THE PRECAUTIONARY PRINCIPLE AS A GENERAL PRINCIPLE OF INTERNATIONAL LAW AND GLOBAL HEALTH LAW[1]

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ABSTRACT

Repercussions of the COVID-19 pandemic have been alleged to be attributed to the failure of the World Health Organization (hereinafter "WHO") and states to employ the precautionary principle. In this vein, there have been calls for the precautionary principle to be included in the 2005 International Health Regulations (hereinafter "IHR"). Notwithstanding, the precautionary principle has been a subject of controversy. But what is the precautionary principle? Is it true that the precautionary principle is contrary to the object and purpose of global health law? Why did states invoke the precautionary principle? Can and how can the precautionary principle make any meaningful contribution to global health law? This paper argues that the precautionary principle is a general principle of international law, with no exception concerning global health law. However, global health law takes a restrictive approach to the precautionary principle, which is not in line with the approach of other fields of international and supranational law (hereinafter

[1] In this paper, the phrase "global health law" refers to the body of laws (both hard and soft laws) of World Health Organization [hereinafter WHO] and their predecessors (for example, international sanitary conventions or international sanitary regulations). "Global health law" is not intended to be read in the broadest sense as the body of laws concerning health matters, which can include the law of World Trade Organisation [hereinafter WTO], European Union [hereinafter EU], or environmental protection law, which can cover health matters.

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"international law"). Interestingly, global health law does not offer as much protection to health as other fields of international law. Thus, the precautionary principle and broadly international law have implications for and can contribute meaningfully to the global health project.

KEYWORDS: *precautionary principle, global health law, 2005 International Health Regulations*

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Table of Contents

I. Introduction....431
II. The Precautionary Principle as a General Principle of International Law in Global Health Law....435
A. Objective and Purpose of Prevention and Precaution....440
B. Toolkit of the Precautionary Principle....442
1. The Principle of Cooperation....442
2. The Principle of Comprehensiveness....443
3. The Principle of Reasonableness and Responsibility....443
4. The Principle of Provisional....450
5. The Principle of Effectiveness and Proportional....453
6. The Principle of Transparency....454
III. Two Problems with Global Health Law in Relation to Its Restrictive Approach to the Precautionary Principle....455
A. Overly Technological-Centric: The Matter of an Unobeyable Law....455
B. Vagueness....458
C. Implications....469
IV. Conclusion....470
A. The Precautionary Principle is a General Principle of International Law in Global Health Law....470
B. The Restrictive Approach to the Precautionary Principle of Global Health Law Offers Less Protection to Health Compared to Other Fields of International Law....471
C. Implications from Jurisprudence and International Law....474
1. The WHO....474
2. States....475
3. Courts....475

I. INTRODUCTION

Repercussions of the COVID-19 pandemic have been alleged to be attributed to the failure of the World Health Organization (hereinafter "WHO") and states to employ the precautionary principle. The Independent Panel for Pandemic Preparedness and Response commissioned by the WHO (hereinafter "the Independent Panel")[2] claimed that WHO and states did not

[2] *See* Seventy-Third World Health Assembly, *COVID-19 Response*, at 2, World Health Organization Doc. WHA73.1 (2020), https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf; Seventy-Third World Health Assembly, *Progress Report from the Co-Chairs of the Independent Panel for Pandemic Preparedness and Response*, at 3, WHO Doc. A73/INF./4 (2020), https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_INF4-en.pdf.

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apply the precautionary principle when they should have,[3] resulting in failures in handling the disease.[4] Similarly, José E. Alvarez claimed that "WHO's singular reliance on public health professionals may cause it to be less nimble with respect to reasonable state measures that are not (yet) backed by rigorous testing or peer-reviewed studies but which are warranted by the precautionary principle".[5]

Meanwhile, many states have or have been claimed to have taken into account the precautionary principle in responding to the COVID-19 Pandemic, *inter alia*, Australia and Australian states,[6] China,[7] New Zealand,[8] European states,[9] the United Kingdom,[10] Vietnam.[11]

Concerning the revision of the International Health Regulations (2005) (hereinafter "2005 IHR"), the Czech Republic submitted a proposed amendment to Article 3 of the 2005 IHR, which reads, "When implementing

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[3] *COVID-19: Make It the Last Pandemic*, THE INDEPENDENT PANEL FOR PANDEMIC PREPAREDNESS & RESPONSE, 26 (2021), https://theindependentpanel.org/wp-content/uploads/2021 /05/COVID-19-Make-it-the-Last-Pandemic_final.pdf.

[4] *Id.* at 31.

[5] José E. Alvarez, *The WHO in the Age of the Coronavirus*, 114(4) AM. J. INT'L. L. 578, 586 (2020).

[6] For example, *Victorian Public Health and Wellbeing Act 2008* (Vic.) s 185D (Austl.); *Loielo v Giles* [2020] VSC 722, ¶¶ 98, 183-86 (Austl.).

[7]

> [T]he Chinese government has been committed to a people-first and life-first philosophy, to an approach featuring preventing imported cases from abroad and resurgence at home, and to a dynamic zero-COVID policy. We have been adapting prevention and control protocols to the evolving situation . . . China's dynamic zero-COVID policy is not aimed at realizing zero infection, but rather at bringing COVID-19 under control at the minimum social cost in the shortest time possible so as to effectively protect the health, normal life and production of the 1.4 billion Chinese people to the maximum.

See Foreign Ministry Spokesperson Zhao Lijian's Regular Press Conference on May 11, 2022, MINISTRY FOREIGN AFF. CHINA (May 11, 2022), https://www.fmprc.gov.cn/mfa_eng/xwfw_665399/s2510_665401/202205/t20220511_10684604.html.

[8] "[W]e must go hard, and go early, and do everything we can to protect New Zealanders health." *See* Jacinda Ardern, *Major Steps Taken to Protect New Zealanders from COVID-19*, BEEHIVE.GOVT.NZ (Mar. 14, 2020), https://www.beehive.govt.nz/release/major-steps-taken-protect-new-zealanders-covid-19. *See also* Amanda Kvalsvig & Michael G. Baker, *How Aotearoa New Zealand Rapidly Revised Its Covid-19 Response Strategy: Lessons for the Next Pandemic Plan*, 51(1) J. ROYAL SOC'Y NEW ZEALAND 143, 153 (2021); David Clark, *Travel Restrictions to Remain in Place as Coronavirus Precaution*, BEEHIVE.GOVT.NZ (Feb. 15, 2020), https://www.beehive.govt.nz/release/travel-restrictions-remain-place-coronavirus-precaution.

[9] *See generally* Emiliano Frediani, *The Administrative Precautionary Approach at the Time of Covid-19: The Law of Uncertain Science and the Italian Answer to Emergency*, 17(3) UTRECHT L. REV. 6 (2021).

[10] Dep't of Health & Soc. Care et al., *Precautionary and Temporary Measures Introduced to Improve COVID Surveillance from China*, GOV.UK (Dec. 30, 2022), https://www.gov.uk/government/news/precautionary-and-temporary-measures-introduced-to-improve-covid-surveillance-from-china.

[11] *See generally* Hai Doan et al., *The Precautionary Principle in Public Health Emergency Regime: Ethical and Legal Examinations of Vietnamese and Global Response to COVID-19*, 38(1) BIOETHICS 11 (2023).

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these Regulations, Parties and WHO should exercise precaution, in particular when dealing with unknown pathogens".[12] The IHR Review Committee regarding amendments to International Health Regulations (hereinafter "IHR Amendments RC")[13] interpreted the proposed amendment as the introduction of the precautionary principle into the IHR.[14] However, the IHR Amendments RC critically opposed that proposal, claiming that the precautionary principle is inherently incompatible with the 2005 IHR and global health law:

> [T]he proposed addition of precaution to paragraph 3 should be *analysed in depth and considered with care*. Measures in the Regulations are meant to be *evidence-based, which may preclude or at least limit the application of precaution*; however, *uncertainties during an outbreak response may require action in the absence of evidence or with insufficient evidence*. The concept does not seem to have a commonly accepted definition. . . .[15] [Emphasis added and footnotes omitted].

Although the Czech recommendation is not included in the Amendments to the 2005 IHR, similar to many issues and ideas in international law, this non-inclusion does not mean the negation of the precautionary principle. Nor does it mean to be conclusive (though the opinion of the IHR Amendments RC can be considered as providing a clue for the [undisclosed] underlying reason for the non-inclusion). Thus, there are strong academic and practical merits for inquiring about the precautionary principle and its status in global health law. The questions are: (1) What is the precautionary principle? (2) Is it true that the precautionary principle is inherently contrary to the object and purpose of the 2005 IHR and global health law? (3) Why did states invoke the precautionary

[12] Submission of proposed amendments to the International Health Regulations (2005), pursuant to decision WHA75(9) of the World Health Assembly, by the Czech Republic, the current Presidency of the Council of the European Union, as a State Party to the IHR and in coordination with the European Union, and on behalf of the Member States of the European Union. *See* The Working Group on Amendments to the International Health Regulations (2005) [hereinafter WGIHR], *Proposed Amendments to the International Health Regulations (2005) Submitted in Accordance with Decision WHA75(9) (2022)*, at 27, WHO Doc. A/WGIHR/2/6 (Feb. 6, 2023), https://apps.who.int/gb/wgihr/pdf_files/wgihr1/WGIHR_Submissions-en.pdf.

[13] Convened under Articles 50.1.(a)2, 47 of the IHR and Decision WHA75(9). *See* Seventy-Fifth World Health Assembly, *Strengthening WHO Preparedness for and Response to Health Emergencies*, at 1, WHO Doc. WHA75(9) (May 27, 2022), https://apps.who.int/gb/ebwha/pdf_ files/WHA75/A75(9)-en.pdf.

[14] WGIHR, *Report of the Review Committee Regarding Amendments to the International Health Regulations (2005) – Report by the Director-General*, at 28, WHO Doc. A/WGIHR/2/5 (Feb. 6, 2023), https://apps.who.int/gb/wgihr/pdf_files/wgihr2/A_WGIHR2_5-en.pdf?sfvrsn=4b549603_12.

[15] *Id.* at 29.

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principle? (4) Can and how can the precautionary principle make any meaningful contribution to global health law?

The paper is conducted by means of the functional comparative method. The starting point for the study is the common problems of public health risks, harms, and crises and uncertainty and the need to deal with and respond to the risks, harms, and crises, especially in uncertainty.[16] Systematic comparisons between the totality of global health law and the structure and jurisprudence of other fields of international law and between instruments of global health law *inter se* are conducted to determine whether there is a precautionary principle in global health law, what its current shape is, and what shortcomings of global health law in relation to the precautionary principle there are. This paper argues that

1. The precautionary principle is a general principle of international law, with no exception concerning global health law. It is embodied in the objective and purpose of global health law, its structure and arrangements and specific rules thereof, and conversely, the precautionary principle should be fleshed out by specific rules for which the precautionary principle is a device assisting the interpretation and implementation of these rules. Thus, the precautionary principle is relevant to policy and judicial considerations.

2. Notwithstanding this, global health law takes a restrictive approach to the precautionary principle, which is not in line with the approach of other fields of international law. Interestingly, global health law does not offer as much protection to health as other fields of international law.

3. The precautionary principle and broadly international law have implications for and can contribute meaningfully to the global health project. However, naturally, the specific implications of the precautionary principle for various actors, e.g., the WHO and states, and their propositions, behaviours, and measures vary.

Section II argues that the precautionary principle is a "general legal principle" in global health law. Section III points out certain shortcomings of global health law, namely, being overly technological-centric and vagueness. It also points out that global health law takes a restrictive approach to the precautionary principle.

This paper was prepared based on the version of the 2005 IHR predating the amendments accepted at the Seventy-Seventh World Health Assembly on June 1, 2024. Generally, changes to the 2005 IHR do not significantly touch on or reverse issues studied by this paper and the analysis of this paper. Thus, only changes considered closely relevant to this paper are mentioned as a kind of further development. They shall be analysed separately from the analysis of the extant 2005 IHR. This approach helps to reflect more

[16] On functionalism, see KONRAD ZWEIGERT ET AL., INTRODUCTION TO COMPARATIVE LAW 34 (1998).

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precisely the formulations and issues of each version of the IHR. Interestingly, as an afterthought point, the precautionary thinking has been more salient in the Amendments to the 2005 IHR than in the 2005 IHR. Amendments to the 2005 IHR also demonstrate even more clearly that global health law takes a restrictive approach to the precautionary principle. Amendments to the 2005 IHR, thus, do not make this paper irrelevant or cast doubt on its analysis but testify to and further demonstrate the points made here.

II. THE PRECAUTIONARY PRINCIPLE AS A GENERAL PRINCIPLE OF INTERNATIONAL LAW IN GLOBAL HEALTH LAW

"General principles" is an intriguing concept in international law. Article 38.(1).(c) of the Statute of the International Court of Justice (hereinafter "ICJ") refers to "general principles" as "the general principles of law recognized by civilized nations". There is not a neat and clear-cut boundary between "rules" and "principles", but "principles", especially "general principles", are often associated with a sense of "more general and more fundamental character".[17] "Principles" are norms,[18] describe norms,[19] are the container and the totality of norms, the totality of a legal regime,[20] are propositions of a general or very general character[21], are certain normative ideas or "source" of normative ideas.[22] For both "rule" and "principle", there is a level of "indeterminacy";[23] the phenomenon that a rule or principle across instruments in a legal system or different legal systems can be formulated differently is not rare or abnormal and not prejudiced to the existence and status of the rule or principle. However, principles are believed to be more flexible than rules. According to Kolb, principles do not "deal with the fixed meaning of rules to be applied, but with the adaptation of the rules to some constitutional necessities" to conform with ideas of justice, and so on.[24]

[17] Delimitation of Maritime Boundary in Gulf of Maine Area (Can./U.S.), Judgment, 1984 I.C.J. 246, ¶ 79 (Oct. 12).
[18] Martti Koskenniemi, *General Principles: Reflexions on Constructivist Thinking in International Law*, *in* SOURCES OF INTERNATIONAL LAW 359, 364 (Martti Koskenniemi ed., 2000).
[19] *Id.*
[20] *Id.* at 366, 371.
[21] GAETANO ARANGIO-RUIZ, THE UNITED NATIONS DECLARATION ON FRIENDLY RELATIONS AND THE SYSTEM OF THE SOURCES OF INTERNATIONAL LAW WITH AN APPENDIX ON THE CONCEPT OF INTERNATIONAL LAW AND THE THEORY OF INTERNATIONAL ORGANISATION 53 (1979).
[22] Robert Kolb, *Principles as Sources of International Law (with Special Reference to Good Faith)*, 53(1) NETH. INT'L. L. REV. 1, 9 (2006).
[23] Koskenniemi, *supra* note 18, at 370.
[24] Kolb, *supra* note 22, at 9.

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General principles can exist in and be developed from, *inter alia*, agreements,[25] customs,[26] principles of organizations,[27] natural law[28] and "elementary considerations of humanity",[29] of "human conscience",[30] and "very general legal propositions derived from the system of international law".[31] Thus, many principles, e.g., good faith,[32] self-determination,[33] have roots in or are the payoff of the process of legalizing moral, political concepts. Notwithstanding, legal principles are distinguishable and separable from general moral, political concepts[34] because principles can be identified by defining, slitting[35] and listing their various legal aspects. Components of principles are often the product of the process in which principles are defined and redefined.[36]

The precautionary principle is such an instance of "general principles". The idea of being precautionary where there [are or] is [risks of] calamity, in times of uncertainty and in times where information is insufficient can be found back in ancient times. For example, Mencius said, "[m]en . . . who keep their hearts under a sense of peril, and use deep precautions against calamity . . . become distinguished for their intelligence".[37]

Around the 1980s, West German environmental law articulated "Vorsorgeprinzip" ("foresight principle"—the precautionary principle).[38] However, Swedish scholars claimed that though the 1941 Swedish Water

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[25] ARANGIO-RUIZ, *supra* note 21, at 54-55.
[26] *Id*; Statement of the Czech Republic, U.N. GAOR, 74th Sess., Agenda Item 79, *Report of the International Law Commission, Cluster III*, at 5; Statement of Iran, 74th Sess., *Report of the International Law Commission, Cluster III*, at 2; Statement of Mr. Rajput, U.N. Doc. A/CN.4/ SR.3490, at 15.
[27] U.N. Charter art. 2.
[28] South West Africa (Liber. v. S. Afr.), Judgment, 1966 I.C.J. 6, 294 (July 18) (dissenting opinion by Tanaka, J.).
[29] Corfu Channel (U.K. v. Alb.), Judgment, 1949 I.C.J. 4, 22 (Apr. 9).
[30] Pulp Mills on the River Uruguay (Arg. v. Uru.), Judgement, 2010 I.C.J. 14, ¶ 52 (Apr. 20) (separate opinion by Cançado Trindade, J.) [hereinafter Pulp Mills on the River Uruguay (separate opinion by Cançado Trindade, J.)]
[31] Alain Pellet, *Part Three Statute of the International Court of Justice, Chapter II. Competence of the Court, Article 38*, *in* THE STATUTE OF THE INTERNATIONAL COURT OF JUSTICE: A COMMENTARY 731, 734 (Andreas Zimmermann et al. eds. 2012); M. Cherif Bassiouni, *A Functional Approach to General Principles of International Law*, 11(3) MICH. J. INT'l. L. 768, 771 (1990).
[32] Kolb, *supra* note 22, at 14.
[33] *Id.* at 26; Wolfgang Danspeckgruber & Anne-Marie Gardner, *Self-Determination*, PRINCETONIENSIS ENCYCLOPEDIA, https://pesd.princeton.edu/node/656#:~:text=. Though its roots lie in the early twentieth century.
[34] Kolb, *supra* note 22, at 9; Koskenniemi, *supra* note 18, at 365.
[35] Kolb, *supra* note 22, at 9.
[36] *Id*. at 10.
[37] JAMES LEGGE, THE FOUR BOOKS: CONFUCIAN ANALECTS, THE GREAT LEARNING, THE DOCTRINE OF THE MEAN, AND THE WORKS OF MENCIUS: WITH ENGLISH TRANSLATION AND NOTES, THE WORKS OF MENCIUS 309 (1933).
[38] DIDIER BOURGUIGNON, THE PRECAUTIONARY PRINCIPLE: DEFINITIONS, APPLICATIONS AND GOVERNANCE 4 (2015).

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Code had not explicitly articulated, it embraced the precautionary principle.[39]

Today, the precautionary principle or the precautionary approach[40] has been manifested in a wide range of international documents. Many instruments, scholars, states, and judges read that the precautionary principle has been a general principle of international law.[41] Notably, in *Gabčíkovo-Nagymaros*, ICJ stated:

> [T]he 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

[39] JOAKIM ZANDER, THE APPLICATION OF THE PRECAUTIONARY PRINCIPLE IN PRACTICE: COMPARATIVE DIMENSIONS 153 (2010).

[40] There are controversies as to whether the precautionary principle is different from the precautionary approach. However, there cannot be any distinction between the precautionary principle and precautionary approach. There is no rule that separates and differentiates the precautionary principle and the precautionary approach in terms of the binding effect or the extent to which the precautionary principle is stronger and more rigid than the precautionary approach. For example, Principle 15 of the Rio Declaration which uses the term "precautionary approach" is considered as an exemplary formulation of the precautionary principle. Meanwhile, Article 4 of the 1991 Bamako Convention on the Ban of Import into Africa and the Control of Transboundary Movement of Hazardous Wastes within Africa refers to "precautionary principle", "precautionary approach", "precautionary measures" without indicating any distinction.

[41] Agreement for the Implementation of the Provisions of the United Nations Convention on the Law of the Sea of 10 December 1982 Relating to the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks art. 5, Sep. 8, 1995, 2167 U.N.T.S. 3 [hereinafter U.N. Fish Stocks Agreement]; United Nations Framework Convention on Climate Change art. 3, May 9, 1992, 1771 U.N.T.S. 107 [hereinafter UNFCCC]; Ole W. Pedersen, *From Abundance to Indeterminacy: The Precautionary Principle and Its Two Camps of Custom*, 3(2) TRANSNAT'L ENV'T L. 323, 338 (2014); Owen McIntyre & Thomas Mosedale, *The Precautionary Principle as a Norm of Customary International Law*, 9(2) J. ENV'T L. 221, 223 (1997); NICOLAS DE SADELEER, ENVIRONMENTAL PRINCIPLES : FROM POLITICAL SLOGANS TO LEGAL RULES 179, 359 (2d ed. 2021). Some judges and arbitrators shared this view. For example, in the Nuclear Tests (New Zealand v. France) Case, Judge Sir Geoffrey Palmer asserted that "the precautionary principle . . . may now be a principle of customary international law relating to the environment." Request for an Examination of the Situation in Accordance with Paragraph 63 of the Court's Judgment of 20 December 1974 in Nuclear Tests (N.Z. v. Fr.), Order, 1995 I.C.J. 288, 412 (Sep. 22) (dissenting opinion by Geoffrey Palmer, J.). In the MOX Case, Gavan Griffith asserted that the precautionary principle is an established rule of customary international law. OSPAR Arb. (Ir. v. U.K.), PCA Case No. 2001-03, Final Award, at 86, ¶ 73, fn. 46 (Perm. Ct. Arb. 2003). In the Pulp Mills Case, Judge ad hoc Vinuesa asserted that "the precautionary principle is . . . a rule of law within general international law." Pulp Mills on the River Uruguay (Arg. v. Uru.), Order, 2006 I.C.J. 113, at 152 (July 13) (dissenting opinion by Vinuesa, J. ad hoc); Pulp Mills on the River Uruguay (separate opinion by Cançado Trindade, J.), *supra* note 30, at 156-71. *See* positions of the European Communities and Canada. Panel Report, *European Communities — Measures Concerning Meat and Meat Products*, ¶ 8.157, WTO Doc. WT/DS26/AR/USA (adopted Feb. 13, 1998); Appellate Body Report, *EC — Hormones*, ¶¶ 60, 121, WTO Doc. WT/DS26/AB/R (adopted Feb. 13, 1998) [hereinafter Appellate Body Report, *EC — Hormones*]; Panel Report, *European Communities — Measures Affecting the Approval and Marketing of Biotech Products*, 97, ¶ 4.523, WTO Doc. WT/DS291/R (adopted Nov. 21, 2006) [hereinafter Panel Report, *EC — Biotech*].

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> this type of damage . . . Owing to new scientific insights and to a growing awareness of the risks for mankind . . . .[42] [Emphasis added]

Judge Ad Hoc Charlesworth read the ICJ's passage as it referred to the precautionary approach.[43] In the Pulp Mills case, ICJ considered that "a precautionary approach may be *relevant in the interpretation and application of the provisions* [of the 1975 Statute of the River Uruguay]"[44] [Emphasis added]. Judge Cançado Trindade argued that the precautionary principle is among the general principles of law.[45]

Within the context of European Law, the Court of Justice of the European Union (hereinafter "CJEU") recognized that the precautionary principle is a general and autonomous principle of EU law[46] and that [though the precautionary principle is only explicitly mentioned in relation to environmental protection] it surpasses the boundary of environmental protection.[47]

The US and some scholars have criticized the precautionary principle that "it has no clear content and therefore cannot be said to provide any authoritative guide for a State's conduct" and does not have a uniform definition.[48] But, as demonstrated above, indeterminacy and various abstract definitions are not the unique features of the precautionary principle. Even if it can be conceded that the precautionary principle is opaquely worded,[49] it is not meaningless or overly uncertain and can be a general principle of international law. An inquiry can be raised: what is the precautionary principle? Legal provisions, opinions, and soft law instruments can give a sense in this regard.

For example, the UN Framework Convention on Climate Change (UNFCCC) sensibly captures the precautionary principle:

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[42] Gabčíkovo-Nagymaros Project (Hung. v. Slovk.), Judgment, 1997 I.C.J. 7, ¶ 140 (Sep. 25).
[43] Whaling in the Antarctic (Austl. v. Japan: N.Z. intervening), Judgment, 2014 I.C.J. 226, 455, ¶ 7 (Mar. 31) (separate opinion by Charlesworth, J. ad hoc) [hereinafter Whaling in the Antarctic (separate opinion by Charlesworth, J. ad hoc)].
[44] Pulp Mills on the River Uruguay (Arg. v. Uru.), Judgment, 2010 I.C.J. 14, 61, ¶ 164 (Apr. 20) [hereinafter Pulp Mills on the River Uruguay]
[45] Pulp Mills on the River Uruguay (separate opinion by Cançado Trindade, J.), *supra* note 30, ¶ 52.
[46] Case T-74/00, Artegodan GmbH and Others v. Commission of the European Communities, ¶ 184, 2002 E.C.R. II-4945. [hereinafter Artegodan GmbH and Others v. Commission of the European Communities]
[47] *Id.* ¶¶ 184-85. *See also* Eur. Comm'n, Communication from the Commission on the Precautionary Principle, Summary, ¶ 3 at 2, COM(2000) 1 final (Feb. 2, 2000) [hereinafter Eur. Comm'n].
[48] Appellate Body Report, *EC — Hormones*, *supra* note 41, ¶ 43; Panel Report, *EC — Biotech*, *supra* note 41, ¶ 4.542.
[49] *See* Rüdiger Wolfrum, *Precautionary Principle*, *in* NEW TECHNOLOGIES AND LAW OF THE MARINE ENVIRONMENT 203, 211 (Jean-Pierre Beurier et al. eds., 2000).

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> [W]here there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures, taking into account that policies and measures to deal with climate change should be cost-effective so as to ensure global benefits at the lowest possible cost. To achieve this, such policies and measures should take into account different socio-economic contexts, be comprehensive, cover all relevant sources, sinks and reservoirs of greenhouse gases and adaptation, and comprise all economic sectors. Efforts to address climate change may be carried out cooperatively by interested Parties.[50]

Within the context of European law, according to the CJEU, the precautionary principle requires the competent authorities to *take appropriate measures to prevent specific potential risks to public health*, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests.[51]

According to Judge Cançado Trindade, two key elements that account for the application of the precautionary principle are (i) risks and (ii) scientific uncertainties.[52] Meanwhile, according to the European Commission, the precautionary principle has two distinct aspects: (i) the political decision to act or not to act as such, linked to the *factors triggering recourse to the precautionary principle*; (ii) in the affirmative, how to act, the application of the precautionary principle.[53] The precautionary principle can be triggered where (i) potentially negative effects resulting from a phenomenon, product or procedure have been or are identified (the identification of potentially negative effects) and (ii) a scientific evaluation of the risk which because of the insufficiency of the data, their inconclusive or imprecise nature, makes it impossible to determine with sufficient certainty the risk in question (scientific evaluation and scientific uncertainty).[54] So, the two positions are comparable. These observations resonate with the moral account of the precautionary principle.

Meanwhile, diseases and epidemics are, by nature, featured by risks and scientific uncertainties. As a result, presumably, the precautionary principle

[50] UNFCCC, *supra* note 41, art. 3(3).
[51] Artegodan GmbH and Others v. Commission of the European Communities, *supra* note 46, ¶ 184.
[52] Pulp Mills on the River Uruguay (separate opinion by Cançado Trindade, J.), *supra* note 30, ¶ 62. *See also* Southern Bluefin Tuna (N.Z. v. Japan; Austl. v. Japan), Case No. 3 & 4, Provisional Measures, Order of August 27 1999, 1999 ITLOS Rep. 280, 296, ¶ 77.
[53] Eur. Comm'n, *supra* note 47, at 12.
[54] *Id.*

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is relevant to matters concerning diseases and epidemics.[55] But is it true that there is a precautionary principle in the field of global health law?

As recognized by scholars, states,[56] and judges[57] and manifested by jurisprudence,[58] being a general principle, the precautionary principle does not need to be explicitly pronounced by an instrument to be relevant and applicable thereof, but it can be found in the objective and purpose, structure, and rules of a legal instrument or regime. By examining the totality of global health law, it is valid to claim that the precautionary principle can be found as a general principle thereof.

A. Objective and Purpose of Prevention and Precaution

What shapes a legal regime is, first and foremost, its objective and purpose. The prevention of diseases and broadly public health risks is the core objective and purpose of global health law. For example, the Preamble of the 1894 International Sanitary Convention (hereinafter "ISC") Signed at Dresden read "Sa Majesté l'Empereur d'Allemagne . . . Ayant décidé *d'établir des mesures communes pour sauvegarder la santé publique* en temps d'épidemie cholérique, sans apporter d'entraves inutiles aux transactions commerciales et au mouvement des voyageurs"[59] ["His Majesty the Emperor of Germany . . . Having decided to establish common measures to safeguard public health in times of cholera epidemic, without bringing unnecessary obstacles to commercial transactions and the movement of travellers"]. Meanwhile, the Foreword and Article 2 of the 2005 IHR articulated that "The purpose and scope of these Regulations are to *prevent, protect against, control and provide a public health response to the international spread of disease* in ways that are *commensurate with* and restricted to public health risks, and which *avoid unnecessary interference* with international traffic and trade" [Emphasis added]. The amendment to the 2005 IHR[60] adds the phrase "prepare for" ("The purpose and scope of

[55] M. Martuzzi & R. Bertollini, *The Precautionary Principle, Science and Human Health Protection*, 11(1) HUM. ECOL. RISK ASSESS. 63, 63 (2005); *see generally* N. Pearce, *Public Health and the Precautionary Principle*, *in* THE QNCIPLE: PROTECTING PUBLIC HEALTH, THE ENVIRONMENT AND THE FUTURE OF OUR CHILDREN 49 (Marco Martuzzi & Joel A. Tickner eds., 2004).
[56] Panel Report, *EC — Biotech*, *supra* note 41, ¶ 4.524; Cass R. Sunstein, *Beyond the Precautionary Principle*, 151(3) UNIV. PA. L. REV. 1003, 1006 (2003).
[57] Whaling in the Antarctic (separate opinion by Charlesworth, J. ad hoc), *supra* note 43, ¶¶ 6-10.
[58] Appellate Body Report, *EC — Hormones*, *supra* note 41, ¶ 124.
[59] International Sanitary Convention Signed at Dresden, Apr. 15, 1893, and Protocol Recording Accession of Great Britain, July 13-15, 1893, Preamble, 1894 U.K.T.S. 4. [hereinafter ISC Signed at Dresden].
[60] WHO, Seventy-Seventh World Health Assembly Agenda Item 13.3: International Health Regulations (2005), art. 2, WHO Doc. A77/A/CONF./14 (2024), https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_ACONF14-en.pdf. [hereinafter Seventy-Seventh World Health Assembly]

臺灣大學學術期刊資料庫

these Regulations are to prevent, prepare for . . . ."), which emphasizes the degree of earliness and being precautionary.[61]

Necessary measures and restrictions to protect public health and prevent diseases are thus envisaged, allowed, and coordinated to the extent that they are *commensurate with* and *restricted to* public health risks. This vision can also be found in the *travaux preparatoire* of the conception of the field of global health law.[62]

In light of the objective and purpose of global health law, uncertainty and the precautionary approach/principle are always relevant to global health law and its rules; however, they were not and have not been adequately recognized or appreciated. For example, it should be noted that "public health risk" is the concept underlying many provisions of the 2005 IHR (e.g., Articles 2, 9, 10, 11, 13, 16, 19, 21, 23, 27, 28, 30, 31, 43 . . . .) Article 1 of the 2005 IHR defines "public health *risk*" as "a *likelihood* of an event that may adversely affect the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct" [Emphasis added]. Meanwhile, "public health event" defined as "a *manifestation* of disease or an *occurrence* that creates a potential for disease" [Emphasis added] is mentioned more infrequently than "public health risk". In this regard, it is helpful to note that the approach of global health law is comparable to European law. In European law, "risk" constitutes *the degree of probability that the acceptance* of certain measures or practices will adversely affect the interests safeguarded by the legal order[63] while "hazard" describes any product or procedure capable of having an adverse effect on human health.[64] For something being a "risk" and being a "likelihood" or "degree of probability" (rather than the manifestation or the occurrence), there is a level of uncertainty (rather than the full apparency). Though in a number of limited cases, an objective and accurate probability or likelihood can be established, unfortunately, it is often not the case.[65] It should also be further noted that the uncertainty of public health risks is especially relevant and salient in the case of "unknown causes or sources"[66] and "novel cause".[67] The precautionary principle is about taking into account the uncertainty in determining whether the [level of protection of the] interests safeguarded by the legal order is/are threatened by certain measures or

[61] *See e.g.*, Doan et al., *supra* note 11.
[62] *See* N. HOWARD-JONES, THE SCIENTIFIC BACKGROUND OF THE INTERNATIONAL SANITARY CONFERENCES 495 (1975), https://iris.who.int/bitstream/handle/10665/62873/14549_eng.pdf.
[63] Case T-13/99, Pfizer Animal Health SA v. Council, ¶ 126, 2002 E.C.R. II-3318 [hereinafter Pfizer Animal Health SA v. Council].
[64] *Id.*
[65] *See generally* D. Weisbach, *Introduction: Legal Decision Making Under Deep Uncertainty*, 44(52) J. LEGAL STUD. S319 (2015).
[66] International Health Regulations (2005), Annex II, May 23, 2005, 2509 U.N.T.S. 79 [hereinafter 2005 IHR].
[67] Seventy-Seventh World Health Assembly, *supra* note 60, Annex II.

臺灣大學學術期刊資料庫

practices or substances or products or procedures and in determining responses thereto.

B. Toolkit of the Precautionary Principle

1. The Principle of Cooperation — Cooperation is necessarily required by the precautionary principle.[68] "Cooperation" is envisaged with a double-prong purpose: (i) to progressively enhance scientific knowledge, develop the technical capacity, make such information available, and circulate such information, [69] and (ii) measures and activities are cooperated and coordinated.[70] Judge Bhandari acknowledged that conventions "couch the precautionary principle in terms similar to the progressive realization of enhanced scientific capabilities and available knowledge".[71] To that effect, first, research is carried out to collect and provide accurate data, while scientific, technical and statistical data are collected and tools are exchanged and transferred. [72] Second, various legal mechanisms, *inter alia*, Precautionary Reference Points, [73] scientific advisory/technical expert bodies[74] have been established. That understanding naturally flows from the need to deal with and respond to uncertainty: the need to address and, where possible, eliminate or reduce uncertainty and determine appropriate courses of action from available information. It is also self-evident that studying and researching are among what can be called *measures* under the umbrella of the precautionary principle. In this vein, the precautionary principle should be recognized as continuous and progressive rather than only momentary (though, as shall be further demonstrated in the subsequent subsections, continuous and progressive measures and momentary measures are interconnected (i.e., the right and obligation to take provisional measures are subject to, among requirements, the obligation to seek to obtain the

[68] UNFCCC, *supra* note 41, art. 3.(3); Bamako Convention, art.10.(2).(d), 16, Jan. 31, 1991, 2101 U.N.T.S. 177 [hereinafter Bamako Convention]; U.N. Fish Stocks Agreement, *supra* note 41, art. 25.
[69] Bamako Convention, *supra* note 68, art. 10; U.N Fish Stocks Agreement, *supra* note 41, art. 14.
[70] Wolfrum, *supra* note 49, at 209; U.N. Conference on Straddling Fish Stocks and Highly Migratory Fish Stocks, *Guidelines for the Application of Precautionary Reference Points in Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks of the Fish Stocks Agreement*, art. 6.(3).(d), 6.(5), U.N. Doc. A/CONF.164/37, Annex II (Sep. 8, 1995); Stockholm Convention on Persistent Organic Pollutants, art. 1, 8, Annexes A, B and C, May 22, 2001, 2256 U.N.T.S. 119 [hereinafter Stockholm Convention]; Convention on the Protection of the Marine Environment of the Baltic Sea Area, art. 3, reg. 2, 3, Annex 2, June 22, 1988, 1507 U.N.T.S. 166. [hereinafter Helsinki Convention].
[71] Certain Activities Carried Out by Nicaragua in the Border Area (Costa Rica v. Nicar.), Judgment, 2018 I.C.J. 15, at 795, ¶ 18 (Feb. 2) (separate opinion by Bhandari, J.).
[72] UNFCCC, *supra* note 41, arts. 4, 5, 6; U.N. Fish Stocks Agreement, *supra* note 41, arts. 14, 7 of Annex 1.
[73] U.N. Fish Stocks Agreement, *supra* note 41, art. 6.(3).(d).
[74] UNFCCC, *supra* note 41, art. 9.

臺灣大學學術期刊資料庫

additional information necessary for a more objective assessment of risk)). The principle of cooperation also entails the obligation not to jeopardise cooperation and common objectives through unilateral behaviours.

Global health instruments emphasize cooperation. This can be observed as early as in the preamble of some first ISCs (mentioned above). Early ISCs also established a regime concerning information for the sake of cooperation.[75] States have recognized the necessity of having an independent technical expert body that would offer empirical- or scientific-based advice, circulate empirical- or scientific-based information, coordinate actions based on empirical or scientific information, advance scientific knowledge, and make suggestions to adjust health measures taken into account empirical or scientific information.[76] With that view, sanitary/health bodies have been established, e.g., the OIPH,[77] the Pan-American Sanitary Bureau — now known as the Pan-American Health Organization (PAHO),[78] the Health Organization of the League of Nations (HOLN), and the WHO.[79] As a corollary, the WHO should be highly regarded for its scientific expertise and for coordinating [measures of] states. The WHO coordinates states' measures via its measures and scientific advice.

2. The Principle of Comprehensiveness — The precautionary principle entails that measures must be comprehensive.[80] Article 1 of the 2005 IHR embraces the all-hazards approach. It defines "disease" as "an illness or medical condition, *irrespective of origin or source*, that presents or could present significant harm to humans" [Emphasis added] and "public health risk" as "*likelihood* of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger" [Emphasis added].

3. The Principle of Reasonableness and Responsibility — The precautionary principle's two-prong principle of reasonableness and responsibility is expressed via the right, obligation, and encouragement to act responsibly and duly to protect public interests, public health included. The renowned Principle 15 of the Rio Declaration reads, "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall be not used as a reason for postponing cost-effective measures to prevent

[75] ISC Signed at Dresden, *supra* note 59, Annexes I Chapter I; International Sanitary Convention Signed at Paris, art. 3, 4, 5, Dec. 3, 1903 [hereinafter 1903 ISC Signed at Paris]
[76] 1903 ISC Signed at Paris, *supra* note 75, art. 181.
[77] Econ. & Soc. Council, *International Agreement Signed at Rome 9 December 1907 for the Creation in Paris of an International Office of Public Health*, art. 4, U.N. Doc. E/H/L/W.2 (June 17, 1946).
[78] *History of the Pan American Health Organization (PAHO)*, PAN AM. HEALTH ORG., https://www.paho.org/en/who-we-are/history-paho.
[79] Constitution of the World Health Organization art. 2, July 22, 1946, 14 U.N.T.S. 185. [hereinafter WHO Constitution].
[80] U.N. Conf. on Env't & Dev., *Rio Declaration on Environment and Development*, Principle 15, U.N. Doc. A/CONF.151/26 (Vol. I), Annex I (Aug. 12, 1992). [hereinafter Rio Declaration]; UNFCCC, *supra* note 41, art. 3.(3); U.N. Fish Stocks Agreement, *supra* note 41, art. 5.(f).

臺灣大學學術期刊資料庫

environmental degradation." Section 11 of the UN World Charter for Nature reads:

> Activities which might have an impact on nature shall be controlled, and the best available technologies that minimize significant risks to nature or other adverse effects shall be used; in particular: (a) Activities which are likely to cause irreversible damage to nature shall be avoided; (b) Activities which are likely to pose a significant risk to nature shall be preceded by an exhaustive examination . . . .

In *EC — Hormones*, the WTO Appellate Body held 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".[81] The right, obligation, and encouragement to act responsibly and reasonably to protect public interests entail:

1. There must be risk assessments to detect risks for measures and activities to be deployed with a view to preventing risks and crises, and measures deployed to prevent risks and crises must be preceded by risk assessments.[82]

Within the context of the SPS Agreement, with the recognition of the precautionary principle, "risk" must be "ascertainable risk".[83] Similarly, within the context of European Law, the CJEU recognized that the precautionary measures cannot properly be based on a purely hypothetical approach.[84] There must be a risk assessment to assess the degree of probability of a certain product or procedure having adverse effects and the seriousness of any such adverse effects.[85] The competent public authority must ensure that any measures that it takes are *based on as thorough a scientific risk assessment as possibl*e.[86] Scientific advice must be based on the principles of excellence, independence and transparency.[87] In the Activities in the Border Area case, the ICJ asserted that states have an obligation [under customary law] to exercise due diligence [and, where necessary, EIA] with a view to preventing or minimizing the realization of

[81] Appellate Body Report, *EC — Hormones*, *supra* note 41, ¶ 123.
[82] *See, e.g.*, G.A. Res. 37/7, World Charter for Nature, art. 11 (Oct. 28, 1982); Rio Declaration, *supra* note 80, Principle 15.
[83] Appellate Body Report, *EC — Hormones*, *supra* note 41, ¶ 186.
[84] Pfizer Animal Health SA v. Council, *supra* note 63, ¶¶ 143-45; *see also* Eur. Comm'n, *Communication from the Commission on the Precautionary Principle*, *supra* note 47, ¶ 5; Appellate Body Report, *EC — Hormones*, *supra* note 41, ¶ 124.
[85] Pfizer Animal Health SA v. Council, *supra* note 63, ¶ 148.
[86] *Id.* ¶ 162.
[87] *Id*. ¶ 159.

臺灣大學學術期刊資料庫

significant transboundary environmental harm.[88] A state must "before embarking on an activity having the potential adversely to affect the environment of another State, ascertain if there is a risk of significant transboundary harm, which would trigger the requirement to carry out an environmental impact assessment."[89] Environmental Impact Assessment (hereinafter "EIA") and Due Diligence (DD) are, in essence, a kind of risk assessment.

Within the context of global health law, the 2005 IHR requires each State Party to develop, strengthen and maintain the capacity to *detect, verify, assess, notify, report, and respond to public health events, which* cover the entire territories of states.[90] Pursuant to Articles 6.(1) and 7 of the 2005 IHR, [each] State Parties shall make use of risk assessment tools[91] to assess whether a particular event occurring within its territory or an unexpected or unusual public health event within its territory, irrespective of origin or source, detected by their national surveillance system may constitute a potential Public Health Emergency of International Concern (hereinafter "PHEIC") that should be notified to WHO. In addition, State Parties shall, as far as practicable, inform WHO within 24 hours of receipt of evidence of a public health risk identified outside their territory that may cause international disease spread, as manifested by exported or imported. On its part, the WHO is capable of collecting *by itself* information regarding events through its surveillance activities as well as receiving and taking into account reports from sources other than states.[92]

2. States and authorities can set a high level of protection provided that it is not contrary to the law.

According to the WTO Appellate Body, states and authorities do not have to conform to only "the view of a majority of the relevant scientific community" but can act in good faith on the basis of [minority] views coming from qualified and respected sources.[93] According to the CJEU, to the extent to which an authority opts to disregard a scientific opinion, an authority can "base its decision on a supplementary opinion from the same experts or other evidence, whose probative value is at least commensurate with that of the opinion concerned."[94] Meanwhile, states and authorities can set a higher level of protection than what could be achieved by the

[88] Certain Activities Carried Out by Nicaragua in the Border Area (Costa Rica v. Nicar.), Judgment 2018 I.C.J. 15 (Feb. 2); Construction of a Road in Costa Rica along the San Juan River (Nicar. v. Costa Rica), Judgment, 2015 I.C.J 665, ¶ 104 (Dec. 16).
[89] *Id.*
[90] WHO, International Health Regulations (2005) Core Capacity Workbook, Annex 1, WHO Doc. WHO/HSE/GCR/2015.13 (2015), https://iris.who.int/bitstream/handle/10665/190819/WHO_HSE_GCR_2015.13_eng.pdf?sequence=1.
[91] 2005 IHR, *supra* note 66, Annex II.
[92] *Id*. art. 5(4), 9(1).
[93] Appellate Body Report, *EC — Hormones*, *supra* note 41, ¶ 194.
[94] Pfizer Animal Health SA v. Council, *supra* note 63, ¶ 198.

臺灣大學學術期刊資料庫

recommendations of a technical expert body (i.e., being more cautious than that implied in existing international standards, guidelines and recommendations) provided that such measures do not operate contrary to the law, e.g., measures must not be arbitrary and discriminatory.[95] Both the CJEU and the WTO Appellate Body recognized that the opinions of scientists and scientific bodies and international standards are of "probative value" but not dispositive.[96]

Within the context of global health law, states can deploy "additional social-public health measures". Early ISCs allowed states to decide on exceptional measures.[97] The 2005 IHR made clear that "temporary recommendations" and "standing recommendations" are "non-binding advice".[98] This is also reflected by in Article 43 of the 2005 IHR and its *travaux preparatoire*.[99] Article 43.(1) reads

> These Regulations shall not preclude States Parties from implementing health measures, in accordance with their relevant national law and obligations under international law, in response to specific public health risks or public health emergencies of international concern, which:
>
> (a) *achieve the same or greater level of health protection than WHO recommendations*; or
>
> (b) are otherwise prohibited under Article 25, Article 26, paragraphs 1 and 2 of Article 28, Article 30, paragraph 1(c) of Article 31 and Article 33,
>
> provided such measures are otherwise consistent with these Regulations.
>
> Such measures shall not be more restrictive of international traffic and not more invasive or intrusive to persons than reasonably available alternatives that *would achieve the appropriate level of health protection*. [Emphasis added]

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[95] Appellate Body Report, *EC — Hormones*, *supra* note 41, ¶ 124.

[96] Pfizer Animal Health SA v. Council, *supra* note 63, ¶ 198; Appellate Body Report, *US — Continued Suspension of Obligations in the EC — Hormones Dispute*, ¶¶ 708, 711, WTO Doc. WT/DS320/AB/R (adopted Oct. 16, 2008) [hereinafter Appellate Body Report, *US — Continued Suspension*].

[97] ISC Signed at Dresden, *supra* note 59, Preamble, Annex I, Chapter V-VI; 1903 ISC Signed at Paris, *supra* note 75, arts. 23, 24, 30, 41, 44, 83, 84.

[98] 2005 IHR, *supra* note 66, art. 1.

[99] Provisions of Document IGWG/IHR/Working paper/12.2003 contained initial proposed revisions of the 1969 IHR, which prohibited states from taking measures in the absence of or taking measures which are not covered by WHO recommendations, were eliminated; the provision concerning additional measures was added. *See* Intergovernmental Working on Revision Int'l Health Regul., *Review and Approval of Proposed Amendments to the International Health Regulations: Explanatory Notes*, WHO Doc. A/IHR/IGWG/2/INF.DOC./2 (Jan. 27, 2005).

臺灣大學學術期刊資料庫

Pursuant to Article 43.(2), in determining whether to implement the health measures referred to in Article 43.(1) or additional health measures under Article 23.(2), Article 27.(1), Article 28.(2) and Article 31.2.(c), States Parties shall *base their determinations upon* (a) scientific principles; (b) available scientific evidence of a risk to human health, or *where such evidence is insufficient, the available information including from WHO and other relevant intergovernmental organizations and international bodies*; and (c) any *available specific guidance or advice* from WHO.

As established by other jurisprudences, the phrase "*base . . . upon*" should not be interpreted as synonymous with "*conform . . . to*".[100] The phrase "*including*", used by Article 43.(2).(b), means the list is non-exhaustive. Thus, available information can come from the WHO and other relevant intergovernmental organizations and international bodies, as well as from other credible sources of information. The use of "other sources of information", in fact, has been envisaged by the 2005 IHR under Article 9.[101] The possibility that other sources of information are resorted to by states to justify additional measures should not be neglected or taken lightly. It is because it is not entirely natural or logical if a state can resort to and rely on the [same] piece of information as provided by the WHO to implement additional measures—the piece of information based upon which the WHO does not recommend such measures (assuming that the information from other relevant [formal] intergovernmental organizations and international bodies should be accessible to the WHO and the WHO should diligently explore, study, and examine these sources of information, and as a result, recommendations from the WHO in the first place should have taken into account such pieces of information from such sources). This interpretation is reinforced by the obligation of States to provide WHO with "relevant scientific information" under Article 43.(1) and WHO's obligation to share scientific evidence and information under Article 43.(3).[102] Notwithstanding, there should be certain circumstances where a state or states can rely on the [same] piece of information as provided by the WHO and/or other relevant [formal] intergovernmental organizations and international bodies to implement additional measures (and as a corollary, the state acts in discordance with the WHO's recommendations). These instances can be grounded on the cornerstone principle of international law—the Lotus Principle[103] and on the full acknowledgement that *sometimes*

[100] Appellate Body Report, *EC — Hormones*, *supra* note 41, ¶ 163.
[101] According to the ICJ, the interpretation of an instrument should be conducted in such a manner that maintains the consistency of the instrument, Maritime Delimitation in the Indian Ocean (Som. v. Kenya), Preliminary Objections, 2017 I.C.J Rep. 3, ¶ 84 (Feb. 2).
[102] *See infra* Section II.B.6, III.A; *See infra* Section III.A.
[103] S.S. Lotus (Fr. v. Turk.), Judgement, 1927 P.C.I.J. (ser. A) No. 10, at 18 (Sep. 7):

臺灣大學學術期刊資料庫

scientific information does not fully entail or reflect specific social and economic conditions and issues of a society or a location (and for that reason, accommodation and flexibility should be needed).[104] However, for clarity, in light of the precautionary principle and the established jurisprudence in international law, the state that invokes this capacity and acts in discordance with WHO's advice, of course, should be put under more stringent Onus Operandi.[105] Thus, although a portion of political powers still resides with states, it is not the case that, in exercising such powers, there are no obligations and constraints on the side of states. To the extent that it is so recognized, states' measures are subjected to be reviewed, scientifically[106] and judicially.[107]

The difference between the two groups of provisions referred to by Article 43.(1).(b) and 43.(2) except for those provided under Article 43.(1).(b) is that the provisions referred to by Article 43.(1).(b) are prohibitive in nature ["*otherwise prohibited measures*"].[108] Meanwhile, the provisions referred to by Article 43.(2) except for those provided under Article 43.(1).(b) have "additional health measures build-ins", being such build-ins as manifested by the phrases "additional . . . health measures" (Article 23.(2), Article 27.(1), Article 31.2.(c)) or "other measures" (Article 28.(2)). Meanwhile, it can be observed from Article 43.(1) that states can opt for and set a high[er] level of protection [than the one recommended by the WHO].

> The rules of law binding upon States therefore emanate from their own free will as expressed in conventions or by usages generally accepted as expressing principles of law and established in order to regulate the relations between these co-existing independent communities or with a view to the achievement of common aims.

[104] *See supra* Section III.1.

[105] It should be noted that, however, the higher standard of proof or judicial review does not necessarily equate to the contested so-called "reversal of the burden of proof". *See* Pulp Mills on the River Uruguay, *supra* note 44, ¶ 164; Artegodan GmbH and Others v. Commission of the European Communities, *supra* note 46, ¶ 191; Whaling in the Antarctic (separate opinion by Charlesworth, J. ad hoc), *supra* note 43, ¶ 67; Perhaps, "reversal of the burden of proof" should be considered "opaquely worded", *see* Wolfrum, *supra* note 49 at 211; *see also* Caroline E. Foster, *Methodologies and Motivations: Was Japan's Whaling Programme for Purposes of Scientific Research?*, *in* WHALING IN THE ANTARCTIC: SIGNIFICANCE AND IMPLICATIONS OF THE ICJ JUDGMENT 9, 11 (Malgosia Fitzmaurice & Dai Tamada eds., 2016).

[106] 2005 IHR, *supra* note 66, arts. 43.(4), 43.(6).

[107] *Id.* art. 56.

[108] They contain phrases such as "no health measure shall be applied" (Articles 25, 26), "shall not be prevented" (Article 28.(1)), "shall not be refused" (Article 28.(2)), "shall not be required" (Article 31.(1).(c)), "shall not be subject to" (Article 33). Article 30 has an implied prohibitive nature: "a suspect traveller who on arrival is placed under public health observation may continue an international voyage, if the traveller does not pose an imminent public health risk", i.e., states shall not or at least should not prevent a suspect traveller who on arrival is placed under public health observation if the traveller does not pose an imminent public health risk.

臺灣大學學術期刊資料庫

3. Protective measures can be taken on a provisional basis where there is uncertainty and insufficiency of evidence.

Within the context of EU law, in the BSE Case, the CJEU opined that "[w]here there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent".[109] According to the CJEU, in a situation in which there is scientific uncertainty, "a risk assessment cannot be required to provide the Community institutions with *conclusive scientific evidence* of the reality of the risk and the seriousness of the potential adverse effects were that risk to become a reality". [110] The precautionary principle allows the competent public authorities to take, on a provisional basis, preventive protective measures on what is as yet an incomplete scientific basis, pending the availability of additional scientific evidence. [111] However, preventive measures cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified or confirmed.[112] Rather, preventive measures may be taken only if the risk, although the reality and extent thereof have not been "fully" demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time when the measure was taken.[113] In the latter case, there is the existence of *solid evidence* which, while not resolving scientific uncertainty, may reasonably raise doubts as to the safety of matters.[114]

The WTO Appellate Body recognized "scientific uncertainty" and insufficiency of evidence as grounds for [provisional] protective measures. "Scientific uncertainty" may be indicated by divergent views presented by qualified scientists who have investigated a particular issue.[115] Scientific evidence will be considered "insufficient" "*if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks*. . . ."[116] It follows that measures can be taken on a provisional basis where there is no conclusive evidence of a causal relationship between the inputs and the effects[117] or

[109] Case C-180/96, United Kingdom v. Commission of the European Communities, ¶ 99, 1998 E.C.R. I-2265 [hereinafter United Kingdom v. Commission of the European Communities].
[110] Pfizer Animal Health SA v. Council, *supra* note 63, ¶ 142.
[111] *Id.* ¶ 387.
[112] *Id.* ¶ 143.
[113] *Id.* ¶ 144.
[114] Case T-229/04, Sweden v. Commission, ¶ 161, 2007 E.C.R. II-2441.
[115] Appellate Body Report, *EC — Hormones*, *supra* note 41, ¶ 194.
[116] Appellate Body Report, *Japan — Measures Affecting the Importation of Apples*, ¶ 179, WTO Doc. WT/DS245/AB/R (adopted Dec. 10, 1998).
[117] *See* Agreement on the Application of Sanitary and Phytosanitary Measures art. 5.7, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 493;

臺灣大學學術期刊資料庫

where new evidence from a qualified and respected source "puts into question the relationship between the pre-existing body of scientific evidence and the conclusions regarding the risks."[118] However, hypothesis and "theoretical uncertainty"[119] cannot be the grounds for measures.

In global health law, even in the case where the States Parties at stake are not obliged to notify an event to the WHO, in particular where there is *insufficient information available to complete the decision instrument*, the States Parties may nevertheless keep WHO advised thereof through the National IHR Focal Point and consult with WHO on appropriate health measures.[120] As demonstrated, certain additional measures of states can be conditionally permitted where scientific evidence is insufficient. In fact, throughout its history, global health law envisaged different measures under uncertainty.[121]

4. The Principle of Provisional — As mentioned, in light of scientific uncertainty and insufficiency of evidence, the precautionary principle entails that measures are to be deployed on an emergency and provisional basis. It also entails that instruments and mechanisms are "living". I call these components "[t]he principle of provisional". This principle embraces, inter alia, the obligation to study and examine scientific developments.[122]

(a) Provisional and Emergency — Article 6.(7) of the Fish Stocks Agreement requires measures to be taken on an *emergency basis*.[123] Measures taken on an emergency basis shall be *temporary* [provisional] and shall be *based on the best scientific evidence available.*[124] In the "*Southern Bluefin Tuna Cases (New Zealand v. Japan; Australia* v. *Japan), Provisional Measures*", Judge Treyes opined that "The precautionary approach can be seen . . . inherent in the very notion of provisional measures. . . ."[125] EU institutions had also invoked the precautionary principle on an emergency basis.[126] In *EC — Hormones*, it is a consensus that Article 5.(7) of the SPS

MOX Plant (Ir. v. U.K.), Institution of Proceedings, Case No. 10, Request for Provisional Measures and Statement of Case of Ireland, 2001 ITLOS Rep. 95, ¶ 101 (Nov. 9).

[118] Appellate Body Report, *US — Continued Suspension*, *supra* note 96, ¶ 703.

[119] Appellate Body Report, *EC — Hormones*, *supra* note 41, ¶ 186.

[120] 2005 IHR, *supra* note 66, art. 8.

[121] For example, the 1893 ISC envisaged the construction of health facilities such as hospitals, disinfection and isolation stations that comprised of, inter alia, disinfection ovens, baths, showers, water tanks, a laundry room in the lack of consensus of whether these would help to prevent the spread of cholera. *See* HOWARD-JONES, *supra* note 62, at 76; David P. Fidler, *SARS: Political Pathology of the First Post-Westphalian Pathogen*, 31(4) J. L., MED. & ETHICS 485, 487 (2003).

[122] Eur. Comm'n, *supra* note 47, at 19-20.

[123] U.N. Fish Stocks Agreement, *supra* note 41, art. 6(7).

[124] *Id.*

[125] Southern Bluefin Tuna (Austl. & N.Z. v. Japan), Case No. 3, ITLOS, ¶ 9 (separate opinion by Treves, J.) (Aug. 27, 1999).

[126] United Kingdom v. Commission of the European Communities, *supra* note 109, ¶ 53, 1998 E.C.R. I-2265; Case C-157/96, R v. MAFF and Others, *ex parte* National Farmers' Union and Others, ¶ 88, 1998 E.C.R. I-2236.

臺灣大學學術期刊資料庫

Agreement, which is about provisional measures, manifests the precautionary principle. Within the context of the SPS Agreement, if provisional measures are taken, four obligations must be satisfied:

1. The measures are imposed in respect of a situation where "relevant scientific information is insufficient";
2. The measures are adopted "on the basis of available pertinent information";
3. The state [that adopted the measures] must "seek[s] to obtain the additional information necessary for a more objective assessment of risk"; and
4. The state must review the measure within a reasonable period of time.[127]

In the context of global health law, the WHO is endowed with emergency powers.[128] The 2005 IHR's provisions concerning PHEIC were designed to flesh out Article 28 of the WHO's Constitution in such a way that emergency powers are institutionalized with rules of procedure.[129] Notwithstanding, the 2005 IHR not only institutionalized emergency powers but also provided a ground for extrapolating such powers beyond an emergency. The transition from emergency powers to provisional measures is manifested in the fact that the WHO can employ measures in the absence of PHEIC. Concerning the provision of information, a declaration of PHEIC is *a* situation in which the WHO may provide information to Member States, non-state parties at stake and the public; however, there are other situations which are prescribed under *Articles 10*[130] and *11*[131] of the 2005 IHR. Concerning recommendations, although the 2005 IHR only provides that

[127] Appellate Body Report, *Japan — Measures Affecting Agricultural Products*, ¶ 89, WTO Doc. WT/DS76/AB/R (adopted Feb. 19, 1999); Appellate Body Report, *US — Continued Suspension*, *supra* note 96, ¶ 676. United Kingdom v. Commission of the European Communities, *supra* note 109, ¶ 101.

[128] WHO Constitution, *supra* note 79, art. 28(i).

[129] 2005 IHR, *supra* note 66, art. 1.

[130] WHO may also share with other States Parties the information available to it in cases where the State Parties who are requested to verify events which may constitute a Public Health Emergency of International Concern [hereinafter PHEIC] allegedly occurring in its territory does not accept the offer of collaboration in assessing the potential for international disease spread, possible interference with international traffic and the adequacy of control measures of WHO (and other standard-setting organizations), when justified by the magnitude of the public health risk, taking into account the views of the State Party concerned.

[131] the event is determined to constitute a PHEIC; or

(i) information evidencing the international spread of the infection or contamination has been confirmed by WHO in accordance with established epidemiological principles; or

(ii) there is evidence either that:

- control measures against the international spread are unlikely to succeed because of the nature of the contamination, disease agent, vector or reservoir, or
- the states lacks sufficient operational capacity to carry out necessary measures to prevent further spread of disease; or

(iii) the nature and scope of the international movement of travellers, baggage, cargo, containers, conveyances, goods or postal parcels that may be affected by the infection or contamination requires the immediate application of international control measures.

臺灣大學學術期刊資料庫

temporary recommendations shall be issued where PHEIC is declared,[132] for years, Emergency Committees have *consistently* formulated recommendations, though PHEIC was advised against being declared.[133] In 2023, for the first time in the history of the WHO, three months after the WHO declared COVID-19 had ceased to be an emergency, standing recommendations have been issued.[134] Standing recommendations are of a provisional nature.[135]

Consequently, the WHO's Constitution and the 2005 IHR also entrust the WHO with certain political functions and powers, for which the WHO bears certain political responsibilities.

(b) Living instruments and Mechanisms — Similar to instruments concerning health and environment in other fields,[136] health instruments and mechanisms in global health law, both hard and soft law, are "living".[137] That is, they are kept under continued review and evaluation and subjected to frequent revisions in line with the increase in knowledge. The preamble of the 1951 International Sanitary Regulations explicitly affirmed that "periodical revisions of international measures will be facilitated, taking into account, *inter alia*, the changing epidemiological situation, the experience gained and the progress of science and technique". This can be observed in soft law instruments of global health law as well.[138]

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[132] 2005 IHR, *supra* note 66, art. 15(1).

[133] *See e.g.*, *Statement on the First Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Outbreak of Novel Coronavirus (2019-nCoV)*, WHO (Jan. 23, 2020), https://www.who.int/news/item/23-01-2020-statement-on-the-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov); *WHO Statement on the Fifth Meeting of the IHR Emergency Committee Concerning MERS-CoV*, WHO (May 14, 2014), https://www.who.int/news/item/23-01-2020-statement-on-the-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov); That practice can be argued as subsequent practice in the application of a legal instrument in the sense of Article 31.(3).(b) of the VCLT (inasmuch as Article 31 represents customary rule of interpretation) and Draft Articles on the Responsibility of International Organizations (DARIO) (*See e.g.*, Alleged Violations of Sovereign Rights and Maritime Spaces in the Caribbean Sea (Nicar. v. Colom.), Preliminary Objections, Judgment, 2016 I.C.J. 3, ¶ 35 (Mar. 17); Application of the Convention on the Prevention and Punishment of the Crime of Genocide (Bosn. & Herz. v. Serb. & Montenegro), Judgment, 2007 I.C.J. 43, ¶¶ 109-10 (Feb. 26).

[134] *WHO Director-General's Opening Remarks at the Media Briefing – 9 August 2023*, WHO (Aug. 9, 2023), https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing---9-august-2023?fbclid=IwAR1f8ciSiA3PCKP2eFXc0ky1igkhvqipmDzfeOX5j0ZgzqcYQjuJsfS_-7c.

[135] *Id.*

[136] Bamako Convention, *supra* note 68, arts. 15(4), 17, 18; U.N. Fish Stocks Agreement, *supra* note 41, art. 36; UNFCCC, *supra* note 41, arts. 4, 7, 10, 12; Stockholm Convention, *supra* note 70, art. 19; Helsinki Convention, *supra* note 70, art. 20.

[137] *See e.g.*, Whaling in the Antarctic (Austl. v. Japan: N.Z. intervening), Judgment, 2014 I.C.J. 226, 348, ¶¶ 33-34 (Mar. 31) (separate opinion by Cançado Trindade, J.).

[138] *See e.g.,* WHO, WHO HANDBOOK FOR GUIDELINE DEVELOPMENT 166 (2d ed. 2014).

臺灣大學學術期刊資料庫

5. The Principle of Effectiveness and Proportional — The precautionary principle entails that measures must be effective, cost-effective,[139] and proportional,[140] and take into account different socio-economic contexts.[141] Socio-economic considerations embrace risks (the harms, the probability of the occurrence of harms), costs of such harms, social-economic costs associated with such harms, and costs associated with measures and solutions for such harms, e.g., the usage of certain technologies.[142] That is, there is a proportionality and effectiveness test which can take the form of or be realized by the employment of, non-exhaustively, cost-benefit analysis, decision-making tools, and decision-making procedure.[143] In the Whaling in the Antarctic case, according to the ICJ, the Japan's research whaling in the Antarctic (hereinafter "JARPA") II Research Plan should have included some analysis of the feasibility of non-lethal methods, e.g., relative costs of any methods or a comparison of how the expense of lethal sampling might be measured against the cost of a research programme that more extensively uses non-lethal alternatives.[144] Inasmuch as "research" is a precautionary measure, that case evinces that the precautionary measures themselves are also subjected to being assessed in accordance with the precautionary principle and thus must be proportional.

Although core instruments of global health law do not explicitly pronounce the phrase "proportional[ity]" specifically, the demand of acting proportional is implied by the Preamble of the WHO's Constitution via the all-rounded definition of "health": "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity", i.e., disproportional measures that aim to protect health but adversely impact health are not acceptable. ISCs and the 2005 IHR pronounce that measures must be "*commensurate with* and restricted to public health risks" and "*avoid unnecessary interference* with international traffic and trade". Further, Article 43.(1).(b) subjects the group of provisions to which it refers to modifications, *inter alia*: "achieve *the same or greater level of health protection* than WHO recommendations", "such measures shall not be more restrictive of international traffic and not more invasive or intrusive to persons than reasonably available alternatives that would achieve the *appropriate level of health protection*". Likewise, each provision contained in the group referred to by Article 43.(2) (except for those

[139] Rio Declaration, *supra* note 80, Principle 15; UNFCCC, *supra* note 41, art. 3.(3); U.N. Fish Stocks Agreement, *supra* note 41, art. 5.(f).
[140] Eur. Comm'n, *supra* note 47, at 3.
[141] UNFCCC, *supra* note 41, art. 3.(3); Stockholm Convention, *supra* note 70, Annex F.
[142] Pfizer Animal Health SA v. Council, *supra* note 63, ¶ 147; United Kingdom v. Commission of the European Communities, *supra* note 109, ¶¶ 93-111.
[143] *See also* Eur. Comm'n, *supra* note 47, at 18-19; Wolfrum, *supra* note 49, at 210-11.
[144] Whaling in the Antarctic (separate opinion by Charlesworth, J. ad hoc), *supra* note 43, ¶¶ 137, 144.

臺灣大學學術期刊資料庫

provided under Article 43.(1).(b)) either explicitly or implicitly mentions similar modifications separately thereof.[145]

6. The Principle of Transparency — Considering the precautionary principle, transparency is a necessary requirement in relation to activities and measures.[146] In the Whaling in the Antarctic case, it is observed that the "Standard of Review" imposed upon Japan the obligation to explain.[147] It follows that [where the precautionary principle is relevant] states must be transparent and must not be arbitrary in their conduct (so that they can provide reasons—but not pretexts—for their behaviours). In fact, the JARPA II was inferred to lack transparency.[148] The obligation to state reasons and explain can also be found in the CJEU's jurisprudence. As mentioned, the CJEU opined that a competent public authority must ensure that any measures that it takes are based on as thorough a scientific risk assessment as possible,[149] which, in turn, must be based on the principles of excellence, independence and *transparency*.[150]

> To the extent to which an authority opts to disregard a scientific opinion, it must *provide specific reasons* for its findings by comparison with those made in the opinion and its statement of reasons must explain why it is disregarding the latter. The statement of reasons must be of a scientific level at least commensurate with that of the opinion in question.[151]

Within the context of global health law, the WHO's obligation to provide information where it declares PHEIC and make recommendations can be considered as discharging the obligation to state reasons. Meanwhile, unless being covered by a temporary or standing recommendation, a state

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[145] Article 23.(2) reads:

> On the basis of evidence of a public health risk . . . States Parties may apply additional health measures, in accordance with these Regulations . . . on a case-by-case basis, the least intrusive and invasive medical examination that would achieve the public health objective of preventing the international spread of disease.

Article 27.(1) uses the phrase "as necessary, to prevent the spread of disease", Article 28.(2) and 31.(2).(c) using phrases *mutatis mutandis* similar to that used by 27.(1).

[146] Eur. Comm'n, *supra* note 47, at 16-17.

[147] Whaling in the Antarctic (Austl. v. Japan: N.Z. intervening), Judgment, 2014 I.C.J. 226, 420, ¶ 15 (Mar. 31) (separate opinion by Xue, J.); Shotaro Hamamoto, *From the Requirement of Reasonableness to a 'Comply and Explain' Rule: The Standard of Review in the Whaling Judgment: The Significance and the Implications of the ICJ Judgment*, *in* WHALING IN THE ANTARCTIC: THE SIGNIFICANCE AND THE IMPLICATIONS OF THE ICJ JUDGMENT 38, 45-46 (Malgosia Fitzmaurice & Dai Tamada eds., 2016).

[148] Whaling in the Antarctic (separate opinion by Charlesworth, J. ad hoc), *supra* note 43, ¶¶ 158–59, 188, 193.

[149] *Id.* ¶ 162.

[150] *Id.* ¶ 159.

[151] Pfizer Animal Health v. Council, *supra* note 63, ¶ 199.

臺灣大學學術期刊資料庫

which invokes measures provided under Article 43.(2) (except for those provided under Article 43.(1).(b)) shall inform WHO of "such measures" and "health rationale",[152] whereas if the state invokes measures provided under Article 43.(1) (otherwise prohibited measures), they must also *additionally* provide the WHO with "relevant scientific information".[153] That is, states bear an obligation to state reasons and explain them to the WHO.

Suffice it to conclude that there is a precautionary principle underlying the totality of global health law.

III. TWO PROBLEMS WITH GLOBAL HEALTH LAW IN RELATION TO ITS RESTRICTIVE APPROACH TO THE PRECAUTIONARY PRINCIPLE

If it can be concluded that there is a precautionary principle underlying the totality of global health law, why are there controversies as to the precautionary principle in global health law? This paper argues that it is because global health law takes a restrictive approach to the precautionary principle, which is not in line with the approach of other fields of international law. This approach manifests and results in two problems: (i) being overly technological-centric, and (ii) vagueness. Interestingly, global health law does not offer as much protection to health as other fields of international law.

A. Overly Technological-Centric: The Matter of an Unobeyable Law

As mentioned, Article 43 categorizes measures into two groups which are subjected to different requirements: Article 43.(2) (except for measures provided under Article 43.(1).(b)) is subject to the obligation of states to inform the WHO of "*such measures*" and "*health rationale*",[154] whereas Article 43.(1).(b) is subject to the obligation of states to inform the WHO of "*relevant scientific information" in addition to* "*such measures*" and "*health rationale*".[155]

"Public health rationale", "scientific information", "scientific evidence" and "scientific principles" cannot be synonymous for four reasons:

First, under the customary rule of interpretation, every word in the text of an instrument must be able to be attributed meaning.[156]

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[152] 2005 IHR, *supra* note 66, art. 43(5).
[153] *Id.* art. 43(3).
[154] *Id.* art. 43(5).
[155] *Id.* art. 43(3).
[156] *See* Anglo-Iranian Oil Co. (U.K. v. Iran), Judgment, 1952 I.C.J. 93, 105 (July 22) [hereinafter Anglo-Iranian Oil Co.].

臺灣大學學術期刊資料庫

Second, Article 1 of the 2005 IHR provides two separate definitions for "scientific principles" *and* "scientific evidence": "scientific evidence" means *information furnishing a level of proof* based on the established and accepted *methods of science*; "scientific principles" means the accepted fundamental laws and *facts of nature* known *through the methods of science*;

Third, Article 12.(4), Article 17.(c), and Article 43.(2). mention separately "scientific principles", "scientific information" *and* "scientific evidence". For example, Article 43.(2).(b) reads, "In determining whether to implement the health measures . . . States Parties shall base their determinations upon: . . . (b) available scientific evidence *of a risk to human health*, *or where such evidence is insufficient, the available information* including from the WHO. . . ." [Emphasis added].

Fourth, if it is a situation where a state must provide both "health rationale" and "scientific information", the WHO has an obligation to *share this information and information regarding the health measures* implemented with other states (Article 43.(3)); the WHO bears *no* such an obligation in situations under Article 43.(5) in relation to solely "public health rationale". The act of sharing information also suggests that the 2005 IHR provides a mechanism through which *novel scientific information can be offered an opportunity to be accessible to and considered by the WHO and each state individually*. This obligation serves the coordinating purpose.

Meanwhile, because, under Article 12.(4) and Article 17.(c), "scientific principles", "scientific information" *and* "scientific evidence" are grouped together, presumably, they are *ejusdem generis* and share certain commonalities. In observing the definitions of "scientific principles" and "scientific evidence", the commonalities are (i) facts and (ii) known through the methods of science. It follows that, presumably, "scientific information" must share these commonalities. However, because "scientific information" cannot be synonymous with "scientific evidence", they have a difference. The second component of the definition of "scientific evidence"—"*established and accepted methods*"—seems to suggest that "scientific evidence" must be of *scientific consensus*. Meanwhile, Article 43.(2) signals that "scientific information" *is not of a threshold of scientific consensus* similar to "scientific evidence".

Meanwhile, there are two indicators that the common component "facts" of "scientific principles", "scientific information", and "scientific evidence" refers to "*biological facts*" ascertainable in science laboratories.

First, while Article 1 of the 2005 IHR reads that "scientific principles" are "the accepted fundamental laws and *facts of nature*. . .", Article 43.(2) refers to scientific evidence *of a risk to human health.*

Second, the WHO's obligation to share *scientific* evidence and information when it receives such information and the fact that the WHO is not obliged to share "public health rationale" with countries seems to mean

臺灣大學學術期刊資料庫

that "public health rationale" refers to*, inter alia, social-economic risks and repercussions* (social-economic risks and repercussions of/in a state are presumed to be not of interests to other states).

It follows that the 2005 IHR seems to establish a distinction between risk assessment and risk management—the distinction can be observed, for example, in the Codex Alimentarius. The 2005 IHR also restricts the definition and scope of "risk assessment" to the assessment of biological facts. If so, though it is clear that the precautionary principle is relevant, the 2005 IHR takes a restrictive approach to the precautionary principle. "Measures otherwise prohibited" are subjected to the obligation to provide the WHO with biological facts (which, presumably, cast doubt on the WHO's recommendations). This approach is not in line with the approach of other fields of international law. Paragraph 4 of Annex A of the SPS Agreement recognizes biological and economic risks and consequences. In *EC — Hormones*, the WTO Appellate Body rejected the rigid distinction between risk assessment and risk management and asserted that "risk that is to be evaluated is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist . . . . "[157] Within the context of European Law, the CJEU accepted "the lack of a system for tagging animals and controlling their movements", "a significant proportion of slaughterhouses were failing to comply with the legislation" as among the basics to uphold measures of the European Commission.[158]

As a result, there can be an inquiry as to whether the 2005 IHR's restrictive approach to the precautionary principle is sound (that is, it can be asked whether the 2005 IHR's approach (and thus the approach of the global health law) is better than the approach of other fields of international law). It does not seem so. The approach of the global health law *first* raises questions of justice and equity: Does it mean to the extent that there is, where the WHO's recommendation and biological facts are absent, notwithstanding deaths and/or social-economic repercussions, necessary and effective measures cannot be deployed? This also exaggerates injustice and inequality because, presumably, developing states are less likely than developed states to have the capacity to produce scientific evidence and information but have more fragile health, social, and economic infrastructures. *Second,* in opting for that approach, the 2005 IHR frustrates the objective and purpose of itself and global health law because the protection of health, ironically, can be prejudiced. The 2005 IHR and global health law, thus, offer less protection for health than other fields of international law. *Third,* it can hardly be believed that to the extent that

[157] Appellate Body Report, *EC — Hormones*, *supra* note 41, ¶ 187.
[158] United Kingdom v. Commission of the European Communities, *supra* note 109, ¶¶ 88, 102-04.

臺灣大學學術期刊資料庫

deaths and socio-economic repercussions are significant, but where the WHO's recommendation and biological facts are absent, states shall obey the 2005 IHR. Global health law, thus, becomes the *law that cannot be obeyed*.

The reason for which the precautionary principle is restricted is, *perhaps*, that the public health rationale was imagined as too broad and subjective a category that can even comprise unreasonable rationales and pretexts.[159] However, in observing the jurisprudences of other fields of international law, that image is inaccurate.

B. Vagueness

The 2005 IHR does not explicitly regulate certain measures that existed in previous conventions and regulations, e.g., in-land frontiers closure.[160] It is hard to find a clear rationale for that. Notwithstanding, *ex-facie*, measures not mentioned by the WHO can significantly restrict international traffic and trade to a *very* great extent. The 2005 IHR also does not explicitly regulate

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[159] The IHR Amendments RC suggested that "[m]easures in the Regulations are meant to be *evidence-based, which may preclude or at least limit the application of precaution*; however, *uncertainties during an outbreak response may require action in the absence of evidence or with insufficient evidence.*" WGIHR, *supra* note 14, at 28. Obviously, this statement is vague and its clauses are sharply opposing to each other. The first clause indicates that only measures which the WHO, the IHR Amendments RC, and WHO's expert committees consider "*evidence-based* " are considered compatible with the IHR. Then the IHR Amendments RC claims that "*uncertainties during an outbreak response may require action in the absence of evidence or with insufficient evidence*". It can be read from that statement of the IHR Amendments RC that "evidence-based" excludes "insufficient evidence". It would follow from this that, given uncertainties during an outbreak, while measures taken in uncertainties are often incompatible with the IHR or are *not meant* by the IHR, the IHR cannot operate with its primary intention. This is a strange statement because the IHR and the global health structure are designed to address outbreaks and public health issues where uncertainties are relevant and must be taken into account. Roojin Habibi and her coauthors suggested that:

> Article 43 is vague on what may constitute a public health rationale, though the most reasonable interpretation may be that a public health rationale is formulated from . . . (1) scientific principles; (2) available scientific evidence of a risk to human health; and (3) any available specific guidance or advice from the WHO

See Roojin Habibi et al., *The Stellenbosch Consensus on Legal National Responses to Public Health Risks*, 19(1) INT'L ORG. L. REV. 90, 116 (2020). They observe that there is "[a] second possible interpretation" which "is that a state's public health rationale for implementing additional health measures could include any factual statement". According to them, this interpretation "would likely frustrate the underlying purpose and objective of requiring states to explain their rationale in the first place, and other overarching public health goals of the IHR". Roojin Habibi et al., *The Stellenbosch Consensus on Legal National Responses to Public Health Risks*, 19(1) INT'L ORG. L. REV. 90, 117 (2020). It is exaggerated to argue that if "public health rationale" is not interpreted as something being formulated from scientific principles, available scientific evidence of a risk to human health, or any available specific guidance or advice from the WHO, it must be interpreted as including any [unreasonable] factual statement.

[160] ISC Signed at Dresden, *supra* note 59, Annex I, arts. 83-84.

臺灣大學學術期刊資料庫

measures arising due to technological advancements, for example, ultraviolet light, modifying humidity, surveillant apps, spraying chemicals to disinfect persons (as opposed to objects, e.g., baggage, cargo, containers, conveyances, goods and postal parcels).[161] However, it is not clear whether such measures were banned by the 2005 IHR; that is, such measures are *per se* illegal. Relevant articles of the 2005 IHR are, inter alia, Articles 18, 29 and 43; however, these articles do not clarify the matters. Article 18 enumerates measures, but it is not clear whether the list is exhaustive and measures are limited. "[O]ther measures" is mentioned only in conjunction with quarantine ("implement quarantine *or other health measures* for suspect persons"). Presumably, "other health measures" must be *of the same kind as quarantine* rather than "free-standing" any other measures (the rule "*noscitur a sociis*"). Likewise, Article 43 also enumerates measures and categorizes them into two groups.[162] Meanwhile, Article 29 reads that "WHO . . . shall develop guiding principles for applying health measures to civilian lorries, trains and coaches at points of entry and passing through ground crossings". Thus, it can be inferred that certain measures are *delegated* by the 2005 IHR to be guided by *guiding principles and/or guidelines developed by the WHO*. However, the positions of the WHO and global health law concerning these matters have been vague.

Upon reading the 2005 IHR and recommendations of Emergency Committees, many people have formed an impression that the WHO is antagonistic to travel measures.[163] However, in the Guidelines and some recommendations of Emergency Committees, it is acknowledged that travel measures can be justified and effective. WHO Recommendations on 29 February 2020 in relation to COVID-19 Outbreak claimed that restrictive measures "*allow affected countries to implement sustained response measures, and non-affected countries to gain time to initiate and implement effective preparedness measures*".[164] WHO's Guidelines concerning *Non-Pharmaceutical Public Health Measures for Mitigating the Risk and Impact of Epidemic and Pandemic Influenza* (hereinafter "WHO's Guidelines") provides scientific studies which read:

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[161] See generally some of these measures in WHO, NON-PHARMACEUTICAL PUBLIC HEALTH MEASURES FOR MITIGATING THE RISK AND IMPACT OF EPIDEMIC AND PANDEMIC INFLUENZA (2019). The fact that a measure can be applied to objects should not mean that the measure is applicable to living creatures. *See also* Doan et al., *supra* note 11, at 13-14.

[162] *See supra* Section II.B.3, II.B.6, III.A.

[163] Gian Luca Burci, *The Legal Response to Pandemics: The Strengths and Weaknesses of the International Health Regulations*, 11(2) J. INT'L HUMANITARIAN LEGAL STUD. 204, 214 (2020); Alvarez, *supra* note 5, at 578, 586.

[164] *Updated WHO Recommendations for International Traffic in Relation to COVID-19 Outbreak*, WHO (Feb. 29, 2020), https://www.who.int/news-room/articles-detail/updated-who-recommendations-for-international-traffic-in-relation-to-covid-19-outbreak.

臺灣大學學術期刊資料庫

> An epidemiological study suggested an important influence of international air travel on the timing of influenza introduction. Another historical analysis . . . suggested that *strict border control was a successful method for delaying and preventing influenza from arriving in South Pacific islands* . . . Strict border control . . . may be effective in *delaying the epidemic peak by 6 weeks* . . . .[165] [Emphasis added]

It concludes that "border closures may be considered . . . by small island nations . . . "[166] and "border closure is *not recommended unless required by national law* . . . ."[167] [Emphasis added]

Similar vagueness can be observed concerning contact tracing or modifying humidity. For example, concerning contact tracing, WHO's Guidelines opine that:

> Active contact tracing is *not recommended* . . . because there is *no obvious rationale* . . . This intervention could be considered *in some locations* and circumstances to collect information on the characteristics of the disease and to identify cases, or *to delay widespread transmission in the very early stages of a pandemic in isolated communities*[168] [Emphasis added].

Concerning modifying humidity, it suggests that:

Elevated humidification (absolute humidity at 9 millibars) was shown to reduce influenza A virus detections in the air and on fomite (markers and wooden toys) in a preschool classroom. A simulation study also predicted a 17.5-31.6% reduction of influenza virus survival in rooms with a humidifier operating in a residential setting . . . .[169]

but it raises concerns for "increase the growth of mould and mildew, harming health" and "cost".[170] These are quite confusing and problematic. *First*, when reading each instrument and all these instruments together, it is hard to comprehend the position and recommendations of the WHO. For various measures, before adopting the phrase "*not recommended*," the WHO mentioned various compelling and valid reasons for such measures to be employed and circumstances where it is desirable, if not imperative, for the

[165] WHO, *supra* note 161, at 67.
[166] *Id.* at 4.
[167] *Id.* at 69.
[168] *Id.* at 38.
[169] *Id.* at 35.
[170] *Id.* at 35-36.

臺灣大學學術期刊資料庫

deployment of such measures. That is, somehow, it seems that certain ultimate recommendations are at odds with the studies and rationales provided and that certain measures do not deserve the phrase "*not recommended* ". For example, there are obvious reasons for contact tracing as provided by WHO's Guidelines, particularly in pandemic influenza or any pandemic of novel cause — and not "*there is no obvious rationale*" as the WHO ultimately *categorically* disrecommended. It might be that it is very hard to make judgments concerning various measures *in abstracto* and *as a whole category*, notwithstanding specific use and relevant circumstances. Thus, the WHO's practices of in abstracto categorically judging, discrediting, and disrecommending measures are vague, unconstructive, problematic, and controversial. As a result, in many instances and for many measures, it is better to assess the measures on a case-by-case basis, taking into account the relevant circumstances and the specific use and the manner in which the measures are implemented. *Second,* although the statements of the WHO are vague, the phrase "*not recommended*," which the WHO uses, seemingly suggesting non-endorsement of and advice against many measures, including mild, non-invasive, nonintrusive measures, can render the WHO contested. *Third*, to the extent that WHO's Guidelines refer to national law, the object and purpose of global health law can be frustrated. Most-restrictive measures are put at the unfettered discretion of national laws without proper guidelines. *Fourth*, most-restrictive measures are subject to uncertain or even no legal requirements. For example, concerning border closure, though the Guidelines mention that the measure should only be resorted to during a pandemic and countries implementing this measure "should notify WHO as required by the IHR (2005),"[171] both the 2005 IHR and the Guidelines do not provide a definition of "pandemic". It is also not clear which group of measures under Article 43 border closure is subjected to as well.

In light of the aftermath of the COVID-19 pandemic, the Amendments to the 2005 IHR attempted to remedy the mentioned issue of the absence of the definition of "pandemic". "Pandemic emergency" [pandemic] is defined as *a public health emergency of international concern* that is *caused by a communicable disease* and:

> (i) has, or is at high risk of having, wide geographical spread to and within multiple States; and
>
> (ii) is exceeding, or is at high risk of exceeding, the capacity of health systems to respond in those States; and

[171] *Id.* at 68.

臺灣大學學術期刊資料庫

> (iii) is causing, or is at high risk of causing, substantial social and/or economic disruption, including disruption to international traffic and trade; and
>
> (iv) requires rapid, equitable and enhanced coordinated international action, with whole-of-government and whole-of-society approaches. [172]

This amendment reinforces the relevancy of the precautionary principle in global health law (the Amendments to the 2005 IHR) but again points out that global health law takes a restrictive approach to the precautionary principle.

It should be noted that, previously, the definition of "pandemic" was subjected to scientific controversies[173] which blocked any meaningful use of this concept for the purpose of governance. Thus, the definition of pandemic and the reference to "risk" in relation to "the capacity of health systems" and "substantial social and/or economic disruption"[174] is an appreciable step of the Amendments to the 2005 IHR, which reinforces the relevancy of the precautionary principle. This observation can be made clearer and be reinforced when the mentioned amendment is read together with other related amendments, for example, the inclusion of the availability of, and accessibility to relevant health products[175] in considerations relevant to the WHO's recommendations (Article 17) or the emphasis of "*clusters of cases of severe acute respiratory disease of unknown or novel cause*" in the middle box of Annex 2. In relation to the latter, it should be recalled that prior to the COVID-19 pandemic, the presumption of risk and the general knowledge was that a *coronavirus* is a type of common virus that typically causes only mild to moderate upper respiratory illness, with the only exceptions being

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[172] Seventy-Seventh World Health Assembly, *supra* note 60, art. 1.1.

[173] Peter Doshi argued that the WHO provided many descriptions of pandemic influenza but had not established a formal definition. *See* Peter Doshi, *The Elusive Definition of Pandemic Influenza*, 89(7) BULL. WORLD HEALTH ORG. 532, 532 (2011). Heath Kelly disagreed with Peter Doshi, arguing that there is a classical epidemiological definition of a pandemic that "is not elusive". *See* Heath Kelly, *The Classical Definition of a Pandemic Is Not Elusive*, 89(7) BULL. WORLD HEALTH ORG. 540, 540 (2011). Heath Kelly suggested that, according to the classical epidemiological definition, "a pandemic" is defined as "an epidemic occurring worldwide, or over a very wide area, crossing international boundaries and usually affecting a large number of people". The classical definition includes nothing about population immunity, virology or disease severity. Heath Kelly believed that "[s]imultaneous worldwide transmission of influenza is sufficient to define an influenza pandemic and is consistent with the classical definition of 'an epidemic occurring worldwide'. There is then ample opportunity to further describe the potential range of influenza pandemics in terms of transmissibility and disease severity". However, observing the practice of the WHO and its expert committees and the definition of pandemic provided by the Amendments to the 2005 IHR, it is not clear whether the understanding of Heath Kelly has ever been consistently practised by the WHO.

[174] *See* Section III.B.

[175] Defined as "those health products needed to respond to public health emergencies of international concern, including pandemic emergencies, which may include medicines . . . ."

臺灣大學學術期刊資料庫

SARS and MERS,[176] not to mention the broader category of *any "severe acute respiratory disease of unknown or novel cause"*. It should also be recalled that, in advising the precautionary principle to be included in the 2005 IHR, the Independent Panel suggested that for any outbreak caused by a new pathogen causing respiratory infections, the *human-to-human transmission will be assumed to occur unless the evidence specifically indicates otherwise*. [177] That recommendation has the potential for undesirable consequences.[178] At the end of the day, the amendment adopted by the 2005 IHR is milder. "Severe acute respiratory disease of unknown or novel cause" as a fact serves as a device assisting the risk assessment of states and the WHO.[179] This does not depart from the precautionary principle despite being a significantly reduced version of it. In other areas of international law, given the status of the precautionary principle as a general principle of law, it serves as a device assisting detailed legal provisions[180] and is relevant to policy and judicial considerations.[181] Thus, it can be observed that the Amendments to the 2005 IHR take a restrictive approach to the precautionary principle. This gives rise to ambiguous and normatively questionable rules and situations.

First, the technique of entertaining only a specific fact (rather than a general principle that may embrace several factors, both explicitly and implicitly, which can be developed and refined later) as an assisting device (in relation to the interpretation and implementation of the detailed rules) significantly limits the scope of application of the device and makes the device too rigid and immunized from being evolved in light of and adapting to circumstances and new challenges.

Second, by definition, pandemic is a *sui generis* category of PHEIC in the sense that it is a heightened PHEIC, which is strictly limited to communicable diseases. This is evident in the fact that one component of PHEIC is "to potentially require a coordinated international response" while one component of pandemic is "*enhanced* coordinated international action". Further, Article 12 reads, "[t]he Director-General shall determine, on the basis of the information received . . . whether an event constitutes a public health emergency of international concern, including*, when appropriate,* a pandemic emergency, in accordance with the criteria and the procedure set out in these Regulations". There is the phrase *"when appropriate"* appearing in Article 12, and as a rule of the law of interpretation in international law, every word in the text of an instrument must be able to be attributed

[176] G.A., *Protecting Humanity from Future Health Crises*, at 76, U.N. Doc. A/70/723 (2016).
[177] *COVID-19: Make It the Last Pandemic*, *supra* note 3, at 25-26.
[178] *See generally* Doan et al., *supra* note 11.
[179] *See* Seventy-Seventh World Health Assembly, *supra* note 60, art. 12, Annex II.
[180] Pulp Mills on the River Uruguay, *supra* note 44, ¶ 164.
[181] *Id.*; Case T-229/04, Kingdom of Sweden v. Commission of the European Communities, ¶ 161, 2007 E.C.R. II-2441 [hereinafter Kingdom of Sweden v. Commission of the European Communities].

臺灣大學學術期刊資料庫

meaning,[182] certain significance can be attached to the phrase "when appropriate". It is self-evident in the definition of pandemic that it is strictly restricted to communicable diseases.

While the adoption of a three-tier model can be welcomed as it reduces the frictions of the binary determination model,[183] it is questionable whether limiting the three-tier model to communicable diseases is a prudent policy choice. It should be noted that though not all measures applicable to communicable diseases should be applicable to other types of risks, the three-tier model can be necessary for other kinds of risks.

Third, it is unclear whether PHEIC must have been established in the first place for a pandemic to be established or whether a pandemic can be established separately and independently [from PHEIC]. The definition of pandemic encompasses certain aspects of PHEIC but enhances these into slightly different conditions as well as encompassed other conditions. The amendment to Article 12 with the word "when appropriate" does not make it clear in this regard as well.

It should be noted that the definition of PHEIC is a combination of two components: (i) factual risk assessment and (ii) subjective value determination. "To constitute a public health risk to other States through the international spread of disease" is a factual risk assessment made on account of available evidence. Meanwhile, "to potentially require a coordinated international response" is a subjective value determination that is nearly immunized from being scrutinized. This is prone to a level of discretion which has been subjected to criticism for years[184] [but is inevitable in the management of risks]. A similar combination can be observed concerning the definition of "pandemic", though it is more problematic in this latter case.

Because the definition of "pandemic" does not use "or" but "and", all conditions thereof *must be met altogether*.

Points (i), (ii), and (iii) of the definition of pandemic refer to the factual risk assessment. Bearing in mind that one condition is "diseases [that] have, or are at high risk of having, wide geographical spread to and within multiple States", while there can be settings [of one or more states] in which the healthcare system can be easily exceeded, there can be settings [of one or more states] in which it is less likely to be the case as well. It follows that, presumably, it can be very contested and lack consensus as to whether all points (i) to (iii) have been simultaneously satisfied. As a result, the drafting of the definition of "pandemic" in relation to factual risk assessment makes

[182] *See* Anglo-Iranian Oil Co., *supra* note 156, at 105.
[183] *See e.g.*, WGIHR, *supra* note 14, at 46; Burci, *supra* note 163, at 213.
[184] Lucia Mullen and her colleagues found that "[i]nterpretation of the criteria were often vague and applied inconsistently. ECs often failed to describe and justify which criteria had been satisfied". *See generally* Lucia Mullen et al., *An Analysis of International Health Regulations Emergency Committees and Public Health Emergency of International Concern Designations*, 5(6) BMJ GLOB. HEALTH 1 (2020).

臺灣大學學術期刊資料庫

this concept subject to more controversies and uncertainties than that of PHEIC. This, in turn, reinforces the relevancy of the precautionary principle.

In relation to the final condition, "requires rapid, equitable and enhanced coordinated international action, with whole-of-government and whole-of-society approaches" is a matter of highly subjective value determination and can be problematic.

Phrases such as "equitable action", "whole-of-government", and "whole-of-society approaches" are not legal concepts or still remain unclear as to how they can be interpreted or established or satisfied (for clarity, this paper does not say that they cannot be legal terms, but they do not seem to be so at present).

It seems that among possible ways of interpreting this condition, the first way of interpretation (interpretation (i)) is that the whole phrase can be read as communicating a single message. That message seems to refer to the concept of precautionary measures and related requirements as understood in and read within the international legal order. Therefore, in light of interpretation (i), the final condition may mean that precautionary measures in tandem with certain requirements for them and/or qualities of them are assessed to be required.[185]

But that way of interpretation is not self-evidently appropriate. It is possible to interpret the phrase as comprising several autonomous component conditions (interpretation (ii)).

For example, in relation to "equitable", it is helpful to recall that pursuant to Article 31.(1) of the Vienna Convention on the Law of Treaties "A treaty shall be interpreted . . . 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", the Amendments of the 2005 IHR and other documents of the WHO refer to "equitable" and "equity" in, e.g., "equitable access to relevant health products",[186] "everyone in the world has equal access to vaccines",[187] "rejecting vaccine nationalism",[188] "vaccines are distributed free . . . to prioritize affected communities and the voices of essential workers in decision-making and ensure gender equality is central to all actions",[189] and universal health coverage.[190] Pursuant to Article 3 of the Proposal for the Pandemic Agreement, equity is "*a goal and outcome* of pandemic prevention, preparedness and response, *striving for the absence* of unfair,

[185] It, thus, seems that the term "precaution[ary]" is avoided from being mentioned.
[186] Seventy-Seventh World Health Assembly, *supra* note 60, art. 13.
[187] *COVID Vaccines: Widening Inequality and Millions Vulnerable*, U.N. NEWS (Sep. 19, 2021), https://news.un.org/en/story/2021/09/1100192.
[188] *Call to Action: Vaccine Equity*, WHO, https://www.who.int/campaigns/vaccine-equity/vaccine-equity-declaration.
[189] *Id.*
[190] WHO, *Proposal for the WHO Pandemic Agreement*, art. 6, WHO Doc. A/INB/9/3 Rev.1 (Apr. 22, 2024).

臺灣大學學術期刊資料庫

avoidable or remediable differences among and between individuals, communities and countries". In this vein, equitable/equity in global health law can be quite ambitious and subtly different from what equitable/equity means in international law.[191]

On the other hand, "whole-of-government", and "whole-of-society approaches" are not defined. "Whole-of-government", for example, may refer to broad and not coherent ideals that "can best be seen as an umbrella term describing a group of responses to the problem of increased fragmentation of the public sector and public services and a wish to increase integration, coordination, and capacity".[192] Meanwhile, Article 17 of the Proposal for the Pandemic Agreement provides that "the Parties are encouraged to adopt whole-of-government and whole-of-society approaches at national level, including to empower and enable community ownership of, and contribution to, community readiness for and resilience to pandemic prevention, preparedness and response". It should be noted that there is a significant gap between "*encourage*" and "*require*". Notwithstanding, it does not seem that Article 17 of the Proposal for the Pandemic Agreement can clarify the issue. It is unclear as to what "empower and enable community ownership" really means or entails.[193] Meanwhile, given that

[191] *See generally* Francesco Francioni, *Equity in International Law*, MAX PLANCK ENCYCLOPEDIAS PUB. INT'L L. (2020), https://opil.ouplaw.com/display/10.1093/law:epil/9780199231690/law-9780199231690-e1399.

[192] *See* Tom Christensen & Per Lægreid, *The Whole-of-Government Approach to Public Sector Reform*, 67(6) PUB. ADMIN. REV. 1059, 1060 (2007). Tom Ling mentioned some historical aspects of joined-up government (JUG) and suggested that "JUG was taken up with enthusiasm in many different contexts and in many different ways. It soon became an umbrella term covering different dimensions." Tom Ling, *Delivering Joined-Up Government in the UK: Dimensions, Issues and Problems*, 80(4) PUB. ADMIN. 615, 624 (2002).

[193] It should be remembered that "pandemic prevention, preparedness and response" is not a subject of *proprietorship/ownership* in a legal sense. While "pandemic prevention, preparedness and response" is a matter of *"public affairs"*, "*governance*", and "*administration*", "[community] ownership" is established on properties, such as lands and resources. The establishment of ownership entails rights to use, to possess, and to dispose, which are not typically established to governance affairs. It is possible to form the opinion that "community ownership" obliquely alludes to the concept of "indigenous/communal governance" which is important for "pandemic prevention, preparedness and response". Ownership can mean "responsibility". However, community ownership is a terminology with a popular defined meaning, except otherwise defined by relevant documents (which is not the case). It can also be asked as to what "empower and enable" community's responsibility means or entails. Be that as it may, via connecting the dots, One possible way of interpretation is that the phrase seems to refer to the right to public participation or certain procedural requirements. Thus, it is the way of interpretation of or aligned with interpretation (i). Given that the decisions from authorities taken in light of the precautionary principle are of a political nature and these decisions stem from responsible and representative governance authorities, it is also an important component or requirement for the proper application of the precautionary principle. The "irregularities in the procedure" is among the factors that can lead to a finding that measures are not justified. *See* Kingdom of Sweden v. Commission of the European Communities, *supra* note 181, ¶¶ 99-125. Meanwhile, with full awareness that people have a right to public participation, which should be realized by concrete measures and mechanisms, the questions concerning the

臺灣大學學術期刊資料庫

Art. 1.1. of the Amendments to the 2005 IHR must be read within the international plane, it is questionable concerning how "whole-of-government" and "whole-of-society" can fit in the international context of the IHR. There can be a charitable reading according to that "whole-of-government" and "whole-of-society" are of or related to the logic of municipal law's structure. "[W]ith whole-of-government and whole-of-society approaches" (and its preceding phrase) is not a part of the definition of pandemic as the construction of the provision may give an impression, but is part of what drafters of the Amendments to the 2005 IHR declared as circumstances in which pandemic can be declared by an Emergency Committee. Provided that other legs and/or components of the provision are deemed as met, an Emergency Committee may determine a pandemic if it considers that in order to response to a disease, it is desirable or necessary or obligated to mobilize all sectors of a government and society of Member States. This can be a stringent and controversial requirement if the phrase is intended to be read as a requirement insofar as Emergency Committees must read contexts of different nations to determine. The phrase and determination of Emergency Committee, however, can also be or can even be more about being implicative: the determination of an Emergency Committee can be read as a piece of advice that Member States should mobilize all sectors thereof to handle the disease. Regardless of with or without any binding legal obligation, it can be controversial as to whether Emergency Committees can turn into administrators of domestic affairs. A great deal of precaution should be demanded from the WHO and its Committees to minimize unintended reactions, which can be anticipated. Meanwhile, it is also unclear whether any legal test can be possible to delimitate the threshold for, e.g., "coordinated international response" vs "enhanced coordinated international action".

It should also be acknowledged that issues mentioned by this interpretation are the subject of perennial discussions and contestations in bioethical, political studies, and global health affairs and are constantly constrained by the practical capacity or are too broad ideals that do not seem to fit into the context of legal conditions, particularly, as (a) specific factor(s) for establishing pandemic. As a result, interpretation (ii) leads to plenty of uncertainties as to how pandemic can be established.

For both interpretations, whether measures of the described features are required and what measures are of the described features are highly subjective and uncertain; thus, satisfying the definition of "pandemic" is highly subjective and uncertain. Meanwhile, there should be distinctions between triggering conditions and requirements or between triggering

determination of pandemic are how or in what manner Emergency Committees can determine pandemic by reference to "community ownership" and whether Emergency Committees are in ideal position to judge or to gauge "community ownership" in deliberating the declaration of pandemic.

臺灣大學學術期刊資料庫

conditions and specific measures. For example, although in certain situations of pandemic, precautionary/equitable actions can be desirable and should be implemented, fastening the measures with the status of public health risks and events (by way of considering the determination of the necessitate to employ the measures as a triggering condition of pandemic and, vice versa, limiting measures on the account of the status of public health risks and events) is not desirable.[194] This can either impose unnecessary restrictions on measures or load unnecessary political controversies onto the status of public health risks and events.

Following the above analysis, it can be observed that, presumably, it is difficult to establish a pandemic or a consensus on the satisfaction of criteria for establishing a pandemic. Meanwhile, to the extent that the determination is highly subjective, discretionary, and uncertain, challenging or scrutinizing the determination faces great difficulties.

Fourth, in reading the Amendments to the 2005 IHR, it is not clear what is/are the difference(s) in implications of pandemic compared to that/those of PHEIC. Meanwhile, when Article 12 of the Amendments to the 2005 IHR is read together with the mentioned WHO's Guidelines concerning *Non-Pharmaceutical Public Health Measures for Mitigating the Risk and Impact of Epidemic and Pandemic Influenza*, "pandemic" can be observed as a "communicating vessel" or a "pathway" or a "pass" to most restrictive measures such as border closure, travel restriction and travel ban. This also exposes the problem: bearing in mind the title of the Guidelines, although the 2005 IHR has taken the so-called all-hazard approach, certain measures and requirements for the measures provided therein and in the Guidelines are prepared to be applied, only or primarily, to communicable diseases (the Amendments to the 2005 IHR) or even a specific communicable disease—influenza (the Guidelines).

Meanwhile, legal requirements concerning contact tracing, humidity modification, and other measures cannot be found. This, thus, means that WHO and global health law can be very generous to some of the most restrictive measures. This can prejudice rights, health, and the objective and purpose of global health law. This approach is also not logical and reasonable because less restrictive measures are subjected to [strict[er]] requirements established by the 2005 IHR. This, again, gives the impression that there is the precautionary principle in global health law, but the precautionary principle is restricted as to its components and requirements.

[194] *See infra* Section III.C.

臺灣大學學術期刊資料庫

C. Implications

As can be observed in previous subsections, an interpretation of the 2005 IHR's approach suggests that protective measures are subjected to very stringent requirements (and can even be enumerated and limited). Meanwhile, an interpretation of the approach of WHO's Guidelines suggests that the portfolio of measures is broad and even unlimited. Some of the most restrictive measures are subjected to broad, uncertain and even no requirements. The two positions can hardly be reconciled. They also result in a somewhat weird issue/phenomenon: Health is not protected as much as it should be by global health law, and global health law is less protective of health than other fields of international law. Meanwhile, both approaches of the 2005 IHR and WHO's Guidelines restrict the precautionary principle ("*the restrictive approach to the precautionary principle*"). This approach is reinforced in the Amendments to the 2005 IHR. From these instruments, it seems to be the case that, with respect to the matter at stake, instead of engaging with and learning from the jurisprudences and/or experiences of other disciplines of international law, as far as practicable and compatible with global health law, in preparing solutions addressing the common issues, global health law keeps its door closed and summarily dismisses accounts of other fields of international law, i.e., on the ground that global health law is evidence-based (that justification can be arguably interpreted as implicitly claims that other fields of international law neglect or dismiss evidence, which is clearly false). Unfortunately, in committing to that, global health law paves the way for uncertainties and problems. It is doubtful whether the approach of global health law is desirable. It follows that global health law should reconcile its approach with and adopt the precautionary approach of other fields of international law. Components of the precautionary principle, as established by other fields of international law and lessons from other fields of international law, should be helpful in supplementing the rules of global health law. Thus, the precautionary principle and broadly international law have implications for and can contribute meaningfully to the global health project.

Perhaps it should be the case that in the absence of a pandemic or PHEIC or the consensus on the satisfaction of criteria for establishing a pandemic or PHEIC, a measure or certain measures should still be justified where, taking into account uncertainty and specific social and/or economic conditions, the respective threshold for triggering the measure(s) is satisfied, provided that the measures are not contrary to the law. Meanwhile, even when a "pandemic" or "PHEIC" is declared, that should not be equal to a ticket to all measures; otherwise, the purpose of global health law can be defeated. Likewise, there should be a distinction between the status of public health risks and events (e.g., whether they are PHEIC or pandemic) and the scrutiny

臺灣大學學術期刊資料庫

and legality of specific measures. Limiting the application of the measures to or assigning the legality of the measures on the status of public health risks and events, e.g., as the approach of the Guidelines, is too rigid and undesirable because this can defeat the purpose and objective of global health law. It also self-loads upon the status of public health risks and events the gunpowder of political controversies, which should be cooled off and relieved instead. Thus, the legality of certain specific measures should be determined by scrutinizing the respective measures. That is, the legality of measures should be scrutinised upon the standard of review according to which the context (e.g., specific objective indicators and/or the status of public health risks or events and/or specific locations) and specific interests involved should be duly regarded. For example, measures negatively impact certain interests and rights which accept no restrictions or derogation, e.g., the right not to be subjected to torture or to cruel, inhuman or degrading treatment or punishment, can never be justified. Measures that negatively impact highly valued interests and rights, e.g., certain kinds of different treatments related to religion (i.e., measures suspected to be discriminatory), should be subjected to strict scrutiny or heightened burden of proof. Meanwhile, the status of public health risks or events, e.g., pandemic, PHEIC, suggests that certain compelling public interests are at risk or are damaged, thus counterbalancing the interests at stake (though pandemic or PHEIC should not be, on its own, a conclusive factor that negates all other considerations). Certain rights and interests, when being affected, however, only implicate minimum scrutiny, and the status of public health risks and events (e.g., PHEIC or pandemic) may not be a prerequisite for the measures to be justified. These, in turn, have implications for the determination of authorities as to the measures they will resort to.

VI. CONCLUSION

A. The Precautionary Principle Is a General Principle of International Law in Global Health Law

By means of the comparative legal method, this paper asserts that the precautionary principle is a general principle of international law in the field of global health law insofar as the precautionary principle can be found in the totality of global health law. The precautionary principle is embodied in the objective and purpose of global health law, its structure and arrangements, and specific rules thereof. Conversely, the precautionary principle is and should be fleshed out by specific rules for which the precautionary principle is a device assisting the interpretation and implementation of these rules. Thus, the precautionary principle is relevant to policy and judicial considerations.

臺灣大學學術期刊資料庫

B. The Restrictive Approach to the Precautionary Principle of Global Health Law Offers Less Protection to Health Compared to other Fields of International Law

Notwithstanding the above, *global health law takes a restrictive approach to the precautionary principle*. This is not in line with the approach of other fields of international law.

The divergence might possibly be because of many concerns of some public health experts concerning the precautionary principle. Some people can argue that the challenges faced by global health law in dealing with contagious diseases and pandemics are unique,[195] which may justify the departure of global health law from other fields of international law. People can argue that global health law operates on an evidence-based basis and issues in global health law, specifically, contagious diseases and pandemics, are often more acute and greater and broader in terms of magnitude and sphere of influence compared to issues faced by trade law and environmental law, where ramifications lie in the far future and humanity enjoys a noticeable time to muse about solutions and research or where the impact can be narrower.[196]

However, while comparativists are mindful of the potential inherent differences between areas of law, the approach to the matters should be or at least started with bona fide, which recognises and respects the reasons, knowledge, and experiences of areas of international law. This approach, directly or indirectly, is supported by and supports the uniformity of international law and is fruitful for areas of law and their interactions.[197] It follows that global health law *should engage in dialogues with other fields of international law in preparing its solutions*. This stands in *stark contrast* with the current approach of global health law in which global health law keeps its door closed and summarily dismisses accounts of other fields of international law, i.e., on the ground that global health law is evidence-based (*that justification can be arguably interpreted as implicitly claiming that other fields of international law neglect or dismiss evidence, which is clearly false*). In fact, though specific rules and tools of global health law are different from those of trade and environment law, the rationale and considerations for and of the precautionary principle in those fields are

[195] This can be interpreted from the comment of the IHR Amendments RC. *See e.g.*, WGIHR, *supra* note 14, at 28.

[196] Whether these arguments are really sound and valid is not a question that this paper necessarily delivers opinions and provides analysis on for the sake of its arguments.

[197] Clearly, conflicting laws and rules are undesirable. Unsurprisingly, there have been calls for the WHO to prevent and address conflicts between the 2005 IHR and other international instruments. INTERGOVERNMENTAL WORKING GRP. ON REVISION INT'L HEALTH REGUL. [IGWG], *Review and Approval of Proposed Amendments to the International Health Regulations: Relations with other International Instruments*, WHO, ¶ 1, WHO Doc. A/IHR/IGWG/INF.DOC./1 (Sep. 30, 2004).

臺灣大學學術期刊資料庫

similar because they reflect the foundational logic of the law, e.g., reasonableness, responsibility, non-arbitrariness. This foundational logic implies and entails that

On the one hand, while *the precautionary principle is not an antithesis to* "*evidence*", uncertainty and insufficiency of information should not mean paralysis and inaction. It is obvious that in imminent and ongoing catastrophic risks and dangers like COVID-19, it is plainly unreasonable to take no measure to relieve the damage and await "better" or "uncontroversial" scientific findings or narrow down the factual grounds required for measures to be taken to only uncontroversial or peer-reviewed scientific findings. Although the "Pandemic Agreement" had not yet been finalized at the time this paper was written and was not a direct subject of study in this paper, Article 3.(6) of this Agreement echoes the conventional wisdom: [public health] *decisions* [for pandemic prevention, preparedness and response] should be made on the basis of the *best available* science and evidence — *this should not be less but should not be more*.

On the other hand, precaution is not intrinsically equivalent to groundless and excessive behaviours and measures, and uncertainty and insufficiency of information should not mean an authorization of arbitrary, illegitimate, and illegal acts. The precise propositions and measures to address uncertainties and insufficiencies of information depend on and vary with circumstances. It should be noted that we do not address uncertainties and insufficiencies of information only in emergencies. It is unnecessary and undesirable to take radical measures in ordinary times, but to enable the capacity and knowledge useful to be deployed in dangers and emergencies against risks that humanity has not yet known at present requires *long-term preparations, planning, investments and studies*. *That is the very rationale of the precautionary principle.*

These further refute arguments that global health law should be considered as an exceptional area of law where there can be no precaution.

In fact, it can be predicted from the overall structure of the Proposal for the Pandemic Agreement that the precautionary principle shall be more relevant to global health law while still being discredited. Several developments thereof embrace the lessons, experiences, and mechanisms found in areas of international law, which can be validly argued as embodying and implementing the precautionary approach.[198] For example, in relation to *the principle of cooperation*, a Conference of the Parties is envisaged to be established.[199] The Conference of the Parties may adopt guidelines, recommendations, and standards, including those related to

[198] *See supra* Section II.B.2.

[199] *See e.g.,* WHO, *Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response*, Appendix, Proposal for the WHO Pandemic Agreement, art. 21, WHO Doc. A77/10 (May 27, 2024).

臺灣大學學術期刊資料庫

pandemic prevention capacities, to support the implementation of pandemic prevention and public health surveillance.[200] Sharing of information as governed under Articles 5, 6, 7, and 43 of the 2005 IHR, which are of the momentary nature (when facing PHEIC or pandemic), is reinforced.[201] It is under a continuous basis and has permanent arrangements under the WHO Pathogen Access and Benefit-Sharing System (PABS System)[202] and the encouragement to identify, promote and/or strengthen, as appropriate, relevant international data standards and interoperability that enable timely sharing of public health data for preventing, detecting and responding to public health events.[203] The Proposal for the WHO Pandemic Agreement provides for the transfer of technology and know-how,[204] with particular emphasis paid to the production of pandemic-related health products during pandemics[205] and sustainable and geographically diversified production.[206] Research (and thus, cooperation and collaboration in research) is an important measure, on a continuous basis, to address pandemic (though access to research for the rapid sharing of information and results during pandemics is emphasized).[207] It is also envisaged that the WHO, in partnership with relevant organizations, building on relevant tools, shall develop, implement and regularly assess pandemic prevention, preparedness and response monitoring and evaluation system.[208] The aspect of *taking into account national and regional circumstances* is emphasized in various provisions.[209] In relation to *comprehensiveness, preparedness, and prevention*, the interconnection between people, animals and the environment is recognized under the "One Health approach".[210] This should promote the interlinkage between global health law and international environment law. Addressing animal and environmental health for the sake of human health and introducing and integrating one-health interventions into relevant pandemic prevention, preparedness, and response plans[211] clearly expresses the precautionary thinking. The Proposal for the WHO Pandemic Agreement also provides that "[p]arties *recognize that environmental, climatic, social, anthropogenic and economic factors increase the risk of pandemics* and *endeavour to identify these factors* and *take them into consideration* in the development and implementation of

[200] *Id.* art. 4.
[201] *See e.g.*, *id.* art. 9.
[202] *Id.* art. 12.
[203] *Id.* art. 6.
[204] *Id.* arts. 10-11.
[205] *Id.*
[206] *Id.* art. 10.
[207] *Id.* art. 9.
[208] *Id.* art. 6.
[209] *Id.* arts. 4, 5, 7, 9, 11, 17, 19.
[210] *Id.* art. 5.
[211] *Id.*

臺灣大學學術期刊資料庫

relevant policies, strategies and measures at the international, regional and national levels."[212] This includes *strengthening synergies with other relevant international instruments and their implementation*.[213] Further, the Proposal for the Pandemic Agreement also prescribes that each Party take the necessary steps to establish, safeguard, protect, invest in and *sustain* a multidisciplinary, skilled, trained and diverse workforce to prevent, prepare for and respond to health emergencies *closest to where they start*, while maintaining quality essential health services and essential public health functions during pandemics.[214]

The divergence of global health law from other areas of international law—marked by rigid and problematic understanding of and approach to risks and evident, the generalized, vague, confusing, and contradictory statements of high and far expert committees, and the categorical turning down of various measures, all of which have the effects of limiting the discretion of municipal authorities to protect their populace while offering tickets to various far-reaching measures—questions the stance and balance of global health law and gives an impression that *global health law does not offer as much protection to health as other fields of international law*.

Suffice it to conclude that the precautionary principle and international law have implications and can contribute meaningfully to the global health project and so are valuable for the project.

C. Implications from Jurisprudence and International Law

As argued, the precautionary principle has implications for global health law, including softening rigid rules as well as providing a general legal basis for measures and reviewing measures. Naturally, the specific implications of the precautionary principle for various actors, e.g., the WHO and states, and their propositions, behaviours, and measures vary.

1. The WHO — The WHO's Constitution and the 2005 IHR entrust the WHO with certain political powers and functions for which the WHO bears certain political responsibilities.[215] The WHO is prominent for its scientific expertise and coordinating [measures of] states. The WHO may enjoy *a range of discretion* in dealing with and responding to public health risks, especially those of novel or unknown causes or sources. However, to be in

[212] *Id.* art. 4.
[213] *Id.*
[214] *Id.* art. 6.
[215] Whether and to what extent the WHO can be held legally liable for its propositions, behaviours, and measures are not questions that have received clear answers in international law. Addressing these questions also face procedural difficulties. However, it is not the topic that this paper addresses. *See generally* Mark Eccleston-Turner & Pedro A. Villarreal, *The World Health Organization's Emergency Powers: Enhancing Its Legal and Institutional Accountability*, 19(1) INT'L ORG. L. REV. 63 (2022).

臺灣大學學術期刊資料庫

line with the precautionary principle, the WHO must be mindful and prudent in its considerations and recommendations. It must be mindful and prudent not only in the overall considerations and recommendations but also in drafting and formulating its recommendations as well as employing and implementing measures so as not to impose a burden on certain locations or states, create contradictions, or defeat the very purpose of global health law, either by excessiveness or insufficiency.[216] It might need to work with municipal and local authorities to provide specific and fit-to-circumstance recommendations.

2. States — States retain a large portion of political powers and responsibilities vís-à-vis their populace and the international community. States can also avail themselves of the precautionary measures in dealing with and responding to risks, especially those of novel or unknown causes or sources. However, the exercise of states' powers and functions, undoubtedly, is subject to scientific and legal review. The precautionary principle can assist states during the courses of opting for the appropriate level of protection and for the measures and the course of review. However, measures, propositions, and behaviours can be put in the so-called "suspicious category", and for this reason, states bear a heightened burden of proof or strict scrutiny, for example, where overly restrictive and intrusive measures are taken contrary to the recommendations in which the WHO is confident. Gross violations of human rights, disguises of trade restrictions, discrimination, or measures attempting to defeat the very purpose of global health law can hardly be justified.

3. Courts — Courts should be external and autonomous checks on the legality of propositions, behaviours, and measures of relevant actors. However, a court cannot, by itself, implement scientific research or manifestly determine which evidence is more scientifically valuable.[217] Nor can it substitute its policy preference with policy determinations made by states or authorities derived from their political responsibilities. Courts can only review the legality of the measures, propositions, or behaviours in light of the evidence presented before them as well as with the mindful acknowledgement of the state of science at the time the issue arose and the hindsight bias. As shown, the precautionary principle captures the previously mentioned capacity and is a legal device available to courts to ensure compliance with the rules of the relevant authorities and actors amidst situations of uncertainty and crisis. It follows that, amidst the mentioned

[216] Thus, the question that needs to be addressed is not whether the propositions, behaviours, and measures of the WHO are the best or whether we like these propositions, behaviours, and measures or not but whether, in light of the precautionary principle and specific rules and obligations, whether these propositions, behaviours, and measures are legally justified.

[217] *See* Whaling in the Antarctic (separate opinion by Charlesworth, J. ad hoc), *supra* note 43, ¶¶ 69, 86, 172.

臺灣大學學術期刊資料庫

context, the precautionary principle should be capable of being used to challenge the measures of authorities.

Notwithstanding the above, it should be acknowledged that there is a possibility that, due to the acuteness and seriousness of public health emergencies, there are risks of overactions. While such overactions are independent of the precautionary principle, the restrictive approach to the precautionary principle, as opted for by global health law, is not a good solution. Rather, the solution should be the *more appropriate* set of laws that *rule the situation* so that all relevant parties are aware of it in advance so that they can reduce the possibility of overreactions. That is, the solution for overreactions is the development of jurisprudence—which also facilitates the capacity to address legal issues on a progressive basis.[218] However, it should be acknowledged that in light of the progressive development in law and knowledge and the inherently limited knowledge of humanity and resources, though we can have better solutions, we can never have the zero risk or zero harm solution or the best of the best solution (the solution despite being the best, due to constrained knowledge, is unperceivable, infeasible or unavailable).

[218] This happens in various municipal jurisdictions where the pandemic and the employment of the precautionary principle to address legal issues concerning the pandemic have established jurisprudences in this regard. *See* cases such as R (Gardner and Harris) v. Secretary of State for Health and Social Care and others, [2022] EWHC 967 (Admin), ¶ 275 (U.K.); Four Aviation Security Service Employees v. Minister of Covid-19 Response, [2021] NZHC 3012, [2022] 2 NZLR 26, ¶ 110 (N.Z.); Yardley v. Minister for Workplace Relations and Safety, [2022] NZHC 291, [2022] 19 NZLR 125, ¶¶ 95-96 (N.Z.). These jurisprudences look similar to the jurisprudences in trade law and environment law in certain respects. However, the paper is of full knowledge and acknowledgment of the discussions concerning the distinction between the logic of municipal law and international law and that some general principles of international law are rooted in general principles of municipal law of certain jurisdictions, e.g., legitimate expectations. *See also* Giorgio Gaja, *General Principles of Law*, MAX PLANCK ENCYCLOPEDIAS INT'L L. (2020), ¶¶ 3, 7-16, https://opil.ouplaw.com/display/10.1093/law:epil/9780199231690/law-9780199231690-e1410; Rüdiger Wolfrum, *General International Law (Principles, Rules, and Standards)*, MAX PLANCK ENCYCLOPEDIAS INT'L L. (2010), ¶¶ 20, 28-32, https://opil.ouplaw.com/display/10.1093/law:epil/9780199231690/law-9780199231690-e1408. But it is not necessary for this paper to delve further into these matters here for the sake of its arguments.

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