules, especially article XX (b) and (g). The main argument was that because United States imposed the ban unilaterally, without consulting the multilateral trading system, it created an unjustifiable measure (i.e., *chapeau* of article XX), since if every member imposed a ban based on a personal perception of environmental protection, the multilateral trade system would cease to exist, hence an abuse of article XX.

233 Appellate Body, United States - Import Prohibition of Certain Shrimp And Shrimp Products, WT/DS58/AB/R, para. 3: “[...] 1996 Guidelines, the Department of State "shall certify any harvesting nation meeting the following criteria without the need for action on the part of the government of the harvesting nation: (a) Any harvesting nation without any of the relevant species of sea turtles occurring in waters subject to its jurisdiction; (b) Any harvesting nation that harvests shrimp exclusively by means that do not pose a threat to sea turtles, e.g., any nation that harvests shrimp exclusively by artisanal means; or (c) Any nation whose commercial shrimp trawling operations take place exclusively in waters subject to its jurisdiction in which sea turtles do not occur.”

234 *Id.* supra, paras. 2–6: “[...] initiate negotiations as soon as possible for the development of bilateral or multilateral agreements with other nations for the protection and conservation of [...] sea turtles" and to "initiate negotiations as soon as possible with all foreign governments which are engaged in, or which have persons or companies engaged in, commercial fishing operations which, as determined by the Secretary of Commerce, may affect adversely such species of sea turtles, for the purpose of entering into bilateral and multilateral treaties with such countries to protect such species of sea turtles; [...]"

235 Available at https://cites.org/eng/disc/text.php

236 Appellate Body, United States - Import Prohibition of Certain Shrimp And Shrimp Products, WT/DS58/AB/R, para 35: “Joint Appellees argue that the flaw in Section 609, and in the appellant’s argument, is the appellant’s failure
India, Malaysia, Pakistan, and Thailand also stated that an exception to article XX (g) would not apply to the US ban as "exhaustible natural resource" would only include minerals, not living organisms like turtles. As previously mentioned in this work, the Appellate Body reversed some of the Panel’s findings, especially extending the meaning of the term "exhaustible natural resource" to living organisms, as part of an evolutionary interpretation.237

[...] Textually, Article XX(g) is not limited to the conservation of "mineral" or "non-living" natural resources. The complainants' principal argument is rooted in the notion that "living" natural resources are "renewable" and therefore cannot be "exhaustible" natural resources. We do not believe that "exhaustible" natural resources and "renewable" natural resources are mutually exclusive. One lesson that modern biological sciences teach us is that living species, though in principle, capable of reproduction and, in that sense, "renewable", are in certain circumstances indeed susceptible of depletion, exhaustion and extinction, frequently because of human activities. Living resources are just as "finite" as petroleum, iron ore and other non-living resources.238

The words of Article XX(g), "exhaustible natural resources", were actually crafted more than 50 years ago. They must be read by a treaty interpreter in the light of contemporary concerns of the community of nations about the protection and conservation of the environment. While Article XX was not modified in the Uruguay Round, the preamble attached to the WTO Agreement shows that the signatories to that Agreement were, in 1994, fully aware of the importance and legitimacy of environmental protection as a goal of national and international policy. The preamble of the WTO Agreement -- which informs not only the GATT 1994, but also the other covered agreements -- explicitly acknowledges "the objective of sustainable development.239

From the perspective embodied in the preamble of the WTO Agreement, we note that the generic term "natural resources" in Article XX(g) is not "static" in its content or reference but is rather "by definition, evolutionary".109 It is, therefore, pertinent to note that modern international conventions and declarations make frequent references to natural resources as embracing both living and non-living resources.240

to accept that conditioning access to markets for a given product upon the adoption of certain policies by exporting Members, can violate the WTO Agreement. A Member must seek multilateral solutions to trade-related environmental problems. The threat to the multilateral trade system cited by the Panel is unrelated to the appellant’s support for TEDs or turtle conservation. The threat is much simpler: the United States has abused Article XX by unilaterally developing a trade policy, and unilaterally imposing this policy through a trade embargo, as opposed to proceeding down the multilateral path. The multilateral trade system is based on multilateral cooperation. If every WTO Member were free to pursue its own trade policy solutions to what it perceives to be environmental concerns, the multilateral trade system would cease to exist. By preventing the abuse of Article XX, the chapeau protects against threats to the multilateral trading system. The prevention of abuse and the prevention of threats to the multilateral trading system are therefore inextricably linked to the object, purpose and goals of Article XX of the GATT 1994."

237 See page 105.
239 Id supra, para. 129.
240 Id supra, para. 130.
As for the claim that the ban was unjustifiable, the Appellate Body kept the Panel’s finding, in the sense that although the concern with protecting turtles is valid, since the United States set only one type of technology, excluding all similar others, it did not conform with the *chapeau* of article XX. In other words, the ban was not exclusively aiming at environmental protection, but also favoring a specific type of technology — TEDs.

Furthermore, when this dispute was before the Panel and before us, the United States did not permit imports of shrimp harvested by commercial shrimp trawl vessels using TEDs comparable in effectiveness to those required in the United States if those shrimp originated in waters of countries not certified under Section 609. In other words, shrimp caught using methods identical to those employed in the United States have been excluded from the United States market solely because they have been caught in waters of countries that have not been certified by the United States. The resulting situation is difficult to reconcile with the declared policy objective of protecting and conserving sea turtles. This suggests to us that this measure, in its application, is more concerned with effectively influencing WTO Members to adopt essentially the same comprehensive regulatory regime as that applied by the United States to its domestic shrimp trawlers, even though many of those Members may be differently situated. We believe that discrimination results not only when countries in which the same conditions prevail are differently treated, but also when the application of the measure at issue does not allow for any inquiry into the appropriateness of the regulatory program for the conditions prevailing in those exporting countries.241

Even striking down the United States ban, by stressing the importance of protecting turtles, the Appellate Body gave some indication on how the WTO can and will incorporate new environmental concerns, converted into protection measures, since GATT may not be explicit on the topic. Furthermore, this case also displays WTO’s interaction with other non-trade MEAs.

By deciding whether the United States’ measure was unjustifiable, the Appellate Body had to not only check its decision on Trade and Environment (CTE), but it also applied other provisions of International Environmental Law:

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[...] the protection and conservation of highly migratory species of sea turtles, that is, the very policy objective of the measure, demands concerted and cooperative efforts on the part of the many countries whose waters are traversed in the course of recurrent sea turtle migrations. The need for, and the appropriateness of, such efforts have been recognized in the WTO itself as well as in a significant number of other international instruments and declarations. As stated earlier, the Decision on Trade and Environment, which provided for the establishment of the CTE and set out its terms of reference, refers to both the Rio Declaration on Environment and Development and Agenda 21.242

Despite not being a source of hard law, the Appellate Body uses principle 12 of the Rio Declaration on Environment and Development, which demands a collective response to environmental challenges outside national jurisdiction:

States should cooperate to promote a supportive and open international economic system that would lead to economic growth and sustainable development in all countries, to better address the problems of environmental degradation. Trade policy measures for environmental purposes should not constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade. Unilateral actions to deal with environmental challenges outside the jurisdiction of the importing country should be avoided. Environmental measures addressing transboundary or global environmental problems should, as far as possible, be based on an international consensus.243

Likewise, the WTO’s decision also mentioned Agenda 21 and the CBD: 244

Governments should encourage GATT, UNCTAD and other relevant international and regional economic institutions to examine, in accordance with their respective mandates and competences, the following propositions and principles: …(i) Avoid unilateral action to deal with environmental challenges outside the jurisdiction of the importing country. Environmental measures addressing transborder problems should, as far as possible, be based on an international consensus.245

[...] each contracting party shall, as far as possible and as appropriate, cooperate with other contracting parties directly or, where appropriate, through competent international organizations, in respect of areas beyond national jurisdiction and on other matters of mutual interest, for the conservation and sustainable use of biological diversity.246

242 Id supra, para. 168
243 Rio Declaration on Environment and Development, principle 12
244 Appellate Body, United States - Import Prohibition of Certain Shrimp And Shrimp Products, WT/DS58/AB/R, para 168.
245 Agenda 21, para. 2.22 (i)
246 Convention on Biological Diversity, article 5.
Therefore, the DSB can use other Environmental Agreements and international environmental governance instruments to back an argument, which would help the analysis of provisions stated in trade rules. This is positive, because it shows that even though the DSB procedural rules state it must use customary law for interpretation purposes, it can use, even if timidly, references of other non-trade related statutes.

However, the DSB will only truly apply environmental principles once they become customary law or general principles of International Law. Therefore, the evolution of these principles must continue so that the global community may acknowledge them as a custom. For this, it is increasingly essential that environmental measures and treaties be created and used by countries.

To sum up, both ICJ and WTO precedents showed an ongoing evolution of environmental principles (e.g., Precautionary Principle) into a source of international law, and that these must be taken into account regarding international rule making:

<table>
<thead>
<tr>
<th>ICJ</th>
<th>WTO</th>
</tr>
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<tbody>
<tr>
<td><strong>Cases</strong></td>
<td></td>
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<tr>
<td>Hungary v. Slovakia</td>
<td>US – Shrimp (ref. to exhaustible resources)</td>
</tr>
<tr>
<td>Argentina v. Uruguay</td>
<td>EC - Biotech</td>
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<tr>
<td>New Zealand v. France</td>
<td>EC - Hormones</td>
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<tr>
<td><strong>Rulings</strong></td>
<td></td>
</tr>
<tr>
<td>Environmental norms are part of international law and of growing importance</td>
<td>Precautionary Principle is implicit on SPS para.7.78: “The European Communities asserts that the precautionary principle has by now become a fully-fledged and general principle of international law”</td>
</tr>
</tbody>
</table>

Table 5: WTO and ICJ precedents on the evolution of environmental principles
Source: Author
CHAPTER 4

4. Current WTO Cases and an Analogy of SECs

Because there are no WTO cases, whether completed or underway, directly addressing SEC measures, only by analogy with existing cases it is possible to assess how the WTO would fit SECs within the trade rules and their related uncertainties. As previously pointed out in this study, from all three main trade rules (i.e., GATT, TBT and SPS), it is more plausible to imagine a SEC measure being directly related to a SPS and/or a GATT exception.

Initially, since a SEC measure, regarding the use of LMOs, would seek to ensure better income and livelihood for farmers and communities, it could connect with a public moral concern as described in GATT article XX, (a). The EC—Seal Products case can provide some guidance, as it is WTO’s main case where both panel and Appellate Body thoroughly assessed the exception of public moral and which type of trade restriction it could encompass, especially those concerning ethical values, according to the broad SEC definition proposed by the AHTEG SEC, negotiated at the CBD.

The implementation of SEC measures could also relate to the SPS provisions. Article 5.3 of the SPS is the only provision of all rules which expressively mentions "economic factors" as part of risk assessments,247 thus the most natural scenario where SECs could fit. Because SPS involves

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247 Article 5.3: In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry,
sanitary issues, it demands scientific certainty, exceptionally and temporarily allowing the lack of scientific certainty as justification to impose trade restrictions. In this regard, SPS somehow carries a direct link with the precautionary principle when it comes to environmental issues.

Therefore, EC – Biotech case is important, because it is not the only WTO case that addresses LMOs, but also debates the Precautionary Principle within the scope of trade. Also, it must be stressed that EC – Biotech uses attempted findings regarding the Precautionary Principle and its evolution in International Law, set by EC – Hormones.248

4.1. EC—Seal Products and Public Moral Values

The public morals exception of GATT was introduced in 1945 with GATT’s first drafts. This exception demonstrates the relevance of public morals and the concept of morality in the context of government regulation, which has been subject of legal and philosophical debate since the seventeenth century.249 Therefore, this connection between trade and morals did not present any further explanation or clear guidance on how it should be invoked; in other words, "public moral" establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.

Para. 121: The basic submission of the European Communities is that the Precautionary Principle is, or has become, “a general customary rule of international law” or at least a “general principle of law. Referring more specifically to Articles 5.1 and 5.2. of the SPS Agreement, applying the precautionary principle means, in the view of the European Communities, that it is not necessary for all scientists around the world to agree on the “possibility and magnitude” of the risk, nor for all or most of the WTO Members to perceive and evaluate the risk in the same way. It also stressed that Articles 5.1. and 5.2 do not prescribe a particular type of risk assessment and do not prevent Members from being cautious in their risk assessment exercise in nature and satisfied the requirements of Articles 2.2 and 3.2, as well as of Articles 5.1, 5.2, 5.4, 5.5 and 5.6 of the SPS Agreement. See also para. 123: The status of the precautionary principle in international law continues to be subject of debate among academics, law practitioners, regulators, and judges. The precautionary principle is regarded by some as having crystallized into a general principle of customary law less than clear. We consider, however, that is unnecessary, and probably imprudent for the Appellate Body in this appeal to take a position on this important, but abstract question. We note that the Panel itself did not make any definitive finding with regard to the status of the precautionary principle in international law and precautionary principle, a least outside the field of the international environmental law, still awaits authorities’ formulation.

Para. 249: The status of the precautionary principle in international law continues to be subject of debate among academics, law practitioners, regulators, and judges. The precautionary principle is regarded by some as having crystallized into a general principle of customary law less than clear. We consider, however, that is unnecessary, and probably imprudent for the Appellate Body in this appeal to take a position on this important, but abstract question. We note that the Panel itself did not make any definitive finding with regard to the status of the precautionary principle in international law and precautionary principle, a least outside the field of the international environmental law, still awaits authorities’ formulation.

had no specific definition. Therefore, over time scholars, have tried to better understand what this concept means and encompasses.

Steve Charnovitz acknowledges the lack of clarity involving the public moral exception even before GATT. The scholar mentions several examples in history where a humanitarian or social concern was reflected into morality-based trade measures, to democratize it as a broader value, but never truly defining it, thus raising questions: 250

GATT article XX(a) provides an exception from GATT rules for the "protection of public morals." The vagueness of this provision gives rise to two central questions. First, what type of behavior implicates public morals? Is heroin use a matter of public morals? How about alcohol or cigarette use? Can public morals differ from one country to another, or is there a uniform international standard? Second, whose morals can be protected? It seems clear that a government can use a trade measure to protect a state's own population. But can a trade measure be used to protect morals elsewhere? For example, would an import ban against goods made by indentured children be GATT-legal? 251

In this regard, he recalls that anti-slavery measures were adopted by Great Britain against Portugal in 1817, with the Prevention of the Slave Trade Convention, forbidding the importation of slaves to Brazil. The International Opium Convention of 1912 was another use of morality-based trade measure used by the United States against China to tackle the overuse of opium narcotics in America. The application of morality-based trade measures as an exception is also seen in alcohol cases, such as the General Act of 1890 and the African Liquor Convention of 1919 prohibiting the importation of liquor into areas of sub-Saharan Africa where liquor consumption did not exist back then. 252

251 Id. supra, page 4.
252 Id. supra, page 10.
In all situations mentioned above, countries were imposing their social values into trade practices aiming at influencing and even terminating behaviors (e.g., slavery, alcohol, and drugs), both domestically and internationally. In those cases, a public moral restriction can be initially applied to preserve a national custom or behavior— inwardly-directed. However, a national custom or behavior is eventually internationalized when influencing trade relations with other countries— outwardly-directed.253

After GATT and public morals being established as an exception to the norm, the same vagueness remained on whether this could disguise a protectionist measure. Charnovitz affirms that even using the interpretation methods of the Vienna Convention (i.e., article 31), is it not enough to fully clarify the subject. Therefore, the WTO precedents interpreting the public moral exception are essential.254

253 Id. supra, page 27.
254 Id. supra, page 7: The Vienna Convention provides more applicable guidance in stating that interpretation shall take into account "[a]ny relevant rules of international law." The WTO Appellate Body has endorsed the proposition that the GATT "is not to be read in clinical isolation from public international law." The rules of international law are perhaps better examined in connection with specific moral issues—e.g., trade in goods produced by indentured children. Article 32 of the Vienna Convention provides guidance for "[s]upplementary means of interpretation." It states that recourse may be had to supplementary means in order to "confirm" the meaning resulting from the application of article 31, or to "determine" the meaning when the interpretation according to article 31 would leave the meaning "ambiguous or obscure" or would lead to a result which is "manifestly absurd or unreasonable." Article 31 seems to leave the meaning of "public morals" ambiguous. Thus, using supplementary means of interpretation is justified. The supplementary means identified in article 32 are "the preparatory work of the treaty and the circumstances of its conclusion." Examining the preparatory work is consistent with the approach taken by many GATT panels which had the task of interpreting GATT provisions. The Dispute Settlement Understanding (DSU) of the WTO also provides guidance on how the GATT should be interpreted. Article 3.2 of the DSU states that the dispute settlement system may "clarify the existing provisions of those [WTO] agreements in accordance with customary rules of interpretation of public international law." In its first decision, the WTO Appellate Body cited article 3.2 when it used the Vienna Convention rules of treaty interpretation. This accords with the views of commentators who state that the DSU provision quoted above refers to articles 31 and 32 of the Vienna Convention.
The first time the DSB had to address this issue was at US — Gambling\textsuperscript{255} in 2003. In that case, Antigua filed a complaint against the United States for banning the cross-border supply of Internet gambling services, claiming that the American trade restriction would have severe impacts on Antigua’s small economy, and that it was discriminatory, as it targeted international practices rather than gambling services within the United States,\textsuperscript{256} thus violating article XVI\textsuperscript{257} of the General Agreement on Trade and Services (GATS).

The United States presented its defense alleging that the ban protected American public moral values, as set forth in the exception of GATS article XIV (a)\textsuperscript{258} (i.e., the equivalent of GATT, XX (a)):

\begin{itemize}
\item First, the remote supply of gambling services is particularly vulnerable to exploitation by organized crime due to low set-up costs, ease of provision, and geographic flexibility. Protecting American society against the "destructive influence" of organized crime on persons and property was a matter of public morality.
\item Second, the Internet could introduce gambling into inappropriate settings, such as homes and schools, where it would not be subject to traditional, in-person controls. Internet gambling would facilitate gambling by children and have detrimental effects on compulsive gamblers by allowing anonymous, twenty-four-hour access\textsuperscript{259}
\end{itemize}

\textsuperscript{255} United States—Measures Affecting the Cross-Border Supply of Gambling and Betting Services.
\textsuperscript{256} Request for the Establishment of a Panel by Antigua and Barbuda, supra note 45, at 1.
\textsuperscript{257} GATS, article XVI, 1: With respect to market access through the modes of supply identified in Article I, each Member shall accord services and service suppliers of any other Member treatment no less favourable than that provided for under the terms, limitations and conditions agreed and specified in its Schedule.\textsuperscript{261}
\textsuperscript{258} GATS, article XIV: Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where like conditions prevail, or a disguised restriction on trade in services, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any Member of measures: (a) necessary to protect public morals or to maintain public order.
The Appellate Body followed the Panel’s decision regarding the public moral value constituting a country’s notion of right and wrong to preserve the fundamental interests of society, including social, cultural, ethical, and religious values, thus falling under the exception of provision (a):

We are well aware that there may be sensitivities associated with the interpretation of the terms "public morals" and "public order" in the context of Article XIV. In the Panel's view, the content of these concepts for Members can vary in time and space, depending upon a range of factors, including prevailing social, cultural, ethical and religious values. Further, the Appellate Body has stated on several occasions that Members, in applying similar societal concepts, have the right to determine the level of protection that they consider appropriate. Although these Appellate Body statements were made in the context of Article XX of the GATT 1994, it is our view that such statements are also valid with respect to the protection of public morals and public order under Article XVI of the GATS. More particularly, Members should be given some scope to define and apply for themselves the concepts of "public morals" and "public order" in their respective territories, according to their own systems and scales of values.

However, it concluded that the United States failed to demonstrate the restriction was not discriminatory, since it did not have any similar domestic requirements. In other words, the United States failed the two-tiered test of the article’s chapeau. This case is relevant, as it shows that the first understanding of the DSB setting the Public Moral Doctrine was a flexible/dynamic interpretation of a public moral value, depending on social, cultural, ethical, and religious factors.

The second case where the DSB of the WTO had to face a public moral trade restriction dispute was with China — Audiovisuals in 2007, where the United States filed a complaint against China for imposing a measure on the sale and distribution of imported audiovisual entertainment products, consequently violating GATS provision on market access (i.e., article XVI).

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On the other hand, China argued that this restriction was designed and applied to review content that could collide with significant values of the Chinese society:

> China considers that reading materials and finished audiovisual products are so-called "cultural goods", i.e., goods with cultural content. China submits that they are products of a unique kind with a potentially serious negative impact on public morals. China explains that, as vectors of identity, values and meaning, cultural goods play an essential role in the evolution and definition of elements such as societal features, values, ways of living together, ethics and behaviours. China notes in this respect the UNESCO Universal Declaration on Cultural Diversity, which China says was adopted by all UNESCO Members, including the United States. In its Article 8, the Declaration states that cultural goods are "vectors of identity, values and meaning" and that they "must not be treated as mere commodities or consumer goods". In China's view, it is clear, therefore that, depending on their content, cultural goods can have a major impact on public morals.

However, as opposed to US – Gambling where Antigua questioned the American ban as a public moral exception, the United States did not question whether the Chinese restriction was made to protect public morals, but rather if it was necessary and not discriminatory. The Panel and the Appellate Body reapplied the US – Gambling public moral interpretation, which was flexible, broad and with a great deal of ambiguity.

Finally, in the recently completed EC – Seal Products case, the DSB faced, for the third time, the public moral issue.

### 4.1.1. Facts

In 2009 and 2010, the European Communities enacted Regulation (EC) No. 1007/2009 (i.e., "Basic Regulation") and Commission Regulation (EU) No. 737/2010 (i.e., "Implementing Regulation"), jointly entitled the EU Seal Regime, banning the importation and placing on the market of mink, Mus musculus Linnaeus, in particular:

262 Panel Report, China – Audiovisuals, para. 7.751.
263 The dispute began before the Treaty of Lisbon entered into force in December 2009, which led to the replacement, for WTO purposes, of the European Communities with the European Union.
market of seal products deriving from "commercial" hunts, while allowing seal products from 
hunts that satisfied certain criteria related to the hunter’s identity purpose, aiming to the welfare of 
seals. These regulations allow the Inuit and the Marine Resource Management (MRM) exception – 
Inuit hunting practices are found to be more humane than commercial hunt, since the hunts are 
traditionally conducted for their subsistence. The MRM is a more individual small-scale hunting 
practice done by local certified fishers:

Article 3. 1. The placing on the market of seal products shall be allowed only where the seal products 
result from hunts traditionally conducted by Inuit and other indigenous communities and contribute to 
their subsistence. These conditions shall apply at the time or point of import for imported product.264

Article 3.2.B: the placing on the market of seal products shall also be allowed where the seal products 
result from by-products of hunting that is regulated by national law and conducted for the sole purpose 
of the sustainable management of marine resources. Such placing on the market shall be allowed only 
on a non-profit basis. The nature and quantity of the seal products shall not be such as to indicate that 
they are being placed on the market for commercial reasons.265

Article 3 1. Seal products resulting from hunts by Inuit or other indigenous communities may only be 
placed on the market where it can be established that they originate from seal hunts which satisfy all of 
the following conditions: (a) seal hunts conducted by Inuit or other indigenous communities which have 
a tradition of seal hunting in the community and in the geographical region; (b) seal hunts the products 
of which are at least partly used, consumed or processed within the communities according to their 
traditions; (c) seal hunts which contribute to the subsistence of the community.266

As exporters of seal products, Canada and Norway felt their economy could be harmed with this 
European restriction, so, in 2011, they filed a complaint against it at the WTO, under the argument 
that it violated GATT articles I, I, III, 4 and TBT articles 2.1 and 2.2. Of many other arguments, 
the European Union argued that the EU Seal Regime was a measure aimed at protecting European

264 Regulation (EC) No. 1007/2009, article 3.1. Available at: https://eur-lex.europa.eu/legal-
content/EN/TXT/PDF/?uri=CELEX:32009R1007&rid=1
265 Id. supra, article 3.2.B.
266 Commission Regulation (EU) No. 737/2010, article 3.1. Available at: https://eur-
public moral values regarding seal welfare and the socioeconomic interests of the Inuit community

– GATT, XX (a):

7.3. The European Union asserts that the measure is fully consistent with its WTO obligations. The European Union claims that the EU Seal Regime is aimed at addressing public moral concerns on the welfare of seals. The EU Seal Regime is thus not based on conservation concerns. The complainants contest the objective of the measure as put forward by the European Union. According to the complainants, the measure pursues a multiplicity of objectives such as the protection of seal welfare; the protection of the social and economic interests of Inuit or indigenous communities; and the promotion of sustainable marine resource management. Based on its identified objective, the European Union argues that any inconsistencies of the measure under the GATT 1994 should be justified under the general exceptions provisions of the GATT 1994, namely Articles XX(a) and XX(b), because the measure is necessary to protect public morals (regarding the welfare of seals) and to protect seals' health, respectively. Further, the European Union argues that any distinction made under the EU Seal Regime, for instance a distinction based on the type and purpose of the hunt, is legitimate within the meaning of Article 2.1 of the TBT Agreement. The European Union also contends that no other measure can protect its public moral concerns on seals at the same level as does the current Regime. 267

It must be stressed that, for the first time, the European Union makes a clear connection between public moral and the community’s socioeconomic interests. In other words, socioeconomic factors are regarded as a public moral value.

On this issue, Canada and Norway argued that the EU Seal Regime does not fall under GATT’s exception XX (a). Canada specifically argues that article XX (a) requires a moral norm that is a standard of conduct applied throughout the society and broadly accepted in the community, but the European Union does not have a general domestic rule addressing seal welfare, especially commercial hunts related to inhumane practices:

7.627. Canada argues that the EU Seal Regime does not fall within the scope of the protection of public morals. Article XX(a) of the GATT 1994 requires a moral norm that is a standard of conduct applied generally throughout the community or society and broadly accepted within the community. Canada contends that the European Union has not set out a clearly discernible and unambiguous rule of moral conduct, particularly with respect to the claimed distinction between "commercial" and "non-commercial" hunts. The public "concerns" cited by the European Union do not rise to the level of public

267 Panel Report, EC – Seals, para. 7.3
morals, and the idea that the EU Seal Regime addressed public moral concerns rests on a false premise that the commercial seal hunt is inherently inhumane.\textsuperscript{268}

For Norway, the European Union failed to demonstrate that the EU Seal Regime, with the Inuit hunting exception, is necessary to protect the alleged public morals, that is, it is a protectionist measure restricting access to European markets covered by a public moral excuse:

\textsuperscript{7.629} Norway argues that the European Union has failed to meet its burden to show that the violation of the GATT 1994 resulting from the IC and MRM exceptions is necessary to protect public morals. With respect to the arguments of the European Union under Article 2.2 of the TBT Agreement, Norway submits that the legal standards and the allocation of the burden of proof are not the same under Article XX of the GATT 1994 and Article 2.2 of the TBT Agreement.\textsuperscript{269}

\textbf{4.1.2. Judgment}

\textbf{A) Panel}

With regard to the arguments made for GATT, article XX (a), the Panel concluded that the EU Seal Regime constituted a public moral trade restriction. The Panel stated that by designing those regulations, the European Union actually intended to protect public morals regarding seal welfare concerns and the protection of animals, which is an important value or interest:

\textsuperscript{7.631} With this guidance in mind, we begin our analysis by considering whether the European Union's policy objective pursued through the EU Seal Regime falls within the range of policies designed to protect public morals as prescribed in Article XX(a). We recall our conclusion in section 7.3.3.1 that the European Union seeks to address the public moral concerns on seal welfare through the EU Seal Regime. We reached this conclusion by confirming, based on the evidence before us, the existence of the EU public concerns on seal welfare in general and by finding that such concerns are of a moral nature within the European Union. In this connection, we followed the guidance provided by previous panels concerning the scope of the notion "public morals" as stipulated in Article XX(a) of the GATT 1994 and Article XIV(a) of the GATS. In light of these considerations, we find that the policy objective pursued by the European Union ("addressing the EU public moral concerns on seal welfare") falls within the scope of Article XX(a) ("to protect public morals").\textsuperscript{270}

\textsuperscript{268} Id. supra, para. 7.627.

\textsuperscript{269} Id. supra, para. 7.629.

\textsuperscript{270} Id. supra, para. 7.631.
7.632. The European Union submits that the "moral concern with regard to the protection of animals" is regarded as a value of high importance in the European Union. We consider, and the parties do not dispute, that the protection of such public moral concerns is indeed an important value or interest.271

Also, the Panel found that the EU Seal Regime contributes to the European Union’s objective of protecting seals and tackling inhumane hunting practices:

7.637. With respect to the ban aspect of the EU Seal Regime, we recall our earlier finding that the ban does contribute to the European Union’s objective by reducing, to a certain extent, the global demand for seal products and by helping the EU public avoid being exposed to seal products on the EU market that may have been derived from seals killed inhumanely. To the extent that such seal products are prohibited from the EU market979, we find that the ban makes a material contribution to the objective of the measure.272

As to Norway’s claims that the EU Seal Regime was not necessary to achieve this goal, the Panel decided that the alternative options proposed by the complainants were not enough to achieve the objective intended with the measure, thus it was necessary to protect European public morals:

7.639. Based on the assessment above, the EU Seal Regime can be provisionally deemed "necessary" within the meaning of Article XX(a) of the GATT 1994, unless it is demonstrated that the European Union could have adopted a GATT-consistent or less trade-restrictive measure as an alternative to the EU Seal Regime. For the reasons discussed in detail in section 7.3.3.3.4 above, however, we concluded that the alternative measure proposed by the complainants was not reasonably available to the European Union given inter alia the animal welfare risks and challenges found to exist in seal hunting in general. Therefore, we consider that the EU Seal Regime is provisionally deemed necessary within the meaning of Article XX(a) of the GATT 1994.273

The Panel concluded that the EU Seal Regime in fact was a measure to protect public moral as a GATT exception. However, when applying the two-tiered test and checking whether the public

271 Id. supra, para. 7.632.
272 Id. supra, para. 7.637.
273 Id. supra, para. 7.639.
moral exception was arbitrary and discriminatory of GATT article XX chapeau.\textsuperscript{274} the Panel found that the EU Seal Regime failed:

7.645. The focus of the chapeau, according to the Appellate Body, is on the application of a measure already found inconsistent with an obligation of the GATT 1994 but falling within one of the paragraphs of Article XX. Specifically, the existence of one of the three types of situations regarding the application of measures might lead to an inconsistency with the chapeau of Article XX: (a) arbitrary discrimination between countries where the same conditions prevail; (b) unjustifiable discrimination between countries where the same conditions prevail; or (c) a disguised restriction on international trade. We observe that in previous disputes, the first two situations (i.e. arbitrary or unjustifiable discrimination) were often addressed together. We are also mindful of the Appellate Body's guidance that "the fundamental theme – when interpreting the chapeau – is to be found in the purpose and object of avoiding abuse or illegitimate use of the exceptions to substantive rules available in Article XX.\textsuperscript{275}"

The Panel backed its arguments on the rationale that both Inuit and MCM exceptions allowed by the EU Seal Regime create a discriminatory environment with commercial hunts and other countries.

7.650. More specifically, under Article 2.1 of the TBT Agreement, we examined, first, whether the regulatory distinctions drawn between commercial and IC/MRM hunts were rationally connected to the objective of the EU Seal Regime as a whole or otherwise based on justifiable grounds, and, second, whether such distinctions, as reflected in the IC and MRM exceptions under measure, were designed and applied in an even-handed manner among the potential beneficiaries. For the IC exception, given the recognized benefits to Inuit, we found the distinction between commercial and IC hunts (and hence the products regulated based on that distinction) to be justifiable despite the lack of a rational connection to the measure's objective. For the same reasons discussed under the TBT Agreement, however, we find that due to the lack of even-handedness in the design and application of the IC exception, the IC exception does not meet the requirements under the chapeau of Article XX. Regarding the MRM exception, we found that the distinction between commercial and MRM hunts is neither rationally connected to the objective nor based on any justifiable grounds. Further, consistent with our view under the TBT Agreement, the MRM exception is not designed and applied in an even-handed manner and hence is inconsistent with the requirements of the chapeau of Article XX.\textsuperscript{276}

B) Appellate Body

\textsuperscript{274} GATT article XX: “Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures.”

\textsuperscript{275} Panel Report, EC – Seals, para. 7.645

\textsuperscript{276} Id. supra, para. 7.650.
All Parties eventually appealed from the Panel’s decision. Canada and Norway affirmed that the Panel erred in accepting the EU Seal Regime as a public moral as an exception of GATT, XX (a), and the European Union did not agree with the Panel’s judgment that it was a discriminatory/arbitrary measure, not falling within the *chapeau* of article XX.

Canada claimed that the EU Seal Regime was not designed to protect public morals, hence not a GATT exception, arguing that the term "to protect," as established in article XX (a), would imply the existence of risk. Canada used the element of risk from EC – Asbestos case,\(^{277}\) where the DSB concluded that a measure as an exception to protect human, animal and plant health or life (i.e., article XX, (b)) would have to identify a risk.\(^{278}\) In other words, Canada was importing the ruling used for provision (b) exception, from EC – Asbestos, for the provision of (a) of public morals, consequently extrapolating the test set by previous precedents\(^{279}\) concerning article XX, (a):

2.28. Canada appeals the Panel's finding that the EU Seal Regime was designed to protect public morals and therefore falls within the scope of application of Article XX(a) of the GATT 1994. Relying on the Panel report in US – Gambling, Canada notes that the first element of the test under Article XX(a) is to determine whether a given measure is designed "to protect" public morals.\(^{98}\) Canada highlights that the phrase "to protect" is also used in Article XX(b). In EC – Asbestos, the panel observed that "the use of the word 'protection' implies the existence of a risk."\(^{99}\) In Canada's view, "[g]iven the close similarity between Articles XX(a) and XX(b), the interpretive reasoning of the panel in EC – Asbestos is highly relevant to this dispute".\(^{100}\) For these reasons, Canada "extrapolate[s] that the test to be applied" in determining whether a measure falls within the scope of application of Article XX(a) includes three elements: (i) "identification of a public moral"; (ii) "identification of a risk to that public moral"; and (iii) "establishing that a nexus exists between the challenged measure and the protection of the public moral against that risk in the sense that the measure is capable of making a contribution to the protection of that public moral".\(^{280}\)

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\(^{277}\) European Communities — Measures Affecting Asbestos and Products Containing Asbestos.

\(^{278}\) In EC – Asbestos, the Appellate Body stated that "the objective pursued by the measure is the preservation of human life and health through the elimination, or reduction, of the well-known, and life-threatening, health risks posed by asbestos fibres."


\(^{280}\) Appellate Body Report, EC – Seals, para. 2.28
Norway appealed that since both exceptions made by EU Seal Regime, Inuit and MCM, were not regarded by the Panel necessary and being rationally disconnected to protect public morals, those cannot justify the EU seal regime within GATT’s article XX, (a):

[...] By contrast, Norway submits that, under Article XX(a), the Panel was required to assess whether the "discriminatory IC and [M]RM 'exceptions' are 'necessary' to protect EU public morals", and therefore the necessity of the prohibitive ban element and the contribution it makes are "irrelevant" to the analysis under Article XX(a). Since the Panel found that the IC and MRM exceptions are "rationally disconnected" from the public moral concerns, and undermine its achievement, the exceptions cannot be found to be necessary to protect public morals.281 Norway requests the Appellate Body to reverse the Panel's finding that the EU Seal Regime, as a whole, should be provisionally justified under Article XX(a), and to complete the legal analysis to find that the IC and MRM exceptions cannot be provisionally justified under Article XX(a) of the GATT 1994. Specifically, Norway argues that, since the Panel found that the IC and MRM exceptions are not "rationally connected" to the objective of addressing the EU public moral concerns regarding seal welfare, and since the requirements under the two exceptions "counteract and prejudice" the achievement of the EU Seal Regime's objective, the IC and MRM exceptions "could never contribute, much less be 'necessary', to protect the public moral at issue"281

In response, specifically for article XX (a), the Appellate Body decided to uphold the Panel’s judgement, that is, the EU Seal Regime regarded as a public moral measure. This decision is interesting because it shows how the WTO considers the concept of public morals so far. By repeating the Panel’s decision, the Appellate Body confirms the ruling of the US — Gambling precedent, which acknowledged a public moral value as a right or wrong concept with a flexible/dynamic interpretation depending on social, cultural, ethical, and religious factors, even citing it in its decision.282 The Appellate Body did not see any problems in considering the EU Seal Regime as a tool to protect European public morals regarding animal welfare:

281 Id. supra, para. 289.
282 See Panel Report, US – Gambling, para. 6.461: “We are well aware that there may be sensitivities associated with the interpretation of the terms “public morals” and "public order" in the context of Article XIV. In the Panel's view, the content of these concepts for Members can vary in time and space, depending upon a range of factors, including prevailing social, cultural, ethical and religious values. Further, the Appellate Body has stated on several occasions that Members, in applying similar societal concepts, have the right to determine the level of protection that they consider appropriate.904 Although these Appellate Body statements were made in the context of Article XX of the GATT 1994, it is our view that such statements are also valid with respect to the protection of public morals and public order under Article XVI of the GATS. More particularly, Members should be given some scope to define and apply
5.199. For this reason, we also have difficulty accepting Canada's argument that, for the purposes of an analysis under Article XX(a), a panel is required to identify the exact content of the public morals standard at issue. The Panel accepted the definition of "public morals" developed by the panel in US – Gambling, according to which "the term 'public morals' denotes 'standards of right and wrong conduct maintained by or on behalf of a community or nation'". The Panel also referred to the reasoning developed by the panel in US – Gambling that the content of public morals can be characterized by a degree of variation, and that, for this reason, Members should be given some scope to define and apply for themselves the concept of public morals according to their own systems and scales of values. Canada does not challenge these propositions on appeal. In addition, we note that, although Canada indirectly questions the existence of EU public moral concerns regarding seal welfare by contending that the Panel ought to have considered the similarity of animal welfare risks in both terrestrial wildlife hunts and seal hunts, Canada does not directly challenge the Panel's finding that there are public moral concerns in relation to seal welfare in the European Union. 283

Consequently, the Appellate Body denied Canada’s arguments regarding the need of the risk element to invoke article XX (a):

5.200. Finally, by suggesting that the European Union must recognize the same level of animal welfare risk in seal hunts as it does in its slaughterhouses and terrestrial wildlife hunts, Canada appears to argue that a responding Member must regulate similar public moral concerns in similar ways for the purposes of satisfying the requirement "to protect" public morals under Article XX(a). In this regard, we note that the panel in US – Gambling underscored that Members have the right to determine the level of protection that they consider appropriate, which suggests that Members may set different levels of protection even when responding to similar interests of moral concern. Even if Canada were correct that the European Union has the same moral concerns regarding seal welfare and the welfare of other animals, and must recognize the same level of animal welfare risk in seal hunts as it does in its slaughterhouses and terrestrial wildlife hunts, we do not consider that the European Union was required by Article XX(a), as Canada suggests, to address such public moral concerns in the same way. 284

Therefore, the Appellate Body concluded that the European Union’s moral concern regarding protection of animals, especially seals, is a value of high importance for that society. Thus, the EU Seal Regime was necessary to protect this public moral and in fact contributed to achieving this objective, having no other better alternative 285:

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283 Appellate Body Report, EC – Seals, para. 5.199.
284 Id. supra, para. 5.200.
285 Id. supra, para. 5.289: “The foregoing discussion has entailed an extensive assessment of the Panel's analysis of whether the EU Seal Regime is necessary to protect public morals within the meaning of Article XX(a) of the GATT 1994. We have also been called upon to consider claims and arguments by Canada and Norway that were related to
Accordingly, having rejected the claims on appeal by Canada and Norway as they relate to Article XX(a), we uphold the Panel's finding at paragraph 7.639 of its Reports that "the EU Seal Regime is provisionally deemed necessary within the meaning of Article XX(a) of the GATT 1994". Since we have upheld the Panel's finding that the EU Seal Regime is provisionally justified under Article XX(a), we are not called upon to address the European Union's conditional other appeal with respect to Article XX(b).

However, just like the Panel, the Appellate Body also found that although the measure is accepted as a public moral exception given its flexible interpretation granted by previous precedents, it was considered arbitrary and discriminatory, therefore, not within article XX chapeau (i.e., two-tiered test).286 The Appellate Body stated that the Inuit and MCM EU Seal Exceptions constituted means of unjustifiable discrimination between countries and conditions, because the European Union did not demonstrate clearly how Inuit hunting products were treated compared to those from commercial hunts.287

286 Id. supra at para. 5.339: “For these reasons, we find that the European Union has not demonstrated that the EU Seal Regime, in particular with respect to the IC exception, is designed and applied in a manner that meets the requirements of the chapeau of Article XX of the GATT 1994. It follows that the European Union has not justified the EU Seal Regime under Article XX(a) of the GATT 1994.”
287 Id. supra at para. 5.338: “In sum, we have identified several features of the EU Seal Regime that indicate that the regime is applied in a manner that constitutes a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, in particular with respect to the IC exception. First, we found that the European Union did not show that the manner in which the EU Seal Regime treats seal products derived from IC hunts as compared to seal products derived from "commercial" hunts can be reconciled with the objective of addressing EU public moral concerns regarding seal welfare. Second, we found considerable ambiguity in the "subsistence" and "partial use" criteria of the IC exception. Given the ambiguity of these criteria and the broad discretion that the recognized bodies consequently enjoy in applying them, seal products derived from what should in fact be properly characterized as "commercial" hunts could potentially enter the EU market under the IC exception. We did not consider that the European Union has sufficiently explained how such instances can be prevented in the application
Therefore, the Appellate Body eventually found that the EU Seal Regime was creating an unfair trade relation between those parties granted exception benefits (i.e., Inuit communities and some fishers) and those with no benefits.

4.1.3. Findings

Despite European Union not having successfully used the EU Seal Regime as a measure to protect public morals on animal welfare, the EC — Seals case is an extremely relevant precedent.

It reaffirmed the WTO’s ruling on the subject matter of both US — Gambling and China — Audiovisuals, regarding public moral as a country’s notion of right and wrong to preserve the fundamental interests of society, including social, cultural, ethical, and religious factors. In other words, these precedents regard the Public Moral Doctrine as a flexible and adaptive interpretation of what could be a national public moral. As for the element of risk, as claimed by Canada in EC — Seals, the Appellate Body denied this request, by also reaffirming the same doctrine constructed with the past precedents:

of the IC exception. Finally, we were not persuaded that the European Union has made "comparable efforts" to facilitate the access of the Canadian Inuit to the IC exception as it did with respect to the Greenlandic Inuit. We also noted that setting up a "recognized body" that fulfils all the requirements of Article 6 of the Implementing Regulation may entail significant burdens in some instances."
Therefore, for a measure to be acknowledged as a public moral and a GATT exception, it has relatively flexible triggers to activate. However, although all three cases have successfully checked these triggers of article XX (a), they failed the article *chapeau* two-tiered test, being regarded as arbitrary and discriminatory. This happened because the countries applying the restriction measure neither have nor enacted a similar obligation domestically (e.g., US – Gambling), nor have they any rule exceptions creating trade differences between suppliers (e.g., EC – Seals).

This shows that for a country to have a successful trade restriction, based on the public moral exception, it must demonstrate that the restriction really targets a genuine society’s value, already addressed somehow in national laws and demanding the same/similar requirements for both domestic and international suppliers or sellers, without any exceptions. On the good side, this tries to prevent fake and discriminatory trade rules, using a noble argument such as public moral
protection as a legal excuse to disguise green protectionism. On the bad side, some exceptions such as the Inuit exception of the EU Seal regime could be used to benefit indigenous communities and traditional practices.

4.2. EC—Biotech and Precautionary Principle as a Sanitary Measure

The SPS agreement entered into force in 1995 and dictates measures aiming at food safety, animal, human and plant safety, thus phytosanitary measures, which cannot be discriminatory and a disguised restriction to international trade. To avoid this, article 5.6 demands that a measure should not be more trade restrictive than the necessary to achieve the appropriate level of sanitary protection.

To assess if article 5.6 is met (i.e., level of sanitary protection), the DSB established in the Australia – Salmon case a cumulative three-element test: (i) technical and economic feasibility, (ii) appropriate level of sanitary protection and (iii) less restrictive to trade than the SPS measure contested.

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288 2.3. Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

3.2. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.

289 SPS, 5.6: “Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.”

290 Appellate Body Report, Australia, - Salmon, para. 194
In order to ensure the sanitary levels of protection, the SPS agreement is based on risk assessments that use scientific evidence, processes, methods of production, inspection and testing\textsuperscript{291}. If there is no scientific evidence to attest a risk, the SPS agreement permits temporary measures\textsuperscript{292}.

The lack of scientific evidence and data in a certain way translates the Precautionary Principle, which is even recognized in EC – Hormones\textsuperscript{293}. However, EC – Approval and Marketing of Biotech Products (hereafter EC – Biotech) is the WTO dispute case that most addressed this link,\textsuperscript{294} therefore, a relevant case, as it shows how environmental principles are evolving in the context of both the WTO and International Law.

Understanding how Environmental Law Principles are evolving is important because once acknowledged as customary Law, the WTO can use them more easily to interpret trade norms and agreements in case of international disputes, consequently incorporating them into legal decision making.

\textsuperscript{291} 5.1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.

5.2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest — or disease — free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

\textsuperscript{292} Appellate Body Report, EC – Hormones, para. 187

\textsuperscript{293} Appellate Body Report, EC – Hormones, paras. 124 and 125; “[A] Panel charged with determining, for instance, whether "sufficient scientific evidence" exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g., life-terminating, damage to human health are concerned. ... [H]owever, the precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a Panel from the duty of applying the normal (i.e., customary international law) principles of treaty interpretation in reading the provisions of the SPS Agreement.

\textsuperscript{294} Panel Report, EC – Approval and Marketing of Biotech Products, para. 7.3065.
4.2.1. Facts


295 Article 1.1.: “The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment: — when carrying out the deliberate release of genetically modified organisms into the environment, — when placing on the market products containing, or consisting of, genetically modified organisms intended for subsequent deliberate release into the environment. 2. This Directive shall not apply to the carriage of genetically modified organisms by rail, road, inland waterway, sea or air.” Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31990L0220&from=EN

296 Preamble: “(4) Living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers thereby affecting other Member States. The effects of such releases on the environment may be irreversible. (5) The protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release into the environment of genetically modified organisms (GMOs). (6) Under the Treaty, action by the Community relating to the environment should be based on the principle that preventive action should be taken. (7) It is necessary to approximate the laws of the Member States concerning the deliberate release into the environment of GMOs and to ensure the safe development of industrial products utilising GMOs” See also article 1: “Article 1 Objective In accordance with the precautionary principle, the objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment when: — carrying out the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market within the Community, — placing on the market genetically modified organisms as or in products within the Community.” Available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2001L0018:20080321:EN:PDF


298 Article 1 1.: “This Regulation concerns the placing on the market within the Community of novel foods or novel food ingredients. 2. This Regulation shall apply to the placing on the market within the Community of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community and which fall under the following categories: (c) foods and food ingredients with a new or intentionally modified primary molecular structure; (d) foods and food ingredients consisting of or isolated from microorganisms, fungi or algae; (e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use; (f) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.” Available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1997R0258:20090120:EN:PDF
Specifically, Directive 90/220/EEC, article 16.1, allowed a Member State to provisionally prohibit or restrict the use and sale of products regarded as a risk to human health and the environment:

Article 16.1.: "Where a Member State has justifiable reasons to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision."\(^{299}\)

These norms, creating LMO product requirements to enter the European Common Market, were eventually challenged by the United States, Canada and Argentina, all exporters of LMO commodities. The complainants claimed that the European regulations created a *de facto* moratorium on the approvals of new biotech products, since the European Union Member States had allegedly not approved new LMO events since 1998,\(^ {300}\), based on safeguard provisions of regulations 90/220/EEC, 258/97 and 2001/18 (i.e., article 23).\(^ {301}\) A moratorium of biotechnology would be a violation of SPS articles 5.1, 5.5, 5.6, 2.2:

4.175 The general moratorium is also inconsistent with the European Communities' obligation under Article 2.2 of the SPS Agreement. Article 2.2's "sufficient scientific evidence" obligation requires that there be a "rational or objective relationship between the SPS measure and the scientific evidence. The basic obligations provided in Article 2.2 have been viewed as being specifically applied in Article 5.1. Therefore, panels and the Appellate Body have found that where a Member maintains a measure in violation of Article 5.1 – that is, where the measure is not based on a risk assessment as required under

300 Panel Report, EC - Biotech, paras. 4.143 and 4.144: “4.143 Since October 1998 – the last date of a biotech product approval -- the European Communities has failed to approve any new biotech products under its novel foods or deliberate release legislation. The United States submits that this failure to approve all pending applications is the result of a de facto moratorium under which the European Communities has suspended the consideration of applications for, or granting of, approval of biotech products under its pre-market approval system. 4.144 The moratorium became widely known no later than June 1999, when it was announced by Environment Ministers of five member States. In particular, at a Council Meeting of EC Environment Ministers in June 1999, Environment Ministers of Denmark, Greece, France, Italy and Luxembourg issued a Declaration stating: "in exercising the powers vested in them regarding the growing and placing on the market of genetically modified organisms… they will take steps to have any new authorizations for growing and placing on the market suspended."

301 Id. supra, para. 4.152: “Six EC member States – France, Germany, Austria, Italy, Luxembourg, and Greece – have invoked the so-called "safeguard" provisions in Directive 90/220 and Regulation 258/97 with respect to biotech products that have been approved for sale on the European market. Five member States enacted marketing bans (Austria, France, Germany, Italy, and Luxembourg) and one (Greece) enacted an import ban.”
Article 5.1 and Annex A, paragraph 4 – the Member, by implication, “also act[s] inconsistently with its more general obligation in Article 2.2.”

The European Union responded that a moratorium did not exist, since the regulations never mentioned it, but instead a delay of only 27 approvals, because with new regulations, new requirements, and legislative updates to strengthen inadequate risk assessment and risk management were necessary. Also, the European Union affirmed that due to lack of scientific certainty concerning the LMO issue, the suspension safeguards were based on the Precautionary Principle set forth in article 5 of the SPS agreement, backed by the Biosafety Cartagena Protocol, the adequate international treaty regulating the use and management of LMOs.

The complainants argued that even this delay explained by the European Union was also a violation of SPS. The United States, followed by Canada and Argentina, stated that although SPS allows a temporary suspension due to lack of scientific certainty, it cannot cause undue delay as stated in Annex C:

United States on Paragraph 4.164: The European Communities has failed to comply with the requirements of Article 8 and Annex C, paragraph 1(a) of the SPS Agreement. These provisions require that "with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, ... such procedures are undertaken and completed without undue delay ... ."

Argentina on Paragraph 4.657: In its response to the Panel's Question 37, the European Communities is again trying to reduce the claim to a simple question of delays. Argentina strongly objects to this "reductionist" view. Argentina relies heavily on the scientific evidence on which any SPS measure must be based, and this substantive requirement goes far beyond the simple question of undue delay. Both the de facto moratorium and the "suspension and failure to consider" must meet substantive

302 Id. supra, para. 4.175
303 Id. supra, para. 4.582: “The European Communities attempts to rationalize the delays on several grounds, including:
   • The need for legislative changes to strengthen inadequate risk assessment and risk management provisions;
   • The need for legislative changes necessary to comply with the European Communities' other international obligations, such as those under the Biosafety Protocol;
   • The distinction between risk assessment and risk management;
   • The existence of scientific uncertainty; and/or
   • Requests for more information and objections by regulatory authorities”
304 SPS Annex C, article 1.a: “Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that: (a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products;”
305 Id. supra, para. 4.164.
requirements, i.e. the need for scientific evidence, and thus be consistent with Articles 5.1, 2.2, 5.5, 2.3 and 5.6 of the SPS Agreement.306

Therefore, the Panel had to face a major legal issue regarding SPS: whether the regulations caused a moratorium on the approvals of LMOs or whether it was undue delay.

4.2.2. Judgment

A) Panel

It is important to stress that this is the first WTO case addressing LMOs, thus there was a doubt whether this type of biotechnology and its risks could be within the scope of the SPS agreement (i.e., sanitary measures could be applied). The Panel clarified that since most LMOs are plants, their risks, harm and pests, such as possible allergenic effects on human health, do fall under the definition set in provision (c) of Annex I.

As mentioned previously in this study, SPS Annex I (c) defines "sanitary measure," which is applied "to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests."307

Therefore, by acknowledging LMOs as plants that can cause harm to human health, like a pest, the Panel decided that LMOs are a technology subject to sanitary measures regulated by the SPS agreement:

306 Id. supra at para. 4.657
307 SPS Annex I, (c)
7.350 We consider that if interaction with, and exposure to, GMOs other than as or in a food produced allergenic effects in persons, the GMOs in question could be viewed as "pests" within the meaning of Annex A(1). We recall our view that the term "pests" in Annex A(1) encompasses plants which are destructive, or which cause harm to the health of other animals, plants or humans. We also recall our view that allergens may be understood as substances which cause a damaging immune response by the body in humans, and that such immune responses can be very damaging to health, and in some cases may even be fatal, e.g., in the event of an anaphylactic shock. In the light of this, we consider that to the extent a GM plant produces allergenic effects other than as a food, it would be a plant which causes harm to the health of humans and, as such, would qualify as a "pest". We recognize that a GM crop producing this type of allergenic effects would often be cultivated intentionally. From the perspective of the farmer cultivating the GM crop, the GM crop would not, therefore, constitute a "pest." 308

7.361 In light of the above considerations, we are of the view that, of the potential adverse effects of GMOs identified in Annex II of Directive 2001/18, the following falls within the scope of Annex A(1)(c) of the SPS Agreement: "disease to humans including allergenic or toxic effects." 309

Here, the Panel also demonstrated that Annex I does not only specifically encompass LMOs, but is also flexible, as the Panel defined "pest" broadly, meaning not only the strict idea of disease, but also a general harm to human health. Hence, the SPS agreement (i.e., Annex I) can include other new technologies in the future if necessary.

As for the moratorium/delay issue, the Panel rejected the complainants’ arguments about the moratorium. The Panel explained that the stop on the approvals of LMO applications was a failure to act in a timely manner, which is set at Annex C (1), 310 stating that sanitary procedures should be completed without undue delay:

7.1364 […]. However, this potential effect of a procedural decision to delay final approval decisions does not provide sufficient grounds for equating that decision with a substantive decision to ban biotech products. The distinction between substance and procedure is a fundamental legal distinction and we see no justification for disregarding it in this case. Annex C(1)(a) of the SPS Agreement specifically requires Members to complete their approval procedures without undue delay. […]

309 Id. supra, para. 7.361.
310 Annex C, 1: “Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that: (a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products;”
Additionally, the Panel affirmed that the European Union did not take any decisions to ban or halt all LMO applications, which would constitute a moratorium, but rather delayed the approval of some specific products; in other words, a moratorium is general:

7.1379 It is clear from the preceding analysis that we are unable to accept either of the alternative legal characterizations of the general moratorium on approvals which the Complaining Parties have put forward. Accordingly, we confirm the view and conclusion we offered at the beginning of our analysis, namely that the European Communities' decision to apply a general moratorium on approvals should be characterized as a procedural decision to delay final substantive approval decisions. The decision was procedural in nature insofar as it was a decision relating to the application, or operation, of the existing EC approval procedures.

However, despite not characterizing the European directives as a moratorium, but as a delay instead, the Panel decided this delay was unjustifiable. This decision was backed by Annex C (i.e., a sanitary must be completed without undue delay) clarifying that this delay was an unjustifiable loss of time due to its long duration:

7.1496 [...] Thus, what matters is whether there is a legitimate reason, or justification, for a given delay, not the length of a delay as such. Accordingly, if a Member causes a relatively short, but unjustifiable delay, we do not consider that the mere fact that the delay is relatively short would, or should, preclude a panel from finding that it is "undue". Similarly, we do not consider that a demonstration that a particular approval procedure has been delayed by, say, two years would always and necessarily be sufficient to establish that the relevant procedure has been "unduly" delayed. Having said this, we note that a lengthy delay for which no adequate explanation is provided might in some circumstances permit the inference that the delay is "undue".

The Panel goes further, by responding to the European Union’s Precautionary Principle argument, that the delay was caused due to lack of scientific knowledge, not knowing which legislation and assessment updates would be necessary to ensure sanitary safety. The Panel elucidated that, even
though the SPS agreement permits, in article 5.7, provisionary sanitary measures because of insufficient scientific evidence, it cannot be unreasonable. Therefore, if invoked, the provisory measure of article 5.7 must have a definite timeframe.

7.1525 We note in this regard that if relevant scientific evidence were insufficient to perform a risk assessment as defined in Annex A(1) of the SPS Agreement and as required by Article 5.1 of the SPS Agreement, pursuant to Article 5.7 of the SPS Agreement, a Member may provisionally adopt an SPS measure on the basis of available pertinent information. Contrariwise, in situations where relevant scientific evidence is sufficient to perform a risk assessment, a Member must base its SPS measure on a risk assessment. Of course, the mere fact that relevant scientific evidence is sufficient to perform a risk assessment does not mean that the result and conclusion of the risk assessment are free from uncertainties (e.g., uncertainties linked to certain assumptions made in the course of the performance of a risk assessment). Indeed, we consider that such uncertainties may be legitimately taken into account by a Member when determining the SPS measure, if any, to be taken. In view of these uncertainties, a given risk assessment may well support a range of possible measures. Within this range, a Member is at liberty to choose the one which provides the best protection of human health and/or the environment, taking account of its appropriate level of protection, provided that the measure chosen is reasonably supported by the risk assessment and not inconsistent with other applicable provisions of the SPS Agreement, such as Article 5.6. 

7.1523. […] it is clear that application of a prudent and precautionary approach is, and must be, subject to reasonable limits, lest the precautionary approach swallow the discipline imposed by Annex C(1)(a), first clause. Indeed, if a Member could endlessly defer substantive decisions on the grounds of a perceived need for caution and prudence in the assessment of applications, Annex C(1)(a), first clause, would be devoid of any meaning or effect. In applying the provisions of Annex C(1)(a), first clause, it is therefore important always to bear in mind that Annex C(1)(a), first clause, implies as a core obligation the obligation to come to a decision on an application.

Here, it is important to stress that although article 5.7 does not explicitly cite the Precautionary Principle, the Panel makes the link between the Precautionary Principle with the lack of scientific evidence of article 5.7. This is link has already been made by the Appellate Body in the EC – Hormones case, thus the EC – Biotech’s Panel reaffirmed this ruling.

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311 Article 5.7: “7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

312 Panel Report, EC – Biotech, para. 7.1525

313 Id. supra at 7.1523

The Appellate Body further stated that Article 5.7 reflects the precautionary principle, and that the precautionary principle as such has not been written into the SPS Agreement as a ground for justifying an SPS measure that is otherwise inconsistent with that Agreement. The European Communities asserts that each of the safeguard measures at issue in this dispute is based on the precautionary principle. Since we examine below whether the relevant safeguard measures are consistent with the requirements of Article 5.7, in view of the aforementioned statement by the Appellate Body, we see no need separately to examine the European Communities' argument that these measures are based on the precautionary principle.\footnote{Panel Report, EC – Biotech, para. 7.3220.}

As for the Precautionary Principle as a source of International Law, from all WTO precedents, EC—Biotech and EC—Hormones are the ones the most address this topic. The Panel found the Precautionary Principle was a principle of law that should be considered:

\begin{enumerate}
\item[7.76] We have stated earlier that, in our view, the relevant rules of international law to be taken into account include general principles of law. The European Communities contends that the so-called "precautionary principle" is a relevant principle of this kind, and so we address this issue below, after summarizing the Parties' arguments.\footnote{Id. supra, 7.76.}
\item[7.78] The European Communities asserts that the precautionary principle has by now become a fully-fledged and general principle of international law. […]\footnote{Id. supra, 7.78.}
\end{enumerate}

It should be noted that the Panel uses the term "general principle of international law," agreeing with the argument made in the European Union written submission. However, the European Union did not clarify what it meant with it, that is, if it argued it was a principle of Law in general (i.e., \textit{lato sensu}) or a general principle of international law (i.e., \textit{stricto sensu}), as a source of law defined in article 38 of the ICJ Statute.\footnote{Statute of the International Court of Justice, article 38: “The Court, whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply: international conventions, whether general or particular, establishing rules expressly recognized by the contesting states; international custom, as evidence of a general practice accepted as law; the general principles of law recognized by civilized nations;”}

\footnotesize
\begin{enumerate}
\item Panel Report, EC – Biotech, para. 7.3220.
\item Id. supra, 7.76.
\item Id. supra, 7.78.
\item Statute of the International Court of Justice, article 38: “The Court, whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply: international conventions, whether general or particular, establishing rules expressly recognized by the contesting states; international custom, as evidence of a general practice accepted as law; the general principles of law recognized by civilized nations;”
\end{enumerate}
7.86 The Panel notes the European Communities’ contention that the precautionary principle has “by now” become a fully-fledged and general principle of international law. The European Communities has not explained exactly what it means by the term "general principle of international law". We note that this term may be understood as encompassing either rules of customary law or the recognized general principles of law or both.\textsuperscript{257} Given this, we are prepared to consider whether the precautionary principle fits within either of these categories. This approach is consistent with the position taken by the European Communities in EC – Hormones where the European Communities contended on appeal that the precautionary principle was a general customary rule of international law or at least a general principle of law.\textsuperscript{319}

Therefore, again, the Panel turns to the EC – Hormones precedent, deciding that since the issue of whether the Precautionary Principle was already crystalized as a customary or general principle of law, and continued to be subject of debate, it needed further legislative and authority formulation.

Rephrasing it, the WTO maintained an omissive posture on this specific question.

"The status of the precautionary principle in international law continues to be the subject of debate among academics, law practitioners, regulators and judges. The precautionary principle is regarded by some as having crystallized into a general principle of customary international environmental law. Whether it has been widely accepted by Members as a principle of general or customary international law appears less than clear. We consider, however, that it is unnecessary, and probably imprudent, for the Appellate Body in this appeal to take a position on this important, but abstract, question. We note that the Panel itself did not make any definitive finding with regard to the status of the precautionary principle in international law and that the precautionary principle, at least outside the field of international environmental law, still awaits authoritative formulation."\textsuperscript{320}

But this is already extremely positive, as there are WTO precedents clearly demonstrating the ongoing evolution of the Precautionary Principle as an Environmental Law Principle, becoming not only a criterion established in treaties, but also a customary law — Environmental Law principles are evolving to customary law concerning trade disputes.

\textsuperscript{319} Panel Report, EC – Biotech, para. 7.86.
\textsuperscript{320} Appellate Body Report, EC – Hormones, para. 123. See also the Gabčíkovo-Nagymaros Project (Hungary/Slovakia), where the International Court of Justice recognized that in the field of environmental protection "... new norms and standards have been developed, set forth in a great number of instruments during the last two decades. Such new norms have to be taken into consideration, and such new standards given proper weight ...". However, we note that the Court did not identify the precautionary principle as one of those recently developed norms. It also declined to declare that such principle could override the obligations of the Treaty between Czechoslovakia and Hungary of 16 September 1977 concerning the construction and operation of the Gabčíkovo/Nagymaros System of Locks. See, Case Concerning the Gabčíkovo-Nagymaros Project (Hungary/Slovakia), I.C.J. Judgement, 25 September 1997, paras. 140, 111-114.
4.2.3. Findings

The EC — Seals case is unique because it clarified three main issues lacking specific answers regarding the SPS agreement and LMOs: whether LMOs are within the scope of SPS; how a measure is constituted as a moratorium or as a delay; and how the Precautionary Principle is applied to trade disputes.

Concerning whether a SPS measure is a moratorium, the Panel stated it must be general over a whole specific group of technologies or products. On the other hand, a delay in approvals, applications etc. happens randomly, without determining a protectionist pattern — it is simply a failure to act in a timely manner. The SPS agreement permits this, even in case of no scientific evidence; however, this delay cannot be unreasonable, thus the European Union should have created a timeframe and clear deadlines when it suspended the approvals of LMO applications.

The European argument of no scientific evidence delaying legislative updates for LMO approvals made the Panel address the link between the SPS agreement and the Precautionary Principle. The Panel decided that article 5.7 does relate to the Precautionary Principle, reaffirming the previous ruling of EC – Hormones case. Additionally, the Panel repeated this precedent when it addressed how the Precautionary principle is evolving in the context of International Law, which is crystalizing into customary principle, but this discussion needed further legislative and authority formulation. Therefore, the precautionary principle must be taken into account, but not accepted as a customary law yet.
4.3. SEC Analogy Assessment and Findings

Both EC – Seal and EC – Biotech cases have findings which not only can be used to imagine how the WTO would react to a SEC measure, but also what actions a country would have to take when drafting a legislation for it to be a successful SEC rule, not regarded as discriminatory or protectionist.

4.3.1. Public Morals Applied to LMOs

Among all GATT exceptions of article XX, SECs can be more easily regarded as a public moral. As previously discussed, exceptions (b) and (g) are very specific, with determined and restrictive concepts, which would not be appropriate for social and economic impacts of transgenic products.

Regarding provision (b) aiming to protect human, animal, or plant life or health, the WTO’s jurisprudence had already defined these terms. In Thailand — Restrictions on Importation of and Internal Taxes on Cigarettes, the Panel found that article XX (b) refers to a necessary\(^{321}\) measure to protect its public health (i.e., human, animal and plants).\(^{322}\) For article XX (g), regarding the conservation of exhaustible natural resources, in US — Import Prohibition of Certain Shrimp and Shrimp Products, the Panel decided that the term "exhaustible natural resource" should not be limited to mineral or non-living resources. Instead, it should encompass living and renewable

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\(^{321}\) Thailand - Restrictions on Importation of and Internal Taxes on Cigarettes at para 76: “The Panel noted that the principal health objectives advanced by Thailand to justify its import restrictions were to protect the public from harmful ingredients in imported cigarettes, and to reduce the consumption of cigarettes in Thailand. The measures could thus be seen as intended to ensure the quality and reduce the quantity of cigarettes sold in Thailand.”

\(^{322}\) Id. supra, para. 73: “The Panel then defined the issues which arose under [Article XX(b)]. In agreement with the parties to the dispute and the expert from the WHO, the Panel accepted that smoking constituted a serious risk to human health and that consequently, measures designed to reduce the consumption of cigarettes fell within the scope of Article XX(b). The Panel noted that this provision allowed contracting parties to give priority to human health over trade liberalization; however, for a measure to be covered by Article XX(b) it had to be ‘necessary.’
natural resources subject to exhaustion. Thus, none of these two options might be applicable to SECs, unless a clear causation between social economic factors with health is identified in the future.

On the other hand, article XX, (a) seems more promising. As observed in EC — Seal Products, both the Panel and the Appellate Body reaffirmed the US — Gambling ruling, stating public moral as a country’s notion of right and wrong to preserve its society’s fundamental interest, including social, cultural, ethical, and religious factors. These precedents set the Public Moral Doctrine as a flexible and adaptive interpretation of what could be a national public moral.

From this perspective, both SEC definition proposals currently being discussed at the CDB, which are strict (i.e., only socio and economic factors) and broad (i.e., social, cultural, ethical, and religious factors — see Annex 1), can fall within this concept established in GATT article XX (a) and confirmed by the WTO’s precedents. Therefore, both types of SEC legislations already existing in some countries could in theory fall under this GATT exception (e.g., Brazil/strict, and Nigeria/broad) (See Chapter 2).

Although SEC measures are likely to be acknowledged as a public moral trade exception, it does not mean they can be successful. As shown by the respective precedents (i.e., US — Gambling,

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323 United States – Import Prohibition of Certain Shrimp and Shrimp Products, para. 141: "In its general design and structure, therefore, Section 609 is not a simple, blanket prohibition of the importation of shrimp imposed without regard to the consequences (or lack thereof) of the mode of harvesting employed upon the incidental capture and mortality of sea turtles. Focusing on the design of the measure here at stake, it appears to us that Section 609, cum implementing guidelines, is not disproportionately wide in its scope and reach in relation to the policy objective of protection and conservation of sea turtle species. The means are, in principle, reasonably related to the ends. The means and ends relationship between Section 609 and the legitimate policy of conserving an exhaustible, and, in fact, endangered species, is observably a close and real one. In our view, therefore, Section 609 is a measure 'relating to' the conservation of an exhaustible natural resource within the meaning of Article XX(g) of the GATT 1994."
China — Audiovisuals and EC — Seals), despite being accepted as public moral, the measures did not pass the two-tiered text of the *chapeau* of article XX, hence arbitrary and discriminatory restriction.

Either by not truly having a nationally determined value or law (e.g., gambling was allowed in the US, despite its attempt to forbid international electronic gambling) or by making specific legislative exemptions (e.g., European Union exempting Inuit seal hunting from the EU Seal Regime), the WTO finds this lack of balance and equality between national norms and international requirements as discriminatory. Therefore, a SEC measure must not only be considered a public moral exception, but the country requesting it must apply exactly the same SEC demands for LMOs approved both nationally and internationally — with no exemptions or differences.

### 4.3.2. SPS and Risk Assessment with Economic Factors

From all WTO rules, the SPS Agreement is the only one which allows economic factors as part of a risk assessment (i.e., article 5.3).\(^{324}\) Due to this explicit language linking economic factors with sanitary risk assessments, it directly relates to SEC standards.

The WTO first approach to this issue was in Russia — Pigs, recognizing that the assessment of economic factors could occur in situations where there is scientific relevance (article 5.1) and when

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\(^{324}\) SPS, article 5.3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.
there is no scientific evidence (article 5.7). 325 Regarding SECs, this is important, because, for the Cartagena Protocol, it is discussed whether a voluntary SEC assessment (i.e., Cartagena article 26) should be done separately or along with a mandatory risk assessment (i.e., Cartagena article 15). According to this precedent, SECs would become mandatory as part of the risk assessment within the context of the SPS Agreement.

Furthermore, in EC — Biotech, the WTO stated that the "relevant economic factor" of article 5.3 could be financial impacts of diseases within the concepts of Annex A of the SPS Agreement, especially as a "damage", referring to different types of harms resulting from a reduction of economic value. In other words, the SPS Agreement, in theory, could be used to justify sanitary measures of LMOs, which could cause economic loss of properties, sales etc.:

"The residual category of 'other damage' is potentially very broad. In our view, 'other damage' could include damage to property, including infrastructure (such as water intake systems, electrical power lines, etc.). In addition, we think 'other damage' could include economic damage (such as damage in terms of sales lost by farmers). The dictionary defines the term 'damage' as 'physical harm impairing the value, usefulness, or normal function of something' and 'unwelcome and detrimental effects', or 'a loss or harm resulting from injury to person, property, or reputation'. These definitions cover harm resulting in a reduction of economic value, adverse economic effects, or economic loss. Also, interpreting 'other damage' to include economic damage is consistent with the context of Annex A(1)(d). Article 5.3 of the SPS Agreement states that relevant 'economic factors' to be taken into account in a risk assessment include 'the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or a disease'. Thus, Article 5.3 shows that the SPS Agreement elsewhere uses the term 'damage' in an economic sense, and it does so in connection with damage from 'pests'. Thus, Article 5.3 contemplates a similar situation to that contemplated in Annex A(1)(d)." 326

325 Panel Report, Russia – Pigs (EU), para. 7.772: "[I]f a measure is adopted pursuant to Article 5.7 of the SPS Agreement, a Member does not have the obligation to base its provisional measure on an assessment of risk pursuant to Article 5.1. As a consequence, a Member in such situation will not have to take into account the relevant economic factors listed in Article 5.3 for the purposes of assessing the risk to animal or plant life and health. However, even when a Member has adopted a provisional SPS measure pursuant to Article 5.7, it will still have the obligation to take into account, in determining the measure it will apply to achieve its ALOP, the relevant economic factors listed in Article 5.3."

This rationale could be useful to protect small farmers when deciding whether to invest in LMOs, by making sure their crops would not cause any economic loss to the community. The main challenge would be enforcing a feasible assessment to attest the absence of financial harm.

4.3.3. SPS and Evolution of the Precautionary Principle on International Law

EC — Biotech is also a leading case, as it demonstrated how the Precautionary Principle affects the decisions of the WTO. This identifies how environmental principles stated both in declarations as Soft Law and in treaties as Hard Law are evolving to become a customary or general principle of International Law.

This evolution was already acknowledged in the ICJ cases. In the Gabčíkovo-Nagymaros Project case, the ICJ stressed that environmental concerns, such as sustainable development, have a growing importance and the court is willing to accept new International Law principles. As for WTO disputes, the recognition of environmental principles appeared in US — Import Prohibition of Certain Shrimp and Shrimp Products, where the Appellate Body used principle 12 of the Rio Declaration on Environment and Development, which demands collective response to

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328 Separate Opinion of Vice President Weeramantry on page 95.: “In 1992, the Rio Conference made it a central feature of its Declaration, and it has been a focus of attention in all questions relating to development in the developing countries. The principle of sustainable development is thus a part of modern international law by reason not only of its inescapable logical necessity but also by reason of its wide and general acceptance by the global community.”

329 States should cooperate to promote a supportive and open international economic system that would lead to economic growth and sustainable development in all countries, to better address the problems of environmental degradation. Trade policy measures for environmental purposes should not constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade. Unilateral actions to deal with environmental challenges outside the jurisdiction of the importing country should be avoided. Environmental measures addressing transboundary or global environmental problems should, as far as possible, be based on an international consensus.
environmental challenges outside national jurisdiction, hence a source of Soft Law to guide a decision-making process.\textsuperscript{330}

In EC — Hormones and EC – Biotech, the WTO approached the issue more specifically regarding the Precautionary Principle. In both cases, the WTO found that the Precautionary Principle was a principle of law that should be considered in trade disputes since it is a "principle of law," hence demonstrating this evolutionary process of environmental principles being used as sources of law.\textsuperscript{331}

However, when it comes to officially declaring as a customary or general principle of law, as listed in the ICJ Statute regarding sources of International Law, in both cases, the WTO takes an omissive approach, stating that this issue specifically should be further discussed by academics, law practitioners, regulators and judges with more legislative formulation.\textsuperscript{332}

\textsuperscript{330} US — Import Prohibition of Certain Shrimp and Shrimp Products, para. 168: “[…] the protection and conservation of highly migratory species of sea turtles, that is, the very policy objective of the measure, demands concerted and cooperative efforts on the part of the many countries whose waters are traversed in the course of recurrent sea turtle migrations. The need for, and the appropriateness of, such efforts have been recognized in the WTO itself as well as in a significant number of other international instruments and declarations. As stated earlier, the Decision on Trade and Environment, which provided for the establishment of the CTE and set out its terms of reference, refers to both the Rio Declaration on Environment and Development and Agenda 21.”

\textsuperscript{331} Panel Report, EC — Biotech, paras. 7.76 and 7.78: “7.76 We have stated earlier that, in our view, the relevant rules of international law to be taken into account include general principles of law. The European Communities contends that the so-called "precautionary principle" is a relevant principle of this kind, and so we address this issue below, after summarizing the Parties' arguments. 7.78 The European Communities asserts that the precautionary principle has by now become a fully-fledged and general principle of international law. […]”

\textsuperscript{332} Appellate Body Report, EC — Hormones, para. 123: “The status of the precautionary principle in international law continues to be the subject of debate among academics, law practitioners, regulators and judges. The precautionary principle is regarded by some as having crystallized into a general principle of customary international environmental law. Whether it has been widely accepted by Members as a principle of general or customary international law appears less than clear. We consider, however, that it is unnecessary, and probably imprudent, for the Appellate Body in this appeal to take a position on this important, but abstract, question. We note that the Panel itself did not make any definitive finding with regard to the status of the precautionary principle in international law and that the precautionary principle, at least outside the field of international environmental law, still awaits authoritative formulation.”
Even though the Precautionary Principle has not officially been consolidated as customary law yet, this trend continues. Recently, the General Assembly of the United Nations issued Resolution A/76/L.75 of July 26, 2022, recognizing a healthy and sustainable environment as a human right. The General Assembly goes further and affirms that the promotion of human rights and a sustainable environment requires the full implementation of multilateral environmental agreements and other rights of the existing International Law:

Noting also that a vast majority of States have recognized some form of the right to a clean, healthy and sustainable environment through international agreements, their national constitutions, legislation, laws or policies,

1. Recognizes the right to a clean, healthy and sustainable environment as a human right;
2. Notes that the right to a clean, healthy and sustainable environment is related to other rights and existing international law;
3. Affirms that the promotion of the human right to a clean, healthy and sustainable environment requires the full implementation of the multilateral environmental agreements under the principles of international environmental law;
4. Calls upon States, international organizations, business enterprises and other relevant stakeholders to adopt policies, to enhance international cooperation, strengthen capacity-building and continue to share good practices in order to scale up efforts to ensure a clean, healthy and sustainable environment for all.333

Thus, the General Assembly of the United Nations is indicating that environmental principles are indeed becoming a customary law accepted by most countries, which should be used in connection with other areas of the International Law, and trade is one of them.

The evolution of environmental principles is a broader agenda that can be used for not only SEC measures, but in any environmental dispute at the WTO, assisting the DSB to take decisions by using other treaties and concepts of Environmental Law for a better interpretation of the cases. For instance, the discussions regarding the Carbon Border Adjustment Mechanism (CBAM) can impact trade and become a WTO dispute. In short, the CBAM is a tool expected to counteract

carbon leakage (i.e., when industries with high greenhouse gas emissions move production from a determined jurisdiction to jurisdictions with lower climate policy standards). Accordingly, a country can demand that international manufacturers and importers buy CBAM certificates to cover a price difference coming from national cap and trade allowances. In theory, this trade requirement would boost climate neutrality.\textsuperscript{334}

This toll is currently under discussion in the European Union as part of its new European Green Deal, which sets out a clear path towards realizing the EU’s ambitious target of a 55% reduction in carbon emissions by 2030, compared to 1990 levels, and to become a climate-neutral continent by 2050.\textsuperscript{335}

Therefore, SECs will not be the only possible environmental requirement for trade relations, but others such as CBAM, showing that the environment will share a common agenda with trade, especially at the WTO. Also, the evolutionary process of environmental principles becoming a customary law is unavoidable.

Concluding this chapter, the precedent analysis showed SEC can be regarded as a public moral exception for GATT. On this perspective, the GATT exception can even be used for other environmental trade restrictions, since it has a more broad and flexible interpretation (i.e., evolutionary interpretation) if compared the other GATT article XX exception (b) for human, animal, and plant health; and exception (g) for natural exhaustible resources. In addition, the


\textsuperscript{335} See https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_3661
precedents demonstrated the Precautionary Principle’s implicit on the SPS’s article 5.3 text, which according to WTO Panels and Appellate Body although not part of trade agreements, must be also taken into account by DSB as a source of law.
CHAPTER 5

5. Conclusions

Although the socio-economic impacts of LMOs, especially within the WTO context, are an uncharted subject, this study managed to draw some conclusions and findings on its related issues.

Initially, it demonstrated that some countries already have national biosafety laws that set out the prerogative to request socio-economic assessments for the approval of LMOs. Some regulations already apply a stricter concept of SECs that only include social and economic factors, such as Brazil, and others apply a broader concept that also involve religious, ethical, and cultural factors, such as Nigeria.

Regarding whether LMOs actually improve the income and livelihood of small farmers and communities, there are not many specific studies on the subject. FAO\textsuperscript{336} has some studies demonstrating that micropropagation biotechnology in Africa improves income, allowing farmers to spend more on health and education. Specifically, for LMOs, Brazil has a 20-year study showing that Brazilian farmers also had their incomes increased by using transgenic crops.\textsuperscript{337} However, these initial assessments are not enough to ensure this finding for every approved LMO product, thus SECs are decisive to clarify this issue.

\textsuperscript{336} Andrea Sonnino, Zephaniah Dhlamini, Fabio Maria Santucci, Patrizio Warren, Food and Agriculture Organization of the United Nations (FAO) study Socio-Economic Impacts of Non-Transgenic Biotechnologies in Developing Countries – The case of plant micropropagation in Africa. Rome 2009. Available at: http://www.fao.org/3/i0340e/i0340e00.htm

\textsuperscript{337} 20 anos de transgênicos: impactos ambientais, econômicos e sociais no Brasil, Conselho de informações sobre Biotecnologia, Agroconsult, 2018. Available at: https://agroavances.com/img/publicacion_documentos/153575459920-anos-de-transgenicos-no-brasil.pdf
As for SECs as a trade requirement compatible with WTO rules, this work assessed WTO’s three main agreements: GATT, TBT and SPS. As for GATT, from all three possible environmental trade exceptions of article XX (i.e., (b), (c) and (a)), it is more likely that SECs are regarded as public moral.

Based on WTO’s precedents, a public moral has a more flexible interpretation, in that it must reflect a society’s values of right and wrong, including religious, ethical, and cultural factors, as seen in US – Gambling and EC – Seals cases. For SECs, this is more adequate, as a concern with the social and economic impacts of LMOs seems more a public moral than a protection of exhaustible resources or human health. Also, the WTO precedents shows that SECs would fit within both proposed definitions being discussed — the strict definition, and the broad one, including religious, ethical, and cultural factors.

SECs could also be regarded as a sanitary measure within SPS. WTO’s EC — Biotech case shows that LMOs are subject to sanitary measures, since they are plants which can cause disease. This case also explains that sanitary measures can have economic assessments, as stated in SPS article 5.3, due to the potential of a sanitary damage of a LMO to cause financial loss. Therefore, as opposed to the Cartagena Protocol, which defines SECs as a voluntary instrument, for SPS, it can be mandatory.

Although they can be regarded as trade exceptions, in all assessed cases, the measures fail to prove they were not discriminatory and arbitrary. All countries that imposed environmental restrictions on trade did neither have similar requirements domestically nor created exemptions for some
groups, processes, or specific technologies. For a SEC and an environmental requirement to be legal, it must be general (nationally and internationally), not benefiting a group or technology, but focusing on the environment or moral itself.

The EC — Biotech case also mentions the Precautionary Principle. For its Panel, SPS article 5.7, referring to the lack of scientific evidence, connects with the Precautionary Principle, which is an Environmental Principle stated in declarations and some treaties, but not yet a custom or a general principle of International Law. The Panel does not define it as customary law, leaving it for future debate.

The evolutionary process of Environmental Principles becoming a customary law is ongoing for a while. It started at the ICJ, with Hungary v. Slovakia, where the case rulings stated that environmental concerns should be taken into account. Afterwards, this could also be found in the WTO decisions, such as US — Import Prohibition of Certain Shrimp and Shrimp Products, EC — Hormones and EC — Biotech. In these cases, the WTO uses the Rio Declaration’s principles, however, it does not conclude that they constitute a custom.

Acknowledging Environmental Principles as customary law is relevant because crystallizing environmental concerns into a global custom will not only strengthen national laws but will also impact trade. When deciding a commercial dispute, the WTO must interpret trade rules and agreements, and use customary rules of interpretation of Public International Law and, exceptionally, nontrade treaties. By setting Environmental Principles as customary law, the WTO will directly incorporate the environmental agenda into its decision-making process.
In this respect, SECs, as well as other environmental commercial requirements like the Carbon Border Adjustment Mechanism, can help to crystalize environmental principles into a custom or general principle of International Law.

To conclude, this work demonstrated that SECs can be a feasible instrument to clarify the financial advantages or disadvantages of LMOs, consequently benefiting small farmers and communities, with the potential of becoming a successful trade requirement within the WTO. Additionally, it can be one more decisive element to elevate environmental principles to the level of customary law, which is an unstoppable process.
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UNEP-UNCTAD Capacity Building Task Force on Trade and Environment and Development and IFOAM-FAO-UNCTAD International Task Force on Harmonization and Equivalence in Organic Agriculture
ANNEX 1

CBD

Convention on Biological Diversity

CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY SERVING AS THE MEETING OF THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY
Ninth meeting
Sharm El Sheikh, Egypt, 17-29 November 2018
Item 18 of the provisional agenda

SOCIODEMOMIC CONSIDERATIONS (ARTICLE 26)

Note by the Executive Secretary

1. INTRODUCTION

1. In the Strategic Plan for the Cartagena Protocol on Biosafety (2011-2020), socio-economic considerations are addressed under operational objective 1.7: “To, on the basis of research and information exchange, provide relevant guidance on socio-economic considerations that may be taken into account in reaching decisions on the import of living modified organisms”. One of the outcomes under this objective refers to “Guidelines regarding socio-economic considerations of living modified organisms developed and used, as appropriate, by Parties”.  

2. At its sixth meeting, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety decided to establish an Ad Hoc Technical Expert Group on Socio-Economic Considerations (AHTEG) to develop conceptual clarity in the context of paragraph 1 of Article 26 of the Protocol (decision BS-VII/13).  

3. At its seventh meeting, the Conference of the Parties serving as the meeting of the Parties decided to extend the AHTEG to work in a stepwise approach on (a) the further development of conceptual clarity and (b) developing an outline for guidance with a view to making progress towards achieving operational objective 1.7 of the Strategic Plan and its outcomes (decision BS-VII/13).  

4. At its eighth meeting, the Conference of the Parties serving as the meeting of the Parties noted with regret that a face-to-face meeting of the AHTEG could not be held during the inter-sessional period due to a lack of funds and that as a consequence, certain elements of the AHTEG’s mandate could not be addressed. The meeting of the Parties took note of the revised Framework for Conceptual Clarity and decided to extend the mandate of the AHTEG to allow it to meet face-to-face to work on the guidelines envisaged under the outcomes for operational objective 1.7 of the Strategic Plan for the Protocol. The AHTEG was requested to submit a report for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its ninth meeting (decision CP-VIII/13).

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1 See UNEP/CBD/BSCOP-MOP/8/13, annex. The revised Framework for Conceptual Clarity was prepared through an online discussion held from 9 May to 17 June 2016. The discussion was held to enable the AHTEG to undertake certain aspects of its mandate.
II. MEETING OF THE AD HOC TECHNICAL EXPERT GROUP ON SOCIO-ECONOMIC CONSIDERATIONS

6. The AHTEG on Socio-economic Considerations held its face-to-face meeting in Ljubljana, from 9 to 13 October 2017 following an offer to host the meeting by the Government of Slovenia and the financial support of the European Union and the Governments of Finland, France and the Netherlands. The meeting was co-chaired by Mr. Andreas Heissenberger (Austria) and Ms. Ranjini Warrier (India). The meeting was attended by 23 experts from the following Parties: Austria; Belarus; Bolivia (Plurinational State of); Brazil; China; Dominican Republic; European Union; France; Germany; Honduras; Hungary; India; Mauritania; Mexico; Niger; Nigeria; Norway; Philippines; Republic of Korea; Republic of Moldova; Slovenia; South Africa; and Thailand. It was also attended by five experts from the following observer countries and organizations: Canada; Third World Network; Global Industry Coalition; GENOK – Centre for Biosafety; and International Indigenous Forum on Biodiversity.²

7. As per paragraph 2 of decision CP.VIII/13, the AHTEG was mandated to work on the guidelines envisaged under the outcomes for operational objective 1.7 of the Strategic Plan for the Protocol.

8. The outcomes of the deliberations of the AHTEG in response to its mandate are set out in paragraphs 8 to 16 of its report,¹ reproduced below. The draft “Guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety”, agreed to by the AHTEG, is provided in annex II of the report of the AHTEG, and has been reproduced in the annex to the present note.

9. The following is a verbatim excerpt from the Report of the Ad Hoc Technical Expert Group on Socio-economic Considerations, under item 3:

8. Under this item, the Co-Chairs introduced the text entitled “Draft guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety” (CBD/CP/SEC/AHTEG/2017/1/2, annex). The Co-Chairs provided further information on the development of the text, which they had prepared to facilitate the discussions of the AHTEG. They explained that the document was based on previous outcomes of the work of the AHTEG, in particular the “Revised Framework for Conceptual Clarity”, which had been noted by the Conference of the Parties serving as the meeting of the Parties to the Protocol in decision CP.VIII/13 and also taking into account information provided during the online discussion of the AHTEG. They also explained that submissions made in response to notification 2017-39 as well as other existing guidance documents made available on the Portal on socio-economic considerations had been considered in drafting the Co-Chairs’ text.

9. Mr. Heissenberger further indicated the Co-Chairs had chosen to follow a process-based approach in the document, i.e. to focus on how an assessment could be performed, rather than focusing on parameters to be assessed, as the latter highly depended on regional and national circumstances.

10. The AHTEG considered the Co-Chairs’ text and agreed that the process-based approach in the Co-Chairs’ text was a constructive way forward.

11. The AHTEG elaborated the assessment process contained in the document and revised the sections on “introduction and objective” as well as the “principles for the assessment of socio-economic considerations.”

12. During the deliberations, some experts proposed including language on the precautionary approach in the Co-Chairs’ text. While agreeing on the importance of the issue.

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² The list of participants is contained in annex I of the report of the meeting.

¹ The report was made available as CBD/CP/SEC/AHTEG/2017/1/3.
other members did not agree to include that language, as they felt that the precautionary principle addresses decision-making while the Guidance focuses on the process for conducting a socio-economic assessment.

13. Furthermore, an expert did not support the inclusion of the examples in the list of areas that can be encompassed by the assessment.

14. Following extensive deliberations, the AHTEG agreed on the draft “Guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety”, as contained in annex II below.

15. The AHTEG recommended that the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its ninth meeting:

   (a) Consider the report of the meeting, including the draft “Guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety”, as contained in annex II;

   (b) Invite Parties and other Governments to make use, if applicable, of the “Guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety”.

16. The AHTEG noted that further work was needed to supplement the “Guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety”, in particular on the application of methodologies and examples of application of socio-economic considerations, and recommended that the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its ninth meeting:

   (a) Invite Parties, other Governments and organizations to submit examples of methodologies and applications of socio-economic considerations in the light of the elements of the “Guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety” and request the Executive Secretary to compile the information submitted;

   (b) Consider the utility of extending the mandate of the AHTEG to supplement the “Guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety” making use of the information submitted.

III. SUGGESTED ELEMENTS FOR A DRAFT DECISION

10. The Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to consider the report of the AHTEG, including the recommendations in paragraphs 15 and 16, as well as the draft “Guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety” and adopt a decision along the following lines:

   Recalling decisions BS-VI/13, BS-VII/13 and CP-VIII/13.

   1. Welcomes the “Guidance on the Assessment of Socio-Economic Considerations in the Context of Article 26 of the Cartagena Protocol on Biosafety”;  

   2. Invites Parties and other Governments to make use of the “Guidance on the Assessment of Socio-Economic Considerations in the Context of Article 26 of the Cartagena Protocol on Biosafety”, as appropriate;

   3. Invites Parties, other Governments and organizations to submit examples of methodologies and applications of socio-economic considerations in the light of the elements of the “Guidance on the
Assessment of Socio-Economic Considerations in the Context of Article 26 of the Cartagena Protocol on Biosafety” and requests the Executive Secretary to compile the information submitted;

4. **Decides** to extend the Ad Hoc Technical Expert Group on Socio-Economic Considerations with a mandate to supplement the “Guidance on the Assessment of Socio-Economic Considerations in the Context of Article 26 of the Cartagena Protocol on Biosafety” with examples of methodologies and applications of socio-economic considerations, taking into account the information submitted in response to paragraph 3 above, for consideration by the tenth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol;

5. **Requests** the Executive Secretary, subject to the availability of resources, to convene a face-to-face meeting of the Ad Hoc Technical Expert Group on Socio-Economic Considerations.
Annex

GUIDANCE ON THE ASSESSMENT OF SOCIO-ECONOMIC CONSIDERATIONS IN THE CONTEXT OF ARTICLE 26 OF THE CARTAGENA PROTOCOL ON BIOSAFETY

Introduction and objective

Article 26, paragraph 1, of the Cartagena Protocol on Biosafety states: “The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.”

Parties have a right to take into account socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, although Article 26 does not impose an obligation on Parties to do so.

This document is aimed at providing guidance on the process for assessing socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous peoples and local communities. The document also provides an operational definition and lists important principles for the process of assessing socio-economic effects.

Operational definition

Socio-economic considerations in the context of Article 26 of the Cartagena Protocol may, depending on national or regional circumstances and on national measures to implement the Protocol, cover economic, social, cultural/traditional/religious/ethical aspects, as well as ecological and health-related aspects, if they are not already covered by risk assessment procedures under Article 15 of the Protocol.

Principles for the assessment of socio-economic considerations

If a Party chooses to take socio-economic considerations into account, then there are certain aspects of an assessment of socio-economic effects which should be considered:

1. Taking socio-economic considerations into account in decision-making on the import of living modified organisms must be consistent with relevant international obligations, which include, inter alia, trade agreements, environmental agreements and human rights agreements.

2. Taking socio-economic considerations into account in decision-making on the import of living modified organisms should be consistent with existing national regulatory frameworks and policies.

3. In taking into account socio-economic considerations, Parties should consider their local and national circumstances, priorities and needs as well as, if applicable, regional circumstances, priorities and needs. Such circumstances, priorities and needs could include different cultural practices and religious beliefs and practices as well as indigenous, traditional and local knowledge and practices, in particular those related to the value of biological diversity to indigenous peoples and local communities.

4. The assessment process of socio-economic considerations should be science-based and evidence-based and lead to defensible results.

5. Lack of knowledge, scientific consensus or information on socio-economic effects should not necessarily be interpreted as indicating a particular positive or negative effect, or an absence of an effect.

6. The assessment of socio-economic considerations and the risk assessment may be conducted concurrently, consecutively or in an integrated manner, as applicable. Planning and conducting a risk assessment and an assessment of socio-economic considerations may be complementary and both may contribute to the decision-making process.
CBD/CP/MOP/9/10

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7. Article 23 of the Protocol creates obligations regarding public awareness, education and participation. Public participation and consultation, and access to information, may form part of the process of taking socio-economic considerations into account.

8. Where required by national regulatory frameworks, the assessment of socio-economic considerations should involve indigenous peoples and local communities, including obtaining their free, prior and informed consent for participation in the assessment, and their views on any potential introduction of the living modified organism into their territories, taking into account customary laws and community protocols.

9. The results of any assessment of socio-economic considerations associated with a decision on the import of living modified organisms may be subject to a review in the light of new relevant information or knowledge or a change in national policy or protection goals.

The overall assessment process

The principles identified above apply throughout the assessment process. The assessment of socio-economic considerations should follow, like any other impact assessment, a systematic approach. This approach could include the following:

Stage A: Preparation for assessment

Stage B: Assessment and evaluation

   Step 1: Scoping

   Step 2: Assessment

   Step 3: Evaluation of results and drawing conclusions

Stage C: Review and monitoring

The stages and steps, which set out an iterative process, are elaborated below.

Stage A: Preparation for assessment

This stage is meant to take stock of existing information and instruments and identify the actors to be involved in the assessment process. This stage is led by regulators and may include the involvement of stakeholders that may be engaged through consultative processes. The following activities may be carried out in the preparatory stage:

(a) Identifying relevant national legal and policy instruments, as well as responsibilities, protection goals and socio-economic objectives, taking into account regional and international policy and legal instruments;

(b) Deriving nationally relevant protection goals from regional and international instruments, in particular those provided in the Cartagena Protocol on Biosafety and the Convention on Biological Diversity, where national protection goals are absent;

(c) Identifying how national protection goals relate to socio-economic objectives;

(d) Determining what information is needed to carry out the assessment as a basis for identifying what information is available and what information is missing;

(e) Identifying relevant actors to be involved in the assessment, including outlining information flows between different actors and determining mechanisms for public participation, paying due regard to applicable requirements concerning free, prior and informed consent.
Stage B: Assessment and evaluation

Step 1: Scoping

This step is aimed at framing and defining the boundaries of the assessment based on the elements identified in Stage A. Scoping is led by regulators.

Based on a problem statement, possible socio-economic effects can be identified for consideration in the assessment. The assessment can encompass the following areas, as appropriate:

- Economic: e.g. effects on income;
- Social: e.g. effects on food security;
- Ecological: e.g. effects on ecosystem functions;
- Cultural/traditional/religious/ethical: e.g. effects on seed saving and exchange practices;
- Human health-related: e.g. effects on nutritional status.

In determining the boundaries of the assessment, the following could also be considered:

- Uses of the living modified organism (e.g. intended, expected);
- Alternatives to address the stated problem;
- Time scale;
- Geographical scale;
- Level of assessment (e.g. macro- or microeconomic, farm-scale, whole supply chain);
- Direct and/or indirect effects;
- Relevant stakeholders.

As the scope of the assessment highly depends on the national or regional circumstances and on national measures implementing the Protocol, it may vary considerably, but should in any case be determined at the beginning of the assessment in order to ensure the credibility and transparency of the process.

Step 2: Assessment

In this step, the possible effects identified in the scoping step are assessed. The assessment may be led by regulators, or by assessors or by a combination of both and may include the involvement of stakeholders that may be engaged through consultative processes. The assessment of socio-economic effects can be carried out ex ante, ex post or both.

i. Methodology and data

A wide array of methodological approaches is available to assess socio-economic effects, including both quantitative and qualitative methods, as well as participatory approaches. Each method has strengths and limitations; therefore, a combination of different methods may be used, as appropriate. Factors which may influence the choice of the assessment include:

(a) Information needs of decision makers;
(b) Data availability (e.g. baselines and data linked to the context of introduction and use of the living modified organism);
(c) Data sources (e.g. those derived from reports, literature, statistics, surveys and consultations as well as traditional, indigenous and local knowledge);
(d) Available assessment capacities.

Methods chosen should be science-based and evidence-based, or be based on other accepted approaches where scientific methods are not applicable, subject to national practices and requirements. Assessment methods should be reliable and applied in a transparent and verifiable manner and may be based on a comparative approach.

ii. Aspects of the assessment
The assessment of socio-economic effects may cover the following aspects:

- Relation between the impact of the living modified organism and the socio-economic effects;
- Beneficial or adverse nature of the effects;
- Likelihood of effects to occur;
- Intensity or magnitude of the effects;
- Possible downstream and cumulative effects;
- Reversibility of the effects;
- Mitigation of the effects;
- Effects on different communities and groups, in particular vulnerable or marginalized groups and indigenous peoples and local communities;
- Anticipated onset and duration of the effects (e.g. sustainability and persistence).

**Step 3: Evaluation of results and drawing conclusions**

The evaluation of results is meant to analyse the assessment outcomes in an integrated manner, taking into account the context of the introduction of the living modified organism. Based on the evaluation, conclusions are drawn which can be used in decision-making. This step is led by regulators.

The evaluation of assessment outcomes may be based on the following:

- Significance of evaluated effects;
- Distribution of effects among stakeholders;
- Limitations of the applied methods;
- Uncertainties;
- Comparison with available alternatives to the living modified organism;
- Validity of claimed benefits and harms.

Based on the evaluation, conclusions are drawn which can be used in decision-making. In the evaluation process, needs for additional information may be identified, and they have to be clearly stated in the final report.

The evaluation results could be presented to stakeholders for feedback. Feedback received from stakeholders should be included in the final report.

The final report should be submitted to decision makers for consideration.

**Stage C: Review and monitoring**

Review refers to the re-evaluation of the assessment outcomes in the light of new relevant information or knowledge, or a change in national policy or protection goals. Review is led by regulators.

Monitoring refers to the process of observing socio-economic effects of the living modified organism concerned over time. Monitoring may be led by assessors, regulators or a combination of both, according to the national regulatory framework. If monitoring is conducted, the findings may feed into a review process.