

The Burden of Proof in WTO Public Health Protection Disputes

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Abstract

The relationship between international trade and public health is complex. The accessibility of a diverse range of goods and services brings opportunities for health improvement. Meanwhile, there are risks of disease transmission. The WTO provides a framework for managing trade-related public health concerns, such as the GATT 1994, SPS, TBT, and TRIPS Agreements. In disputes involving public health measures that restrict trade, the burden of proof lies on the party seeking to justify the measure, requiring scientific evidence. The burden of proof can shift to the defending party, who may also present evidence in defense of their measure. There are many challenges to the necessity of protecting public health, including legal uncertainty, balancing necessity and trade interests, and the burden of proof for non-arbitrary discrimination. It also discusses the cost imbalance in presenting evidence and the lack of sufficient evidence for discrimination. The author suggests ways forward for developing standardized frameworks for assessing trade restrictions, harmonizing public health and trade standards, increasing cooperation, addressing the misuse of exceptions and trade barriers, and strengthening scientific expertise within WTO panels and dispute resolution bodies.

Keywords: Burden of Proof, Public Health Protection, WTO, Necessary, Arbitrary or Unjustifiable Discrimination, Scientific Evidence

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1. Introduction

Public health protection is a critical global concern that requires a delicate balance between promoting free trade and preventing discriminatory practices within the WTO system. Conflicts often arise when trade rules and public health objectives clash, raising significant legal and policy challenges. The WTO agreements, including the GATT 1994, the SPS Agreement, the TBT Agreement, and the TRIPS Agreement, have implications for public health protection measures. The allocation of the burden of proof in disputes related to public health protection, the necessity of measures, and non-arbitrary discrimination. This is a critical aspect that requires thorough analysis and understanding. This article also explores the relationship between scientific evidence and policy decisions, the standard of review for scientific evidence and the challenges involved in using scientific evidence in public health policies.

Obtaining sufficient evidence is essential for addressing non-arbitrary or unjustifiable discrimination in trade disputes. The WTO dispute settlement system plays a crucial role in this regard, requiring countries to provide clear and convincing evidence to substantiate their claims of discrimination. Sufficient evidence can take various forms, including economic analyses, scientific studies, expert opinions, or documentation of specific instances of discriminatory practices. In the case of sanitary and phytosanitary measures, the WTO's SPS Agreement stipulates those countries must base their measures on scientific evidence to justify trade restrictions. Provisional measures can be adopted in the absence of conclusive scientific evidence, but they must be reviewed and based on the available pertinent information.¹

The problems in the interpretation and application of the necessity test in the TBT Agreement are unclear, leading to legal uncertainty and inconsistencies in rulings. This lack of clarity makes it difficult for WTO Members to determine the compliance of their measures and poses challenges in designing and implementing policies that address public health concerns. Clarifying the necessity test is crucial to enhance the predictability and stability of the multilateral trading system² and promote a better understanding of the test's implications for other WTO agreements.

The WTO may face challenges in formulating a precise definition of the burden of proof and determining the appropriate standard of proof given the varying facts and circumstances of each case. However, WTO dispute settlement panels possess the authority to establish the general nature of the circumstances that constitute a prima facie case. Panels can choose to interpret prima facie based on its literal meaning, ensuring fairness to all parties and ending the current practice of issuing decisions solely based on thorough evidence analysis.

¹ WHO and WTO, A joint study by the WHO and the WTO Secretariat, *WTO Agreements & Public Health* (2002), 37.

² Gisele Kapterian, "A Critique of the WTO Jurisprudence on Necessity," *International and Comparative Law Quarterly Journal* 59, no.1, (2010): 89.

2. WTO Agreements Concerning Public Health Protection

As of September 2023, the World Trade Organization (WTO) comprises 164 members,¹ encompassing both industrialized nations and most developing countries.² Serving as a multilateral international body, the WTO assumes the responsibility of creating, regulating, and managing trade between nations. Its core objectives include providing a negotiation forum, resolving disputes, and conducting trade policy reviews. The WTO functions as a negotiation forum where member governments convene to address trade-related matters.³ In this capacity, the organization establishes a comprehensive set of rules that member states are obliged to comply with. These rules are encapsulated in the WTO agreements, which have been meticulously negotiated and ratified by the world's trading nations.⁴ These agreements serve as the legal framework governing international commerce, effectively binding governments to uphold specific trade policies and regulations. While the negotiation and ratification by governments, their ultimate purpose extends far beyond administrative formalities. The primary goal of the WTO is to facilitate the smooth, predictable, and unimpeded flow of trade.⁵

However, it is undeniable that the accessibility of a diverse range of goods and services for consumers brings both opportunities for health improvement and risks of disease transmission. The WTO agreements pertaining to the protection of public health have both positive and negative implications for global health governance. On one hand, these agreements provide a framework for addressing trade-related public health concerns and foster cooperation among member states. They also establish mechanisms for resolving trade disputes related to public health measures. On the other hand, concerns have been raised regarding potential conflicts between trade rules and public health objectives, particularly in areas such as access to affordable medicines and the preservation of public health measures.

2.1 The Relationship between International Trade and Public Health

Trade has been present in human societies since ancient times, but the establishment of treaties regulating trade between nations is a recent phenomenon. Following World War II, negotiations for international trade rules began, culminating in the WTO in 1995.⁶ WTO agreements introduced principles, tariff reduction schedules, dispute settlement rules, and agreements covering services, intellectual properties, agriculture and non-tariff trade barriers. WTO-Plus bilateral⁷ and regional trade and investment agreements complicate these rules, providing foreign investors with additional options to challenge new government health measures intended to safeguard public or environmental health.

Public health and international trade are inextricably linked, and their relationship has profound implications for global health outcomes. While trade can promote economic growth, enhance access to essential health-related goods and services, and facilitate knowledge sharing and collaboration, it also presents potential risks,⁸ such as the spread of diseases, environmental degradation, and inequalities in health outcomes. These factors should be considered when evaluating the overall impact of trade on public health.

2.2 The WTO Agreements Relevant to Public Health Protection

In 2002, the WHO and WTO Secretariat conducted a study on WTO agreements and public health, focusing on eight key health issues⁹ affecting national policymakers. WTO agreements have far-reaching implications for various sectors, including public health. Several WTO legal agreements and measures are relevant to public health protection and this research focuses on four agreements: GATT, SPS, TBT and TRIPS as follows:

1) General Agreement on Tariffs and Trade (GATT), The GATT 1994 served as a foundation for the World Trade Organization (WTO), which governs the rules and regulations of global trade. Its provisions on non-discrimination, reduction of trade barriers, dispute settlement, and trade and development have far-reaching implications for various sectors, including public health. Aimed to create a level playing field for domestic and foreign producers, promote free and fair trade, and integrate developing countries into the global trading system. Its establishment of a dispute settlement mechanism played a vital role in enforcing the principles of non-discrimination and fair trade, enhancing the stability and predictability of the global trading system, which Article XX(b) is a provision that allows member countries to adopt measures necessary to protect human,

¹ wto.org, Understanding the WTO: The Organization, Members and Observers, available at https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm last visited on 2 September 2023.

² Peter Norgaard Pedersen, 'The WTO decision-making process and Internal Transparency, World trade review, vol.5, issue.1, (2006), p.103.

³ WTO (2015), 'understanding World Trade organization', 5th edition Geneva, p.9.

⁴ Semon Lester et al. (2018), World trade law: text materials and commentaries', third edition, Hart publisher, London, p.63.

⁵ WTO (2015), 'understanding World Trade organization, Loc.cit.

⁶ John H. Jackson, *The World Trading System: Law and Policy of International Economic Relations*. (The MIT Press Publishing, 1997)

⁷ Deborah Gleeson, Ronald Labonte, "Trade Agreements and Public Health: A Primer for Health Policy Makers, Researchers and Advocates," *Foreign Investment Law Journal* 35, no.3, (2020): 7.

⁸ WHO and WTO, *WTO Agreements & Public Health*, 77.

⁹ The specific health issues are as follows: infectious disease control, food safety, tobacco control, access to drugs, environment, food security and emerging issues in biotechnology, information technology and traditional knowledge, *Ibid.*, 58.

animal, or plant life or health.

2) Sanitary and Phytosanitary (SPS) Agreement serves as a crucial framework for promoting both trade and public health by addressing the complex issues surrounding food safety, animal health, and agricultural products in international trade. The SPS Agreement emphasizes the use of scientific principles in the development of sanitary and phytosanitary measures, recognizes the concept of equivalence and regionalization, and encourages harmonization with international standards. Adhering to the SPS Agreement contributes to a safer and more secure global trade environment, benefiting consumers, producers, and the environment alike. Efforts to provide technical assistance and capacity-building support to developing countries are crucial for ensuring the equitable participation of all members in the success of the agreement.

3) Technical Barriers to Trade (TBT) Agreement: This agreement aims to ensure that technical regulations, standards, and conformity assessment procedures do not create unnecessary barriers to trade, while also protecting consumers' health and safety.

4) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS): This agreement includes provisions that allow WTO members to take measures to protect public health, such as granting compulsory licenses for the manufacturing and distribution of patented pharmaceuticals.

There are also other agreements and measures, such as the General Agreement on Trade in Services (GATS), which includes provisions for the regulation of health services, for instance, measures to ensure the quality and safety of medical services. The Agreement on Agriculture (AOA) aims to create a more open and fair global agricultural market, promote sustainable agricultural practices, and improve food security worldwide. Moreover, the Doha Declaration on TRIPS and Public Health reaffirms the right of WTO members to use the flexibilities in the TRIPS Agreement to promote access to medicines for all, particularly in developing countries.

3. Burden of Proof of WTO's Necessary Protection to Public Health

The burden of proof refers to the obligation of a party to prove its claims or defenses in a legal proceeding.¹ It is particularly relevant in disputes related to public health protection within the WTO system. In WTO disputes,² the burden of proof is often imposed on the party seeking to justify a measure that restricts trade, requiring them to provide evidence from scientific and technical sources to support their position.³ The burden of proof is evaluated based on the evidence and legal arguments presented by both parties and can shift to the defending party, who may also present evidence in defense of their measure.⁴ Which influences the outcome of the case and upholds the rights and obligations of the parties

3.1 The Burden of Proof in Article XX(b) of GATT 1994

In Article XX(b) of the GATT 1994, the "burden of proof" refers to the obligation placed on a member country seeking to justify a measure that could otherwise be considered a violation of GATT rules. Article XX(b) allows for exceptions to the general prohibition on trade restrictions if a measure is necessary to protect human, animal, or plant life or health. The burden of proof lies with the member country invoking this exception to demonstrate that the measure meets the criteria of necessity.⁵

To establish necessity, the member country must show that the measure is necessary to achieve the stated objective and that there is no alternative measure that would be less trade-restrictive while still achieving the desired level of protection.⁶ The requirement of necessity implies that the measure must be proportionate to the legitimate objective pursued, meaning that it should not go beyond what is reasonably required to achieve that objective. The structure of the article, policy objectives, and necessity of measures are as follows:

1) The structure of the article: Subparagraph (b) of GATT justifies the implementation of "measures necessary to protect human, animal, or plant life or health." This subparagraph typically covers SPS measures, import or export restrictions, domestic regulations aimed at ensuring the safety of food and products, as well as certain environmental regulations. The requirements are that 1) the measure's policy objective is to protect human, animal, or plant life or health and 2) that the measure is necessary for achieving this objective.⁷

2) Policy objectives: The Panel and Appellate Body have accepted the explanation that policy objectives claimed

¹ Bryan A. Garner, *Black's Law Dictionary*, "Burden of Proof," 11th ed. (US: Thomson Reuters, 2019).

² States that "the complainant shall have the burden of proving its claims." This means that the party bringing the claim (the complainant) must provide sufficient evidence to support its argument, Annex 2 of the WTO Agreement 1994, Understanding on rules and procedures governing the settlement of disputes, Article 3.8.

³ See, e.g., Appellate Body Report, US – COOL (Article 21.5 – Canada and Mexico), [5.370]; Panel Report, US – Tuna II (Article 21.5 – Mexico), [7.45]. See also Bradley Condon, "Treaty Structure and Public Interest Regulation in International Economic Law," *Journal of International Economic Law*, (2014), (advance access version, 4-10).

⁴ *International Thunderbird Gaming Corporation v Mexico (Award)*, UNCITRAL (NAFTA), (January 26, 2006): 95.

⁵ WTO, Analytical Index of the GATT: article XX general exceptions, 565.

⁶ Bradley Condon, "Treaty Structure and Public Interest Regulation in International Economic Law," *Journal of International Economic Law*, (2014): 11.

⁷ Ministry of Economy, Trade and Industry, "Major Trading Partners with Trade Agreements-WTO, FTA/EPA and IIA: Part II WTO Rules and Major Cases, Chapter 4 Justifiable Reasons: 389" (Report on Compliance 2015).

by respondent countries often fall under the policy objectives of subparagraph (b). For instance, cases "prevention of atmospheric pollution (US – Gasoline),"¹ "prohibition of import or distribution of Asbestos that is hazardous to human health and products containing Asbestos (DS135: EC – Asbestos)," and "prevention of propagation of mosquitoes that transmit malaria and dengue fever (DS332: Brazil - Retreaded Tires)" were determined to fall under the policy objectives of subparagraph (b).

3) Necessity of the measure: The determination of necessity under subparagraph (b) involves several factors. Firstly, the importance of the policy objectives is assessed, with the protection of human life/health being deemed the most essential,² followed by the protection of animal and plant life/health. Secondly, the trade-restrictive effect of the measure is considered, with export duties, for example, being less restrictive than a total prohibition on export but still having a significant impact on trade.³ Lastly, proving the relationship between the means (the measure) and the ends (the policy objectives) is necessary, although qualitative proof is not always required.⁴

3.2 *The Burden of Proof in Article 2.2 of TBT Agreement*

The burden of proof lies with the member implementing the measure under Article 2.2 to demonstrate that the measure is necessary and does not create unnecessary obstacles to international trade, while primarily aiming to protect public health. The member must show that the measure is based on scientific evidence and that alternative measures that are less trade-restrictive have been adequately considered but are deemed inadequate to achieve the desired level of public health protection. Unnecessary obstacles to international trade, must ensure that their technical regulations are two things: First, legitimate objective: According to article 2.2 of the TBT Agreement, there are five legitimate objectives, 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. Second, not being more trade-restrictive than necessary to fulfill a legitimate objective and by this, Members should ensure that any of these measures are proportionate to their legitimate objective and consider the risks non-compliance can create.⁵ To analyze the compliance of this measure, several elements need to be considered:⁶

1) Contribution of the challenged measure to the objective, refers to how effectively it helps achieve the intended goal. It requires an assessment of whether the measure is directly linked to the objective and whether it is proportionate to achieving that objective.

2) Trade restrictiveness of the challenged measure, regarding the meaning of trade restrictiveness, the Appellate Body in US – Tuna II (Mexico) stated as follows:⁷ "We recall that the Appellate Body has understood the word 'restriction' as something that restricts someone or something, a limitation on action, a limiting condition or regulation. Accordingly, it found, in the context of Article XI:2(a) of the GATT 1994, that the word 'restriction' refers generally to something that has a limiting effect. As used in Article 2.2 in conjunction with the word 'trade', the term means something having a limiting effect on trade."⁸

3) Comparison with proposed alternative measures, when considering the trade restrictiveness of a measure, it is important to compare it with proposed alternative measures. This involves examining whether there are less trade-restrictive alternatives available that can achieve the same legitimate objective.⁹

4) The risks non-fulfilment would create various risks. This aspect focuses on the potential risks to human health, safety, or the environment that would arise if the legitimate objective were not fulfilled. It is crucial to assess the severity of these risks in relation to the measure's trade restrictiveness. Article 2.2 aims to balance important objectives with minimizing negative trade effects. Member countries are urged to use the least trade-restrictive measures while providing evidence to support regulations and prevent unnecessary barriers to international trade. The burden of proof is on the member country to justify regulations and show they do not impede trade.

3.3 *The Burden of Proof in Article 8.1 of TRIPS Agreement*

¹ Appellate Body Report on United States Standards for Reformulated and Conventional Gasoline, 35 I.L.M. 603, WT/DS2/AB/R (1996). The AB found that the US' application of the reformulated gasoline provisions of the Clean Air Act discriminated against imported gasoline compared to domestically refined gasoline, which could not be justified by environmental objectives. The regulations were considered discriminatory due to enforcement considerations rather than air quality concerns. Consequently, the AB concluded that the discrimination in the US gasoline rules was "unjustifiable" under Article XX.

² Brazil – Retreaded Tires (DS332), Panel Report, paras. 7.108-7.112.

³ China – Raw Materials (DS394, 395, 398), paras. 7.558-7.563.

⁴ Brazil – Retreaded Tires (DS332), paras. 7.115-7.119

⁵ Natalia R. Uribe, "Dispute resolution and "environmental" provisions in the WTO: promising developments for environmental matters," in *Anuario Colombiano de Derecho Internacional* (Sydney: Macquarie University, 2010), 176.

⁶ Analytical Index of TBT Agreement – Article 2 (DS reports), p. 1.

⁷ Appellate Body Report, US – Tuna II (Mexico), para. 319.

⁸ The Appellate Body addressed this question in the context of Article XI:2(a) of the GATT 1994 in Appellate Body Reports, China – Raw Materials, para. 319.

⁹ Appellate Body Reports, US – COOL (Article 21.5 – Canada and Mexico), para. 5.215.

The TRIPS Agreement requires WTO member countries to establish minimum standards for protecting and enforcing intellectual property rights. The Agreement's objectives are to promote technological innovation, transfer and dissemination of technology, and balance the rights and obligations of producers and users of technological knowledge.¹ Governments can implement their intellectual property regimes in a manner that takes account of public health considerations. The Agreement provides for certain exemptions from patentability, limited exceptions to patent owners' exclusive rights, compulsory licensing, and parallel importation. The burden of proof is on the complaining party to demonstrate the violation of IP rights in civil and administrative procedures, and the accused entity can challenge the claim with counterevidence. In copyright and trademark infringement cases, the burden of proof rests with the party claiming infringement. Customs officials must determine whether imported or exported goods infringe intellectual property rights based on the evidence submitted by the rightsholder.

The panel emphasized that Article 8.1 of the TRIPS Agreement allows member states to adopt laws and regulations for specific objectives, such as public health, nutrition, and socio-economic and technological sectors, as long as they align with the TRIPS Agreement's provisions. This provision provides context for interpreting the term "unjustifiably" in Article 20 and reflects the WTO's intention to preserve societal interests while ensuring measures may impact intellectual property rights.² As outlined in Article 8.1, does not provide broad exceptions for the grant of positive rights to exploit or use specific subject matter. Instead, it grants negative rights to prevent specific acts, allowing Members to pursue legitimate public policy objectives. This principle allows Members to pursue legitimate public policy objectives without requiring exceptions. An example of this is Thailand's compulsory licensing of patents for HIV/AIDS drugs in 2006.³ Pharmaceutical companies argued that Thailand's actions violated their intellectual property rights and were not necessary to protect public health. However, Thailand provided evidence that compulsory licenses were necessary to ensure affordable access to life-saving medications.⁴ The World Trade Organization upheld Thailand's right to issue compulsory licenses.

3.4 Challenges of Necessity for the Protection of Public Health

The legal challenges to the burden of proof of necessary protection to public health within the World Trade Organization (WTO) context are multi-faceted and complex. One of the main challenges is the lack of legal clarity on the necessity of protection of public health tests. The interpretation of the necessity requirement can vary among WTO members and panels, leading to inconsistent rulings and creating uncertainty in the resolution of disputes. Meeting the burden of proof requires proving the necessity of measures taken for the protection of public health. This burden can be demanding and requires a strong evidentiary basis. It involves demonstrating a clear connection between the trade measure and the legitimate public health objective, as well as proving that the measure is proportional and the least trade-restrictive option available.

Public health evidence is often uncertain and subject to evolving scientific understanding, making it difficult to establish a clear connection between a trade measure and the legitimate public health objective. due to factors such as data collection limitations, bias and confounding, and evolving knowledge in the field. This uncertainty can impact the effectiveness and legality of public health measures, making it challenging to meet the burden of proof for the necessity requirement. Meeting the burden of proof requires presenting compelling evidence and arguments to support the necessity and proportionality of the measure. Determining the proportionality of a measure can be subjective and subject to different interpretations, leading to legal disputes and challenges

Additionally, striking a balance between public health protection and trade interests is a challenging task. The burden of proof, coupled with the complexities of scientific evidence, unpredictable health risks, and potential trade-offs, further complicates the decision-making process. And balancing the necessity of public health measures with international trade law and standards can be a challenge. The need to ensure that health measures are in line with international trade law may limit governments' ability to adequately protect public health.

4. Burden of Proof of Non-Arbitrary or Unjustifiable Discrimination in WTO Public Health Protection Disputes

GATT was established in 1947 and continues to exist today as GATT 1994.⁵ Article XX allows countries to

¹ The Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 7.

² Panel Reports, Australia – Tobacco Plain Packaging, paras. 7.2403 – 7.2404.

³ Ministry of Public Health and National Health Security Office, *Facts and Evidences on the 10 Burning Issues Related to the Government use of Patents on three Patented Essential Drugs in Thailand*. (2007),13, accessed October 25, 2023, <http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf>.

⁴ Jakkrit Kuanpoth, *Compulsory Licences: Law and Practice in Thailand*, eds. Reto M. Hilty and Kung-Chung Liu (Heidelberg: Springer 2015), 70.

⁵ General Agreement on Tariffs and Trade, October 30, 1947,61 Stat. A- 11, T.I.A.S. 1700, 55 U.N.T.S. 194 [hereinafter GATT]

deviate from normal trading rules to protect human, animal, or plant life or health.¹ The inclusion of a defining chapeau in the agreement has sparked controversy and raised concerns about its impact on trade regulations and developing countries. The chapeau² was added to the International Trade Organization charter to protect against potential manipulation and serves as a requirement for reasonableness and good faith in implementing trade regulations within the exceptions. However, the Dispute Settlement Board (DSB) has interpreted the chapeau in a way that undermines regulations, primarily focusing on the potential consequences for developing countries

4.1 Requirement under Article XX of GATT 1994

The requirement under Article XX of GATT 1994 encompasses three main aspects: non-discrimination, not being a disguised restriction on trade, and permitted purposes. Non-Discrimination: Article XX of GATT 1994 prohibits arbitrary or unjustifiable discrimination between countries with the same prevailing conditions or between countries with different prevailing conditions. This means that the measures implemented by member countries should not unfairly favor domestic products over imports or discriminate against specific trading partners. The principle of non-discrimination is crucial for maintaining fairness and preventing protectionist practices in international trade.³

Not a Disguised Restriction on Trade: The measures implemented by member countries should not be disguised restrictions on international trade. They should not be aimed at imposing unnecessary barriers or hindering the free flow of goods and services across borders. A disguised restriction on trade refers to situations where a measure, although appearing legitimate and justifiable under the exceptions of Article XX, has the primary purpose of restricting international trade or discriminating against certain trading partners.

Permitted Purposes: Article XX of GATT 1994 provides exceptions for measures that would otherwise be considered discriminatory under GATT rules. These exceptions aim to balance non-trade concerns with non-discrimination and free trade principles. The measure must aim to achieve a policy objective listed in Article XX and be judged as necessary, with no less trade-restrictive alternative available. Compliance with these requirements is crucial for maintaining fairness, transparency, and stability in international trade relations.

4.2 The Burden of Proof in Article 2.3 of SPS Agreement

in Article 2.3 of the SPS Agreement, the burden of proof lies on the complaining party to demonstrate non-arbitrary or unjustifiable discrimination⁴ in public health protection disputes. The complaining party must show that the measures taken by the defending country are discriminatory and not based on scientific evidence or justifiable reasons. The Appellate Body has determined that the burden of establishing a prima facie case of inconsistency rests on the complainant. The provision aims to ensure that SPS measures are not used as disguised restrictions on international trade and that they are based on legitimate objectives. Both substantive SPS measures and procedural or information requirements can lead to discrimination under Article 2.3. The interpretation and application of the concept of non-arbitrary or unjustifiable discrimination require a case-specific analysis of the facts and circumstances.

4.3 Challenges to Burden of Proof for Non-Arbitrary or Unjustifiable Discrimination in Public Health Protection

Challenges to the burden of proof for non-arbitrary or unjustifiable discrimination in public health protection can arise in several aspects. One main challenge is the cost imbalance between the complainant and the respondent in presenting evidence. The relative cost-of-proof theory suggests that there is a significant cost imbalance between the parties involved. While both parties may submit evidence, information about the respondent's measure can often be found in the public domain, making it less costly for them to provide evidence.⁵ On the other hand, the complainant may face difficulties in gathering and evaluating scientific evidence, especially for developing countries or smaller economies with limited resources and technical capabilities.

Additionally, developing countries may struggle to access relevant and timely information needed to effectively present their case and defend their interests. This can put them at a disadvantage when it comes to proving non-arbitrary or unjustifiable discrimination. Furthermore, The WTO faces challenges in obtaining sufficient evidence to prove discrimination in public health protection disputes. Gathering convincing evidence can be difficult and resource intensive. Addressing these challenges can promote fair dispute resolution, ensure

¹ Nordstrom And Vaughan, *supra* note 10, at 9.

² 'Chapeau,' defined as a top hat is the term generally used to refer to the introductory provision of Article XX. See together, they are Collegiate Dictionary 184 (g. & C. Merriam Co. 1980).

³ See, e.g., US-Shrimp, EC-Tariff Preferences, US-Gambling, Brazil-Retreaded Tires, and US-Tuna.

⁴ See, SPS Agreement *supra* note 128, art. 2, para. 3 ("Members shall ensure that their ... measures ... do not arbitrarily or unjustifiably discriminate... measures shall not... constitute a disguised restriction in international trade."). The E.C. Treaty language, which roughly parallels GATT Article XX, omits only the term "unjustifiable."

⁵ Michelle T. Grando, "Allocating the Burden of Proof in WTO Disputes: A Critical Analysis," *Journal of International Economic Law* 9, no 3, (2006): 652.

equal playing fields, and uphold non-arbitrary or justifiable discrimination principles. Overall, the burden of proof of non-arbitrary or unjustifiable discrimination in WTO public health protection disputes need for fairness, non-discrimination, and transparency in international trade. The WTO assesses the legitimacy of a country's measures to balance public health and fair trade, prevent protectionist practices and maintain a level playing field for member countries.

5. Burden of Proof of Scientific Evidence in WTO Public Health Protection Disputes

Scientific evidence in public health protection refers to empirical data. It plays a crucial role in assessing health risks, developing interventions, and evaluating the effectiveness of policies,¹ guiding policymakers and public health authorities in making informed decisions based on reliable data and research.² This evidence can come from various sources such as epidemiological studies, clinical trials, and laboratory research. It justifies public health measures, particularly when they are challenged or disputed by other countries or stakeholders in international trade disputes. Furthermore, scientific evidence is essential in health issues like food safety and trade hold significant importance, and unlike some other health concerns, food safety is particularly addressed by the WTO Agreement. The SPS Agreement pertains to trade-related measures aimed at safeguarding human life or health from risks associated with additives, contaminants, toxins, veterinary drug and pesticide residues, or disease-causing organisms in foods or beverages. It is important to note that while the SPS Agreement allows governments to restrict trade to fulfill health objectives, these measures must be based on scientific evidence.³

The burden of proof for scientific evidence in public health protection refers to the responsibility of the complainant country in WTO disputes to provide sufficient scientific evidence to substantiate their claims that the respondent country's measures are inconsistent with WTO rules and have a detrimental effect on public health. The complainant country must demonstrate that the measure is not based on scientific evidence or that the scientific evidence relied upon by the respondent country is insufficient or flawed. In the context of the SPS Agreement, the burden of proof for scientific evidence is particularly critical, as measures must be based on scientific principles and should not be maintained without sufficient scientific evidence.

The challenges associated with the burden of proof for scientific evidence in WTO public health protection disputes are multifaceted. One challenge is the complexity and uncertainty inherent in scientific research. There can be difficulties in demonstrating the scientific basis for measures restricting trade, particularly in cases⁴ where risk assessments are involved the burden of proof is often challenging to meet due to the complexities of scientific evidence and its interpretation. Limited resources and expertise can also pose challenges for developing countries or smaller economies in meeting the burden of proof. Furthermore, there are concerns about the ability of WTO panels to assess the validity of health and safety regulations due to a potential lack of scientific expertise.⁵ Balancing the precautionary principle with the burden of proof for scientific evidence in trade disputes presents legal complexities. As a result, there have been calls to interpret the requirement in line with the precautionary principle, which advocates for taking preventive action in the face of scientific uncertainty.⁶ The rapid development of new technologies and the changing nature of scientific evidence are posing challenges to the interpretation and application of international trade regulations.

Finally, the challenge of standards of scientific evidence, which developing countries may struggle to meet the burden of proof due to limited resources and expertise. Concerns also arise about WTO panels lacking scientific expertise and the potential hindrance of preventive measures without scientific evidence. Balancing trade objectives and public health protection requires ongoing dialogue and collaboration among WTO members. Implementing recommendations and working collaboratively can address these challenges and foster a more effective approach within the WTO framework.

6. Conclusion and Ways Forward

The burden of proof in WTO disputes related to public health protection measures under WTO agreements. It emphasizes the necessity test and examines the burden of proof in various WTO agreements. The burden of proof lies with the country implementing measures to justify their necessity and proportionality, considering societal interests like public health. The TBT Agreement places the burden on the member country to justify the necessity of regulations without being excessively trade-restrictive. The necessity test demands compelling

¹ Marc C. Willemsen, "Tobacco Control Policy in the Netherlands: Between Economy, Public Health, and Ideology," in *Public Health Policy Research*, eds. Patrick Fafard and Evelyne de Leeuw Maastricht: Maastricht University, 2018), 165.

² Tania Voon, "Evidentiary Challenges for Public Health Regulation in International Trade and Investment Law," *Journal of International Economic Law* 18 (2015): 802.

³ WHO and WTO, *WTO Agreements & Public Health*, 65.

⁴ Appellate Body Report, Brazil – Retreaded Tyres, para 151, 172.

⁵ M. Echols, "Sanitary or Phytosanitary Measures," in *The World Trade Organisation, the Multilateral Framework for the 21st Century*, ed. Thomas P. Stewart (US: Implementing Legislation, 1996)

⁶ McDonald J, "Big Beef or Consumer Health Threat?: The WTO Food Safety Agreement, Bovine Growth Hormone and the Precautionary Principle," *Environment and Planning Law Journal* 15, (1998)

evidence and arguments to support the necessity and proportionality of the measure, especially in protecting public health and the challenges associated with international standards. It suggests stakeholder collaboration, clear proportionality tests, harmonization of public health and trade standards, and in-depth case studies as potential ways forward within the WTO framework.

Moreover, the burden of proof in WTO disputes is non-arbitrary or unjustifiable discrimination. It highlights the role of the WTO in evaluating measures based on scientific principles and international standards, aiming to balance public health protection with fair trade practices. The study found cost imbalances between the complainant and the respondent in presenting evidence, with developing countries facing difficulties in gathering and evaluating scientific evidence. The research recommends increasing transparency, information sharing, and cooperation among international organizations, harmonizing public health and trade standards, developing clear guidelines for public health protection measures, and investing in improved data collection methods, as well as capacity-building initiatives to achieve a balance between promoting trade and protecting public health.

The importance of public health protection and the role of scientific evidence in informing policy decisions. It emphasizes the burden of proof for scientific evidence lying with the complainant country and the need for evidence-based decision-making, rigorous risk assessments, and periodic reviews of measures based on the latest scientific evidence. Due to the challenges of using scientific evidence, such as complexity and uncertainty, as well as the importance of effective communication of scientific findings to diverse stakeholders and maintaining transparency, efforts to address the burden of proof in WTO public health protection disputes include strengthening scientific expertise within WTO panels, encouraging the development of new scientific evidence, and providing technical assistance to developing countries. The aim is to ensure a fair and informed evaluation of public health measures, address resource constraints, and improve the quality of the evidence presented. Additionally, the WTO could develop guidance on fairly applying new technologies and enhancing the transparency of scientific evidence.

In addition, the author proposes potential solutions, such as 1) reverse presumptions; in specific cases where information asymmetry is particularly pronounced, introducing reverse presumptions could be considered. This would shift the initial burden of proof to the responding Member to justify certain measures, particularly those affecting developing countries. 2) Procedural adjustments, such as implementing flexible timelines for evidence gathering and allowing for expert assistance, could help level the playing field and address resource constraints faced by some Members. 3) Enhanced transparency and information sharing: increased transparency in domestic policymaking and greater information sharing between Members could make it easier for complaining Members to prove violations, particularly in complex areas like subsidies. 4) Alternative dispute settlement mechanisms: Exploring alternative dispute settlement mechanisms, such as mediation or arbitration, could offer more flexible and cost-effective ways to resolve disputes without the strict burden of proof requirements. Ultimately, there is no single perfect solution to the issue of the burden of proof in WTO dispute settlement. Finding a way to balance the concerns of predictability, access to justice, and fairness will require careful consideration of the diverse perspectives and interests of all WTO Members. Additionally, it is important to remember that the burden of proof is just one aspect of the larger WTO dispute settlement system, and any improvements need to be made within the context of the system's overall objectives and effectiveness.

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