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Trading Precaution:

The Precautionary Principle and the WTO



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Foreword

Biotechnology promises new benefits and poses new risks. Biotechnology has the potential to provide new drugs for the poor, increase agricultural yields, decrease environmental impacts and to provide new energy sources. Yet, biotechnology has the potential to cause enormous damage. Managing the risks of this technology is a complex task. How a society chooses to tackle this task will be affected by a wide range of factors such as confidence in the regulators, acceptance of new technologies, the need for the new benefits and general levels of awareness.

The importance of biotechnology is evident in the growing number of international organizations developing rules to govern its use. The diversity of organizations, often pursuing different objectives, makes for a complex policy and regulatory environment.

An important and common element amongst these different attempts to regulate biotechnology is the need for caution in managing the risks raised by new technology. The exact level of caution and the specific procedural, administrative and legal consequences flowing from different standards is the subject of intense debate, political activity and legal dispute. The seriousness of these differences and the importance of the technology threaten great damage to international cooperation and law. More and more commentators are beginning to openly wonder whether the World Trade Organization (WTO) will be able to survive the full effects of the *EC-Biotechnology* panel, for example.

A significant cause of tension around this issue stems from a failure to properly understand the differences and similarities in the various standards that do exist. For example, many differences arise from the simple failure to distinguish the identification of risk from the entirely separate question of how to respond to that risk.

The specific purpose of this paper is to explore the role of precaution in the WTO Agreements. The paper is part of a series of studies being undertaken at the United Nations University Institute of Advanced Studies (UNU-IAS) to explore the differing standards for regulating biotechnology in different regimes, including the Biosafety Protocol, the FAO Agreements and in various countries that have adopted legislation on these matters, such as Canada, Brazil and India. We hope that this series of case studies will highlight the overlaps and similarities between the various regimes, as well as their differences and the consequences of these differences.

The series is motivated by a belief that a clearer understanding of the various uses of the precautionary principle or approach will contribute to a more cohesive and harmonious approach to the regulation of biotechnology at the international

level and mitigate some of the damage that is threatened by the current state of affairs.

The UNU-IAS was established in 1996 as a research and training centre of UNU to undertake research and post graduate education on emerging issues of strategic importance for the United Nations and its Member States. Pursuant to its Statute, UNU-IAS undertakes its work in an independent, neutral and objective manner. A key purpose of the Institute is to promote interaction between the UN System and other bodies. Development of this report is part of the wider programme on biodiversity at the Institute. The programme is also looking at bioprospecting in the deep seabed, certificates of origin for genetic resources and training for developing country officials.

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Introduction

The precautionary principle is central to environmental policy making and is a key element of several multilateral environmental agreements (MEAs); notably, it is a fundamental part of the Cartagena Protocol on Biosafety. In light of scientific uncertainty regarding how to deal with a myriad of health, safety and environment-related concerns, governments are putting in place precautionary measures to address local and global issues. The precautionary principle is used in several multilateral agreements and domestic policies to take proactive measures in response to serious risks of environmental harm. However, such measures, which include trade restrictions on goods, such as ozone depleting substances, beef and genetically modified organisms (GMOs), are also a lightning rod of concern with respect to potential protectionist use by creating barriers to trade.

In large part, these concerns stem from the application of the disciplines of the World Trade Organization (WTO) in an era of globalization, where trade liberalization is viewed as encompassing not only border measures, but as delving further into the arena of domestic health and environmental regulations. What are the implications for the trading system from the incorporation of the precautionary principle in policy decisions? How are different perceptions of risk and use of science shaping the emerging Transatlantic divide, for example in the realm of genetically modified organisms? What are the implications for developing countries in this debate? How best to seek a balanced approach to regulation that promotes scientific innovation, such as biotechnology, while addressing health, safety and environmental concerns?

This paper examines the debate on the evolution of the precautionary principle in the context of the WTO. In so doing, it attempts to shed light on proposals to enhance the incorporation of this principle in the rules of the multilateral trading system and to diminish tensions in this regard between the WTO and MEAs. It is highly likely that the interaction between the WTO and MEAs will continue to increase as governments tackle trade-related issues linked to certain environmental concerns, such as trade in genetically modified organisms.

A greater understanding of the precautionary principle is necessary in the multilateral trading system, while there is also a need to grapple with the economic harm that can be caused by the implementation of the principle. Predictable regulatory frameworks that encourage technological innovation and facilitate international trade are important components of economic development, particularly for developing countries. The paper poses some relevant questions in an attempt to discern the issues at stake, and argues that a better understanding of the elements of precaution may avoid confusing the precautionary principle with

protectionism. It is important that this confusion not arise in developing countries, whose biodiversity may be the beneficiary of the application of the precautionary principle in the Biosafety Protocol, yet whose exports may also be affected by protectionist measures.¹

The analysis in the paper looks at how the WTO is responding to the challenges posed by Member States raising the precautionary principle before panels in disputes. The Appellate Body has recognized that an absolute level of certainty cannot be required for a Member to be entitled to apply the exceptions provisions of the WTO.² The relationship between WTO rules and the precautionary principle may also be further tested in the forthcoming reinvigoration of the *Hormones* dispute, whereby the EU intends to challenge the continued imposition of sanctions against it by the US and Canada with respect to imports of hormone-treated beef.³

This paper also puts forward that the WTO dispute settlement system may not be the best way in which to resolve disputes in these important areas of policy making. The question is whether there is a need for the dispute settlement system to clarify the ambiguities that may exist in the implementation of precaution, or whether WTO Members can muster the political will to go back to the negotiating table. The temptation is to enforce a broader array of non-trade concerns through the WTO dispute settlement system; the result being to overburden the WTO with disputes that the WTO may not be able to resolve.

1 The precautionary principle

Policy makers and civil society concerned with health and environmental issues argue that precautionary measures should be taken when there is insufficient scientific proof of danger, yet when inaction could lead to irreversible damage or risks to human health or the environment. Benefiting from technological progress invariably has to be weighed against any potential risk that might be posed by the new technology. While there are numerous cases in which the risks posed by new technologies have been underestimated by society (for example, persistent organic pollutant chemicals used in agriculture and industry, the use of refrigerants that deplete the ozone layer), there are also numerous instances of technology with the potential to enhance human welfare (for example, agricultural biotechnology).⁴ As noted by the UN Millennium Task Force on Science, Technology and Innovation, “a focus on technological risks can overshadow the possible benefits of an emerging technology, which are often difficult to predict.”⁵

Underpinning the debate on the precautionary principle is the fundamental question of how to develop public health and safety and environmental policies when, on the one hand, there is a lack of scientific consensus and, on the other, an important public constituency may have irrational (from a scientific perspective) opinions on the matter. Is it possible to have some common threshold of risk, or, at a minimum, a common practice of risk assessment?

The precautionary principle is related to a range of broader policies and approaches to deal with situations of incomplete or inconclusive scientific information in an era of rapid technological advances. The precautionary principle attempts to fill the gap between scientific uncertainty and risk regulation. The application of precaution will vary according to the circumstances. Nevertheless, while for some it is an overreaching concept, for others the application of precaution is context specific and will vary accordingly. It is precisely these considerations that make it difficult to develop a generally applicable definition of the precautionary principle.⁶

Divergent regulatory approaches in the United States and the European Union are based on public perception of risk and are reflective of differing social preferences. While both regional players take into account aspects of risk and precaution in forming decisions, the manner in which precaution is operationalized is fundamentally different, as well as the principle’s status in their domestic laws. Importantly, differing Transatlantic preferences, in some instances, have translated into stricter measures in Europe that place restrictions on trade in certain goods, which are considered acceptable or even desirable products in the United States. For example, the EU has imposed strict control measures on the approval and marketing of GMOs and GM products, as well as mandatory labelling schemes, to address the potential

adverse effects on health and the environment.⁷ Likewise, some food products, such as unpasteurized cheese, which are highly valued in EU countries, are equally highly regulated in the US for health purposes.

The framework for biotechnology in the US differs markedly from that in the EU. There has been no new legislation introduced in the US specifically to regulate biotechnology products.⁸ Moreover, US government policy aims to minimize the regulatory burden to foster innovation, while protecting health and the environment.⁹ On the other side of the Atlantic, the US is challenging the legitimacy of the *de facto* EU moratorium on GM products in a drawn out panel process in the WTO (*EC-Measures Affecting the Approval and Marketing of Biotech Products - “Biotech”*).

Two examples in the context of WTO dispute settlement, which illustrate the regulatory differences between the EU and US, are the disputes on hormone-treated beef and genetically modified organisms. A Transatlantic divide has become clear with respect to these disputes, whereby there are fundamentally divergent understandings of science and its role in risk assessment and regulation.¹⁰ As set out in this paper, the WTO Dispute Settlement Body (DSB) has struggled to rule on how best to determine the appropriateness of domestic regulations, which are based on precaution and arguably not sufficiently supported by scientific risk assessment.

The debate on the precautionary principle is complex and often abstract. To a certain extent, the precautionary principle can be seen as a “culturally framed concept [...] muddled in policy advice and subject to the whims of international diplomacy and the unpredictable public mood over the true cost of sustainable living.”¹¹ The controversial issue surrounding the use of a precautionary principle concerns how to determine when precautionary action is triggered and the burden of proof shifts towards ensuring health and safety or protecting the environment. This threshold can be higher, for example when the potential risks involve ‘serious or irreversible harm’ to the environment, or lower, for example when there is merely a threat that some ‘harm’ may be caused to the environment. In any event, the precautionary principle aims to safeguard against potential risks, which have not yet been fully explored by scientific research and analysis.

To what extent does a common understanding of precaution exist which would allow the WTO dispute settlement mechanism to properly assess its use? Can the answer be found in an assessment of the invocation of the principle in other international agreements?

2 Precaution as a principle of international law

Many environmental lawyers have argued that the precautionary principle is already a principle of customary international law.¹² What is clear is that the principle is certainly the underlying rationale for several MEAs. The principle has been applied to various environmental issues and has over twelve different definitions in international agreements.¹³ Besides the operative use of precaution in the Biosafety Protocol,¹⁴ the principle has been incorporated in a number of international environmental agreements.

Reference to precaution is included in the preamble of the Vienna Convention on the Protection of the Ozone Layer¹⁵ and the Montreal Protocol on Substances that Deplete the Ozone Layer.¹⁶ It is reflected in the articles of agreements, such as the UN Framework Convention on Climate Change and the UN Conference on Environment and Development Rio Declaration. Other treaties, such as the Convention on Biological Diversity do not mention the principle by name, but define its properties within the agreement.¹⁷

What is lacking is a uniform description of the precautionary principle in these agreements, leading some critics to argue that the principle is overused without a clear understanding of its meaning and consideration of its implementation. The flexible definition of the precautionary principle may be its strength, but also one of its greatest weaknesses. Several WTO Members have noted in the Committee on Trade and Environment (CTE) that the difficulty of further integrating precaution in the WTO lies in the lack of an internationally-agreed definition of the precautionary principle.¹⁸

International jurists writing on the principle generally rely on two similar definitions of the precautionary principle. The first is found in the *Bergen Ministerial Declaration on Sustainable Development* (1990):

In order to achieve sustainable development, policies must be based on the *precautionary principle*. Environmental measures must anticipate, prevent and attack the causes of environmental degradation. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.¹⁹

The second often-cited definition is found in Principle 15 of the Rio Declaration on Environment and Development (1990):

In order to protect the environment, the *precautionary approach* shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.²⁰

These two definitions of the precautionary principle, which at first glance seem similar, differ greatly. The Bergen Ministerial Declaration definition does not mention economics, except

in reference to sustainable development. Rio Principle 15, however, promotes precaution, but only if the measures are 'cost effective,' which balances the need for the measure taken with its potential economic impact. These two definitions are consistent when it comes to what triggers precautionary action – a threat of serious or irreversible harm. The threshold of harm is not consistent, however, in all MEAs. The Biosafety Protocol, for example, has a much lower trigger as precaution may be justified "with potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity."²¹

Principles can form the basis of customary international law if they are consistently defined and applied in international treaties and in decisions of international tribunals and the International Court of Justice (ICJ). The importance of customary law is that it establishes binding obligations for states. Customary law is developed through State practice: a consistent approach to treaty negotiation and ratification; application in domestic legislation and decisions of domestic courts; and statements by government officials are all evidence of the acceptance of a principle as custom. A second way in which to discern customary law is *opinio juris*, determining whether States act as though they are bound by the principle. Consistent action on the part of States may help determine *opinio juris* as it reveals an underlying belief that the State is obligated to follow a principle, as required by law. Evidence that a principle has reached the status of customary law can also be determined by persistent objections from States that refuse to be bound by the practice.²²

The European Union clearly has taken the position that the precautionary principle is customary international law, as evidenced by the fact that environmental policy in the European Union is based explicitly on precaution.²³ The EU presented its position on the precautionary principle in the WTO affirming that "the precautionary principle is gradually asserting itself as a principle of international law in the fields of environmental and health protection."²⁴ While the Treaty Establishing the European Community does not provide a definition of the precautionary principle, decisions by the European Court of Justice and other EU courts denote elements of a general application of the precautionary principle in EU law to support action. These include uncertainty, risk, and lack of a direct causal link between the risk and the perceived harm.²⁵ The EU has announced its objective to establish guidelines for use of the precautionary principle in order to clarify arrangements for its application. During the discussion on the EU *Communication on the Precautionary Principle* in the CTE, the need to further integrate this principle in the WTO or to establish guidelines was questioned. Importantly, it was pointed out that the EU had failed to provide a definition of the principle.²⁶

An important aspect in implementing precaution is to use the least-trade restrictive measure available; that is to say that where there are a number of possible means of attaining the same level of health or environmental protection, the

least-trade restrictive measure should be opted for.²⁷ In the EU, the discretion of policy makers to use precaution may take precedence over economic interests and the principles of proportionality and non-discrimination.²⁸

While the idea of exercising precaution in the face of risk and uncertainty is not new in the United States,²⁹ the Government maintains that precaution is an approach, as opposed to a more formalized principle. Thus, “precautionary approach” and “precautionary measures” is the language that has been negotiated into many MEAs. A report prepared by a Federal Advisory Committee to the US Environmental Protection Agency sheds some light on the reluctance of the United States to formally adopt the precautionary principle. This report recognizes American laws are “replete with examples of caution exercised in the face of scientific or technological uncertainty,” but that, despite the principle’s scientific and government support in Europe, “there has been some criticism that the implementation of the principle may generate litigation.”³⁰ Perhaps the fear of providing the litigious American society with another tool to challenge governmental decisions is hindering the principle’s acceptance.³¹ Certainly, the economic costs of applying the precautionary principle are a genuine concern, but these costs should be balanced by the threat of irreversible harm.

While as a general rule, cost-benefit analysis is a requirement of US law, cost-benefit analysis is not applicable in most food safety decisions.³² Although the US takes into consideration precaution when developing domestic responses to health and environmental concerns, there is a clear policy to reject the application of the precautionary principle in international law. As such, the US is not a Party to several MEAs that are based on precaution, such as the Convention on Biological Diversity and its Biosafety Protocol.

Canada has taken the middle ground in recognizing the precautionary principle. Despite acceptance of the principle domestically, Canada has twice challenged the invocation of precaution by the EU at the WTO. Canada took the position before the WTO Appellate Body that the principle is “an emerging principle of international law, which may further crystallize into one of the general principles of law recognized by civilized nations.”³³ The precautionary principle is reflected in Canada’s federal environmental laws,³⁴ and Canada’s highest Court seems persuaded that the principle is, in fact, international custom.³⁵ However, a discussion paper prepared by the Canadian Government exemplifies the struggle of formally adopting the principle as government policy: “[t]here are concerns that the precautionary approach could be applied to perceived risks for which there is no sound scientific basis, which would unnecessarily stifle innovation or impose unfair costs on sectors of society.” On the other hand, many “may view the precautionary principle as a new approach that can lead to more responsive decision making.”³⁶ This discussion paper also refers to the need to choose the “least-trade restrictive” option, if an alternative measure would adequately respond to the risk.

The judiciaries of several developing countries have also recognized the precautionary principle, as illustrated by recent decisions of the Supreme Court of India. The Indian Supreme Court has acknowledged that the precautionary principle has emerged as customary law. The Court has referred to the Indian Constitution and environmental statutes to show that the precautionary principle was already implied and that, in view of these constitutional and statutory provisions, it had “no hesitation in holding that the Precautionary Principle and the Polluter Pays Principle are part of the environmental law of the country.”³⁷

Although some international scholars do not believe that there is significance to the debate between the terminology “approach” and “principle,”³⁸ in its decision on *Reformulated Gasoline*, the WTO Appellate Body recognized that the Dispute Settlement Understanding directed them to apply the “customary rules of interpretation of public international law” to clarify WTO provisions.³⁹ The Appellate Body further noted that the WTO Agreements were not to be read “in clinical isolation from public international law.”⁴⁰ This is a welcome step to integrating WTO law into the broader framework of public international law, so that the WTO does not become hermetically sealed.⁴¹ Nevertheless, in the *Hormones* dispute, the Appellate Body noted that the precautionary principle “at least outside the field of international environmental law,” still awaits “authoritative formulation as a customary principle of international law.”⁴²

The lack of a determination by the ICJ that the precautionary principle is (or is not) customary international law, despite the fact that the principle has been raised in more than one hearing,⁴³ supports the Appellate Body’s conclusion that the status of this principle as custom is still “emerging.” While it is clear that the WTO Agreements, including the Agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT), are to be interpreted in the broader context of customary international law,⁴⁴ the status of the precautionary principle as custom has yet to unequivocally be solidified.

The significance of the term “principle” is that principles create obligations. This is evidenced by the Supreme Court decisions in Canada and India, which used similar reasoning to apply an international principle to domestic law. The Canadian decision, for example, interpreted a municipal by-law that limited the use of pesticides in a manner that was consistent with the precautionary principle. What types of obligations would ensue for Member States if the WTO Appellate Body were to accept that precaution is not merely an “approach,” but a “principle”? Could the acceptance of the precautionary principle change existing WTO obligations with respect to risk assessment in the Agreement on Sanitary and Phytosanitary Measures?

3 Precaution in the WTO Agreements

Precautionary language was foreign to the original General Agreement on Tariffs and Trade (GATT), which is not surprising as the GATT predates the first international reference to the principle by almost 40 years. The concept of precaution was first introduced in Germany at the 1984 International Conference on the North Sea.⁴⁵ Although the principle was not mentioned by name, the agreement contained the idea of limiting pollutants due to a lack of knowledge, and in advance of proof of their harmful effects.⁴⁶ The exceptions provision contained in Article XX(b) of the GATT uses quite different language as it provides an exception for a Member to take measures “*necessary* to protect human, animal or plant life or health.”

Elements of precaution have been incorporated into the WTO Agreement on Sanitary and Phytosanitary Measures (SPS).⁴⁷ The SPS Agreement sets out the right of each WTO Member to adopt measures that are necessary to achieve the level of health and phytosanitary protection it deems appropriate (preamble and Article 2.1). Such a measure has to be *based* on scientific principles and should be *based* on international standards. A measure may result in a higher level of protection than what is determined by international standards if there is scientific justification. The specific disciplines for sanitary and phytosanitary measures for the protection of human, animal or plant life or health include that such measures are “applied only to the extent necessary to protect human, animal or plant life or health;” are “based on scientific principles;” are “not maintained without sufficient scientific evidence” (Article 2.2); “do not arbitrarily or unjustifiably discriminate between members;” and are “not applied in a manner which would constitute a disguised restriction on international trade” (Article 2.3).

As stated in the Preamble, the SPS Agreement is an elaboration of Article XX(b). However, while the SPS Agreement permits Members to enact SPS measures if specific obligations are met, Article XX(b) sets out general exceptions for violations to the GATT. The “necessity test” is a much higher threshold, which does not seem to allow for preventative action when there is a lack of scientific evidence. The term “necessary” places the burden of proof squarely on the Member taking the action, and, until recently in *EC – Asbestos*,⁴⁸ no WTO Member has been able to pass the “necessary” hurdle.⁴⁹

Although the SPS Agreement includes the same language as Article XX, it is tempered by the inclusion of provisional measures in Article 5.7. Whereas in Article XX, it is an exception, in the SPS Agreement, there is a right, albeit a conditional right, to take provisional measures subject to the requirements for risk assessment laid out in Article 5.1, 5.5 and 5.6.

Article 5.7 of the SPS Agreement allows for the adoption of sanitary and phytosanitary measures on a *provisional*

basis in cases of scientific uncertainty, if the following conditions have been fulfilled: the measure was initially conceived as an emergency measure; the measure is imposed in a situation where relevant scientific information is insufficient; and the measure is adopted on the basis of available pertinent information. Moreover, the measure cannot be maintained unless the Member adopting it seeks to obtain additional information, and conducts a review within a reasonable period of time, which is established on a case-by-case basis. Article 5.7 necessitates that countries invoking precaution to stop imports substantiate their action with a risk assessment. If the SPS measure adopted by the importing country is not based on international standards, the exporter can ask for an explanation of the measure in Article 5.7, which the defending Member must provide.

Arguably, the requirement that the provisional measure must be initially implemented as an emergency measure sheds doubt as to whether this article is, in fact, precautionary in tone. The precautionary principle would allow for action to be taken to prevent harm and, therefore, to avoid provisional measures being adopted on an emergency basis; in effect, negating the need for provisional measures as provided for in Article 5.7.

Precautionary language is also found in the WTO Agreement on Technical Barriers to Trade (TBT). The language in Article 2.2, which refers to “taking account of the risks of non-fulfillment” of a legitimate objective, such as protection of human health or safety, animal or plant life or health or the environment, may become subject to debate in the future.

The basis upon which a precautionary measure is put in place is a crucial aspect of an examination of the relationship between the WTO and the precautionary principle. In the context of the Cartagena Protocol on Biosafety, it has been noted that “risk assessment is an approach for evaluating and characterizing risks, whereas precaution is an attitude of decision makers, reflecting their values and/or the values of those they represent, in taking a particular decision.”⁵⁰ Risk assessment plays a key role in characterizing the potential adverse effects of certain actions, while precaution is an attitude in decision making that reflects an aversion to risk in the face of uncertainty. Risk assessment is also central to the SPS Agreement, as Article 5 of the Agreement states that Members shall ensure their SPS measures are based on risk assessment. Provisional measures are seen as more of a stop-gap measure to allow the Member to collect the evidence required by Article 5. As interpreted to date, the language in the SPS Agreement allows Members to adopt provisional measures when science is insufficient or in the process of being established, but these measures must be reviewed as more objective information becomes available.⁵¹

There have been several recent panels in the WTO involving SPS measures.⁵² The clearest insight regarding the relationship between the precautionary principle and WTO law, specifically with respect to the SPS Agreement and a measure put in place on a precautionary basis, comes from the interpretation of the WTO Appellate Body in the *EC – Hormones* case. The EU ban on the use of hormones for animal growth production in 1989 signaled a fundamental turning point in the way in which the US and the EU envisage the application of precaution to protect health. The precautionary principle was one of the guiding principles with respect to the response of the EU concerning the *Hormones* and *Biotech* panels.⁵³

In the *Hormones* case, the Appellate Body stated that the risk to be evaluated under Article 5.1 “is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.”⁵⁴ Therefore, a high (and precautionary) level of protection may in some circumstances be considered legitimate and necessary under WTO law. The pivotal point is that the State putting in place a measure based on the precautionary principle must continue its scientific research and perform serious reviews of the precautionary measure to show evidence of its good faith.

In the WTO, the underlying basis for determining risk is international standards. The WTO is not a standards-setting body. The SPS Agreement favours the use of international standards for the benefit of harmonized food safety standards, so even though Members can establish their own level of protection, they must first provide evidence, which may be at odds with the relevant international standard. The idea of multilateral standards is attractive, especially for exporters who only have to conform to one standard. This increases predictability, transparency and greatly reduces expenses as well as simplifies the process of gaining access to markets. The TBT and SPS Agreements, negotiated during the Uruguay Round, recognize that standards and technical regulations bring many benefits to producers and consumers with respect to providing information on products. These Agreements were put in place to ensure that standards and technical regulations do not create unnecessary obstacles to trade in order to facilitate secure and predictable market access.

The SPS Agreement relies on multilateral standards, such as those developed in the joint FAO – WHO Codex Alimentarius Commission (Codex) for food safety. However, there seems to be little consensus evidenced, for example, in the Codex standard for minimum residue levels for growth promoting hormones that were referenced in the *EC – Hormones* dispute, as the standard was adopted by a vote of 33 to 29, with seven

abstentions.⁵⁵ This result shows why some countries and NGOs are skeptical of international standardization processes, such as Codex. As such, the SPS Agreement requires that the EU implement a full risk assessment for beef treated with hormones based on minimum levels, which effectively were agreed to by less than half the Codex experts. The Codex *Ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology is still in the process of developing principles for the risk analysis of foods derived from modern biotechnology, including labelling of GM foods.⁵⁶ When developed, these principles should provide guidance for regulators.

In *EC – Hormones*, the Appellate Body stated that “the precautionary principle indeed finds reflection in Article 5.7 of the SPS Agreement.” The Appellate Body went on to note that several articles of the SPS Agreement “explicitly recognize the right of Members to establish their own appropriate level of sanitary protection, which level may be higher (i.e. more cautious) than that implied in existing international standards, guidelines and recommendations.”⁵⁷ Nevertheless, a higher level of protection must be justified through available, pertinent scientific information.

The EU banned the importation of hormone-treated beef based on the fear and mistrust of its population for hormones in beef products, irrespective of the lack of scientific certainty underlying these concerns. The WTO Appellate Body acknowledged that “a panel charged with determining, for instance, whether ‘sufficient scientific evidence’ exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned.”⁵⁸ Yet, there seems to be no application of this precautionary approach in the actual Appellate Body *Hormones* decision.

The EU invoked the precautionary principle to justify its ban on hormone-treated beef in support of its claim that the measure was based on a risk assessment.⁵⁹ On appeal, the EU argued that the general principle of precaution should be taken into account to interpret the other SPS provisions. The Appellate Body held that Article 5.7 does not exhaust the possible application of the precautionary principle in the interpretation of other provisions of the SPS Agreement.⁶⁰ The Appellate Body thus recognized the precautionary principle as reflected in the SPS Agreement and established guidance for applying elements of precaution in risk regulation. This, arguably, signals a potentially wider application of precaution in the SPS Agreement.

The US and Canada decided that there was little or no risk to their population from hormones found in beef;

the EU wished to reduce the risk closer to zero. Which government was acting from the perspective of prudence? The Appellate Body found the EU ban on hormone-treated beef to be inconsistent with the requirements of the SPS Agreement under Article 5.1.⁶¹ This signals that a zero-risk policy has to be based on a foundation of science. Even though the EU was ordered to bring the measure into conformity with its obligations under the WTO, Europeans do not seem to be willing to accept beef enhanced with hormones in the dining rooms of their citizens. Thus, the EU has maintained the import ban and has continued to pursue risk assessment to support its ban.⁶²

Although the Government of the United States might vehemently deny it, it would seem that recognition of the precautionary principle made its way into WTO law, or, at least was considered an exception to WTO rules, when the Appellate Body allowed a European moratorium on asbestos products from Canada. The Appellate Body effectively broadened the interpretation of what is “necessary” to include preventative action in the face of a health risk.

In the *EC – Asbestos* case, the Appellate Body interpreted Article XX alongside the provisions of the SPS Agreement and arguably “read in” precaution. The Appellate Body stated that “responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources.”⁶³ Furthermore, on the role of science vis-à-vis justifying a measure under Article XX(b), “a Member may also rely, in good faith, on scientific sources which, at that time, may represent a divergent, but qualified and respected, opinion.”⁶⁴ Thus a Member is not obligated, in setting health policy, “automatically to follow what, at a given time, may constitute a majority scientific opinion.”⁶⁵ These are strong statements towards permitting countries to implement precaution while not abrogating their WTO obligations.

The panel in *EC – Asbestos* also recognized that, for a Member to be entitled to apply Article XX, an absolute level of certainty cannot be required as “to make the adoption of health measures concerning a definite risk depend upon establishing with certainty a risk [...] would have the effect of preventing any possibility of legislating in the field of public health.”⁶⁶

The controversial *Biotech* case was brought by Argentina, Canada and the US against the EU’s alleged *de facto* moratorium on the approval of new agricultural biotech products. The claim is that the EU had failed to approve any new GMOs between 1998 and 2004, which constitutes a *de facto* moratorium that has not been justified scientifically and, therefore, is not in conformity with WTO rules. The *Biotech* dispute is a test case for the treatment of precaution in the multilateral trading system.

The *Hormones* and *Asbestos* decisions and the current *Biotech* dispute in the WTO raise crucial issues with respect to the role of science in managing public risk. There needs to be a balanced approach to regulation, whereby health and safety concerns are addressed while allowing scope for the development of technology. The question is how to go about ensuring the appropriateness of domestic regulation in the face of scientific uncertainty and in view of public demands to take precautionary measures.⁶⁷ If scientific evaluation does not permit the determination of the existence of risk with sufficient certainty, recourse to precautionary action will depend on the level of protection chosen by the government authority and the exercise of its discretion. This is a normative decision – a political choice.⁶⁸

As noted above, it has been suggested that the solution for some precautionary action is to assess the idea of “least-trade restrictive” for implementing precautionary measures. However, choosing the “least-trade restrictive” option is only a partial solution. States also need to work towards adopting a common understanding of precaution. Notwithstanding work towards a common understanding of precaution, interpretations may well continue to vary between States. In the context of the WTO, for example, Members may interpret their obligations under the rules of the trading system differently; hence the recourse to dispute settlement. However, a common understanding or rules allow WTO panels and the Appellate Body to render consistent judgments when disputes arise. In the same manner, a common understanding of the precautionary principle would further consistency in judicial decisions in the event of disputes.

It would seem that it is only possible to work towards developing agreement on a common application of the precautionary principle in the context of bilateral, regional and multilateral agreements. As noted earlier, precaution is a cornerstone of many MEAs, and thus far, measures taken pursuant to these agreements have not been challenged at the WTO. However, the tenuous relationship between trade and environment may be further threatened by the interplay between WTO rules and the Biosafety Protocol, with its emphasis on the precautionary principle.

4 The *status quo* - can it be maintained?

As an underlying principle of the Convention on Biological Diversity's (CBD) Cartagena Protocol on Biosafety, precaution has real economic and social implications in its interface with international trade. Compatibility between the WTO Agreements and MEAs, such as the CBD, has long been a prominent feature in the discussions in the CTE.⁶⁹ Following the mandate in the WTO Doha Declaration, the relationship between the WTO and MEAs is the subject of negotiation in the CTE Special Session.⁷⁰ The majority of countries have adopted the position at the WTO that there is already sufficient scope under WTO provisions to use trade measures for environmental purposes in MEAs. Therefore, there is no need to alter existing WTO rules to accommodate MEAs. The approach not to amend or clarify WTO rules has been labelled the *status quo*.

Maintaining the *status quo* between MEAs and the WTO is built around the premise that only a small number of MEAs contain trade measures and that thus far there has not been any conflict between MEAs and the WTO. Although the relationship between MEAs and the WTO has often seemed theoretical, without any real world examples, there are several recent cases to indicate that this is changing. The belief that the two spheres can coexist without incident is being sorely tested for example in the *Biotech* dispute unfolding at the WTO between the European Union, on the one hand, and the United States, Canada and Argentina, on the other, over genetically modified organisms. Although the United States is not a signatory to the Biosafety Protocol, Argentina, the European Union and Canada have ratified the Protocol, indicating its general acceptance in the international community.⁷¹

The relationship between the Biosafety Protocol and international agreements, including the WTO, is addressed in the Protocol's preamble. The preamble recalls the concept of mutual supportiveness between trade and environment agreements, affirms that the Protocol shall not be interpreted as implying a change in rights and obligations of parties under any other existing international agreements, and takes into account that this shall not mean that the Protocol is subordinate to other international agreements. The relationship between the Protocol and WTO rules was one of the crucial issues during the negotiation of the Protocol.⁷²

According to the arguments presented by the EU to the *Biotech* panel, "there is authority to support the proposition that the Protocol and the SPS Agreement (as well as the TBT Agreement and the GATT) are so closely connected that they should be interpreted and applied consistently with each other, to the extent that is possible."⁷³ In effect, the EU is arguing that MEAs, in this case the Biosafety Protocol, are setting international standards. In keeping with the preamble to the Biosafety Protocol, the EU maintains that its

own internal processes are consistent, therefore, with both WTO rules and the Biosafety Protocol.

A desire for precaution in taking decisions related to biotechnology clearly has been expressed by Parties to the Convention on Biological Diversity in drafting the Biosafety Protocol, as well as by NGOs.⁷⁴ Indeed, the report by the WTO panel adjudicating the *Biotech* case has once again been delayed to December 2005.⁷⁵ Originally, the Panel was to have presented its findings in September 2004. As a result, this long-awaited ruling will not be released before the Hong Kong WTO Ministerial Conference in December 2005. In large part, the cause of the delay is the enormous amount of scientific data presented by the EU in its defense and the Panel's decision to consult experts.⁷⁶

The battle lines seem to be drawn – with the precautionary principle and the Biosafety Protocol on one side and "science-based risk assessment" and WTO rules on the other. However, the approval by the EU of a variety of GMO maize for use as feed in the Spring of 2004,⁷⁷ and a second maize variety in the Summer of 2004,⁷⁸ may mean that no country would be willing to finalize this dispute in the WTO, despite the important principles at issue.

5 Developing country concerns

From an exporting perspective, precaution is certainly an issue of relevance for developing countries for whom the economic costs of applying the precautionary principle are a genuine concern.⁷⁹ Developing countries fear the potential impacts on trade from precautionary measures in developed countries, which may be disguised protectionist trade measures that negatively impact their exports. Concerns also have been expressed by developing countries that the application of precautionary measures, which are not sufficiently supported by scientific evidence, threaten economic interests, distort trade, increase transaction costs and divert resources from addressing the environmental issues at stake.

If, in fact, there may be differing levels of acceptable risk in developed and developing countries, how best to address such a dichotomy? Certainly, risk assessment can be costly and developing countries may encounter a lack of capacity to adopt and implement precautionary measures and develop a comprehensive regulatory framework. In this regard, many international agreements recognize the difficulties faced by developing countries and contain specific provisions for technical assistance and special and differential treatment, which allow specific, time-limited exceptions that take into account their developmental needs.⁸⁰

Solutions may be found by enhancing transparency in order that developing countries understand why the measures are being taken, as well as allowing for the sharing of relevant scientific research to facilitate risk assessment and enable developing countries to comply with standards in their export markets.

It is noteworthy that while developing countries appear suspicious of the use of measures based on precaution in the trade context for fear of protectionist abuse, several have embraced a precautionary approach domestically, and the majority has agreed to the inclusion of the precautionary principle in MEAs. Precautionary action has been accepted by developing countries in multilateral negotiations to address specific environmental harm despite the proportionality of risks to the costs involved. This is to say that developing countries may consider precautionary action to incur disproportionately high short-term costs of implementation when compared with the long-term environmental risks. This was the case with global environmental concerns such as ozone depletion and climate change. Developing countries agreed to participate in the MEAs because they were offered delayed phase-in timetables, financial compensation and capacity building to address the high costs of implementation. The principle of “common but differentiated responsibilities” with respect to preventative measures to avert environmental harm managed to bring developing countries on board in the negotiations.

Biotechnology is a challenging issue for developing countries as they seek to balance development objectives with the potential risks and benefits of biotechnology. The trade implications of their choices in this respect can be daunting. There has been little consideration given internationally to finding ways to provide a balanced assessment of the potential for biotechnology for developing countries.⁸¹ By way of example, several African countries – including Malawi, Mozambique, Zambia and Zimbabwe – rejected donated maize derived from GM seeds during famines in 2002 and 2004.⁸² Also, many developing countries – particularly in Africa where the EU is a major export market for agricultural products – are waiting to see the outcome of the *Biotech* dispute before deciding on a biosafety policy. Naturally, they are concerned about the WTO-compatibility of any eventual policy. Sri Lanka has back-tracked from a GMO ban for this reason. Thus, the repercussions of the *Biotech* dispute at the WTO could be far-reaching beyond just the Parties involved in the dispute.

Although some developing countries produce GMOs for domestic consumption, few export GMO products, which is key to understanding the elevated profile of the precautionary principle in the Biosafety Protocol. Developing countries, which are in the process of developing a domestic framework for GMOs, have to balance their export interests with the desire to benefit from biotechnology. To preserve their exports of conventional agricultural products, particularly to the EU, some developing countries are finding that they need to maintain a “GMO-free” status.⁸³

6 Concluding remarks

When developing policies and implementing measures, especially related to social and environmental spheres, governments are continuously balancing various interests and perspectives. Policy makers are often not sufficiently cognizant of the unintended consequences of their regulatory measures, particularly with respect to how a particular measure will be received by other countries. The objective of the precautionary principle in environmental policy making is to provide government decision makers with a rationale to avoid potential risks in the face of scientific uncertainty. This approach to decision making is based on the belief that in cases where there is a lack of scientific certainty and there is a risk of serious or irreversible harm to human health or the environment, action should be taken to prevent that harm. The same action that may protect the environment, however, may also serve to afford protection to domestic industries.

From a trade perspective, the history of trade-distorting tariffs in the GATT-WTO reveals the reasons why there is such an inherent skepticism of well-intentioned policy making. In order for the precautionary principle to avoid being an easy target for criticism and skepticism, the difficulty lies in distinguishing precautionary from protectionist motivations.

In the context of the trade rules of the WTO, the precautionary principle has been invoked as a health or environmental defense when justifying a trade restriction, specifically in the context of the SPS Agreement. Recent interpretations in the WTO of the parameters surrounding the use of precaution, as set out in this report, reveal that countries are permitted to take precautionary measures in certain circumstances, but that they face real challenges when defending a precautionary action before the WTO Dispute Settlement Body.

Despite the new light that has been shed on the relationship between the WTO and the precautionary principle by the Appellate Body in several recent panels, even if the precautionary principle were more firmly established in the WTO, the question remains whether the obligations would be diminished with respect to risk assessment pursuant to the SPS Agreement, whereby evaluation of risk must be ascertainable.

There are fundamental differences in perception as to the appropriate role of science and technology in society. While countries may choose their level of protection based on a variety of policy considerations, there must be a mutually acceptable, rational basis for concern that is based on available information when invoking precaution. Moreover, while flexibility of interpretation of the precautionary principle may be its strength, the inherent tension created by the lack of a concrete definition of this concept also serves as a weakness with respect to its incorporation into WTO law. The varied application of the precautionary principle and the debate over which

party has to shoulder the burden of proof as to whether there is harm, or irreversible harm, also does not allow for the principle's ready acceptance as part of customary international law.

While science has an important role to play in assessing risk and in informing decision makers on possible approaches to health and environmental concerns, the management of the risks involved invariably falls into the realm of political choice, where determining an acceptable level of risk must take into account a multitude of different considerations. The appropriateness of these domestic policy decisions is an issue that the WTO is being forced to grapple with in areas that delve deep into the domestic regulatory system and involve differing perceptions of risk. Even if precaution is accepted more formally within the WTO, individual countries will have different risk thresholds. While it can be argued that there is sufficient flexibility built into the WTO to incorporate precautionary measures, these measures will eventually need to be supported by international standards or risk assessment.

In order to address successfully the precautionary principle at the WTO, the focus must remain on developing supportive linkages between trade and environment in policy making, through international consensus building. It would be naïve to dismiss the danger that trade protectionists may pursue their commercial interests behind a cover of environmental or health concerns. The WTO cannot be faulted for remaining vigilant in this regard and for endeavoring to enhance transparency in the policy making process through notification of measures. Yet it would be cynical to conclude that environmental policy makers dealing with urgent environmental concerns cannot find support for efficient and effective policy measures under the WTO. The WTO cannot and does not stand for free trade at any cost. The challenge for trade policy is to bridge the differences on the application of precaution to uphold a rules-based multilateral trading system that ensures secure and predictable market access, while respecting health and environmental concerns.

The path forward for precautionary measures should be supported through bilateral, regional and multilateral agreements. Measures implemented in furtherance of these agreements should be respected by other WTO Members, or, failing that, the Dispute Settlement Body. Unilateral measures, adopted by States without the protection afforded by international standards, multilateral agreements or rigorous risk assessment are not only economically damaging, but create skepticism for other actions that truly embody the intent of the precautionary principle. In the meantime, countries will continue trading with precaution, while the WTO dispute settlement system attempts to come to terms with rather different interpretations of this complex and controversial concept.

Endnotes

- ¹ Sabrina Shaw and Risa Schwartz, "Trade and Environment in the WTO: State of Play," *Journal of World Trade*, 36(1), 2002, pages 129-154.
- ² Report of the Appellate Body, *European Communities – Measures Affecting Asbestos and Asbestos Containing Products (EC – Asbestos)*, WT/DS135/AB/R, 12 March 2001, paragraph 142.
- ³ EC Press Release, dated 8 November 2004, at www.europa.eu.int/comm/food/fs/gmo/_index_en.html.
- ⁴ United Nations Development Programme, *Human Development Report 2001: Making New Technologies Work for Human Development*, New York: UNDP, 2001.
- ⁵ United Nations, *Report of the UN Millennium Project, Task Force on Science, Technology, and Innovation*, New York: UN, 2005, page 175.
- ⁶ Theofanis Christoforou, "The Precautionary Principle and Democratizing Expertise: A European Legal Perspective," *Science and Public Policy*, 30(3), 2003, page 206.
- ⁷ EC Directive 2001/18 as amended by Regulation 1830/2003 at www.europa.eu.int/comm/food/fs/gmo/gmo_index_en.html. For a thorough treatment of risk governance and the interplay of science, law and politics in the regulation of GMOs in the European Union see Theofanis Christoforou, "The Regulation of GMOs in the EU: The Interplay of Science, Law and Politics," *Common Market Law Review*, 41, 2004, pages 637-709. Also see Konrad von Moltke, "The relationship between policy, science, technology, economics and law in the implementation of the precautionary principle," in Freestone, D. and E. Hey, (eds.), *The Precautionary Principle and International Law, the Challenges of Implementation*, 1996.
- ⁸ Calestous Juma, "Biotechnology in a Globalizing World: The Coevolution of Technology and Social Institutions," *BioScience*, 55(3), March 2005, page 4.
- ⁹ *Ibid.*, pages 2-9.
- ¹⁰ For an in-depth treatment of the Transatlantic divergences on precaution see Theofanis Christoforou, "The Precautionary Principle, Risk Assessment, and the Comparative Role of Science in the EC and the US Legal Systems," in Norman Vig and Michael Faure (eds.), *Green Giants?: Environmental Policies of the US and the EU*, MIT, 2004, Chapter 1; Nigel Purvis, "Building a Transatlantic Biotech Partnership," *Biotechnology Regulation*, Fall 2004, pages 67-74; Lawrence Kogan, "The Precautionary Principle and WTO Law: Divergent Views Toward the Role of Science in Assessing and Managing Risk," *Seton Hall Journal of Diplomacy and International Relations*, V(1), Winter/Spring 2004, pages 77-123.
- ¹¹ T. O'Riordan and James Cameron, "The History and Contemporary Significance of the Precautionary Principle," *Interpreting the Precautionary Principle*, in T. O'Riordan and J. Cameron (eds.), Earthscan, London, 1994.
- ¹² Some experts argue that there is sufficient state practice to support the emergence of the precautionary principle as a principle of customary international law. See Theofanis Christoforou, "The Precautionary Principle in EC Law and Science," in Joel Tickner (ed.), *Environmental Science and Preventive Public Policy*, Island Press, 2003, Chapter 16; J. Cameron and J. Abouchar, "The Status of the Precautionary Principle in International Law," in D. Freestone and E. Hey (eds.), *The Precautionary Principle in International Law*, Kluwer, 1996, p. 52. Other academics consider that the precautionary principle is not yet a principle of international law particularly given the variety of interpretations. See P. Birnie and A. Boyle, *International Law and the Environment*, Oxford University Press, 2002, page 98.
- ¹³ For a discussion of the precautionary principle in international environmental instruments see OECD, *Uncertainty and Precaution: Implications for Trade and Environment*, Joint Working Party on Trade and Environment, COM/ENVTD(2000)114/FINAL, Paris, 5 September 2002, Annex 1, pages 37-50.
- ¹⁴ Articles 1, 10 and 11 of the Cartagena Protocol on Biosafety (2000) of the Convention on Biological Diversity (1992).
- ¹⁵ *Mindful also of the precautionary measures for the protection of the ozone layer which have already been taken at the national and international levels. The Vienna Convention (1985) serves as an example of the importance of science in permitting the international community to negotiate preventative action to address ozone layer depletion in the light of scientific uncertainty.*
- ¹⁶ *Determined to protect the ozone layer by taking precautionary measures, and Noting the precautionary measures for controlling emissions of certain chlorofluorocarbons that have already been taken at national and regional levels.*
- ¹⁷ The Preamble to the CBD states that: "Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat."
- ¹⁸ See the Report of the meeting of the WTO Committee on Trade and Environment held on 5-6 July 2000, WT/CTE/M/24; *Trade and Environment Bulletin No.33*.
- ¹⁹ Bergen Ministerial Declaration on Sustainable Development in the ECE Region (Norway), Paragraph 7, done 16 May 1990, reprinted in UN document A/CONF.151/PC/10, Annex I; *Yearbook of International Environmental Law*, Oxford University Press, 1990, page 429.
- ²⁰ Report of the United Nations Conference on Environment and Development (UNCED), Rio de Janeiro, 3-14 June 1992, Annex I.
- ²¹ See, for example, Article 11, paragraph 8 of the Cartagena Protocol on Biosafety (2000) of the Convention on Biological Diversity (1992).
- ²² For more detail on the development of customary international law relating to environmental law, see

Phillipe Sands, *Principles of International Environmental Law*, Manchester University Press, 1995.

- ²³ *Treaty Establishing the European Community*, Title XVI, Environment, Article 130r (2) states that: "Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the **precautionary principle** and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay. Environmental protection requirements must be integrated into the Community's other policies."
- ²⁴ *Communication from the EC on the Precautionary Principle*, G/SPS/GEN/225-G/TBT/W/154-WT/CTE/W/181, 31 January 2001, page 3. This document was circulated and discussed in the CTE, as well as the TBT and SPS Committees, indicating the breadth of the issues invoked. This WTO document contains the 2 February 2000 EC Communication on the Precautionary Principle, which was endorsed by the Nice European Council Resolution in December 2000.
- ²⁵ Case C-157/96, BSE (1998), ECR1-2211; Case T-13/99 Pfizer (2002) ECR 11-3305, and Case T-70/99 Alpharama (2002) ECR 11-3945. For an in-depth treatment of these cases see Theofanis Christoforou, "The Precautionary Principle in EC Law and the WTO Legal System," in G. Kremlis, G. Balias and A. Sifakis (eds.), *The Precautionary Principle*, Athens: Sakkoulas, 2004, pages 99-149.
- ²⁶ Report of the meeting of the WTO Committee on Trade and Environment held on 13-14 February 2001, WT/CTE/M/26, page 16.
- ²⁷ The idea of least-trade restrictive is also set out as optimal in the position of the EU on precaution, WT/CTE/W/181, page 4. It is also addressed in a Canadian discussion paper, *A Canadian Perspective on the Precautionary Approach/Principle*, Discussion document, Regulatory Affairs and Orders in Council Secretariat, Privy Council Office, Government of Canada, September 2001.
- ²⁸ Theofanis Christoforou, "The Precautionary Principle in EC Law and the WTO Legal System," in G. Kremlis, G. Balias and A. Sifakis (eds.), *The Precautionary Principle*, Athens: Sakkoulas, 2004, page 116.
- ²⁹ The United States was among the pioneers of a precautionary approach to environmental concerns in its laws to protect air and water quality in the 1970's.
- ³⁰ *Advancing Environmental Justice through Prevention*, Pollution Prevention Report, June 2003, Report developed from the National Environmental Justice Advisory Council meeting of 9-13 December 2002.
- ³¹ As noted by Sanderson and Solomon, the precautionary principle can be seen as an attempt to litigate and accelerate the tension between environmental policymaking and environmental science. Hans Sanderson and Keith Solomon, "Precautionary Limits to Environmental Science and Risk Management – Three Types of Errors," *Journal of Transdisciplinary Environmental Studies*, 2(1), 2003.
- ³² Executive Order 12866, Regulatory Flexibility Act. See Food and Drug Administration, US Department of Agriculture, *US Food Safety System: Precaution in US Food Safety Decision Making: Annex II to the US National Food Safety System Paper*, 3 March 2000, presented to the OECD *ad hoc* Committee on Food Safety, 24-25 January 2000, paragraphs 209-213 at <http://www.foodsafety.gov/~fsg/fssyst4.html#c-precaution>.
- ³³ Report of the Appellate Body in *EC – Measures Concerning Meat and Meat Products (EC – Hormones)*, WT/DS48/AB/R, 13 February 1998, paragraph 60.
- ³⁴ See, for example, the *Oceans Act*, S.C. 1996, c. 31, Preamble (para. 6); *Canadian Environmental Protection Act, 1999*, S.C. 1999, c. 33, Preamble, s. 2(1)(a) and s.6 (1.1); *Canadian Environmental Assessment Act 1992*, cc. 37, s. 4(1)(a) and 4(2).
- ³⁵ See the decision of L'Heureux-Dubé in *114957 Canada Ltée (Spraytech, Société d'arrosage) v. Hudson (Town)*, 2001, 2 S.C.R. 241, 2001 SCC 40, which also states that "scholars have documented the precautionary principle's inclusion in virtually every recently adopted treaty and policy document related to the protection and preservation of the environment. As a result, there may be currently sufficient state practice to allow a good argument that the precautionary principle is a principle of customary international law."
- ³⁶ *A Canadian Perspective on the Precautionary Approach/Principle*, Discussion document, Regulatory Affairs and Orders in Council Secretariat, Privy Council Office, Government of Canada, September 2001.
- ³⁷ *Vellore Citizens' Welfare Forum v. Union of India and Others*, 1996 (5) SCC 647. The status of the precautionary principle in Indian law was recently confirmed by *T.N. Godavarman Thirumalpad v. Union of India*, 2002 (10) SCC 606.
- ³⁸ P.W. Birnie and A.E. Boyle, *International Law and the Environment*, Oxford University Press, 2002, page 116; and James Cameron, "The Precautionary Principle," in Gary Sampson and Bradnee Chambers, *Trade, Environment and the Millennium*, Tokyo: United Nations University Press, 1999.
- ³⁹ Article 3(2) of the Dispute Settlement Understanding, *Marrakesh Agreement Establishing the World Trade Organization*, 15 April 1994.
- ⁴⁰ Report of the Appellate Body in *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, 29 April 1996, page 16.
- ⁴¹ For an extensive discussion of coherence in international law as between the WTO and MEAs, see Gabrielle Marceau, "A Call for Coherence in International Law – Praises for the Prohibition Against "Clinical Isolation" in WTO Dispute Settlement," *Journal of World Trade*, 33(5), October 1999. Also see Jost Pauwelyn, *Conflict of Norms in Public International Law*

– *How WTO Relates to Other Rules of International Law*, Cambridge Studies in International and Comparative Law, Cambridge University Press, 2003, Chapter 8.

⁴² Report of the Appellate Body in *EC – Hormones*, paragraph 123.

⁴³ During the 1990's, the precautionary principle was discussed in two disputes before the ICJ – the *Nuclear Tests* case by New Zealand against France (1995) and the *Gabcikovo – Nagymaros* dam dispute between Hungary and Slovakia (1997). For a treatment of precaution as related to these ICJ decisions as well as in the WTO and the International Law of the Sea Tribunal, see Kati Kulovesi, "Cautious about Precaution: Recent Judicial Practice concerning the Status of the Precautionary Principle in International Law," *Journal of Environmental Law*, 2, 2000, pages 8-26.

⁴⁴ This is the argument stressed by the European Union in its first written submissions to the Panel on *European Communities – Measures Affecting the Approval and Marketing of Biotech Products (EC – Biotech)*, WT/DS291, WT/DS292, WT/DS293, paragraph 456.

⁴⁵ The Declaration of the First International Conference on the Protection of the North Sea, "The Bremen Declaration," 1984, states that: "Conscious that damage to the marine environment can be irreversible or remediable only at considerable expense and over long periods and that, therefore, coastal states and the EEC must not wait for proof of harmful effects before taking action."

⁴⁶ The 1987 Ministerial Declaration for the North Sea, the "London Declaration," references the principle by name: "Accepting that, in order to protect the North Sea from possibly damaging effects of the most dangerous substances, a **precautionary approach** is necessary which may require action to control inputs of such substances even before a causal link has been established by absolutely clear scientific evidence."

⁴⁷ For a discussion see Gabrielle Marceau, *The Precautionary Principle Under WTO Law*, paper prepared for the UNEP Roundtable on the Precautionary Principle, 16 May 2002, Geneva.

⁴⁸ Report of the Appellate Body in *EC – Asbestos*, WT/DS135/AB/R, 12 March 2001.

⁴⁹ Specifically "necessary to protect human, animal or plant life or health" which would not "constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade."

⁵⁰ Ryan Hill, Sam Johnston, and Cyrie Sendashonga, *Risk Assessment and Precaution in the Biosafety Protocol*, UN University, July 2004.

⁵¹ In the Report of the Appellate Body in *Japan – Measures Affecting Agricultural Products*, WT/DS76/AB/R, 19 March 1999, the Appellate Body stated that provisional SPS measures should be reviewed in a reasonable period of time, based on a case-by-case basis, depending on the circumstances and the difficulty in obtaining necessary information for the review. In this case, three years were

too long to have waited as it would have been relatively easy for Japan to have supplied additional information.

⁵² For a general overview, see Makane Moise Mbengue and Urs Thomas, "The Precautionary Principle's Evolution in Light of the Four SPS Disputes," *Journal of Trade and Environment Studies*, EcoLomic Policy and Law Series, 3, 2004; Gabrielle Marceau and Joel Trachtman, "The TBT Agreement, the SPS Agreement, and the GATT: A Map of the WTO Law of Domestic Regulation of Goods" *Journal of World Trade*, 36(5) 2002, page 811; Jost Pauwelyn, "The WTO SPS Agreement as Applied in the First Three SPS Disputes," *Journal of International Economic Law*, 2(4), 1999, pages 641-665; Michael Trebilcock and Julie Soloway, "International Trade Policy and Domestic Food Safety Regulation: The Case for Substantive Deference by the WTO Dispute Settlement Body under the SPS Agreement," in D. Kennedy and J. Southwick (eds.), *The Political Economy of International Trade Law: Essays in Honor of Robert E. Hudec*, Cambridge: Cambridge University Press, 2002, page 18.

⁵³ Theofanis Christoforou, "The Precautionary Principle in EC Law and the WTO Legal System," in G. Kremlis, G. Balias and A. Sifakis (eds.), *The Precautionary Principle*, Athens: Sakkoulas, 2004, page 108.

⁵⁴ Report of the Appellate Body in *EC – Hormones*, paragraph 187.

⁵⁵ Steve Charnovitz, "The World Trade Organization, Meat Hormones, and Food Safety," *International Trade Reporter* 41, 1997, page 1786; Jan McDonald, "Big Beef Up or Consumer Health Threat?: the WTO Food Safety Agreement, Bovine Growth Hormone and the Precautionary Principle," *Environmental and Planning Law Journal*, 15(2) 115, page 123.

⁵⁶ Codex Alimentarius Commission, *Report of the 4th Session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology*, 11-14 March 2003, Yokohama, Japan.

⁵⁷ Report of the Appellate Body in *EC – Hormones*, paragraph 124.

⁵⁸ *Ibid.*

⁵⁹ *Ibid.*, paragraph 120.

⁶⁰ *Ibid.*, paragraph 124.

⁶¹ *Ibid.*, paragraph 125.

⁶² In a Press Release dated 8 November 2004, the EC announced that it was initiating a dispute in the WTO against the US and Canada concerning their continued imposition of sanctions against EC exports to retaliate against the EC ban on hormone-treated beef. The EU argues that it now has sufficient scientific evidence to justify its ban.

⁶³ Report of the Appellate Body in *EC – Asbestos*, WT/DS135/AB/R, 12 March 2001, paragraph 194.

⁶⁴ *Ibid.*, paragraph 178.

⁶⁵ *Ibid.*

⁶⁶ Report of the Panel in *EC – Asbestos*, WT/DS135/R, 18 September 2000, paragraph 8.203.

- ⁶⁷ See Duncan Brack et. al., *The Next Trade War? GM Products, the Cartagena Protocol and the WTO*, The Royal Institute of International Affairs, Sustainable Development Programme, Briefing Paper No. 8, September 2003.
- ⁶⁸ Theofanis Christoforou, "The Precautionary Principle and Democratizing Expertise: A European Legal Perspective," *Science and Public Policy*, 30(3), 2003; Theofanis Christoforou, "The Precautionary Principle in EC Law and the WTO Legal System," in G. Kremlis, G. Balias and A. Sifakis (eds.), *The Precautionary Principle*, Athens: Sakkoulas, 2004, page 126.
- ⁶⁹ The relationship between MEAs and the WTO is controversial. The Appellate Body Report on *Shrimp – Turtle* set out that international environmental law is relevant in the broader context in which WTO rules are interpreted. See the Report of the Appellate Body in *United States – Import Prohibition of Certain Shrimp and Shrimp Products (Shrimp – Turtle)*, WT/DS58/AB/R, 6 November 1998.
- ⁷⁰ Paragraph 31 of the Doha Declaration mandates negotiations in a Special Session of the WTO Committee on Trade and Environment on, *inter alia*, "(i) the relationship between existing WTO rules and specific trade obligations set out in MEAs. The negotiations shall be limited in scope to the applicability of such existing WTO rules as among parties to the MEA in questions. The negotiations shall not prejudice the WTO rights of any Member that is not a party to the MEA in questions; and (ii) procedures for regular information exchange between MEA Secretariats and the relevant WTO committees, and the criteria for the granting of observer status."
- ⁷¹ The Protocol was adopted on 29 January 2000, and entered into force on 11 September 2003. As of November 2005, 125 countries including the EC have ratified or acceded to it.
- ⁷² For a discussion of the negotiating dynamics of the Protocol see Aarti Gupta, "Governing Trade in Genetically Modified Organisms," *Environment*, May 2000.
- ⁷³ First Written Submission by the European Communities in *EC – Biotech*, WT/DS291, WT/DS292, WT/DS293, paragraph 457.
- ⁷⁴ Center for International Environmental Law, Friends of the Earth – US, Defenders of Wildlife, Institute for Agriculture and Trade Policy, and Organic Consumers Association, *Amicus Curiae Brief to the World Trade Organization: EC – Biotech*, 1 June 2004. http://www.ciel.org/Publications/WTOBiotech_AmicusCuriaeBrief_June04.pdf; and Maria Julia Olivia, Science and Precaution in EC-Biotech: A brief analysis of the first US submission, May 2004, in *Bridges*, Geneva: ICTSD, Vol. 8, No.5. http://www.ciel.org/Publications/EC_Biotech_05May05.pdf.
- ⁷⁵ *Communication from the Chairman of the Panel in EC – Biotech*, WT/DS291/29, WT/DS292/23 and WT/DS293/23, 3 October 2005.
- ⁷⁶ Communication from the Chairman of the Panel in *EC – Biotech*, WT/DS291/27, 2 November 2004.
- ⁷⁷ EC Press Release, IP/04/663, *Commission authorizes import of canned GM-sweet corn under new strict labelling conditions*, 19 May 2004.
- ⁷⁸ EC Press Release, IP/04/957, *GMOs: Commission authorizes import of GM-maize for use in animal feed*, 19 July 2004.
- ⁷⁹ For a discussion of precaution and developmental concerns surrounding GMOs, see the summary of the UNCTAD session on *International Trade in GMOs: Trends and Capacity Building Needs*, Sao Paulo, 13-18 June 2004. See also UNCTAD, *The Biotechnology Promise – Capacity Building for Participation of Developing Countries in the Bioeconomy*, Geneva 2004.
- ⁸⁰ The preamble to the SPS Agreement, for example, sets out that "developing country Members may encounter special difficulties in complying with the sanitary or phytosanitary measures of importing Members, and as a consequence in access to markets, and also in the formulation and application of sanitary and phytosanitary measures in their own territories." Articles 9 and 10 deal with technical assistance and special and differential treatment for developing countries.
- ⁸¹ Calestous Juma, Science and Technology: The New Age of Biodiplomacy," *Georgetown Journal of International Affairs*, Winter/Spring 2005, page 109.
- ⁸² *Ibid.*, page 110; and the International Centre for Trade and Sustainable Development, *Bridges Trade Biores*, 11 July 2002.
- ⁸³ For a discussion of the proliferation of domestic biosafety schemes and their complication of international trade in agro-biotechnology products, which will indirectly affect international trade in conventional agricultural products see Simonetta Zarrilli, *International Trade in GMOs: Legal Frameworks and Developing Country Concerns*, Geneva: UNCTAD, UNCTAD/DITC/TNCD/2004/1, 8 November 2004, pages 8-10; and Calestous Juma, "Biotechnology in a Globalizing World: The Coevolution of Technology and Social Institutions," *BioScience*, 55(3), March 2005, pages 6-7.

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