

THE PRECAUTIONARY PRINCIPLE IN WTO LAW

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Dissertation

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ABBREVIATIONS

AIA	Advance Informed Agreement
ADI	Acceptable Daily Intake
AJIL	American Journal of International Law
Am. U. Int'l Law R.	American University International Law Review
Basel Convention	Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal
Biodiversity Convention	Convention on Biological Diversity
BISD	Basic Instruments and Selected Documents
BSE	Bovine Spongiform Encephalopathy
BST	Bovine Somatotrophin
Cartagena Protocol	Cartagena Protocol on Biosafety
CFI	Court of First Instance
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
Climate Change Convention	United Nations Framework Convention on Climate Change
CMLR	Common Market Law Review
Cornell Int'l L. J	Cornell International Law Journal
Cornell L. R.	Cornell Law Review
Colo. J. Int'l Env't'l L. & Pol'y	Colorado Journal of International Environmental Law and Policy
Colum. J. Eur. L.	Columbia Journal of European Law
CPB	Cartagena Protocol on Biosafety
CTE	Committee on Trade and Environment
DSB	Dispute Settlement Body
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes
Drake J. Agric. L.	Drake Journal of Agricultural Law
EC	European Communities
ECJ	European Court of Justice
EJIL	European Journal of International Law
Env'tl. Law.	Environmental Lawyer
EU	European Union
EuZW	Europäische Zeitschrift für Wirtschaftsrecht
FAO	Food and Agriculture Organization
FAZ	Frankfurter Allgemeine Zeitung

GATS	General Agreement on Trade in Services
GATT'47	General Agreement on Tariffs and Trade, as adopted in 1947
GATT'94	General Agreement on Tariffs and Trade, as reenacted under the Agreement Establishing the World Trade Organization, and entered into force in 1994
Geo. Int'l Env't'l L. Rev.	Georgetown International Environmental Law Review
GMO	Genetically Modified Organism
Harvard Env'tl. L. Rev	Harvard Environmental Law Review
ICJ	International Court of Justice
ICPM	Interim Commission on Phytosanitary Measures
ILM	International Legal Materials
Int'l Law.	International Lawyer
IPPC	International Plant Protection Convention
J. Env'tl. Law and Litigation	Journal of Environmental Law and Litigation
JIEL	Journal of International Economic Law
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LMO	Living Modified Organism
MEAs	Multilateral Environmental Agreements
Minn. J. Global Trade	Minnesota Journal of Global Trade
Montreal Protocol	Montreal Protocol on Substances that Deplete the Ozone Layer
MRL	Maximum Residue Limit
NAFTA	North American Free Trade Agreement
NGO	Non-Governmental Organization
NJW	Neue Juristische Wochenschrift
NVwZ	Neue Zeitschrift für Verwaltungsrecht
Nw. J. Int'l L& Bus.	Northwestern Journal of International Law and Business
OIE	International Office of Epizootics
OSPAR Convention	The Convention for the Protection of the Marine Environment of the North-East Atlantic
PIC	Prior Informed Consent
rBST	recombined Bovine Somatotrophin
RECIEL	Review of European Community and International Environmental Law

Rio Declaration	The Rio Declaration on Environment and Development
Rotterdam Convention	Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
Syracuse J. Int'l L. & Com	Syracuse Journal of International Law and Commerce
TBT Agreement	Agreement on Technical Barriers to Trade
TREMs	Trade-Related Environmental Measures
TRIMS Agreement	Agreement on Trade-Related Investment Measures
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNEP	United Nations Environmental Programme
Vand. L. Rev.	Vanderbilt Law Review
Vand. J. Transnat'l L.	Vanderbilt Journal of Transnational Law
Vienna Convention	Vienna Convention on the Law of the Treaties
Virginia Env'tl. L. J.	Virginia Environmental Law Journal
WHO	World Health Organization
WTO	World Trade Organization
Yale H.R. & Dev. L. J.	Yale Human Rights and Development Law Journal
Yale L. R.	Yale Law Review
ZLR	Zeitschrift für Lebensmittelrecht

WHERE RUNS THE LINE BETWEEN PRECAUTION AND PRECAUTIONISM?

The Appellate Body of the World Trade Organization (the "WTO") noted in the shrimp/turtle dispute: "Locating and marking out the line of equilibrium" between the right of WTO Members to pursue their national environmental policy goals and the rights of other Members is a "delicate" task.¹ The tension between trade, health and environment peaked in the trade conflicts arising from hormone-treated beef and genetically modified organisms (GMOs). A combination of three factors makes their resolution particularly difficult: First, scientists can neither prove nor exclude risks arising from these products. Second, governments respond to diverging consumer attitudes and risk-aversions. Third, at stake are agricultural products, a sector where protectionism abounds.

The buzz word in these trade rows is the "precautionary principle". In essence, it guides governments to err on the side of caution where scientific evidence remains uncertain, contradictory or inconclusive. The European Communities invoked it to justify its import restrictions. Agricultural exporters fiercely protested against this "phoney" concept which they see as nothing but a veil to disguise protectionism of inefficient agricultural markets. They maintain that the *Uruguay Round Agreement on the Application of Sanitary and*

¹See, Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products* ("United States – Shrimp"), WT/DS58/AB/R, adopted 6 November 1998, para. 159.

Phytosanitary Measures (the "*SPS Agreement*") requires measures to be based on "sound science". Where scientific evidence is insufficient, Members may only adopt a provisional measure under the conditions set forth by Article 5.7 of the *SPS Agreement*.

There has been much disagreement between WTO Members, environmental organizations and business groups, whether the safeguard in Article 5.7 is a "carte blanche for precaution" or whether it fails to take proper account of the need to protect humans, animals and plants in accordance with the precautionary principle.

Yet, at the turn of the millennium, a significant move occurred with the adoption of the *Cartagena Protocol on Biosafety* (the "*Cartagena Protocol*")² which specifies conditions under which Parties may take precautionary trade restrictions on biotechnological products. Under the umbrella of the Codex Alimentarius Commission, States are currently negotiating a precautionary principle for food safety.

The joint search for the proper limits of precaution involves many difficult economic, scientific and constitutional issues. This thesis addresses the core legal problems arising from the precautionary principle in WTO law.

I. PROBLEM

The key legal issues relating to the precautionary principle in WTO law are coined in a succinct, but syllabic paragraph in the landmark decision *European Communities - Measures Affecting Meat and Meat Products (Hormones)*, ("*European Communities – Hormones*").³ The Appellate Body was faced with the question

²Adopted at Montreal on 29 January 2000. As of 2 November 2000, 78 States have signed the Protocol. See <<http://www.biodiv.org/biosafe/Protocol/>> (visited 10 November 2000).

³WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, para. 124 reads in full: "First, the principle has not been written into the *SPS Agreement* as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of that Agreement.

whether the precautionary principle can be used to interpret the obligation under Articles 5.1 and 5.2 of the *SPS Agreement* to base a measure on a risk assessment.⁴

Essentially, the Appellate Body emphasized that WTO law has its own mechanism to deal with precautionary measures in which the precautionary principle "finds reflection": Article 5.7 of the *SPS Agreement*. The precautionary principle cannot form an alternative "ground for justifying SPS measures that are otherwise inconsistent with the obligations" of the Members. As regards a possible interpretative function of the precautionary principle, the Appellate Body affirmed the finding of the Panel that it "does not override" the provisions in Articles 5.1 and 5.2 of the *SPS Agreement*.⁵

A. ARTICLE 5.7 OF THE *SPS AGREEMENT*

The long-festering trade conflict on hormone-treated beef made analysts conclude that the discrimination-based "like product" test in Article III:4 of the GATT 1947, coupled with the exception under Article XX could not grasp the difficulties of scientific

Secondly, the precautionary principle indeed finds reflection in Article 5.7 of the *SPS Agreement*. We agree, at the same time with the European Communities, that there is no need to assume that Article 5.7 exhausts the relevance of the precautionary principle. It is reflected also in the sixth paragraph of the preamble and in Article 3.3. These 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. Thirdly, 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. Lastly, however, the precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e., customary international law) principles of treaty interpretation in reading the provisions of the *SPS Agreement*".

⁴*Ibid.*, paras. 120-124.

⁵*Ibid.*, paras. 124 and 125. The Appellate Body consistently referred to this reasoning. See also, Appellate Body Report, *Japan – Measures Affecting Agricultural Products* ("*Japan – Agricultural Products*"), WT/DS76/AB/R, adopted 19 March 1999, para. 81.

uncertainty⁶ and issues of "regulatory protectionism" which, according to *Sykes*, can be caused by indistinctly applicable standards that disadvantage foreign producers "in a manner unnecessary to the attainment of some genuine non-protectionist regulatory objective."⁷

To ensure that the liberalization of trade in agricultural products achieved in the Uruguay Round would not be undermined by trade barriers disguised as measures to protect human, animal or plant life or health, Members negotiated a more elaborate filter technique in the *SPS Agreement*.

Very briefly, the *SPS Agreement* acknowledges the right of Members to determine their own appropriate level of protection, but sets forth seven obligations, including a harmonization requirement, a necessity test, an obligation to ensure regulatory consistency and transparency. The chief filter, however, is the science test. Articles 2.2, 5.1, 5.2, 5.3 of the *SPS Agreement* set forth an obligation to base a measure on a risk assessment and not to maintain it without sufficient scientific evidence. The Appellate Body held that the precautionary principle is relevant to the application of these provisions by directing Panels to "bear in mind", when applying these provisions, 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."⁸

Indeed, when applying Articles 2.2 and 5.1 of the *SPS Agreement* by using a rational relationship test⁹, the Appellate Body acknowledged that reliance on minority views would not necessarily

⁶*Roberts*, Donna, "Preliminary Assessment of the Effects of the WTO Agreement on Sanitary and Phytosanitary Trade Regulations", 1 JIEL (1998), pp. 377-405, at 379; *Wirth*, David A., "The Role of Science in the Uruguay Round and NAFTA Trade Disciplines, 27 Cornell Int'l L. J. (1994), pp. 817-859, at 824.

⁷*Sykes*, Alan O., "Regulatory Protectionism and the Law of International Trade", 66 U. Chi. L. R. 1999, pp. 1-46, at 3.

⁸Appellate Body Report, *European Communities – Hormones*, para. 124. (emphasis added).

⁹*Ibid*, para. 193. See also, Appellate Body Report, *Japan – Agricultural Products*, para. 73.

indicate the absence of a rational relationship and Members are not required to demonstrate a minimum threshold of risk.¹⁰ However, at the same time, the obligation under Article 5.1 was interpreted to require Members to specifically and systematically assess the risk.¹¹ "Some evaluation" and reference to "uncertain elements" are not enough.¹² The Appellate Body emphasized that the "quality and quantity" of the scientific evidence counts and cautioned that "an overly broad interpretation of that obligation would render Article 5.7 meaningless".¹³

To date, all measures brought to the WTO were found to be at odds with Articles 2.2 and 5.1 of the *SPS Agreement*. Given the few and controversial scientific evidence on GMOs and the fact that the European Communities have proposed to implement the ruling in *European Communities –Hormones* by adopting a provisional ban on five of the hormones¹⁴, it appears that the right to take a provisional measure under Article 5.7 of the *SPS Agreement* will be the decisive norm to adjudicate trade conflicts arising in situations of scientific uncertainty. Article 5.7 of the *SPS Agreement* provides in full:

A Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary

¹⁰Appellate Body Report, *European Communities – Hormones*, paras. 186 and 194. See also, Appellate Body Report, *Japan – Agricultural Products*, para. 77.

¹¹*Ibid.*, paras. 198-200.

¹²Appellate Body Report, *Australia – Measures Affecting Importation of Salmon* ("*Australia – Salmon*"), WT/DS18/AB/R, adopted 6 November 1998, para. 128.

¹³Appellate Body Report, *Japan – Agricultural Products*, paras. 80 and 84.

¹⁴Proposal for a Directive of the European Parliament and of the Council amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, Brussels, 24.5. 2000, COM(2000) 320 final.

or phytosanitary measure accordingly within a reasonable period of time.

The case law on this provision is still thin. It was only addressed in the third SPS case, *Japan – Agricultural Products*, which was decided by using the procedural requirements in the second sentence of Article 5.7. Their interpretation provides little guidance for most precautionary measures, in particular GMO cases, but also the proposed Hormones Directive: The "information sought must be germane to conducting a risk assessment".¹⁵ What constitutes a "reasonable period of time" has to be established on a "case-by-case basis" and depends on the "specific circumstances of each case", including the "difficulty of obtaining the additional information necessary for the review *and* the characteristics of the provisional SPS measure".¹⁶ Would a GMO ban which is taken with a view to long-term effects associated with GMOs and what if...? questions meet these requirements? Would Article 5.7 allow turning a permanent ban into a provisional one as intended in the hormones case? The substantive requirement in Article 5.7, first sentence, to adopt a measure "on the basis of available pertinent information" is equally ambiguous. Does it set forth a mini-rational relationship test? Does the term "more objective assessment of risk" imply a mini-risk assessment obligation, whereby a Member must, at least, provide a *subjective* risk evaluation? How specific does the "pertinent available" information have to be?

Where the substantive tests boil down to what has been criticised as "we know it when we see it stances",¹⁷ the rules governing the fact-finding process become decisive, in particular, the burden of proof. According to the Appellate Body, Article 5.7 of the

¹⁵ Appellate Body Report, *Japan – Agricultural Products*, para. 92.

¹⁶ *Ibid.*, para. 93.

¹⁷ *Hurst*, David R., "Hormones: European Communities – Measures Affecting Meat and Meat Products", *EJIL* Vol. 9 (1998), at 182.

SPS Agreement operates as "qualified exemption".¹⁸ This raises the question, whether the burden of proof is on the defendant as in the cases of exceptions¹⁹, or whether the general burden of proof under the *SPS Agreement* applies²⁰, whereby the initial burden is on the complainant to make a *prima facie* case of inconsistency and then "moves" to the respondent who must counter or refute the claimed inconsistency.²¹ The "*prima facie*" standard has been criticized for being too low and for causing uncertainty, whether the burden of proof in the strict sense shifts", i.e. the risk of non-persuasion in cases where the evidence is in equipoise.²²

Similarly, no clear standard of review has been developed for the *SPS Agreement* which would mark the point up to which WTO panels may second-guess national risk determinations. Municipal courts apply a reduced standard of review in situations of scientific uncertainty by scrutinizing, e.g., whether the authorities have committed a "manifest error".²³ The Appellate Body determined that the standard of review applicable in the *SPS Agreement* is neither "*de novo* review as such, nor total deference" but succinctly coined in the obligation of panels to make an objective assessment of facts according to Article 11 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (the "*DSU*").²⁴ Only, e.g., an "egregious error" on the part of the panel constitutes a reviewable violation of Article 11 of the *DSU*.²⁵ Panels were

¹⁸Appellate Body Report, *European Communities – Hormones*, para. 80.

¹⁹So, Pauwelyn, Joost, "The WTO Experience under the SPS Agreement", World Trade Forum, 2000 (forthcoming), pp. 95-108, at 101.

²⁰So, Charnovitz, Steve "The Supervision of Health and Biosafety Regulation by World Trade Rules", World Trade Forum, 2000 (forthcoming), pp. 121-150, at 135.

²¹Appellate Body Report, *European Communities – Hormones*, para. 98.

²²Pauwelyn, Joost, "Evidence, Proof and Persuasion in WTO Dispute Settlement: Who bears the Burden?", 2 JIEL 1998, pp. 227-258.

²³See, e.g. Judgement of the European Court of Justice, Case C-180/96, *UK v. Commission*, [1998] ECR I-2265, para. 93.

²⁴Appellate Body Report, *European Communities – Hormones*, para. 117.

²⁵*Ibid.*, para. 133.

criticised for heavily second-guessing scientific evidence.²⁶ Recently, the DSU 21.5 Panel in *Australia – Salmon*, though, seemed to apply a standard of "reasonable confidence".²⁷

In short, the substantive and procedural conditions for the taking of a provisional measure under Article 5.7 of the *SPS Agreement* are still unclear.

B. THE ROLE OF "OUTSIDE" PRECAUTIONARY PRINCIPLES

The adoption of the *Cartagena Protocol on Biosafety* and the current negotiations of *Draft Working Principles for Risk Analysis* in the Codex Alimentarius Commission put the spotlight on the link between these principles and WTO law.

According to Article 3.2 of the DSU, the WTO agreements shall be clarified "in accordance with customary rules of interpretation of public international law". In *United States – Standards for Reformulated and Conventional Gasoline* ("*United States – Gasoline*"), the Appellate Body emphasized that the direction in Article 3.2 of the DSU "reflects a measure of recognition that the *General Agreement* is not to be read in clinical isolation from public international law".²⁸ In *United States – Shrimp*, the Appellate Body has expressly referred to Article 31.3(c) of the *Vienna Convention on the Law of Treaties* (the "*Vienna Convention*")²⁹, and interpreted Article XX of the GATT 1994 in light of several multilateral environmental agreements.³⁰

²⁶Walker, Vern R., "Keeping the WTO from Becoming the 'World Trans-science Organization', Scientific Uncertainty, Science Policy, and Factfinding in the Growth Hormones Dispute", *Cornell Int'l L. J.*, Vol. 31 (1998), pp. 251-320.

²⁷*Australia – Measures Affecting Importation of Salmon* – Recourse to Article 21.5 by Canada ("*Australia – Salmon 21.5*"), WT/DS18/RW, adopted 20 March 2000, para. 7.51.

²⁸WT/DS2/AB/R, adopted 20 May 1996, at 11.

²⁹Done at Vienna, 23 May 1969, 1155 U.N.T.S. 33; 8 International Legal Materials 679.

³⁰Appellate Body Report, *United States – Shrimp*, para. 158.

As regards the precautionary principle, the Appellate Body, in *European Communities – Hormones*, declined an interpretative function in *casu*, albeit not excluding it generally when holding that "the precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e., customary international law) principles of treaty interpretation in reading the provisions of the *SPS Agreement*".³¹ By only affirming that the precautionary principle, "does not override the obligations under Articles 5.1 and 5.2 of the *SPS Agreement*", the Appellate Body has not clearly specified *why* it has rejected its use. The main reason appears to be that a reading of Article 5.1 of the *SPS Agreement* in light of the precautionary principle would have broadened the scope of that provision to the detriment of Article 5.7. This could square with *United States – Shrimp*, where the Appellate Body, before interpreting Article XX of the GATT in light of environmental conventions, carefully examined, whether the text of the provisions was "mutually exclusive", i.e. conflicting.³²

Another reason can be gleaned from the statement that "at least outside the field of international environmental law, [the precautionary principle] still awaits authoritative formulation".³³ Indeed, the precautionary principle has only been articulated in international environmental law, in particular the *Rio Declaration on Environment and Development* (the "*Rio Declaration*").³⁴

Appellate Body pointed to the crux of the precautionary principle in SPS disputes: The lack of a formulation in the area of health and food safety not only invites suspicions that the principle

³¹Appellate Body Report, *European Communities – Hormones*, para. 124.

³²Appellate Body Report, *United States – Shrimp*, para. 128.

³³Appellate Body Report, *European Communities – Hormones*, para. 123.

³⁴Adopted 13 June 1992, 31 ILM 874 (1992). Principle 15 provides: "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."

might be abused for protectionist purposes. Article 31.3(c) of the *Vienna Convention* requires that a norm must be *relevant*, i.e. pertaining to the subject-matter. A precautionary principle formulated for the protection of the global environment would not offer much interpretative assistance in a food safety dispute. Thus, the Appellate Body did not even address the "important, but abstract" question, whether the precautionary principle had attained the status of a customary or general principle of international law.³⁵

Yet, the situation has changed. A precautionary principle for food safety might emerge from the negotiation in the Codex Alimentarius Commission.³⁶ Some have raised concerns that it would be a "slippery slope" towards eroding the science based mechanism of the *SPS Agreement*.³⁷ In *Japan – Agricultural Products*, the Appellate Body rejected the interpretation of Article 2.2 of the *SPS Agreement* in light of a Codex principle by simply referring to the case law in *European Communities – Hormones*.³⁸ However, the fact that the *SPS Agreement* sets forth a more nuanced relationship to the "privileged" standards of the Codex Alimentarius Commission³⁹ warrants a careful examination of its effect, in particular, on Article 5.7 of the *SPS Agreement*.

³⁵Appellate Body Report, *European Communities – Hormones*, para. 123. Possibly this statement also implies jurisdictional self-restraint towards the International Court of Justice (the "ICJ") or that the existence of a norm with "fundamentally norm-creating character" logically preceeds the examination of its status and effect in international law. See, *North Sea Continental Shelf Cases (Federal Republic of Germany/Denmark; Federal Republic of Germany/Netherlands)*, Judgement of 20 February 1969, I.C.J. Reports 1969, p. 3, para. 72. In the *Asylum Case (Colombia/Peru)* Judgement of 20 November 1950, I.C.J. Reports, 1950, p.266, at 277, the Court denied the existence of a customary norm on diplomatic asylum because of "unresolved controversies as to the exact meaning and scope of this notion".

³⁶See, Report of the Fifteenth Session of the Codex Committee on General Principles, Paris, France, 10-14 April 2000, ALINORM 01/33. The draft contained in Annex III to the Report is still at step 3 of the standard setting process.

³⁷So, Senator *John Ashcroft* of Missouri in his letter of April 19th 2000, available at <http://www.insidetrade.com> (visited 2 June 2000).

³⁸Appellate Body Report, *Japan – Agricultural Products*, para. 81.

³⁹*SPS Agreement*, Articles 3, 5.1 and Annex A.3(a).

The inclusion of a precautionary principle and its possible conflict with WTO law was one of the main sticking points in the negotiations of the *Cartagena Protocol*. Its operative provisions provide in relevant part:

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism ... shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism [...] in order to avoid or minimize such potential adverse effects.⁴⁰

In addition, the *Cartagena Protocol* sets forth further procedural obligations regarding the review of import decisions under the Protocol.⁴¹ This new version of the precautionary principles rather resembles Article 5.7 of the *SPS Agreement* than Principle 15 of the *Rio Declaration*, but some have raised concerns that it clashes with the *SPS Agreement*.⁴² Indeed, the *Cartagena Protocol* does not require a measure to be adopted provisionally and automatically reviewed by the country of import. Do these differences cause a conflict requiring the application of the rules of conflict in Article 11.3 of the *SPS Agreement*, with the consequence that the *Cartagena Protocol* could not be considered in WTO dispute settlement proceedings? The Preamble to the *Cartagena Protocol* envisages a "mutually supportive relationship" between "trade and environment agreements" and mandates that the Protocol "shall not be *interpreted*" as implying a change in the obligations under other international agreement, albeit not being "subordinated" to them.⁴³ This suggests

⁴⁰CPB, Articles 10 (6) and 11 (8).

⁴¹CPB, Article 12.

⁴²So, Phillips, Peter W.B./Kerr, William A., "The WTO Versus the Biosafety Protocol for Trade in Genetically Modified Organisms", 34(4) *Journal of World Trade* (2000), pp. 63-75.

⁴³CPB, 9th – 11th preambular paragraph (emphasis added).

that states have sought to avoid conflicts and to allow mutual influence through harmonious interpretation so that both treaties can apply cumulatively.⁴⁴ However, this requires a careful analysis of the effect of the new precautionary principle for GMOs in WTO law before the background of the broader trade-and-environment debate.⁴⁵

II. THE STATE OF THINKING

Although, there is no dearth of literature on the precautionary principle and the *SPS Agreement*, the role of the precautionary principle in the *SPS Agreement* has not been subject to thorough scholarly analysis.⁴⁶ Treatises have been written about the precautionary principle in international environmental law.⁴⁷ Scholars are now sharpening their pencils to analyze the developments following the *Cartagena Protocol on Biosafety* which has only been subject to a preliminary analysis.⁴⁸

⁴⁴*Eggers, Barbara/Mackenzie, Ruth*, "The Cartagena Protocol on Biosafety", 3 JIEL 525 (2000), pp. 525-543,

⁴⁵See, *Esty, Daniel C.*, "Greening the GATT: Trade, Environment, and the Future" (Washington, D.C.: Institute of International Economics, 1994); *Hilf, Meinhard*, "Freiheit des Welthandels contra Umweltschutz?", NVwZ 2000, pp. 481-600; *Mavroidis, Petros C.*: Trade and Environment after the Shrimps-Turtles Litigation, Journal of World Trade 34 (1) 2000, pp. 73-88.

⁴⁶The cut-off date for literature and case law was 1. October 2000.

⁴⁷*O'Riordan, Tim/Cameron, James*, "Interpreting the Precautionary Principle" (London: Cameron May, 1994); *Cameron, James/Abouchar, Juli*, "The Status of the Precautionary Principle in International Law", in: *Freestone, David/Hey, Ellen* (eds.), "Implementing the Precautionary Principle" (Den Haag/London/Boston: Kluwer Law International, 1996) pp. 249-268; *Hickey, James E./Walker, Vern R.*, "Refining the Precautionary Principle in International Environmental Law", Virginia Environmental Law Journal, Vol, 14 (1995), pp. 424-454; *Epiney, Astrid/Scheyli, Martin*, "Strukturprinzipien des Umweltvölkerrechts" (Baden-Baden: Nomos Verlagsgesellschaft, 1998); *Hohmann, Harald*, "Precautionary Legal Duties and Principles of Modern International Environmental Law" (London/Dordrecht/Boston: Graham&Trotman/Martinus Nijhoff, 1994); *Moltke, Konrad von*, "The Vorsorgeprinzip in West German Environmental Policy, Royal Commission on Environmental Pollution", Twelfth Report: Best Practicable Environmental Option (London: HMSO, 1988), pp. 57-70; *Sadeleer, Nicolas de*, "Les Principes du Polluter-Payeur, de Prévention et de Précaution", Bruylant, Brussels 1999

⁴⁸*Eggers/Mackenzie*, above n.44; *Phillips/Kerr*, above n.42.

Several scholars, in particular *Pauwelyn*, have reviewed the *SPS Agreement* as interpreted in the first cases.⁴⁹ The landmark decision in *European Communities – Hormones* was commented by many, including *Quick/Blüthner* and *Roberts*.⁵⁰ The two other rulings, in particular *Japan – Agricultural Measures*, where Article 5.7 was addressed, have not gained much attention in the literature.⁵¹ The procedural issues of burden of proof⁵² and standard of deference⁵³ were addressed on a cross-sectoral basis, in particular by *Croley* and *Jackson*. *Christoforou* and *Walker* provided a critical analysis of the

⁴⁹*Barceló*, John, "Product Standards to Protect the Local Environment – the GATT and the Uruguay Round Sanitary and Phytosanitary Agreement", 27 *Cornell Int'l L. J.* (1994), pp. 755-776; *Carter*, Michele D., "Selling Science under the *SPS Agreement*: Accomodating Consumer Preference in the Growth Hormones Controversy", 6 *Minnesota Journal of Global Trade*, 1997, pp. 626-656; *Charnovitz*, Steve, "The Supervision of Health Regulation by World Trade Rules", *Tulane Environmental Law Journal*, (forthcoming); *Pauwelyn*, Joost, "The WTO Agreement on Sanitary and Phytosanitary (SPS) Measures as Applied in the First Three SPS Disputes – EC – Hormones, Australia – Salmon and Japan – Varietals", *JIEL* Vol. 2 (1999), pp. 641-664; *Roberts*, Donna, above, n.; *Shin*, Yukyun, "An Analysis of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures and its Implementation in Korea", *Journal of World Trade*, Vol. 32, No. 1, 1998, pp. 85-119; *Stanton*, Gretchen, "Implications of the WTO Agreement on Sanitary and Phytosanitary Measures", in: David Orden and Donna Roberts (eds.) *Understanding Technical Barriers to Trade* (St. Paul: International Agricultural Trade Research Consortium, 1997).

⁵⁰*Hurst*, David R., "Hormones European Communities – Measures Affecting Meat and Meat Products", *EJIL* Vol. 9 (1998), pp. 182; *Quick*, Reinhard/*Blüthner*, Andreas, "Has the Appellate Body Erred? An Appraisal and Criticism of the Ruling in the WTO Hormones Case", *JIEL* Vol. 2 (1999) pp. 603-639; *Roberts*, above, n. 6; *Walker*, above., n. 26.

⁵¹*Goh*, Gavin/Ziegler, Andreas R., "A Real World Where People Live and Work and Die: Australian SPS Measures After the WTO Appellate Body's Decision in the Hormones Case", 32(5) *Journal of World Trade* (1998), pp. 271-290; *Landwehr*, Oliver, "Decisions of the Appellate Body of the World Trade Organization", *EJIL* 1999, available at <<http://www.ejil.org>>.

⁵²*Martha*, Rutsel Silvestre J., "Presumptions and Burden of Proof in World Trade Law", 14 (1) *Journal of International Arbitration* 67 (1997). *Pauwelyn*, Joost, "Evidence, Proof and Persuasion in WTO Dispute Settlement: Who bears the Burden?", 2 *JIEL* 1998, pp. 227-258.

⁵³*Croley*, Steven P./*Jackson*, John H., "WTO Dispute Procedures, Standard of Review, and Deference to National Governments", 90 *AJIL* 1996, pp. 193-213; *Desmedt*, G. Axel, "Hormones: 'Objective Assessment' and (or as) standard of review", 1 *JIEL* 1998, pp. 695-698; *Gomula*, Joanna, "The Standard of Review of Art. 17.6 of the Anti-Dumping Agreement and the Problem of its Extension to other WTO Agreements", in: *Mengozzi*, Paolo (ed.), "International Trade Law on the 50th Anniversary of the Multilateral Trading System" (Milano: Dott. A. Giuffrè editore, 1999) pp. 577-608.

fact-finding in *European Communities – Hormones*.⁵⁴ Only recently, participants of the *World Trade Forum*, started a more detailed discussion of some of the issues relating to scientific uncertainty and the precautionary principles in the *SPS Agreement*.⁵⁵

II. SCOPE AND METHODOLOGY OF THIS STUDY

This study takes an analytical state of the law approach. Its goal is not to add another criticism of the science test, or to replace the current SPS rules by alternative tests, e.g., economic tests to screen out "welfare-reducing regulatory protectionism while leaving unconstrained consumer welfare-enhancing risk regulation", as recently suggested by *Trebilcock*.⁵⁶

Responding to the current trend at the international level, where WTO Members attempt to negotiate precautionary principles in other fora rather than re-opening the *SPS Agreement*, this study follows the approaches of "principle-orientation" of WTO law as elaborated by *Hilf*⁵⁷, and *Sands*' plea for "cross-fertilization in international law".⁵⁸ The interpretation of WTO law in light of outside principles raises two concerns: First, *Bronckers* warned of undemocratic developments through rule-making by judges.⁵⁹

⁵⁴*Christoforou*, Theofanis, "Settlement of Science-Based Trade Disputes in the WTO: A Critical Review of the Developing Case Law in the Face of Scientific Uncertainty", 8 New York University Environmental Law Journal, (2000), pp. 622-648; *Walker*, above n. 26.

⁵⁵See, in particular the papers by *Charnovitz*, above n.20, *Matsushita*, Mitsuo, "WTO Perspective – The SPS Agreement", World Trade Forum, 2000, (forthcoming), pp. 109-120, and *Pauwelyn*, above n.19.

⁵⁶*Trebilcock*, Michael, "International Trade Policy and Domestic Food Safety Regulation", The Case for Substantial Deference by the WTO Dispute Settlement Body under the SPS Agreement", Minnesota Conference, 15-16 September 2000. See also, *Mattoo*, Aaditya/Subramanian, Arvind, "Regulatory Autonomy and Multilateral Disciplines: The Dilemma and a possible Resolution", 1 JIEL (1998), pp. 303-322

⁵⁷*Hilf*, Meinhard, "Power, Rules and Principles – Which Orientation for WTO/GATT Law?" 4 JIEL (2001) forthcoming.

⁵⁸*Sands*, Philippe: Treaty, Custom and the Cross-fertilization of International Law, 1 Yale H.R. & Dev. L. J. Vol. 1 85 (1998).

⁵⁹*Bronckers*, Marco, "Better Rules for a new Millennium: A Warning Against Undemocratic Developments in the WTO", 2 JIEL (1999), pp. 547-566.

However, considering outside norms created by democratically elected governments in a multilateral environmental agreement would ensure "better rules for the new millennium". Second, as cautioned by *Hilf*, the use of "outside" principles is a "sensitive process", where the WTO adjudicators must be anxious not to change the finely tuned balance between the respective rights of Members.⁶⁰

To ensure a careful, precise legal analysis within the interstice between clarifying and changing WTO obligations, this study concentrates on one segment of the line between precaution and precautionism, which, albeit the essential one has not yet been thoroughly analyzed: The conditions for measures taken in situations of scientific uncertainty as set forth by Articles 2.2, and 5.1, 5.2, 5.3 and, in particular Article 5.7 of the *SPS Agreement*, including the procedural determinants of the burden of proof and the standard of review as well as their possible interpretation in light of the new precautionary principles

The study picks up the term "precautionary measures" which is more and more used in discussions of measures taken in situations of scientific uncertainty⁶¹, and the ongoing fine-tuning, e.g., the notion of emergency measures in the BSE cases.⁶² Moreover, some have pointed to the problems of "mixed measures", i.e., measures taken to pursue several legislative goals.⁶³ As of March 1999, more than 1.1.00 sanitary and phytosanitary measures had been notified to the SPS Committee.⁶⁴ This registry is a treasury of different sanitary and

⁶⁰*Hilf*, above, n.57.

⁶¹See, *Roberts*, above n.6, at 379, and for example the notification of Hong Kong G/SPS/N/HKG/9 of 17 April 2000.

⁶²*Ibid.*

⁶³*Pauwelyn*, above, n. 49., at 644.

⁶⁴Report of the SPS Committee, "Review of the Operation and Implementation of the Agreement on Sanitary and Phytosanitary Measures", G/SPS/12, 11 March 1999. See also the overview of trade conflicts regarding sanitary and phytosanitary measures which have been settled, *Roberts*, above, n. 99, at 396 and *Shin*, above n.64.

phytosanitary measures. Although, the study cannot consider all of them, a taxonomy warrants at least two further differentiations:

First, distinctions can be made between differing degrees of scientific uncertainty. While GMOs, e.g., involve a high degree of scientific uncertainty, i.e., short term data stand against a few controversial studies and a bunch of "what if...?" questions, more evidence has been gathered, e.g., on the effects of hormones, where scientists rather disagree which inferences to draw from existing data. Second, there are considerable differences between "old" pre-Uruguay Round measures, where Members were scientifically idle, e.g., in *Japan – Agricultural Products*, and recent measures taken in the antibiotic cases or *Hormones II*, which refer to scientific evidence in their Preambles and are labelled provisional or temporary.⁶⁵

The analysis also includes elements of a horizontal comparative law approach. It examines the core features of the precautionary principle and how these concepts are reflected in the *SPS Agreement*. In particular, when exploring the possible legal effects of the new outside precautionary principles on the obligations under the *SPS Agreement*, a careful consideration of the respective legal texts is warranted. The *Cartagena Protocol*, for example, contains at least six different provisions relevant for scientific uncertainty, and the devils of "conflict", "cross-fertilization" and "principle-orientation" might be in the detail.

⁶⁵Commission Regulation, 2788/98, Preamble, 6th to 13th whereas clause. Council Regulation (EC) 2821/98, Preamble, 8th to 22nd whereas clause. Proposal for a Directive of the European Parliament and of the Council amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists. Brussels, 24.5. 2000, COM(2000) 320 final, Article 2 read together with Annex II

III. OUTLINE OF ARGUMENT

This thesis is divided into three parts and a conclusion.

Part 1 starts off with a brief survey of precautionary principles in municipal law, European Community law and at the international level. The focus is on recent developments, including the consolidation of a precautionary principle in European Community law, the *Cartagena Protocol on Biosafety* and the current negotiations under the *Codex Alimentarius Commission*. The goal is to develop a clearer definition of the precautionary principle and to distil its emerging features. Together with the description of the precautionary principles, Part 1 also provides the necessary factual and legal background on GMOs, hormones, mad cow disease, and antibiotics as well as issues of scientific uncertainty underlying the trade conflicts.

Part 2 turns to the flip-side of the precautionary principle in WTO law. A background chapter briefly addresses economic issues of agricultural and regulatory protectionism and precautionism. It also describes the legal framework in WTO law, in particular the *SPS Agreement* and the rulings in the first SPS cases. Before addressing the WTO filter, a section sets forth seven hypotheticals, which are built on current and emerging trade conflicts and the precautionary principles discussed in Part 1. What follows is a step-by-step examination of the conditions for the taking of precautionary measures under Articles 2.2, 5.1, 5.2, 5.3 and, in particular 5.7 of the *SPS Agreement*, including the issues of burden of proof and standard of review. After analyzing the key legal issues arising from precautionary measures in light of WTO jurisdiction and the literature, and playing through the mechanism with the help of the hypotheticals, the analysis concludes that it sets relatively predictable conditions for blatant cases of "scientific idleness" and model emergency measures like, e.g., the BSE cases. However, for most cases, i.e. *Hormones II*

and the biotechnology measures, the "accordion like concepts" under Article 5.7 of the *SPS Agreement* would allow WTO adjudicators to come down on both sides.

Part 3 then picks up from the prior analysis, by exploring the effect of the post-*Hormones* "outside" precautionary principles in the *SPS Agreement*. At the outset, a general analysis of the possible relationships between the *SPS Agreement* and "outside" precautionary principles is provided. The following chapter then examines the status and effect of the *Draft Codex Working Principles for Risk Analysis* as "privileged standards" in the *SPS Agreement*. The last chapter, titled, "Beyond Conflict: Cross-Fertilizations between the *Cartagena Protocol on Biosafety* and the *SPS Agreement*" analyzes the interaction between the precautionary principle under the *Cartagena Protocol* and the *SPS Agreement*. After carefully considering the relationship between both agreements, it argues that the precautionary principles under the *Cartagena Protocol* do not conflict with Article 5.7, but that there is a scope for cross-reflections. Finally, it identifies several ways how WTO Panels might tailor a biotechnology specific interpretation of Article 5.7 while not impairing the rights and obligations of WTO Members when referring to the *Cartagena Protocol*.

PART 1

THE PRECAUTIONARY PRINCIPLE

The precautionary principle is a red rag in international trade relations. Originally developed to provide "guidance in the development and application of international environmental law where there is scientific uncertainty"¹, it was invoked by the European Communities in several trade conflicts arising from hormone-treated beef or GMOs. Agricultural exporters fiercely protested against this "phoney concept" which is, according to them, nothing but a veil to disguise protectionism of inefficient agricultural markets.

In *European Communities - Measures Affecting Meat and Meat Products (Hormones)*, ("European Communities – Hormones"), the European Communities argued that the precautionary principle had attained the status of a customary or general principle of law and could be used to interpret its obligations under WTO law.² The United States and Canada contented that no internationally agreed definition of a precautionary principle exists, but at best a precautionary "approach"

¹Sands, Philippe, "Principles of International Environmental Law I", (Manchester and New York: Manchester University Press, 1995), at 208.

²Appellate Body Report, *European Communities – Hormones*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, para. 121.

which varies from context to context.³ The Appellate Body shared this view. Declining to take a position on the "important, but abstract, question" of the status of the precautionary principle in international law, it noted that "at least outside the field of international environmental law, [it] still awaits authoritative formulation".⁴

This statement points to the crux of the precautionary principle in international trade. Apart from environmental law, there have been no definitions governing precautionary action in the areas where trade conflicts arise, i.e. particular food safety and GMOs. The lack of a clear definition not only invites suspicions that the principle might be abused for protectionist purposes. It also bars judges from determining its status in international law, because the existence of a norm with "fundamentally norm-creating character" logically preceedes the examination of its status and effect in international law.⁵

Yet, as a partial response to the ruling of the Appellate Body and the continuous allegations that the precautionary principle is "wobbly", the European Communities currently strive to articulate its meaning and to consolidate it in the area of food safety and health protection.⁶ A precautionary principle governing restrictions on imports of GMOs has explicitly been incorporated in the *Cartagena Protocol on Biosafety* which was adopted in 2000, and the Codex

³United States' appellee's submission, para. 92 and Canada's appellee's submission, para. 34 (both on file with author); See also Appellate Body Report, *European Communities – Hormones*, para. 122, and, most recently, statement of the United States, Committee on Trade and Environment, Report of the Meeting Held on 5-6 July, WT/CTE/M24, 19 September 2000, at 21

⁴Appellate Body Report, *European Communities – Hormones*, para. 123.

⁵See, *North Sea Continental Shelf Cases (Federal Republic of Germany/Denmark; Federal Republic of Germany/Netherlands)*, Judgement of 20 February 1969, I.C.J. Reports 1969, p. 3, para. 72. In the *Asylum Case (Colombia/Peru)* Judgement of 20 November 1950, I.C.J. Reports, 1950, p.266, at 277, the Court denied the existence of a customary norm on diplomatic asylum because of "unresolved controversies as to the exact meaning and scope of this notion".

⁶See, most recently, "Council Resolution on the Precautionary Principle", endorsed by the "Presidency Conclusions, Nice European Council Meeting, 7, 8 and 9 December 2000", para. 35 and reprinted in Annex III thereto, available at <<http://europa.eu.int>> (visited 28 December 2000).

Alimentarius Commission currently hosts negotiations of a precautionary principle for food safety.

Part 1 of this thesis serves two purposes. First, it aims at developing a clearer definition of what is called the "precautionary principle", in particular in the areas relevant for trade conflicts. To this end, chapter 1 surveys precautionary principles in municipal law, European Community law and at the international level. This review allows some conclusions about emerging features of the precautionary principle which are summarized in chapter 2, titled "close to authoritative formulation". It also provides the necessary legal and factual background of the measures taken pursuant to the precautionary principle which are then analyzed in Part 2.

§ 1 SURVEY OF PRECAUTIONARY PRINCIPLES

The precautionary principle was first introduced in Germany under the name of *Vorsorgeprinzip*. Subsequently, it found its way into European Community law and international environmental law. The precautionary principle has many different facets and its development is head-spinning. The following sections can by no means take account of all details and specific emanations, but are forced to give a rough overview.⁷ They first look at the municipal level, in particular, German law, then at the precautionary principle in European Community law and finally turn to the international level. The focus is on recent developments and those precautionary regulations which are particularly relevant in international trade conflicts.

I. MUNICIPAL LAW

The precautionary principle originates in continental Europe, and is to date known in several European countries, e.g., France⁸, Belgium and Sweden.⁹ Of the common law jurisdictions, only few have explicitly recognized the precautionary principle, e.g., India,

⁷Compare for a more detailed analysis: *O'Riordan*, Tim/*Cameron*, James, "Interpreting the Precautionary Principle" (London: Cameron May, 1994); *Cameron*, James/*Abouchar*, Juli, "The Status of the Precautionary Principle in International Law", in: *Freestone*, David/*Hey*, Ellen (eds.), "Implementing the Precautionary Principle" (Den Haag/London/Boston: Kluwer Law International, 1996) pp. 249-268; *Hickey*, James E./*Walker*, Vern R., "Refining the Precautionary Principle in International Environmental Law", *Virginia Environmental Law Journal*, Vol. 14 (1995), pp. 424-454; *Epiney*, Astrid/*Scheyli*, Martin, "Strukturprinzipien des Umweltvölkerrechts" (Baden-Baden: Nomos Verlagsgesellschaft, 1998); *Hohmann*, Harald, "Precautionary Legal Duties and Principles of Modern International Environmental Law" (London/Dordrecht/Boston: Graham & Trotman/Martinus Nijhoff, 1994); *Moltke*, Konrad von, "The Vorsorgeprinzip in West German Environmental Policy, Royal Commission on Environmental Pollution", Twelfth Report: Best Practicable Environmental Option (London: HMSO, 1988), pp. 57-70; *Sadeleer*, Nicolas de, "Les Principes du Polluter-Payeur, de Prévention et de Précaution", Bruylant, Brussels 1999.

⁸*Kourilsky*, Philippe/*Viney*, Geneviève, "Le Principe de Précaution" (Paris: Edition Odile Jacob, 2000).

⁹See for an overview *Sadeleer*, above, n. 7, at 161-163.

whose Supreme Court in *M.C. Mehta v. Union of India* was faced with the question whether the destruction of the Taj Mahal Palace through pollution would justify the closing down of nearby manufacturers.¹⁰ The Court derived a precautionary principle from the constitutional duties of the state to improve health and the standard of living and held that "not even one per cent chance can be taken when – human life apart – the preservation of a prestigious monument like the Taj is involved".¹¹

Comparative analyses of other common law jurisdictions have concluded that albeit not explicitly recognizing a precautionary principle, the environmental law of the United States and Australia are "precautionary in nature".¹² The United States have recently acknowledged that "precaution has been a long-standing and essential element of the US regulatory system in health and safety matters, particularly for foods, drugs and chemicals".¹³ Indeed, the American system of "positive listing" and pre-marketing approval for pesticides, food additives and other potentially toxic substances is well-known for its strictness. Under the US Federal Food, Drugs and Cosmetics Act¹⁴, for example, a substance that is a food or color additive cannot be used legally in foods or feeds unless FDA has established a regulation specifying the conditions under which the additive may be used safely.¹⁵ The most prominent example for a precautionary

¹⁰*M.C. Mehta v. Union of India* (1997) 2 S.C.C. 353.

¹¹*Ibid.*, para. 13.

¹²See *Barton*, Charmian, "The Status of the Precautionary Principle in Australia: Its Emergence in Legislation and as a Common Law Doctrine", 22 Harv. Env'tl L. Rev. (1998), pp. 509-558; *Bodansky*, Daniel, "The Precautionary Principle in US Environmental Law", in: *O'Riordan*, Tim/*Cameron*, James, "Interpreting the Precautionary Principle" (London: Cameron May, 1994), pp. 203-228, at 204 and 213; *Rehbinder*, Eckard, "Das Vorsorgeprinzip im internationalen Vergleich", (Düsseldorf: Werner, 1991); *Shelton*, Dinah, "The Impact of Scientific Uncertainty on Environmental Law and Policy in the United States", in: *Freestone*, David/*Hey*, Ellen (eds.), "The Precautionary Principle and International Law" (Den Haag/London/ Boston: Kluwer Law International, 1996) 209-229.

¹³Committee on Trade and Environment, Report of the Meeting held on 5-6 July 2000, WT/CTE/M/24, at 21.

¹⁴21 U.S.C. §301 ff.

¹⁵See Food Drug Cosmetic Law Reporter 56.056, (1996).

approach is the Delaney clause which prohibits the addition of food additives, color additives, and animal drugs to foods or feeds if the substance is found to induce cancer in humans or animals.¹⁶

The following section goes back to the roots of the precautionary principle in German law.

A. THE LEGAL ORIGINS OF THE PRECAUTIONARY PRINCIPLE IN GERMANY

German law does not operate, as, e.g., the United States with a catch-all notion of risk¹⁷, but distinguishes very precisely between different categories of risk. The spectrum reaches from immediate hazard (*Gefahr im Verzuge*) to residual risk (*Restrisiko*).¹⁸ The concept of precaution (*Vorsorge*) specifically deals with situations where a hazard (*Gefahr*) cannot be scientifically established, while the risk is not only residual (*Restrisiko*).¹⁹

The precautionary principle (*Vorsorgegrundsatz*) was developed by the social democratic government when facing the issue of acid rain and dying forests in the 1970s.²⁰ It is one of five principles enshrined in German Environmental law and mentioned in the German Clean Air Act²¹, the Nuclear Energy Act²², and the

¹⁶21 U.S.C. Sect. 348 (c) (3) (A). Compare Bartlett P. Miller, "The Effect of the GATT and the NAFTA on Pesticides Regulation: A hard look at harmonization, Colorado Journal of International Environmental Law and Policy, Vol. 6, p. 201, at 204 ff.

¹⁷See for an overview of the American notion of risk, *Bodansky*, above n.12.

¹⁸See, e.g. *Fleischhygienegesetz (FlHG)* (German Meat Act) as promulgated on 8 July 1993, BGBl. I at 1189, § 22e, and *Kloepfer*, Michael, "Umweltrecht" (2nd ed., München: C.H. Beck'sche Verlagsbuchhandlung, 1998).

¹⁹See, *Kloepfer*, above, n.18, at 169 with further references; *von Moltke*, above, n. 7, and *Lübbe-Wolff*, Gertrude, "IVU-Richtlinie und Europäisches Vorsorgeprinzip", NVwZ 1998, at 777 (778); *Rehbinder*, Eckard, "Prinzipien des Umweltrechts in der Rechtsprechung des Bundesverwaltungsgerichts: Das Vorsorgeprinzip als Beispiel", in *Franßen*, Everhardt (ed.), "Bürger-Recht-Staat, Festschrift für Horst Sendler" (München: 1991) pp. 269-284.

²⁰*Boehmer-Christiansen*, Sonja, "The Precautionary Principle in Germany – enabling Government", in: *O'Riordan*, Tim/Cameron, James, "Interpreting the Precautionary Principle" (London: Cameron May, 1994), at 35.

²¹*Gesetz zum Schutz vor schädlichen Umwelteinwirkungen durch Luftverunreinigungen, Geräusche, Erschütterungen und ähnliche Vorgänge* (the

German Biotechnology legislation.²³ These statutory provisions only refer to the term *Vorsorge*, but -apart from stipulating that precautionary measures shall be taken according to the state of science and technology- do not further specify its conditions and boundaries. The German Constitutional Court (the "*Bundesverfassungsgericht*") as well as the Federal Administrative Court (the "*Bundesverwaltungsgericht*") were faced with situations of scientific uncertainty in several decisions involving, e.g., atomic power plants. The case law further enlightens the constitutional foundations of the precautionary principle, the level of risk which triggers a precautionary measure, and the question who decides whether scientific evidence is sufficient to justify interference with economic activities.

1. Protective Duties (*Schutzpflichten*)

The German Constitutional Court continuously applies the concept of protective duties (*Schutzpflichten*).²⁴ These flow directly from the fundamental right to health enshrined in Article 2.2, of the German Constitution (*Grundgesetz*) and require all state entities to take protective action.²⁵ The precise content of protective duties depends on the health issues involved.²⁶ The German Constitutional Court determined that the *Schutzpflicht* and, thus, the right to health is

"*BImSchG*") (German Clean Air Act) as promulgated on 14 May 1990, BGBl. I. at 880, § 5.1(2).

²²*Gesetz über die friedliche Verwertung der Kernenergie und den Schutz gegen ihre Gefahren* (the "*AtomG*") as promulgated on 15 July 1985, BGBl. I, at 1565, § 7.2(3).

²³*Gesetz zur Regelung der Gentechnik* (the "*GenTG*") (German Biotechnology Act), as promulgated on 16 December 1993, BGBl. I, at 2066, § 6.

²⁴*Bundesverfassungsgericht* (the "*BVerfG*"), judgement of 8 August 1978 - 2 BvL 8/77 "*Kalkar I*", Entscheidungen des Bundesverfassungsgericht [Official Reporter of the *Bundesverfassungsgericht*] BVerfGE 49, 89, at 142; Decision of 20 December 1979 - 1 BvR 385/77 "*Mühlheim-Kärlich*", BVerfGE 53, 30, at 57.

²⁵BVerfG, judgement of 25 February 1975 - 1 BvF 1, 2, 3, 4, 5, 6/74, "*Fristenlösung*", BVerfGE 39, 1, at 41.

²⁶BVerfG, *Kalkar I*, at 142.

violated by a non-negligible risk to human health.²⁷ More specifically: "already a remote probability of an adverse effect on human health" requires the State to take protective action.²⁸

2. Conditions and Limits of the Precautionary Principle

The Federal Court of Appeals for Administrative Law further elaborated the concept of *Vorsorge* enshrined in §7.2(3) of the Atomic Energy Act in the *Whyl* nuclear reactor case and held:²⁹

"Precaution requires consideration of those possibilities of damages which due to a lack of existing scientific knowledge about certain causal relationships cannot be excluded (*Besorgnispotential*). Precaution means further that the appreciation of such possibilities of damages cannot be made on the basis of experience and existing data, and that theoretical concerns and models need to be taken into account so as to be able to sufficiently and reliably exclude the risks arising from uncertainties and *lacunae* in scientific understanding.³⁰ The evaluation should refer to "the current level of science and technology" (*Stand der Wissenschaft und Technik*). Uncertainties relating to research and risk assessment must be considered according to the reasons for concern associated with them under sufficiently conservative hypotheses. In this process, the administrative authority charged with granting the authorisation "should not only rely on dominant theory but should take account of all tenable scientific knowledge.³¹

²⁷*Ibid.*, at 141.

²⁸*Ibid.*, at 142. Confirmed by the Bundesverwaltungsgericht [German Federal Administrative Court] Judgement of 19 December 1985, "*Whyl*", Bundesverwaltungsgerichtsentscheidungen [Official Reporter of the German Federal Administrative Court] BVerwGE, 72, 300, at 315.

²⁹*Ibid.*

³⁰BVerwG, *Whyl*, at 315, where it elaborated its earlier definition of precaution, given in judgement of 14 February 1984, BVerwGE 55, p. 250.

³¹BVerwG, *Whyl*, at 316.

The line between *Vorsorge*, where action has to be taken, and residual risks which need to be accepted by society is drawn by reference to practical reasoning, i.e., no actions against speculations, where human perception is not able to provide answers.³²

On the other side, the limiting factor is the principle of proportionality, which excludes an attempt to eliminate all environmental disturbances.³³

3. Standard of Review

Depending on the peculiarities of each case, the ability of the Court to appraise the facts, and the value of the endangered good, German Courts grant a margin of appreciation to governmental authorities.³⁴ In situations of scientific uncertainty, e.g., nuclear risks or biotechnology, the Federal Court of Appeals for Administrative Law only controls whether the authorities had studied differing scientific opinions according to the requirements of the precautionary principle, and verified whether the contentious risk assessment was based on sufficient information and non-arbitrary assumptions.³⁵

B. SUMMARY

The precautionary principle is enshrined in several municipal legal orders. It is explicitly acknowledged in continental Europe. Apart from India, most common law jurisdictions have not articulated a precautionary principle, but are "precautionary in nature", including the area of health and food safety. A closer look at the roots of the precautionary principle in German law has shown that it emanates from protective duties of the government. It marks the point between

³²*Ibid.*, 315 ff., See also, *Rehbinder*, "Das Vorsorgeprinzip im internationalen Vergleich", above n., at 9 and 12.

³³*von Moltke*, above n. 35, at 104.

³⁴BVerfGE 77, 170 (215).

³⁵BVerwGE, *Whyl*, at 316 and more recently, BVerwG, NVwZ 1999, at 1232. The most comprehensive and recent overview is provided by *Pache*, Eckhard, "Tatbestandliche Abwägung und Beurteilungsspielraum", (forthcoming).

a residual risk which must be accepted by society and those risks which justify interference with markets. Although the term "*Vorsorge*" is not further refined in statutory law, courts have carved out triggering factors, i.e. a remote possibility of risk, even if only supported by minority opinions, and limiting factors, including the principle of proportionality.

II. EUROPEAN COMMUNITY LAW

At present, the European Community is the main promoter of the precautionary principle. A precautionary principle is explicitly incorporated in Article 174 (2) of the *Treaty Establishing the European Community* (the "*EC Treaty*")³⁶ which stipulates:

"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"

While the precautionary principle for environmental protection is firmly established in European Community law,³⁷ with respect to

³⁶The *Treaty Establishing the European Community* (hereinafter "*EC Treaty*" or "*EC*") was modified and renumbered by the Treaty of Amsterdam, OJ No. C 340, p. 1, which entered into force 1 May 1999. See for an overview, *Hilf, Meinhard/Pache, Eckehard*, "Der Vertrag von Amsterdam", *Neue Juristische Wochenschrift (NJW)* Vol. 11 (1998), pp. 705-713. References to the Treaty follow the uniform system of citation developed by the European Court of Justice, available at www.curia.eu.int. Thus, "Article 174 EC" denotes the article of the Treaty as it stands after 1 May 1999, whereas "Article 130r of the EC Treaty (now Article 174)" refers to Article 130r of that Treaty before 1 May 1999.

³⁷See for an overview of the Precautionary Principle in Community Law, *Doyle, Alan*, "Precaution and Prevention, Giving Effect to Article 130r without direct effect, *European Environmental Law Review*", 1999, p. 44; *Grabitz, Eberhard/Nettesheim, Martin*, EWGV, Artikel 130r, paras. 37-42, in: *Grabitz, Eberhard/Hilf, Meinhard* (eds), "Kommentar zur Europäischen Union", Band II, Artikel 137-248, EWGV, 12th supplement, 1998; *Epiney, Astrid*, "Umweltrecht in der Europäischen Union" (1997) at 100. *Krämer, Ludwig*, Artikel 130 r, para 21, in: *von der Groeben, Hans/Thiesing, Jochen/Ehlermann, Claus-Dieter*, "Kommentar zum EU-/EG Vertrag", Band 3, Artikel 102a-136a EGV (5th edition, Baden-Baden: Nomos Verlagsgesellschaft, 1999); *Sadeleer, Nicolas de*, "Les Principes du Polluter-Payeur, de Prévention et de Précaution", (Brussels: Bruylant, 1999).

food safety and health protection the *EC Treaty* only provides that Community institutions must aim at a "high level of protection".³⁸

Following the Commission's initiative to restructure the European food safety system on the basis of a cross-sectoral precautionary principle, Community institutions currently strive to incorporate an overarching precautionary principle into Community law.³⁹ Meanwhile, explicit reference to the precautionary principle has been made in secondary legislation in the area of health.⁴⁰

Before looking at the emerging abstract definitions of the precautionary principle in Community law, the following sections first review some examples of "precautionary" measures which triggered international trade conflicts.

A. FOUR EXAMPLES OF "PRECAUTIONARY" MEASURES

The following sections briefly canvass four "precautionary" measures taken by the European Communities in the areas of GMOs, BSE, hormones and antibiotics, which have triggered international trade conflicts. Each section is preceded by a short overview of the scientific background.

³⁸*EC Treaty*, Articles 3(p), 95.3, and 152.1.

³⁹See, most recently, "Council Resolution on the Precautionary Principle", endorsed by the "Presidency Conclusions, Nice European Council Meeting, 7, 8 and 9 December 2000", above, n. 6; Communication from the Commission on the precautionary principle COM (2000) 1 of 2 February 2000 (the "Communication"), para. 3; Green Paper on the General Principles of Food Law in the European Union of 30 April 1997 (COM(97) 176 final), Resolution of the Council of 13 April 1999 and Resolution of the European Parliament of 10 March 1998 Com (97) 176 final of 30 April 1997, p. 10. Luxembourg European Council 12 and 13 December 1997, Presidency Conclusions, Annex, Declaration by the European Council on Food Safety, available at <http://europa.eu.int/council/off/conclu/index.htm>.

⁴⁰See, e.g., Commission Decision of 7 December 1999 adopting measures prohibiting the placing on the market of toys and childcare articles intended to be placed in the mouth by children under three years of age made of soft PVC containing one or more of the substances di-iso-nonyl phthalate (DINP), di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), di-iso-decyl phthalate (DIDP), di-n-octyl phthalate (DNOP), and butylbenzyl phthalate (BBP) (1999/815/EC), OJ No. L 315/46 of 9 December 1999, p. 46. See for an overview, Streinz, Rudolf, "The Precautionary Principle in Food Law", 4 *European Food Law Review* (1998), pp. 413-432.

1. GMOs

The most contentious example of a precautionary legislation is the regulation of GMOs in the European Communities.

(a) Background

The use and release of GMOs has rapidly expanded since the early 1990s, in particular in the area of agricultural biotechnology. A first generation of GMOs was designed to make the production of food more efficient. They express their own herbicides, are equipped with a resistance towards pesticides, or engineered to be stored over a longer period of time.⁴¹ A second generation is currently being developed which is said to enhance the quality of food, e.g., equipping rice with more vitamine E⁴² or designing new plants which jump the yield barrier.⁴³

The extent to which GMOs pose risks of adverse effects on the environment or human health is controversial and remains uncertain.

With respect to human health, no adverse effects of GM foods have been reported in the peer-reviewed scientific literature.⁴⁴ Some reports conclude, on the basis of laboratory and field testing, that GM

⁴¹See for an overview: *Runge, Ford/Jackson, Lee Ann*, "Labelling, Trade and Genetically Modified Organisms – A Proposed Solution, 34 (1) Journal of World Trade (2000), pp. 111-122 and *Eggers, Barbara/Mackenzie, Ruth*, "The Cartagena Protocol on Biosafety", 3 JIEL 525 (2000), pp. 525-543.

⁴²"Field of Dreams", *Financial Times* (25 February 2000).

⁴³"Crop Scientists seek a New Revolution", *SCIENCE Magazine*, Vol. 283, (15 January 1999), pp. 310-314, at 313.

⁴⁴See, "GM Food Safety, Facts, Uncertainties, and Assessment, The OECD Edinburgh Conference on the Scientific and Health Aspects of Genetically Modified Foods", 28 February–1 March 2000, Rapporteur's Summary, available at <http://www.oecd.org/ehs/icgb/>. However, in 1999, a study which suggested possible adverse effects of GM potatoes that were engineered to produce the lectine of snowdrops when ingested by mice, was issued and heavily disputed: parts of the scientific Community supported the data, others claimed they were wrong and premature. See, *Ensernik, Martin*, "Bioengineering: Preliminary Data Touch off Genetic Food Fight," *SCIENCE Magazine*, Vol. 283 (19 February 1999), pp. 1094-1095 and Vol. 284 (21 May 1999), p. 1247.

food does not pose other risks than existing food.⁴⁵ Others acknowledge the existence of uncertainties.⁴⁶ More specifically, they point to certain "what if...?" questions, for example, that antibiotic resistance markers could be transferred to humans, when digested in the gut, and thus contribute to the spread of drug-resistant diseases.⁴⁷ Such hypotheses are fiercely debated and no hard science exists.⁴⁸

The major concerns, however, relate to long-term effects on the environment, which might only become visible after 10-140 years.⁴⁹ While most short term studies do not point to any adverse effects, several what if... ? questions persist.⁵⁰ These include the potential impacts of GMOs on non-target species, which was highlighted by the contentious Monarch Butterfly study: a group of scientists had fed larvae of the monarch butterfly with pollen of *Bt* maize, i.e., maize that was genetically engineered to express *bacillus thuringiensis*, a natural pesticide, and found that Bt maize slowed the growth of monarch caterpillars and resulted in their early death.⁵¹

⁴⁵Joint FAO/WHO Consultation on Biotechnology and Food Safety, 30 September–4th October 1996, Rome, Italy, available at <http://www.fao.org> (visited 30 March 2000).

⁴⁶*Ibid.*, at 4.

⁴⁷See for further categories, *Eggers/Mackenzie*, above n. 41.

⁴⁸See, "Novartis seeks to ease biotech fears", *Financial Times*, (23 May 2000), which also reports that Novartis has developed a new positech gene, which does not operate on the basis of antibiotic resistance to meet these concerns.

⁴⁹*Eggers*, Barbara, "Novel Regulations for a Novel Technology", 6 RECIEL, (1997), at 69 with further references.

⁵⁰These can be grouped into six main categories, including the potential spread of crops as weeds, the potential for cross pollination between GM crops and non-GM crops and wild plants, the potential impacts on soil bacteria and the nitrogen cycle, indirect effects on the environment, for example through more use of a combination of "basta" kill all herbicides, that would extinct any weed which is not equipped with a resistance gene or GM salmon escaping from aquaculture farms. See, the list in *Eggers/Mackenzie*, above n. 59.

⁵¹"Transgenic Pollen harms monarch larvae", *NATURE*, Vol. 399, 20 May 1999, at 214. Critical: "Cautionary tale on safety of GM crops", *NATURE*, Vol. 399, 3 June 1999, at 405.

(b) The legislative response to GMOs

The European Communities subject the deliberate release and marketing of GMOs to a prior authorization. Directive 90/220⁵² covers GMOs⁵³ and is complemented by the Novel Food regulation which applies, inter alia, to foods and food ingredients containing or consisting of GMOs or products thereof.⁵⁴ To date, neither of them explicitly refers to the precautionary principle. However, the European Court of Justice (the "ECJ"), has confirmed that the precautionary principle is reflected in several provisions of Directive 90/220⁵⁵. Directive 90/220 is currently being amended so as to explicitly incorporate the precautionary principle.⁵⁶

(i) *The Pre-Marketing Approval Mechanism*

The authorization procedures for GMOs take place at both, the national and the Community level and result in a Community wide market permit. First, the producer is obliged to submit a notification including a dossier with scientific data and a risk assessment to the competent authority of the Member State where he first wants to

⁵²Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, OJ No L 117 of 8 May 1990, pp. 15-27.

⁵³According to Article 2 (1 and 2) of Directive 90/220, "GMO" means an organisms, i.e., any biological entity capable of replication or of transferring genetic material, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. The definition refers to techniques listed in Annex I A Part 1 that are considered to result in genetic modification and a list of techniques in Annex 1 A, Part 2, that are not considered to result in genetic modification.

⁵⁴Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (hereinafter Novel Food Regulation), OJ No L 43 of 14 February 1997, pp. 1-7. See for an overview *Pardo Quintillán*, Sara "Free Trade, Public Health Protection and Consumer Information in the European and WTO Context", 33(6) *Journal of World Trade* 147 (1999) at 180; *Streinz*, Rudolf "Die EG-Verordnung über neuartige Lebensmittel und neuartige Lebensmittelzusätze", *EuZW* 1997, pp. 487-491.

⁵⁵Case C-6/99 *Association Greenpeace France and Others and Ministère de l'Agriculture et de la Pêche and Others*, [2000] ECR, n.y.r, para 44.

⁵⁶Common Position (EC) No 12/2000 adopted by the Council on 9 December 1999, OJ No C 64 of 6. 3. 2000, pp. 1-46, Preamble 8th whereas clause and Article 1.

market his product.⁵⁷ The national authorities evaluate the risks⁵⁸ and, after 90 days, either reject the application or forward the dossier with a favorable opinion to the European Commission. The Commission then circulates the dossier to the other Member States⁵⁹, who can object and thereby trigger a comitology procedure under Article 21 of the Directive, whereby either the Council, or in case it does not reach a majority decision, the Commission take the final decision. Most of the applications for GMOs were controversial between the Member States and the Commission adopted fifteen decisions, in which it found the genetically modified products to meet the safety requirements.⁶⁰

(ii) *Moratoria*

Due to increased consumer concerns, which were partly triggered by the Monarch Butterfly study, the Council decided to amend Directive 90/220 so as to explicitly incorporate the precautionary principle.⁶¹ In 2000, a *de facto* Moratorium on the approval of new varieties was adopted until the new scheme would enter into force.⁶² In addition, some Member States declined to implement the favourable decisions already issued by the Commission, or they invoked their right to take provisional measures under Article 16 of the GMO Directive 90/220.⁶³ Since then, no new

⁵⁷Directive 90/220/EEC, Article 11.

⁵⁸*Ibid.*, Article 12 (1) Appendix II contains a list of points to consider in the risk assessment.

⁵⁹*Ibid.*, Article 12 (2).

⁶⁰See, e.g., Commission Decision 97/98/EC of 23 January 1997 concerning the placing on the market of genetically modified maize (*Zea mays* L.) with the combined modification for insecticidal properties conferred by the Bt-endotoxin gene and increased tolerance to the herbicide glufosinate ammonium pursuant to Council Directive 90/220/EEC, OJ No L 31 of 1. 2. 97, p. 69.

⁶¹Common Position (EC) No 12/2000 adopted by the Council on 9 December 1999, OJ No C 64 of 6. 3. 2000, pp. 1-46, Preamble 8th whereas clause and Article 1.

⁶²"Barshevsky hints at considering possible Biotech Case against EU", Inside U.S. Trade, 16 June 2000, and Dooley Letter to USTR of 13 April 2000.

⁶³Article 16 of Directive 90/220 provides: "Where a Member State has justifiable reasons to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health

varieties had been approved. A moratorium was also adopted on the marketing of rBST until 1999.⁶⁴ With a view to that decision, the Commission rejected the authorization of rBST.⁶⁵

2. Mad Cow Disease

The advent of the mad cow disease triggered several precautionary measures. Again, the following section first provides an overview of the scientific background and then looks at the legal response.

(a) Background

Bovine spongiforme encephalopathy ("BSE") or mad cow disease was first detected in the United Kingdom in 1986.⁶⁶ It is believed to be caused by prions, i.e., abnormal proteins, which take hold in previously healthy parts of the body's central nervous system and only degenerate at very high temperatures.⁶⁷ Upon detection of BSE, one scientist warned of the possibility that the disease could leap the species barrier from cows to people.⁶⁸ However, the majority of scientists and the government did not share this view.⁶⁹ On 20 March 1996 a group of scientists referred to ten cases of Creutzfeld-Jakob disease and stated: "Although there is no direct evidence of a link, on

or the environment, it may provisionally restrict or prohibit the use and/or sale of that product in its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decisions." Several Member States made use of this opt out clause following the contentious authorization of *Bt*-Maize by the European Commission in the comitology proceedings. See *Stewart*, Terence P./*Johanson*, David P., "Policy in Flux: The European Union's Laws on Agricultural Biotechnology and their effects on international trade", 4 *Drake J. Agric. L.* (1999), pp. 243-295, at 259 with further references.

⁶⁴Council Decision 94/936 of 20 December 1994 amending Decision 90/218 of 25 April 1990 concerning the administration of bovine somatotropin (BST).

⁶⁵Commission Decision COM (97) 148 of 14 January 1997.

⁶⁶*Thomas*, Ryan David, "Where's the Beef? Mad Cows and the Blight of the SPS Agreement", 32 *Vand. J. Transnat'l L.* 487 (1999). "Birth of a disaster", *Economist* (14 March 1998), at 22.

⁶⁷*TIME Magazine*, (11 December 2000), at 32.

⁶⁸*FAZ*, 2 December 2000, at 41.

⁶⁹*Economist*, (29 May 1999) at 40.

current data and in the absence of any credible alternative, the most likely explanation at present is that these cases are linked to exposure to BSE.⁷⁰

Subsequent studies have shown a link between BSE and brain disorders in humans.⁷¹ However, the exact ways of transmission, and, thus, the sources of infection are still unknown.⁷² While proteins carrying the disease may occur in all parts of an infected animal, the head and spine of cattle are believed to have specific risks of harbouring BSE, and are thus called "specified risk materials".

(b) Emergency Measures of the Commission

The European Commission, in 1996, immediately responded to the concern that BSE might be linked to the increased incidences of Creutzfeldt-Jacobs disease by first adopting emergency measures prohibiting the import from the United Kingdom of potentially BSE infected beef⁷³, and then enacting a permanent ban on specified risk material.⁷⁴ The measures were not explicitly designated as "precautionary". However, when the government of the United Kingdom as well as British farmers challenged the emergency measures, the ECJ upheld them and found:

Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective

⁷⁰Statement of the Spongiform Encephalopathy Advisory Committee (SEAC), quoted in the Judgement of the ECJ of 5 May 1998, Case C-180/96, *UK v. Commission*, [1998] ECR I-2211, para 9.

⁷¹Economist, "Coping with BSE" (14 March 1998).

⁷²The Guardian, "New Scientific Evidence on BSE" (29 August 2000).

⁷³Commission Decision 96/239/EC of 27 March 1997 on emergency measures to protect against bovine spongiform encephalopathy OJ 1996 No L 78, p. 47. See for a factual and legal overview, *De Grove Valdeyron*, Nathalie, "Libre Circulation et Protection de la Santé Publique: La Crise de << La Vache Folle >>", *Revue du Marché commun e de l'Union européenne*, Vol. 403 1996, p.759-767.

⁷⁴Commission Decision 97/534 of 30 July 1997 on the prohibition of the use of material presenting risks as regards transmissible spongiform encephalopathies, OJ No L 216 of 8. 8. 1997, pp. 95-98. The decision was based on Article 9 (4) of Council Directive 89/662/EEC of 11 December 1989, OJ No L 395 of 30. 12. 1989, at 13.

measures without having to wait until the reality and seriousness of those risks become fully apparent.⁷⁵

This test was based on the precautionary principle as enshrined in Article 130 of the *EC Treaty* (now, after amendment, Article 174 EC).⁷⁶ As regards the threshold of scientific uncertainty the Court regarded it as sufficient that it was not possible "on the basis of the available scientific data, to exclude the danger of transmission of the infection through muscle meat".⁷⁷ The mere warning of the scientific committee suggesting that the link between BSE and Creutzfeld-Jakob disease had ceased to be a theoretical hypothesis and had become a possibility⁷⁸, was, thus, regarded as sufficient.

Confronted with the significant economic costs of the ban on potentially BSE infected beef, the Court held that "the protection of public health must take precedence over economic considerations."⁷⁹

The Court did not second-guess the risk determination of the Commission. In applying the standard, whether the Commission has committed a "manifest error of assessment and breach of the principle of proportionality", the Court considered the "seriousness of the risk and the urgency of the situation" and found that the Commission "did not react in a manifestly inappropriate manner by imposing, on a

⁷⁵Case C-157/96, *The Queen v The Minister for Agriculture, Fisheries and Food and the Secretary of State for Health, ex parte: National Farmers' Union* ("NFU") [1998] ECR I-2211, para. 63 and Case C-180/96, *UK v. Commission*, [1998] ECR I-2265, para. 96. The Court of First Instance applied the same principles in subsequent decisions. See, Case T-199/96, *Laboratoire pharmaceutiques Bergaderm SA and Jean Jacques Goupil* [1998] ECR II – 2805, para. 66. The appeal at the ECJ, Case C-352/98 P is still pending. See also, Case T-13/99R, *Pfizer Animal SA/NV v. Council of the European Union*, Orders of 8 April 1999 and 30 June 1999, n.y.r., on file with author; Case T-70/99R, *Alpharma Inc. v. Council of the European Union*, Order of 30 June 1999, n.y.r., on file with author.

⁷⁶Case C-157/96, *NFU*, para. 64.

⁷⁷*Ibid.*, para. 69.

⁷⁸*Ibid.*, para. 31.

⁷⁹See Case C-180/96R, *U.K. v. Council*, para. 93 and Case C-183/95, *Affish* [1997] ECR, para. 43.

temporary basis and pending the production of more detailed scientific information, a general ban on exports" of bovine animals.⁸⁰

3. Hormones

In *European Communities – Hormones*, the European Communities argued that its prohibition of hormone-treated beef was required by the precautionary principle.

(a) Background

Hormones are chemicals produced by the human body to regulate its growth, reproduction, and energy management. Since the 1950s some of them have been used for growth promotion purposes in the beef production: implants containing a fixed amount of compound are plugged into the ears of the cattle and are discarded at slaughter.⁸¹ The six hormones used most often are: (i) the natural hormones oestradiol 17 β , testosterone and progesterone which are responsible for female respectively male characteristics and the maintenance of pregnancy⁸²; (ii) the synthesized hormones trenbolone, zeranol and melengestol acetate (MGA), to mimic the actions of natural hormones.

Scientists generally agree that hormones may cause cancer in hormone receptive tissues, e.g., female breasts. However, there is disagreement regarding the question whether a so-called acceptable daily intake level ("ADI"), i.e., certain levels to which the use of hormones following a good husbandry practice is safe, can be fixed.

⁸⁰Case C-180/96 *UK v. Commission*, para. 75 and C-157/96, *NFU*, para. 31.

⁸¹*MacNeil*, Dale E, "The First Case under the WTO's Sanitary and Phytosanitary Agreement: The European Union's Hormone Ban", 39 *Virginia Journal of International Law* (1998), pp 89-134.

⁸²*Ibid.*

Risk assessments carried out by the United States of America⁸³ and a number of international studies conclude that the use of hormones for growth promotion purposes is safe if used following a good husbandry practice.⁸⁴ The Codex Alimentarius Commission recommended acceptable daily intake levels for humans⁸⁵ and maximum residue limits (MRLs) for animal flesh⁸⁶ with respect of two synthetic hormones (except MGA) and endorsed the use of the three natural hormones where it believed ADIs were not necessary.⁸⁷

By contrast, the European Communities maintain that no acceptable daily intake levels can be fixed. The Scientific Committee on Veterinary Measures Relating to Public Health (the "SCVPH") issued an opinion in April 1999 which was confirmed on 3 May 2000 concerning the assessment of potential adverse effects to human health from hormone residues in bovine meat and meat products.⁸⁸

⁸³The United States, for instance, based an ADI on the calculation that incremental level for natural hormone residues added for fattening purposes, amounts to 1% of the daily production of hormones by prepubertal boys. This amount was then divided through the average daily consumption of beef (500g), to fix an Acceptable Daily Intake levels. With respect to the synthetic hormones, "no observable effect levels" (NOEL) were fixed on the basis of animal tests, which were then divided by a safety factor to determine the ADI. See, *McNiel*, above n., at 98 with further references to non published studies of the FDA.

⁸⁴Joint FAO/WHO Expert Committee on Food Additives ("JECFA"), Codex Alimentarius, Vol. 3 – 1995, Section 1, pp. 7, 12 and 14 (the "JECFA Report"), The "Lamming Report", Report of the (EC) Veterinary Committee, Scientific Committee for Animal Nutrition and the Scientific Committee for Food on the Basis of the Report of the Scientific Group on Anabolic Agents in Animal Production; *DG VIII, Report of a Commission Scientific Group on Anabolic Agents in Animal Production, Kom (Doc) Nr. VI/2924/82-EN rev. 2 (0118g)*, (hereinafter "*Lamming Report*"). EC Scientific Conference on Growth Promotion in Meat Production, Brussels, 29 November to 1 December 1996, See "Assessment of Health Risks – Working Group II", in 1995 EC Scientific Conference Proceedings, at 20 and 21 (the "1995 EC Scientific Conference").

⁸⁵An ADI is "an estimate by JECFA of the amount of a veterinary drug, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risks", see JECFA Report, at 65.

⁸⁶An MRL is designed to ensure that intake of animals does not exceed the ADI and that good animal husbandry practice is observed. It fixes a maximum concentration of residue resulting from the use of a veterinary drug on a µg/kg basis.

⁸⁷ALINORM 95/37, Appendix 4, at 2.

⁸⁸"Assessment of the Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products", Commission Document XXIV/B3/SC4 of 30 April 1999, (available at <http://europa.eu.int.comm/dg24>),

This opinion concludes, that on the basis of scientific evidence gathered between 1998 and 2000, "first, as concerns excess intake of hormone residues and their metabolites, and in view of the intrinsic properties of hormones and the epidemiological findings, a risk to the consumer has been identified with different levels of conclusive evidence for the six hormones evaluated. Second, for the six hormones endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic, and carcinogenic effects could be envisaged and, of the various susceptible risk groups, prepubertal children is the group of greatest concern and, third, in view of the intrinsic properties of the hormones and taking into account epidemiological findings, no threshold levels and, therefore, no Acceptable Daily intake (ADI) can be established for any of the six hormones evaluated when they are administered to bovine animals for growth promotion purposes."⁸⁹

More specifically, the report held that, as regards oestradiol 17 β , "a substantial body of recent evidence suggests that it has to be considered as complete carcinogen, as it exerts both tumour initiating and tumour promoting effects and that the data currently available does not make it possible to give a quantitative estimate of the risk."⁹⁰ As regards the other five hormones, the SCVPH assessed that "in spite of the individual toxicological and epidemiological data available, which were taken into account, the current state of knowledge does not make it possible to give a quantitative estimate of the risk to consumers".⁹¹

summarized by *Michael Balter*, Scientific Cross-Claims Fly in Continuing Beef War, *SCIENCE*, Vol. 284, (28 May 1999), at 1454.

⁸⁹Cited in "Proposal for a Directive of the European Parliament and of the Council amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists. Brussels, 24.5. 2000, COM(2000) 320 final, 5th whereas clause.

⁹⁰*Ibid.*, 6th whereas clause.

⁹¹*Ibid.*, 7th whereas clause.

These studies were controversial in the scientific community. In particular, scientists question the conclusion that genotoxicity excludes the fixing of safety levels.⁹² Moreover, it was reiterated that much higher levels of hormones are contained in several foods, e.g., eggs, soya and broccoli, which are consumed daily and not prohibited.⁹³ A third group of reports examines the possibility of ensuring the proper administration of hormones for growth promotion purposes.⁹⁴ In particular there have been reports that farmers do not implant the hormone pellets in the ear, but directly attach it to the neck, where blood circulation is higher.⁹⁵ Random controls of American beef in the European Communities, indicated that 12% of the "hormone free" beef contained the growth promoters exceeding the safety limits.⁹⁶

(b) The Hormone Directives

Community institutions addressed the issue of growth hormones after consumer protests had peaked in 1980, by gradually harmonizing the differing regulations in the EC Member States.

The first Hormone Directive 81/602/EEC⁹⁷ was designed to prohibit the placing on the market of hormones as a "precautionary measure" while the harmful effects of Oestradiol 17/ β , Progesterone,

⁹²Genotoxicity refers to the ability of hormones to induce a cell-proliferation in oestrogen sensitive tissues, which can metabolite into cancer. See, *Balter*, above n. 88, at 1455.

⁹³*Ibid.*, at 1455.

⁹⁴Pimenta Report, [insert] and also the Collins Report: European Parliament, Committee on the Environment, Public Health and Consumer Protection, Report on "The USA's Refusal to comply with Community legislation on slaughterhouses and hormones and the consequences of this refusal", EP 128 381/B, 7 February 1989.

⁹⁵*Economist*, (15 May 1999), at 101.

⁹⁶*Balter*, above, n. 88, at 1455.

⁹⁷Council Directive 81/602/EEC of 31 July 1981 concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action, OJ No L 222 of 7.8. 1981, pp. 32-33.

Testosterone, Trenbolone and Zeranone would be examined in detail.⁹⁸ It interdicted the placing on the market of both domestically produced and imported meat and meat products derived from animals which had been treated with growth hormones, but allowed for two exceptions: first, the use of hormones for therapeutic purposes, and the use of Oestradiol 17 β , Testosterone, Progesterone, Trenbolone and Zeranone, i.e., all six hormones, except MGA.

A permanent and comprehensive ban was then imposed by the second Hormone Directive 88/146/EEC⁹⁹ on the use of these substances for fattening purposes, only allowing derogations for therapeutic purposes.¹⁰⁰ It was based on varying assessments of these substances on the effect to human health by Member States and aimed at preventing barriers to intra-community trade, at corresponding to consumer anxieties and expectations, and at increasing meat consumption.¹⁰¹

As of July 1997 this scheme was re-enacted without substantive changes under Directive 96/22/EC¹⁰² which held, in addition, that hormones "may be dangerous for consumers" and that improper use can be a "serious risk to human health".¹⁰³

⁹⁸*Ibid.*, Preamble, 8th whereas clause.

⁹⁹Council Directive 88/146/EEC of 7 March 1988 prohibiting the use in livestock farming of certain substances having a hormonal action, OJ No L 70 of 16. 3. 1988, pp. 16-18. (Council Directive 85/358 of 16 July 1985 supplementing Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action OJ No L 191 of 23. 7. 1985, pp. 46-49. set out control measures.)

¹⁰⁰Directive 88/146, Articles 1 and 2.

¹⁰¹*Ibid.*, Preamble, 5th and 6th whereas clause.

¹⁰²Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC, OJ No L 125 of 23. 5. 1996, pp. 3-9.

¹⁰³*Ibid.*

On 24 May 2000, the Commission presented a new proposal for a Directive amending Council Directive 96/22, according to which Member States are required to maintain the "permanent prohibition" of oestradiol 17 β ¹⁰⁴ and to "provisionally prohibit" the other five hormones (testosterone, progesterone, trenbolone acetate, zeranol and melengestol acetate).¹⁰⁵ The proposal does not set a time limit for the provisional prohibition, but specifies that the "Community will seek additional information and keep the measures under regular review". The preamble explicitly refers to Article 5.7 of the *SPS Agreement*.¹⁰⁶ Interestingly, the proposal does not mention the precautionary principle.

4. Antibiotics

A less known but important example for a precautionary legislation is the response to antibiotic resistances.

(a) Background

Antibiotics are substances of biological or synthetic origin, specifically acting at an essential stage of the metabolism of bacteria. They are used, both to treat bacterial disease, and as growth promoters in the cattle industry.¹⁰⁷ Since the late 1960s, scientists have alerted to a growing antimicrobial resistance in humans.¹⁰⁸ The term "antibiotics resistance" refers to the "ability of a bacterium to live in the presence of an antibiotic which should, in normal circumstances,

¹⁰⁴Proposal for a Directive of the European Parliament and of the Council amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists. Brussels, 24.5. 2000, COM(2000) 320 final, Article 2 read together with Annex II.

¹⁰⁵*Ibid.*, Article 3 read together with Annex III.

¹⁰⁶*Ibid.*, 10th whereas clause.

¹⁰⁷Case T-13/99R *Pfizer Animal Health SA/NV v. Council of the European Union*, Order of 30 June 1999, n.y.r., paras 13 ff.

¹⁰⁸"Containment of Antibiotic Resistance", *SCIENCE*, Vol. 279, (20 February 1998), at 1153; and Case T-13/99 R, *Pfizer Antibiotics*, para. 175 with references to the 1969 SWANN report and reports of the World Health Organization.

prevent its replication or kill it.¹⁰⁹ Recently, it has been observed that certain bacteria, e.g., *salmonella typhi* or *enterococcus faecium* developed resistances against antibiotics in animals.¹¹⁰ Scientific evidence also suggests that such bacteria have entered the food-supply chain, in particular through meat products.¹¹¹ Microbiological and clinical evidence on a possible transmission of resistant bacteria from animals to humans is mounting.¹¹² Although a direct causal relationship between the use of a specific growth promoter and the antibiotic resistance in a particular clinical case cannot be proven, some reports suggested to phase out the use of antimicrobial agents for growth promotion, which are used in human therapeutics.¹¹³ Two of these are virginiamycin and bacitracin zinc, which are used for dual-use both as growth promoters in livestock and in human medicine.

(b) Withdrawal of Authorizations

As a measure of precaution, the authorisation for certain animal feeding stuffs, e.g., antibiotics¹¹⁴ and carbadox and olaquinox¹¹⁵ was withdrawn in 1998. The decisions were characterized as "interim protective measure taken as a precaution".¹¹⁶

¹⁰⁹Case T-13/99R, *Pfizer Animal Health SA/NV v. Council of the European Union*, Order of 30 June 1999, n.y.r., paras 12-14.

¹¹⁰"Medical Consequences of Antibiotic Use in Agriculture", *SCIENCE Magazine*, Vol. 279 of 13 February 1998, pp. 996-997 at 997.

¹¹¹*Ibid.*, at 997.

¹¹²World Health Organization, *Impact of the Use of Antimicrobial in Food Animals*, Berline 13-17 October 1997, WHO/EMC/ZOO/97.4.

¹¹³WHO Report, above n. 112, at p. 7. Report of the Select Committee on Science and Technology of the House of Lords in the UK, "Resistance to Antibiotics and other antimicrobial agents, March 1998, House of Lords Paper 81-I, 7th Report, Session 1997-98, 17 March 1998.

¹¹⁴Council Regulation (EC) No 2821/98 of 17 December 1998 amending as regards withdrawal of the authorisations of certain antibiotics, Directive 70/524/EEC concerning additives in feedingstuffs, OJ No L 351 of 29/12/1998, p. 4.

¹¹⁵Commission Regulation (EC) No 2788/98 of 22 December 1998 amending Council Directive 70/524 concerning additives in feedingstuffs as regards the withdrawal of authorisation for certain growth promoters, OJ No. L 347, 23/12/1998/, p. 31.

¹¹⁶Council Regulation (EC) 2821/98,, Preamble, 29th whereas clause.

They specifically refer to existing scientific knowledge compiled by the competent Advisory Scientific Committee¹¹⁷, a summary of the risk assessment by the Commission and indicate that they would be reexamined within a certain time-frame.¹¹⁸

When examining whether the authorisation of two of the four antibiotics where lawfully withdrawn, the President of the Court of First Instance (the "CFI") in his order of 30 June 1999 observed that it is "not impossible that bacteria which have become resistant due to the feeding to livestock of antibiotic additives such as virginiamycin and bacitracin zinc may be transmissible from animals to humans, and that the risk of increased antimicrobial resistance in human medicine resulting from their use in animal feed cannot therefore be ruled out."¹¹⁹

B. DEVELOPMENT OF AN OVERARCHING PRECAUTIONARY PRINCIPLE

Responding to the food safety crises triggered by the BSE and other scandals, the Community currently seeks to reform the European food safety system. A series of policy orientations sets out proposals for the establishment of a European Food Authority¹²⁰, and the incorporation of an overarching precautionary principle into Community law.¹²¹

¹¹⁷Commission Regulation, 2788/98, Preamble, 6th to 13th whereas clause. Council Regulation (EC) 2821/98, Preamble, 8th to 22nd whereas clause.

¹¹⁸*Ibid.*, Article 2.

¹¹⁹Case T-13/99/R, at paras 179 and 180; Case T-70/99R, at paras. 164 and 165.

¹²⁰White Paper on Food Safety of 12 January 2000, COM (1999) 719 final.

¹²¹Green Paper on the General Principles of Food Law in the European Union of 30 April 1997 (COM(97) 176 final), Resolution of the Council of 13 April 1999 and Resolution of the European Parliament of 10 March 1998 Com (97) 176 final of 30 April 1997, p. 10. Luxembourg European Council 12 and 13 December 1997, Presidency Conclusions, Annex, Declaration by the European Council on Food Safety, available at <http://europa.eu.int/council/off/conclu/index.htm>.

1. The Communication of the European Commission

To clarify the "factors leading to recourse to the precautionary principle and its place in decision making", and to establish guidelines for its application, the European Commission issued a "Communication from the Commission on the Precautionary Principle" in early 2000.¹²²

It defines the precautionary principle as covering "those specific circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection."¹²³ The *Communication* was criticized for not placing meaningful constraints on the application of the precautionary principle, because public pressure and non-economic factors are used as "thumb on the scale".¹²⁴ The following section does not aim at evaluating the *Communication*, but simply seeks to distil the new definitions, and limiting factors.

(a) Triggering Factors

When describing the triggering factor for precautionary action, the *Communication* uses several different concepts. First the Commission requires "a scientific evaluation, as complete as possible, and where possible identifying at each stage the degree of scientific uncertainty".¹²⁵ The conclusions of this evaluation should show that

¹²²Communication from the Commission on the precautionary principle of 2 February 2000, COM (2000) 1, (the "*Communication*").

¹²³*Ibid.*, para. 3.

¹²⁴See *McNelis*, Natalie, "The EU Communication on the Precautionary Principle", 3 JIEL (2000) and the Reaction of the US Government to the Commission Communication, expressed at the April 10-14 meeting of the Codex Alimentarius Commission's General Principles Committee in Paris, Inside U.S. Trade, Vol. 18 No. 14 of 7 April 2000.

¹²⁵*Communication*, para. 6.1. According to para 5. 1.2 such an evaluation would require "reliable scientific data and logical reasoning, leading to a conclusion which expresses the possibility of occurrence and the severity of a hazard's impact

the desired level of protection for the environment or a population group could be jeopardized."¹²⁶ How exactly the level of protection is determined, is not explained. In addition to this evaluation, an "assessment of the potential consequences of inaction should be considered and may be used as a trigger by the decision-makers".¹²⁷ It appears, that this is the decisive triggering factor, which is then elaborated: "The absence of scientific proof of the existence of a cause-effect relationship, a quantifiable dose/response relationship or a quantitative evaluation of the probability of the emergence of the adverse effects following exposure should not be used to justify inaction. Even if scientific advice is supported only by a minority fraction of the scientific community, due account should be taken of their views, provided the credibility and reputation of this fraction are recognised".¹²⁸

(b) Limiting Factors

The precautionary measure chosen should be proportionate. That means first, that it should not aim at zero risk.¹²⁹ However, long-term risks, i.e., situations in which the adverse effects do not emerge until long after exposure and where the cause-effect relationships are more difficult to prove scientifically, but might nevertheless adversely affect future generations, would not be disproportionate.¹³⁰

Second, the decision-makers should choose a less restrictive alternative which makes it possible to achieve an equivalent level of protection.¹³¹

on the environment, or health of a given population including the extent of possible damage, persistency, reversibility and delayed effect." An evaluation is distinguished from an "assessment of the potential circumstances", see. para. 6.2.

¹²⁶*Ibid.*, para. 6.2.

¹²⁷*Ibid.*

¹²⁸*Ibid.*

¹²⁹*Ibid.*, para. 6.3.1.

¹³⁰*Ibid.*

¹³¹*Ibid.*

The *Communication* further refers to the principles of non-discrimination and regulatory consistency.¹³²

Finally, it requires an examination of the benefits and costs of action and lack of action.¹³³ The Commission stresses that this evaluation should not only include a conventional economic cost-benefit analysis, but also look at the efficacy and the socio-economic impact of the various options and non-economic considerations, e.g. protection of public health, which the society might wish to achieve in spite of high costs.¹³⁴

(c) Procedural Steps

When taking a decision, the Commission endeavours to rely on "procedures as transparent as possible". All interested parties should be involved at the earliest possible stage, i.e., once the results of the scientific evaluation and/or risk assessment are available, to study the various risk management options.¹³⁵ Furthermore, a report should be made to explain the assessment of the existing knowledge and the available information, to provide the views of the scientists on the reliability of the assessment, the remaining uncertainties, and identify topics for further scientific research.¹³⁶ Finally, scientific research should be carried out with a view to obtaining a more advanced or more complete scientific assessment and the measures should be subjected to regular scientific monitoring, so that they can be re-evaluated in the light of new scientific information and if necessary modified.¹³⁷

¹³²*Ibid.*, paras. 6.3.2 and 6.3.3.

¹³³*Ibid.*, para. 6.3.4.

¹³⁴*Ibid.*

¹³⁵*Ibid.*

¹³⁶*Ibid.*, para. 5.1.2.

¹³⁷*Ibid.*, para. 6.3.5.

2. Towards Consolidation

The approach of the Commission was endorsed by the Council and the European Council who called the Commission to systematically apply its guidelines on the conditions for the use of the precautionary principle.¹³⁸ The Council considers that the precautionary principle enshrined in Article 174(2) of the *EC Treaty* is applicable to human health, as well as to the animal health and plant health sector, but that it might be useful to formally consolidate the precautionary principle in other Treaty provisions specifically regarding health and consumer protection.¹³⁹

C. SUMMARY

The precautionary principle is recognized in the *EC Treaty* in the area of environmental protection and is currently being formulated for health and food safety.

The Communication of the European Commission on the precautionary principle is the first over-arching and general formulation of the precautionary principle, applying to both health and the environment. It sets out a set of sometimes oscillating triggering and limiting factors, e.g., the ambiguous "reasonable grounds for concern". This reflects the low thresholds of risk justifying measures regarding GMOs, BSE and antibiotics, where it was sufficient that adverse effects on human health cannot be "excluded" or "ruled out". Although mostly responding to consumer fears, in all circumstances the measures were taken with a view to scientific evidence. While the search for "zero risk" would be disproportionate, the Commission envisages precautionary measures where long-term effects might adversely affect future generations.

¹³⁸"Council Resolution on the Precautionary Principle", endorsed by the "Presidency Conclusions, Nice European Council Meeting, 7, 8 and 9 December 2000", above, n. 6, Annex III, para. 24.

¹³⁹*Ibid.*, 3rd whereas clause.

A significant legal development are the process-oriented steps to be followed when taking precautionary measures. These have been further elaborated by the Communication on the precautionary principles and comprise transparency rules, an evaluation of the risk as complete as possible, and the identification of topics for further research. Accordingly, recent precautionary measures were taken on an interim, temporary or provisional basis, and all explicitly referred to scientific evidence in their Preambles.

III. INTERNATIONAL LEVEL

The discussion of the precautionary principle at the international level is commonly associated with Principle 15 of the *Rio Declaration on Environment and Development* (the "*Rio Declaration*")¹⁴⁰, and the growing number of similar articulations that have been incorporated "in virtually every recent treaty and policy document related to the protection and preservation of the environment".¹⁴¹ Thorough analyses of these precautionary principles have been provided elsewhere.¹⁴²

After briefly recapitulating the different precautionary principles in multilateral environmental agreements, the following sections concentrate on two recent developments. First, the *Cartagena Protocol on Biosafety* (the "*Cartagena Protocol*"). Second, the precautionary principle for food safety, which is currently

¹⁴⁰Adopted 13 June 1992, 31 ILM 874 (1992).

¹⁴¹*Freestone, David/Hey, Ellen*, "Origins and Development of the Precautionary Principle", in: *Freestone, David/Hey, Ellen* (eds.), "The Precautionary Principle and International Law" (Den Haag/London/Boston: Kluwer Law International, 1996), pp. 3-15.

¹⁴²See *Cameron, James/Juli Abouchar*, "The Status of the Precautionary Principle in International Law", in: *David Freestone/Ellen Hey* (eds.): n. 162 above; *Hickey, James E./Walker, Vern R.*, "Refining the Precautionary Principle in International Environmental law, 14 Virginia Environmental Law Journal (1995), pp. 424-454, citing the full set of articulations of the principle in recent Conventions and *Hohmann, Harald*, "Precautionary Legal Duties and Principles of Modern International Environmental Law" (London/Dordrecht/Boston: Graham&Trotman/Martinus Nijhoff, 1994).

being negotiated under the auspices of the Codex Alimentarius Commission.

A. MULTILATERAL ENVIRONMENTAL AGREEMENTS

The *Rio Declaration* contains a general soft law obligation to apply a precautionary approach when protecting the environment, by stipulating:

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.¹⁴³

Specific formulations of the precautionary principle appear mainly as guidelines in the Preamble to environmental treaties protecting the global commons, e.g., the *Montreal Protocol on Substances that Deplete the Ozone Layer* (the "*Montreal Protocol*")¹⁴⁴, and the *Convention on Biological Diversity* (the "*Biodiversity Convention*").¹⁴⁵ However, a soft obligation to take precautionary measures is included in the operative provisions of the *Framework Convention on Climate Change* (the "*Climate Change Convention*").¹⁴⁶ As regards shared resources and the marine

¹⁴³*Rio Declaration*, Principle 15.

¹⁴⁴Adopted September 16, 1987, 26 I.L.M. at 1551, Preamble, 6th and 8th preambular provides: "Parties to this Protocol.. Determined to protect the ozone layer by taking precautionary measures to control equitably total global emissions of substances that deplete it, with the ultimate objective of their elimination on the basis of developments in scientific knowledge, taking into account technical and economic considerations".

¹⁴⁵Entered into force June 5, 1992, 31 ILM 818, the Preamble, 9th paragraph notes "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".

¹⁴⁶Entered into force 21 March 1993, 31 I.L.M. 849 (1992), Article 3 (3) provides: "The Parties should take precautionary measures to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects. Where there

environment, an early version of the precautionary principle is included in the *Convention for the Protection of the Marine Environment of the North-East Atlantic* (the "*OSPAR Convention*").¹⁴⁷ In 1995, a detailed obligation to apply a precautionary approach to the management and conservation of straddling fish stocks and highly migratory fish stocks was adopted.¹⁴⁸ In cases where conventions do not include a precautionary principle in the treaty text¹⁴⁹, the Conference of the Parties sometimes insert it later, e.g., the parties to *CITES* that adopted the principle to be incorporated in the procedure for listing threatened species.¹⁵⁰

B. THE CARTAGENA PROTOCOL ON BIOSAFETY

The *Cartagena Protocol on Biosafety* (the "*Cartagena Protocol*" or "*CPB*") is the first binding international agreement

are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures".

¹⁴⁷Adopted Paris, 22 September 1992, 32 ILM 1069, Article 2 (2)a provides: "The Contracting Parties shall apply the precautionary principle, by virtue of which preventive measures are to be taken when there are reasonable grounds for concern that substances or energy introduced, directly or indirectly, into the marine environment may bring about hazards to human health, harm living resources and marine ecosystems, damage amenities or interfere with other legitimate uses of the sea, even where there is no conclusive evidence of a causal relationship between the inputs and the effects."

¹⁴⁸*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*, adopted New York, 4 August 1995, not yet in force, 34 I.L.M. 1547 (1995), Articles 5 and 6. Article 6 stipulates: "1. States shall apply the precautionary approach widely to conservation, management and exploitation of straddling fish stocks and highly migratory fish stocks in order to protect the living marine resources and preserve the marine environment. 2. States shall be more cautious when information is uncertain, unreliable or inadequate. The absence of adequate scientific information shall not be used as a reason for postponing or failing to take conservation and management measures."

¹⁴⁹*Convention on International Trade in Endangered Species of Wild Fauna and Flora* (hereinafter "*CITES*"), adopted 1973, 12 ILM 1085 (1973); *Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal* (hereinafter "*Basel Convention*"), adopted Basel, 22 March 1989, 28 I.L.M. 657 and the *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade* (hereinafter "*Rotterdam Convention*"), adopted Rotterdam, 10 September 1998, 38 I.L.M.

¹⁵⁰*CITES, Resolution of the Conference of the Parties, Criteria for Amendment of Appendices I and II*, Ninth Meeting of the Conference of the Parties, Fort Lauderdale, USA, November 7-18th 1994, Com. 9. 17.

dealing with modern biotechnology.¹⁵¹ It was adopted in January 2000 under the umbrella of the *Biodiversity Convention*.¹⁵²

Early commentators agree that one of the main achievements of the Protocol was the inclusion of the precautionary principle into its operative provisions.¹⁵³ After providing a brief overview of the new environmental treaty, the following sections describe its articulation of the precautionary principle.

1. Overview

The *Cartagena Protocol* specifically focuses on the transboundary movement of GMOs (called "living modified organisms" (LMOs) under the Protocol).¹⁵⁴ Its scope is comprehensive, covering LMOs which are defined by reference to a list of *in vitro* nucleic acid and fusion of cells techniques.¹⁵⁵ The chief instrument of the Protocol is the Advance informed Agreement (the "AIA") procedure. It was modelled after the Prior Informed Consent (the "PIC") procedures which control international trade in hazardous materials.¹⁵⁶ The Protocol requires an exporter to notify his export, to

¹⁵¹Before, only the 1995 "UNEP Technical Guidelines for Safety in Biotechnology" set out voluntary guidelines on international trade in organisms with novel traits.

¹⁵²Adopted in Montreal on 29 January 2000. The Cartagena Protocol was opened for signature at the United Nations Office at Nairobi from 15 to 26 May 2000, and will remain open for signature at the United Nations Headquarters in New York from 5 June 2000 to 4 June 2001. As of 2 November 2000, 78 States have signed the Protocol. See <<http://www.biodiv.org/biosafe/Protocol/signinglist.asp>> (visited 10 November 2000). For an overview of the negotiations, see *Schweizer*, Gareth W., "The Negotiation of the Cartagena Protocol on Biosafety", 6 *Envtl. Law* 577 (2000) and *Redick*, Thomas P./*Reavey*, William A./*Michels*, Dirk, "Private Legal Mechanisms for Regulating the Risks of Genetically Modified Organisms: An Alternative Path within the Biosafety Protocol", 4 *Envtl. Law*. 1, pp. 1-77.

¹⁵³*Eggers*, Barbara/*Mackenzie*, Ruth: The Cartagena Protocol on Biosafety, 3 *JIEL* (2000), pp. 525-543; *Phillips*, Peter W.B./*Kerr*, William A., "The WTO Versus the Biosafety Protocol for Trade in Genetically Modified Organisms", 34(4) *Journal of World Trade* (2000), pp. 63-75.

¹⁵⁴*CPB*, Article 4.

¹⁵⁵*CPB*, Article 3(i). Pharmaceuticals are excluded from the scope. See Article 5.

¹⁵⁶*Rotterdam Convention*, and *Basel Convention*. See for an overview, *Sands*, above, n.1, 456 et seq.

provide information and to obtain an import permit prior to the shipment.¹⁵⁷ Responding to fears of agricultural exporters that a notification and prior approval requirement for trade in bulk commodities would render international trade in crops unworkable, any LMO that has been declared to be used directly as food or feed, or will be further processed, is exempted from the AIA procedure.¹⁵⁸

For the food and commodities sector, a separate internet-based information sharing process under a Biosafety Clearing-House was established, which contains a "Mini-AIA" for developing countries.¹⁵⁹ Finally, the Protocol sets out identification and labelling requirements.¹⁶⁰

2. Risk Assessment and the Precautionary Principle

The Parties to the *Cartagena Protocol* agreed that a decision to prohibit or restrict the import of an LMO under the AIA procedure has to be based on a "risk assessment carried out in a scientifically sound manner" and taking into account recognized risk assessment techniques.¹⁶¹

The issue of scientific uncertainty is addressed in six provisions of the Protocol. The Preamble and the objective of the Protocol import the precautionary approach contained in Principle 15 of the *Rio Declaration*.¹⁶² However, its operative provisions on the AIA procedures depart from the obligatory form of the existing

¹⁵⁷CPB, Articles 8-10, for a more detailed description see *Eggers/Mackenzie*, above n. 174.

¹⁵⁸CPB, Article 7(2).

¹⁵⁹CPB, Article 11, compare *Eggers/Mackenzie*, above, n. 153.

¹⁶⁰CPB, Article 18, compare for a more specific description, *Eggers/Mackenzie*, above n. 174.

¹⁶¹CPB, Article 10 (1) read together with Article 15 and Annex III. Although there was no consensus on the precise requirements for a risk assessment, Annex III sets out some general principles guiding the risk assessment, its methodology and points to consider.

¹⁶²CPB, 4th preambular paragraph and Article 1.

precautionary principle. Articles 10(6) and 11(8) provide in relevant part:

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism ... shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism [...] in order to avoid or minimize such potential adverse effects.

This biosafety specific articulation of the precautionary principle appears to be, on the one hand, stronger than the general version laid down in principle 15 of the *Rio Declaration* since it does not have a threshold requirement of "threats of serious or irreversible damage" and "cost-effective measures". On the other hand, the *Cartagena Protocol* has not chosen to require parties to err on the side of caution, but only to affirm a right to precaution.¹⁶³

The right to precaution under the *Cartagena Protocol* is limited by the obligation of the Parties of import to review a decision in the light of new scientific evidence upon request of an exporting country.¹⁶⁴ Furthermore, risk management measures shall only be imposed to the extent necessary to prevent adverse effects within the territory of the Party of import.¹⁶⁵ The *Cartagena Protocol* clarifies that the burden of providing and paying for the risk assessment rests on the exporter.¹⁶⁶

¹⁶³This is further reflected in one of the general principles for risk assessment in Annex III, stipulating: "Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk". A further principle for precautionary risk management procedures is set out in Annex II Nr. 8 f of the *CPB*.

¹⁶⁴*CPB*, Article 12 (2) and (3). It is noteworthy that Article 12 of the Protocol on Review of Decision does not apply to LMO-FFPs, as it is part of the Protocol's AIA procedure, see Article 7(1).

¹⁶⁵*CPB*, Article 16 and Annex III Nr. 8 (f).

¹⁶⁶*CPB*, Article 15(2) and (3).

C. THE CODEX ALIMENTARIUS COMMISSION

After the adoption of the *Cartagena Protocol*, the most vivid negotiations regarding precautionary principles take place under the umbrella of the Codex Alimentarius Commission.

1. Overview

The Codex Alimentarius Commission was founded in 1963 as a joint sub-organization of the Food and Agriculture Organization (the "FAO") and the World Health Organization (the "WHO").¹⁶⁷ To date, it has 163 Members and is based in Rome.¹⁶⁸ Its primary aims are to protect the health of consumers and to ensure fair practices to trade.¹⁶⁹ The chief instrument is the harmonization of international food safety standards, which are compiled in the "Codex Alimentarius".¹⁷⁰ To that end, the Codex has established a set of committees.¹⁷¹ Technical and scientific analysis is provided by independent bodies, e.g., Joint FAO/WHO Expert Committee on Food Additives (the "JECFA"). These are composed of independent scientists who do not serve as government representatives but in their individual capacities as experts. When elaborating standards, Codex follows an "eight step

¹⁶⁷See for an overview, *Stewart, Terence P./Johanson, David*, "The SPS Agreement of the World Trade Organization and International Organizations: The Roles of the Codex Alimentarius Commission, the International Plant Protection Convention, And the International Office of Epizootics", 26 *Syracuse J. Int'l L. & Com.*, (1998), pp. 27- 53; *Eckert, Dieter*, "Die neue Welthandelsordnung und ihre Bedeutung für den internationalen Verkehr mit Lebensmitteln" *ZLR* 4/95, pp. 363-395 and *Sikes, Lucinda*, "FDA's Consideration of Codex Alimentarius Standards in Light of International Trade Agreements", 53 (2) *Food and Drug Law Journal* (1998), pp. 327-335.

¹⁶⁸ See <http://www.fao.org/docrep/w9114e/W9114e04.htm> (7 March 2000).

¹⁶⁹Statutes of the Codex Alimentarius Commission, <http://www.fao.org/WAICENT/FAOINFO...OMIC/ESN/codex/Manual/statutes.htm> (7 March 2000), Art. 1 a).

¹⁷⁰Its procedures and principal competences are set out in the *Codex Alimentarius – Procedural Manual*.

¹⁷¹These include nine General Subject Committees, that are concerned with cross-sectoral questions, e.g., General Principles Committee. Twelve Commodity Committees are responsible for drawing up specific "vertical" standards for particular groups of foods, e.g., Meat Hygiene. See organizational chart at www.fao.org/docrep/w9114e/W9114e04.htm (7 March 2000).

procedure".¹⁷² Codex standards are published in the Standards Collection (the "Codex Alimentarius")¹⁷³ and are issued to all Member States. They have no binding effect unless a Member State has notified its acceptance to the Commission.¹⁷⁴

2. The Precautionary Principle in Codex

The precautionary principle is not yet enshrined in any of the Codex standards.¹⁷⁵ So far, standards tended to be adopted on the basis of "sound science".¹⁷⁶ The Codex has adopted several standards despite scientific uncertainty for the use of growth hormones.¹⁷⁷ In 1997, the scientific advisory Committee JECFA proposed an MRL for rBST, which was heavily criticized for not taking account of recent

¹⁷²First, the Commission decides that a standard should be elaborated and which subsidiary body should undertake the work (step 1). The Secretariat prepares a proposed draft standard (step 2) which is then circulated to the governments for comments (step 3). Taking account of the responses from the Member States, the subsidiary Committee then produces a draft standard (step 4) and presents it to the Commission with a view to its adoption as a draft standard (step 5). If the Commission adopts the draft standard, it is, again, sent to the governments for further comments (step 6). The Subsidiary Committee considers the comments and might amend the draft standard (step 7). Step 8 is the adoption of the standard by the Codex Commission. While the Codex usually decides by consensus, in recent years more and more non-consensus approvals, based on majority voting occurred. See, the overview at <<http://www.fao.org/WAICENT/FAOINFO/...>> (visited 7 March 2000).

¹⁷³The Codex Alimentarius is organized as follows: Volume 1 A has eight chapters laying down general requirements for food safety. Volume 1 B bis 5 A contains "horizontal" standards, e.g., general requirements for food hygiene or pesticides, while Volume 5 B to 12 lay down specific standards for certain groups of commodities.

¹⁷⁴*Eckert*, above, n. 189.

¹⁷⁵See Report of the 14 Session of the Codex Alimentarius Committee on General Principles 19-23 April 1999, ALINORM 99/33A paras. 27-34.

¹⁷⁶Section 1 of the "Statements of principle Concerning the Role of Science in the Codex decision-making process and the Extent to which other Factors are taken into account", provides: "The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply. See, ALINORM 95/37, Appendix 2, now contained in the Procedural Manual of the Codex Alimentarius Commission, 10th edition, 1997, p. 146. Critical: *Rosman*, Lewis, "Public Participation in international pesticide regulation: When the Codex Commission decides, who will listen?", *Virginia Environmental Law Journal*, Vol. 12 (1993), pp. 329-365, at 344.

¹⁷⁷Adopted at the 21st Session on the basis of secret majority voting, where 33 delegates approving the standard, 29 opposing them and 7 delegates abstaining from the vote, See ALINORM 95/37 (8 July 1995).

scientific information and other legitimate factors.¹⁷⁸ The adoption of the standard was postponed pending a re-evaluation of the data.¹⁷⁹

However, the Committee on General Principles, is currently elaborating Working Principles for Risk Analysis that take account of the precautionary principle.¹⁸⁰ The "*Proposed Draft Codex Working Principles for Risk Analysis*" contain a -still bracketed text- which sets forth a general formulation of the precautionary principle for food safety:

"when relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food, and where there is reasonable evidence to suggest that adverse effects on human health may occur, but it is difficult to evaluate their nature and extent, it may be appropriate for risk managers to apply precaution through interim measures to protect the health of consumers without awaiting additional scientific data and a full risk assessment, in accordance with the following criteria¹: ...

¹ Some Members refer to this concept as the "precautionary principle".¹⁸¹

The subsequent criteria contain both, procedural requirements, i.e., transparency, provisionality of the measure, continued information gathering and review of the measure, and substantial

¹⁷⁸Section 2 of the "Statements of principle Concerning the Role of Science in the Codex decision-making process and the Extent to which other Factors are taken into account", states "When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair trade practices in food trade ALINORM 95/37, Appendix 2, now contained in the Procedural Manual of the Codex Alimentarius Commission, 10th edition, 1997, p. 146. See for the current discussion: Report of the 23rd Session of the Codex Alimentarius Commission, Alinorm 99/9, Annex 1 para 28, titled "Principles of Risk Analysis", Report of the 13 Session of the Codex Committee, 7-11 September 1998; Alinorm 99/33A, n. above paras 64-76 and Alinorm 99/33 paras. 59-70

¹⁷⁹Codex Alimentarius Commission, Report of the 22nd Session, ALINORM 97/37 (28 June 1997).

¹⁸⁰Report of the Fifteenth Session of the Codex Committee on General Principles, Paris, France, 10-14 April 2000, ALINORM 01/33. The draft contained in Annex III to the Report is still at step 3 of the standard setting process.

¹⁸¹*Ibid.*

requirements, i.e., proportionality of the measure and regulatory consistency with other measures.¹⁸²

D. SUMMARY:

At the international level, the precautionary principle is enshrined in numerous environmental treaties. Most of them contain the precautionary principle as soft obligations or guidelines in the Preamble. Only a few conventions use them in their operative provisions. They follow the basic structure of principle 15 of the *Rio Declaration*, by requiring a lack of full scientific evidence, and a threat of adverse effects, while limiting the preventive measures to "cost-effectiveness". However, the specific thresholds of risk vary according to the context. The *Cartagena Protocol on Biosafety* takes a different approach by setting forth a right to precaution, which is limited by additional procedural obligations including the review of the measure upon provision of new scientific evidence.

In the area of food safety no precautionary principle exists to date at the international level. However, the Codex Alimentarius Commission currently sees negotiations on a refined precautionary principle for food safety.

¹⁸²*Ibid.*

§2 "CLOSE TO AUTHORITATIVE FORMULATION" - EMERGING FEATURES OF THE PRECAUTIONARY PRINCIPLE

The precautionary principle is rapidly evolving. The current developments have many facets. The following sections concentrate on those issues which are of particular relevance for the role of the precautionary principle in WTO law. Although a precautionary principle now exists for trade restrictions on some GMOs, it is only about to be articulated for food safety. Before distilling some emerging features in Part II, Part I briefly deals with basic terminologies.

I. TERMINOLOGY

At the outset, some terminology is useful. In particular, some understanding of the problem of scientific uncertainty and the differing notions of principles is warranted.

A. WHAT IS SCIENTIFIC UNCERTAINTY?

The notion of scientific uncertainty has been subject to much thought.¹⁸³ Its definitions range from catch all phrases, e.g., "a relative lack of consensus in the scientific community"¹⁸⁴ to the very differentiated philosophical model of "great uncertainty".¹⁸⁵

¹⁸³See in particular, Walker, Vern R., "The Siren Songs of Science: Toward a Taxonomy of Scientific Uncertainty for Decisionmakers", 23 Connecticut Law Review (1991), pp. 567-626.

¹⁸⁴Cameron, James/Abouchar Juli, "The Status of the Precautionary Principle in International Law", in: Freestone, David/Hey, Ellen (eds.), "The Precautionary Principle and International Law (Den Haag/London/Boston: Kluwer Law International, 1996) pp. 29-52, at 45.

¹⁸⁵Hansson, Sven Ove, "Decision Making under Great Uncertainty", 26 Philosophy of the Social Sciences (1996), pp. 369-386.

1. What Scientists Say

For scientists, uncertainty is not a problem, but a given. They regard uncertainty, resulting from inadequate data, ignorance, and indeterminacy, as an inherent part of science.¹⁸⁶ Scientists are aware that causal inferences cannot attain the certainty of logical deductions.¹⁸⁷ From their point of view, "uncertainty" stems, in essence, from the following factors:¹⁸⁸ Scientist can err when choosing the variables¹⁸⁹, the correct measurement method¹⁹⁰, the samples¹⁹¹, when describing the findings by translating them into a model¹⁹² and finally, when evaluating the findings, where it can happen that a decisive factor which is in reality responsible for a causal relationship has been overseen.¹⁹³

2. The Uncertainty of Decision Makers

The term scientific uncertainty, is slightly misleading, because the problem is not the uncertainty of scientists, but the uncertainty of decision-makers, who rely on science in the political decision-making process.¹⁹⁴

¹⁸⁶Wynne, Brian/Mayer, Sue, "How Science Fails the Environment", *New Scientist*, (5 June 1993), pp. 31-34, at 34.

¹⁸⁷Rothman, Kenneth J. and Greenland, Sander, "Causation and Causal Inference", in: Rothman, Kenneth J. and Greenland, Sander "Modern Epidemiology", (2nd ed., Philadelphia: Lippincott Williams & Wilkins, 1998), pp. 7-28, at 28.

¹⁸⁸Walker, Vern R., "The Siren Songs of Science: Toward a Taxonomy of Scientific Uncertainty for Decisionmakers", 23 *Connecticut Law Review* (1991), pp. 567-626.

¹⁸⁹*Ibid.*, at 576, called "conceptual uncertainty".

¹⁹⁰*Ibid.*, at 580, called "measurement uncertainty".

¹⁹¹*Ibid.*, at 588, called "sampling uncertainty".

¹⁹²*Ibid.*, at 598, called "measurement uncertainty".

¹⁹³*Ibid.*, at 608, called "causal uncertainty".

¹⁹⁴Barton, above, n. 12, at 510.

Governmental, authorities and judges seek to give clear and unambiguous statements at a certain point of time.¹⁹⁵ Other than scientists, politicians cannot afford the luxury of withholding judgement and may be rather tempted to disregard or even suppress lack of confidence they may have.¹⁹⁶ This more realistic notion of scientific uncertainty has been described by the European Commission, when defining scientific uncertainty as "[s]ituation where due to the advances in communication technology, the public is becoming aware of potential risks and demands governmental action before scientific research has been able to fully illuminate the problems."¹⁹⁷

3. Differing Degrees of Scientific Uncertainty

Hansson has distinguished differing degrees and situations of scientific uncertainty.¹⁹⁸ Already the few examples of situations of scientific uncertainty described above have shown that science is an evolving process, starting off with a first hypothesis, and going through several stages of experimenting and (re-)evaluation of data, with the goal of verifying or falsifying the hypothesis.

In the early days of biotechnology, scientists had no data, but only hypotheses regarding the possible effects of GMOs. To predict how long it would take, until long-term effects manifest themselves, scientists used comparable data from the introduction of alien species

¹⁹⁵*Moltke*, Konrad von, "The Relationship between Policy, Science, Technology, Economics and Law in the Implementation of the Precautionary Principle", in Freestone/Hey (eds.), above n., pp. 97-108.

¹⁹⁶*Bazelon*, David L., "Science and Uncertainty: A Jurist's View", 5 *Harvard Env'tl. Law Review* (1981), pp. 209-215, at 213.

¹⁹⁷"Communication from the Commission on the Precautionary Principle", COM(2000) 1, of 2 February 2000, para 1.

¹⁹⁸*Hansson*, Sven Ove, "Decision Making under Great Uncertainty", 26 *Philosophy of the Social Sciences* (1996), pp. 369-386, who distinguishes, *inter alia*, between "uncertainty of consequences", "uncertainty of reliance", i.e., on whose scientific judgement one should rely, and the uncertainty, which values should be used in the decision-making, in particular where long-term risks are involved, and it is not known, whether values might change over time (Uncertainty of values).

in other ecosystems, e.g. rhododendron in the U.K.¹⁹⁹ Although data is now accumulating from laboratory and field studies, the assessment of the complex interactions with eco-systems are still based on simulations of weed populations in a computer model.²⁰⁰

While GMOs involve a high degree of scientific uncertainty, because data regarding the "what if...?" questions do not exist, the scientific knowledge about hormones has already gone one step further towards scientific certainty. Here, more experimental and clinical data exist and the uncertainty rather takes the form of scientific disagreement on how to interpret them and whether they allow the fixing of ADI levels or not, i.e. uncertainty regarding control measures. These distinctions between differing levels of scientific evidence are particularly important when measuring how much precaution is permitted by WTO law.

B. APPROACH OR PRINCIPLE – A SILLY QUESTION?

The United States continuously argue that the precautionary principle is not a "principle" but an "approach". This disagreement is reflected in "principle" 15 of the *Rio Declaration*, which requires a "precautionary approach to be widely" applied. Is the "precautionary principle" a principle or an approach, or something else?

1. What are Principles?

Legal theorists, in particular *Dworkin* explain the proper role of principles by distinguishing them from rules on the one hand and policies on the other.²⁰¹ While "rules apply in an all or nothing

¹⁹⁹Eggers, Barbara, "Novel Regulations for a Novel Technology", 6 RECIEL, (1997), at 69.

²⁰⁰See, "Bird number under threat from GM crops". Financial Times, September 1, 2000. See also other studies, e.g., C.L. Wraight, A-R. Zangerl, M.J. Carroll and M.R. Berenbaum, "Absence of toxicity of *Bacillus thuringiensis* pollen to black swallowtails under field conditions", Proceedings of the National Academy of the United States of America, 2000.

²⁰¹*Dworkin*, Ronald, "Taking Rights Seriously, (Cambridge MA: Harvard University Press, 1978). This notion of principles is shared by most legal theorists. See the overview by *Penski*, Ulrich, "Rechtsgrundsätze und Rechtsregeln", Juristenzeitung (JZ), 1989, pp. 105-114.

fashion",²⁰² a principle, "states a reason that argues in one direction, but does not necessitate a particular decision".²⁰³ Principles guide the decision of officials by setting out a consideration inclining in one way or another.²⁰⁴ Their role is to link positive rules with extra-judicial and political values and to ensure flexibility.²⁰⁵

Although, principles play an important role in all legal systems, their precise function varies.²⁰⁶ Civil law systems, e.g., the German legal system, incorporate and define their basic values in the constitution. Thus, German courts, systematically interpret statutes with a view to these constitutional principles, with the effect that each interpretation of an administrative statute implies weighing the underpinning principles and basic rights.²⁰⁷

²⁰²According to *Dworkin*, both, principles and rules "point to particular decisions about legal obligations in particular circumstances, but they differ in the character of the direction they give. Rules are applicable in an all-or-nothing-fashion. If their conditions are met, the legal consequence follows automatically, e.g., if a provision sets out a deadline for the filing of an appeal, a notification of appeal would not be considered after the period for appeal has expired. In case two rules clash, only either of them is applicable. The decision which rule prevails is made by another set of provision regulating conflicts. See, above, n. 201, at 24, 25 and 27, and *Alexy*, Robert, "Theorie der Grundrechte (Baden-Baden: Nomos, 1985) at 77-79.

²⁰³*Ibid.*

²⁰⁴*Dworkin*, above, n. 201, at 26.

²⁰⁵*Benedek*, Wolfgang, "Die Rechtsordnung des GATT aus völkerrechtlicher Sicht", (Berlin, Heidelberg, New York, London, Paris, Tokyo, Hong Kong, Barcelona: Springer, 1990) at 49, *de Sadeleer*, Nicolas: Les Principes du Polluter-Payeur, de Prévention et de Précaution, (Brussels: Bruylant, 1999) at 315 et. seq. "A cheval sur le droit positif et sur le non-juridique, ces principes s'inscrivent donc dans une dialectique entre les règles de droit plus précises qu'ils sont censés inspirer et les idéaux régulateurs qui les propulsent", at 319.

²⁰⁶*Summers*, Robert S./*Taruffo*, Michele, "Interpretation and Comparative Analysis", in: *MacCormick*, D. Neil/ *Summers*, Robert S. (eds.), "Interpreting Statutes, A Comparative Study", (Dartmouth: Aldershot, Hants, England; Brookfield, Vt. US, 1991) pp. 461-510, at 466.

²⁰⁷*Ibid.*, at 468. Where two principles collide, judges consider the degree of infringement of one principle in comparison to the other. If both are at risk to be equally violated, the principle representing the higher value prevails, e.g., human health over protection of personal property. However, the guiding principle of proportionality (*Verhältnismäßigkeitsprinzip*) then requires that the balance struck only infringes the ceding principle to the degree necessary to ensure the protection of the prevailing value. See, *Alexy*, n. 202, above with further examples from the jurisdiction of the German Constitutional Court.

The precautionary principles is an emanation of protective duties of governments and, thus ensures the basic right to health and other constitutional values, which would run empty if not being backed up by corresponding measures of the government.²⁰⁸

Although, principles play an important role in Anglo-American legal argument, their function is confined to gap-filling in statutes.²⁰⁹ In particular in the United States, substantive values are rather incorporated into the legal reasoning by reference to policies of the legislature.²¹⁰

Before this background, the reluctance against the precautionary principle becomes understandable. Principles can indeed be used to interpret rules in the light of values, not all of which are equally shared at the international level. However, when recalling that general international law, including WTO law knows an abundance of accepted principles, e.g. good faith, principle of sovereignty, reciprocity, and non-discrimination, the issue seems to be less a problem of "principle" versus "approach" but of continuous disagreement between governments regarding the underlying values. The precautionary principle marks the balance between the protection of health and the environment on the one hand and economic activity and technological progress on the other. Because some societies are more risk averse and more readily inclined to interfere with markets

²⁰⁸Montgomery, Jonathan, "Rights to Health and Health Care", in Coote, A. (ed.), "The Welfare of Citizens – Developing New Social Rights (1992), at 89. Several municipal constitutions as well as the World Health Organization explicitly spell out a duty of the government to take certain steps to achieve full realization of the right to health. See, e.g., Indian Constitution, Articles 47, 48-A and 51-A(g), Constitution of Uruguay, Article 44; Constitution of the Federal Republic of Russia, Article 41o; Japanese Constitution, Article 25o; Constitution of the Arab Republic of Egypt, Articles 16 and 17; Constitution of the People's Republic of China, Article 21o; Greek Constitution, Article 2 and Argentinian Constitution, Article 42o, available at <<http://www.wordlist.com>> (visited 20 July 1999). The 1946 Constitution of the World Health Organization <<http://www.who.org>> (visited 20 July 1999).

²⁰⁹Zenon Bankowski/D. Neil MacCormick, Statutory Interpretation in the United Kingdom, in *MacCormick/Summers*, at. 369, Robert S. Summers, Statutory Interpretation in the United States, in *McCormick/Summers* (eds.), at 414 and ????

²¹⁰Summers/Taruffo, n. above, at. 468.

than others who rather adopt a *laissez-faire* approach, the disagreement on precautionary measures arose.

Moreover, when looking at the recent developments in the *Cartagena Protocol* and the *Draft Codex Working Principles on Risk Analysis*, the more theoretical distinction between principles and rules fades. These set forth very specific conditions on the taking of precautionary measures. Before that background, it is more or less irrelevant whether the precautionary principle is called "principle" or "approach". What counts is that an internationally agreed legal response to situations of scientific uncertainty emerges, setting forth more and more specific conditions on when governments may or should take protective measures.

2. A Guideline, Duty and Right

When setting legal theory aside, and simply looking at the articulations of the precautionary principle, the following general legal effects are noteworthy.

First, it has been generally acknowledged that the precautionary principle is a guideline for the risk assessment and risk management process, i.e., the choice of the appropriate measure to prevent a perceived risk.²¹¹

Second, the precautionary principle is composed of "triggering factors"²¹² and "limiting factors".²¹³ While the triggering factors denote the threshold of risk justifying governmental action, e.g. threat of serious or irreversible damage, the limiting factors ensure that market interference is proportionate by requiring that measures are, e.g. cost-effective. Third, while, initially only incorporated in the

²¹¹Nollkaemper, André, " 'What you Risk Reveals what you Value', and Other Dilemmas Encountered in the Legal Assaults on Risks", in: Freestone, David/Hey, Ellen (eds.): *The Precautionary Principle and International Law* (Den Haag/ London/Boston: Kluwer Law International, 1996) pp. 73-94, at 80.

²¹²This term was introduced by *Cameron/Abouchar*, above n 7., at 44.

²¹³*Hickey/Walker*, above, n. 7; *Cameron/Abouchar*, above, n.7; *Nollkämper*, above, n. 211.

Preamble of environmental treaties, several precautionary principles have now made their way into the operative part of a convention, setting forth binding obligations.

Finally, as noted by *Hohmann*, the precautionary principle, for a long time appeared as "legal duty", telling what governments should or shall do.²¹⁴ However, the *Cartagena Protocol* has formulated the precautionary principle in the form of a right to take a precautionary measure.

C. SUMMARY:

In short, the precautionary principle is a response to scientific uncertainty, specifying the conditions for protective measures. It marks the balance between the protection of health and the environment on the one hand and economic activities and technological progress on the other.

II. EMERGING FEATURES OF THE PRECAUTIONARY PRINCIPLE

The policy declarations of the European Community institutions are the first articulations of a "general" or "comprehensive" precautionary principle applying to both, health and environmental protection. However, all other explicit formulations of the precautionary principle are, indeed, context-specific, i.e. they are tailored for a particular object and geographical area of protection.

A. ENVIRONMENT – CONTEXT SPECIFIC ARTICULATIONS

Principle 15 of the *Rio Declaration* applies in the area of environmental protection. The articulations of the precautionary principle in environmental conventions have confined its application to specific objects of protection, e.g. "the ozone layer"; "climate change", "biodiversity", or "straddling fishstocks and highly migratory fish stocks". They apply extraterritorially to the global commons or

²¹⁴*Hohmann*, above n. 7.

shared resources. The *Cartagena Protocol*, by contrast, only permits the taking of precautionary measures to prevent "potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import", i.e. not allowing extraterritorial protection of the environment. It also covers human health in addition to biodiversity.

Commensurate with the different situations of scientific uncertainty, the conditions, under which precautionary measures may or should be taken vary significantly. While the *Rio Declaration* requires a "threat of irreversible damage"²¹⁵, in the area of climate change a slightly lower "threat of serious damage"²¹⁶ is sufficient to trigger protective action. The *Biodiversity Convention* only requires "significant reduction or loss of biological diversity".²¹⁷ The lowest threshold is spelled out by the *Cartagena Protocol* whereby a "potential adverse effects of a living modified organism" justifies a precautionary measure.²¹⁸ Although common lines are apparent, the differing scopes of applications and conditions for the taking of precautionary measures indicate a clear will of States to use the precautionary principle on a "context-specific" basis.

B. HEALTH – NO CLEAR ARTICULATION

With respect to human health, no internationally agreed norm formulating under which conditions precautionary measures can be taken exists to date. Although the current negotiations in the Codex Alimentarius Commission indicate that governments, as noted by the Appellate Body, "commonly act from perspectives of prudence and precaution" where risks to human health are at stake", the principle is only "close to authoritative formulation". Albeit still emerging, it

²¹⁵*Rio Declaration*, Principle 15.

²¹⁶*Climate Change Convention*, Article 3 (3).

²¹⁷*Biodiversity Convention*, 9th preambular paragraph.

²¹⁸*CPB*, Articles 10(6) and 11(8).

appears to be useful to note some features of the new precautionary principle for health and food safety.

1. Lower Threshold of Risk

The precautionary principle for food safety currently under development by the Codex Alimentarius Commission, appears to justify a precautionary measure at a lower threshold of risk than required for environmental protection, i.e., "where there is reasonable evidence to suggest that adverse effects on human health may occur". This reflects the Communication of the European Communities suggesting that "reasonable grounds for concern are enough" and practical experience, e.g., in the BSE crisis where "a probable link" between a disease affecting cattle in the UK and the fatal Creutzfeldt-Jakobs disease was sufficient or in antibiotics, where the CFI endorsed a health measure in a situation where a risk of antimicrobial resistance was not "impossible" and could, therefore not be "ruled out".

2. No Consumer Threshold

The measures of the European Communities responding to hormones and biotechnology have often been accused for being solely based on consumer fears and anxieties. Indeed, the Commissioner for agricultural policy noted in 1995: "Consumer fears often overpower scientific arguments".²¹⁹ Consumers have rejected the application of hormones for growth promoting purposes as non-ethical and unnatural.²²⁰ Similarly, the aversion against GM food is partly fuelled by religious considerations or political reasons, e.g., they do not want to support a global corporation that produces and patents transgenic seeds.

²¹⁹*Fischler*, Franz, "New Politics and Global Trade, Address Before the World Meat Congress" (June 2 1995) in Commission of the European Communities, June 2, 1995 S. 95-111, at 103.

²²⁰*Southey*, Caroline, Hormones Fuel a Meaty EU Row, FT 7 September 1995, at 2.

This raises the question, whether the so-called "consumer threshold" or "fourth hurdle" is sufficient to justify a measure taken on the basis of the precautionary principle. The answer is clearly no. Although the Communication on the Precautionary Principle by the European Communities indicates that consumer fears and non-economic values are a "thumb on the scale" and play a significant role in the determination which risk is acceptable, the precautionary principle is not triggered by mere consumer anxieties. In all cases, where the precautionary principle has been invoked, the government was faced with a combination of uncertain science and consumer fears and referred to at least some scientific evidence indicating a health risk.

3. Precaution = Prudence?

Precaution and "prudence" are often used in the same breath. The prudential approach is primarily applied when risks to human health are at stake, which cannot, for ethical reasons, be examined in tests on human bodies.²²¹ Prudence requires first, that uncertainty factors are accommodated by relying on animal models to establish potential effects in man.²²² According to the European Commission, precaution is not necessary where usual uncertainty factors can be resolved by a "prudential approach", e.g. relying on animal models to establish potential effects in man, but only in cases where it is "impossible to determine with sufficient certainty the risk in question", e.g. in situations where cause-effect relationships are suspected but have not been demonstrated.²²³

However, the line between prudence and precaution is hazy. According to the American notion of risk assessment, prudential techniques can be applied to areas where European governments employ the precautionary principle. While American risk assessors

²²¹MacGarvin, Malcolm, "Precaution, Science and the Sin of Hubris", in O'Riordan/Cameron (eds.), pp. 69-101, at 70.

²²²Communication, para 5. 1.3.

would use second store models to bridge uncertainties, European risk assessors would rather disclose their uncertainty and rely earlier on values. The precautionary principle recognizes that science will not provide clear answers for policy, but aims at developing criteria to systematically address the resultant uncertainties in the policy process. As noted by *Moltke*, instead, of attempting to reduce uncertainty through a systematic, quasi-scientific process, the precautionary principle focuses on the policy process itself.²²⁴

4. Who has the burden of proof?

The precautionary principle in environmental law has seen a long festering debate whether it has the legal effect of reversing the burden of proof.²²⁵ While the Supreme Court of India²²⁶ and some dissenting opinions²²⁷ have argued that the precautionary principle indeed causes a shift in the burden of proof, most national and international courts do not yet apply the environmental precautionary principle in that way.²²⁸

However, in the area of food safety and health protection the existence of strict pre-marketing approval mechanisms for new products, both in Community law²²⁹ and the United States²³⁰ suggests

²²³*Ibid.*, para 5.1.3.

²²⁴*von Moltke*, above n. 7, at. 101.

²²⁵*Cameron, James and Abouchar, Juli*, "The Precautionary Principle: A Fundamental Principle of Law and Policy, Boston College International and Comparative Law Review, pp. 1-27.

²²⁶In *M.C. Mehta v. Union of India* (1997) 2 Supreme Court Cases 353, para 32, the burden of proof was reversed as a consequence of the precautionary principle.

²²⁷See Dissenting Opinion of Judge Weeramantry in the *Request Concerning the Examination of the Situation (New Zealand v. France)*, 1995 ICJ Reports, at 342.

²²⁸*Rehbinder*, above n., 7, at 97. *Nollkämper*, above n.211, at 85.

²²⁹See in addition to the examples cited above, Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption, OJ No L 40 of 11 February 1989, at 27 and Directive 91/321/EEC, Articles 3 and 4.

that the burden of proof might be reversed in that the producer is obliged to provide studies that his product is safe.

5. Who determines the risk? - Reduced standard of review

It often goes unnoted that, in legal practice, the precautionary principle is intertwined with another legal effect: A large margin of appreciation, usually given by courts to governmental authorities that carried out the risk assessment. In particular the BSE measures, but also antibiotics and hormones illustrated that the ECJ and CFI did not second-guess the determination of risks in situations of scientific uncertainty.²³¹

In the United States, the so-called *Chevron* doctrine instructs courts to defer to expert agency determinations of fact. While the general test for the review of agency actions is whether it is "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law" particular deference is paid where the agency decides at the "frontiers of scientific knowledge".²³²

²³⁰ Examples for burden shifting statutes in the United States are compiled by Bodansky, Daniel, "The Precautionary Principle in US Environmental Law", in: O'Riordan, Tim/Cameron, James: *Interpreting the Precautionary Principle* (London: Cameron May, 1994), pp. 203-228, at 210, who mentions the Toxic Substances Control Act, 15 U.S.C. §§ 2604-2605 and the Federal Insecticides, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §136a(c)(5)(c). The most important example is the pre-marketing approval requirement for additives under the Federal Food, Drugs and Cosmetics Act, 21 U.S.C. § 301 ff.

²³¹ See for hormones, also Slotboom, Marcus M. "The Hormones Case: An increased risk of illegality of Sanitary and Phytosanitary Measures", CMLR Vol. 36 (1999), p. 471. However, in *Lilly*, the Court only granted limited discretion to the Commission when establishing a MRL for rBST. It held that where the competent Scientific Committee having all necessary information at its disposal had issued a favorable opinion, the Commission is under the obligation to draw up a draft regulation and cannot reject the application with a view to a Moratorium on the marketing of rBST which was adopted for socio-economic reasons and not based on public health concerns. See, Case T-120/96, *Lilly Industries v Commission* [1998] ECR II-2571, paras 82-94 and Case T-112/97, *Monsanto Company v Commission of the European Communities* [1999] ECR II- n.y.r. The appeal of Monsanto, Case C-248/99 P, is still pending, See OJ No C 265 of 18. 9. 1999, p. 1.

²³² 5 U.S.C. § 706(2) (A). *Chevron U.S.A., Inc. v. Natural Resources Defence Council, Inc.* 467 U.S. 837 (1984). This catch-all label is replaced by the "substantial evidence test" where an agency is determination is required to be made on the basis of an administrative record. Here, the courts scrutinizes whether the findings are supported by substantial evidence in the record considered as a whole. "Substantial evidence" is "such relevant evidence as a reasonable mind might accept

6. Towards Process-Orientation

Finally, the recent development of the precautionary principle indicates a move towards process-orientation, i.e., the fixing on certain procedures to be followed in situations of scientific uncertainty. Both the *Cartagena Protocol* as well as the *Draft Codex Working Principles for Risk Analysis* set forth very specific guidelines on how to carry out a risk evaluation, review the scientific evidence, and to ensure transparency.

IV. CONCLUDING REMARKS

In the areas particularly relevant for international trade, the precautionary principle is now "close to authoritative formulation". Both, the *Cartagena Protocol on Biosafety* as well as the *Draft Guidelines on Risk Analysis* of the Codex Alimentarius Commission indicate an emerging consensus that health and environmental protection is necessary, but that clear limits need to be placed on the use of the precautionary principle. The *Cartagena Protocol* sets forth a right to precaution with specific conditions for import restrictions on GMOs in situations scientific uncertainty. As regards human health and food safety, some emerging features of a precautionary principle could be distilled. The threshold of risk triggering a protective measure is lower than in environmental protection, albeit not aiming at zero risk. Pure consumer concerns cannot justify interference with markets, but play an important role in the determination of the acceptable level of risk. Other than in the area of environmental protection, there is a trend towards a reversal of the burden of proof. Generally, the precautionary principle is intertwined with a large measure of deference paid to governmental authorities. Overall, the new precautionary principles are more "process-oriented". They require governments to evaluate the risk, and review the measures,

as adequate to support a conclusion." See, *American Textile Manufacturers Inst., Inc. v. Donovan*, 452 U.S. 490, 522 (1981). This general deference is greater if the agency is deciding a specialized issue at the "frontiers of scientific knowledge". See *Industrial Union Dept. v. American Petrol Inst.*, 448 U.S. 607, 656 (1980); *Baltimore Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983).

some of which were taken "provisionally". Do they "reflect" Article 5.7 of the *SPS Agreement*?

PART 2

THE WTO FILTER FOR SCIENTIFIC UNCERTAINTY

The WTO faces the flip-side of the precautionary principle. As the guardian of liberal trade, it has to deal with the allegation of exporters that precautionary measures result in disguised protectionism of inefficient agricultural markets. WTO adjudicators have the difficult task of "locating and marking out the line of equilibrium" between the right of Members to pursue their national policy goals and the rights of other Members.¹ The trade conflicts arising from GMOs and hormones have shown that drawing the line between precaution and precautionism is particularly difficult.

The WTO does not refer to the precautionary principle, but has in Article 5.7 its own specific mechanism to deal with scientific uncertainty. It is part of the science test which, according to the Appellate Body, is "essential for the maintenance of the delicate and carefully negotiated balance in the *SPS Agreement*, between the shared, but sometimes competing, interests of promoting international trade and of protecting the life and health of human beings".²

¹Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products* ("United States – Shrimp"), WT/DS58/AB/R, adopted 6 November 1998, para. 159.

²Appellate Body Report, *European Communities - Measures Affecting Meat and Meat Products (Hormones)*, ("European Communities – Hormones"), WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, para. 177.

Picking up from the thesis of the Appellate Body that the "precautionary principle indeed finds reflection in Article 5.7 of the SPS Agreement"³, this Part focuses on the core filter for scientific uncertainty in the science test and examines where it sets the limits for precautionary measures.

At the outset, some terminology is useful. Chapter 1 provides an introduction into the notion of protectionism with a view to the specific problems which arose in the trade conflicts regarding GMOs and hormone-treated beef. It also gives an overview of the legal order of the WTO and the *SPS Agreement*.

Chapter 2 forms the core of this dissertation. It provides a state of the law analysis of the relevant conditions for precautionary measures under Articles 2.2, 5.1, and in particular 5.7 of the *SPS Agreement*.

Chapter 3 then tackles the procedural aspects of the burden of proof and standard of review.

The analysis concludes that the basic determinants of the *SPS Agreement* allow for precautionary measures following the precautionary principle. However, the line is still hazy and needs to be refined.

³*Ibid.*, para. 124.

§1: BACKGROUND – PROTECTIONISM, WTO LAW AND THE *SPS AGREEMENT*

This chapter provides an introduction into the economic notion of protectionism with a particular focus on the issues raised by the precautionary principle in trade conflicts. It also gives an overview of the legal background, i.e. the legal order of the WTO and the filter techniques of the *SPS Agreement*.

I. PROTECTIONISM AND PRECAUTIONISM

When WTO Members refer to the precautionary principle to justify an import restriction, agricultural exporters smell protectionism. The major trade conflicts arising from the use of the precautionary principle, e.g., the controversy regarding GMOs or hormone-treated beef, have one thing in common: They concern agricultural products, a sector where protectionism is abound. "Protectionism" is generally defined as "the deliberate use or encouragement of restrictions on imports to enable relatively inefficient domestic producers to compete successfully with foreign producers".⁴ Essentially, four different techniques can be distinguished: Tariffs, i.e., a levy on imports, quotas, which are restrictions on the quantity of imports, subsidies, i.e., financial contributions by governments, and product regulations.

At stake in conflicts about measures to protect human health or the environment in situations of scientific uncertainty are two specific forms of protectionism: regulatory protectionism and agricultural protectionism.

A. REGULATORY PROTECTIONISM

The term "regulatory protectionism" has been defined by Sykes, as "any cost disadvantage imposed on foreign firms by a

⁴*Hinkelman*, Allen Joseph, "Dictionary of International Trade" (2nd ed., San Rafael: World Trade Press, 1998), at 164.

regulatory policy that discriminates against them or that otherwise disadvantages them in a manner that is unnecessary to the attainment of some genuine, non-protectionist regulatory objective".⁵ More specifically, this form of protectionism results from "a government regulation of product markets that can increase the costs of production for firms outside of the regulatory jurisdiction (foreign firms) more than it increases costs for firms inside the regulatory jurisdiction (domestic firms)".⁶ By contrast to the common understanding of the term "protectionism", the notion of regulatory protectionism also includes measures that not deliberately disadvantage foreign firms.⁷

Regulatory protectionism can appear in two forms. First, overt discrimination, i.e., where imported products are subjected to additional requirements or restrictions, not imposed on domestic goods, e.g., the prohibition of export/import of beef products from the UK in 1996, where farmers lost export revenues amounting to \$775 annually.⁸

Second, there might be "facially neutral regulatory protectionism", e.g., where both, imported and domestic goods are subject to the same pre-marketing approval and labelling requirements.⁹ This can particularly burden foreign producers, if they do not face the same regulatory hurdles in their own system. A good example are the varying regulatory responses to agricultural biotechnology: These include "no regulation" (to date many developing countries), "horizontal regulation" involving pre-marketing approval and mandatory labelling regimes for GMOs (e.g.,

⁵Sykes, Alan O., "Regulatory Protectionism and the Law of International Trade", 66 U. Chi. L. Rev. (1999), pp. 1-46, at 3.

⁶*Ibid.*

⁷*Ibid.*

⁸*Economist*, "Mad Cows. Second Thoughts" (14. 9. 96).

⁹Sykes, above n. 5, at 4.

EC) and "vertical regulation" simply applying the instruments developed for conventional foods and pesticides (e.g., USA).¹⁰

The United States have not set up a specific regime to control and label GMOs, but regulate them on the basis of existing statutes.¹¹ Thus, pre-marketing approval is only necessary if a GMO is considered to be a food additive or is, e.g., rBST a new animal drug. In a 1992 Working Policy Statement the FDA determined that genetically modified DNA or proteins would not be, as a class, considered as additives under the FDCA.¹² Thus, in the United States the chunk of GM food is only subject to post-marketing control.¹³ By 1999, 500 products had been launched on the US market, only 25 of which had to progress through the regulatory approval procedures.¹⁴ It is estimated that, in the US, between 70-100 per cent of the processed food now contain GMOs.¹⁵ The mere fact, that the European Communities enact a pre-marketing approval affects the possibilities of US producers, that often mix different varieties of crops. Thus, if one variety has been approved in the US, but not in the

¹⁰See, *Eggers, Barbara/Mackenzie, Ruth*, "The Cartagena Protocol on Biosafety, 3 JIEL 525 (2000), pp. 525-543; *Stewart, Terence P./Johanson, David P.*, "Policy in Flux: The European Union's Laws on Agricultural Biotechnology and their Effects on International Trade", 4 *Drake J. Agric. L.* (1999), pp. 243-295.

¹¹These include the Food, Drugs and Cosmetics Act, 21 U.S.C. §301 ff, sect. 402 (a) (1). GMOs that are pesticides are controlled by the Environmental Protection Agency (EPA) under the Federal Insecticide Fungicide and Rodenticide Act, the Plant Pest Act and the Plant Quarantine Act. See for an overview: *Berkeley, Judson*, "The Regulation of Genetically Modified Foods", ASIL Insight, October 1999, <<http://www.asil.org/insigh37.htm>> (25. 10. 1999) and for a more comprehensive description *Echols, Marsha*, "Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws", 4 *Colum. J. Eur. L.* (1998), at 537; *Beach, Judith E.*, "No "Killer Tomatoes": Easing Federal Regulation of Genetically Engineered Plants", 53 *Food & Drug Law Journal* (1998), pp. 181-191.

¹²U.S. FDA Statement of Policy: Foods Derived from New Plant Varieties, 57 *Federal Register* 22984-23005 of 29 May 1992.

¹³According to Section 402 (a) (1) of the Food, Drugs and Cosmetics Act the FDA can take regulatory action against foods that are adulterated.

¹⁴See, Summary "U.S. Regulation of Products Derived From Biotechnology", available at <<http://www.aphis.usda.gov/oa/new/ab/html>> (visited 30 March 2000).

¹⁵See, *Runge, Ford/Jackson, Lee Ann*, "Labelling, Trade and Genetically Modified Organisms – A Proposed Solution", 34 (1) *Journal of World Trade* (2000) pp. 111-122. See also *Economist*, "Sticky Labels" (1 May 1999).

EC, bulk grains cannot be marketed, or US exporters face high segregation costs.¹⁶ American exporters were particularly hurt by the moratorium on the approval of new GM varieties in the European Communities. As a result of the moratorium \$400 million in US corn sales to Spain and Portugal alone had been blocked.¹⁷

B. AGRICULTURAL PROTECTIONISM

Agricultural protectionism, i.e., the application of protectionist instruments to agricultural products, pervades all economies in the industrialized world.¹⁸ The underlying reasons include food security concerns or the protection of the farmer's class.¹⁹ In 1998, all OECD countries paid \$360 billion in agricultural support.²⁰

Allegations of protectionism often target at the Common Agricultural Policy (CAP) of the European Communities. The CAP shields the European agricultural market from outside competition, by using a combination of different techniques, including quotas, tariffs, price support mechanism and direct subsidies.²¹

One example of such protectionism is the regulation of the beef market. US exporters of beef, for example, face barriers at all four levels: Tariffs and quotas imposed on beef imports, subsidies

¹⁶Testimony of *Bob Stallman*, President of the American Farm Bureau, before the Subcommittee on Trade of the House Committee on Ways and Means, 8 February 2000. See, *Inside U.S. Trade*, 9 February 2000.

¹⁷See, "Barshevsky hints at considering possible Biotech Case against EU", *Inside U.S. Trade*, 16 June 2000, and Dooley Letter to USTR of 13 April 2000.

¹⁸See the essays on the US, Canada, Japan and other Members of the CAIRNS Group in: *Fred H. Sanderson*, (ed.) "Agricultural Protectionism in the Industrialized World" (Washington: Resources for the Future, 1990), pp. 64-111.

¹⁹*Jackson*, John H./*Davey*, William/ *Sykes*, Alan O.: "Legal Problems of International Economic Relations", (3rd edition, St. Paul, Minnesota: West Publishing Co., 1995) (hereinafter: "*Jackson/Davey/Sykes*"), at 1169.

²⁰*Economist*, "A not-so-perfect market", (25 March 2000).

²¹See, *Koester*, Ulrich and *Tangermann*, Stefan, "The European Community", in: *Fred H. Sanderson*, (ed.) "Agricultural Protectionism in the Industrialized World" (Washington: Resources for the Future, 1990), pp. 64-111.

paid to farmers, and the import prohibition for hormone treated beef.²² Both European and American farmers are subject to the same prohibition. However, although European farmers lost the net benefit of \$44.21 per animal²³ through the prohibition of hormones and indeed the amount of beef produced in Europe fell by 1b 588 million²⁴, the playing field is not level. American Farmers can only export beef to the European Community if they demonstrate that their beef has been produced without hormones. Probably because of the segregation and certification costs, this quota was never used.²⁵ Thus, almost the entire American beef export to the European Communities broke down, and American farmers lost export revenues of approximately \$250 million.²⁶

C. THE ECONOMIC CASE AGAINST PROTECTIONISM

David Ricardo and John Stuart Mill developed the theory of comparative advantage to show that it is economically beneficial for countries to specialize in goods which they can make "relatively cheaper" for whatever reasons, e.g., better natural or intellectual resources, existing techniques and economies of scale.²⁷

Modern economists have further refined the analysis of protectionist measures. A welfare economic analysis of the four different options to protect domestic industries suggests that

²²The tariffs are currently 20 per cent plus 2763 ECU per ton, which gradually decline to 12.8 per cent plus 1768 ECU per ton 19 Legal Instruments Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations Done at Marrakesh on 15 April 1994 16212 (1994). See also, Regulation (EC) No. 1254/1999 of 17 May 1999, and Regulation 2342/1999 of 28 October 1999.

²³See, *MacNeil*, Dale E., "The First Case under the WTO's Sanitary and Phytosanitary Agreement: The European Union's Hormone Ban", 39 *Virginia Journal of International Law*, (1998), pp. 89-134, at 98 with further references to the legislative acts.

²⁴*Ibid.*

²⁵*Sykes*, above, n. 5, at 4.

²⁶*Wirth*, David A., "European Communities – Measures Concerning Meat and Meat Products", 92 *AJIL* 1998, pp. 755-759, at 756.

²⁷See for an overview: *Bhagwati*, Jagdish, "Protectionism" (Cambridge, Massachusetts, London, England: The MIT Press, 1988), at 24.

regulatory protectionism is the least beneficial option:²⁸ Tariffs create government revenue, but the consumer surplus falls. The rent of quotas is enjoyed by their holders who are able to sell at higher prices, while consumers suffer the same reduction of their surplus as under a tariff system. Subsidies benefit the domestic producer, while leaving the consumer gains at the same level albeit causing government expenditures.²⁹ By contrast, the regulatory options, assumed that it does not confer benefits, has higher dead weight costs and thus, least net social surplus, because no group has an economic advantage of an activity which, e.g., unnecessary labelling costs labour time but could be used more efficiently for other purposes.³⁰ In addition, national regulations impose high information costs as well as the "costs of regulatory surprise" on foreign firms and takes away the possibility to reap benefits from economies of scale.³¹

The theory of public choice seeks to explain, why regulators make economically inefficient economic decisions. First, these can be due to the self-interest of politicians, who aim at maximizing their political fortunes, ensure votes and donations.³² Regulatory processes can be "captured" by interest groups with a vested interest in a particular regulatory outcome.³³ Second, even economically inefficient decisions can be due to information deficiencies of the regulator, e.g., ignorance of adverse impacts on foreign producers, because they have not been involved in the decision-making process.³⁴

²⁸ *Sykes*, above, n. 5, at 7-12.

²⁹ *Ibid.*

³⁰ *Ibid.*, at 10.

³¹ *Ibid.*, at 19-21.

³² *Ibid.*, at 27.

³³ *Roberts, Donna/Orden, David*, "Determinations of Technical Barriers to Trade: The Case of US Phytosanitary Restrictions on Mexican Avocados, 1972-1995", in: *Orden, David and Roberts, Donna* (eds.) "Understanding Technical Barriers to Trade" (St. Paul: International Agricultural Trade Research Consortium, 1997).

³⁴ *Sykes*, above n.5.

D. ISSUES OF PRECAUTIONISM

The measures restricting imports of GMOs or hormone-treated beef would, according to the definitions provided above, be protectionist *if* they did not pursue a "genuine" protective goal and, thus would simply impose "dead weight" costs on foreign producers. The crux of discerning genuine precaution from disguised precautionism is the difficulty to determine, whether there might be a risk or not. The second wave of the BSE crisis in late 2000 illustrates that if governments would have followed early warnings of one scientist who predicted the possible transmission of BSE to humans and recommended to stop using meat and bone meal already in 1987, the costs of \$1.1 billion per year to destroy animals and \$2.6 to destroy waste meat and bone could have been saved.³⁵ Looking back, the risk of BSE, of which Professor Lacey warned in 1987 was, in the words of Sykes "genuine". However, at that time such an expensive interference with agricultural markets was seen as "deadweight" costs.

Furthermore, it appears from the argumentation of the European Communities, that the restrictions on hormone-treated beef and GMOs are taken for non-economic reasons, i.e., that the value of health and environmental protection *per se*, and independently from economic costs outweighs trade benefits. The European Communities continuously refer to consumer pressures. The theory of public choice provides some explanations for this phenomenon, of "unintended" protectionism and the complex interplay between political factors and pressures in the cases of hormones and GMOs. It appears that the trade conflicts are created by diverging consumer values and risk aversenesses in the United States and Europe. The United States are, like the European Communities, controlling whether these products are safe, however, they have decided to loosen controls at an earlier point of time. The intervals between the legal reactions of

³⁵See, Time Magazine, "Good Cow, Bad Cow", (11 December 2000), at 32.

governments and the differing degrees of market interventions burden foreign producers.

The precautionary principle itself balances national interests of entrepreneurs with the protection of health and the environment of citizens. However, it does not take account of the interest of foreign producers which might differ from those of domestic producers. Precisely this is the task of the WTO when dealing with allegations that a measure is not genuinely precautionary, but results in pure precautionism.

II. THE LEGAL BACKGROUND

The following two sections provide an overview of the World Trade Organization (the "WTO") and its chief mechanism to deal with health and environmental measures that pose particular problems of scientific uncertainty, the *SPS Agreement*.

A. WTO LAW

The WTO was created in the Uruguay Round. It is the successor of the General Agreement on Tariffs and Trade (the "GATT"). The WTO is a contractarian institution.³⁶ Its aim is to develop an integrated, more viable and durable multilateral trading system that provides predictability and economic certainty to both private actors and governments.³⁷ Its underlying essence is a concept of symmetric rights and obligations for Member States. It is, thus based on the notion of reciprocity, i.e., a broad balance of market-access obligations by the contracting parties.³⁸

³⁶*Bhagwati*, above n. 27, at 35.

³⁷*WTO Agreement*, Preamble, 4th paragraph.

³⁸*Bhagwati*, above n. 27, at 36.

The following three sections provide a brief overview of the WTO, by first describing its anatomy, second, the dispute settlement mechanism, and third the legal order of the WTO.

1. The Anatomy of the WTO

The WTO is erected by the Agreement establishing the World Trade Organization ("*WTO Agreement*").³⁹ Very briefly, its functions are to "facilitate the implementation, administration and operation and to further the objectives" of the *WTO Agreement* and of the Multilateral Trade Agreements.⁴⁰ The latter are appended to the *WTO Agreement*. Annex 1A contains the Multilateral Agreements on Trade in Goods, including the *General Agreement on Tariffs and Trade 1994* ("*GATT 1994*") and twelve specific Agreements. Annex 1 B sets out the *General Agreement on Trade in Services* ("*GATS*") and Annex 1 C the *Agreement on Trade – Related Aspects of Intellectual Property Rights* ("*TRIPS Agreement*").

In addition, the WTO serves as forum for negotiations.⁴¹ To date, the organization has 140 Members.⁴²

The operational structure of the WTO consists of a Ministerial Conference, which is required to meet every two years in order to take all decisions and actions necessary to carry out the functions of the WTO.⁴³ In the intervals between the ministerial meetings, these

³⁹See, *Steger*, Debra, "The World Trade Organization: A New Constitution for the Trading System", in *Bronckers, Marco/ Quick, Reinhard*, (ed.), "Festschrift for John H. Jackson", (2000). See for an overview *Adamantopoulos, Konstantinos* (ed.), "An Anatomy of the World Trade Organization", (London, Den Haag, Boston: Kluwer Law, 1997); *Quereshi, Asif H.*, "The World Trade Organization, Implementing International Trade Norms" (Manchester and New York: Manchester University Press, 1996).

⁴⁰*WTO Agreement*, Article III:1.

⁴¹*WTO Agreement*, Article III:2.

⁴²See, <<http://www.wto.org>> (visited 4 November 2000).

⁴³*WTO Agreement*, Article IV:1. To date, three Ministerial Meetings have taken place. The First Ministerial Conference was held in Singapore, in December 1996, the second took place in Geneva in 1998 to commemorate the 50th anniversary of the GATT. In December 1999, Seattle hosted the third ministerial meeting.

decisions are taken by the General Council, who has delegated authority from the Ministerial Conference to carry out the day-to-day business. Below the General Council are three councils responsible for the operation of the multilateral trade agreements.⁴⁴ In addition, a total of 21 Committees, five Working Parties and three Working Groups have been erected.⁴⁵

The decisions of the General Councils or other Committees are taken by consensus, i.e., no Member, present at the meeting, formally objects to the proposed decision.⁴⁶ Where Members cannot arrive at a decision by consensus, the WTO Charter allows for decision by majority-voting, unless otherwise provided in that agreement or in the relevant multilateral trade agreement.⁴⁷ Technically, the Rules of Procedure of the General Council, and those of most other Councils and Committees, provide for a quorum of a simple majority of the WTO Members for any meeting.⁴⁸ The most important exception is the DSB which decides generally by consensus, with no possibility of resorting to majority voting⁴⁹, and the rules on amendment, where Article X of the *WTO Agreement* lays down a complicated and differentiated set of requirements depending on the nature of the amendment. *De facto*, the WTO Members have not made use of these fall-back options, but continued the practice of decision-making by

⁴⁴*WTO Agreement*, Article IV:5. These are the Council for Trade in Goods, the Council for Trade in Services, and the Council for TRIPS.

⁴⁵*WTO Agreement*, Article IV:6. See the overview <<http://www.wto.org>> (visited 4 November 2000).

⁴⁶*WTO Agreement*, Article IX:1, which provides that the "WTO shall continue the practice of decision-making by consensus followed under the GATT 1947.

⁴⁷*WTO Agreement*, Article IX:1. For example, interpretations of the *WTO Agreement* and the adoption of waivers require a three-fourths majority (Article IX:2 and 3). The accession of a new WTO Member must be approved by two-thirds of the WTO Membership (Article XII:2).

⁴⁸WT/L/161, h. VI, Rule 16.

⁴⁹DSU, Article 2.4.

consensus of the GATT.⁵⁰ The Secretariat of the WTO is based in Geneva.

2. The Dispute Settlement Mechanism

The Dispute Settlement mechanism forms the core of the WTO. It operates on the basis of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (the "DSU").⁵¹ It is a central element in providing security and predictability to the multilateral trading system.⁵² Its goal is to accomplish a "positive solution of a dispute".⁵³ The DSU offers several instruments for the settlement of disputes, including consultations, panel proceedings and good offices and mediation.⁵⁴ It is administrated by the Dispute Settlement Body (the "DSB").⁵⁵

The panel proceedings are automatic and binding in that sense that the defending party can neither block the establishment of a panel, nor the adoption of the report in the DSB. These dispute settlement proceedings can be parsed into four distinct phases.

They begin with a request for consultations. If these do not result in a successful resolution of the dispute within 60 days, the Member can request the establishment of a panel, and thus, start the second phase, the panel proceedings. They are regulated in Articles 6 to 16 of the DSU, including provisions on the terms of reference, composition and function of panels, panel procedures, their right to seek information, and confidentiality. They have been further

⁵⁰*Steger*, above n.39, at 39.

⁵¹OJ No L 336 of 23. 12. 1994, pp. 234-250.

⁵²*DSU*, Article 3.2.

⁵³*DSU*, Article 3.7.

⁵⁴See for an overview, *Petersmann*, Ernst-Ulrich, "The GATT/WTO Dispute Settlement System: International Law, International Organizations and Dispute Settlement" (London, Den Haag, Boston: Kluwer Law International, 1996) and *Palmeter*, N. David/*Mavroidis*, Petros C., "Dispute Settlement in the World Trade Organization, Practice and Procedure" (Den Haag, London, Boston: Kluwer Law International, 1999).

⁵⁵*DSU*, Article 2.

elaborated by the Appellate Body, including the right to receive unsolicited *amicus curiae* briefs, or the admission of outside counsel.⁵⁶

Panel reports can be appealed. The Appellate Body is composed of seven persons, three of whom serve on any one case. According to Article 17.6 of the DSU, an appeal shall be limited to issues of law covered in the panel report and legal interpretations developed by the panel. The Appellate Body operates under very short time frames. In no case, the appellate proceedings shall exceed 90 days.⁵⁷ The report of the Appellate Body is adopted unless the DSB decides by consensus not to adopt it.⁵⁸

Prompt compliance with the recommendations or rulings of the DSB is seen as essential.⁵⁹ Where Members cannot implement them immediately, a reasonable period of time for implementation can be mutually agreed or determined by arbitration.⁶⁰ Disagreements about the existence or consistency of a measure taken to comply with the recommendations are, according to Article 21.5 of the DSU decided through recourse to the dispute settlement procedures, usually by resorting to the original panel. If the respondent fails to comply within the set time for implementation, the complainant may obtain authorization to suspend the application of concessions, or other obligations.⁶¹ The level of suspension can also be subject to

⁵⁶Feliciano, Florentino P./Van den Bossche, Peter L.H., "The Dispute Settlement System of the World Trade Organization: Institutions, Process and Practice", in *Blokke*, N. and *Schermers* H., "Proliferation of International Legal Issues (Kluwer Law International, forthcoming).

⁵⁷DSU, Article 17. 5.

⁵⁸DSU, Article 17.14.

⁵⁹DSU, Article 21.

⁶⁰DSU, Article 21.3(b) and (c).

⁶¹DSU, Article 22.

arbitration.⁶² Legal scholars agree that this means an important step from power orientation towards "rule orientation".⁶³

3. The Legal Order of the WTO

The WTO legal system is part of international economic law. It focuses on regulatory activities of governments, as opposed to the transactional activities of private entrepreneurs.⁶⁴ The following sections provide a brief overview of the sources of WTO law and the methods of interpretation.

(a) The Sources of WTO Law

To determine, where the law stands, all legal systems refer to sources of law and a hierarchy between them. In general international law, the sources of law are listed under Article 38 of the *Statute of the International Court of Justice* (the "*ICJ Statute*"), which refers to covenants, custom, general principles of law, and learned writings.⁶⁵

⁶²DSU, Article 22.6.

⁶³Jackson, John H., "Restructuring the GATT System" (New York: Council on Foreign Relations Press, The Royal Institute of International Affairs, 1990), at 51 and "The World Trade Organization", at 103.

⁶⁴According to John H., Jackson, international economic law can be divided into two broad approaches, which he terms "transactional" or "regulatory". See, Jackson, John H., "Global Economics and International Economic Law" 1 JIEL (1998), pp. 1-23, at 9.

⁶⁵Article 38 of the *ICJ Statute* provides in full:

The Court whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply.

(a) international conventions, whether general or particular, establishing rules expressly recognized by the contesting States;

(b) international custom, as evidence of a general practice accepted as law;

(c) the general principles of law recognized by civilized nations;

(d) judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.

See, for an overview, Malanczuk, Peter, "Akehurst's Modern Introduction to International Law" (7th edition, London: Routledge, 1997), at 35.

WTO law takes a different approach. According to Article 3.2 of the DSU, the dispute settlement system is to "preserve the rights and obligations of Members under the *covered agreements*, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law." Pursuant to Article 7.2 of the DSU "panels shall address the relevant provisions in *any covered agreement or agreements* cited by the parties to the dispute."⁶⁶

(i) *Covered Agreements*

The covered agreements are the *WTO Agreement* together with the multilateral trade agreements contained in Annex 1, the DSU and, if agreed so by the parties, the plurilateral trade agreements.⁶⁷ These, together with amendments made under Article X of the *WTO Agreement*, are obviously sources of WTO law.

(ii) *GATT Acquis*

With respect to the GATT Acquis, Article XVI:1 of the *WTO Agreement* provides that "the WTO shall be guided by the decisions, procedures and customary practices followed by the CONTRACTING PARTIES to GATT 1947 and the bodies established in the framework of GATT 1947". These include adopted panel reports, which create legitimate expectations among WTO Members and are taken into account where relevant to any dispute.⁶⁸ Unadopted panel reports, by contrast, "have no legal status in the GATT or WTO system since they have not been endorsed through decisions by the Contracting Parties to GATT or WTO Members".⁶⁹ The Appellate Body also clarified

⁶⁶(Emphasis added).

⁶⁷DSU, Article 1.1 and Appendix 1.

⁶⁸Appellate Body Report, *Japan – Taxes on Alcoholic Beverages*, ("Japan – Alcoholic Beverages"), WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, adopted 1 November 1996, at 14.

⁶⁹*Ibid.*, at 11.

that Panels can find "useful guidance in the reasoning of an unadopted panel report that is considered to be relevant".⁷⁰

(iii) *Interpretations*

According to Article IX:2, the Ministerial Conference and the General Council shall have the exclusive authority to adopt interpretations of the WTO Agreement and the other Multilateral Trade Agreements. However, such interpretations cannot be used to amend the rights and obligations of the Members.

(iv) *Appellate Body and Panel Reports*

Panel and Appellate Body reports are only binding between the parties. The Appellate Body, however, found it "worth noting" that Article 59 of the *ICJ Statute*, which has the same effect has not inhibited the development of a body of case law with *de facto* precedential effect.⁷¹ Panels follow the interpretation of the Appellate Body.⁷² While the precise legal status of Appellate Body reports is still debated in the literature, there is overall agreement that the reports of the Appellate Body share the nature of the reports of the International Court of Justice or municipal supreme courts.⁷³ This was described by *Shabtai Rosenne* in the following way: "Precedents may be followed or discarded, but not disregarded".⁷⁴

⁷⁰*Ibid.* The guidance to be found in other decisions and understandings of the Contracting Parties has been interpreted in a restrictive manner, See Appellate Body Report, *United States – Tax Treatment for "Foreign Sales Corporations"* ("*United States – FSC*"), para. 119.

⁷¹Appellate Body Report, *Japan – Alcoholic Beverages*, at 14, footnote 30.

⁷²See Table IV, Part A "BISD and Dispute References sorted by dispute settlement decision", in: *Bernan's Annotated Reporter*, World Trade Organization, Dispute Settlement Decisions, Annotations, Tables & Cumulative Index, Decisions Reported Volumes 1-10, January 20, 1996-April 14, 1999.(Lanham, Maryland, USA: Bernan Press, 1999).

⁷³*Chua*, Adrian T. L., "Precedent and Principles of WTO Panel Jurisprudence", *Berkeley Journal of International Law*, Vol. 16, 171, at 183; *Palmeter/Mavroidis*, above n. at 404.

⁷⁴*Rosenne*, Shabtai, "The Law and Practice of the International Court", 1920-1996, Volume III: Procedure (3rd edition, The Hague, Boston, London: Martinus Nijhoff Publishers, 1997), at 56.

(v) *Other International Treaties*

Some of the multilateral trade agreements incorporate provisions of other international treaties which then enjoy the status of enforceable WTO obligation.⁷⁵ For example, the *TRIPS Agreement* refers to obligations incurred under the Paris Convention or the Berne Convention.⁷⁶ Another technique of importing international rules can be found in the *SPS Agreement*, which refers to standards set by international organizations, e.g., the Codex Alimentarius Commission. These standards are a reference-point for the interpretation of WTO obligations.

Where no such linkage provisions exist, the precise status of external treaties is not crystal clear. Some suggest, that such rules, belong to WTO law.⁷⁷ Others have emphasized the distinction between sources of WTO obligations in the strict sense and other "outside" treaties, which can be used for the interpretation of WTO law, but cannot create enforceable obligations.⁷⁸ Indeed, the text of Articles 3.2, 7.2. and 11 of the DSU indicates that disputes can only be adjudicated with reference to the covered agreements, the provisions of which are *clarified* in accordance with customary rules of interpretation of public international law. According to the Appellate Body, Article 3.2 of the DSU "reflects a measure of recognition that the *General Agreement* is not to be *read* in clinical isolation from public international law."⁷⁹ In *European Communities*

⁷⁵See, Maresceau, Gabrielle, "A Call for Coherence in International Law – Praises for the Prohibition Against "Clinical Isolation" in WTO Dispute Settlement, 33 (5) *Journal of World Trade* 87 (1999), at 112.

⁷⁶*TRIPS Agreement*, Articles 9 and 10.

⁷⁷Palmeter, N. David/Mavroidis, Petros C., "The WTO Legal System: Sources of Law", *AJIL* Vol. 92 (1998), at 398-413, list the sources of WTO law following Article 38 of the ICJ statute and also include custom, general teachings, general principles of law and other international instruments.

⁷⁸See, Marceau, Gabrielle, "A Call for Coherence in International Law – Praises for the Prohibition Against "Clinical Isolation" in WTO Dispute Settlement, 33 (5) *Journal of World Trade* 87 (1999), at 109-115.

⁷⁹Appellate Body Report, *United States – Gasoline*, p. 17 (emphasis on "read" added).

– *Measures Affecting Importation of Certain Poultry Products* ("European Communities – Poultry"), the Appellate Body held that an agreement which is not a "covered agreement" within the meaning of Articles 1 and 2 of the DSU cannot form the legal basis of a dispute.⁸⁰ The Appellate Body clarified that the legal basis of a dispute can only be an obligation set forth in one of the agreements covered by the DSU, "which must be interpreted in accordance with the "customary rules of interpretation of public international law".⁸¹ Although the line between the use of a norm as source of law, and for its interpretation might sometimes be hazy, it appears to be important to distinguish carefully between sources of law in the strict sense and interpretative material.

(vi) *Custom, General Principles of Law, etc.*

The other sources of general international law, as listed in Article 38 of the *ICJ Statute* share the nature of international treaties, and are, thus, not sources of WTO law in the strict sense. However, the line between sources of law and sources of interpretation got sometimes blurred, e.g. in *Korea – Measures Affecting Government Procurement* ("*Korea – Government Procurement*")⁸², where the Panel filled a gap with respect to non-violation complaints in cases of legitimate expectations from negotiations by referring to the general international law.⁸³ Such jurisdiction affects the proper role of the precautionary principle in WTO law, and will, thus, be discussed in more detail in Part 3 of this thesis.

(b) Methods of Interpretation

Article 3.2 of the DSU requires to clarify the existing provisions of the WTO agreements "in accordance with customary rules of interpretation of public international law". The Appellate

⁸⁰WT/DS69/AB/R, adopted 23 July 1998, para. 81.

⁸¹*Ibid.*

⁸²Panel Report, WT/DS163/R, adopted 19 June 2000.

⁸³*Ibid.*, paras. 7. 83 and 7. 93 ff.

Body, in interpreting Article 3.2 of the DSU, confirmed that the rules of treaty interpretation in Articles 31 and 32 of the *Vienna Convention on the Law of Treaties* (the "*Vienna Convention*")⁸⁴ apply in interpreting the WTO agreements.⁸⁵ The Appellate Body has repeatedly stressed that pursuant to the principles of treaty interpretation provided for in Article 31 of *Vienna Convention*⁸⁶, the words of a particular treaty are the foundation of the interpretative process, and that these words are to be given their ordinary meaning, in their context and in the light of the object and purpose of the treaty.⁸⁷ This reference to Articles 31 and 32 of the *Vienna Convention* has become a common pattern of treaty interpretation in the Appellate Body jurisdiction.⁸⁸ The purpose of treaty interpretation

⁸⁴Done at Vienna, 23 May 1969, 1155 U.N.T.S. 33; 8 I.L.M. 679.

⁸⁵Appellate Body Report, *United States – Gasoline*, p. 17. See also, Appellate Body Report, *Japan – Alcoholic Beverages*, p. 10.

⁸⁶Article 31 of the *Vienna Convention* provides in full:

1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.

2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes:

(a) any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty;

(b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.

3. There shall be taken into account, together with the context:

(a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;

(b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation;

(c) any relevant rules of international law applicable in the relations between the parties.

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

⁸⁷Appellate Body Report, *Japan – Alcoholic Beverages*, pp. 11-12. See also Appellate Body Report, *Argentina – Measures Affecting Imports of Footwear, Textiles, Apparel and Other Items* ("*Argentina – Textiles and Apparel*"), WT/DS56/AB/R, adopted 22 April 1998, para. 47.

⁸⁸*Skouteris*, Thomas, "Customary Rules of Interpretation of Public International Law and Interpretative Practices in the WTO Dispute Settlement System", in: *Mengozi*, Paolo (ed.), "International Trade Law on the 50th Anniversary of the Multilateral Trading System", (Milano: Dott. A. Giuffrè editore, 1999) pp. 113-144.

under Article 31 of the *Vienna Convention* is "to ascertain the common intentions of the parties".⁸⁹ Starting point is the text of a provision of WTO law⁹⁰, followed by an inquisition into its object and purpose, which can also be inferred from the Preamble of the *WTO Agreement*.⁹¹ The drafting history has been used as a supplementary means of interpretation, if, after applying Article 31 the meaning of the term remains ambiguous or obscure, or leads to a result which is manifestly absurd or unreasonable.⁹²

In addition, the Appellate Body uses general rules of interpretation, e.g., the principle of effective treaty interpretation⁹³ (*ut res magis valeat quam pereat*)⁹⁴, whereby the interpreter "is not free to adopt a reading that would result in reducing whole clauses or paragraphs of a treaty to redundancy or inutility"⁹⁵, but "must read all applicable provisions of a treaty in a way that gives meaning to all of them harmoniously".⁹⁶

Moreover, also other interpretative principles, commonly used in international law have already been applied in the interpretation of

⁸⁹Appellate Body Report, *European Communities – Customs Classification of Certain Computer Equipment* ("European Communities – Computer Equipment"), WT/DS62/AB/R, WT/DS67/AB/R, WT/DS68/AB/R, adopted 22 June 1998, para. 84.

⁹⁰Appellate Body Report, *Japan – Alcoholic Beverages*, p. 11. See also, Appellate Body Report, *United States – Shrimp*, para. 114.

⁹¹Appellate Body Report, *United States – Shrimp*, para. 153. See generally, Sinclair, Ian, "The Vienna Convention on the Law of Treaties", (2nd edition Manchester: Manchester University Press, 1984), at 127 and 130.

⁹²Appellate Body Report, *Japan – Alcoholic Beverages*, p. 10. See also, Appellate Body Report, *European Communities – Computer Equipment*, para. 92.

⁹³Where a treaty is open to two interpretations one of which does not enable the treaty to have appropriate effect, good faith and the object and purpose of the treaty demand that the former interpretation be adopted. See, Report of the Commission to the General Assembly, Yearbook of International Law Commission 1966, VO. II, at 219; Ipsen, Knut, "Völkerrecht" (3rd edition, München: Beck, 1990) § 11 para. 16, and Sinclair, above n.91, at 118.

⁹⁴Appellate Body Report, *Japan – Alcoholic Beverages*, p. 8. See also, Appellate Body Report, *Guatemala - Cement*, para. 75 and *Argentina - Safeguards*, para. 88.

⁹⁵Appellate Body Report, *United States – Gasoline*, p. 23.

⁹⁶Appellate Body Report, *Argentina – Footwear*, para. 81.

WTO law, including the *in dubio mitius* principle.⁹⁷ This suggests that all interpretative principles used in general international law, such as, e.g., the *argumentum e contrario*⁹⁸ or *a fortiori*, can be applied in the interpretation of WTO law.

⁹⁷Appellate Body Report, *European Communities – Hormones*, para. 165. See, *Ipsen*, above n. 93, §11 para. 20; *McNair*, Lord, "The Law of Treaties" (Oxford: Clarendon Press, 1961) at 765, who refers to this rule as rule of restrictive interpretation, and *Jennings*, Sir Robert/*Watts*, Sir Arthur (eds.), "Oppenheim's International Law", Vol. I Peace, Teil 2-4 (Longman House, Harlow, 9. Aufl. 1992), at 1278.

⁹⁸Anglo-American legal systems refer to this rule as *expressio unius est exclusio alterius*. See, *McNair*, above, n.97, at 399.

B. THE SPS AGREEMENT

The *Agreement on Sanitary and Phytosanitary Measures* (the "SPS Agreement") was inspired by two developments during the Uruguay Round: First, the hormones conflict. Several attempts to resolve that long festering trade dispute were made without success.⁹⁹ Analysts concluded that the rules and procedures provided by the GATT 1947 and the Tokyo Round Agreement on Technical Barriers to Trade¹⁰⁰ did not adequately address the specific problems posed by sanitary and phytosanitary measures.¹⁰¹

The second major development was the negotiation of the *Agreement on Agriculture*, which achieved significant liberalization of trade in agricultural goods, i.e., the freezing and gradual reduction of subsidies, tariffication of market access barriers and a tariff reduction of 36 per cent.¹⁰² Negotiators wanted to ensure that governments would not undermine the effects of these commitments by resorting to

⁹⁹The United States raised the issue of the European ban in March 1987. After bilateral consultations had failed to resolve the dispute, the United States requested the establishment of a technical export group to evaluate the scientific basis for the ban. This request was denied following the European Communities response that the use of hormonal growth promotants in beef production was a PPM that did not violate the Standards Code. After the Hormones ban entered into force, the US introduced retaliatory measures in the form of 100 per cent duties on a list of products. The European Communities requested the establishment of a GATT dispute settlement panel to rule on the legality of these duties, but the US denied the request. See for further details, *Meng*, Werner P., "The Hormone Conflict Between the EEC And the United States within the Context of GATT", 11 *Michigan Journal of International Law*, (1990), pp. 819-839., at 836; *Wirth*, above n. 26, at 822. *Roberts*, Donna, "Preliminary Assessment of the Effects of the WTO Agreement on Sanitary and Phytosanitary Trade Regulations", 1 *JIEL* 1998, pp. 377-405, at 380 f.

¹⁰⁰*Tokyo Round Agreement on Technical Barriers to Trade*, OJ No L 71 of 17. 3. 1980, pp. 29-43.

¹⁰¹*Roberts*, above, n. 99, at 379; *Stanton*, Gretchen, "Implications of the WTO Agreement on Sanitary and Phytosanitary Measures", in: *Orden*, David/*Roberts*, Donna (eds.) "Understanding Technical Barriers to Trade" (St. Paul: International Agricultural Trade Research Consortium, 1997); *Wirth*, David A., "The Role of Science in the Uruguay Round and NAFTA Trade Disciplines, 27 *Cornell Int'l L. J.* (1994), pp. 817-859, at 824.

¹⁰²See for an overview, *Brosch*, Kevin J., "The Uruguay Round Agreement on Agriculture", *Practising Law Institute, Commercial Law and Practice Course Handbook Series*, 1995, 722, at 865.

regulatory compensation.¹⁰³ Therefore, the *Declaration of Punta del Este* envisaged to "achieve greater liberalization of trade in agriculture", by "minimizing the adverse effects that sanitary and phytosanitary regulations and barriers can have on trade in agriculture, taking into account the relevant international agreements".¹⁰⁴ The *Agreement on Agriculture* expressly stipulates the commitment of Members to reach and implement an agreement on sanitary and phytosanitary measures.¹⁰⁵

The *SPS Agreement* has essentially been negotiated within the years of fall 1988, when the Working Group on Sanitary and Phytosanitary Measures was established, and the 1990 Ministerial Meeting in Brussels.¹⁰⁶ The main negotiating groups were the European Communities, United States, the Cairns Group, the Nordic Group and the developing countries.¹⁰⁷

1. Overview

The *SPS Agreement* elaborates and refines the obligations under the GATT.¹⁰⁸

¹⁰³Roberts, above, n. 99, at 378 with further references.

¹⁰⁴"Ministerial Declaration on the Uruguay Round", Punta del Este, 1986, reprinted in Stewart, Terence P. (ed.), "The GATT Uruguay Round", Vol. III: Documents (Deventer and Boston: Kluwer Law and Taxation Publishers, 1993), 6.

¹⁰⁵*Agreement on Agriculture*, 4th preambular paragraph and Article 14.

¹⁰⁶Breen, John M., "Agriculture", in Stewart, Terence P. (ed.), "The GATT Uruguay Round", Vol. I: Commentary (Deventer and Boston: Kluwer Law and Taxation Publishers, 1993), pp.125-254, at 200.

¹⁰⁷*Ibid.*, at 193.

¹⁰⁸Compare for an overview, Barceló, John, "Product Standards to Protect the Local Environment – the GATT and the Uruguay Round Sanitary and Phytosanitary Agreement", 27 Cornell Int'l L. J. 755 (1994); Ritter, Markus, "Das WTO-Übereinkommen und seine Auswirkungen auf das Deutsche und Europäische Lebensmittelrecht", EuZW 1997, pp. 133-138; Stanton, Gretchen, "Implications of the WTO Agreement on Sanitary and Phytosanitary Measures", in: Orden, David/Roberts, Donna (eds.) "Understanding Technical Barriers to Trade" (St. Paul: International Agricultural Trade Research Consortium, 1997); Wirth, David A., "The Role of Science in the Uruguay Round and NAFTA Trade Disciplines", 27 Cornell Int'l L. J. (1994), pp. 817-859.

(a) The GATT: Non-Discrimination Test and Exception

The GATT employs a non-discrimination test coupled with an exception for human, animal and plant life or health. Article XI of the GATT prohibits quantitative restrictions and Article III:4 essentially requires that Members accord "treatment no less favourable" to imported products "than that accorded to like products of national origin". Commentators agreed that as long as imported and domestic goods were subject to the same requirements, governments were free to pursue any national regulatory objective.¹⁰⁹

In the hormones conflict it became evident, that the "like" product test was not sophisticated enough to answer the question whether beef treated with growth hormones, and natural beef are similar, and whether Article III:4 of the GATT was violated.¹¹⁰ The "accordion" like concept of likeness¹¹¹, did not provide a clear guidance whether risks associated with a certain product make it unlike another product although both serve the same end uses and are otherwise substitutable.¹¹²

Could one argue that growth hormones or genetic modification only affect the production process, but not the product itself, so that following the product-process doctrine developed in the Tuna/Dolphin

¹⁰⁹See for an overview, *Hudec*, Robert E., "GATT/WTO Constraints on National Regulation: Requiem for an "Aim and Effects" Test", 32 *The International Lawyer* (1998), pp. 619-649; *Petersmann*, Ernst-Ulrich, "Trade and Environmental Protection: The Practice of GATT and the European Community Compared", in *Cameron, James/Demaret, Paul/Geradin, Damien*, "Trade & The Environment: The Search for Balance", London, 1994, pp. 147-181.

¹¹⁰See *Jackson*, John H., "World Trade Rules and Environmental Policies: Congruence or Conflict?" 49 *Washington and Lee Law Review*, (1992), at 1237; *Meng*, above n., 99, at 830 and 835.

¹¹¹Appellate Body Report, *Japan – Alcoholic Beverages*, p. 21.

¹¹²Essentially, in applying the "like" product criterion panels have to determine, on a case-by-case basis, whether two products are "similar" by taking into account the following criteria: the product's end-uses in a given market; consumer's tastes and habits, which change from country to country; the product's properties, nature and quality. See, GATT, "Border Tax Adjustment": Report of the Working Party, adopted 2 December 1970, BISD 18S/97, at 102.

cases, Article III:4 would have been violated?¹¹³ Or should panels have followed the "aims and effects" test¹¹⁴ which only examines whether the legislative background and policy goals of a measure reflect a protectionist purpose or effect?¹¹⁵ Yet, public fears are easily aroused and, at least, for the protection for human, animal, plant life or health, Article XX(b) of the GATT suggests that measures protecting against risks associated with a product must be justified following the conditions set out therein. Article XX(b) of the GATT provides: "[s]ubject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: ... (b) necessary to protect human, animal or plant life or health".

When invoking Article XX, the burden of proof rests on the party claiming the exception.¹¹⁶ However, neither the exception under Article XX(b) nor the chapeau provide any further guidance for situations where the risk itself is uncertain. GATT Panels were not faced with that problem.¹¹⁷

¹¹³Reports of the Panel in *United States – Restrictions on Imports of Tuna from Mexico* ("Tuna/Dolphin I") DS21/R (unadopted), dated 3 September 1991, 39S/155; *United States – Restrictions on Imports of Tuna* ("Tuna/Dolphin II") DS29/R, (unadopted), dated 16 June 1994, ILM 1994, 842.

¹¹⁴ Hudec, Robert E., "GATT/WTO Constraints on National Regulation: Requiem for an 'Aim and Effects' Test", *The International Lawyer*, Vol. 32 (1998), pp. 619-649. See also, Mattoo, Aaditya/Subramanian, Arvind: *Regulatory Autonomy and Multilateral Disciplines: The Dilemma and a possible Resolution*, 1 JIEL (1998), pp. 303-322.

¹¹⁵GATT Panel Report, *United States – Measures Affecting Alcoholic and Malt Beverages* DS23/R, adopted 19 June 1992, 39S/206

¹¹⁶ Appellate Body Report, *United States – Gasoline*, p. 22.

¹¹⁷See, Panel Reports, *Canada – Measures Affecting Exports of Unprocessed Herring and Salmon* ("Canada – Herring"), adopted 22 March 1988, BISD 35S/98; *Thailand – Restrictions on Importation of and Internal Taxes on Cigarettes* ("Thailand – Cigarettes"), DS10/R, adopted 7 November 1990. Panel Reports, *United States – Tuna I* and *United States Tuna II*; Panel Report, *United States – Prohibition of Imports of Tuna and Tuna Products from Canada*, ("United States – Tuna") L/5198, adopted 22 February 1981.

(b) The *SPS Agreement*: Right – Limit Technique

The *SPS Agreement* takes a different approach. Its purpose is "to maintain the sovereign right of any government to provide the level of health protection it deems appropriate, but to ensure that these sovereign rights are not misused for protectionist purposes and do not result in unnecessary barriers".¹¹⁸

The *SPS Agreement* expressly acknowledges the right of Members to determine their appropriate level of sanitary or phytosanitary protection. Throughout the *SPS Agreement*, reference is made to the "appropriate level of protection", a new legal concept developed under the *SPS Agreement*. It is defined as "the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory."¹¹⁹ The Preamble clarifies that Members are not required "to change their appropriate level of protection".¹²⁰

However, this right is limited by a set of general and specific obligations. Its chief tools are a science test, a harmonization requirement, a necessity test, an obligation to ensure regulatory consistency and transparency.¹²¹ Measures that comply with the obligations under the *SPS Agreement* are presumed to be compatible with Article XX(b) of the GATT 1994.¹²²

It appears that the new standards under the *SPS Agreement* transgress the traditional obligation-exception technique used by the GATT. The new filter, which works on the basis of a "right-limits" mechanism requires the Member challenging a SPS measure to show that it is inconsistent with the obligations under the *SPS Agreement*.

¹¹⁸*SPS Agreement*, Preamble, 1st para., See, *WTO*, Understanding the World Trade Organisation Agreement on Sanitary and Phytosanitary Measures, (Geneva: WTO, 1996), at 4.

¹¹⁹*Ibid.*, Annex A Nr. 5.

¹²⁰*SPS Agreement*, Preamble 6th para.

¹²¹These are described in more detail below.

Commensurate with the more specific obligations, the scope of the *SPS Agreement* is limited. The *SPS Agreement* only covers sanitary and phytosanitary measures ("SPS measures"). These are all measures applied "to protect human, animal or plant life or health within the territory of the Member from certain "food-borne risks" and "pest- and disease-related risks".¹²³ The *SPS Agreement* prevails over the GATT 1994 to the extent of any conflict between the provisions.¹²⁴ The *SPS Agreement* and the *TBT Agreement* are mutually exclusive, i.e., the *TBT Agreement* is not applicable to SPS measures.¹²⁵

The *SPS Agreement* is administered by the *Committee on Sanitary and Phytosanitary Measures* (the "*SPS Committee*"), which provides a regular forum for consultations and carries out the functions necessary to implement the provisions of this Agreement.¹²⁶

As regards dispute settlement, the *SPS Agreement* provides that the DSU applies to disputes arising under the Agreement with the deviation that Panels are not only entitled, but "should seek advice" from experts on scientific and technical issues.¹²⁷

(c) The Seven Obligations under the *SPS Agreement*

The *SPS Agreement* sets forth seven distinct obligations.¹²⁸ These can be grouped as follows: (i) harmonization and the use of

¹²²*SPS Agreement*, Article 2.4

¹²³*SPS Agreement*, Annex A.1. See for a more precise discussion of the scope below, §2. See generally, Pauwelyn, Joost, "The WTO Agreement on Sanitary and Phytosanitary (SPS) Measures as Applied in the First Three SPS Disputes - EC – Hormones, Australia – Salmon and Japan – Varietals", 2 JIEL 1999, pp. 641-664.

¹²⁴See general interpretative note to Annex 1 A.

¹²⁵*TBT Agreement*, Article 1.5.

¹²⁶*SPS Agreement*, Article 12.

¹²⁷*SPS Agreement*, Article 11.2.

¹²⁸Charnovitz counts eight by including Article 4 on equivalence. However, the obligation to accept the sanitary or phytosanitary measure of another Member as equivalent does not flow directly from Article 4 of the *SPS Agreement*,

international standards (Article 3); (ii) the science test (Articles 2.2 and 5.1 and 5.7); (iii) regulatory consistency and the prohibition of arbitrary and unjustifiable discrimination, and application of measures that cause disguised restrictions to trade (Articles 2.3 and 5.5) (iv) the necessity test in Article 5.6, (v) adaptation to regional conditions (Article 6), (vi) transparency (Article 7, Annex B) and (vii) provisions concerning control, inspection, and approval procedures (Article 8, Annex C).

(i) *Harmonization: Article 3*

According to the Preamble of the *SPS Agreement*, Members desire "to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and [...] the International Plant Protection Convention".¹²⁹

To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Article 3.1 of the *SPS Agreement* uses a "stick effect" by obliging Members to base their SPS measures on international standards, guidelines or recommendations where they exist except as otherwise provided for in Article 3.3. Article 3.3 stipulates that Members may introduce and maintain SPS measures which result in a higher level of sanitary or phytosanitary protection than measures based on the relevant international standards, or as a consequence of the level of sanitary or phytosanitary protection a member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5. Article 3.2 of the *SPS Agreement*, by contrast, uses a "carrot effect". It provides that SPS measures which conform to international standards, guidelines or

but arises only through bilateral agreements which are encouraged by Article 4.2 of the *SPS Agreement*.

¹²⁹*SPS Agreement*, Preamble, 6th paragraph.

recommendations be presumed to be consistent with provisions of the *SPS Agreement* and of the GATT 1994.

The privileged standards are defined in Annex A.3 of the *SPS Agreement*. These are the standards, guidelines and recommendations of the Codex Alimentarius Commission¹³⁰ relating to food safety, those of the International Office of Epizootics (OIE)¹³¹, and the International Plant Protection Convention (IPPC).¹³²

(ii) *The Science Test: Articles 2.2 and 5.1, 5.2, 5.3, and 5.7*

The *SPS Agreement* neither defines science, nor does it set forth a coherent test. What is often called the "science test"¹³³ consists of different provisions, which can be grouped as follows.

First, the general obligation under Article 2.2 states that any SPS measure shall be "based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5".

Second, according to Article 5.1, measures need to be "based on an assessment [...] of the risks to human, animal or plant life or health". The term risk assessment is defined in Annex A 4 and reference is also made to risk assessment techniques developed by

¹³⁰*SPS Agreement*, Annex A.3(c). Compare the overview above, Part 1, §1.

¹³¹*SPS Agreement*, Annex A.3(b). The International Office of Epizootics (the "OIE") was established in 1924 and has currently 155 Member Countries. Its objectives are to inform governments of the occurrence and course of animal diseases throughout the world, and of ways to control these diseases, to coordinate, and to harmonize regulations for trade in animals among Member Countries. See, <http://www.oie.int/overview/a_oie.htm> (visited 6 March 2000).

¹³²*SPS Agreement*, Annex A.3(c). The IPPC was adopted in 1951 under the auspices of FAO and has been amended in 1997. Its purpose is "to secure common and effective action to prevent the spread and introduction of pests and plants and plant products and to promote measures for their control". The IPPC provides rules for import restrictions of plants and plant products. See for an overview, <<http://www.fao.org/Legal/TREATIES/Treaty-e.htm>> (visited 6 March 2000).

¹³³Walker, Vern R., "Keeping the WTO from Becoming the „World Trans-science Organization“: Scientific Uncertainty, Science Policy, and Fact-finding in the Growth Hormones Dispute", 31 Cornell Int'l L. J., (1998), pp. 251-320; Carter, Michele D., "Selling Science under the *SPS Agreement*: Accommodating Consumer Preference in the Growth Hormones Controversy", 6 Minn. J. Global Trade, 1997, pp. 626-656.

relevant international organizations. Paragraphs 2 and 3 of Article 5 further elaborate on the factors to be taken into account in a risk assessment. Thus, Article 5.2 stipulates that, in the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest-or disease free areas; relevant ecological and environmental conditions; and quarantine or other treatment. Article 5.3 requires that, in the risk assessment, a country shall take into account as relevant economic factors the potential damage in terms of loss of production or sales in the event of entry or spread of a pest or disease and the costs of control or eradication in the territory of the importing country.

Third, Article 5.7 of the *SPS Agreement* deals with cases "where relevant scientific evidence is insufficient". Members "may provisionally adopt" measures "on the basis of available pertinent information". If they choose to do so, they must seek additional information" and review the measure "within a reasonable period of time".

(iii) *Regulatory Consistency: Article 5.5*

If a Member is particularly strict in regulating the risks from one product, while accepting similar risks in other cases, this can be a signal for protectionism. However, it can also be the simple result of a political reality, where politicians react to scandal driven needs to prohibit one product, a process, which cannot be rational. Article 5.5 of the *SPS Agreement* lays down in which cases regulatory inconsistency results in protectionism. The provision obligates each Member to avoid arbitrary or unjustifiable distinctions in the level it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Thus, Article 5.5 elaborates on the general obligation in

Article 2.3 which states that SPS measures may not be discriminatory and arbitrary.

(iv) *The Necessity Test: Article 5.6*

The necessity test plays a central role in the assessment of health and environmental measures under Article XX of the GATT. Article 5.6 of the *SPS Agreement* does not use the term "necessary", but prohibits measures that are more trade-restrictive than required to achieve a Member's appropriate level of protection. When read together with its accompanying footnote, a violation of Article 5.6 of the *SPS Agreement* can only be found if another measure is reasonably available taking into account technical and economic feasibility and if that measure not only achieves the Member's appropriate level of sanitary or phytosanitary protection but is also significantly less restrictive to trade than the SPS measure contested.

(v) *Transparency: Article 7 and Annex B*

The transparency provisions of the *SPS Agreement* have been said to offer the greatest promise of eliminating barriers to trade, because exporters often report undocumented *de facto* measures as significant impediment to gaining access to a market.¹³⁴ According to Article 7 of the *SPS Agreement*, Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B.¹³⁵ The obligation covers any instrument which is applicable generally and similar in character to laws, decrees or ordinances.

(vi) *Adaptation to Regional Conditions: Article 6*

Next, Members are obligated, under Article 6 of the *SPS Agreement*, to adapt their SPS measures to the "characteristics of the

¹³⁴Roberts, above n. 99, at 399.

¹³⁵Annex B of the *SPS Agreement*, essentially requires the publication of SPS regulations, the establishment of national enquiry points, and notification of new measures that are not substantially the same like international standards.

area – whether all of a country, part of a country, or all or parts of several countries – from which the product originated and to which the product is destined". The specific obligation under Article 6.2 and 3 of the *SPS Agreement* to take into account eradication or control programmes, and to recognize the concepts of pest-or disease-free areas, is particularly important for BSE measures. In line with paragraph 3 of Article 6, the exporting Member is required to provide the necessary evidence that e.g., herds or areas are BSE-free. Article 6, thus, complements the obligation to carry out a risk assessment, in that sense, that even where a risk exists in some parts of an exporting Member, this does not justify an import ban, which lumps all products together.

(vii) *Control, Inspection and Approval Procedures: Article 8, Annex C*

In particular in the conflicts on GMOs, the obligation under Article 8 of the *SPS Agreement*, to "observe the provisions of Annex C in the operation of control, inspection and approval procedures...", might gain relevance. Annex C to the *SPS Agreement* requires that procedures shall be undertaken and completed without undue delay¹³⁶, information requirements are limited to what is necessary for appropriate control¹³⁷ and whenever specifications of a product are changed subsequent to its control and inspection in light of the applicable regulations, the procedure for the modified product is limited to what is necessary to determine whether adequate confidence exists that the product still meets the regulation concerned.¹³⁸

2. The First Three Disputes in Brief

Early commentators of the *SPS Agreement* pointed to several ambiguities in the provisions of the *SPS Agreement*, which made it difficult to assess, which of the new concepts would be the relevant

¹³⁶*SPS Agreement*, Annex C 1(a).

¹³⁷*SPS Agreement*, Annex C 1(c).

¹³⁸*SPS Agreement*, Annex C 1(h).

test.¹³⁹ The *SPS Agreement* has, to date, been applied in three disputes: *European Communities – Measures Affecting Meat and Meat Products (Hormones)* ("*European Communities – Hormones*")¹⁴⁰, *Australia – Measures Affecting Importation of Salmon* ("*Australia – Salmon*")¹⁴¹ and *Japan – Measures Affecting Agricultural Products* ("*Japan – Agricultural Products*").¹⁴² Although still in its infancy, a case law is slowly emerging. A comprehensive description and analysis of these cases has been given elsewhere.¹⁴³ The following section provides a brief overview of the decisions, including DSU Article 21.3(c) and 21.5 and 22 proceedings and the key legal developments.

(a) *European Communities – Hormones*

In 1996, the United States and Canada brought the long irritant trade conflict regarding the import ban on hormone-treated beef to the WTO.¹⁴⁴

(i) *Facts of the Case*

The measure at stake was the prohibition on imports of beef treated with either of six hormones under Directive 88/146/EEC¹⁴⁵ as

¹³⁹Barceló, John, above n. 108, Eckert, Dieter, "Die neue Welthandelsordnung und ihre Bedeutung für den internationalen Verkehr mit Lebensmitteln", ZLR 4/95, pp. 363-395; Ritter, Markus, "Das WTO-Übereinkommen und seine Auswirkungen auf das Deutsche und Europäische Lebensmittelrecht", EuZW 1997, pp. 133-138; Stanton, Gretchen, "Implications of the WTO Agreement on Sanitary and Phytosanitary Measures", in: David Orden and Donna Roberts (eds.) "Understanding Technical Barriers to Trade" (St. Paul: International Agricultural Trade Research Consortium, 1997); Wirth, David A., "The Role of Science in the Uruguay Round and NAFTA Trade Disciplines", 27 Cornell Int'l L. J. (1994), pp. 817-859

¹⁴⁰WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998.

¹⁴¹WT/DS18/AB/R, adopted 6 November 1998. See also, Panel Report, *Australia – Measures Affecting Importation of Salmon*, Recourse to Article 21.5 by Canada ("*Australia – Salmon, 21.5*"), WT/DS18/RW, adopted 7 June 2000.

¹⁴²WT/DS76/AB/R, adopted 19 March 1999.

¹⁴³See, the references cited below and for a general overview, Pauwelyn, Joost, "The WTO Agreement on Sanitary and Phytosanitary (SPS) Measures as Applied in the First Three SPS Disputes - EC – Hormones, Australia – Salmon and Japan – Varietals", 2 JIEL 1999, pp. 641-664.

¹⁴⁴Requests for consultations, WT/DS26/1 (US) and WT/DS48/1 (CAN). See for the measure and the scientific background, Part I, § .

re-enacted by Directive 96/22/EC¹⁴⁶ (the "Hormones Directive"). The legal and scientific background has been described in Part 1, §1 and shall not be repeated here.

(ii) *Panel Reports*

Two panels –with identical panelists– were established and found that the European Communities had acted inconsistently with Articles 5.1, 5.5, 3.1 and 3.3 of the *SPS Agreement*.¹⁴⁷ The analysis departed from Article 3.1 of the *SPS Agreement*. The Panel found that the European Communities had not based its measure on a standard of the Codex Alimentarius Commission, recommending the use of growth hormones in line with good husbandry practice.¹⁴⁸ Reversing the burden of proof the Panel then held that the European Communities had not demonstrated that its measure is based on a risk assessment in line with Article 5.1 of the *SPS Agreement*.¹⁴⁹ The Panel also found a violation of 5.5 of the *SPS Agreement*.¹⁵⁰ The legal interpretations developed by the Panel were immediately subject to scholarly discussions and appealed.¹⁵¹

¹⁴⁵Council Directive 88/146/EEC of 7 March 1988 prohibiting the use in livestock farming of certain substances having a hormonal action, OJ No L 70 of 16. 3. 1988, pp. 16-18.

¹⁴⁶Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC, OJ No L 125 of 23. 5. 1996, pp. 3-9.

¹⁴⁷Panel Report, *European Communities – Measures Affecting Meat and Meat Products (Hormones)*, ("European Communities – Hormones"), WT/DS26/R, (US) adopted as modified by the Appellate Body, 13 February 1998 and Panel Report, *European Communities – Measures Affecting Meat and Meat Products (Hormones)*, ("European Communities – Hormones"), WT/DS48/R, (CAN) adopted as modified by the Appellate Body, 13 February 1998.

¹⁴⁸Adopted at the 21st Session on the basis of secret majority voting, where 33 delegates approving the standard, 29 opposing them and 7 delegates abstaining from the vote, See ALINORM 95/37 (8 July 1995). See, Panel Reports, *European Communities – Hormones*, paras. 8.56 ff. (US) and paras. 8.58 ff. (CAN).

¹⁴⁹Panel Report, *European Communities – Hormones*, paras. 8.91 ff (US) and paras. 8. 94 ff. (CAN).

¹⁵⁰*Ibid.*, paras. 8.167 ff (US) and 8.170 ff. (CAN).

¹⁵¹Meinhard/Eggers, Barbara, "Der WTO-Panelbericht im EG/USA-Hormonstreit: Anstoß zum grenzenlosen Weltbinnenmarkt für Lebensmittel oder Eigentor der WTO? EuZW 1997, pp. 559-566; Seilheimer, Lisa K., "The SPS

(iii) *The Appellate Body Report*

The decision of the Appellate Body is one of its landmark rulings and has been thoroughly described and annotated elsewhere.¹⁵² Very briefly, the Appellate Body reversed the interpretation of Article 3.1 and 3.3 of the *SPS Agreement*, with the effect, that the harmonization requirement does not yet bite.¹⁵³ The Appellate Body also modified the interpretation of Article 5.1 by adopting a broad notion of risk and risk assessment.¹⁵⁴ The requirement that a measure be "based on" a risk assessment was interpreted, by essentially using a "rational relationship" test.¹⁵⁵ The Appellate Body emphasized that minority opinions could form the basis of a risk assessment, but found that the European Hormones Directive was not based on a risk assessment, because the studies regarding adverse health effects of control problems as well as the opinions provided by one of the experts advising the Panel were not "specific" enough to show that beef treated with hormones following a good husbandry practice would cause risks.¹⁵⁶

Agreement as Applied: The WTO Hormone Beef Case", 4 *Env'tl. Law.* (1998) pp. 537-576.

¹⁵²See in particular the annotations by *Hurst*, David R., "Hormones European Communities – Measures Affecting Meat and Meat Products", *EJIL* Vol. 9 (1998), at 182; *Pauwelyn*, Joost, "The WTO Agreement on Sanitary and Phytosanitary (SPS) Measures as Applied in the First Three SPS Disputes – EC – Hormones, Australia – Salmon and Japan – Varietals", *JIEL* Vol. 2 (1999), pp. 641-664; *Quick*, Reinhard/*Blüthner*, Andreas, "Has the Appellate Body Erred? An Appraisal and Criticism of the Ruling in the WTO Hormones Case", 2 *JIEL* (1999) pp. 603-639. *Roberts*, above n.; *Walker*, Vern R., "Keeping the WTO from Becoming the "World Trans-science Organization": Scientific Uncertainty, Science Policy, and Fact-finding in the Growth Hormones Dispute", 31 *Cornell Int'l L. J.*, (1998), pp. 251-320; *Wynter*, Marie, "The Agreement on Sanitary and Phytosanitary Measures in the Light of the WTO Decision on EC-Measures concerning Meat and Meat Products (Hormones)", in: *Mengozzi*, Paolo (ed.), "International Trade Law on the 50th Anniversary of the Multilateral Trading System", (Milano: Dott. A. Giuffrè editore, 1999) pp. 471-526.

¹⁵³Appellate Body Report, *European Communities – Hormones*, paras. 160 to 177. In *Japan – Agricultural Products*, the Appellate Body gave further guidance on what "scientific justification" means by equating it with the rational relationship test (para. 79).

¹⁵⁴*Ibid.*, paras. 178-187.

¹⁵⁵*Ibid.*, paras. 188-209.

¹⁵⁶*Ibid.*, paras. 194 and 196-209.

Furthermore, the Appellate Body reversed the finding that the Hormones Directive violated Article 5.5 of the *SPS Agreement*.¹⁵⁷ The Appellate Body also clarified that the burden of proof rests on the complainant, who has to make a *prima facie* case of what he claims is true, which then needs to be rebutted by the respondent.¹⁵⁸ Finally, the Appellate Body was faced with the issue of deference. The European Communities challenged the assessment of the facts and use of expert opinions by the Panel. The Appellate Body held that absent an express standard of review under the *SPS Agreement*, it could neither adopt a standard of *de novo* review nor total deference, but referred to Article 11 of the *DSU*, which directs Panels to carry out an objective assessment of the facts.¹⁵⁹

(iv) *DSU Article 21.3(c) and 22.6 Arbitrations*

The European Communities expressed its intention to implement the recommendations of the Appellate Body, as adopted on 13 February 1998. However, within the reasonable period of time for implementation, which was determined by an arbitrator under Article 21.3 c) of the *DSU* to be 15 months, i.e., until 13 May 1999, the European Communities did not repeal the Directive.¹⁶⁰ Instead, it chose to accept retaliatory measures authorized under Article 22.6 of the *DSU* in the form of a tariff increase on EC products entering the United States and Canada worth US \$116.8 and CAN \$11, 3 annually.¹⁶¹ The European Communities are currently re-enacting the Hormones Directive on the basis of a "complementary" risk assessment.¹⁶² In 2000, the European Communities challenged the

¹⁵⁷*Ibid.*, paras. 211-246.

¹⁵⁸*Ibid.*, para. 104.

¹⁵⁹*Ibid.*, paras. 110-119.

¹⁶⁰*European Communities – Hormones*, Award of the Arbitrator (under Article 21.3(c) of the *DSU*, WT/DS26/15, WT/DS48/13, circulated 29 May 1998.

¹⁶¹*European Communities – Hormones*, *Recourse to Arbitration by the European Communities under Article 22.6 of the DSU*, WT/DS26/ARB, WT/DS48/ARB.

carousel retaliation enacted by the US.¹⁶³ Thus, to date, the long festering trade conflict regarding the prohibition of hormone treated beef has not been resolved.

(b) *Australia – Salmon*

This dispute concerns allegations of Canada that Australia unjustifiably blocks the market access for fresh chilled or frozen salmon.¹⁶⁴

(i) *Facts of the Case*

Australia has prohibited the importation of fresh, chilled or frozen salmon from Canada since 1975.¹⁶⁵ According to Australia, Canadian salmon could introduce 24 exotic disease agents with negative consequences for the health of wild and cultured Australian salmon.¹⁶⁶ Human health issues are not at stake.¹⁶⁷

(ii) *Panel Report*

The Panel found that the Australian heat-treatment was not based on a risk assessment as required by Article 5.1 and 2.2 of the *SPS Agreement* and that Australia had also acted inconsistently with Articles 2.3 and 5.5 as well as 5.6 of the *SPS Agreement*.¹⁶⁸

¹⁶²Proposal for a Directive of the European Parliament and of the Council amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action of beta-agonists, COM(2000) 320 final of 24 May 2000.

¹⁶³See Request for Consultations of the European Communities, United States – Section 306 (Retaliation) WT/DS/200.

¹⁶⁴An additional case brought by the United States, *Australia – Measures Affecting the Importation of Salmonids*, ("Australia – Salmonids"), WT/DS21 is presumed to be settled.

¹⁶⁵Quarantine Proclamation No. 86 A, *Australian Government Gazette*, No. S33, 21 February 1975.

¹⁶⁶Panel Report, *Australia – Measures Affecting Importation of Salmon* ("Australia – Salmon"), WT/DS18/R, adopted, as modified by the Appellate Body, 6 November 1998, paras. 2.27-2.30.

¹⁶⁷*Ibid.*, para. 2.11.

¹⁶⁸*Ibid.*, para. 9.1

(iii) *Appellate Body Report*

The Appellate Body, in that case, further developed the interpretation of Article 5.1 of the *SPS Agreement* by clarifying the requirements for a risk assessment for measures protecting animal health.¹⁶⁹ It stressed that "some evaluation of the likelihood or probability" of risk is not enough.¹⁷⁰

As regards Article 5.5 of the *SPS Agreement*, the Appellate Body identified further warning signals, on a when a measure which achieves a different level of protection in a comparable situation results "in discrimination or a disguised restrictions". These warning signals include a "finding of inconsistency with Article 5.1".¹⁷¹

Australia – Salmon was the first case which involved the necessity test under Article 5.6 of the *SPS Agreement*. However, because the Panel had looked at the wrong measure, i.e. the heat-treatment requirement instead of the import prohibition, the Appellate Body, due to insufficiency of relevant factual findings by the Panel and of facts that are undisputed by the parties, reversed the findings of the Panel without completing the legal analysis.¹⁷² Thus, the *Australia – Salmon* case illustrated the lack of remand authority for the Appellate Body.¹⁷³ Apart from that it has gained little attention in the literature.¹⁷⁴

¹⁶⁹Appellate Body Report, *Australia – Measures Affecting Importation of Salmon* ("Australia – Salmon"), WT/DS18/AB/R, adopted 6 November 1998, paras. 119-138.

¹⁷⁰*Ibid.*, para. 124.

¹⁷¹*Ibid.*, paras. 164-166.

¹⁷²*Ibid.*, paras. 241 and 242.

¹⁷³*Palmeter*, David, "The WTO Appellate Body needs Remand Authority", 32 Nr. 1 *Journal of World Trade* (1998), pp. 41-44.

¹⁷⁴See only, *Goh*, Gavin/Ziegler, Andreas R., "A Real World Where People Live and Work and Die: Australian SPS Measures After the WTO Appellate Body's Decision in the Hormones Case", 32(5) *Journal of World Trade* (1998), pp. 271-290; *Taylor*, Matthew D., "Comment: The WTO panel decision on Australia

(iv) *DSU Article 21.3(c) and 21.5 Proceedings*

In terms of implementation, the parties could not agree on a reasonable time for implementation, which was determined through arbitration to be 8 months, i.e., from 6 November 1998, the date of adoption of the Appellate Body Report, to 6 July 1998.¹⁷⁵

Other than the European Communities in the *Hormones* dispute, Australia informed the DSB that it had fully implemented the DSB's recommendations through an Australian Quarantine and Inspection Services (AQIS) decision of 19 July 1999, which was based on a new risk assessment. Canada challenged the implementation measure under Article 21.5 of the DSU. The Panel found that the new risk assessment fulfilled the conditions set by Article 5.1 of the *SPS Agreement*, because the flaws were not so serious as to prevent the Panel from having "reasonable confidence in the evaluation made and the levels of risks assigned".¹⁷⁶ However, it found that there was no rational relationship between the risk assessment and the "consumer ready requirement", which, thus, violated Article 5.1 of the *SPS Agreement*.¹⁷⁷ The Panel did not find a violation of Article 5.5 of the *SPS Agreement*, but held that the measure was at odds with Article 5.6 because there were less trade restrictive measures than the consumer ready requirement which could achieve the same level of protection.¹⁷⁸

(c) *Japan – Agricultural Products*

The third dispute, *Japan – Agricultural Products* is a rather technical case. Because the facts are quite tricky, but important to

Salmon import guidelines: Evidence that the *SPS Agreement* can effectively protect human health interests", 9 Pac. Rim L. & Pol'y J. 473-506.

¹⁷⁵Award by the Arbitrator, *Australia – Salmon*, WT/DS18/9, of 23 February 1999.

¹⁷⁶Panel Report, *Australia – Measures Affecting Importation of Salmon – Recourse to Article 21.5 by Canada ("Australia – Salmon 21.5")*, WT/DS18/RW, paras. 7.57 and 7.71.

¹⁷⁷*Ibid.*, para. 7.85.

¹⁷⁸*Ibid.*, paras. 7.137 and 7.153.

understand the ruling, which is the first one that involves Article 5.7 of the *SPS Agreement*, they are set out in more detail before summarizing the findings.

(i) *The facts of the case*

At stake in this dispute is a quarantine measure against codling moth, a pest which invades apples, cherries, nectarines and other fruit crops. It occurs in the US and other temperate zones, but not in Japan.¹⁷⁹ To prevent the spread of codling moth from imported fruit, Japan, in 1950, prohibited the importation of eight agricultural products, originating from, *inter alia*, the United States.¹⁸⁰ This ban can only be lifted if an exporting country proposes an alternative quarantine treatment, which achieves the Japanese level of protection. It places the burden of proving such quarantine safety on the exporter and specifies, through a set of guidelines, a "varietal testing" requirement, i.e. efficacy of quarantine treatment must be proven for each additional varieties of that product.¹⁸¹

The US challenged the Japanese varietal testing requirement, as unjustified barrier to trade, arguing that it was maintained ostensibly for plant health considerations, but in reality protected Japanese producers against US producers of the same variety.¹⁸²

The US argued that it had, since the 1970s, carried out rigorous research efforts and developed effective treatments to meet the Japanese quarantine conditions.¹⁸³ It pointed to the test results for seven varieties of apples, nine varieties of cherries, four varieties of walnuts and ten varieties of nectarines, which never indicated a

¹⁷⁹Panel Report, *Japan – Measures Affecting Agricultural Products* ("Japan – Agricultural Products"), WT/DS76/R, adopted as modified by the Appellate Body Report on 19 March 1999, paras. 2.1-2.8.

¹⁸⁰Law No. 151 of 1950, enacted 4 May 1950, as last amended in 1996.

¹⁸¹"Experimental Guidelines for Cultivar Comparison Test on Insect Mortality – Fumigation".

¹⁸²Panel Report, *Japan – Agricultural Products*, para. 3.1

¹⁸³*Ibid.*, para. 4.20.

difference from one variety to another.¹⁸⁴ Japan could not cite to one single example in which any agricultural exporting country had had to modify a treatment for killing codling moth among varieties of the same product. This would also be supported in scientific literature.¹⁸⁵ To engage in an additional testing for each variety would be time consuming and expensive.¹⁸⁶

Japan was of the view, that the US had the burden of proving that variety does not matter, whereas Japan is only obliged to continuously review whenever additional information becomes available in respect of the introduction of a pest.¹⁸⁷ Japan claimed that some dose-mortality test had shown different responses to the fumigation by varieties of nectarines.¹⁸⁸ According to the US argument, if there were 100 varieties in one product category, a treatment based on selective tests of any variety would have to be presumed to be effective for the other 99 varieties. Furthermore, there was no information on products yet to be developed, possibly through rapidly advancing biotechnology.¹⁸⁹

The scientific expert group convened by the Panel in *Japan – Agricultural Products*, sided with the United States in that "even though in theory, there may be relevant varietal differences – to date there is not sufficient evidence in support of the varietal testing requirement."¹⁹⁰ The data provided by Japan would allow the hypothesis that varietal differences affect quarantine efficacy, but would not show that the differences in responses of different varieties to the same fumigation treatment were due to varietal differences.¹⁹¹

¹⁸⁴*Ibid.*, para. 4.37.

¹⁸⁵*Ibid.*

¹⁸⁶*Ibid.*, para. 4.23.

¹⁸⁷Panel Report, *Japan – Agricultural Products*, para. 4.27.

¹⁸⁸*Ibid.*, para. 4.46.

¹⁸⁹*Ibid.*, para. 4.72 and 4.73.

¹⁹⁰Panel Report, *Japan – Agricultural Products*, para. 8.35.

¹⁹¹*Ibid.*, paras. 8.37-8.39.

They adduced a series of factors that could have alternatively caused the differences, e.g., variable fruit loads, leakages, experimental errors, sorption by packaging material, etc., and then found that "there is a lack of precise studies on this subject".¹⁹² At the same time, it would have been relatively easy to study the varietal differences, e.g., by conducting so called sorption tests on different varieties of products.¹⁹³

(ii) *The Panel Report*

The Panel did not start the analysis of the case with the specific obligation under Article 5.1 of the *SPS Agreement*, but approached it by first looking at the general obligation under Article 2.2 of the *SPS Agreement*, not to maintain a sanitary or phytosanitary measure without sufficient scientific evidence. It found a violation of Articles 2.2, which was not justified under Article 5.7, and that Japan had acted inconsistently with Article 5.6 and 7 of the *SPS Agreement*.¹⁹⁴

(iii) *Appellate Body Report*

The Appellate Body affirmed the finding of the Panel that the measure was maintained without sufficient scientific evidence and interpreted Article 2.2 by using the same "rational relationship" test as developed under Article 5.1 of the *SPS Agreement*.¹⁹⁵ Japan invoked Article 5.7 of the *SPS Agreement*. The Appellate Body held that the right to take a provisional measure is a "*qualified exemption*".¹⁹⁶ The Appellate Body affirmed that the Japanese measure did not fulfil the requirements set out under Article 5.7, because the Japanese

¹⁹²*Ibid.*, para. 8.40.

¹⁹³*Ibid.*, para. 8.41.

¹⁹⁴*Japan – Measures Affecting Agricultural Products* ("Japan – Agricultural Products"), WT/DS76/R, adopted as modified by the Appellate Body Report on 19 March 1999.

¹⁹⁵Appellate Body Report, *Japan – Measures Affecting Agricultural Products* ("Japan – Agricultural Products"), WT/DS76/AB/R, adopted 19 March 1999, para. 84.

¹⁹⁶*Ibid.*, para. 80.

government had violated the procedural obligation to "seek to obtain additional information" and to "review the measure within a reasonable period of time".¹⁹⁷ Both requirements were interpreted by using a case-by-case test.¹⁹⁸ Because the information on whether varietal differences affect the efficacy of quarantine treatment would have been easily obtainable, the Appellate Body found that the 30 year old Japanese measure could have been reviewed after the entry into force of the *SPS Agreement* in 1995, and could, therefore, not be considered as provisional measure under Article 5.7 of the *SPS Agreement*.¹⁹⁹ The Appellate Body also found a violation of the transparency provisions under Article 7 of the *SPS Agreement*²⁰⁰ and reversed the finding of the Panel that there was a less trade restrictive measure, because the alternative measure had not been proposed by the claimant, but only emerged during the deliberations of the scientific experts advising the Panel.²⁰¹

(iv) *Mutually Agreed Time for Implementation*

The parties to the dispute agreed on a reasonable time for implementation according to Article 21.3(b) of the DSU, which expired on 31 December 1999.²⁰² Japan has repealed the varietal testing requirement towards imports from the United States, but not *erga omnes* in relation to imports from the European Communities or Australia.²⁰³

C. SUMMARY

WTO Members have, through the *SPS Agreement*, developed a very refined filter for Article XX(b) measures, which goes beyond the

¹⁹⁷*Ibid.*, paras. 86-94.

¹⁹⁸*Ibid.*, paras. 92-94.

¹⁹⁹*Ibid.*, paras. 93 and 94.

²⁰⁰*Ibid.*, paras. 102-108.

²⁰¹*Ibid.*, paras. 95 to 101.

²⁰²WT/DS76/9.

²⁰³Meeting of the DSB of 23 October 2000.

discrimination-exception technique used in the GATT. It recognizes the right of each Member to determine its own appropriate level of protection, but imposes seven different obligations, including a harmonization requirement, the science test, a necessity test, and obligations to ensure regulatory consistency and transparency. A complainant must make a *prima facie* case of inconsistency with these obligations. The provisions have been interpreted in three disputes, thus far: *European Communities – Hormones*, *Australia – Salmon*, and *Japan – Agricultural Products*. As regards the different parts of the filter, it can be summarized that the harmonization requirement in Articles 3.1 and 3.3 does not yet bite. Only if a measure conforms to an international standard, is presumed to be consistent with the *SPS Agreement*. The second stage is the science test under Articles 2.2, 5.1, 5.2, 5.3, and 5.7. If a measure falls through this, it is automatically inconsistent with WTO law, no matter, whether the measure is necessary or the Member observed its other obligations under the *SPS Agreement*. Even, where a measure is based on a risk assessment, it must still pass five further tests, i.e. it is only consistent with WTO law, if there is no less trade-restrictive measure, if the has assured regulatory consistency, proper adaptation to regional conditions, transparency, and observed certain obligations in the administration of approval and control procedures.

In all three decisions, the measures were found to violate Articles 2.2 and 5.1, because no sufficient scientific evidence existed, or the Member had not carried out a risk assessment.

§2 THE RIGHT TO PRECAUTION AND ITS LIMITS

When listening to discussions between representatives of business groups and environmental NGOs, one might gain the impression that the precautionary principle and the science test of the *SPS Agreement* are as different as chalk and cheese. Agricultural exporters constantly argue that the *SPS Agreement* obliges Members to base their health and environmental measures on "sound science", while environmental groups demand that the precautionary principle be incorporated into the *SPS Agreement*.²⁰⁴ The Appellate Body held that the precautionary principle finds "reflection" in Articles 5.7, 3.3, 2.2, and the Preamble of the *SPS Agreement*. "Reflection" means that an image of something is shown on the surface of something else.²⁰⁵

Indeed, the WTO is not concerned with protective duties, or, as put by *Charnovitz*, it is not a "World Health Authority". Structurally, WTO law does not oblige Members to take certain measures following the precautionary principle, but needs to determine to which extent Members have a *right* to precaution.

At first glance, it appears that Members have a strong right to precaution. The Appellate Body emphasized that Members have a right to establish their "own appropriate level of sanitary protection which level may be higher (i.e. more *cautious*) than that of other Members or international standards".²⁰⁶ Members may even choose

²⁰⁴See, e.g. Senator *John Ashcroft* of Missouri in his letter of April 19th 2000, available at <http://www.insidetrade.com> (visited 2 June 2000). Transatlantic Consumer Dialogue, "Recommendations on Food, Electronic Commerce and Trade" Brussels Meeting, 23-24 April 1999, at 18, demanding that the word "provisional" be deleted. See also, World Wildlife Foundation, "A Reform Agenda for the WTO Seattle Ministerial Conference" (1999).

²⁰⁵*Simpson, J.A./Weiner, E.S.C.*, (eds.), "The Oxford English Dictionary", Vol. XIII, (2nd ed, Oxford: Clarendon Press, 1989) at 472.

²⁰⁶Appellate Body Report, *European Communities – Hormones*, para. 124 (emphasis added).

zero risk,²⁰⁷ which is more than warranted by any precautionary principle. The choice of an appropriate level of protection is "a *prerogative* of the Member concerned" and cannot be second-guessed by a panels or the Appellate Body".²⁰⁸ In particular, the definition of appropriate level of protection as "acceptable level of risk" in Annex A.4 of the *SPS Agreement*, suggests that the WTO would not intrude into the determination, how much risk a society wishes to accept, be it the possible death of 1 woman in a million or of one butterfly in a million.

Yet, the Appellate Body emphasized that the "right of a Member to define its appropriate level of protection is, however, not an absolute or unqualified right".²⁰⁹ Although limited by all seven obligations under the *SPS Agreement*, the science test is "essential for the maintenance of the delicate and carefully negotiated balance in the *SPS Agreement*, between the shared, but sometimes competing, interests of promoting international trade and of protecting the life and health of human beings".²¹⁰

This chapter focuses on the limits of precaution set by the core filter of Articles 2.2, 5.1 and 5.7 of the *SPS Agreement* and analyzes to which extent it allows the taking of precautionary measures.

Part I of this chapter sets forth seven hypotheticals which illustrate the key legal problems arising in trade conflicts on measures

²⁰⁷Appellate Body Report, *Australia – Salmon*, para. 132.

²⁰⁸Appellate Body Report, *Australia – Salmon*, para.. 198. The concept of appropriate level of protection has already been used in past GATT Panel practice when applying Article XX of the GATT. See, Report of the Panel, *Thailand – Restrictions on Importation of and Internal Taxes on Cigarettes* ("Thailand – Cigarettes"), DS10/R, adopted on 7 November 1990, BISD 37S/200, para. 74. See also, Panel Report, *United States – Gasoline*, para. 6.22 and Panel Report, *European Communities – Asbestos*, para. 8. 179.

²⁰⁹*Ibid.*, para. 173.

²¹⁰Appellate Body Report, *European Communities - Measures Affecting Meat and Meat Products (Hormones)*, ("European Communities – Hormones"), WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, para. 177.

taken pursuant to the precautionary principle, e.g., measures on GMOs, hormone-treated beef and BSE.

Part II examines the obligations under Articles 2.2, 5.1, 5.2, and 5.3 of the *SPS Agreement*, with a view to derive the conditions set for precautionary measures.

Part III then provides a state of the law analysis of Article 5.7, the right to take provisional measures.

I. PRECAUTIONARY MEASURES: 7 HYPOTHETICALS

When discussing trade measures that pose particular problems of scientific uncertainty judges, scholars and diplomats have started using the term "precautionary measure".²¹¹ It is not a legal definition, but rather as a generic term. Precautionary measures could be defined as measures taken pursuant to the precautionary principle to protect human, animal, and plant life or health, or the environment, which are taken in situations of scientific uncertainty, and may, directly or indirectly, affect international trade.

However, the fine-tuning has not stopped there. Practitioners already use further sub-categories, e.g., emergency measures denoting the BSE cases.²¹² Moreover, some have pointed to the problems of "mixed measures", i.e., measures taken to pursue several legislative goals.²¹³ As of March 1999, more than 1.1.00 sanitary and phytosanitary measures had been notified to the SPS Committee.²¹⁴

²¹¹See, *Roberts*, above, n. 99, at 379, and for example the notification of Hong Kong G/SPS/N/HKG/9 of 17 April 2000. See also, Case T-13/99R *Pfizer Animal Health SA/NV v. Council of the European Union*, Order of 30 June 1999, n.y.r., para. 181.

²¹²See, for example, the notification of Hong Kong G/SPS/N/HKG/9 of 17 April 2000 and Case C-352/98 P *Laboratoire pharmaceutiques Bergaderm SA and Jean Jacques Goupil*, Opinion of Advocate General Fennelly, delivered on 27 January 2000, para. 34

²¹³*Pauwelyn*, above, n. 123, at 644.

²¹⁴Report of the SPS Committee, "Review of the Operation and Implementation of the Agreement on Sanitary and Phytosanitary Measures", G/SPS/12, 11 March 1999. See also the overview of trade conflicts regarding sanitary and phytosanitary measures which have been settled, *Roberts*, above, n. 99,

This registry is a treasury of different sanitary and phytosanitary measures. When browsing through it to identify "precautionary measures", some common patterns but also significant differences become evident.

The following seven hypotheticals aim at distilling the most important legal and factual differences between these measures which are relevant in international trade conflicts. They are largely built on the precautionary principles described in Part 1 and cannot give the full picture of all measures taken in situations of scientific uncertainty. However, it is submitted, that with these seven hypotheticals, the core mechanism for scientific uncertainty under Articles 2.2, 5.1 and in particular 5.7 of the *SPS Agreement* can be tested.

A. SEVEN HYPOTHETICALS

As regards GMOs, it is not possible to represent the full picture of possible measures. However, two hypotheticals might coin some of the problems encountered so far:²¹⁵

1. **Hypothetical: Moratorium on the Import of GM Foods**²¹⁶

Country I adopts a two year moratorium on the authorization and importation of food containing GMOs. The measure responds to a new wave of consumer concerns triggered by a study which found adverse effects of GM potatoes on mice. Exporting Country E challenges the measure, arguing that first, the study is flawed and therefore heavily disputed in the scientific community, second it could not justify a general ban on all novel

at 396 and *Shin*, Yukyun, "An Analysis of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures and its Implementation in Korea", 32(1) *Journal of World Trade*, 1998, pp. 85-119.

²¹⁵These are inspired by an earlier hypothetical developed by John H. Jackson. See, *Jackson*, John H., "World Trade Rules and Environmental Policies: Congruence or Conflict?" 49 *Washington and Lee Law Review* (1992), pp. 1227-1259, at 1234.

²¹⁶The adoption of moratoriums is quite common in the area of biotechnology. Most recently, Brazil adopted a moratorium. A federal court ruling barred the Brazilian government from authorizing the planting or marketing of GMO crops until a full environmental impact study was undertaken. See, Decision of Judge Souza Prudente of 18 June 2000 and newsletter of July 1999, BINAS Online, <<http://binas.unido.org>> (visited 25 June 2000). The European Communities adopted a moratorium on the approval of new GM varieties and the marketing of rBST.

foods. There are no scientific reasons to treat GMOs as a class different from existing products.

2. Hypothetical: Import Restrictions on GMOs under the *Cartagena Protocol*

Exporter E wishes to sell *Bt* maize seeds in developing country D. D refuses its consent under the *Cartagena Protocol on Biosafety*. It points to the Monarch Butterfly study and estimates that one of its tropical Emperor butterflies in a million might be adversely affected by *Bt* maize pollen. Moreover, older studies indicate that the long-term effects of GMOs can only be fully assessed after 100 years. To avoid any adverse effects on its centers of genetic diversity, D wants to take a long term ban.

E challenges the measure in WTO dispute settlement proceedings and argues that it is at odds with both, Articles 2.2 and 5.7 of the *SPS Agreement*. All new laboratory and field tests suggest that *bacillus thuringiensis* is safe. D has not sought to obtain information of how *Bt* maize affects its emperor butterfly or "center of genetic diversity". D contends that it has no financial means to carry out such specific studies and argues that it is up to E to show that his product is safe.

In the second hypothetical, E does not contest the *Cartagena Protocol* as such. Although WTO law provides for the possibility of challenging "legislation as such"²¹⁷, it is very unlikely that a multilateral environmental agreement itself would be contested. An observer has described that debate as "overstated", since no such measures was ever attacked at the WTO.²¹⁸ However, there will be further disputes about the existence of a risk, where exporters allege that measures are only taken on the basis of public fears or "what if...?" questions. As shown in the background chapter on GMOs in Part 1, a growing body of scientific evidence based on laboratory and field studies, concludes that GMOs have no adverse effects.²¹⁹ These conflict with controversial studies indicating, e.g., adverse effects on

²¹⁷Appellate Body Report, *United States – Anti-Dumping Act of 1916* ("*United States – 1916 Act*"), WT/DS136/AB/R, WT/DS162/AB/R, adopted 26 September 2000.

²¹⁸*Sampson*, Gary P., "Trade, Environment, and the WTO: The Post-Seattle Agenda" (Washington, D.C.: Overseas Development Council, 2000).

²¹⁹The US cite an abundance of Scientific Literature, Reports of the US National Academy of Sciences, the US National Research Council, The World Health Organization and the Organization for Economic Cooperation and Development, in their support. See, "U.S. Comments on Japanese Labeling Proposal", Inside U.S. Trade 15 October 1998 and "Barshevsky hints at considering possible Biotech Case against EU", Inside U.S. Trade, 16 June 2000.

non-target organisms, or general opinions about possible adverse ramifications in the long run.

3. Hypothetical: Scientific Idleness

Country I is concerned about the "red moth", a pest which does not occur on its territory, but in vegetables exported by E. To ensure that the pest would not be introduced by imports, I requires E to demonstrate, for each new variety of, e.g., paprika, that a fumigation treatment is effective. E agrees that it carries the burden to ensure that its exports are subject to proper quarantine treatment, but contends that it has carried out rigorous research efforts and developed effective treatments to meet I's quarantine conditions for paprika. However, the "varietal testing requirement" is not based on any scientific evidence. In the last 30 years, no single example existed where quarantine treatment for the "red moth" had to be modified for a new variety of paprika. I points to some dose-mortality tests on paprika which indicate difference between varieties, however, I never carried out further research whether these difference were induced by the varietals differences or by other factors.

This case is built on the facts of *Japan – Agricultural Products*. It has been chosen to denote the example of many "old" measures taken on the basis of a scientific hypothesis, but where the Member was "idle", i.e., did not endeavour to seek information to verify this hypothesis.

4. Hypothetical: Emergency Measure – Mad Cow Disease

Following a communique of a group of scientists who refer to 10 cases of a new variety of Creutzfeldt-Jakob disease and state that although there is no direct evidence, the most likely explanation is that these cases are linked to the exposure to BSE, Country I immediately takes an "emergency measure", i.e., it prohibits the import of beef, semen and cheese. Exporting Country E opposes the complete ban, arguing that there is no scientific evidence that BSE can be transmitted via these products.

This hypothetical is based on a couple of emergency measures taken both by the European Communities against meat imports from the UK²²⁰, as well as by other countries. The BSE conflict involves many further questions, e.g., the permanent ban by the European Communities of all specified risk materials in tallow products.²²¹

²²⁰See for an overview of the factual and legal background, Part 1, §1 II, A.

²²¹In the wake of the BSE crisis, the European Communities promulgated a permanent ban on specified risk materials. Commission Decision 97/534 of

However, for the purpose of this analysis of Article 5.7 of the *SPS Agreement*, the outstanding feature of the BSE cases appears to be the emergency situation, where no scientific evidence is available, and the government reacts immediately by prohibiting the import of the product.

5. Hypothetical: Antibiotic Resistance

Country I is concerned about the growing resistance of its population to antibiotics. Recent studies indicate that some bacteria, e.g., *salmonella typhi* have developed resistances against antibiotics which are administered to cattle for growth promotion purposes. It is suspected that these bacteria have entered the food chain and caused antimicrobial resistance in humans. I withdraws existing authorizations for antibiotics on its market and prohibits the import of meat treated with antibiotics. Exporting Country E argues that antimicrobial resistance is only due to overprescription of antibiotics. Moreover, there is no evidence for a causal link between the use of a specific growth promoter and the antibiotic resistance in a particular clinical case.

6. Hypothetical: Hormones I

Responding to consumer concerns, Country I prohibits the use of hormones for growth promotion purposes in stockfarming and bans the import of foreign beef to which hormones have been administered. The legislation refers to several legislative goals including health protection, and the stabilization and harmonization of agricultural markets. I has general studies on possible cancerous effects and an opinion of one scientific expert who estimates that there is a risk of one woman in one million dying from breast cancer induced by added growth hormones. Exporting Country E contends that the ban is without scientific evidence, because it has been scientifically established in several studies that the administration of growth hormones following a good husbandry practice is safe.

7. Hypothetical: Hormones II

After E has won a ruling of the WTO finding that the hormones ban is, indeed, not based on a specific risk assessment, I has solicited new studies, requested information from E and international organizations and, on the basis of new scientific evidence carried out a "complementary risk assessment". The opinion of its scientific committee concludes that for one hormone, a substantial body of scientific evidence exists that the establishment of ADI levels is not possible. With respect to the other five hormones, the scientific evidence is still inconclusive. I wishes to implement the ruling of the DSB by maintaining the permanent ban of the first hormone. The other five hormones shall be "provisionally" prohibited following Article 5.7 of the *SPS Agreement*. The proposal does not set a

30 July 1997 on the prohibition of the use of material presenting risks as regards transmissible spongiform encephalopathies, OJ No L 216 of 8. 8. 1997, pp. 95-98.

time limit for the provisional prohibition, but specifies that I "will seek additional information and keep the measures under regular review".

These hypotheticals do not grasp the whole complexity of issues raised by the hormones case. However, they coin some of the core questions, including the issue of minority opinions, the consumer threshold and the interesting question whether a permanent measure which was taken on the basis of Article 5.1 can be implemented by turning it into a provisional measure?

B. ARE THESE MEASURES COVERED BY THE *SPS AGREEMENT*?

Before moving to the analysis of these measures under the science test, this section briefly double-checks whether they are covered by the *SPS Agreement*.

1. The Scope of the *SPS Agreement*

The scope of the *SPS Agreement* is regulated in Article 1.1, which provides: "This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement."

Annex A.1 of the *SPS Agreement* defines "Sanitary or phytosanitary measure" as

any measure applied:

(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;

c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

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

Footnote 4 provides:

For the purpose of these definitions, "animal" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" include weeds; and "contaminants" include pesticide and veterinary drug residues and extraneous matter.

Whether a measure falls under the scope of the *SPS Agreement* is determined on the basis of the subjective criterium, whether the measure aims at preventing certain "food-borne" or "pest-or-disease related risks".²²² In *European Communities – Hormones*, the Appellate Body clarified that all measures that existed when the

²²²*Pauwelyn, Joost, "The WTO Agreement on Sanitary and Phytosanitary (SPS) Measures as Applied in the First Three SPS Disputes - EC – Hormones, Australia – Salmon and Japan – Varietals", 2 JIEL 1999, pp. 641-664, at 644.*

SPS Agreement entered into force or were adopted after that date, are subject to its disciplines.²²³

When applying these criteria to the hypotheticals, it is apparent that "red" moth is a pest within the meaning of Annex A.1(a) of the *SPS Agreement*. The BSE and antibiotics measures aim at the protection from risks arising from "disease-causing organisms in foods, beverages or feedingstuffs" as defined in Annex A.1(b). The assessment of the biosafety measures is less clear. They are often "mixed measures", aiming at both, the protection of human health, the environment (or biodiversity) and consumer protection. A similar problem arose with respect to the hormones ban, which was not only taken to protect human health, but also aimed at harmonizing and stabilizing the internal market of the European Communities.

2. WTO Jurisdiction

In *European Communities – Hormones*, the Panel found that the residues from the six hormones at issue are "contaminants" within the meaning of Annex A.1(b) and held that the "contested EC measures are, *inter alia* applied to protect human ... life or health" which can be "inferred from the Preambles to and legislative history of the Directives at stake."²²⁴ Thus, because a measure was at least partly aimed at the protection of human health, it fell under the scope of the *SPS Agreement*. The Panel in *Australia - Salmon* had to tackle the overlap between Annex A.1(a) and (b). Australia argued that its measure would fall under both definitions: The import ban of fresh, chilled and frozen salmon protects Australian salmonids and other aquatic animals from disease directly stemming from such salmon. However, if consumed as food by humans, salmon wastes could accidentally enter Australian waterways where it might be ingested by

²²³Appellate Body Report, *European Communities – Hormones*, paras. 126-130.

²²⁴Panel Report, *European Communities – Hormones*, para. 8.22 (US) and para. 8.25 (CAN) (emphasis added).

wild salmon.²²⁵ Although finding that both definitions of a sanitary measure might be applicable, the Panel argued that the objectives mentioned in several of the Australian legislative acts rather support that the measure was indeed a "quarantine measure", which more generally aims at avoiding the spread of pests or diseases and is not limited to protecting life and health of humans or animals against food-borne risks.²²⁶

3. Analysis

This case law suggests that mixed measures which, at least partly, aim at the prevention of risks defined in one of the paragraphs of Annex A, fall under the *SPS Agreement*. Applying it to the different biosafety measures suggests that an import ban on *Bt* maize that allegedly harms domestic beneficial insects would be a SPS measure protecting animal health from a "disease-causing-organism".

The pre-marketing approval requirement for novel food containing GMOs and labelling requirements directly related to food safety, e.g., labels warning of potentially allergenic genes could be covered by Annex A.1(b) of the *SPS Agreement*, if GMOs were contaminants, toxins or disease causing organisms. According to *Charnovitz*, protection against (real or imagined) human health risks from bio-engineered processed food, is not covered by the *SPS Agreement*, because genetic modification is not listed in Annex A.1.²²⁷ This appears to be straightforward in that processed food does not contain organisms any longer. However, as regards unprocessed GMOs, it should be recalled that the *SPS Agreement*, in Annex A.1 operates on the basis of a subjective criterium. When determining whether a measure is a SPS measure, panels only affirm that the importing country perceives a GMO as disease causing organism.

²²⁵Panel Report, *Australia – Salmon*, para. 8.32.

²²⁶*Ibid.*, paras 8. 34 – 8. 37.

²²⁷*Charnovitz*, Steve, "The Supervision of Health and Biosafety Regulation by World Trade Rules", World Trade Forum, 2000 (forthcoming), pp. 121-150, at 126.

However, such a finding does not mean that a GMO *is* disease causing. It only allows the application of the science test and other criteria under the *SPS Agreement* to verify this assumption. Thus, pre-marketing approvals of GMOs and novel food, as well as import restrictions would be covered by the *SPS Agreement*.

II. THE OBLIGATIONS UNDER ARTICLES 2.2 AND 5.1 OF THE *SPS AGREEMENT*

This part examines the obligations under Articles 2.2 and 5.1 of the *SPS Agreement*. The Appellate Body has applied both, Articles 2.2 and 5.1 of the *SPS Agreement* by using a rational relationship test. This approach has been heavily criticized as "we know it when we see it stance" which does not provide predictable guidance for governments.²²⁸ The goal of the following analysis is to determine the conditions for the taking of precautionary measures under both provisions. After briefly addressing their relationship, it first examines the requirement of "sufficient scientific evidence" under Article 2.2 of the *SPS Agreement* and then the obligation to base a measure on a risk assessment under Article 5.1 of the *SPS Agreement*.

A. THE RELATIONSHIP BETWEEN ARTICLES 2.2 AND 5.1

Article 2 of the *SPS Agreement*, titled "basic rights and obligations", provides in relevant part:

2. Members shall ensure that any sanitary or phytosanitary measure ... is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.

²²⁸Thomas, above n. 293, at 506. See also, Hurst, David R., "Hormones: European Communities – Measures Affecting Meat and Meat Products", EJIL Vol. 9 (1998), at 182.

Article 5 of the *SPS Agreement* contains the more specific obligation to base a measure on a risk assessment. Article 5.1 provides in full:

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

The Appellate Body has acknowledged that Article 2.2 and 5.1 is a "specific application" of the "basic obligation" under Article 2.2, which means that a violation of Article 5.1 automatically implies a violation of Article 2.2.²²⁹ However, not all violations of Article 2.2 are covered by Article 5.1.²³⁰ According to the Appellate Body, it is logically attractive to begin the analysis with Article 2.2.²³¹ Indeed, in *Japan – Agricultural Products*, the assessment of the measure was based on Article 2.2 of the *SPS Agreement*. The Appellate Body continuously held that "Articles 2.2 and 5.1 should constantly be read together. Article 2.2 informs Article 5.1: the elements that define the basic obligation set out in Articles 2.2 impart meaning to Article 5.1."²³² When interpreting the "based on" requirement in Article 5.1, the Appellate Body referred to Article 2.2 of the *SPS Agreement* and held "that the results of the risk assessment must sufficiently warrant - that is to say, reasonably support -- the SPS measures at stake", which means "that there be a rational relationship between the measure and the risk assessment."²³³ Precisely this rational relationship test was imported back into Article 2.2, when determining

²²⁹Appellate Body Report, *European Communities – Hormones*, para. 180. See also, Appellate Body Report, *Australia – Salmon*, para. 137.

²³⁰*Ibid.*

²³¹Appellate Body Report, *European Communities – Hormones*, para. 250.

²³²*Ibid.*, para. 180. See also, Appellate Body Report, *Japan – Agricultural Products*, para. 75.

²³³*Ibid.*, para. 193.

whether a measure is maintained without sufficient scientific evidence. The Appellate Body held, Article 2.2 "requires the existence of a sufficient or adequate relationship between two elements, *in casu*, between the SPS measure and the scientific evidence".²³⁴ It appears that the development of the rational relationship test, to some extent, blurred the legal relationship of the basic obligation under Article 2.2 and the specific obligation under Article 5.1 of the *SPS Agreement*.

A. ARTICLE 2.2 OF THE *SPS AGREEMENT*

This section examines the case law regarding the requirement under Article 2.2 of the *SPS Agreement* whereby SPS measures shall not be "maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5". As noted above, the Appellate Body has interpreted this obligation by using the same rational relationship test as developed for the "based on" requirement of Article 5.1 of the *SPS Agreement*. To distill the conditions set by the "rational relationship" test, the following sections will consider the full case law bearing on that subject together.

1. **WTO Jurisdiction: The Rational Relationship Test**

The Appellate Body addressed the requirement of "sufficient scientific evidence" in *Japan – Agricultural Products*. Noting that the ordinary meaning of the word "sufficient" is "of a quantity, extent, or scope adequate to a certain purpose or object"²³⁵, the Appellate Body concluded that "sufficiency" is a relational concept. More specifically, "sufficiency", according to the Appellate Body, requires the existence of a "sufficient or adequate relationship between two elements, *in casu*, between the SPS measure and the scientific

²³⁴Appellate Body Report, *Japan – Agricultural Products*, paras. 73 to 84.

²³⁵Appellate Body Report, *Japan – Agricultural Products*, para. 73, referring to *Onions*, C.T. (ed.), "The Shorter Oxford English Dictionary on Historical Principles", Vol. II, N-Z, (3rd ed, Oxford: Clarendon Press, 1983).

evidence."²³⁶ Reading Article 2.2 in its context, i.e. Articles 5.1, 3.3 and 5.7, it emphasized that Articles 2.2 and 5.1 should constantly be read together and that both concepts impart meaning to each other.

This reasoning mirrors the approach taken in *European Communities - Hormones*, where the Appellate Body, in interpreting the "based on" requirement in Article 5.1, referred to Article 2.2 of the *SPS Agreement* and held "that the results of the risk assessment must sufficiently warrant -- that is to say, reasonably support -- the SPS measures at stake", which means "that there be a rational relationship between the measure and the risk assessment."²³⁷ The Appellate Body, in *European Communities – Hormones*, clarified, at the outset, that this standard is a "case-to-case" test and held: "Determination of the presence or absence of that relationship can only be done on a case-to-case basis, after account is taken of all considerations rationally bearing upon this issue of potential adverse health effects."²³⁸

Precisely this "rational relationship" concept, has been imported into Article 2.2 of the *SPS Agreement* in *Japan – Agricultural Products*, where the Appellate Body elaborated the test in the following way:

Whether there is a rational relationship between an SPS measure and the scientific evidence is to be determined on a case-by-case basis and will depend upon the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence.²³⁹

Although Panels sometimes used slightly different language, e.g., "actual causal link" "reasonable relation", "reasonably warrant",

²³⁶Appellate Body Report, *Japan – Agricultural Products*, para. 73.

²³⁷*Ibid.*, para. 193.

²³⁸Appellate Body Report, *European Communities – Hormones*, para. 194.

²³⁹*Ibid.*, para. 84.

sufficiently support, they have essentially followed this approach.²⁴⁰ What does rational relationship mean in practical terms for the question whether scientific evidence is sufficient or not?

(a) Further Principles and Factors

The Appellate Body, in *European Communities – Hormones* and *Japan – Agricultural Products*, developed further principles for the application of the rational relationship test.

(i) *Minority Views*

In *European Communities – Hormones*, the Appellate Body directed Panels charged with determining whether "sufficient scientific evidence" exists, to "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."²⁴¹ In determining whether the import ban on hormone treated beef was based on a risk assessment, the Appellate Body acknowledged that governments do not have to base their measures on "mainstream opinions", but can equally follow "divergent opinions". Because this case law directly bears on the precautionary principle, it is worth quoting the relevant paragraph from *European Communities – Hormones*, in full:

The risk assessment could set out both the prevailing view representing the "mainstream" of scientific opinion, as well as the opinions of scientists taking a divergent view. Article 5.1 does not require that the risk assessment must necessarily embody only the view of a majority of the relevant scientific community. In some cases, the very existence of divergent views presented by

²⁴⁰Panel Report, *Australia – Salmon*, para. 8. 94, Panel Report, *Australia – Salmon*, 21.5, para. 7.72. See also, Panel Report, *Japan – Agricultural Products*, para. 8.42.

²⁴¹Appellate Body Report, *European Communities – Hormones*, para. 124.

qualified scientists who have investigated the particular issue at hand may indicate a state of scientific uncertainty. Sometimes the divergence may indicate a roughly equal balance of scientific opinion, which may itself be a form of scientific uncertainty. In most cases, responsible and representative governments tend to base their legislative and administrative measures on "mainstream" scientific opinion. In other cases, equally 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. By itself, this does not necessarily signal the absence of a reasonable relationship between the SPS measure and the risk assessment, especially where the risk involved is life-threatening in character and is perceived to constitute a clear and imminent threat to public health and safety.²⁴²

The Appellate Body referred to the same paragraph in *Japan – Agricultural Products*.²⁴³ Interestingly, the Appellate Body, in its citation of paragraph 194 of its report in *European Communities – Hormones*, left out the addendum in the third sentence, whereby reliance on a minority view does not necessarily signal the absence of a reasonable relationship, especially where the risk involved is life-threatening in character.²⁴⁴ This suggests, that minority views can be taken into account irrespective of whether human, animal or plant life or health is at stake. Moreover, it appears that a minority opinion can signal the *presence* of a rational relationship.

(ii) *The risk assessment*

A second factor relevant for the rational relationship test is the requirement for a risk assessment, more specifically, the Appellate

²⁴² Appellate Body Report, *European Communities – Hormones*, para. 194.

²⁴³ Appellate Body Report, *Japan – Agricultural Products*, para. 77.

²⁴⁴ *Ibid.*

Body referred to its statement in *Australia – Salmon*, whereby it is not sufficient that a risk assessment conclude that there is a possibility of entry, establishment or spread A proper risk assessment ... must evaluate the "likelihood", i.e., the "probability", of entry, establishment or spread"²⁴⁵ Some evaluation of the likelihood is not enough.²⁴⁶

(iii) *The relationship with Article 5.7*

Third, the Appellate Body stressed that that the concept of "sufficient scientific evidence" needs to be interpreted with a view to Article 5.7 of the *SPS Agreement*.²⁴⁷ Because Article 5.7 operates as a "qualified exemption" from Article 2.2 the Appellate Body cautioned that: "An overly broad and flexible interpretation of that obligation would render Article 5.7 meaningless".²⁴⁸

(b) The Application of the Rational Relationship Test in Practice

The rational relationship test as well as its principles and factors are still rather broad. Further guidance on when scientific evidence can be considered as sufficient might be gleaned from the application of the rational relationship tests in practice.

(i) *European Communities – Hormones*

In *European Communities – Hormones*, the Panel compared the scientific conclusions reached in each of the studies with the

²⁴⁵*Ibid.*, para. 78.

²⁴⁶*Ibid.*

²⁴⁷Appellate Body Report, *Japan – Agricultural Products*, para. 80. The Appellate Body also clarified the relationship between Article 2.2 and 3.3, which has already been discussed above, and rejected Japan's argument that Article 2.2 of the *SPS Agreement* should be interpreted in light of the precautionary principle (para. 81). The latter will be addressed in the 3. Part of this thesis.

²⁴⁸*Ibid.*, para. 80.

scientific conclusions reflected in the import prohibition for imported beef to see whether the latter are in conformity with the former.²⁴⁹

The Appellate Body stated that "the relationship between the two sets of conclusions (risk assessment and measure) is relevant, but not "to the exclusion of everything else". It stressed: "We do not believe that a risk assessment has to come to a monolithic conclusion that coincides with the scientific conclusion or view implicit in the SPS measure."²⁵⁰ While this suggests considerable wiggle-room for Members, the Appellate Body, in its assessment of the evidence submitted by the European Communities, appeared to be strict. In assessing the statement by Dr. Lucier, one of the experts advising the Panel, who estimated that one woman in a million would get breast cancer from eating meat containing oestrogens as a growth promoter if used as prescribed²⁵¹, the Appellate Body noted that "this opinion by Dr. Lucier does not purport to be the result of scientific studies carried out by him under his supervision focusing specifically on residues of hormones in meat from cattle fattened with such hormones".²⁵² Such a single divergent opinion would not be reasonably sufficient to overturn the contrary conclusions reached in the scientific studies referred to by the European Communities that related specifically to residues of the hormones in meat from cattle to which hormones had been administered for growth promotion.²⁵³ The specificity criterion was also used to dismiss other general studies regarding cancerous effects of hormones.²⁵⁴ In discussing studies regarding control problems, the Appellate Body noted that only one of the studies "systematically" discusses some of the problems, and while presenting

²⁴⁹Panel Report, *European Communities – Hormones*, para. 8. 117 (US) and para. 8. 120 (CAN).

²⁵⁰Appellate Body Report, *European Communities – Hormones*, para. 194.

²⁵¹See, Panel Report, *European Communities – Hormones*, paragraph 819 of the Annex to the US and Canada Panel Report.

²⁵²*Ibid.*, para. 198.

²⁵³*Ibid.*

²⁵⁴*Ibid.*, para. 199.

a theoretical framework for the systematic analysis, did not itself investigate and evaluate the actual problems.²⁵⁵

(ii) *Japan – Agricultural Products*

As regards plant health, the Appellate Body in *Japan – Agricultural Products*, affirmed the Panel's finding that "some data – taken from several individual studies – possibly hinting at relevant varietal differences are not enough, if such evidence does not make the actual causal link between the differences in the test results and the absence of varietal difference".²⁵⁶ The available evidence does not demonstrate that the varying responses are due to varietal differences, but could also have been caused by a series of other factors which are not related to varietal differences.²⁵⁷ Essentially, the Panel criticised that there was a lack of precise studies on this subject, but that such a specific research programme could relatively easily be made.²⁵⁸ In that case, the Panel heavily relied on the opinion of one of the experts, who stated:

"The argument put forth by Japan for requiring varietal trials are not based on scientific data. They are supported by a few experimental data in which varietal difference exists, in terms of LD50, among a lot of other data in which it does not. These observations lead them to suspect all existing varieties and even more so those of the future, in which, in their eyes, genetic engineering and biotechnology might well create even greater differences. This is not based on any scientific data."²⁵⁹

²⁵⁵Appellate Body Report, *European Communities – Hormones*, para. 107.

²⁵⁶Panel Report, *Japan – Agricultural Products*, para. 8. 24 and 8. 42.

²⁵⁷*Ibid.*, para. 8. 39.

²⁵⁸*Ibid.*, paras. 8. 40 and 8. 41.

²⁵⁹Panel Report, *Japan – Agricultural Products*, para. 8. 36.

Thus, a study is not sufficient, if it is not specific, systematic and the author has not, himself investigated the issue at hand, and if it is only based on few experimental data.

(iii) *Australia – Salmon 21.5*

Most recently, the Panel in *Australia – Salmon 21.5*, denied a "rational relationship" between the consumer-ready-requirement for salmon and the risk assessment, because the study concluded that other means, i.e., evisceration, etc., "would already significantly reduce risk" or only present a "negligible risk", and Australia had not indicated that it aims at a "zero-risk" approach, but at a "high or very conservative level of protection aimed at reducing risk to very low levels".²⁶⁰ Here, the Panel tied the defendant to its own study, thus leaving less wiggle room than provided for human health.

2. Literature: What does the "We know it when we see it test" Mean?

The rational relationship test has been heavily criticized as "we know it when we see it stance" and for abandoning the science requirement under the *SPS Agreement*.²⁶¹ Most comments focused on the issue of minority views.

In that respect, *MacNiel* raised the concern that the loose requirements for minority views would allow Members to "buy" scientific studies and it would be difficult to assess where a study is a "genuine divergent opinion or just a puppet".²⁶²

²⁶⁰Panel Report, *Australia – Salmon, 21.5*, paras. 7.134 and 7.137.

²⁶¹*Thomas*, above n.293, at 506. See also, *Hurst*, David R., "Hormones: European Communities – Measures Affecting Meat and Meat Products", *EJIL* Vol. 9 (1998), at 182.

²⁶²*McNiel*, Dale E., "The First Case under the WTO's Sanitary and Phytosanitary Agreement: The European Union's Hormone Ban", 39 *Virginia Journal of International Law*, (1998), pp. 89-134, at 134.

Walker alleviated such concerns by suggesting some criteria of how to discern "false science from true science".²⁶³ According to him, an indirect evidence is the existence of good faith disagreement among respected scientists that the alternative accounts are scientifically plausible.²⁶⁴ Analyzing the requirements set by the Appellate Body, *Pauwelyn* questioned whether "qualified and respected sources" means that an opinion coming from a retired scientist who could well have been paid to come to certain conclusions, or evidence backed up only by scientists employed by the government imposing the measure, would pass the science test.²⁶⁵ He distinguished between a 49 per cent minority and a 1 per cent minority and argued that the likelihood that a divergent view is found to be sufficient is higher, the bigger the minority.²⁶⁶ According to him, there might also be a difference between a low risk to human health (1 in every million dies) and a low risk to a plant or animal (1 in every million dies).²⁶⁷

Matsushita cautioned that there is no "abstract rule" to decide whether majority or minority views should be accepted, but that a set of factors, e.g., the craftsmanship of the report and the reputation of the research institute have to be taken into account and weighed together.²⁶⁸ He also indicated that in "life-threatening" situations, the opinion of "one scientists among many" could play an important role, while a "sharp division of views" might make the evidence

²⁶³*Walker*, Vern R., "Keeping the WTO from Becoming the „World Trans-science Organization“: Scientific Uncertainty, Science Policy, and Factfinding in the Growth Hormones Dispute", 31 *Cornell Int'l L. J.*, (1998), pp. 251-320, at 259.

²⁶⁴*Ibid.* He referred to *McLean v. Arkansas Board of Education*, where the District Court of Arkansas found that "science is what scientists do and what is accepted by the scientific community", 519 F.Supp. 1255 (E.D. Ark. 1982).

²⁶⁵*Pauwelyn*, Joost, "The WTO Experience Under the *SPS Agreement*", *World Trade Forum*, 2000, (forthcoming), pp. 95-108, at 100.

²⁶⁶*Ibid.*

²⁶⁷*Ibid.*

²⁶⁸*Matsushita*, Mitsuo, "WTO Perspective – The *SPS Agreement*", *World Trade Forum*, 2000 (forthcoming), pp. 109-120, at 117.

insufficient, and trigger a provisional measure under Article 5.7 of the *SPS Agreement*.²⁶⁹

3. Analysis: Still an "accordion like concept"

It appears that the "rational relationship" test is, as the "like" product criterion in Article III:4 of the GATT, an "accordion like concept". Two issues are of particular relevance for precautionary measures.

(a) Debunking the Myth of the Sound Science Standard

First, the Appellate Body has clarified that sufficient scientific evidence does not mean "sound scientific evidence" implying the preponderance of scientific thinking.²⁷⁰ A requirement where governments would have to wait until the majority of scientists agrees that a risk exists, would have seriously undermined the precautionary principle. However, other than alleged by critical voices in the literature, it is not the Appellate Body that has watered down the science test from "sound scientific evidence" to a rational relationship requirement. The ordinary meaning of "sufficient" itself suggests a broad and flexible interpretation of Article 2.2. This can be buttressed, in accordance with Article 32 of the *Vienna Convention*, by looking at the negotiating history of the *SPS Agreement*. While the initial proposals suggested rather strict requirements, e.g., "based on a sound scientific basis", "not against sound scientific evidence"²⁷¹ or "consistent with available scientific evidence"²⁷², the negotiators later used the term "not against scientific evidence", which was contained

²⁶⁹*Ibid.*, at 117 and 118.

²⁷⁰Stewart, Terence P. (ed.): *The World Trade Organization – The Multilateral Trade Framework for the 21st Century and U.S. Implementing Legislation* (Washington: American Bar Association, 1996), at 199.

²⁷¹Synoptic Table of Proposals Relating to Key Concepts, Note by the Secretariat, MTN.GNG/NG5/WGSP/W/17, 30 April 1990.

²⁷²Draft Text for the Framework of an Agreement on Sanitary and Phytosanitary Measures, NTN.GNG/NG5/WGSP/W/23, 28 June 1990.

in the Brussels and Dunkel Draft,²⁷³ before they adopted the final version "not maintained without sufficient scientific evidence".

- (b) Not Minority or Majority, but Quality and Quantity of the Evidence

Yet, after setting the "sound science" standard aside, the important question for precautionary measures is the minimum standard of "sufficient scientific evidence. When carefully looking at the case law of the Appellate Body, it appears that the distinction between minority and majority views is less important than the "quality and quantity" of the evidence.

First, the Appellate Body has required that such evidence comes from "qualified and respected sources, who have investigated the particular issue at hand". The use of the plural in "sources" could indicate that one opinion is not enough. While searching for criteria for what is a "qualified and respected" source, some scholars appear to have overseen the real yardstick used by the Appellate Body when determining whether scientific evidence is insufficient. As *Matsushita* pointed out, not the reputation of a scientist counts, but the craftsmanship of the report.

The Appellate Body scrutinises whether there is specific scientific evidence, derived from a systematic study, which is based on sufficient experimental data, that has been cross-checked so as to exclude wrong cause-and effect relationships. This appears to be in line with the text of Article 2.2, which requires *evidence* not *opinions*.

The term "specific" is not mentioned in the *SPS Agreement*. However, it can be derived from the ordinary meaning of Annex A.4, second sentence requiring "an evaluation of the potential for adverse *effects* on human or animal health *arising from* the presence of

²⁷³See, Draft Text on Sanitary and Phytosanitary Measures, MTN.GNG/NG5/WGSP/7, 20 November 1990 and *Stewart*, Terence P. (ed.), "The GATT Uruguay Round", Vol. IV: The End Game (Deventer and Boston: Kluwer Law and Taxation Publishers, 1993), at 229.

additives, contaminants, toxins or disease causing organisms *in food*, beverages or feedstuffs". This mandates a Member to specifically look at the possible adverse effects of an imported product before banning its importation. The use of a "specificity" requirement also reflects the purpose of the *SPS Agreement* which is to prevent countries from using "stone-wall strategies" by giving general "declarations" rather than "explanations" for their measures.²⁷⁴

4. Summary

The Appellate Body has interpreted the term "sufficient scientific evidence" by using a "rational relationship" test, which has been criticized as "we no it when we see it" stance. The analysis of the case law allows two conclusions which are relevant for precautionary measures. First, sufficient scientific evidence does not, as often stated, imply a "sound scientific evidence" requirement, but allows for the consideration of minority views. This leaves room for precautionary measures which are not based on the preponderance of scientific thinking. The hot debate about the requirements for minority views is overstated. The quantity and quality of the scientific evidence is what counts. The minimum standards for sufficient scientific evidence are that studies must be specific and systematic. They must come from qualified and respected sources, and be authored by scientists who have, themselves investigated the issue at hand. Moreover, few experimental data is not sufficient, in particular if it is not free of error.

C. ARTICLES 5.1, 5.2, 5.3 OF THE SPS AGREEMENT

This section examines the relevant conditions under the obligation to base a measure on a risk assessment.

Article 5 of the *SPS Agreement* provides in relevant part:

²⁷⁴Roberts, above n., at 402.

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

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

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

The *SPS Agreement* in Annex A.4 sets forth two technical definitions of risk assessment, which differ depending on whether a risk arises from diseases or pests, or a "food-borne" risk is at stake. Annex A.4 defines the term risk assessment as:

The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measure which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins

or disease-causing organisms in food, beverages or feedstuffs.

8. Notion of Risk Assessment

The notions of risk and risk assessment are very important for precautionary measures. The key legal questions are, whether consumer concerns can be the sole or at least one of the factors to be taken into account in the risk assessment, and whether there is a differing threshold of risk for food-borne risks and pest and disease-related risks. The Appellate Body has interpreted the notion of "risk assessment" with respect to "food-borne" risks in *European Communities – Hormones*. In *Australia – Salmon*, it addressed the requirement for pest-and disease related risks.

(a) Food-Borne Risks

The requirements for food-borne risks, as spelled out under Annex A.3, second sentence were only addressed in *European Communities – Hormones*.

(i) WTO Jurisdiction: *European Communities - Hormones*

As regards the general notion of risk assessment, the Panel adopted a narrow interpretation of risk assessment by characterizing it as "*scientific* process aimed at establishing the *scientific* basis for the sanitary measure a Member intends to take", and distinguished it from a "non-scientific" policy exercise involving social value judgements made by political bodies" and the term "risk management".²⁷⁵ Consumer preferences and difficulties of control, could not be factors in a risk assessment exercise.²⁷⁶

By contrast, the Appellate Body adopted a much broader notion of risk assessment, i.e., "a process characterized by systematic, disciplined and objective enquiry and analysis, that is, a mode of

²⁷⁵Panel Reports, *European Communities – Hormones*, paras. 8.94 and 8.107 (US) and paras. 8.97. and 8.110 (CAN),

²⁷⁶Panel Reports, *European Communities – Hormones*, para. 105 (US) and para. 8.108 (CAN).

studying and sorting out facts and opinions".²⁷⁷ According to the Appellate Body, the list of factors to be taken into account, as laid down in Article 5.2 of the *SPS Agreement*, is not exhaustive. Thus, control risks, i.e., "risks arising from failure to comply with the requirements of good veterinary practice in the administration of hormones for growth promotion purposes, as well as risks arising from the difficulties of control, inspection and enforcement of the requirements of good veterinary practice" could be taken into account in a risk assessment.²⁷⁸ However, whether such examination of risks arising from possible abuse is necessary or proprietary would be assessed on a case-by-case basis.²⁷⁹

While, thus, acknowledging that control factors can be taken into account in the risk assessment, the Appellate Body has not explicitly addressed the role of consumer preferences.²⁸⁰ However, the Appellate Body emphasized that it:

is essential to bear in mind that the risk that is to be evaluated in a risk assessment of 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.²⁸¹

As regards the minimum requirements for a risk assessment of food-borne risks, the Panel in *European Communities – Hormones* interpreted Annex A.4, second sentence to prescribe a two-step process, whereby it "should (i) identify the adverse effects on human health (if any) arising from the presence of the hormones at issue

²⁷⁷Appellate Body Report, *European Communities – Hormones*, para. 187.

²⁷⁸*Ibid.*, para. 206.

²⁷⁹*Ibid.*

²⁸⁰Panel Reports, *European Communities – Hormones*, para. 105 (US) and para. 8. 108 (CAN).

²⁸¹*Ibid.*

when used as growth promoters in meat (ii) if any such adverse effects exist, evaluate the potential or probability of occurrence of such effects."²⁸²

The Appellate Body wiped out the term "probability" because it would imply a higher degree or a threshold of potentiality or possibility, and, thus, introduce a "quantitative dimension" to the notion of risk.²⁸³ Article 5.1, according to the Appellate Body, does not require to establish a "minimum magnitude of risk" or the exercise of a "quantitative risk assessment".²⁸⁴ The Appellate Body specified that a risk must be "ascertainable"²⁸⁵ as opposed to "theoretical uncertainty" which "always remains since science can *never* provide *absolute* certainty that a given substance will not *ever* have adverse effects".²⁸⁶

In the examination of the risk assessment provided by the European Communities, the Appellate Body reiterated the "specificity" requirement. The Appellate Body also clarified that the general risk arising from the inability of studies to prove beyond doubt that hormones present no risk whatsoever, would not be sufficient as risk assessment, since, as noted by the scientists advising the Panel: "science can never provide a certainty, i.e., exclude once and for all that a specific substance can ever have adverse health effects."²⁸⁷

(ii) *Literature*

The interpretation of the risk assessment requirement by the Appellate Body in *European Communities – Hormones* has given rise to a controversial debate in the literature.

²⁸²Panel Reports, *European Communities - Hormones*, para. 8.98 (US) and para. 8. 101 (CAN).

²⁸³Appellate Body Report, *European Communities - Hormones*, para. 184.

²⁸⁴*Ibid.* para. 186.

²⁸⁵*Ibid.*

²⁸⁶*Ibid.*

The statement that risks of the real world, where people live and work and die has given rise to considerable criticism. In particular *Quick/Blüthner* have criticised the "unnecessarily broad interpretation of risk assessment".²⁸⁸ The possibility of taking account other factors than science would water down the science test, and is, thus, incompatible with the text of the *SPS Agreement*, in particular Article 2.2, which requires that measures be based on sufficient scientific evidence.²⁸⁹ Also the negotiating history shows that the drafters required scientific justification.²⁹⁰ At best, the Appellate Body created considerable uncertainty, whether one could go as far as saying that those factors could be considered even if there was not scientific evidence.²⁹¹ This criticism was shared by other commentators, in particular *MacNiel* and *Maruyama*, who all demanded that science should be the sole criterion in appraising sanitary and phytosanitary measures and that the reference to bald consumer anxieties should not be relevant.²⁹² *Thomas* pointed out that the low threshold of risk would support the adoption of a precautionary measures in the face on any amount of risk.²⁹³ Thus, even, the BSE measure would pass the science test of Article 5.1 of the *SPS Agreement*.²⁹⁴

²⁸⁷Panel Report, *European Communities - Hormones* paras. 8. 149-5.152 (US) and paras. 8. 152-8. 155 (CAN).

²⁸⁸*Quick*, Reinhard/ *Blüthner*, Andreas: Has the Appellate Body Erred? An Appraisal and Criticism of the Ruling in the WTO Hormones Case, 2 JIEL 1999, pp. 603-639, at 618.

²⁸⁹*Ibid.*

²⁹⁰*Ibid.*

²⁹¹*Ibid.*

²⁹²*MacNiel*, Dale E., "The First Case under the WTO's Sanitary and Phytosanitary Agreement: The European Union's Hormone Ban", 39 Virginia Journal of International Law, (1998), pp. 89-134 and *Maruyama*, Warren H., "A New Pillar of the WTO: Sound Science", 32 The International Lawyer, (1998), pp. 651-677, at 672. *Carter*, Michele D., "Selling Science under the *SPS Agreement*: Accommodating Consumer Preference in the Growth Hormones Controversy", 6 Minn. J. Global Trade, 1997, pp. 626-656, at 655.

²⁹³*Thomas*, Ryan David, "Where's the Beef? Mad Cows and the Blight of the SPS Agreement", 32 Vand. J. Transnat'l L. 487 (1999), at 497.

²⁹⁴*Ibid.*

A second strand of comments welcomed the broad interpretation of the science test, because the Appellate Body acknowledges that societal values do already influence the exercise of the risk assessment.²⁹⁵ *Atik* remarked that the broad definition of risk assessment leaves room for consideration of different scientific cultures and approaches which vary significantly between the continents.²⁹⁶ However, in particular, *Walker*, in his very thorough analysis of *European Communities – Hormones*, raised the concern that the specificity requirement would be too strict, i.e., *de facto* making almost any sanitary measure a precautionary measure, because it cannot be supported by sufficient data.²⁹⁷ *Walker* also pointed out that most risk assessments, due to the presence of scientific uncertainty, are not purely scientific, but are based on science policies in order to complete risk assessments.²⁹⁸

(iii) *Analysis: No consumer threshold*

Despite the poetic sentence about the "real world in which people live and work and die", the Appellate Body has not acknowledged a "consumer threshold", whereby consumer perceptions of risks which are not founded on scientific evidence can be the sole basis of a risk assessment. Such an interpretation of Articles 5.1 and 5.2 could, indeed, not be squared with the ordinary meaning of Article 5.2, which requires Members to take into account available scientific evidence, but does not cite to consumer tastes and preferences. However, at the same time, Article 5.2 is not framed as a closed list. Also, the definition of risk assessment in Annex A.4 does not further define the factors to be taken into account. This supports a broad

²⁹⁵*Hughes*, Layla, "Limiting the Jurisdiction of Dispute Settlement Panels: The WTO Appellate Body Beef Hormone Decision", 10 *Georgetown Int'l Env'tl. L. Rev.* (1998), at 929.

²⁹⁶*Atik*, Jefferey, "Science and International Regulatory Convergence", 17 *Nw. J. Int'l L. & Bus.* 736, at 739.

²⁹⁷*Walker*, Vern R.: Keeping the WTO from Becoming the "World Trans-science Organization": Scientific Uncertainty, Science Policy, and Fact-finding in the Growth Hormones Dispute, *Cornell Int'l L. J.*, Vol. 31 (1998), 251-320, at 300.

²⁹⁸*Ibid.*, at 304.

reading of Article 5.2 in that sense, that consumer concerns and other factors can be taken into account *together* with available scientific evidence. In fact, the role of "consumer preferences" or "cultural factors" was heavily debated in the negotiations with some Members wishing to explicitly mentioning them in the *SPS Agreement*.²⁹⁹ Albeit not being expressly mentioned in Article 5.2 as a factor which alone can support the existence of a risk, the wording of that provision, as read in context, does not exclude their consideration *together* with available scientific evidence. Any other reading of Article 5.2 would be unrealistic, because democratic governments commonly respond to consumer concerns. The notion of "real world" risks of the Appellate Body coins this reality and allows, in line with the text of Articles 5.1 and 5.2, that governments, in their risk assessment take account of social values and consumer concerns. Thus, precautionary measures, in particular the biotechnology and hormones cases would not be incompatible with WTO law just because there is a pinch of consumer concerns in the risk assessment.

(b) Pest-and-disease Related Risks

The requirements for pest-and-disease related risks, as spelled out under Annex A.3, second sentence were addressed in *Australia – Salmon* and *Japan – Agricultural Products*.

(i) *WTO Jurisdiction: Australia – Salmon*

With respect to pest- and disease related risks, the Appellate Body, in *Australia – Salmon*, set out a three-pronged test, whereby a risk assessment must:

- (1) *identify* the diseases whose entry, establishment or spread a Member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these diseases;

²⁹⁹*Breen*, above n., at 199.

(2) *evaluate the likelihood* of entry, establishment or spread of these diseases, as well as the associated potential biological and economic consequences; and

(3) evaluate the likelihood of entry, establishment or spread of these diseases *according to the SPS measures which might be applied*.³⁰⁰

aa) "Likelihood" means "Probability"

The Appellate Body emphasized that the first type of risk assessment in paragraph 4 of Annex A is substantially different from the second type of risk assessment in the same paragraph. While the second sentence of Annex A.4 requires only the evaluation of the potential for adverse effects on human or animal health, the first type of risk assessment demands an evaluation of the "likelihood" of entry, establishment or spread of a disease, and of the associated potential biological and economic consequences.³⁰¹

The Appellate Body stressed that it is not sufficient if a risk assessment for pest-and disease-related risks concludes that there is a possibility of entry, establishment or spread of diseases and associated biological and economic consequences. A proper risk assessment must evaluate the likelihood, i.e., "probability" of such risk occurring.³⁰² Thus, it drew a clear distinction between a threshold of probability and a mere possibility.

However, at the same time, the Appellate Body stressed, as before in *European Communities – Hormones*, that "likelihood" may be expressed either quantitatively or qualitatively and that there is "no requirement for a risk assessment to establish a certain magnitude or threshold level of degree of risk."³⁰³ The notion of risk under this

³⁰⁰ Appellate Body Report, *Australia – Salmon*, para. 122.

³⁰¹ *Ibid.*, para. 123.

³⁰² *Ibid.*

³⁰³ *Ibid.*, para. 124.

second form of risk assessment is the same. Referring to *European Communities – Hormones*, the Appellate Body held:

the "risk" evaluated in a risk assessment must be an ascertainable risk; theoretical uncertainty is "not the kind of risk which, under Article 5.1 is to be assessed." This does not mean, however, that a Member cannot determine its own appropriate level of protection to be zero risk.³⁰⁴

The Panel in *Australia – Salmon* equated "theoretical uncertainty" with the "*possibility* of an adverse event occurring, however remote, associated with most (if not all) imports".³⁰⁵

bb) To "Evaluate": The Degree of Specificity and Objectivity

As regards the notion of evaluation, the Appellate Body did not "agree with the Panel that a risk assessment of this type needs only *some* evaluation of the likelihood or probability".³⁰⁶ While these criteria do not clearly indicate, which degrees of scientific uncertainty would fall under Article 5.1 and which not, the requirement that risks be assessed "on a disease specific basis", i.e., the "risk for any given disease of concern [must be evaluated] separately" gives clearer indications. An assessment of the "overall risk" or "some evaluation of the likelihood is not enough".³⁰⁷

As regards the degree of specificity required some guidance can be gleaned from the assessment of the Australian study regarding risks of diseases associated with imports of salmon.

In *Australia – Salmon*, the Appellate Body was not satisfied with a study that "lends more weight to the unknown and uncertain elements of the assessment", and results in "general and vague

³⁰⁴*Ibid.*, para. 125.

³⁰⁵Panel Report, *Australia – Salmon*, para. 8.81

³⁰⁶Appellate Body Report, *Australia – Salmon*, para. 124.

³⁰⁷*Ibid.*, para. 128. Panel Report, *Australia – Salmon*, para. 8.74.

statements of mere possibility". This would neither be a quantitative nor a qualitative assessment of probability."³⁰⁸ To support that "unknown and uncertain elements" in a study do not fulfill the requirements of Articles 5.1, it cited to the obligation under Article 5.2 to take into account "available scientific evidence" and the requirement in Article 2.2, according to which measures shall not be maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5".³⁰⁹ This suggests that measures, where risk assessments entail "unknown" and uncertain elements" would not meet the obligation under Article 5.1 of the *SPS Agreement*.

However, in *Australia – Salmon*, 21.5 where the Panel looked at the revised version of the Australian risk assessment, it elaborated on the threshold of an evaluation of likelihood consistent with the *SPS Agreement*. It noted that paragraph 4 of Annex A does not set out "specific requirements such that minor flaws or misconceptions at a detailed level would preclude a study from falling within the SPS definition of risk assessment."³¹⁰ Some degree of subjectivity must be allowed, and only where studies are "flawed or biased to such extent that they cannot be said to meet any standard of objectivity" they would be at odds with the risk assessment requirement.³¹¹ Thus, the Panel advocated a reasonableness test:

We hold the view that the level of objectivity to be achieved in a risk assessment must be such that one can have *reasonable* confidence in the evaluation made, in particular in the levels of risk assigned.

Reviewing the Australian measure it concluded that "the flaws identified are not so serious as to prevent us from having reasonable

³⁰⁸Appellate Body Report, *Australia – Salmon*, para. 129 citing to Panel Report, para. 8. 83.

³⁰⁹Appellate Body Report, *Australia – Salmon*, para. 130.

³¹⁰Panel Report, *Australia – Salmon*, 21.5., para. 7.47.

³¹¹*Ibid.*

confidence in the evaluation made and the levels of risk assigned."³¹² The Panel in *Australia – Salmon*, 21.5, also held that the obligation to assess the risk "according to the measure applied" does not "include the obligation to make the link between the assessment, the measures finally selected and the necessity to use these measures."³¹³

(ii) *Literature: Legal Uncertainty*

The more recent literature which takes account of *Australia – Salmon* and *Japan – Agricultural Products* unanimously criticizes that the conditions set forth by the Appellate Body are contradicting.³¹⁴ More specifically, they criticize that, on the one hand, the Appellate Body uses the concept of "ascertainable risks" versus "theoretical uncertainty" and also distinguishes between the requirement for a "possibility" and "probability" of a risk which needs to be assessed. On the other hand, however, in all three decisions the Appellate Body reiterated that the *SPS Agreement* does not prescribe a minimum magnitude of risk.

(iii) *Analysis: How Much Risk Must be Shown?*

The case law of the Appellate Body is sybilline. The following analysis might not fully resolve the paradoxon, but wishes to make two points.

aa) "Ascertainable" Risks

First, the Appellate Body spawned the bow between "ascertainable risks" on the one hand and "theoretical uncertainty" on the other. What exactly does theoretical risk mean, and where runs the line between "ascertainable risk" which can form the basis of a sanitary or phytosanitary measure, and a "theoretical risk", which can

³¹²*Ibid.*, para. 7.57.

³¹³Panel Report, *Australia – Salmon*, 21.5, para. 7.68.

³¹⁴See, *Eggers/Mackenzie*, at 537; *Trebilcock*, Michael, "International Trade Policy and Domestic Food Safety Regulation: The Case for Substantial Deference by the WTO Dispute Settlement Body under the *SPS Agreement*", Minnesota Conference, 15-16 September 2000.

not be pursued under the *SPS Agreement*? The term ascertainable has not been further defined. It refers to something "that may be ascertained", while to ascertain means "to find out or learn for a certainty; to make sure of, get to know".³¹⁵ *A contrario*, a theoretical risk would be a suspicion, which is not subject to scientific enquiry, and could not be verified or falsified. The definition given by the Panel in *Australia – Salmon*, whereby theoretical risk is a "*possibility* of an adverse event occurring, however remote, associated with most (if not all) imports"³¹⁶, would have been more restrictive on precautionary measures, because it assumes that zero risks from imports is not possible, and that some risks must always be accepted. The Appellate Body appears to have dismissed this notion of a minimum risk when noting that one must distinguish carefully between the right of a Member to choose "zero" risk as the appropriate level of protection and going on to analyze whether Australia had met the requirements for a risk assessment as set forth in Annex A4. The notion of ascertainable risk versus theoretical risk, appears to mark the outer limit of when a Member can take a precautionary measure. This allows sufficient room for the distinctions drawn by some precautionary principles between, e.g., a remote risk and a risk beyond practical reasoning.

bb) Minimum Threshold for Human Health and Animal or Plant Life or Health?

The second issue is the paradoxon, that Annex A.3 indicates differing thresholds of risk ("likelihood" versus "potential") to be met, which have been interpreted by the Appellate Body as requiring a "probability" versus "possibility", while at the same time the Appellate Body stressed with respect to both issues that no minimum magnitude of risk is required. Would this mean that Members are free to decide that a risk of 1 butterfly in a million dying is as valid a risk

³¹⁵ *Onions*, C.T. (ed.), "The Shorter Oxford English Dictionary on Historical Principles", Volume I, A-M (Oxford: Clarendon Press, 1967), at 105.

³¹⁶ Panel Report, *Australia – Salmon*, para. 8.81

as that of one woman dying from breast-cancer, or is there a difference?

When reading Annex A.3 contextually with the definition of the appropriate level of risk in Annex 5, which is also defined as "acceptable level of risk" deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health, one could argue, that the obligation to evaluate the potential and likelihood of a risk is purely process-oriented. Thus, Panels are only called upon to examine whether Members carried out a risk assessment following these requirements that a "potential" respectively "likelihood" of adverse effects must be identified. However, panels would not second-guess the outcome of the evaluation that certain evidence and studies indicate a "potential" or "likelihood" of risk. Otherwise Members would no longer be free to choose a very low level of risk as appropriate level of protection.

This would square with the reasonable-confidence test employed in *Australia – Salmon 21.5*, where the Panel only examined whether the risk assessment reasonably evaluated the potential for adverse effects.

As regards the differences between human health and animal or plant life or health, one could argue that the requirements for studies, data, et.c., which support the existence of risk are lower for human health. Thus, in the case of hormones less scientific evidence can fulfil the conditions for a risk assessment than in the case of GMOs which might have long-term adverse effects on biodiversity.

In short, Annex A.4 rather than prescribing a certain result of a risk assessment, obligates governments to follow a certain process when assessing risks.

9. "Based On": A Procedural Requirement?

As noted above, the Appellate Body has interpreted the term "based on" so as to require a "rational relationship" between the measure and the risk assessment". The case law regarding the rational relationship test and its consequences for precautionary measures has been analyzed above and shall not be repeated here. Yet, in *European Communities – Hormones*, a further question arose, which has triggered considerable discussion. This is whether, in addition to the substantive requirement of a rational relationship between the measure and the risk assessment, the notion of "based on" under Article 5.1 of the *SPS Agreement* entails a procedural requirement allowing Panels to scrutinize whether the Member took the scientific risk assessment into account before enacting the measure. The question, whether governments need to show that they took into account a risk assessment, affects precautionary measures in two ways. First, most of the "old", i.e., pre-Uruguay Round measures do not refer to scientific risk assessments in their Preamble. Second, in the area of precaution, science is evolving. Thus, often science is changing with the effect that the risk assessment on which governments relied when taking a measure might be out of date at the time of the panel proceedings.

(a) WTO Jurisdiction: Against Procedural Requirement

The Panel in *European Communities – Hormones*, indeed interpreted the term "based on" so as to entail a minimum procedural requirement, whereby a Member would have to submit evidence that "at least it actually took into account a risk assessment when it enacted or maintained its sanitary measure in order for that measure to be considered as based on a risk assessment."³¹⁷ Absent any evidence submitted by the European Communities on that subject, the Panel scrutinized the Preamble of the EC Directives whether they mention

³¹⁷Panel Report, *European Communities – Hormones*, (CAN), para. 8. 116.

these scientific studies.³¹⁸ With respect to the "new evidence" which was put forward by the European Communities during the Panel process, the Panel did not exclude its relevance. However, it required some evidence that the competent institutions actually considered these articles and opinions or re-examined the potential risks related to the specific substances at issue in light of these articles and opinions.³¹⁹

The Appellate Body dismissed the procedural requirement, because it is not rooted in the text of Article 5.1 of the *SPS Agreement*.³²⁰ According to the Appellate Body, the text would call for an objective relationship between an SPS measure and a risk assessment.³²¹ Other than the more subjective procedural requirement, such test would allow the consideration of new scientific evidence, which was particularly important for the large group of "old" SPS measures that were adopted before the entry into force of the *SPS Agreement*.³²²

(b) Literature: Demanding a procedural requirement

This decision of the Appellate Body has been severely criticised in the literature. According to *Hurst*, only the procedural requirement proposed by the Panel in *European Communities – Hormones*, would force governments to actually take into account scientific evidence.³²³ Similarly, *MacNiel* argued in favour of a procedural requirement.³²⁴

³¹⁸*Ibid.*, para. 8. 117.

³¹⁹*Ibid.*, para. 8. 118.

³²⁰Appellate Body Report, *European Communities – Hormones*, para. 189.

³²¹*Ibid.*, para. 189.

³²²*Ibid.*, para. 190.

³²³*Hurst*, David R., *Hormones: European Communities – Measures Affecting Meat and Meat Products*, *EJIL* Vol. 9 (1998), at 182.

³²⁴*MacNiel*, Dale E.: The First Case under the WTO's Sanitary and Phytosanitary Agreement: The European Union's Hormone Ban, *Virginia Journal of International Law*, Vol. 39, No. 1, 1998, pp. 89-134, at 129.

(c) Analysis: Not practical because science is involving

The procedural requirement only seems to provide an easy litmus test at first glance. Even, if one puts the problem of "old measures" apart, and takes into account that, as illustrated by the *Hormones II* hypothetical, a recent trend in precautionary measures indicates that governments do refer to certain studies and recommendations of scientific experts in the Preambles to their measures, the problem remains that science is never static. In particular, if a Member enacts a measure, which is then challenged by another Member, it might update its scientific record. The word "based on" in Article 5.1 of the *SPS Agreement*, when read together with Article 2.2 of the *SPS Agreement*, which requires that a measure not be maintained without sufficient scientific evidence, clearly indicates that negotiators wanted to include a substantive requirement to ensure that a measure is not taken without sufficient scientific evidence.

A formalistic application of a procedural requirement could result in a situation where a Member did not have sufficient science when taking the measure, but got such reports during the panel proceedings, and can show, that there is a real risk. If the Panel and the Appellate Body would be forced to dismiss a measure on that ground, unnecessary DSU Article 21.5 proceedings would be triggered, where the Member would then present exactly the same scientific evidence as implementation measure. It appears that this is not the purpose of the WTO dispute settlement proceedings, which aim at securing a positive solution to a dispute.³²⁵ At the same time the indicative effect of compliance with a procedural obligation to take into account scientific evidence is negligible. It is relatively easy to refer to scientific reports in the Preamble to a measure. But this does not absolve Panels from the duty of scrutinizing whether a measure was substantively based on such risk assessments.

³²⁵DSU, Article 3.7, second sentence.

10. Summary:

The "based on" requirement, as spelled out in Article 5.1 of the *SPS Agreement* only sets forth a substantive obligations that there be a rational relationship between the measure and the risk assessment. However, it does not include a "procedural requirement" whereby the Member must show that it has actually taken into account the risk assessment.

C. CONCLUSIONS AND APPLICATION TO PRECAUTIONARY MEASURES

When playing through the hypotheticals, it appears that most of the precautionary measures run the risk of not meeting the requirements set forth by Articles 2.2 and 5.1 of the *SPS Agreement*, in particular, the condition that there must be sufficiently specific scientific evidence. The moratorium on imports of GMOs is based on one study which does not specifically scrutinize the effects of all GMO imports on human health.³²⁶ As regards the long-term ban of GM seeds from the center of genetic diversity, it appears that there is only few experimental data supporting long-term risks. To date, the Appellate Body has not used the obligation under Article 5.3 of the *SPS Agreement* to take into considerations the cost-effectiveness of alternative measures when appraising a risk. One might argue that there are other cost-effective measures than an import ban, e.g., monitoring, or the prohibition of field test in centres of genetic diversity as opposed to agricultural land. Thus, while a Panel would probably not rule that a risk of one butterfly in a million dying might not be enough, it might find that this risk could be significantly reduced by separating GM crops from areas where these butterflies occur.

A lack of experimental data also existed, when the BSE emergency measures were taken, and in the "red moth" hypo, where

³²⁶The US have already raised the argument that the *Cartagena Protocol on Biosafety* does not identify "specific risks". See, Committee on Sanitary and Phytosanitary Measures, Minutes of the Meeting of August 1998, G/SPS/R/11.

only a hypothesis existed, which has not yet been further tested against possible other factors. More difficult to appraise are the antibiotics cases. On the one hand, only general studies exist with respect to the surging antimicrobial resistance of humans. Specific studies have shown that bacteria might develop resistances in animals treated with antibiotics. However, the link between a specific antibiotic and a human disease has not been shown by specific studies, but could never be shown. When determining whether sufficient scientific evidence exists, the Appellate Body mandates Panels to bear in mind that Article 5.7 still exists. Thus, where it is possible to obtain more data, e.g. in the BSE cases, or GMOs, governments can fare well by taking a provisional measure. However, in cases such as the antibiotics situation, where a certain situation has been researched for many years, but scientists have reached a limit in showing a certain cause and effect relationship, the road via Article 5.7 might be a blind alley. As regards the Hormones II measure, the Article 21.5 proceedings might find that sufficient scientific evidence and a risk assessment exists with respect to the ban on oestradiol 17 β , if the evidence is indeed sufficiently specific and free of errors so as to stand against the existing body of scientific evidence which concludes that the administration of hormones is safe when following a good husbandry practice. The fact that the European Communities have based their implementation measure with respect to the five remaining hormones on Article 5.7 by only prohibiting them provisionally illustrates the relevance of the exemption for precautionary measures. Indeed, all of the seven hypotheticals (apart from the oestradiol 17 β ban) might have to be resolved under Article 5.7 of the *SPS Agreement*.

III. ARTICLE 5.7 OF THE *SPS AGREEMENT*

At first glance, Article 5.7 of the *SPS Agreement* looks like one of the many escape clauses in WTO law which permit Members

to deviate from their substantive obligations to safeguard certain economic or non-economic interests. Article 5.7 provides in full:

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

Provisional measures are also known under, e.g., the *Agreement on Safeguards*³²⁷, or the *Agreement on the Implementation of Article VI of the General Agreement on Tariffs and Trade 1994* (the "*Anti-Dumping Agreement*")³²⁸. However, they specifically deal with safeguards taken to protect the domestic economy from fair or unfair trade practices, but not, as Article 5.7 of the *SPS Agreement* for non-economic reasons of human, animal or plant life or health.³²⁹ Moreover, they generally assume that the final determination of injury or dumping can be made within a few months, while Article 5.7 of the *SPS Agreement* specifically deals with scientific uncertainty which might be insufficient for a longer period of time.

In international trade discussions, Article 5.7 is discussed controversially. Some view Article 5.7 as a "potential loophole" for measures which are not taken to prevent real risks.³³⁰ Consumer

³²⁷*Agreement on Safeguards*, Article 6.

³²⁸*Anti-Dumping Agreement*, Article 7.

³²⁹This difference had been noted by *Jansen, Bernhard/Lugard*, Maurits: Some Considerations on Trade Barriers erected for non-economic reasons and WTO obligations, 2 JIEL (1999), pp. 530-536.

³³⁰See, e.g., Senator *John Ashcroft* of Missouri in his letter of 19 April 2000, available at <http://www.insidetrade.com> (visited 2 June 2000).

groups and environmental NGOs, are concerned that Article 5.7 does not cover the whole range of precautionary measures, in particular measures affecting biotechnology products, where long term risks are at stake.³³¹ Their stumbling block is the requirement that measures can only be adopted "provisionally" and they demand that the Agreement be amended to incorporate the precautionary principle.³³²

The case law regarding Article 5.7 is still in its infancy. This warrants a thorough analysis of its conditions.

The following sections first discuss the legal nature of Article 5.7, and then go step by step through its requirements.

A. THE LEGAL NATURE OF ARTICLE 5.7: EXEMPTION, EXCEPTION OR AUTONOMOUS RIGHT?

Traditionally, exceptions for non-economic interests, e.g., Article XX of the GATT are "limited and conditional exceptions from the substantive obligations contained in the other provisions of the GATT 1994, not positive rules establishing obligations in themselves".³³³ Article 5.7 of the *SPS Agreement*, is not, as Article XX of the GATT 1994, titled "exception". When Article 5.7 was first invoked in *Japan – Agricultural Products*, it has been called

³³¹See Transatlantic Consumer Dialogue Recommendations on Food, Electronic Commerce and Trade and European Commission Services" Responses, Brussels Meeting, 23-24 April 1999, at 18, demanding that the word "provisional" be deleted. See also, World Wildlife Foundation, A Reform Agenda for the WTO Seattle Ministerial Conference (1999).

³³²*Ibid.*

³³³Appellate Body Report, *United States – Shirts and Blouses*, pp. 15-16 and *United States – Shrimp*, para. 157. See also Report of the Panel in *United States – Section 337 of the United States Tariff Act of 1930* ("*United States – Section 337*"), adopted 7 November 1989, BISD 365/345, para. 5.9.

an "exemption from the obligation in Article 2.2"³³⁴, "an exception"³³⁵ and a "derogation".³³⁶

1. WTO Jurisdiction: "*Qualified Exemption*"

The Appellate Body, in *Japan – Agricultural Products*, held: "Article 5.7 operates as a *qualified* exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence. An overly broad and flexible interpretation of that obligation would render Article 5.7 meaningless."³³⁷ The Appellate Body has not further elaborated the legal concept "qualified exemption". However, it appears that the choice of the term exemption instead of exception is deliberate, and that the Appellate Body has overruled the statement of the Panel in *Australia – Salmon* which characterized Article 5.7 as "an exception to the obligation to base sanitary measures on a risk assessment".³³⁸ Article 5.7 has not been used as a defence in the strict sense, i.e., a defence which can only be considered by the Panel if invoked by the defendant. In *Australia – Salmon*, the Panel noted that Australia had not invoked 5.7, neither did the Panel find the provision applicable.³³⁹ Only where a Member explicitly refuses to rely on Article 5.7, as the European Communities in the hormones case, the Panels would not consider it.³⁴⁰

2. Literature: From exception to autonomous right

Pauwelyn regards Article 5.7 as an exception to be invoked by the defendant and for which the defendant bears the burden of

³³⁴Appellate Body Report, *Japan – Agricultural Products*, para. 11.

³³⁵*Ibid.*, para. 57.

³³⁶*Communication*, para. 4.

³³⁷Appellate Body Report, *Japan – Agricultural Products*, para. 80.

³³⁸Panel Report, *Australia – Salmon*, para. 8.57.

³³⁹*Ibid.*

³⁴⁰Panel Report, *European Communities – Hormones*, paras. 8. 157 and 8. 158 (US) and paras. 8. 160 and 8. 161 (CAN).

proof.³⁴¹ Exceptions are affirmative defences with the consequence that the burden of establishing the defence rests on the party asserting it and that they are generally interpreted narrowly.³⁴²

Mackenzie and myself pointed to the parallels between Articles 5.7 and Article 3.3 of the *SPS Agreement*, which had been interpreted as an "autonomous right".³⁴³ The concept of autonomous rights is not explicitly mentioned in any of the WTO agreements, but was developed by the Appellate Body in *European Communities – Hormones* to distinguish Article 3.3 from exceptions. The Appellate Body held: "Article 3.1 of the *SPS Agreement* simply excludes from its scope of application the kinds of situations covered by Article 3.3 of that Agreement, that is, where a Member has projected for itself a higher level of sanitary protection than would be achieved by a measure based on an international standard."³⁴⁴ The practical consequence of declaring a provision as autonomous right is that the burden of proof does not shift and the interpretation of the treaty provision is not "stricter" or "narrower" than would be warranted by the application of normal rules of treaty interpretation.³⁴⁵

3. Analysis: The hermaphroditic nature of Article 5.7

By calling Article 5.7 of the *SPS Agreement* a "qualified exemption", the Appellate Body has, again, created a term that transgresses the traditional distinction between substantive obligations and exceptions. In *United States – Shirts and Blouses* the Appellate Body argued that Article 6.2 of the *Agreement on Textiles*, a transitional safeguard³⁴⁶, cannot be an exception, because that would

³⁴¹*Pauwelyn*, above n. 143, at 660.

³⁴²Appellate Body Report, *United States – Shirts and Blouses*, pp. 15-16.

³⁴³*Eggers/Mackenzie*, above n. 10, at 538.

³⁴⁴Appellate Body Report, *European Communities - Hormones*, para. 104.

³⁴⁵Appellate Body Report, *European Communities – Hormones*, para. 104 referring to *United States – Shirts and Blouses*, p. 14.

³⁴⁶ATC, Article 2.4 provides that no "new restrictions in terms of products shall be introduced except under the provisions of this Agreement". Article 6 then

not "appropriately grasp the finely tuned balance between rights and obligations".³⁴⁷

(a) No Exception

As indicated in *European Communities - Hormones*, the far reaching consequences of exceptions cannot be lightly assumed. Other than Article XX of the GATT, Article 5.7 is not titled as exception. An important argument for Article 5.7 being an exception is the phrase "*except* as provided for in para 7 of Article 5" in Article 2.2 of the *SPS Agreement*. However, Article 3.1 of the *SPS Agreement* uses the same semantic structure, by obliging Members to base their measures on international standards, "*except* as otherwise provided ... in paragraph 3", and this was not regarded as sufficient textual basis, by the Appellate Body, to call Article 3.3 an exception. The explicit use of the term "exception" in other new Uruguay Round Agreements, e.g., the *TRIPS Agreement*³⁴⁸, suggests that where Members do not use it, they did not want to create the legal effects of an exception. Finally, the fact that, according to Article 2.4 of the *SPS Agreement*, measures which comply with the provisions of the *SPS Agreement* are presumed to be in accordance with Article XX(b) of the GATT 1994, indicates that Article 5.7 transgresses the traditional distinction between substantive obligations and exceptions. Thus, the creation of a new legal term appears to be well founded in the ordinary meaning, context and purpose of the *SPS Agreement*.

allows for a specific transitional safeguard mechanism, whereby "safeguard action may be taken under this Article when, on the basis of a determination by a Member, it is demonstrated that a particular product is being imported into its territory in such increased quantities as to cause serious damage or actual threat thereof, to the domestic industry".

³⁴⁷*United States – Measures Affecting Imports of Woven Wool Shirts and Blouses from India*, ("United States - Shirts and Blouses") WT/DS33/AB/R, adopted 23 May 1997, para. 4.13.

³⁴⁸The following Articles in WTO agreements are titled as "exception": Articles XIV, XIV bis and XXI of the GATT 1994, Article 3 *TRIMS Agreement*, Article XIV of the GATS and Articles 13, 17, 30, 37 of the *TRIPS Agreement*. The notion of limited exception was further elaborated by the Panel in *Canada – Patent Protection of Pharmaceutical Products* ("Canada – Pharmaceutical Patents"), WT/DS114/R, adopted 7 April 2000, paras. 7.18 – 7.30.

(b) No "autonomous right"?

Some parallels between Article 3.3 of the *SPS Agreement* and Article 5.7 support that Article 5.7 shares the nature of an autonomous right. Article 5.7 is like 3.3, an expression of the right to precaution, which aims at achieving a finely tuned balance between the right to protect human health and the obligation to avoid protectionism by providing scientific evidence.³⁴⁹ If the burden to provide scientific evidence was one-sided on the complainant, and the provision would *prima facie* have to be interpreted narrowly, the right to protect the health of their citizens might run empty. However, declaring it as autonomous right, with the consequence that the burden of proof rests only on the complainant might not adequately reflect the precise qualifications for provisional measures to be fulfilled by the defendant. Moreover, Article 3.3, itself refers to Article 5.7 as an additional and separate obligation, which suggests that Article 5.7 is something else.

(c) What are exemptions?

Yet, what is a "qualified exemption"? The term exemption originates from tax law and stands for the "freedom from a general duty, immunity from a general burden, tax or charge".³⁵⁰ WTO law uses the word exemption, e.g., in Article II of the *GATS* when allowing Members to maintain, on a temporary basis, measures that violate the MFN obligation if these are listed in the schedules.³⁵¹ This suggests that an exemption excludes certain measures from the reach of an obligation, whereas an exception justifies a violation of an obligation. However, the precise legal meaning of exemptions, in particular who bears the burden of proof is not yet clarified. As regards the burden of proof, this is an intricate issue which will be

³⁴⁹The Appellate Body, in *European Communities – Hormones*, para. 124 mentioned Article 5.7 together with Article 3.3 as right to be cautious.

³⁵⁰Black's Law Dictionary, at 681.

³⁵¹*GATS*, Article II.2 and Annex on Article II Exemptions, para. 1. See also, *Agreement on Agriculture*, Article 13 (a) (ii), (iii), (b) (i-iii), (c) (ii).

addressed below. What can be said at this juncture is that Article 5.7 does not share the nature of an affirmative defence in the strict sense, i.e., it can also be considered by Panels if the defendant has not explicitly invoked it, except for cases where a Member expressly refuses to rely on it. Moreover, Article 5.7 does not need to be interpreted narrowly. By contrast, as indicated by the Appellate Body in *Japan – Agricultural Products*, the problem is rather not too interpret Articles 2.2 and 5.1 too broadly, but to leave some room for Article 5.7. This question concerns the delimitation of the substantive scope of both provisions, i.e., whether scientific evidence is sufficient or insufficient.

11. Summary:

Article 5.7 transgresses the traditional distinction between obligations and exceptions. It is not an exception, or an affirmative defence which would require the provision to be interpreted narrowly or a shift in the burden of proof. The term "qualified exemption" stems from taxation law. In WTO law it is used to temporarily exclude certain measures from the reach of an obligation, whereas an exception justifies a violation of an obligation. The burden of proof remains to be analyzed.

B. THE FOUR-PRONGED TEST FOR PROVISIONAL MEASURES

As regards the relationship between the different elements of Article 5.7 of the *SPS Agreement*, the Appellate Body held in *Japan – Agricultural Products*:

Article 5.7 of the *SPS Agreement* sets out four requirements which must be met in order to adopt and maintain a provisional SPS measure. Pursuant to the first sentence of Article 5.7, a Member may provisionally adopt an SPS measure, if this measure is:

(1) imposed in respect of a situation where relevant scientific information is insufficient"; and

(2) adopted "on the basis of available pertinent information"

Pursuant to the second sentence of Article 5.7, such a provisional measure may not be maintained unless the Member which adopted the measure:

(1) "seek [s] to obtain the additional information necessary for a more objective assessment of risk"; and

(2) "review[s] the ... measure accordingly within a reasonable period of time".³⁵²

Upon appeal, Japan argued that sentence 2 of Article 5.7 is merely an ancillary obligation, which is not decisive for the question whether a provisional measure can be justified under Article 5.7. The Appellate Body held that all four elements are cumulative in nature and equally important for the purpose of determining consistency with Article 5.7.³⁵³ The test as developed by the Appellate Body fully reflects the text of Article 5.7 of the *SPS Agreement*, but for one element. The Appellate Body has not incorporated the requirement that a measure be adopted "provisionally", but only refers to a "provisional measure". The interesting question whether the Appellate Body has mitigated the "strict" time element in Article 5.7, which is the major stumbling block for environmental NGOs will be addressed below together with obligation to review the measure within a reasonable period of time.

D. TRIGGERING FACTORS – THE FIRST SENTENCE OF ARTICLE 5.7

Pursuant to the first sentence of Article 5.7 of the *SPS Agreement*, a provisional measure can only be taken "in cases, in

³⁵² Appellate Body Report, *Japan – Agricultural Products*, para. 89.

³⁵³ *Ibid.*, para. 89

which relevant scientific evidence is insufficient" and must be adopted "on the basis of available pertinent information". It appears that these requirements reflect the "triggering" factors of the precautionary principles which require, at a minimum, a threat of adverse effects, and a lack of full scientific certainty. The two first elements of Article 5.7 have not been interpreted by the Appellate Body in *Japan – Agricultural Products*. The following sections aim at providing a first, tentative analysis of these requirements, taking into account WTO jurisdiction, the arguments of the participants and third participants in *Japan – Agricultural Products*, as well as the literature.

1. "Cases, in which relevant scientific evidence is insufficient"

The entrance requirement to Article 5.7 of the *SPS Agreement* is that a measure is taken "in cases, in which relevant scientific evidence is insufficient". This requirement is important for two reasons. First, it denotes the scope of application of the safeguard clause, and second, it bears on the relationship between the obligations under Articles 2.2 and 5.1 on the one hand and Article 5.7 on the other. Does "insufficiency" refer to the absence of sufficient information to conduct a risk assessment or does it simply embrace all situations where Panels have found that there is not "sufficient scientific evidence"? The issue was raised in *Japan – Agricultural Products*.

- (a) No safe harbour for measures where scientific evidence exists

In that case, the United States argued that Article 5.7. should only cover situations where scientific evidence is not "sufficient to perform an objective assessment of risk".³⁵⁴ Lack of scientific evidence would mean that there is no such evidence, but only

³⁵⁴ Appellate Body Report, *Japan – Agricultural Products*, para. 27. See also US' appellee's submission, paras. 59-65 (on file with author).

pertinent information".³⁵⁵ The concepts of sufficiency under Article 2.2 and 5.7 are not coextensive. Article 5.7 is only triggered by a minimum threshold requirement that scientific evidence is insufficient to perform a risk assessment.³⁵⁶ In cases where the existence of scientific evidence has been firmly established, Article 5.7 should not be applicable. Thus, if a defendant first claims that sufficient scientific evidence exists, and this claim is disproved under Article 5.1, the respondent is precluded from invoking Article 5.7.³⁵⁷ Article 5.7 should not provide a safe harbour for measures that do not meet the requirements for Article 2.2 and 5.1. If insufficient meant "I have no evidence, because all of the existing evidence runs counter my risk assessment"³⁵⁸ the obligation under Article 5.1 would be rendered meaningless.³⁵⁹

- (b) "Fall back" for any measures that failed to fulfil Article 5.1 and 2.2

The *European Communities* contended that the explicit connection between Article 5.7 and 2.2, spelled out there, suggests a uniform application meaning that Article 5.7 embraces all measures which do not pass the science test in Article 2.2 and 5.1 of the *SPS Agreement*.³⁶⁰ Thus, if a Member fails to comply with Articles 2.2 and 5.1, because it cannot perform a risk assessment and when the risk assessment shows that relevant scientific evidence is "insufficient, conflicting, inconclusive or uncertain"³⁶¹, it can have resort to

³⁵⁵*Ibid.*

³⁵⁶Appellate Body Report, *Japan – Agricultural Products*, para. 33. and Panel Report, paras. 4.189 and 4.190.

³⁵⁷Appellate Body Report, *Japan – Agricultural Products*, para. 33, Panel Report, *Japan – Agricultural Products*, para. 4. 190.

³⁵⁸United States' appellee's Submission, para. 65.

³⁵⁹*Ibid.*, para. 27.

³⁶⁰Appellate Body Report, *Japan – Agricultural Products*, para. 65.

³⁶¹*Ibid.*, paras. 12 and 64. European Communities' third participant's submission, para. 51.

Article 5.7 without having to start a new fact-finding exercise about the existence of data.³⁶²

Japan advanced a similar argument, indicating that "some scientific evidence" is enough to trigger Article 5.7, which has been presented *in casu* because a "scientific hypothesis exists".³⁶³ In its Communication on the precautionary principle, the European Communities argued that Article 5.7 covers all cases where "scientific data are inadequate".³⁶⁴ According to *Wirth*, Article 5.7 should broadly cover all cases of scientific uncertainty.³⁶⁵

(c) WTO Jurisdiction: Coextensive Interpretation

In *Japan – Agricultural Products*, neither the Panel nor the Appellate Body elucidated the meaning of "insufficient" scientific evidence in Article 5.7 of the *SPS Agreement*.³⁶⁶

Still, the Appellate Body stressed that Article 2.2 explicitly refers to Article 5.7 and that an "overly broad and flexible interpretation of that obligation would render Article 5.7 meaningless", thus hinting at a coextensive application of both concepts. A further indication in that direction can be gleaned from a footnote in *European Communities – Hormones*, where the Panel, when discussing theoretical uncertainties noted "that the *SPS Agreement* explicitly deals with situations where there is scientific uncertainty regarding risks related to a substance, in Article 5.7, but

³⁶²Appellate Body Report, *Japan – Agricultural Products* paras. 46, see also Japan's appellant's submission, paras. 62-66..

³⁶³Appellate Body Report, *Japan – Agricultural Products*, para. 46 and Panel Report, para. 4. 187.

³⁶⁴Communication from the Commission on the Precautionary Principle, Brussels, 2. 2. 2000, COM (2000)1, para. 4.

³⁶⁵*Wirth*, above n., at 835.

³⁶⁶Panel Report, *Japan – Agricultural Products*, para. 8. 55.

the European Communities has not invoked this provision in this case".³⁶⁷

(d) Analysis:

A reading of "insufficient scientific evidence" as only catching those cases where a party had determined in advance that science is insufficient and does not want to defend it under Article 2.2 or 5.1, could not be squared with the wording and context of Article 5.7. The term "insufficient" in Article 5.7 is the mere negation of "sufficient" in Article 2.2. Both are explicitly linked in Article 2.2 through the phrase "not maintained without sufficient scientific evidence except, as provided for in paragraph 7 of Article 5". The Appellate Body has stressed several times that the use of different words within one Uruguay Round Agreement indicates a different meaning.³⁶⁸ A *contrario*, the use of the *same* words must mean that two provisions are coextensive. Thus, "insufficient" should be read broadly so as to catch all cases where a measure does not fulfil the test in Article 2.2 or 5.1 of the *SPS Agreement*.

This interpretation of Article 5.7 is also supported by practical considerations. Since the "sufficiency" concept under Article 2.2 has been interpreted to involve an unpredictable "we know it when we see it test", defendants would be placed in a "trap of tragic decision", whether to defend a measure as being based on a risk assessment or label it as provisional under Article 5.7. A uniform application of both concepts would save panels from exercising unnecessary fact-finding. Panels could simply review the existence of scientific studies, and, after finding that a measure does not meet the science requirement, could automatically switch over to Article 5.7 without

³⁶⁷Panel Report, *European Communities – Hormones*, footnote 366 (US) and footnote 364 (CAN).

³⁶⁸Appellate Body Report, *European Communities – Hormones*, para. 164. See also, Appellate Body Report, *United States – Underwear*, at 17.

having to redo the fact-finding on the rather abstract question whether scientific evidence is insufficient to carry out a risk assessment.

It is important to note that a broad entrance requirement "in cases where scientific evidence is insufficient" is complemented by the requirement that a measure must be adopted "on the basis of available pertinent information", which ensures that Article 5.7 cannot be abused as safe harbour for measures where scientific evidence exists.

(e) Summary

The element "in cases where scientific evidence is insufficient" means that the measure has been found to be inconsistent with Article 2.2 or 5.1 of the *SPS Agreement*. Thus, all measures which fall through the first hurdle of the science test are generally eligible for the mechanism under Article 5.7.

2. "On the basis of available pertinent information"

It appears that the requirement that an Article 5.7 measure be adopted "on the basis of available pertinent information" could be the triggering factor for permissible precautionary measures. The resemblance to the "based on a risk assessment" clause in Article 5.1 of the *SPS Agreement* suggests that this element is a mini-rational relationship test, which could be the decisive substantive limit of Article 5.7. Several questions arise: First, how strictly does it impede precaution? Would it give governments huge wiggle room, to react to pure consumer anxieties, or very theoretical speculations, or would it require a fairly specific record of scientific information or some kind of risk evaluation before a provisional measure can be taken?

(a) Spectrum of Positions

In *Japan – Agricultural Products*, the participants left this element rather unnoted. Japan essentially claimed that as soon as scientific evidence supports the articulation of a scientific hypothesis,

the requirement is fulfilled. Thus, *in casu*, existing evidence that variety affects the efficacy of disinfection treatment would be sufficient information.³⁶⁹ The United States argued that "in the absence of any available pertinent information beyond speculation, a Member should not be permitted to maintain a provisional measure".³⁷⁰ In its *Communication* on the precautionary principle, the European Communities indicated that some evaluation of a risk be carried out before taking a precautionary measure.³⁷¹ The United States requested further explanation asking which scientific criteria apply and which role play consumer concerns.³⁷²

(b) No WTO Jurisdiction

Neither the Panel nor the Appellate Body addressed this requirement in *Japan - Agricultural Products*.³⁷³ In *Australia – Salmon, 21.5*, the Panel indicated:

that the words "more objective assessment of the risk" in Article 5.7 imply that "except for provisional measures – not at issue here – a risk assessment has to meet a certain level of objectivity".³⁷⁴

This suggests that the concept of risk and risk assessment in Articles 5.1 and 5.7 of the *SPS Agreement* are linked.

(c) Analysis:

When speaking with the words of the Appellate Body, one could say, the first sentence of Article 5.7 is not a "model of clarity".

³⁶⁹Panel Report, *Japan – Agricultural Products*, para. 4.187.

³⁷⁰United States' appellee's submission, para. 68.

³⁷¹*Communication from the Commission on the Precautionary Principle*, Brussels, 2. 2. 2000, COM (2000)1, para. 4.

³⁷²Codex Alimentarius Commission, Risk Analysis: 1) Working Principles for Risk Analysis additional comments of the United States, at 4.

³⁷³Appellate Body Report, *Japan – Agricultural Products*, para. 91. See also, Panel Report, para. 8.55.

³⁷⁴Panel Report, *Australia – Salmon, 21.5*, para. 7.49.

The semantic similarities between Article 5.1 and 5.7 indicate that two elements could be distinguished: First, "available pertinent information" must exist. Second, the measure must have been adopted "on the basis" of such information. At the same time "pertinent" appears to mirror the element "sufficient" scientific evidence in Article 2.2 of the *SPS Agreement*.

(i) "Available pertinent information" – A mini risk evaluation requirement?

Compared to the strict risk assessment and sufficient scientific evidence requirements under Articles 2.2 and 5.1, the term "available pertinent information" appears to be much broader. It does not carry the adjective "scientific". Article 5.7 explicitly refers to information from relevant international organizations and other Members. However, the word "including" indicates that this is not a closed list, but that Members could also obtain this information from the producer or from an NGO or an independent scientific institute.³⁷⁵ These broad terms, indeed, support concerns that Article 5.7 would leave unlimited wiggle-room for governments to take any measure, based on consumer anxieties and what if...? questions. Yet, the second sentence of Article 5.7 requires governments to "seek to obtain the additional information necessary for *a more* objective assessment of risk". The term "a more objective assessment of risk" implies that there is, at the time of taking the provisional measure at least a "subjective" or preliminary assessment of the risk. An obligation to carry out at least an evaluation of risk, as suggested by both, the United States and the European Communities would not entail any additional burdens. An evaluation of risk is always possible, even where there are uncertainties.³⁷⁶ However, the difficult issue is, to which extent the

³⁷⁵The particular role of international organizations, including the question, whether only the three relevant organizations, as named in Annex A 3 to the *SPS Agreement*, or also the Cartagena Protocol on Biosafety, the OECD, etc., could qualify and whether there is a trend towards cooperative fact-finding, will be addressed in more detail in Part III of the thesis.

³⁷⁶Committee on Sanitary and Phytosanitary Measures, Summary Report on the SPS Risk Analysis Workshop, 19-20 June 2000, G/SPS/GEN/209, at 5.

concept of risk assessment as incorporated in Article 5.1 and Annex A 4 to the *SPS Agreement* influences the obligation under Article 5.7

aa) Relevant Factors - No Consumer Threshold

Article 5.7 does not specify the factors to be taken into account when evaluating an uncertain risk. However, since the ultimate destination of the road under Article 5.7 is a more objective assessment of risk, it appears that the available information must relate to the factors spelled out in Article 5.2 of the *SPS Agreement*. The question to which extent consumer concerns are pertinent information under Article 5.7 might be answered by interpreting "pertinent information" in light of to the general notion of risk developed by the Appellate Body. The Appellate Body allowed for the consideration "real world" risks, "where people live and work and die". Yet, as argued above, this does not allow a pure consumer threshold, but only consideration of consumer concerns *together* with scientific evidence. Transferring this finding to Article 5.7, it appears that "pure consumer anxieties" which are not coupled with any kind of information indicating a sanitary or phytosanitary risk, could not justify a provisional measure. However, "pure consumer anxieties" do probably not exist, because in most cases, consumers only respond to "scandals" or new scientific findings, which should usually suffice as pertinent information.

bb) Theoretical Risk as Outer Limit

The wording of sentence 2 of Article 5.7, whereby "Members shall seek to obtain the additional information necessary for a more objective assessment of *risk*" indicates that the information must pertain to a risk to human, animal or plant life or health and that Article 5.7 is based on the same general notion of "risk" as Article 5.1 of the *SPS Agreement*. This would mean that the risk assessed under Article 5.7 must be "ascertainable" and that "theoretical uncertainty", in the sense that science could never provide full certainty is not the kind of risk to be assessed under Article 5.7. In other words, the

requirement that a risk must be ascertainable, i.e. more than mere suspicions and speculations marks the line between permissible precaution under Article 5.7 and precautionism.

(ii) *"Pertinent" and "On the basis of" - A Mini Rational Relationship Test?*

The term "on the basis of" is similar, but not equal to the "based on" requirement in Article 5.1 of the *SPS Agreement*. The ordinary meaning of "basis" is a "foundation" or "groundwork of anything", "that upon which anything may rest" or "the principle component of a thing".³⁷⁷ "On the basis of" suggests a slightly loser relationship between the measure and the pertinent information than "based on" a risk assessment", as prescribed by Article 5.1. "Pertinent" means "applicable" or "relevant" and evidence is pertinent "when it is directed to the issue or matters in dispute, and legitimately tends to prove the allegations of the party offering it".³⁷⁸ It resembles the concept of "sufficiency" under Article 2.2 of the *SPS Agreement*. This suggests that Article 5.7 would be interpreted by using a "mini-rational relationship test", whereby the information must sufficiently warrant the precautionary measure taken, considering the circumstances of the case, the quality and quantity of the information.

The determination of a rational relationship could become particularly problematic at the two ends of the spectrum of scientific uncertainty. First, at the edge towards theoretical uncertainty, and second, where a standing body of scientific evidence already exists.

aa) Delineating "Pertinent Information" from "Sufficient Evidence" and "Theoretical Risk"

When biotechnology was introduced, some scientists calculated the long-term effects of GMOs on the basis of analogies to the introduction of "alien species", e.g., rhododendron, or potato in

³⁷⁷Black's Law Dictionary, at 192.

³⁷⁸*Ibid.*, at 1302.

other eco-systems, which only manifest themselves after 10-140 years.³⁷⁹ Others doubted the fundamental assumptions of genetic modification, e.g., the stability of genes.³⁸⁰ Would these opinions which are not based on experiments with GMOs be pertinent information or already speculations about theoretical risks?

The explicit distinctions in Article 2.2 of the *SPS Agreement* between cases where scientific evidence is "sufficient" and those where scientific evidence is insufficient, indicates that information is still "pertinent" within the meaning of Article 5.7 where no specific, systematic studies and only few experimental data exist. Thus, even where there are only theoretical scientific models regarding long-term effects of GMOs which are not based on specific experimental data, such information might be pertinent. However, the inclusion of the word "pertinent" also means that not any information can justify a provisional measure.

To specify the minimum requirement, it might be helpful to read "pertinent" contextually in the light of the obligation to carry out a more objective assessment of the risk under Article 5.7, second sentence. The ultimate destination of the process under Article 5.7 is to carry out a risk assessment which fulfils the requirements under Article 5.1, i.e. specific and systematic evaluation of risk, without uncertainties. This suggests that to be "pertinent", the information must, at least, trigger a researchable scientific hypothesis, a statement that indicates where there are uncertainties and how these can be examined.

³⁷⁹Eggers, Barbara, "International Biosafety: Novel Regulations for a Novel Technology", RECIEL, Vol. 6. (1997), pp. 68-76, at 69 with further references.

³⁸⁰See, Ingham, Elaine/ Goodwin, Brian/ Mae, Wan Hoe/ Shiva, Vandana et. alia, "Biosafety – Scientific Findings and Elements of a Protocol, Report of the Independent Group of Scientific and Legal Experts on Biosafety", (Penang:Third World Network,1996).

bb) How to Deal with New Science Versus Old Science

The second problem is how to treat cases of scientific uncertainty where a considerable body of data already exists, and the country of export, has authorized the marketing of a product based on that data. This issue will arise in the *Hormones II* case, where a study concluding that no ADI level can be established stands against an existing body of studies which support an ADI level. The term on the basis of *available* pertinent information clearly indicates that all existing studies relating to the subject need to be examined by the Member. Also, when read in context with the first part of sentence one pursuant to which "relevant" scientific evidence must be insufficient", it appears that the new information must be so pertinent that it can cast doubts on the existing relevant scientific information.

This raises the issue of new minority opinions *versus* a standing body of scientific studies, which might be answered by using the same yardsticks as under Article 5.1 of the *SPS Agreement*. There is no valid reason *why* the directive given by the Appellate Body, whereby governments can rely on such minority views, should not apply under Article 5.7 as well. While under Article 5.1 a single opinion of a scientist, which was not founded on specific scientific studies could not overturn the contrary conclusions reached in the scientific studies, the requirements under Article 5.7 might be less stringent. Panels might examine whether the studies specify a clear scientific hypothesis why existing data indicate a researchable risk, and how the data provided by the existing studies could be refined through further scientific research. In *European Communities – Hormones*, the Appellate Body found that general studies, articles and opinions regarding the cancerous potential of hormones, as submitted by the European Communities were "relevant" but not "sufficiently specific" to the case at hand.³⁸¹ Because "relevant" and "pertinent"

³⁸¹ Appellate Body Report, *European Communities – Hormones*, para. 200.

can be used interchangeably, this might indicate that the new data building on these opinions are at least "pertinent information" under Article 5.7 of the *SPS Agreement*. However, also this "mini-rational relationship" test is an "we know it when we see it test", and in particular in cases of biotechnology, where data obtained from short term laboratory field tests stands against a few controversial studies and "what if? questions, no clear predictions are possible.

(d) Summary:

As regards the substantive requirements for a provisional measures, there is no case law. The contextual analysis of the first sentence of Article 5.7, in particular with a view to the obligation under the second sentence, to seek to obtain the additional information for a more objective assessment of risk and the requirements for sufficient scientific evidence under Article 2.2 of the *SPS Agreement* allows the following three tentative conclusions.

First, the obligations to carry out a more objective assessment of risk implies an obligation to carry out at least a subjective evaluation of risk before taking a provisional measure.

Second, the notion of risk as employed under Article 5.1 also applies under Article 5.7 of the *SPS Agreement*. Thus, the risk must be ascertainable as opposed to theoretical uncertainty. Where to draw the line between ascertainable risks and mere speculation is unclear. Third, the notion of "real world risks" as developed by the Appellate Body for Article 5.1 of the *SPS Agreement* would allow consideration of consumer concerns. However, a pure "consumer threshold" is not sufficient, if there is no scientific indication for risks. Fourth, the element "on the basis" of and "pertinent" might be interpreted by using a "mini-rational relationship" test. To ensure that Article 5.7 has its own effective scope as opposed to Article 2.2, there can be no requirement that pertinent information must be specific, systematic and based on experimental data. However, the term pertinent read contextually, requires, at a minimum, that the information enables

scientists to mark the uncertainties and to formulate a researchable hypothesis. Apart from these very broad indications, it is difficult to predict the outcome of yet another "we not it when we see it test", in particular in cases where opinions about long term effects of GMOs stand against existing evidence from laboratory studies and field tests which have not shown adverse ramifications.

D. PROCEDURAL REQUIREMENTS – ARTICLE 5.7 SECOND SENTENCE

Perhaps because the substantive standards set forth in the first sentence of Article 5.7 are difficult to apply, the Panel and Appellate Body, in *Japan – Agricultural Products* have relied on the second sentence of Article 5.7. The second sentence sets forth two further obligations. First, Members who take a provisional measure are required to "seek to obtain the additional information necessary for a more objective assessment of risk". Second, they have to "review the measure accordingly within a reasonable period of time".

1. "Seek to obtain the additional information"

In interpreting the obligation to "seek to obtain additional information for a more objective assessment of the risk", two questions arise: First, "who" has to provide the information? At first glance, Article 5.7, second sentence, suggests that the Member that takes the provisional measure must actively look for additional information to carry out the risk assessment, i.e., solicit and pay for relevant studies. This stands in stark contrast to the usual role allocation between a producer/exporter and the authorities of the importing country. As found in Part 1 of this thesis, these pre-marketing approval systems are one of the core features of the precautionary principle for human health protection. Does Article 5.7 turn these basic principles upside down? The second question is, "what" kind of information does the Member have to seek. Does it have to be "specific" as required for a proper risk assessment under Article 5.1?

(a) Who has to Provide the Information?

The issue of what precisely the obligation under Article 5.7 to seek to obtain the information necessary for a more objective assessment of the risk", entails was heavily disputed in *Japan – Agricultural Products*. Japan argued that the United States have the burden of proving that variety does not matter, whereas Japan is only obliged to continuously review whenever additional information becomes available in respect of the introduction of a pest.³⁸² The United States contended that the mere varietal testing requirement would not be capable of proving whether varietal differences matter and argued that the information to be sought under Article 5.7 should be "directly relevant" for a more objective assessment of the risk.³⁸³ It also pointed to Article 4.1 of the *SPS Agreement* and the practice underlying the legal systems of all WTO Members, whereby the producer has to prove that a product is safe.³⁸⁴

(i) *WTO Jurisdiction*

The report of the Appellate Body in *Japan – Agricultural Products* does not explicitly address that issue. The Panel was beating around the bushes: On the one hand, it held that, "as a general proposition, it is reasonable for Japan to require that the exporting country propose and substantiate the efficacy of an alternative approach or a treatment that achieves Japan's level of phytosanitary protection."³⁸⁵ The issue at stake was, whether "after such validation, no further testing is necessary", and therefore, whether the "very existence of any guidelines imposed for approval of additional varieties" was in line with the *SPS Agreement*.³⁸⁶ The Panel also

³⁸²Panel Report, *Japan – Agricultural Products*, para. 4.27.

³⁸³Appellate Body Report, *Japan – Agricultural Products*, para. 26. United States' appellee's submission, para. 51 (on file with author).

³⁸⁴European Communities' third participant's submission, paras. 10 and 16.

³⁸⁵Panel Report, *Japan – Agricultural Products*, para. 8. 10.

³⁸⁶*Ibid.*, para. 8. 10.

stressed that "what a Member requires from an exporting country before it will approve the import of that country's products" is different from the "burden of proof in WTO dispute settlement proceedings".³⁸⁷

(ii) *Analysis: Three different obligations at three different levels*

The jurisdiction of the Panel in *Japan – Agricultural Products* indicates that three different obligations at three different levels need to be distinguished.

First, pre-marketing approval or quarantine control schemes place the burden on the exporter to demonstrate that his product is safe before the authorities of the importing country make their risk assessment and grant or reject the approval accordingly. Second, if a Member refuses to allow the import of a product, the exporting country may challenge this measure as being at odds with the obligation of Members, under Articles 5.1, and 2.2 of the *SPS Agreement*, to base their determination on a risk assessment. The third level relates to the burden of proving, in a WTO dispute settlement proceeding, that a Member has acted inconsistently with the obligation to ensure that its measure is based on a risk assessment.

The allocation of the burden to provide studies is practically very important. In particular developing countries do not have, as, e.g., the US a very sophisticated and well-funded infrastructure of scientific committees and researchers who continuously evaluate risks and secure scientific knowledge of the authorities.³⁸⁸ Thus, an exporter could, by simply challenging a pre-marketing approval or quarantine mechanism, circumvent his obligation to demonstrate that his product is safe. Article 4 of the *SPS Agreement*, according to which Members shall accept the sanitary or phytosanitary measure of

³⁸⁷*Ibid.*, para. 8. 13.

³⁸⁸See, *Shin*, 32 *Journal of World Trade*, (1998), at 99 and *Miller*, "The Effect of the GATT and the NAFTA on Pesticide Regulations, "A Hard Look at Harmonization", 6 *Colo. J. Int'l Envtl. L & Pol'y*, at 217.

another Member as equivalent, if the exporting Member demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of protection, provides a strong contextual indication that the *SPS Agreement* does not operate at the first level, i.e., WTO law does not discharge exporters from their traditional obligation to show that a product is safe.

This can also be buttressed by the existence of Article 8 and Annex C, which lay down rules for approval and inspection procedures and thus assume that such proceedings are accepted by WTO law. The term "obtain" information, as used in Article 5.7 of the *SPS Agreement* means to "acquire" or to "succeed in gaining possession".³⁸⁹ This language does not necessarily require that the country of import has to solicit and pay for studies. It allows a reading whereby the importing Member is only obliged to take active steps to ensure that more information is being obtained, but where it can discharge this burden by requesting the importer to provide such specific tests and studies.³⁹⁰ Yet, in *Hormones II*, the European Communities solicited and paid for further studies. Does this mean that where no pre-marketing approval system exists, e.g., in situations of outright import bans or post-marketing control measures, the burden of obtaining the information is on the country of import? Or does it mean that where an exporter has provided all existing studies and the importing country still has doubts, the burden of seeking information switches?

In short, while Article 5.7 does not seem to affect the general precautionary principle whereby an exporter has to prove that a product is safe at the first level, it is not clear, how other situations, e.g., post-marketing control measures and permanent bans such as the

³⁸⁹American Heritage Dictionary, at 943.

³⁹⁰This interpretation could also be supported by the wording of sentence one of Article 5.7, according to which the provisional measure only be based on "available" information, including that "*from* sanitary or phytosanitary measures applied by *other Members*" (emphasis added).

hormones ban are regulated. The question, whether the allocation of the burden of proof in WTO dispute settlement proceedings *de facto* changes this allocation of the burden of proof will be addressed below.

(b) What kind of information?

The second issue arising from the obligation to "seek to obtain the additional information necessary" is, what kind of information must be sought.

(i) *WTO Jurisdiction: "Germane"*

The Appellate Body held, in *Japan – Agricultural Products*, that the language of Article 5.7 does not further specify "explicit prerequisites regarding the additional information to be collected or a specific collection procedure. Furthermore, Article 5.7 does not specify what actual results must be achieved; the obligation is "to seek to obtain" additional information."³⁹¹ However, it noted that Article 5.7 states that the additional information is to be sought in order to allow the Member to conduct "a more objective assessment of risk" and set forth the following case-by-case test: "[T]he information sought must be germane to conducting such a risk assessment, i.e., the evaluation of the likelihood of entry, establishment or spread of, *in casu*, a pest, according to the SPS measures which might be applied".³⁹² The Appellate Body has not dropped further principles for the application of this case-to-case test, but stated that Japan did not address the core issue whether "varietal characteristics cause a divergency in quarantine efficacy".³⁹³

The Panel, by contrast, was more explicit. It noted that "the studies these countries provide are designed and carried out to comply with the varietal testing requirement. They do not examine the

³⁹¹ Appellate Body Report, *Japan – Agricultural Products*, para. 92.

³⁹² *Ibid.*

³⁹³ *Ibid.* with reference to the Panel Report, para. 8.5.8.

appropriateness of the varietal testing requirement itself."³⁹⁴ The Panel explicitly agreed with Japan's assertion that "the information gathered through successive demonstrations by exporting countries constitutes experience and that experience is a legitimate means to gather information under Article 5.7. It held that Japan "can take into account the evidence submitted so far by exporting countries", but noted also that this method of collecting information has, to date, not provided the information "necessary for a more objective assessment of risk" and an appropriate review of the varietal testing requirement.³⁹⁵ Because there was not "any study that addresses the specific issue whether varietal characteristics cause a difference", it found the conditions set by Article 5.7 not to be fulfilled.³⁹⁶

(ii) *Analysis*

The Appellate Body has defined "what" kind of information a Member must seek under Article 5.7, second sentence when taking a provisional measure, by using a case-by-case test. Other than the Panel, the Appellate Body avoided the term "specific" in that context. However, it should be noted that "germane" means "being both pertinent and fitting", and, thus, seems to reinforce the "specificity" requirement, albeit more clemently. As discussed above, the ultimate destination of the road under Article 5.7 is a more objective assessment of the risk. Since a risk assessment must be specific, to fulfil the requirements of Article 5.1, it is only reasonable that the information which is sought under Article 5.7 is relevant to overcome the scientific uncertainty. Picking up from the interpretation of the substantive requirement under Article 5.7, first sentence, one would, at least require that such information enables the Member to verify its hypothesis about possible dangers.

³⁹⁴Panel Report, *Japan – Agricultural Products*, para. 8. 56.

³⁹⁵*Ibid.*, para. 8. 60.

³⁹⁶*Ibid.*, para 8. 56.

(c) Summary

The procedural obligation to "seek to obtain additional information necessary for a more objective assessment of the risk" has raised two questions. First, *who* must provide the information. The case law is unclear, but appears to suggest that a distinction must be drawn between: (i) the obligation to show that a product is safe in pre-marketing approval and quarantine proceedings; (ii) the obligation to carry out a risk assessment; and (iii) the burden of proof in WTO dispute settlement proceedings. The text of the *SPS Agreement* can be used to support that WTO law does not change the precautionary principle whereby a producer has to prove that a new product is safe. Yet, for post-marketing situations and bans, the issue appears to be unclear.

As regards the question "what" kind of information must be sought, the Appellate Body ruled that such information must be "germane to conducting" a more objective assessment of the risk, which is to be assessed on a case by case basis. The information must address the "core issue", i.e., respond to the scientific hypothesis which warrants the provisional measure.

2. The time factor: "within a reasonable period of time" and "provisionally"

The term "provisionally" has raised much concern that Article 5.7 would only justify a very limited amount of measures which are explicitly applied on an interim or temporary basis, e.g., the emergency measures in the BSE cases, but would not cover the whole range of precautionary measures, in particular measures affecting biotechnology products, where long term risks are suspected.³⁹⁷

³⁹⁷See Transatlantic Consumer Dialogue Recommendations on Food, Electronic Commerce and Trade and European Commission Services' Responses, Brussels Meeting, 23-24 April 1999, at 18, demanding that the word "provisional" be deleted. See also, World Wildlife Foundation, A Reform Agenda for the WTO Seattle Ministerial Conference (1999).

(a) WTO jurisdiction: Broad Case-to-case Test

In *Japan – Agricultural Products*, Japan and the European Communities argued that "provisional" does not refer to a limited period of time nor would it oblige a Party to declare its measure to be temporary.³⁹⁸ In its *Communication on the Precautionary Principle*, the European Communities expressed the opinion that "the provisional nature is not bound up with a time limit but with the development of scientific knowledge".³⁹⁹ The United States countered that the ordinary meaning of "provisionally" indicates that a measure may only be taken for a limited amount of time, which equals the reasonable period of time referred to in sentence two of Article 5.7 of the *SPS Agreement*.⁴⁰⁰ A measure taken 48 years ago could not be "provisional".⁴⁰¹

The Appellate Body, has not used the term "provisionally adopt", as a separate element of the four-pronged test under Article 5.7, but held that all four elements must be fulfilled for a measure to qualify as "provisional measure" under Article 5.7 of the *SPS Agreement*.⁴⁰² To interpret the term "reasonable period of time", the Appellate Body employed a case-by-case test:

In our view, what constitutes a "reasonable period of time" has to be established on a case-by-case basis and depends on the specific circumstances of each case, including the difficulty of obtaining the additional information necessary for the review *and* the characteristics of the provisional SPS measure."⁴⁰³

³⁹⁸Japan's appellant's submission, paras. 69, 70.

³⁹⁹Communication from the Commission on the Precautionary Principle, Brussels, 2. 2. 2000, COM (2000)1, para. 4.

⁴⁰⁰Appellate Body Report, *Japan – Agricultural Products*, para. 34.

⁴⁰¹Panel Report, *Japan – Agricultural Products*, para. 4. 191.

⁴⁰²Appellate Body Report, *Japan – Agricultural Products*, para. 89.

⁴⁰³*Ibid.*, para. 93.

The Appellate Body clarified, that the reasonable period of time only starts to run after the entry into force of the *SPS Agreement*.⁴⁰⁴ Noting that it was, according to the findings of the panel, relatively easy to collect the necessary additional information, the Appellate Body affirmed that Japan had violated its obligation to review the varietal testing requirement despite the short time since the entry into force of the *SPS Agreement*.⁴⁰⁵ The Appellate Body appears to have rejected the reasoning of the Panel in that case, which heavily relied on the fact that the varietal testing requirement had been around for almost 30 years without Japan's making a move to verify its hypothesis that varietal difference indeed matters for the efficacy of fumigation treatment.⁴⁰⁶ Also, an *obiter dictum* made by the Panel in *Australia – Salmon*, that a measure adopted more than 20 years ago can hardly be seen as "provisionally" adopted would, thus, be moot.⁴⁰⁷

(b) Literature

The literature has not yet discussed that issue in depths. Charnovitz stated that 20 years would be too long to be provisional.⁴⁰⁸ Some scholars indicated that Article 5.7 of the *SPS Agreement* would permit temporary measures, particularly citing to the BSE cases, however, they did not explicitly exclude other types of precautionary measures.⁴⁰⁹ *Quick/Blüthner* argued that where a measure had been

⁴⁰⁴*Ibid.*

⁴⁰⁵*Ibid.*

⁴⁰⁶Panel Report, *Japan – Agricultural Products*, para. 8. 57.

⁴⁰⁷Panel Report, *Australia – Salmon*, para. 8. 57.

⁴⁰⁸Charnovitz, Steve, "The Supervision of Health and Biosafety Regulation by World Trade Rules", World Trade Forum, 2000 (forthcoming), pp. 121-150, at 141.

⁴⁰⁹Roberts, above n.103, at 403. See also, McNelis, Natalie, "The role of the judge in the EU and WTO", Lessons from the BSE and Hormones Case, World Trade Forum (2000), forthcoming.

ten years without scientific evidence, it can "per se" not be provisional in character.⁴¹⁰

(c) Analysis: Issues of Measuring the "reasonable period of time"

At the outset, it should be noted, that this section will not produce a magic formula or "number 42" to resolve the problem of measuring the reasonable period of time. A clear time-limit of 4-6 months or 200 days set for provisional safeguard or anti-dumping measures pending a final determination⁴¹¹ or of 15 months as spelled out in Article 21. 3 c) of the DSU cannot be given for Article 5.7 of the *SPS Agreement* because scientific evidence is only evolving and the outcome of the scientific process cannot be predicted.

The case-to-case test developed by the Appellate Body appears to permit at least emergency measures such as those taken in the BSE crisis, the temporary withdrawal of authorizations of antibiotics⁴¹², or temporary bans, e.g., a two year moratorium on GMOs. Because the Appellate Body dropped the requirement that a measure must be adopted "provisionally" and made the calculation of the reasonable period of time dependant on the "difficulty of obtaining the additional information necessary" there also appears to be room for longer bans responding to concerns about long-term risks.

This interpretation is in line with the text of Article 5.7. The specific obligation under the second sentence of Article 5.7 to review a measure after a reasonable period of time also implies a right to take a measure for a reasonable period of time, and not only temporarily. It can also be buttressed by the negotiating history. The term

⁴¹⁰Quick, Reinhard/ Blüthner, Andreas, "Has the Appellate Body Erred? An Appraisal and Criticism of the Ruling in the WTO Hormones Case", 2 JIEL 1999, pp. 603-639, at 625.

⁴¹¹*Anti-Dumping Agreement*, Article 7; *Agreement on Safeguards*, Article 6.

⁴¹²See, e.g., Commission Decision 1999/815/EC (Phthalates), Article 5; Council Regulation 2821/98 (Antibiotics), Preamble, 29th whereas clause.

"temporarily" was used in an earlier draft of the *SPS Agreement* and was, from the Brussels Draft onwards, substituted by the word "provisionally".⁴¹³

At the same time, however, the use of the term "provisionally adopt", even if not forming part of the test under Article 5.7, must have a meaning. When reading the notion of "reasonable period of time" in context with "provisionally", it appears that the second sentence may not permit a *de facto* permanent ban disguised as "provisional measure".

Some practical guidance on how to calculate the reasonable period of time to review the measure under Article 5.7 of the *SPS Agreement* might be gleaned from the *European Communities – Hormones*, 21.3 c) arbitration.⁴¹⁴ The arbitrators in *European Communities – Hormones* and *Australia – Salmon* acknowledged that the defendants may implement the rulings by providing a risk assessment in line with Article 5.1 of the *SPS Agreement*. However, they strictly refused to include the time necessary to carry out such a risk assessment into the calculation of the reasonable period of time for implementation and drew a clear line between the benefits given by Article 5.7 and the reasonable time for implementation under

⁴¹³Decision by Contracting Parties on Sanitary and Phytosanitary Measures, GATT Doc. MTN.GNG/N5/WGSP/W/23 (28 June 1990). Draft Article 5.7 read: "In cases where relevant and verifiable scientific evidence is insufficient, an importing contracting party shall determine an appropriate level of health assurance temporarily, on the basis of all available pertinent information." (underlining added) and the Brussels Draft, MTN.GNG/NG5/WGSP/7, 20 November 1990.

⁴¹⁴With respect to the problem of measuring the time to "review the measure accordingly", the case law under Article 21.3(c) does provide sufficient guidance. As a general rule, the time should be the shortest possible within the legal system of the Member to implement the recommendations and ruling of the DSB. The precise duration depends on the constitutional requirements of the implementing Member, i.e., whether implementation requires only an administrative or also a legislative process. See, Award of the Arbitrator in *Australia – Salmon*, 21.3(c), para. 38. See also, Award of the Arbitrator in *European Communities – Hormones*, 21.3(c), para. 47.

Article 21.3 c).⁴¹⁵ To support its request for 2 years time to carry out a new risk assessment the European Communities argued:

a "reasonable period" depends upon the time it normally takes scientists in the EC (and around the world) to conduct this type of risk assessment and to review the inconsistent measure in the light of that risk assessment.⁴¹⁶

To identify missing information, avoid duplication of scientific work and reduce, as far as possible, the time necessary to complete the risk assessment, the European Commission had requested relevant information from the United States, Canada, Australia and New Zealand and also suggested to direct a similar request to the Codex Alimentarius Commission.⁴¹⁷ Although no case law exists on that subject, this approach, whereby the reasonable period of time is not calculated on the basis of an estimate given by a domestic scientific committee, but that a global approach be taken, which is based on the existence of data in other countries appears to match the cooperative and process-oriented approach envisaged by Article 5.7 of the *SPS Agreement*

(d) Summary

In brief, the concern that Article 5.7 only allows for a temporary and emergency measures, but not for measures tackling long-term risks is not warranted. The Appellate Body has interpreted Article 5.7 of the *SPS Agreement* without employing the term "provisionally", but relies on the specific obligation that a Member must seek the additional information and review the measure "within a reasonable period of time". That notion has, again, been interpreted by using a broad case-to-case test considering the "specific

⁴¹⁵*European Communities – Hormones*, Arbitration under Article 21.3(c), paras. 41 and 42; *Australia – Salmon*, Arbitration under Article 21.3(c), para. 39.

⁴¹⁶Award of the Arbitrator in *European Communities - Hormones*, 21.3(c), para. 10.

⁴¹⁷*Ibid.*, para. 11.

circumstances of each case, including the difficulty of obtaining the additional information necessary for the review *and* the characteristics of the provisional SPS measure." Thus, also long-term provisional measures might be taken under Article 5.7.

E. CONCLUDING REMARKS: HOW DO PRECAUTIONARY MEASURES FARE UNDER ARTICLE 5.7?

This section plays through the hypotheticals to see where the conditions set by Article 5.7 draw the line between precaution and precautionism.

Some cases are clear. First, the BSE measures would be the model for a provisional measure under Article 5.7. They were taken on the basis of new scientific evidence suggesting a risk for human health from the ingestion of beef that may contain BSE agents. On the other hand, cases of scientific idleness as illustrated by the "red moth" hypo might be easily dismissed through the procedural requirement under Article 5.7, second sentence to seek the additional information and to review the measure within a reasonable period of time. In the *Hormones II* situation, the issues are less clear. The ban on the five hormones is provisional pending the termination of further studies. However, the European Communities are turning a former permanent ban into a provisional one. First, one could argue that the European Communities have failed to fulfil their obligation under Article 5.7, second sentence to seek the additional information in time. However, as pointed out by *Quick/Blüthner*, the obligation to seek additional information only entered into force in 1995 and the measure was challenged soon afterwards, with the European Communities starting to seek additional information.⁴¹⁸

A second concern is that Article 5.7 might be used to hinder a final solution of the hormones conflict.⁴¹⁹ Yet, Article 21.5 of the

⁴¹⁸*Quick/Blüthner*, above n.288, at 625.

⁴¹⁹See, *Wirth*, David A., "European Communities – Measures Concerning Meat and Meat Products", 92 AJIL 1998, pp. 755-759, at 757.

DSU does not legally preclude the European Communities from invoking Article 5.7 in the implementation phase, if there is really new scientific evidence.⁴²⁰ The overall goal of the dispute settlement mechanism, as spelled out in Article 3.7 of the DSU, is to secure a positive solution to a dispute and Article 22 of the DSU indicates a preference for implementation over suspension of concessions. If there is really valid new science a never-ending "spiral of new science" under Article 5.7 might be preferable to a never ending "spiral of retaliation and carousel retaliation".

This turns the problem to the question whether the new hormones ban is adopted "on the basis of available pertinent information". Because this "mini-rational relationship test" is still so unprincipled, the outcome is rather unpredictable.

Even more problematic appears to be the assessment of the biotechnology measures. Because some experimental data exist, which warrant an assumption that the introduction of GMOs might have adverse effects, such risk might not be a merely theoretical one, and can be evaluated by the importing country. However, would these often controversial and general studies stand against a growing body of laboratory and field tests, which specifically evaluate the adverse effects associated with a particular GMO? The mini-rational relationship test would allow WTO panels to come down on both sides.

⁴²⁰This question relates to the legal relationship between Article 5.7 safeguard and the provisions for implementation under Article 21.5 of the DSU. According to Article 21.5 of the DSU the original panel must examine the "consistency" "with a *covered* agreement" of a measure "taken to comply with the recommendations and rulings". This indicates that an analysis of an implementation measure is not confined to the question whether the measure complies with the provisions found to be in violation in the recommendations of the DSB. Moreover, as found above, Article 5.7 is not a defence in the strict sense, which can only be considered by the judge if it has been invoked by the defendant, but an exemption triggered by new "pertinent scientific evidence", which are considered by Panels unless the defendant explicitly refuses its consent. In *Japan – Agricultural Products*, the Panel acknowledged: "Our task in this dispute is to determine whether or not Japan, *to date*, is in breach of this obligation; not whether *in the future* scientific evidence could be produced which would allow Japan to comply with its obligation". See, Panel Report, *Japan – Agricultural Products*, para. 8.31.

Also difficult would be the calculation of the reasonable period of time in the GMO cases, where a Member not only adopts a moratorium. Would it be sufficient to point to studies which estimate that it might take up to 100 years until long-term effects of GMOs manifest themselves?⁴²¹ As the yardstick of the Appellate Body, i.e., "specific circumstances" of the case not only includes the difficulty of obtaining the additional information necessary for the review, but also the "characteristics of the provisional SPS measure", the outcome of this case-to-case test is, again, unpredictable. Even if the Member can show that there might be long-term effects on its biodiversity, would the term "characteristics of the measure" read together with Article 5.3 of the *SPS Agreement*, allow considerations of cost-effectiveness and oblige the Member to switch from a ban to alternative measures, e.g., monitoring of GMOs?⁴²²

In sum, when looking back, the accordion-like concept of the "like-product" test, coupled with the exception under Article XX of the GATT, has, in the end been replaced by another accordion, albeit with fewer keys. Much depends on an case-to-case evaluation of the measure at hand and the scientific evidence. This makes the procedural rules governing the fact-finding exercise in WTO dispute settlement proceedings particularly important.

⁴²¹See the references to scientific assessments of long-term effects of biotechnology in, *Eggers*, Barbara, "International Biosafety: Novel Regulations for a Novel Technology", *RECIEL*, Vol. 6. (1997), pp. 68-76, at 69.

⁴²²Even where the panel comes, after consulting the scientific experts to the conclusion that for example the long-term effects of certain transgenic crops might be assessed within, say, 30 years, the question arises, how deal procedurally with this finding. Should the Panel then uphold the measure as justified by Article 5.7, but make this conclusion dependant on the continuous effort of the defending country to seek the information within 30 years? This solution whereby a measure was upheld upon the conditions that the respondent continues a certain practice was used in *United States – Sections 301-310 of the Trade Act of 1974*, WT/DS152/R, adopted 27 January 2000, See, para. 7.31 and conclusions.

§3: BURDEN OF PROOF AND STANDARD OF REVIEW

The scientific facts involved in trade conflicts regarding precautionary measures are complex and highly disputed. Where the substantive tests boil down to the existence of sufficient scientific evidence which is assessed on a case-to-case basis, the rules regarding fact-finding in WTO dispute settlement proceedings play a crucial rule. Many procedural determinants might affect the final outcome of the fact-finding exercise. This chapter looks at two of them. First, the burden of proof: Who has to provide how much evidence? Second, the standard of review: Who decides whether there is a risk or not, and to which extent will WTO adjudicators pay deference to national decision makers?⁴²³ In particular the issue of deference involves difficult questions of global governance. This chapter does not aim at offering an easy solution for these fundamental issues, but examines how the burden of proof and standard of review are being applied to precautionary measures under the *SPS Agreement*.

Part II of this chapter provides a brief overview of the fact-finding process in WTO Dispute Settlement proceedings. Part III addresses the burden of proof. Part IV deals with the issue of deference.

I. FACT-FINDING IN WTO DISPUTE SETTLEMENT

WTO dispute settlement procedures are adversarial. Hence, the onus of gathering and submitting evidence rests, in principle, on the parties. Article 11 of the DSU spells out the duty of a panel to

⁴²³A third important issue is the role of experts in WTO Dispute Settlement proceedings. See for an overview and suggestions for improving the WTO System, *Christoforou*, Theofanis, "Settlement of Science-Based Trade Disputes in the WTO: A Critical Review of the Developing Case Law in the Face of Scientific Uncertainty", 8 New York University Environmental Law Journal, (2000), pp. 622-648.

"make an objective assessment of the matter before it, including an objective assessment of the facts of the case". Article 13.1 of the DSU equips panels with the "right to seek information and advice from any individual or body which it deems appropriate". Article 13.2 of the DSU specifies that panels may "seek information from any relevant source and may consult experts to obtain their opinion on certain aspects of the matter". Essentially, three sources of information can be distinguished. First, scientific experts, second the parties themselves, and third, non-governmental entities.

Article 11. 2 of the *SPS Agreement* directs panels to seek advice from experts where a dispute involves "scientific or technical issues". In all four disputes under the *SPS Agreement*, as well as in *European Communities – Asbestos*, the panels decided, after consulting with the parties, to seek expert advice from individual experts. While Appendix 4 to the DSU sets out rules and procedures for "expert review groups", expert advice from individual experts are not specifically regulated in the DSU.⁴²⁴ So far, panels have abided by the following proceedings:⁴²⁵ First, the panel chooses, in consultation with the parties and relevant international organizations, three to four experts and prepares a list of specific questions for them. Second, the experts respond in writing to these questions. Third, a joint meeting is held where the Panel, the experts and the parties

⁴²⁴The difference between an expert advisory group and a group of individual experts is the following: An expert advisory group is a 'tribunal within a tribunal', i.e., it is asked to come forward with a consensus view, whereas individual experts are appointed and consulted on their individual capacity. See, Pauwelyn, Joost, "The WTO Agreement on Sanitary and Phytosanitary (SPS) Measures as Applied in the First Three SPS Disputes - EC – Hormones, Australia – Salmon and Japan – Varietals, 2 JIEL 1999, pp. 641-664, at 661.

⁴²⁵Panel Report, *European Communities – Hormones*, paras 6.5 ff. and 8.7 ff.; See also, Panel Reports, *Australia – Salmon*, paras. 6.1–6.6; *Japan – Agricultural Products*, paras. 6.1–6.4; and *Australia – Salmon*, 21.5, paras. 6.1–6.5. The use of expert advice is not an invention of the DSU but was also made under GATT practice. See, for example, Panel Report, *Thailand – Cigarettes*, paras. 3, 51-57 and 73, where the Panel requested a report about the health effects of smoking from an expert of the World Health Organization.

discuss the written answers of the experts. The opinions of the experts are not binding on the panel.⁴²⁶

The second important source of information are the parties themselves. Article 13. 1, third sentence of the DSU provides: "A Member should respond promptly and fully to any request by a panel for such information as the panel considers necessary and appropriate." The Appellate Body decided that "should means shall", in other words, that Members have the duty and obligation to provide certain information requested by the panel.⁴²⁷

Panels have the authority to draw adverse inferences from a party's refusal to provide such requested information.⁴²⁸ The confidentiality of business or government information is guaranteed through several provisions in the DSU.⁴²⁹ In some cases, panels have taken additional steps to ensure the confidentiality of information designated as confidential.⁴³⁰

A third source of information, not mentioned in the DSU, are *amicus curiae* briefs filed by interested non-governmental organizations. The Appellate Body held, that under Article 13 and 12 of the DSU, Panels are entitled to take account of such unsolicited information, where they find it appropriate.⁴³¹ To date, only one panel, in *Australia – Salmon*, 21.5 has considered information

⁴²⁶*Pauwelyn*, above n. 424, at 661.

⁴²⁷Appellate Body Report, *Canada – Measures Affecting the Export of Civilian Aircraft* ("*Canada – Aircraft*"), WT/DS70/AB/R, adopted 20 August 1999, para. 187.

⁴²⁸*Ibid.*, para. 202.

⁴²⁹DSU, Articles 16. 10, 18. 2, and Rule 3 of Appendix 3. The Appellate Body held that the duties spelled out therein, in principle, ensure sufficient protection of confidential information. See, Appellate Body Report, *Canada – Aircraft*, paras. 141-147.

⁴³⁰See, e.g., Panel Report, *Australia – Salmon*, 21.5, para. 7.7.

⁴³¹Appellate Body Report, *United States – Shrimp*, paras. 104-109.

submitted to it by the "Concerned Fishermen and Processors" in South Australia as relevant.⁴³²

Overall, the Appellate Body noted that "the comprehensive nature" of a panel's authority to seek information from external sources suggests that panels have a "significant investigative authority".⁴³³ Article 13 of the DSU provides for "a grant of discretionary authority" whether and from where to seek advice.⁴³⁴ A panel is entitled to seek information and advice from experts and from any relevant source it chooses, [...] to help it to understand and evaluate the evidence submitted and the arguments made by the parties, but not to make the case for a complaining party.⁴³⁵

II. THE BURDEN OF PROOF

One of the core problems posed by scientific uncertainty is to allocate the burden of proof. The precautionary principle, as reflected in pre-marketing approval mechanisms for food, puts the onus of proving that a substance is safe on the producer. The analysis of Article 5.7 has shown that the *SPS Agreement* does not change this fundamental principle. The WTO operates at a different level. Members are obliged to base their national decisions on sufficient scientific evidence. However, the question remains, who has to prove what and how much in WTO dispute settlement proceedings. Could the WTO system be abused by an exporter who cannot show that his novel product is safe by simply challenging the decision of the national authority in WTO dispute settlement proceedings?

The *SPS Agreement* is silent on the burden of proof. Panels and the Appellate Body acknowledged that the complexity of facts

⁴³²Panel Report, *Australia – Salmon*, 21. 5, para. 7. 8

⁴³³Appellate Body Report, *Japan – Agricultural Products*, paras. 127-129.

⁴³⁴Appellate Body Report, *Argentina – Measures Affecting Imports of Footwear, Textiles, Apparel and Other Items* ("Argentina – Textiles and Apparel"), WT/DS56/AB/R, adopted 22 April 1998, para. 84.

⁴³⁵Appellate Body Report, *Japan – Agricultural Products*, para. 129.

involved makes the allocation of the burden of proof under the *SPS Agreement* an issue of particular importance.⁴³⁶ Applying the general burden of proof in WTO law⁴³⁷, the Appellate Body, in *European Communities – Hormones*, held that "the initial burden lies on the complaining party, which must establish a *prima facie* case of inconsistency with a particular provision of the *SPS Agreement* on the part of the defending party, or more precisely, of its SPS measure or measures complained about. When that *prima facie* case is made, the burden of proof moves to the defending party, which must in turn counter or refute the claimed inconsistency".⁴³⁸

With respect to precautionary measures, three questions arise: First, what precisely is a *prima facie* case? How much evidence does the complainant have to submit? Second, does a successful *prima facie* case absolve the proponent from the risk of non-persuasion with the effect that the respondent fails in case of equipoise? Third, who bears the burden of proof under Article 5.7 to show that the conditions for a provisional measure are (not) fulfilled?

A. THE MEANING AND EFFECT OF A *PRIMA FACIE* CASE IN SPS RULINGS

This section analyzes the meaning and effect of the current burden of proof to make a *prima facie* case in the case law under the *SPS Agreement* and the literature with a view to the specific problem of scientific uncertainty.

⁴³⁶Appellate Body Report, *European Communities – Hormones*, para. 97. See also, Appellate Body Report, *Japan – Agricultural Products*, para. 122.

⁴³⁷Appellate Body Report, *United States – Measures Affecting Imports of Woven Wool Shirts and Blouses from India* ("*United States – Shirts and Blouses*"), WT/DS33/AB/R, adopted 23 May 1997, p. 14. See for an overview, Martha, Rutzel Silvestre J., "Presumptions and Burden of Proof in World Trade Law, 14 *Journal of International Arbitration*", 67 (1997).

⁴³⁸Appellate Body Report, *European Communities – Hormones*, para. 98. See also, Appellate Body Report, *Japan – Agricultural Products*, para. 122 and Panel Report, *Australia-Salmon*, para. 8. 40.

1. WTO Jurisdiction in SPS Cases

The Appellate Body has not further defined the term *prima facie* case. In *European Communities – Hormones*, the Appellate Body specified: To provide *prima facie* evidence, the complainant must present "evidence and legal arguments sufficient to demonstrate that the EC measures were inconsistent with the obligations assumed by the European Communities."⁴³⁹

Also a look back to the original ruling where the Appellate Body set forth the principles on the burden of proof does not clarify what needs to be done to make a *prima facie* case. In *United States – Shirts and Blouses*, the Appellate Body held, "precisely how much and precisely what kind of evidence will be required to establish such a presumption will necessarily vary from measure to measure, provision to provision, and case to case."⁴⁴⁰

Can some generalizable rules inferred from the appreciation of the facts in the SPS cases?

(a) *European Communities – Hormones*

In *European Communities – Hormones*, the Appellate Body held that the US and Canada had made a *prima facie* case.⁴⁴¹ In that case, the complainants had referred to international standards and studies which indicated that the use of growth hormones is safe if used with good husbandry practice. To rebut, the European Communities would have had to demonstrate, on the basis of specific studies, that meat treated with hormones in accordance with good husbandry practice would pose a risk.⁴⁴²

⁴³⁹Appellate Body Report, *European Communities – Hormones*, para. 109.

⁴⁴⁰Appellate Body Report, *United States – Shirts and Blouses*, p. 14.

⁴⁴¹Appellate Body Report, *European Communities – Hormones*, para 197, footnote 180.

⁴⁴²*Ibid.*, paras. 195-209.

Neither of the general studies about the dangers of hormones, or control problems, nor the statement by one of the experts that added growth hormones might pose a risk to one woman in a million were found sufficient to convince the Appellate Body that the measure was based on a risk assessment.⁴⁴³ This suggests that the complainant at least needs to submit some proof that his product is safe. However, the handling of the sixth hormone, MGA, for which no international standard or publicly available studies existed, casts doubt on this finding. The United States had claimed that there is no risk assessment, but declined to submit any assessment of MGA upon the ground that the material they were aware of was proprietary and confidential in nature. The European Communities pointed to general studies arguing that because MGA is an anabolic agent which mimics the action of progesterone, the scientific studies and experiments relied on by the 1987 IACR Monographs were highly relevant.⁴⁴⁴ The Appellate Body found these not specific enough, requiring that the comparability should have been shown.⁴⁴⁵ Facing an "almost complete absence of evidence on MGA in the panel proceedings", the Appellate Body upheld the finding of the Panel that there was no risk assessment with regard to MGA.⁴⁴⁶ Thus, although there was no proof whether MGA is safe or not, the absence of data showed that the import ban was not based on a risk assessment.

(b) *Australia - Salmon*

In *Australia – Salmon*, Canada successfully "raised a presumption (i.e., made a *prima facie* case)" that the measure at issue other than those covered by the 1996 Report were not based on a risk assessment and that Australia, in turn, had not provided evidence to rebut that presumption.⁴⁴⁷ Canada had, by simple reference to the

⁴⁴³*Ibid.*

⁴⁴⁴European Communities' appellant's submission, para. 179.

⁴⁴⁵Appellate Body Report, *European Communities – Hormones*, para. 201.

⁴⁴⁶*Ibid.*

⁴⁴⁷Panel Report, *Australia – Salmon*, para. 8. 59.

Australian risk assessment, shown that it only dealt with a limited scope of salmon products compared with the wide scope of the measure. As regards the products which were covered by the risk assessment, the Panel found that Canada had raised a presumption that there is no "rational relationship between the measure and the risk assessment", because the 1996 Report did not provide a rational basis for the heat treatment requirement.⁴⁴⁸ Thus, Canada did not have to prove the absence of diseases in its salmon products, but only that the Australian risk assessment did not adequately cover the measure taken by Australia.

(c) *Japan – Agricultural Products*

While the threshold of proof was ostensibly low in *European Communities – Hormones* and *Australia – Salmon*, the Appellate Body set the bar higher in *Japan – Agricultural Products*. Upon appeal, the Appellate Body affirmed that the US had made a *prima facie* case of inconsistency with Article 2.2, because it provided scientific reports endorsed by the experts – that (i) so far no single instance has occurred in Japan or any other country, where the treatment approved for one variety of a product had had to be modified to ensure an effective treatment for another variety of the same product, (ii) that varietal differences do not matter for quarantine efficacy.⁴⁴⁹ Only against that body of evidence, the Panel found that the individual studies which possibly hinted at relevant varietal differences did not make the actual causal link between the differences in the test results and the presence of varietal differences, and thus, did not sufficiently rebut the presumption raised by the United States.⁴⁵⁰

Japan – Agricultural Products also provides guidance on what is the minimum threshold of proof. In that case, the US had not raised

⁴⁴⁸*Ibid.*, para 8.99. See similarly for the claims under Articles 5.5, paras. 8. 137. 8. 139 and 8. 141 and for Article 5.6 paras. 8. 171, 8.181 and 8. 182.

⁴⁴⁹Appellate Body Report, *Japan – Agricultural Products*, para. 124.

⁴⁵⁰Panel Report, *Japan – Agricultural Products*, para. 8. 48.

a particular alternative measure under Article 5.6. Only the discussion with the expert group had born the possibility of sorption levels as alternative measure.

The Appellate Body reversed the finding of the Panel that the United States had provided a *prima facie* case that the determination of sorption levels would be an alternative measure, because the United States had not even claimed this possibility before the Panel. Even if during the expert hearings an alternative measure would be developed, this would not be enough to discharge the claimant from its duty to make a *prima facie* case.⁴⁵¹ The United States could have obtained expert opinions on that question and submitted it to the panel.⁴⁵²

In short, the precise standard of proof varies from case to case and does not allow predictable rules, on how much proof a complainant must provide to raise a presumption that what he claims is true. The treatment of MGA in *European Communities - Hormones* suggests that to show that no risk assessment in line with Article 5.1 exists, a complainant does not have to provide data that his product is safe. However, when examining whether a measure was, contrary to Article 2.2, maintained without sufficient scientific evidence, the Appellate Body in *Japan – Agricultural Products* emphasized that a proponent cannot make a *prima facie* case by simply alleging a violation of a provision without substantiating its case with sufficient evidence. Apart from that, it appears that the proponent's burden to make a *prima facie* case is easy to discharge, whereas the heavier onus is to rebut a *prima facie* case.

2. Literature: Criticisms of the *Prima Facie* Standard

The principles on the burden of proof as developed by the Appellate Body were heavily criticised in the literature. The thrust of the critique is that the *prima facie* rule and the presumption

⁴⁵¹ Appellate Body Report, *Japan – Agricultural Products*, para. 129.

⁴⁵² *Ibid.*, para. 137.

technique, as employed by the Appellate Body are flawed and that the rules and standards of proofs need to be more differentiated and clarified. More specifically, *Pauwelyn* argues that the presumption technique is not the burden of proof, but a mere standard of proof, i.e., an optional technique used in the evaluation of evidence.⁴⁵³ It would, thus, be legally incorrect to say that the burden of proof "shifts" to the respondent after the proponent has successfully made a *prima facie* case. According to *Pauwelyn*, the complaining party has the burden of proof for the claim/fact in question, a burden which remains with that party during the entire proceedings.⁴⁵⁴

Walker suggested to distinguish more precisely: (i) the standard of proof to be employed by the panel; (ii) the burden of persuasion placed on parties; (iii) the minimum requirements of rational inference; and (iv) the burden of producing evidence.⁴⁵⁵

Both criticize that the Appellate Body did not clarify the standard of proof.⁴⁵⁶ *Pauwelyn* suggests that the standard of proof should be set higher to ensure that the proponent could not discharge his burden by simply pointing at the measure and the SPS provision, but would be required to submit some scientific evidence showing that the measure is not founded in science.⁴⁵⁷

Walker suggested that the greater weight of evidence must support the proposition. In other words, the panel must be convinced that "the proposition at issue is more likely to be true than false".⁴⁵⁸ Furthermore, he criticized that the Appellate Body did not clarify what

⁴⁵³*Pauwelyn*, Joost, "Evidence, Proof and Persuasion in WTO Dispute Settlement: Who bears the Burden?", 2 JIEL 1998, pp. 227-258, at 257.

⁴⁵⁴*Ibid.*, at 246.

⁴⁵⁵*Walker*, Vern R., "Keeping the WTO from Becoming the „World Trans-science Organization“: Scientific Uncertainty, Science Policy, and Factfinding in the Growth Hormones Dispute", 31 Cornell Int'l L. J., (1998), 251-320, at 290.

⁴⁵⁶*Pauwelyn*, above n. 453, at 257.

⁴⁵⁷*Pauwelyn*, Joost: "The WTO Experience Under the SPS Agreement", World Trade Forum, 2000 (forthcoming), pp. 95-108, at. 98.

⁴⁵⁸*Walker*, above n. 455, at 291.

precisely has to be proven, and suggested that under the *SPS Agreement*, evidence should constitute a *prima facie* case "if: (a) it is sufficient to provide the minimum rational support for an inference to the requested finding; and (b) it would be in fact persuasive to the panel if no contrary evidence were produced".⁴⁵⁹

3. Analysis

Although a more precise standard of proof would be desirable, it appears that the critique on that point tilts at windmills. In general international law a *prima facie* case is a commonly used standard of proof, which denotes the minimum quantum of evidence "which unexplained or uncontradicted is sufficient to maintain the proposition affirmed."⁴⁶⁰ In other international proceedings the notion of a *prima facie* case is even more vague.⁴⁶¹ Walker's proposal to adopt a preponderance standard, meaning "evidence higher and greater in weight"⁴⁶², might not change much in practice. As illustrated by the recent ruling in *European Communities – Asbestos*, where the Panel used a preponderance standard under the guise of the *prima facie* case, the distinction between *prima facie* evidence and preponderance of scientific evidence does not necessarily have an impact on the result.⁴⁶³ This is also confirmed by experience under other international tribunals.⁴⁶⁴

Yet, while a lack of precision must –willy nilly- be accepted in respect of the content of the *prima facie* standard, precision is required and possible concerning its effect. The question whether a

⁴⁵⁹*Ibid.*, at 294.

⁴⁶⁰Kazazi, Motjaba, "Burden of Proof and Related Issues, A Study of Evidence Before International Tribunals" (Hague, Boston: Kluwer Law International, 1996), at 328 with further references.

⁴⁶¹*Ibid.*, at 329-336.

⁴⁶²*Ibid.*, at 344.

⁴⁶³Panel Report, *European Communities – Asbestos*, paras. 8. 177 and 8. 193, where the Panel found "that the evidence before it tends to show that handling chrysotile-cement products constitutes a risk to health rather than the opposite".

⁴⁶⁴*Ibid.*, at 349.

prima facie case, indeed, results in a shift in the burden of proof is very important for precautionary measures. According to the Appellate Body the burden of proof shifts to the respondent, once a *prima facie* case is made. At this juncture, again, some terminology is helpful. The notion of "burden of proof" encompasses three different "burdens": First, the burden of persuasion, second the burden of evidence (or burden of production), and third, the burden of proof in the strict sense, which is the allocation of the risks of non-persuasion, i.e., where the evidence is in equipoise, the party carrying the burden of proof fails.⁴⁶⁵ In general international law the effect of *prima facie* evidence is that it shifts the "burden of evidence from the proponent of the burden of proof to the other party".⁴⁶⁶ The respondent then carries the burden of rebutting the *prima facie* evidence. If he succeeds in doing so, the "burden of evidence will shift back to the proponent, and it [sic!] has to carry the burden further".⁴⁶⁷ However, while this presumption technique results in a ping-pong game on the provision of evidence, the burden of proof in the strict sense remains stable throughout this exercise. In public international law, *prima facie* evidence does not have the effect of reversing the burden of proof.⁴⁶⁸

It appears that the Appellate Body, when setting out its general principles on the burden of proof, used the term "burden of proof" in its broader meaning, but did not mean to convey that the burden of proof in the strict sense shifts as a consequence of a *prima facie* case. This assumption is warranted, because the Appellate Body, when setting out the general principles on the burden of proof in *United States – Shirts and Blouses*, founded the WTO principles on the principles employed by "various international tribunals" and a "generally accepted canon of evidence" in most jurisdictions.⁴⁶⁹

⁴⁶⁵ *Black's Law Dictionary*, (7th edition, St. Paul, Minnesota: West Group, 1999), at 190 and 191.

⁴⁶⁶ *Kazazi*, above n. 460, at 332.

⁴⁶⁷ *Ibid.*, at 333.

⁴⁶⁸ *Ibid.*, at 251 and 338.

⁴⁶⁹ Appellate Body Report, *United States – Shirts and Blouses*, p. 14.

These general principles of law clearly indicate that a *prima facie* case does not cause a shift of the burden of proof in the strict sense, and therefore complement and refine the current rule set out by the Appellate Body.

In short, what is necessary to make a *prima facie* case varies from case to case. In very broad terms, one can say that it is easier to make a *prima facie* case than to rebut it. However, it appears to be impractical to fiddle around on the abstract standard of proof, since it does not influence how much evidence is necessary to convince a WTO adjudicator *in casu*. Yet, what has been clarified, the *prima facie* case does not absolve the complainant from the burden of proof in the strict sense, i.e., the risk of non-persuasion where the evidence rests in equipoise.

B. THE BURDEN OF PROOF UNDER ARTICLE 5.7

Article 5.7 transgresses the distinction between exceptions and general obligations and operates as "*qualified exemption*". Does that mean that the general rules governing the burden of proof under the *SPS Agreement* are also applicable to Article 5.7, or is the onus of demonstrating that all conditions for the imposition of a provisional measure shift to the defending country?

1. WTO Jurisdiction: Complainant

The Appellate Body has not specifically addressed the burden of proof for Article 5.7. Although, not expressly tackling that issue, the Panel in *Japan – Agricultural Products*, when determining, whether the conditions under Article 5.7 were met, referred to the general burden of proof as established for Article 2.2 of the *SPS Agreement*.⁴⁷⁰ In assessing whether the United States had made a *prima facie* case of inconsistency with Article 5.7, the Panel found that there was no evidence indicating that Japan had sought to obtain the information necessary and carried out a review of its measure.

⁴⁷⁰Panel Report, *Japan – Agricultural Products*, para. 8.59.

The Panel considered that the United States had established a presumption that Japan failed to comply with its obligation under Article 5.7 second sentence and that Japan was not able to rebut this presumption.⁴⁷¹

Thus, to date, WTO jurisdiction suggests that the complainant must make a *prima facie* case of violation of Article 5.7 of the *SPS Agreement*.

2. Literature: Divided

The literature is divided on the burden of proof. According to *Pauwelyn*, the status of Article 5.7 as "qualified exemption" suggests that the Member imposing the provisional measure has the burden of proof that the four elements are met.⁴⁷² *Charnovitz* concurred with the WTO jurisdiction, that the complainant should establish a violation of Article 5.7.⁴⁷³ This reflects the general literature on the *SPS Agreement*, according to which the burden of proof should always be on the complainant.⁴⁷⁴

3. Analysis: *In dubio pro precaution*

Bearing in mind that rebutting a *prima facie* seems to be a heavier burden than making a *prima facie* case, one might hesitate and wonder for a moment, whether the allocation of the burden of proof on the defending country would not be more beneficial. The notion of "qualified exemptions" simply does not say anything about the burden of proof. Facing an apparent lack of textual arguments,

⁴⁷¹*Ibid.*, para 8.58.

⁴⁷²*Pauwelyn*, Joost, "The WTO Experience Under the *SPS Agreement*", World Trade Forum, 2000 (forthcoming), pp. 95-108, at 101.

⁴⁷³*Charnovitz*, Steve, "The Supervision of Health and Biosafety Regulation by World Trade Rules", World Trade Forum, 2000 (forthcoming), pp. 121-150, at 135.

⁴⁷⁴*Walker*, above n. 455, at 295; *Eckert*, Dieter, "Die neue Welthandelsordnung und ihre Bedeutung für den internationalen Verkehr mit Lebensmitteln", ZLR 4/95, pp. 363-395, at 372, who suggests to allocate the burden of persuasion but not the burden of proof on the defendant.

one needs to look at the purpose of Article 5.7 which is to ensure the right equilibrium between precaution and precautionism. If the burden of proof was on the country that takes a provisional measure, the benefit of doubt would work against health and environmental protection. Presented with inconclusive scientific evidence on highly complex issues such as biosafety, WTO adjudicators might sometimes be forced to base a decision on the burden of proof, because the evidence is in equipoise. Yet, as noted by *Pauwelyn*, "in case of doubt, the health measure should stand".⁴⁷⁵ The principal prevalence of health over trade is well reflected in the very existence of safety valves such as Article XX of the GATT and Article 5.7 of the *SPS Agreement*.

By contrast, allocating the onus of proof on the complainant would not render Article 5.7 useless. At first glance, the complainant might be disadvantaged, because he does not possess the evidence to show that the importing country has no "available pertinent information" to justify its measure. Most often, however, the exporter of a new product, which is subject to pre-marketing control, knows more about its dangers than the authorities of the importing country. Even in cases, of post-marketing control, e.g., where suddenly a disease like BSE breaks out in the country of import, the complainant would not face an insurmountable burden of proof.

The Appellate Body has provided for a very simple presumption technique to deal with these cases. In *Japan – Agricultural Products*, the United States argued, upon appeal, that it would be impossible to prove a negative, namely, that there is no scientific evidence which supports the measure taken with respect to apricots, pears, plums and quince.⁴⁷⁶ The Appellate Body was not convinced by this argument and countered that raising a presumption that there are no relevant studies or reports is not an impossible

⁴⁷⁵*Pauwelyn*, above, n. 472, at 98.

⁴⁷⁶Appellate Body Report, *Japan – Agricultural Products*, para. 133.

burden. The United States could have requested Japan, pursuant to Article 5.8 of the *SPS Agreement*, to provide an explanation of the reasons for its varietal testing requirement.⁴⁷⁷ The failure of Japan to fulfil this obligation would have been a strong indication that there are no such studies or reports.⁴⁷⁸ The *SPS Agreement* does not spell out a similar duty to disclose information for the exporting Members. Where the exporting Member continuously declines to disclose information, as, e.g., the United States regarding the hormone MGA in *European Communities - Hormones*, a panel could request information based on Article 13.1 of the DSU.

Such a combination of presumption techniques with the possibility of drawing adverse inference where a party does not respond would ease the burden of the complaining country to make a *prima facie* that Article 5.7 of the *SPS Agreement* is violated. It creates incentives for parties on both sides to cooperate and to produce adequate evidence. This reflects the duty to cooperate in international dispute settlement proceedings in order to place the facts related to the disputes before the tribunal.⁴⁷⁹ Already the negotiating history of Article 5.7 of the *SPS Agreement* indicates that "ultimately the responsibility of justifying application and compliance with certain regulations rests with both parties".⁴⁸⁰

C. SUMMARY

The analysis of the WTO jurisdiction in the light of scholarly criticism allows three conclusions which are important for precautionary measures. First, the general rule set forth by the

⁴⁷⁷ Article 5.8 of the *SPS Agreement* provides: "When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure."

⁴⁷⁸ Appellate Body Report, *Japan – Agricultural Products*, para. 133.

⁴⁷⁹ *Kazazi*, above, n.460, at 223.

⁴⁸⁰ MTN.GNG/NG5/WGSP/W/17, at 2.

Appellate Body, whereby the burden of proof is initially on the complaining party which must establish a *prima facie* case of inconsistency with a particular provision of the *SPS Agreement*, but then moves to the defendant, once a *prima facie* case is made, does not mean that the burden of proof in the strict sense shifts, but only the evidentiary burden. Thus, the risk of non-persuasion remains on the complainant who fails in situations where the evidence is in equipoise.

Second, the standard of proof is a *prima facie* case. While no precise requirements of a *prima facie* have been developed so far, the Appellate Body ensured that a minimum hurdle needs to be taken, i.e., an exporting country cannot challenge a measure with mere allegations that there is no scientific evidence.

Third, although Article 5.7 of the *SPS Agreement* transgresses the distinction between general obligations and exceptions, by operating as "qualified exemption", the general burden of proof under the *SPS Agreement* is applicable to that provision. Thus, the complaining country must make a *prima facie* case that the conditions for a provisional measure are not fulfilled.

III. DEFERENCE AND STANDARD OF REVIEW

In situations of scientific uncertainty municipal courts pay a large measure of deference to decisions of governmental authorities.

Again, WTO law operates at a different level. *Jackson* has coined the issue in the question "to which degree should a Panel second-guess a decision of national government agencies concerning economic regulations"? or where is the "point up to which panels should respect national decisions"?⁴⁸¹

A standard of review is only incorporated in Article 17. 6 of the *Anti-Dumping Agreement* which distinguishes between the assessment of the facts and the interpretation of the relevant provisions.⁴⁸² According to Article 17.6, panels shall not overturn an establishment of the facts by the Member, if that assessment "was unbiased and objective [...] even though the panel might have reached a different conclusion". Where the panel finds "that a relevant provision of the Agreement admits of more than one permissible interpretation, the panel shall find the authorities' measures to be in conformity with the Agreement if it rests upon one of those

⁴⁸¹ *Croley, Steven P./Jackson, John H., "WTO Dispute Procedures, Standard of Review, and Deference to National Governments", 90 AJIL (1996), pp. 193-213., at 194.*

⁴⁸² Article 17. 6 of the *Anti-Dumping Agreement* provides in full:

In examining the matter referred to in paragraph 5:

(i) in its assessment of the facts of the matter, the panel shall determine whether the authorities' establishment of the facts was proper and whether their evaluation of those facts was unbiased and objective. If the establishment of the facts was proper and the evaluation was unbiased and objective, even though the panel might have reached a different conclusion, the evaluation shall not be overturned.

(ii) the panel shall interpret the relevant provisions of the Agreement in accordance with the customary rules of interpretation of public international law. Where the panel finds

that a relevant provision of the Agreement admits of more than one permissible interpretation, the panel shall find the authorities' measures to be in conformity with the Agreement if it rests upon one of those permissible interpretations.

permissible interpretations.⁴⁸³ The Uruguay Round negotiators left it to the DSU review to decide whether this standard should be applied to other Agreements.⁴⁸⁴

The *SPS Agreement* is silent on the appropriate standard of review for SPS measures. In *European Communities – Hormones*, the Appellate declined to transfer the standard specifically negotiated for Article 17. 6 *Ant-Dumping Agreement* and held that Article 11 of the DSU "articulates with great succinctness but with sufficient clarity the appropriate standard of review for panels in respect of both the ascertainment of facts and the legal characterization of such facts under the relevant agreements."⁴⁸⁵ With respect to fact-finding the Appellate Body held that "the applicable standard is neither *de novo* review as such, nor total deference", but rather an objective assessment of the facts".⁴⁸⁶ In so far as legal questions are concerned, panels have the duty to apply the customary rules of interpretation of public international law, and, according to Article 11 of the DSU have to "make an objective assessment of the matter before it".⁴⁸⁷

This case law raises two questions which are important for the taking of precautionary measures. First, to which extent does WTO dispute settlement pay "legal deference" towards the interpretation of the ambiguous legal concepts of, e.g., "available pertinent information" and "reasonable period of time" in the *SPS Agreement*. Second, to which extent do panels defer to the determination of a Member that it has sufficient scientific evidence or pertinent information which warrants a precautionary measure?

⁴⁸³Article 17. 6 (ii) of the *Anti-Dumping Agreement*.

⁴⁸⁴Decision on Review of Article 17. 6 of the Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994.

⁴⁸⁵Appellate Body Reports, *European Communities – Hormones*, para. 116.

⁴⁸⁶*Ibid.*, para. 117.

⁴⁸⁷*Ibid.*, para. 118.

A. LEGAL DEFERENCE

Both, *Jackson* and *Hudec*, have noted that the Appellate Body generally pays deference in the interpretation of treaty obligations.⁴⁸⁸ This section analyses the degree of "legal" deference paid to Members under the *SPS Agreement* by briefly recapitulating the interpretation of the legal concepts under the *SPS Agreement*.

1. WTO Jurisdiction

The most cited example for legal deference is the interpretation of the term "based on" international standards in Article 3.1 of the *SPS Agreement* in *European Communities – Hormones*. While the Panel had interpreted "based on" as conform to, which would have given *de facto* binding effect to, e.g., standards of the Codex Alimentarius Commission, the Appellate Body cautioned: "We cannot lightly assume that sovereign states intended to impose upon themselves the more onerous, rather than the less burdensome, obligation by mandating conformity or compliance with such standards, guidelines and recommendations. To sustain such an assumption and to warrant such a far-reaching interpretation, treaty language far more specific and compelling than that found in Article 3 of the *SPS Agreement* would be necessary."⁴⁸⁹ The Appellate Body buttressed its deferential interpretation of Article 3.1 with reference to the *in dubio mitius* principle, a supplementary means of interpretation in public international law, whereby in cases of ambiguity that meaning is to be preferred which is less onerous to the party assuming an obligation.⁴⁹⁰

⁴⁸⁸ *Jackson*, John H., "Dispute Settlement and the WTO – Emerging Problems", 1 *Journal of International Economic Law* 329 (1998), p. 341; *Hudec*, Robert E., "The New WTO Dispute Settlement Procedure: An Overview of the First Three Years", 8 *Minn. J. Global Trade* 1 (1999), at 30.

⁴⁸⁹ Appellate Body Report, *European Communities – Hormones*, para. 165.

⁴⁹⁰ *Ibid.*, para 165 and footnote 154 with references to scholarly writings and ICJ decisions.

Although not citing to Article 11 of the DSU or the *in dubio mitius* principle, the Appellate Body, continued to adopt the less restrictive interpretation of other concepts of the *SPS Agreement*. In *European Communities – Hormones*, the Appellate Body also reversed the more onerous interpretation of "based on" in Article 5.1 of the *SPS Agreement*. Instead of a procedural requirement and a substantive requirement that the measure must "conform" to the risk assessment, the Appellate Body only requires that there be a "rational relationship" between the measure and the risk assessment⁴⁹¹, thus leaving more room for manoeuvre to Members, because they do not have to slavishly follow the conclusions of scientific risk assessments.

A further example, where the Appellate Body chose the less deferential interpretation, is the notion of risk. The Appellate Body gives broad wiggle-room to Members to decide which factors to be taken into account or whether to make a qualitative or quantitative risk assessment. While this suggests a large measure of legal deference, it should be noted that the term "evaluate" was interpreted strictly in that sense that "some evaluation" is not enough.⁴⁹²

As far as Article 5.7 is concerned, the Appellate Body, when interpreting the element "seek to obtain the additional information necessary for a more objective assessment of the risk", noted that neither Article 5.7 nor any other provision of the *SPS Agreement* sets out explicit prerequisites regarding the additional information to be collected", and does not "specify what actual results must be achieved". While this, again, signals a deferential approach, the Appellate Body did not pay complete deference to Members in determining how to discharge this obligation. Referring to the goal of Article 5.7 to conduct "a more objective assessment of risk", the Appellate Body required that "the information sought must be

⁴⁹¹*Ibid.*, para. 193.

⁴⁹²Appellate Body Report, *Australia – Salmon*, para. 124.

germane to conducting such a risk assessment".⁴⁹³ Finally, an interpretation of the "reasonable period of time" was not given. The Appellate Body determines what is reasonable on a case-by-case basis.⁴⁹⁴

2. Analysis

The Appellate Body has practiced a high degree of deference in interpreting the relevant legal concepts under the *SPS Agreement*. Where the treaty text allows for two possible interpretations, the Appellate Body chose the less onerous one. The Appellate Body has already interpreted the procedural requirements in Article 5.7, second sentence, in a deferential way. The term "reasonable period of time" does not allow opposing interpretations, but is so ambiguous that it can only be applied on a case by case basis. With regard to this element, the standard of review for fact-finding will be decisive. With respect of Article 5.7, first sentence, it appears that the element "on the basis of available pertinent information" would, as the element "based on", also be interpreted in a deferential way, by using a broad rational relationship test. Possibly, the choice of the words "on the basis of" as compared to "based on", implies even more wiggle room for Members under Article 5.7 than under Article 5.1 of the *SPS Agreement*.

B. FACTUAL DEFERENCE TO NATIONAL RISK DETERMINATIONS

In the first three disputes under the *SPS Agreement*, the defendants had challenged the fact-finding of the panels upon appeal. In particular, in *European Communities – Hormones*, the European Communities contested that the Panel had assigned higher probative

⁴⁹³ Appellate Body Report, *Japan – Agricultural Products*, para. 92.

⁴⁹⁴ *Ibid.*, para. 93.

value to the scientific views expressed by its experts than the scientific evidence presented by the European Communities.⁴⁹⁵

1. WTO Jurisdiction

The Appellate Body clarified in *European Communities – Hormones*, that a panel, should not seek to redo the investigation conducted by the national authority but instead "verify whether the determination by the national authority was 'correct', both factually and procedurally".⁴⁹⁶

a) Limited Scope of Appellate Review

The Appellate Body has not indicated, at which point panels should refrain from second-guessing national risk assessments. A violation of Article 11 is only given where the participant demonstrates an "egregious error" or the "deliberate disregard of, or refusal to consider, the evidence submitted" or the "wilful distortion or misrepresentation of the evidence put before a panel".⁴⁹⁷ Applying this reduced standard of appellate review the Appellate Body upheld the fact-finding of the panels in all three disputes thus far.⁴⁹⁸

b) Emerging Standards at the Panel Level

The degree of deference paid by the Panels themselves varied significantly between the first three cases, and the Article 21.5 proceeding in *Australia – Salmon*:

(i) *European Communities - Hormones*

In *European Communities – Hormones* the Panel stressed that it has "no mandate to re-examine the risk assessment referred to by the European Communities in light of this 'new evidence' nor to make our

⁴⁹⁵Appellate Body Report, *European Communities – Hormones*, para. 110.

⁴⁹⁶*Ibid.*, para. 111.

⁴⁹⁷*Ibid.*, para. 133.

⁴⁹⁸See Appellate Body Reports, *Australia – Salmon*, paras. 262-267. See also, Appellate Body Report, *Japan – Agricultural Products*, para 142.

own risk assessment".⁴⁹⁹ The Panel, however, gathered evidence from the experts and relied on that to support its finding that the studies submitted by the European Communities do not constitute a proper risk assessment.⁵⁰⁰ The Panel referred to the majority opinion of the scientific experts advising the Panel, which confirmed that the conclusions of the scientific studies support that the use of hormones for growth promotion purposes is safe and that any diverging evidence would not invalidate or contradict the scientific conclusions reached in the scientific studies, and found that the hormone ban was not based on a risk assessment.⁵⁰¹ When dealing with diverging views the Panel inquired whether this evidence had already been taken into account in other studies and dismissed the evidence, again following the opinion of one of the experts.⁵⁰²

(ii) *Japan – Agricultural Products*

Similarly, in *Japan – Agricultural Products*, the Panel used the evidence gathered during the panel proceedings, e.g., the possibility to determine sorption levels, to dismiss Japan's assertion that its varietal testing requirement was based on sufficient scientific evidence.⁵⁰³

(iii) *Australia – Salmon*

In *Australia – Salmon*, the Panel rather made random or overall checks to see whether the, risk assessment evaluates the probability of effects. Finding that there is "some" evaluation of the likelihood, it "assumed" that the Australian study meets the

⁴⁹⁹Panel Report, *European Communities – Hormones*, para. 8. 104 (US), para. 8. 118. (CAN).

⁵⁰⁰*Ibid.*

⁵⁰¹Panel Report, *European Communities – Hormones*, paras. 8. 127, 8. 136 (CAN).

⁵⁰²*Ibid.*, para. 8. 135.

⁵⁰³Panel Report, *Japan – Agricultural Products*, paras. 8. 42 ff.

requirements for a risk assessment.⁵⁰⁴ Here, the Appellate Body came down somewhat stricter and held that "some" evaluation is not enough.⁵⁰⁵

(iv) Reasonable Confidence Test in *Australia – Salmon*, 21.5

By contrast, the 21.5 Panel in *Australia – Salmon*, took a different approach. It set forth a reasonableness test. In determining whether the new studies and risk assessment submitted by Australia in the 21.5 proceedings fulfilled the requirements of Article 5.1 of the *SPS Agreement*, the Panel stated: "We hold the view that the level of objectivity to be achieved in a risk assessment must be such that one can have *reasonable* confidence in the evaluation made, in particular in the levels of risk assigned."⁵⁰⁶ Reviewing the Australian risk assessment it concluded that "the flaws identified are not so serious as to prevent us from having reasonable confidence in the evaluation made and the levels of risk assigned."⁵⁰⁷ Accordingly, the Panel concurred with Australia, that its new study constituted a proper risk assessment in line with the requirements spelled out by Articles 5.1 and Annex A.4 of the *SPS Agreement*.

2. Literature

The scholarly positions regarding the standard of review for fact-finding can be roughly divided into three strands of argument.

a) Transplanting National Standards of Review?

Wirth argued in favour of transferring the concepts of deference as applied by national courts to WTO law.⁵⁰⁸ According to him, allowing WTO panels composed of lay persons to substitute their

⁵⁰⁴Panel Report, *Australia – Salmon*, para. 8.83.

⁵⁰⁵Appellate Body Report, *Australia – Salmon*, para. 124.

⁵⁰⁶Panel Report, *Australia – Salmon*, 21.5, para. 7. 51.

⁵⁰⁷*Ibid.*, para. 7.57.

⁵⁰⁸*Wirth*, David A., "The Role of Science in the Uruguay Round and NAFTA Trade Disciplines", 27 *Cornell Int'l L. J.* (1994), pp. 817-859.

judgement for that of technical experts would contradict policy and practice by municipal tribunals at the national level.⁵⁰⁹ Thus, there should be an implicit notion of deference to national scientific determinations.⁵¹⁰ WTO panels should only scrutinize whether a minimum level of scientific rationality supports a national measure.⁵¹¹ The test should rather be procedural than substantial. Thus, a Panel could scrutinize whether the scientific risk assessment of the national authority has obtained peer-review approval. *Wirth* suggested that panels examine whether the adoption of the measure was preceded by an attempt to gather empirical data, whether these data are characterized by indicia of reliability, e.g., reproducibility, whether these data enjoy any following in the scientific community, and whether the assumptions made in performing the risk assessment have been disclosed.⁵¹²

b) Against Misplaced Analogies

Croley and *Jackson* discussed in depths the possibilities of applying municipal standards of review to WTO law.⁵¹³ Analysing the example of the U.S. Chevron doctrine and its underlying rationale, they found that neither of the justifications for according deference to agencies at the national level can be transferred to the relationship between Panels and WTO Members.⁵¹⁴ WTO Members have a natural incentive to cheat, which needs to be curtailed.⁵¹⁵ The underlying rational of the WTO dispute settlement is international cooperation and Members have relinquished at least some minimum powers. Yet, such power does not lessen the importance at the national level of decision-making expertise, democratic accountability

⁵⁰⁹*Ibid.*, at 854.

⁵¹⁰*Ibid.*, at 855.

⁵¹¹*Ibid.*

⁵¹²*Ibid.*

⁵¹³*Croley/Jackson*, above n. 481.

⁵¹⁴*Ibid.*, at 208 and 212.

⁵¹⁵*Ibid.*, at 210.

or institutional efficiency.⁵¹⁶ To respect this delicate balance, "some trade-off is necessary".⁵¹⁷ Thus, *Croley/Jackson* argue in favour of "some international deference to national decisions", but reject misplaced analogies taken from the national-level approach.⁵¹⁸

c) Comments on the Case Law

The decision of the Appellate Body in *European Communities – Hormones* was fiercely criticized by *Walker*, who advocated a "plausibility" standard, i.e., panels should only scrutinize whether a risk assessment is "scientifically plausible".⁵¹⁹ *Desmedt* and *Lugard*, both noted that the use of Article 11 of the DSU, is not a standard of deference as applied by national courts in their relationship to national authorities in the strict sense, but rather a standard of appellate review, which delimits the scope of appellate review.⁵²⁰ *Charnovitz* pointed to the asymmetry between the deference towards national judgements of economic interests which is secured under the *Anti-Dumping Agreement* and the lack of deference to national judgements of health interests.⁵²¹ *Pauwelyn* agreed that often panels are, indeed, called upon to conduct their own assessment of whether, e.g., the use of hormones in beef production is safe.⁵²² He advised that a deferential reasonableness standard cannot function without procedural rules.⁵²³

⁵¹⁶*Ibid.*, at 211.

⁵¹⁷*Ibid.*

⁵¹⁸*Ibid.*, at 211 and 212.

⁵¹⁹*Walker*, Vern R.: Keeping the WTO from Becoming the "World Trans-science Organization": Scientific Uncertainty, Science Policy, and Fact-finding in the Growth Hormones Dispute, *Cornell Int'l L. J.*, Vol. 31 (1998), 251-320, at 303-305.

⁵²⁰*Desmedt*, G. Axel, Hormones: 'Objective Assessment' and (or as) standard of review, 1 *JIEL* 1998, pp. 695-698. *Lugard*, Maurits, "Scope of Appellate Review, Objective Assessment of the facts and issues of law", 1 *JIEL* 323 1998.

⁵²¹*Charnovitz*, Steve, "Environment ad Health Under WTO Dispute Settlement", 14 *International Trade Reporter* (1997), at 913.

⁵²²*Pauwelyn*, Joost, "The WTO Experience Under the *SPS Agreement*", *World Trade Forum*, 2000 (forthcoming), at 104.

⁵²³*Ibid.*

3. Analysis: Towards a Deferential Reasonableness Standard?

The point up to which WTO adjudicators may second-guess national assessments of risks is not yet marked by a clear standard of review.

The Appellate Body declined to adopt a "positive standard" of review which is not clearly rooted in the *SPS Agreement* or to apply Article 17.6 of the *Anti-Dumping Agreement* by analogy against the express will of the Members. For the time being, the Appellate Body has fixed a "negative standard of review" by referring to Article 11 of the DSU. This standard of appellate review of the panel's fact-finding is only triggered by an egregious error, or a wilful distortion of the evidence on the part of the panel. The experience in the first three cases has shown that a reviewable violation of Article 11 of the DSU can hardly be demonstrated. That leaves it *de facto* to panels to which extent they want to defer to national risk assessments. The ruling of the Panel in *Australia - Salmon*, 21.5, indicates that panels are willing to pay deference and raises the question, why the panel in *Australia - Salmon*, 21.5, used a kind of deferential reasonableness standard, while the same panel as well as the other two SPS panels re-assessed the scientific evidence with help of their experts?

One possible answer might be that the first three measures were "old" measures where no risk assessment complying with the rules of the *SPS Agreement* existed. By contrast, *Australia - Salmon*, 21.5, involved a "new measure", taken to comply with the obligations under the *SPS Agreement*, as interpreted by the Appellate Body. Because, a risk assessment pursuant to Article 5.1 and Annex A.4 existed when the measure was taken, the Panel could confine its examination on whether this risk assessment conforms with the procedural guidelines set out by Annex A.4.

It is uncertain, whether the reasonable objectiveness test, as set forth by that 21.5 panel would be endorsed by the Appellate Body. One could argue, that this would be tantamount to applying Article

17.6 of the *Anti-Dumping Agreement*, or the "deferential reasonableness standard" suggested by the European Communities, which was explicitly rejected by the Appellate Body. Moreover, under the *Anti-Dumping Agreement*, clear procedural rules and standards exist, thus allowing panels to pay deference to, e.g., the establishment of injury.

Although national jurisdictions have developed specific standards of review for scientific uncertainty, *Jackson's* argument against misplaced analogies is convincing. The relationship between WTO panels and national governments differs from that between national courts and municipal authorities. The *SPS Agreement* went behind the border to ensure that judicially ill-controlled national sanitary and phytosanitary measures cannot disadvantage foreign exporters. When transplanting the large municipal margins of appreciations to WTO law, the obligations under the *SPS Agreement* might run empty. At the same time, however, only national authorities have the democratic legitimacy and constitutional duty to protect human health and the environment. The WTO could not discharge a responsibility of determining whether there is a risk or not.

The *SPS Agreement* in Articles 2.2, 5.1 and 5.7, takes a process-oriented approach, which allows panels to reduce their review to controlling whether Members have *assessed* the risks, but not whether there *is* a risk. Because the procedural rules, in particular the obligations under Article 5.7 are still in their infancy, panels have, to date, no choice, but must second-guess the data with the help of their experts. Yet, procedures for risk analysis which take due account of the interests of foreign exporters and the obligations under the *SPS Agreement* are currently negotiated in the *Codex Alimentarius Commission*. Pending the further refinement of such procedures, there might only be limited scope for a reasonableness test similar to the one adopted under Article 17. 6 of the *Anti-Dumping Agreement*. However, over the long run, new process-oriented precautionary rules

might mark the "trade off" between national responsibility for food safety and cooperation between the WTO Members.

C. SUMMARY

In short, the standard of review applied under the *SPS Agreement* is Article 11 of the DSU, which requires Panels to make an objective assessment of law and facts. The Appellate Body jurisdiction indicates a considerable degree of deference with respect to the interpretation of legal concepts.

This holds also true for the terms under Article 5.7, as they have already been interpreted by the Appellate Body and warrants a legitimate expectation that the Appellate Body would also interpret the "on the basis of available pertinent information requirement" standard so as to accord considerable wiggle-room to Members taking a precautionary measure.

The point to which WTO adjudicators can second-guess national risk assessments, i.e., the standard of review for fact-finding, is not yet clearly determined. The Appellate Body interprets and applies Article 11 of the DSU as a standard of appellate review, which is only triggered by an egregious error or wilful distortion of facts. This leaves a large measure of discretion to panels to which degree they re-evaluate national assessments. The analysis of the factual determinations has shown that the Panel's have heavily second-guessed the facts in the first three cases where "old" measures were at stake and no risk assessment existed. However, the Australia 21.5 Panel adopted a "reasonable objectiveness" standard in the first assessment of a "new" measure. The status of this test is still unclear. Over the long run there might be a potential for a reasonableness test similar to the one in the *Anti-Dumping Agreement*. However, this requires that the process-oriented obligations under the *SPS Agreement* will be more refined. Pending the formulation of further criteria on how Members should proceed when taking provisional measures, no positive standard of review for facts exists.

III. CONCLUDING REMARKS:

The line between precaution and precautionism is still hazy.

It is essentially drawn by Article 5.7 of the *SPS Agreement*. The analysis of the conditions for precautionary measures under Articles 2.2, 5.1 and 5.7 of the *SPS Agreement* allows the argument that the mechanism, indeed, reflects the precautionary principle at several levels. However, the broad "case-to-case" or "we know it when we see it" tests do not provide legal certainty, to which extent Members may take precautionary measures. Testing the Article 5.7 filter with the hypotheticals suggests that it produces relatively good results for "model" provisional measures, e.g. the emergency actions taken in the BSE cases. The procedural requirements under Article 5.7 second sentence work well to catch blatant cases of "scientific idleness", i.e. "old" measures, where imports have been blocked for years on the basis of unverified scientific assumptions. However, at both ends of the spectrum, i.e. Hormones II and the "what if..?" questions involved in the biotechnology cases, WTO adjudicators might be forced to "determine" whether Members have adopted the measures "on the basis of available pertinent" information. Although the interpretation of the requirement gave some guidance on the application of this possible "mini-rational relationship" test, WTO adjudicators might well come down on both sides.

The validity of these measures will only be decided in WTO dispute settlement proceedings. Although, some issues regarding the burden of proof and standard of review could be resolved, they are also rather unpredictable levers in the mechanism. Thus, when looking back, the accordion-like concept of the "like-product" test, coupled with the exception under Article XX of the GATT, has, in the end, been replaced by another accordion, albeit with fewer keys. It still needs fine-tuning.

PART 3

CROSS-REFLECTIONS

The development of new precautionary principles in the *Cartagena Protocol on Biosafety* (the "*Cartagena Protocol*") and the Codex Alimentarius Commission puts the spotlight on the link between these norms and WTO law. The Preamble of the *Cartagena Protocol* envisages a "mutually supportive" relationship between trade and environment agreements. The WTO Appellate Body noted in *United States – Shrimp* that a "jointly determined" solution for trade conflicts marks out "the line of equilibrium" between trade and the goal of environmental protection.¹ In that case, the Appellate Body exercised what has been called "principle-orientation" of WTO law² or "cross-fertilization of international law"³ by interpreting Article XX of the GATT in the light of multilateral environmental agreements.

However, as *Hilf* cautioned, although WTO law needs the use of outside principle, the interpretation of the obligations under the WTO agreements in the light of "outside" principles is a "sensitive process".⁴ This is particularly true for the precautionary principle. In *European Communities – Hormones*, the Appellate Body emphasized

¹Appellate Body Report, *United States – Shrimp*, para. 170.

²*Hilf*, Meinhard, "Power, Rules and Principles – Which Orientation for WTO/GATT Law?" 4 JIEL (2001) forthcoming.

³*Sands*, Philippe, "Treaty, Custom and the Cross-fertilization of International Law", 1 Yale H.R. & Dev. L. J. Vol. 1 85 (1998).

⁴*Hilf*, above n. 2.

that it may not "override" the *SPS Agreement*.⁵ Observers have expressed concerns that the new precautionary principles might be a "slippery slope" towards eroding the science based mechanism of the *SPS Agreement*.⁶ The *SPS Agreement* provides for a more nuanced relationship with outside norms and other international organizations than most other WTO agreements.

Chapter 1 analyzes the possible relationships between the precautionary principle and the *SPS Agreement*. It argues that they may be used to interpret Article 5.7 of the *SPS Agreement*, either as "incorporated standards" or according to Article 31.3(c) of the *Vienna Convention*, unless there is a conflict.

Chapters 2 and 3 specifically explore the effects of the *Draft Codex Working Principles for Risk Analysis* and the *Cartagena Protocol* in WTO disputes and finds that further "cross-reflections" can refine the line between precaution and precautionism.

⁵Appellate Body Report, *European Communities – Hormones*, para. 125.

⁶So, Senator *John Ashcroft* of Missouri in his letter of April 19th 2000, available at <http://www.insidetrade.com> (visited 2 June 2000).

§1 Possible Relationships between the Precautionary Principle and the *SPS Agreement*

Three norms directly bear on the relationship between the *SPS Agreement* and the precautionary principle. First, Article 3.2 of the DSU directs WTO adjudicators to "clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law." The Appellate Body emphasized that WTO law is not a separate legal order. The direction given in Article 3.2 of the DSU "reflects a measure of recognition that the *General Agreement* is not to be read in clinical isolation from public international law".⁷ The rules of treaty interpretation applicable in the interpretation of WTO law include Article 31.3(c) of the *Vienna Convention*, whereby a treaty interpreter shall take into account, together with the context, "any relevant rules of international law applicable in the relations between the parties."⁸ Article 3.2 of the DSU, thus, draws a basic distinction between norms of WTO law, which form the legal basis of a dispute and "outside" norms which have an interpretative function.

The *SPS Agreement* contains further provisions dealing with the relationship to outside norms. First, the *SPS Agreement* incorporates international standards, guidelines and recommendations, including those of the Codex Alimentarius Commission.⁹ Compliance with such standards can create a presumption of consistency of a measure with the *SPS Agreement*.¹⁰ Moreover, these standards can

⁷Appellate Body Report, *United States – Gasoline*, at 11.

⁸Appellate Body Report, *United States – Shrimp*, para. 158.

⁹*SPS Agreement*, Articles 3, 5.1 and Annex A.3.

¹⁰*SPS Agreement*, Article 3.2.

play a role as risk assessment techniques in Article 5.1 of the *SPS Agreement*.¹¹

Second, the *SPS Agreement* is the only WTO agreement which contains a savings clause regulating possible conflicts with other international agreements. Article 11.3 of the *SPS Agreement* stipulates: "Nothing in this Agreement shall impair the rights of Members under other international agreements, including the right to resort to the good offices or dispute settlement mechanisms of other international organizations or established under any international agreement". This rule suggests that in case of conflict, the other international agreement can prevail, but that the WTO dispute settlement mechanism cannot be used.

Following the Communication of the European Communities on the precautionary principle, both, the SPS Committee and the Committee on Trade and Environment (the "CTE")¹², flagged the relationship between the precautionary principle and the *SPS Agreement*, but have not taken a formal decision on that subject.¹³

I. WTO JURISDICTION

The general relationship between the precautionary principle and the *SPS Agreement* was brought up in *European Communities – Hormones*, and also tackled in *Japan – Agricultural Products*.

A. EUROPEAN COMMUNITIES – HORMONES

In *European Communities – Hormones*, the European Communities invoked *the* precautionary principle to support that the

¹¹The precise effect of outside standards will be examined below.

¹²Established on the basis of the Decision on Trade and Environment of 14 April 1994, (MTN/TNC/45/MIN). See generally, *Nordstroem, Hakan/Vaughan, Scott*, "Trade and Environment" (WTO Special Studies, 1999).

¹³SPS Committee, Summary of the Meeting held on 15-16 March 2000, G/SPS/R/18, 18 April 2000; Committee on Trade and Environment, Report of the Meetings held on 5-6 July 2000. WT/CTE/M/24, see in particular pages 20-22.

ban on hormone-treated beef was based on a risk assessment and, thus, complied with Article 5.1 of the *SPS Agreement*. The European Communities argued that the precautionary principles requires it to give the "benefit of doubt" to consumer protection in cases where the safety of a product is not proven.¹⁴ The Panel responded:

To the extent that this principle could be considered as part of customary international law *and* be used to interpret Articles 5.1 and 5.2 on the assessment of risks as a customary rule of interpretation of public international law (as that phrase is used in Article 3.2 of the DSU), we consider that this principle would not override the explicit wording of Articles 5.1 and 5.2 outlined above, in particular since the precautionary principle has been incorporated and given a specific meaning in Article 5.7 of the *SPS Agreement*.¹⁵

Picking up from the Panel's acknowledgement that the precautionary principle could be used to interpret Article 5.1 of the *SPS Agreement*, the European Communities argued upon appeal that the precautionary principle has attained the status of a customary principle of international law, or at least a general principle of international law. It emphasized that the precautionary principle was not invoked to override Article 5.1 of the *SPS Agreement* but to interpret it. More specifically, reading Article 5.1 of the *SPS Agreement* in the light of the precautionary principle would mean that: (1) it is not necessary for all scientists around the world to agree on the possibility and magnitude of the risk; and (2) it is not necessary for all or most of the WTO Members to perceive and evaluate the risk in the same way.¹⁶ The open and flexible wording of the *SPS*

¹⁴Panel Report, *European Communities – Hormones*, para. 4.202 (US) and para. 4.205 (CAN).

¹⁵*Ibid.*, para. 8. 157 (US) and para. 8. 160 (CAN).

¹⁶European Communities' appellant's submission, para. 88.

Agreement, so the view of the European Communities, would allow its interpretation in the light of the precautionary principle.¹⁷ The United States and Canada, in concert, contended that no precautionary principle exists in international law, but at best a precautionary approach which varies from context to context, and might be an emerging principle of law.¹⁸

The Appellate Body affirmed the finding of the Panel that the precautionary principle does not override the provisions of Articles 5.1 and 5.2 of the *SPS Agreement*.¹⁹ With respect to the requested interpretation of Article 5.1 of the *SPS Agreement* in light of the precautionary principle, the Appellate Body did not give a clear-cut answer.

The Appellate Body first distinguished between a precautionary principle in "general or customary international law" and "the precautionary principle in *environmental law*".²⁰ Noting that the latter is regarded by some as having crystallized into a customary principle of international environmental law, the Appellate Body found it "less than clear" whether it has been "widely accepted by Members as a principle of general or customary international law". Declining to make a ruling on this "important, but abstract, question", the Appellate Body stated that the precautionary principle "at least outside the field of international environmental law, still awaits authoritative formulation".²¹

The Appellate Body then noted four relationships of the precautionary principle to the *SPS Agreement*.

¹⁷*Ibid.*

¹⁸United States' appellee's submission, para. 92 and Canada's appellee's submission, para. 34.

¹⁹Appellate Body Report, *European Communities – Hormones*, para. 125.

²⁰*Ibid.*, para. 123.

²¹*Ibid.*

First, the principle has not been written into the *SPS Agreement* as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of that Agreement. Secondly, the precautionary principle indeed finds reflection in Article 5.7 of the *SPS Agreement*. We agree, at the same time with the European Communities, that there is no need to assume that Article 5.7 exhausts the relevance of the precautionary principle. It is reflected also in the sixth paragraph of the preamble and in Article 3.3. These 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. Thirdly, 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. Lastly, however, the precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e., customary international law) principles of treaty interpretation in reading the provisions of the *SPS Agreement*.²²

"Accordingly", the Appellate Body agreed with the Panel that the "precautionary principle does not override the provisions in Article 5.1 and 5.2 of the *SPS Agreement*".²³

²²*Ibid.*, para. 124.

²³*Ibid.*, para. 125.

B. *JAPAN – AGRICULTURAL PRODUCTS*

In *Japan – Agricultural Products*, Japan invoked a "precautionary principle" to support that its varietal testing requirement was compatible with WTO law. Japan referred to one of the Codex "General Principles for the Use of Food Additives", which states:

1. All food additives, whether actually in use or being proposed for use, should have been or should be subjected to appropriate toxicological testing and evaluation....,
2. Only those additives should be endorsed, which so far as can be judged on the evidence presently available, present no hazard to the health of the consumer at the levels of use proposed.²⁴

According to Japan, when interpreting Articles 2.2 and 5.1 of the *SPS Agreement* in line with this principle, an import ban should be allowed as long as science is uncertain.²⁵ The Appellate Body refused to interpret Article 2.2 of the *SPS Agreement* in light of the precautionary principle.²⁶ It referred to its statement in *European Communities – Hormones*, whereby the "precautionary principle finds reflection in the preamble, Article 3.3 and Article 5.7 of the *SPS Agreement*" and that this principle "has not been written into the *SPS Agreement* as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in the particular provisions of that Agreement."²⁷

²⁴Codex Alimentarius, Vol. A 1, (1995) at 47.

²⁵Japan's appellant's submission, para. 20.

²⁶Appellate Body Report, *Japan – Agricultural Products*, para. 81.

²⁷*Ibid.*

II. THE LITERATURE: INTERPRETATIVE FUNCTION

The case notes to *European Communities – Hormones* which tackled the role of the precautionary principle in the *SPS Agreement* agreed that provisions of multilateral environmental agreements, including the precautionary principle, can have an "interpretative function".²⁸ In particular *Sands* made a plea for "cross-fertilizations" between the precautionary principle as customary rule of international law and WTO law via Article 31.3(c) of the *Vienna Convention*.²⁹ He argued that WTO law should be interpreted consistently with general international law unless it can be shown that such an application would undermine the object and purpose of the WTO system. Using a presumption technique, *Sands* suggested that the burden should be on the party opposing the interpretation compatible with the customary rule to explain why it should not be applied.³⁰ *Marceau* stressed the importance of a clear distinction between sources of WTO law in the strict sense, i.e., provisions contained in the covered agreements, which are enforceable obligations and outside norms which can have an interpretative function under Article 31.3(c) of the *Vienna Convention*, as well as incorporated standards, which can either have an interpretative function or add additional obligations to WTO law.³¹

III. ANALYSIS

The rulings of the Appellate Body regarding the relationship between the precautionary principle and the *SPS Agreement* are sibylline. At first glance, one could conclude that the Appellate Body

²⁸See in particular: *Quick*, Reinhard/*Blüthner*, Andreas, "Has the Appellate Body Erred? An Appraisal and Criticism of the Ruling in the WTO Hormones Case", 2 *JIEL* 1999, pp. 603-639; *Marceau*, Gabrielle, "A Call for Coherence in International Law – Praises for the Prohibition Against 'Clinical Isolation' in WTO Dispute Settlement", 33 (5) *Journal of World Trade* 87 (1999); *Sands*, Philippe, "Treaty, Custom and the Cross-fertilization of International Law", 1 *Yale H.R. & Dev. L. J.* Vol. 1 85 (1998).

²⁹*Ibid.*

³⁰*Ibid.*

³¹*Marceau*, above, n. 28, at 109-115.

consistently refused to consider the precautionary principle when interpreting the *SPS Agreement*. However, when slightly reshuffling the four different relationships identified by the Appellate Body in *European Communities - Hormones* and holding it against the case law in other decisions, another picture of the relationship between the precautionary principle and the *SPS Agreement* emerges.

A. NO LEGAL BASIS IN A WTO DISPUTE

The first statement of the Appellate Body, whereby the precautionary principle has not been written into the *SPS Agreement* as a separate legal ground can be understood to clarify that only provisions included in the agreements covered by the DSU can be taken into consideration by WTO adjudicators. In *European Communities – Poultry*, the Appellate Body has spelled out more clearly that legal provisions not included in one of the covered agreements cannot form the legal basis of a WTO dispute.³² Indeed, the text of Articles 3.2, 7.2 and 11 of the DSU indicates that disputes can only be adjudicated with reference to the covered agreements. Thus, the Appellate Body correctly found that the precautionary principle cannot serve as an additional ground for justifying an SPS measure which is otherwise inconsistent with the *SPS Agreement*.

B. THE INTERPRETATIVE FUNCTION

However, the Appellate Body, in the fourth statement, noted "the duty of applying the normal (i.e., customary international law) principles of treaty interpretation in reading the provisions of the *SPS Agreement*". This appears to be a clear reference to Article 3.2 of the DSU, whereby the existing provisions of WTO law must be clarified "in accordance with customary rules of interpretation of public international law". The Appellate Body has stressed in numerous

³²Appellate Body Report, *European Communities – Measures Affecting Importation of Certain Poultry Products* ("*European Communities – Poultry*"), WT/DS69/AB/R, adopted 23 July 1998, para. 81.

circumstances that this directive refers to Articles 31 and 32 of the *Vienna Convention*. In *United States – Shrimp*, the Appellate Body has expressly referred to Article 31.3(c) of the *Vienna Convention*, thus acknowledging that WTO law can be read in light of relevant rules of international law applicable in the relations between the parties.³³ In other rulings the Appellate Body referred to custom³⁴ or general principles of law³⁵ to fill procedural gaps in the DSU, or used provisions of other environmental treaties to interpret Article XX of the GATT.³⁶ This suggests that outside principles such as the precautionary principle can generally be used to interpret the provisions of the *SPS Agreement*. The only counter-argument could be that the *SPS Agreement* has specifically regulated its relationship with outside norms by providing for the incorporation of "privileged standards" and thus excludes the consideration of additional "outside principles". However, such a reading could not be squared with Article 11.1 of the *SPS Agreement*, whereby the provisions of the DSU apply to disputes arising under the *SPS Agreement*, unless

³³Appellate Body Report, *United States – Shrimp*, para. 158.

³⁴In *European Communities – Bananas*, the Appellate Body adhered to custom when faced with the question whether WTO Members could be represented by outside counsel. Noting that this issue was not regulated in the DSU nor in the Working Procedures, the Appellate Body held "we can find nothing in... customary international law or the prevailing practice of international tribunals, which prevents a WTO Member from determining the composition of its delegation in Appellate Body proceedings." Appellate Body Report, *European Communities – Bananas*, para. 14.

³⁵In *United States – Shirts and Blouses*, the Appellate Body based the concept of the burden of proof, *inter alia*, on "a generally-accepted canon of evidence in civil law, common law and, in fact, most jurisdictions, that the burden of proof rests upon the party, whether complaining or defending, who asserts the affirmative of a particular claim or defence". See, Appellate Body Report, *United States – Shirts and Blouses*, at 14.

³⁶Appellate Body Report, *United States – Shrimp*, paras. 129-170. Reference to custom for gap filling purposes was also made at the panel level. See in particular Panel Report, *Korea – Measures Affecting Government Procurement* ("*Korea – Government Procurement*") WT/DS163/R, adopted 19 June 2000, where the Panel found in para. 7.96: "Customary international law applies generally to the economic relations between WTO Members. Such international law applies to the extent that the WTO treaty agreements do not 'contract out' from it. To put it another way, to the extent there is no conflict or inconsistency, or an expression in a covered WTO agreement that implies differently, we are of the view that the customary rules of international law apply to the WTO treaties and to the process of treaty formation under the WTO."

otherwise provided therein. None of the provisions incorporating international standards excludes the interpretation of the obligations of the *SPS Agreement* in accordance with the customary rules of interpretation as provided by Article 3.2 of the *DSU*.

It appears that the *SPS Agreement* seeks a more nuanced relationship to outside norms by particularly clarifying the role of some international standards while still allowing for an interpretative function of others under Article 31.3(c) of the *Vienna Convention*. These nuances have not yet been further elaborated by the Appellate Body. By contrast, in *Japan – Agricultural Products*, the Appellate Body rejected the interpretation of Article 2.2 of the *SPS Agreement* in the light of a Codex norm on the same grounds as the "customary" precautionary principle in *European Communities - Hormones*. The distinctions between incorporated standards and general rules of international law are, however, important. When "taking into account" the precautionary principle in determining the meaning of a provision, according to Article 31.3(c) of the *Vienna Convention*, the treaty interpreter would need to consider the different roles of outside norms. For example, because Article 3.2 of the *SPS Agreement* provides for a "presumption of consistency" with the *SPS Agreement* if a measure conforms with an international standard, other outside principles might not have the legal effect of a presumption of consistency as suggested by *Sands*.³⁷

C. WHY HAS THE APPELLATE BODY DECLINED TO USE THE PRECAUTIONARY PRINCIPLE TO INTERPRET THE *SPS AGREEMENT*?

Although the Appellate Body acknowledged a possible interpretative function of a precautionary principle in WTO law, it consistently declined to use such principles to interpret Articles 2.2

³⁷The different effects of outside norms which are "incorporated standards" and other relevant norms of international law applicable in the relations between the parties will be examined more carefully below.

and 5.1 of the *SPS Agreement*. To analyze the possible role of a precautionary principle in the *SPS Agreement*, it is important to understand *why* the Appellate Body rejected its relevance in *European Communities – Hormones* and wiped away Japan's argumentation on that point rather brusquely in one brief paragraph in *Japan – Agricultural Products*.

The Appellate Body explicitly stated that it did not even examine the "important but abstract" question whether the precautionary principle forms a general rule of customary international law. Thus, it appears that the reason was not that the precautionary principle was not a "norm applicable in the relations between the parties", either as custom or a general principle of law, but that other conditions of Article 31.3(c) of the *Vienna Convention* were not fulfilled.

1. Ensuring That Article 5.7 is not Overriden

The decisive reason, why the Appellate Body has not used the precautionary principle for the interpretation of Articles 2.2 and 5.1 appears to be that an interpretation of these provisions in light of a precautionary principle which allows measures in situations of scientific uncertainty would have "overridden" the ordinary meaning of these provisions read in context with Article 5.7 of the *SPS Agreement*. The Appellate Body noted that Article 5.7 of the *SPS Agreement* provides a specific mechanism dealing with scientific uncertainty.

As analyzed in Part 2 of this thesis the Appellate Body interprets Articles 2.2 and 5.1 of the *SPS Agreement* with a view to Article 5.7 of the *SPS Agreement* which explicitly deals with scientific uncertainty and seeks to avoid an "overly broad interpretation" of Article 2.2 which would "render Article 5.7

meaningless".³⁸ The Appellate Body appears to have considered that reading Article 2.2 and 5.1 of the *SPS Agreement* broader than the already conceded wide notion of risk and the consideration of minority views would not have been compatible with the ordinary meaning of Articles 2.2 and 5.1 read in context with Article 5.7 of the *SPS Agreement*.

Indeed, as noted by *Sands*, the treaty being interpreted under Article 31.3(c) of the *Vienna Convention* retains a primary role, while the customary rule has a secondary role, i.e., it could never replace the treaty norm being interpreted and applicable.³⁹ A more precise test to determine whether an outside norm "overrides" the treaty norm to be interpreted, or whether there is scope for harmonious interpretation according to Article 31.3(c) of the *Vienna Convention* was given in *United States – Shrimp*. In that case, the Appellate Body was confronted with the question whether the exception for "exhaustible natural resources" in Article XX(g) of the GATT 1994 only applies to "finite" resources, e.g., minerals, or also embraces living, but renewable species such as turtles.⁴⁰ The Appellate Body found that the text of Article XX(g) would allow a reading of "exhaustible natural resources" so as to include "renewable" resources, because "textually", Article XX(g) is "not limited" to the conservation of "non-living" resources⁴¹ and the terms "exhaustible" and "renewable"

³⁸ Appellate Body Report, *Japan – Agricultural Products*, para. 80

³⁹ Article 31.3(c) of the *Vienna Convention* has an integrative function. Its purpose is to ensure that the interpretation of an older treaty takes account of new developments in international law. Other than under Article 30 situations, there may be no conflict, but the treaty being interpreted retains a primary role, while the customary rule has a secondary role, i.e., it could never replace the treaty norm being interpreted and applicable. See, *Sinclair*, Ian, "The Vienna Convention on the Law of Treaties" (2nd edition Manchester: Manchester University Press, 1984), at 139 and *Sands*, Philippe, "Treaty, Custom and the Cross-fertilization of International Law", 1 Yale H.R. & Dev. L. J. 85 (1998).

⁴⁰ Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products* ("*United States – Shrimp*"), WT/DS58/AB/R, adopted 6 November 1998, paras. 127-134.

⁴¹ *Ibid.*, para. 128.

natural resources are not "mutually exclusive".⁴² Thus, an outside norm can only be used for interpretative purposes under Article 31.3(c) of the *Vienna Convention* if the text of the treaty provision to be interpreted is ambiguous and if there is no "conflict" between the text of the WTO norm and the outside principle. This would also square with Article 11(3) of the *SPS Agreement*, whereby in case of conflict another norm can prevail but can not be considered in WTO dispute settlement proceedings.

Because the *SPS Agreement* sets forth its own mechanism to deal with scientific uncertainty in Article 5.7, broadening the scope of Article 5.1 following the precautionary principle would have diminished the scope, and overridden Article 5.7 of the *SPS Agreement*. This reasoning of the Appellate Body appears to be correct. However, it still allows that Article 5.7 could be read in light of the precautionary principle.

2. No Jurisdiction to determine Custom and General Principles?

There might be further reasons why the Appellate Body declined to use the precautionary principle. At the outset, the Appellate Body noted that it is "probably imprudent, for the Appellate Body" to "take a position" on this question and stated that the precautionary principle "at least outside the field of international environmental law, still awaits authoritative formulation".⁴³ In a footnote following this statement, the Appellate Body referred to the judgement of the International Court of Justice (the "ICJ") in the *Case Concerning the Gabčíkovo-Nagymaros Project* where the Court noted that in the field of environmental protection "... new norms and standards have been developed, set forth in a great number of instruments during the last two decades. Such new norms have to be

⁴²*Ibid.*

⁴³Appellate Body Report, *European Communities – Hormones*, para. 123.

taken into consideration, and such new standards given proper weight".⁴⁴ The Appellate Body noted that the Court "did not identify the precautionary principle as one of those recently developed norms."⁴⁵ Does this mean that the Appellate Body defers to the ICJ in determining whether a norm has attained the status of a customary norm of international law? The jurisdictional relationship between the WTO Appellate Body and the ICJ is currently evolving and not clarified.⁴⁶ Yet, the Appellate Body clearly exercises jurisdictional self-restraint. So far, it has not "created" customary rules of general international law, but usually refers to a well-founded practice.⁴⁷

3. No Relevant Content of the Precautionary Principle

Another reason why the Appellate Body refused to consider the precautionary principle becomes apparent when reading the entrance statement that the precautionary principle "at least outside the field of international *environmental* law, still awaits authoritative formulation" together with the directive to panels in the third statement that they should bear in mind that "governments commonly act from a perspective of prudence and precaution where risks of irreversible, e.g., life-terminating, damage to human *health* are concerned." This indicates that even assumed that the precautionary principle in the form of Principle 15 of the *Rio Declaration* would have crystallized into a customary norm of international law⁴⁸, this

⁴⁴Appellate Body Report, *European Communities – Hormones*, para. 123, footnote 93 referring to *Case Concerning the Gabčíkovo-Nagymaros Project (Hungary/Slovakia)*, Judgement of 25 September 1997, I.C.J. Reports 1997, 7, paras. 140, 111-114.

⁴⁵Appellate Body Report, *European Communities – Hormones*, para. 123.

⁴⁶*McRae*, Donald M, "International Law: Tradition Continued or New Frontier?", 3 JIEL (2000), pp. 27-41.

⁴⁷See, Appellate Body Report, *United States – Shirts and Blouses*, p. 14.

⁴⁸This argument was advanced by *Cameron, James/ Abouchar Juli*, "The Status of the Precautionary Principle in International Law, in: *Freestone, David/ Hey, Ellen* (eds.), "The Precautionary Principle and International Law (Den Haag/ London/ Boston: Kluwer Law International, 1996) at 30 and 52; *Sands*, "Principles of International Environmental Law", at 213; *MacIntyre/Mosedale*, "The Precautionary Principle as a Norm of Customary International Law", 9 *Journal of Environmental Law*, (1997) at 241; *Epiney, Astrid/Scheyli, Martin*, 243

principle which relates to the protection of the environment would not be a *relevant* norm of international law in a dispute dealing with food safety issues.⁴⁹

This differentiation between the scopes of application is important. Both, the *SPS Agreement* as well as the current negotiations under the Codex Alimentarius Commission point to a difference in thresholds for protection between human health and the environment, and thus, take a context-specific approach. Even in the area of environmental law, the adoption of the *Cartagena Protocol* which on the one hand restates Principle 15 of the *Rio Declaration*, but then, in its operative provisions takes a new approach of a right to precaution which rather resembles Article 5.7 of the *SPS Agreement* supports a clear will of states to tailor specific norms for different categories of risks and scopes of application.

The Appellate Body, thus, correctly refused to take account of the precautionary principle in the form of Principle 15 of the *Rio Declaration*, because it does not have a relevant content for food safety issues. As shown in Part 1, a precautionary principle for food safety is only now getting close to authoritative formulation. Like the *Cartagena Protocol on Biosafety*, it would directly bear on the subject-matter of the *SPS Agreement*, and ,thus, be *relevant* for the interpretation of Article 5.7.

Strukturprinzipien des Umweltvölkerrechts (Baden-Baden: Nomos Verlagsgesellschaft, 1998), 99-126.

The argument was rejected by Bodansky, Daniel, 1991, Proceedings of the 85th Annual Meeting of the American Society of International Law (ASIL), 413, at 417; Hickey, James E. /Walker, Vern R., "Refining the Precautionary Principle in International Environmental Law", 14 Virginia Env. L. J. (1995) at 438; Doyle, Alan, "Precaution and Prevention, Giving Effect to Art. 130r without direct effect", European Environmental Law Review, 1999, at 47; Gündling, Lothar, "The Status in International Law of the Precautionary Principle", 5 International Journal of Estuarine and Coastal Law (1990), at 30

⁴⁹Similarly, in *Japan – Agricultural Products*, Japan relied on a principle dealing with food additives although plant health was at stake.

IV. SUMMARY

The possible role of precautionary principles in the *SPS Agreement* has, to some extent, been clarified by the Appellate Body, in *European Communities – Hormones* and *Japan – Agricultural Products*.

First, the precautionary principle as outside norm cannot form the legal basis of a dispute. It is not a source of WTO law in the strict sense, which could be an alternative ground for justification of an SPS measure which would otherwise be inconsistent with the provisions of the *SPS Agreement*.

Second, the Appellate Body correctly acknowledged that precautionary principles can be used to interpret the provisions of the *SPS Agreement* under Article 31.3(c) of the *Vienna Convention*. Yet, there might be nuances in the interpretative effect of precautionary principles which enter the *SPS Agreement* via Article 31(3)(c) of the *Vienna Convention* and those which fulfil the conditions of incorporated standards.

Third, the analysis of *European Communities – Hormones* has shown that the Appellate Body has rejected the use of the precautionary principle because a reading of Articles 2.2 and 5.1 in the light of the precautionary principle would have broadened the scope of these provisions to the detriment of Article 5.7 of the *SPS Agreement*, and, thus overridden the text of the *SPS Agreement*. Moreover, there was no "relevant" norm of international law as required by Article 31.3(c) of the *Vienna Convention*, because Principle 15 of the *Rio Declaration* applies to the protection of the environment, but has no content pertinent to a food safety dispute. This case law does not exclude a reading of the ambiguous Article 5.7 of the *SPS Agreement* itself in the light of outside precautionary principles if these are relevant to the subject-matter of the *SPS Agreement*.

§2: Precautionary Principles as "Incorporated Norms" in the *SPS Agreement*

The recent development to negotiate a precautionary principle for food safety in the Codex Alimentarius Commission sheds light on the link between "incorporated" standards and the *SPS Agreement*. The Codex Alimentarius standards are "privileged" standards under the *SPS Agreement*. Charnovitz has argued that even the *Cartagena Protocol* might be a "privileged" standard.⁵⁰ Following the motto "why climb through the window if the door is open?", the analysis first examines a possible role of the two new precautionary principles as "incorporated standards" in the *SPS Agreement* before scrutinizing whether they fulfil the conditions set forth by Article 31.3(c) of the *Vienna Convention*.

The tie with international standard-setting organizations is one of the main features of the *SPS Agreement*. The pledge for the use of internationally harmonized rules arose early in the negotiating process.⁵¹ Already the mid-term review Ministerial Declaration endorsed the incorporation of standards of international organizations.⁵²

According to the Preamble of the *SPS Agreement*, Members desire to "further the use of harmonized sanitary and phytosanitary standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant

⁵⁰Charnovitz, Steve, "The Supervision of Health Regulation by World Trade Rules", Tulane Environmental Law Journal, (forthcoming).

⁵¹Committee on Sanitary and Phytosanitary Measures, "Summary Report on the SPS Risk Analysis Workshop", 19-20 June 2000, G/SPS/GEN/209, 3 November 2000.

⁵²*Ibid.*

international and regional organizations operating within the framework of the International Plant Protection Convention".⁵³

Essentially, the mechanism of incorporating outside norms works as follows.⁵⁴ Annex A.3 of the *SPS Agreement* identifies "privileged" standards and organizations for the main three areas of protection covered by the *SPS Agreement*. These are the Codex Alimentarius Commission for food safety⁵⁵, the International Office of Epizootics (the "OIE") for animal health and zoonoses⁵⁶, and the International Plant Protection Convention (the "IPPC") for plant health.⁵⁷ In addition, Annex A.3(d) provides for the incorporation of further standards guidelines and recommendations dealing with a "matter not covered by the above organizations" if they are promulgated by other "relevant international organizations open for Membership to all Members" and have been "identified" by the *SPS Committee*.

⁵³*SPS Agreement*, Preamble, 6th paragraph.

⁵⁴See for a general overview: Stewart, Terence P. and Johanson, David P., "The *SPS Agreement* of the World Trade Organization and International Organizations: The Roles of the Codex Alimentarius Commission, the International Plant Protection Convention, and the International Office of Epizootics", 26 Syracuse J. Int'l L. & Com. (1998), pp. 27-53. See also, Eckert, Dieter, "Die neue Welthandelsordnung und ihre Bedeutung für den internationalen Verkehr mit Lebensmitteln", ZLR 4/95, pp. 363-395.

⁵⁵*SPS Agreement*, Annex A.3(a). See the overview in Part 1, III, C of this thesis.

⁵⁶*SPS Agreement*, Annex A.3(b). The International Office of Epizootics (the "OIE") was established in 1924 and has currently 155 Member Countries. Its objectives are to inform governments of the occurrence and course of animal diseases throughout the world, and of ways to control these diseases, to coordinate, and to harmonize regulations for trade in animals among Member Countries. The standards adopted in the International Animal Health Code set out requirements for risk assessment. See, <http://www.oie.int/overview/a_oie.htm> (visited 6 March 2000) and International Animal Health Code, 1999 Edition, Article 1.4.2.3.

⁵⁷*SPS Agreement*, Annex A.3(c). The IPPC was adopted in 1951 under the auspices of FAO and has been amended in 1997. Its purpose is "to secure common and effective action to prevent the spread and introduction of pests and plants and plant products and to promote measures for their control". The IPPC provides rules for import restrictions of plants and plant products requiring, *inter alia*, risk assessment. Article XIII of the IPPC'97, sets out a dispute settlement mechanism which explicitly aims at cooperating with the WTO dispute settlement mechanism.

See <<http://www.fao.org/Legal/TREATIES/Treaty-e.htm>> (visited 6 March 2000).

The *SPS Agreement* envisages two different legal effects to incorporated standards. First, they can form the basis of harmonization of SPS measures under Article 3 of the *SPS Agreement*. Second, Article 5.1 of the *SPS Agreement* provides that when carrying out the risk assessment Members shall take into account risk assessment techniques developed by the relevant international organizations.

The following sections explore under which conditions the new precautionary principles could become "incorporated standards" of the *SPS Agreement* and what might be their legal effect.

I. NOTION OF INTERNATIONAL STANDARDS, GUIDELINES AND RECOMMENDATIONS

After the adoption of the *Cartagena Protocol on Biosafety* one observer argued that the new environmental treaty might be a "privileged" standard in the sense of Article 3.2 of the *SPS Agreement*, i.e., where Members base their measure on the *Cartagena Protocol*, these would be presumed to be in line with WTO law.⁵⁸ At first glance, this seems to be surprising because the relationship between the Protocol and WTO law would not have been one of the major sticking points in the negotiations, if it could simply be an incorporated standard in the *SPS Agreement*. Still, it is worth to explore the conditions for outside norms gaining the status of SPS standards by using the example of this new environmental treaty. Less problematic might be the status of the precautionary principles for food safety currently under negotiations in the Codex Committee on General Principles.

This section briefly analyzes whether these two principles fulfil the conditions to become a privileged standard as set forth by Annex A.3 of the *SPS Agreement*.

⁵⁸Charnovitz, Steve, "The Supervision of Health Regulation by World Trade Rules", Tulane Environmental Law Journal, (forthcoming).

Annex A.3 of the *SPS Agreement* provides in full:

International standards, guidelines and recommendations:

(a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;

(b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;

(c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and

(d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee.

A. THE SCOPE OF ANNEX A.3(a) – ARE THE CODEX PRECAUTIONARY PRINCIPLES COVERED?

When carefully reading Annex A.3(a) of the *SPS Agreement*, the text of the provision raises some doubts whether the new precautionary principle included in *the Draft Codex Working Principles for Risk Analysis* would be covered by these provisions. While Annex A.3(b) and (c) provide for the incorporation of all standards, guidelines and recommendations developed under the

auspices of the OIE and IPPC, Annex A.3(a) specifically lists the standards, guidelines and recommendations "relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines for hygienic practice". Guidelines for *risk* analysis are not expressly mentioned. WTO jurisdiction has not addressed the scope of Annex A.3(a). The Panel in *European Communities - Hormones* has automatically assumed that standards relating to the assessment of risks to food safety fall under Annex A.3(a).⁵⁹ This seems to be in line with the ordinary meaning of Annex A.3(a) read contextually with Article 5.2 of the *SPS Agreement*. When browsing through the list of standards named in Annex A.3(a), it appears that some of the norms mentioned lay down minimum standards for residues and food additives, while others relate to procedural methods of analysis and sampling. The term "analysis" is used broadly without a specifying adjective. Because "sampling" methods are referred to as factor for the risk assessment in Article 5.2, it appears that "analysis" must include the analysis of risks. Otherwise it would not be clear what should be analyzed.

Thus, the guidelines for risk analysis currently under development in the Codex Alimentarius Commission would be automatically incorporated into the *SPS Agreement* via Annex A.3(a).

B. THE SCOPE OF ANNEX A.3(d) – AN ENTRANCE POINT FOR THE *CARTAGENA PROTOCOL*?

The conditions for the incorporation of standards promulgated by other relevant international organizations have not yet been addressed in WTO jurisprudence. According to Annex A.3(d) of the *SPS Agreement*, an "outside" standard must: (i) deal with a "matter not covered by the above organizations"; (ii) be promulgated by other

⁵⁹Panel Report, *European Communities – Hormones*, paras. 8.56 to 8.58 (US) and paras. 8.59 to 8.61 (CAN). See also, Panel Report, *Australia – Salmon*, para. 2.18 and Panel Report, *Japan – Agricultural Products*, para. 2.25.

"relevant international organizations open for membership to all Members; and (iii) be "identified by the Committee". It appears that two hurdles would be difficult to take for the *Cartagena Protocol*.

1. The matters of the *Cartagena Protocol* overlap with the Codex and IPPC

First, the question is whether the new treaty on biotechnological products deals with a "matter not covered by the above organizations". The *Cartagena Protocol* has a very broad scope, applying to "the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health."⁶⁰ Because the *Cartagena Protocol* provides for horizontal trade regulation covering a potentially large set of LMOs and several risk categories ranging from the more abstract protection of biodiversity to human health, there might be some overlap with the three "privileged" standard setting bodies in the area of human, animal and plant life or health.⁶¹ Although the Codex Alimentarius Commission focuses on domestic food safety, whereas the *Cartagena Protocol* covers the broader issue of biodiversity, and transboundary movement of LMOs, a closer look at the scopes and activities of both organizations indicates some overlaps.

First, the scope of the *Cartagena Protocol* includes health considerations ("taking also into account risks to human health"). Moreover, food safety measures are affected by the provisions regarding LMOs for food or feed or for processing and the labelling and identification requirements.⁶² Until now, one could argue that the provisions of the *Cartagena Protocol* specifically deal with

⁶⁰CPB, Article 4.

⁶¹*Eggers/Mackenzie*, at 534.

⁶²CPB, Articles 11 and 18.

biotechnology on a horizontal basis whereas the Codex Alimentarius Commission tackles food safety in a vertical manner. However, this argument does not stand in the long run. Although, to date, no specific Codex standards relating to novel food exist, the Codex Alimentarius Commission has decided to elaborate several texts related to foods derived from biotechnology.⁶³ Similarly, the *IPPC* is tackling the phytosanitary aspects of GMOs and biosafety and is currently identifying the scope and role of the *IPPC* in these areas.⁶⁴ Thus, the matters covered by the *Cartagena Protocol*, at least in the future might be covered by one of the "privileged" organizations. Hence, it is fair to say that currently a period of alignment is taking place, where the respective international organizations clarify their scope and role. Pending the outcome of this role-seeking phase one could not conclude that the *Cartagena Protocol* fulfils the first requirement under Annex A.3(d), i.e., that it complements the subject matter already covered by the privileged international organizations.

2. Identification of the *Cartagena Protocol*

While the *Cartagena Protocol* would be an international organization open for Membership to all WTO Members"⁶⁵, the second hurdle to take would be the requirement that it must be "identified" by the SPS Committee. The term "identify" suggests that the SPS Committee must take a decision to accept a standard by

⁶³See, Report of the First Session of the Codex Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology, Chiba 14-17 March 2000, ALINORM 01/34, available at <<http://www.fao.org/>> (visited 25 June 2000).

⁶⁴The IPPC has together with the FAO founded an "Interim Commission on Phytosanitary Measures" (the "ICPM"). See, Committee on Sanitary and Phytosanitary Measures, Summary of the Meeting held on 21-22 June 2000, G/SPS/R/19, 1 August 2000, at 12. See also <<http://www.fao.org/>> (visited 20 August 2000).

⁶⁵The term "international organization" denotes "an association of States established by and based upon a treaty, which pursues common aims and which has its own special organs to fulfil particular functions within the organization." See, *Bindschedler*, Rudolf L., "International Organizations, General Aspects, in: *Bernhardt*, Rudolf (ed.), "Encyclopedia of Public International Law", Volume II (Amsterdam, Lausanne, New York, Oxford, Shannon, Tokyo: Elsevier Science B.V, 1995) at 1289.

another international organization as "SPS standard". The SPS Committee decides by consensus.⁶⁶ Although it appears to be quite burdensome to read the identification requirement as requirement for consensus voting, this high hurdle reflects the constitutional principles in Articles X:1 and X:3 of the *WTO Agreement*, whereby amendments of the WTO agreements of a "nature that would alter the rights and obligations of the Members" shall preferably be made by consensus voting, and, if a consensus cannot be reached, would only take effect for the Members that have accepted them. Thus, the *Cartagena Protocol* could not become an incorporated standard without having been "identified" by consensus voting in the SPS Committee.

3. Summary

In short, the examination of the scope of Annex A.3(a) and (d) has shown that the precautionary principles currently under development in the Codex Alimentarius Commission would, upon its adoption, automatically be incorporated as privileged standard into the *SPS Agreement*. Other than suggested by *Charnovitz*, the *Cartagena Protocol* does not meet the requirements set out by Annex A.3(d), because its subject matter is or will be covered by the Codex and the IPPC and, even if the respective scopes and roles of these organizations will be clarified after a period of alignment, the *Cartagena Protocol* would first need to be identified by the SPS Committee.

II. THE LEGAL EFFECTS OF INCORPORATED PRECAUTIONARY PRINCIPLES

This section examines the possible legal effects of precautionary principles as incorporated standards in the *SPS Agreement*. The *SPS Agreement* is not the only WTO agreement

⁶⁶*SPS Agreement*, Article 12.1. See also *Rules of Procedure for Meetings of the Committee on Sanitary and Phytosanitary Measures*, WT/G/SPS/W/Rev.1, 28 April 1997, Rule 33.

which incorporates outside norms. As noted in the introductory section on sources of WTO law, other agreements, e.g., the *TRIPS Agreement* also refers to provisions of other international treaties.⁶⁷ *Marceau* has pointed out that some of the "outside provisions [...] merely provide interpretative material that must be used by WTO adjudicating bodies when enforcing another WTO obligation", whereas others, e.g., the *TRIPS Agreement* require the outside provision to be enforced within the WTO system.⁶⁸

When holding the obligation under Article 3.1 of the *SPS Agreement* to base a SPS measure on international standards and the obligation under Article 5.1 of the *SPS Agreement* to take into account risk assessment techniques developed by the relevant international organizations against, e.g., Article 9 of the *TRIPS Agreement*, which requires that "Members shall comply with Articles 1 through 21 of the Berne Convention", it appears that the *SPS Agreement* only uses outside standards to refine the existing obligations. As regards the harmonization requirement in Article 3, the Appellate Body had clarified in *European Communities – Hormones* that Article 3.1 of the *SPS Agreement* cannot be read so as to give *de facto* binding effect to Codex standards.⁶⁹ Thus, the legal effect of these standards is reduced to the presumption of WTO consistency of SPS measures that conform to international standards, which is nothing but an interpretative effect.

Similarly, the obligation to take into account risk assessment techniques of the relevant international organizations only appears to refine the existing obligation under Article 5.1 of the *SPS Agreement*.

⁶⁷See Part 2, § 1, II A. A list of further references to non-WTO provisions in WTO agreements is provided by, *Palmer, N. David/Mavroidis, Petros C.*: The WTO Legal System: Sources of Law, *AJIL* Vol. 92 (1998), pp. 398-413.

⁶⁸*Marceau, Gabrielle*: "A Call for Coherence in International Law – Praises for the Prohibition Against 'Clinical Isolation' in WTO Dispute Settlement", 33 (5) *Journal of World Trade* 87 (1999), at 112.

⁶⁹Appellate Body Report, *European Communities – Hormones*, paras. 165-173.

However, depending on how much the outside standard adds to the existing obligation, the *SPS Agreement* might also work so as to *de facto* enforce these risk assessment techniques.

When determining the legal effect of incorporated precautionary principles a preliminary question is, whether the process-oriented guidelines for risk analysis as currently developed under the Codex Alimentarius Commission would fall under Article 3 or under Article 5.1 of the *SPS Agreement*.

A. DISTINGUISHING BETWEEN RESULT-ORIENTED STANDARDS (ARTICLE 3) AND PROCESS-ORIENTED STANDARDS (ARTICLE 5.1)

WTO jurisdiction, in the first three SPS cases, has drawn a clear distinction between those international standards which lay down substantive features of a measure on the one hand and guidelines describing the risk assessment process on the other. Thus, in *European Communities – Hormones*, the Panel and the Appellate Body found that the Codex standard laying down MRLs for three hormones are standards within the meaning of Article 3 of the *SPS Agreement*.⁷⁰ In interpreting Article 5.1 of the *SPS Agreement*, the Panel noted that "no risk assessment techniques developed by the relevant international organizations" in the sense of Article 5.1 which have to be taken into account in a risk assessment for the hormones at issue existed.⁷¹ In *Australia – Salmon*, the Panel referred to the Guidelines for Risk Assessment developed by the OIE.⁷² In *Japan – Agricultural Products*, the Panel report remarked that IPPC Guidelines for Pest Risk Analysis⁷³ "define a procedure by which a pest risk analysis should be performed and lay down relevant factors

⁷⁰Panel Report, *European Communities – Hormones*, paras. 8. 56 to 8.58 (US) and paras 8.59 to 8.61(CAN).

⁷¹Panel Report, *European Communities – Hormones*, para. 8.103 (US) and para. 8.106 (CAN).

⁷²Panel Report, *Australia – Salmon*, para. 8. 78.

⁷³International Standards for Phytosanitary Measures, Guidelines for Pest Risk Analysis, FAO Publications No. 2.

which should be taken into account by the authorities in the process".⁷⁴

Thus, there appears to be an emerging differentiation between result-oriented standards which form the basis for harmonization under Article 3 of the *SPS Agreement*, and more process-oriented guidelines for risk assessment which inform Article 5.1 of the *SPS Agreement*.

This distinction is important and well rooted in the text of the *SPS Agreement*. The provisions regarding the harmonization of standards are tailored for norms that require a certain measure. Otherwise, the distinction between measures that "conform to" international standards and those that are "based on" such standards or result in a higher level of sanitary and phytosanitary protection in Article 3.3 of the *SPS Agreement* would not make sense. Moreover, the purpose of international harmonization as laid down in the Preamble to the *SPS Agreement*, is "to further the use of harmonized sanitary and phytosanitary *measures* between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations".⁷⁵ Article 3 of the *SPS Agreement* aims at the prevention of trade barriers through the use of similar SPS measures, e.g., that ideally all WTO Members use the MRLs for hormones or a standard on rBST adopted by the Codex Alimentarius Commission.⁷⁶ Before this background, it appears that precautionary principles can not have legal effect as basis of harmonization under Article 3 of the *SPS Agreement*. The draft Codex guidelines on risk analysis do not prescribe a certain result, i.e., a measure to be adopted, but a process which could lead Members to

⁷⁴Panel Report, *Japan – Agricultural Products*, paras. 2.29-2.33.

⁷⁵See also, Article 12.4 of the *SPS Agreement*.

⁷⁶Codex Alimentarius Commission, Report of the 22nd Session, ALINORM 97/37 (28 June 1997). The adoption of the rBST standard is currently being postponed pending a re-evaluation of the data.

very different legislative responses.⁷⁷ Thus, the precautionary principles entailed in the Guidelines for Risk Analysis currently under development by the Codex Alimentarius Commission would not be standards in the sense of Article 3 of the *SPS Agreement*, but might have legal effects as risk assessment techniques under Article 5.1 of the *SPS Agreement*.

B. RISK ASSESSMENT TECHNIQUES - ARTICLE 5.1

This section examines the scope of the obligation under Article 5.1 of the *SPS Agreement* to take into account risk assessment techniques developed by the relevant international organizations. Article 5.1 of the *SPS Agreement* provides in full:

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

As noted in the survey of precautionary principles, the Codex precautionary principle currently under negotiations is contained in the section on risk management. *Prima facie* one could argue that this might bar these provisions from being taken into account as "risk assessment techniques". The term risk assessment techniques is not further defined in the *SPS Agreement*. However, the Appellate Body held that the notion of risk assessment used in the *SPS Agreement* is broad and does not warrant a distinction from elements that rather belong to risk management.⁷⁸ Moreover, although catalogued under

⁷⁷The same is true for the *Cartagena Protocol on Biosafety*. Articles 10, 11, 12, 15 and Annex III *CPB* do not tell the Parties which measure to take, but oblige them to carry out a risk assessment and to keep the measure under review. Only if the Conference of the Parties to the *Cartagena Protocol* would, according to Article 7(4) of the *CPB*, take a decision which identifies living modified organisms as "not being likely to have adverse effects", this decision could be an international standard within the meaning of Article 3 of the *SPS Agreement*.

⁷⁸Appellate Body Report, *European Communities – Hormones*, para. 181.

"risk management", the respective Codex principles provide answers on how to deal with uncertain risks which belongs to the issues of risk assessment as addressed under Article 5.1 of the *SPS Agreement*. Finally, in *European Communities – Hormones*, the Panel referred to the definition of "risk assessment" provided by the Codex Committee on General Principles as risk assessment technique.⁷⁹ Precisely this Committee is elaborating the Working Principles on Risk Analysis, which should, therefore be covered by the notion of "risk assessment techniques".

1. The Interpretative Effect

As regards the legal effect of risk assessment techniques, WTO jurisdiction has been consistent in that all three panels have referred to outside principles when interpreting the risk assessment requirement.

Thus, in *Australia – Salmon*, the Guidelines for Risk Assessment developed by the OIE played a considerable role in determining whether the term "likelihood" in Annex A.4 of the *SPS Agreement* means "probability" or "possibility". The Panel referred to the definition of risk assessment under the OIE Guidelines for Risk Assessment which define risk as "probability for adverse effects".⁸⁰ The Panel found "that for the measure at issue in this dispute, a risk assessment – in accordance with Article 5.1 and paragraph 4 of Annex A and taking into account the risk assessment techniques developed by the OIE – not only has to state that there is a *possibility* of the diseases of concern being introduced into Australia when imports of the salmon products further examined would be allowed,

⁷⁹Panel Report, *European Communities – Hormones*, para. 8. 103 (US) and para. 8. 106 (CAN).

⁸⁰Panel Report, *Australia – Salmon*, para. 8. 78.

but also needs to provide some evaluation or estimation of likelihood or probability".⁸¹

This suggests that where the precise meaning of the risk assessment obligation, as defined under Annex A.4 is open to interpretation, the concepts developed by relevant international organizations can be used to buttress a certain interpretation of the obligation under Article 5.1.

2. The Possible Effects of the New Codex Principles – Slippery Slope or Clarification?

This section examines the possible legal effects of the precautionary principle for food safety, currently under negotiation in the Codex Alimentarius Commission. Other than the guidelines on risk analysis used by WTO panels so far, the current negotiating draft for the Codex principles on risk analysis sets forth very elaborate rules regarding the procedures to be followed when taking a food safety measure.⁸²

Some of them only manifest what has already been clarified by the Appellate Body. Thus, draft rule 18, for example, provides "to ensure a transparent risk assessment, a formal record, including a summary, should be prepared and made available to other risk assessors and interested parties so that they can review the assessment. It should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment, and minority opinions". The Appellate Body has already acknowledged that minority opinions can be taken into account under Articles 5.1 and 2.2 of the *SPS Agreement*. In that respect, the following draft rule 9 might alleviate some of the uncertainties regarding the choice of experts. It stipulates that "experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise and their

⁸¹*Ibid.*, para. 8. 80.

independence with regard to the interests involved and the procedures used to select these experts should be documented including a public declaration of any potential conflict of interest".⁸³

The draft Codex rules including the precautionary principle, by contrast, walk on grounds which have not yet been addressed by Appellate Body jurisdiction. Before analyzing the possible interaction of the draft Codex precautionary principle with Article 5.7 of the *SPS Agreement*, it is worth to restate its text in full:

When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food, and where there is reasonable evidence to suggest that adverse effects on human health may occur, but it is difficult to evaluate their nature and extent, it may be appropriate for risk managers to apply precaution through interim measures to protect the health of consumers without awaiting additional scientific data and a full risk assessment, in accordance with the following criteria.⁸⁴

The first criterium requires:

... Following preliminary risk assessment, a specific risk is identified, or there is evidence to suggest that a risk exists, but the cause or extent of any negative effects are unknown due to gaps or uncertainty in the available scientific data.⁸⁵

This criterium could be an important clarification for the interpretation of the requirement "adopted on the basis of available pertinent information" in Article 5.7 of the *SPS Agreement*. The

⁸²Proposed Draft Codex Working Principles for Risk Analysis, ALINORM 01/33, Appendix III, 15 April 2000.

⁸³*Ibid.*

⁸⁴Proposed Draft Codex Working Principles for Risk Analysis, ALINORM 01/33, Appendix III, para. 34 (footnote omitted).

⁸⁵*Ibid.*

analysis in Part 2 of this thesis has shown that this requirement, which has not yet been interpreted by the Appellate Body might well become an unpredictable "mini-rational relationship" test. In particular, it was not clear, to which extent Members are obliged to carry out a specific risk evaluation. According to the Codex principle governments are to carry out a "preliminary risk assessment" identifying a "specific risk" or evidence suggesting that a "risk exists, but the cause or extent of any negative effects are unknown".

Yet, despite the need to clarify Article 5.7, some caution is warranted when incorporating these principles through the notion of risk assessment techniques in Article 5.1 of the *SPS Agreement*. Article 5.7 itself does not explicitly refer to risk assessment techniques developed by the relevant international organizations. Only its second sentence refers to Article 5.1 of the *SPS Agreement* by requiring that a Member "seek to obtain additional information for a more objective assessment of risk". The contextual link between Articles 5.1 and 5.7 could be a strong argument that Article 5.7 implicitly refers to international guidelines.

However, the word "implicit" in connection with the use of international standards raises a red flag. In *European Communities – Hormones*, the Appellate Body rejected a reading of Article 3.1 of the *SPS Agreement*, which would have transformed the Codex standard on growth hormones into "binding norms".⁸⁶ The Appellate Body held that one could not "lightly assume that sovereign states intended to impose upon themselves the more onerous, rather than the less burdensome, obligation".⁸⁷ Referring to the *in dubio mitius* principle, the Appellate Body cautioned that "to warrant such a far-reaching

⁸⁶Appellate Body Report, *European Communities – Hormones*, para. 165.

⁸⁷*Ibid.*

interpretation, treaty language far more specific and compelling than that found in Article 3 of the *SPS Agreement* would be necessary".⁸⁸

Would this mean that without an explicit reference to international standards in Article 5.7 of the *SPS Agreement*, precautionary principles developed under Codex could not be incorporated into the *SPS Agreement* as risk assessment techniques to interpret Article 5.7 of the *SPS Agreement*? With respect to the sovereignty concerns, the argument is unavailing, because precautionary principles do not raise the same sovereignty problems. As noted above, Article 3 of the *SPS Agreement* deals with the substantive harmonization of SPS measures of Members on the basis of international standards. The use of process-oriented guidelines for precautionary situations in the interpretation of Article 5.7 of the *SPS Agreement* would not determine the design and content of a precautionary measure itself, but simply provide guidance on how to take it. The obligation under Article 5.7 of the *SPS Agreement* to adopt a provisional measure on the basis of available pertinent information is likely to be interpreted as unpredictable "we know it when we see it test". A negotiated solution to these problems would neither change nor "override" the very broad and ambiguous provision of Article 5.7 of the *SPS Agreement*, but clarify it.

Most importantly, the discussion of the issue of deference has indicated a need for further procedural guidelines under the *SPS Agreement*: The more the process under Article 5.7 of the *SPS Agreement* is regulated by international norms, the more "deference" can Panels pay to governments in the determination whether the conditions of a provisional measure under Article 5.7 of the *SPS Agreement* are fulfilled.

Thus, when weighing the respective arguments, it appears that precautionary principles contained in the *Draft Codex Working*

⁸⁸*Ibid.*

Principles for Risk Analysis could have the status of "international standards, guidelines and recommendations" in the form of "risk assessment techniques", which flesh out the obligation under Articles 5.1 and 5.7 of the *SPS Agreement*.

III. SUMMARY

The precautionary principle currently under negotiation in the Codex Alimentarius Commission would, upon its adoption, automatically be incorporated as privileged standards into the *SPS Agreement*. Other than suggested by Charnovitz, the *Cartagena Protocol* does not meet the requirements set out by Annex A.3(d), because its subject matter is or will be covered by the Codex and the IPPC. Even if the respective scopes and roles of these organizations will be clarified after a period of alignment, the *Cartagena Protocol* would first need to be identified by the SPS Committee through a consensus decision.

The draft Codex precautionary principle is process-oriented, i.e. it does not prescribe a certain measure and can therefore not form the basis of harmonization under Article 3 of the *SPS Agreement*. However, it could have effect through the obligation under Article 5.1 "taking into account risk assessment techniques developed by the relevant international organizations". This term can be read broadly to include any process-oriented standards relating to risk analysis. Where the definition of risk assessment does not provide further guidelines, these standards can refine the obligations, for example the rules for the choice of experts, could contribute to resolving the issue of minority opinions. However, the real treasury lies in the "criteria" set forth for precautionary measures, more specifically, the conditions for a "preliminary risk assessment". These could refine the hazy obligation under Article 5.7 of the *SPS Agreement*. They further the elaboration of processes in the risk assessment and would be a precondition for paying more deference towards Members in the assessment of risks.

Thus, the precautionary principle currently under development by Codex is an important starting point in that respect.

§3: **Beyond Conflict: Cross-Fertilizations between the *Cartagena Protocol* and the *SPS Agreement***

The *Cartagena Protocol on Biosafety* is not an amicable settlement between the United States and other WTO Members regarding their trade conflicts on GMOs. However, it sets forth detailed provisions governing precautionary measures in the area of biotechnology, where the WTO mechanism does not produce predictable results. In the wake of Seattle, some voices suggested that the WTO should stand back from biotechnology, and leave such decisions to multilateral environmental agreements.⁸⁹ However, this might not be realistic. The DSU serves to preserve the rights and obligations under the covered agreements.⁹⁰ Most biosafety measures are covered by the *SPS Agreement*, and would, thus, be generally eligible for WTO adjudication.⁹¹ Moreover, the United States, as major trading nation in biotechnological products, are unlikely to become a signatory or a party to the Protocol⁹² and the *Cartagena Protocol* does not offer a compulsory dispute settlement mechanism.

In particular the right to take precautionary measures was one of the major sticking points in the negotiations of the *Cartagena Protocol* and will continue to cause trade rows. Early commentators

⁸⁹See, Economist, "The Biosafety Protocol – A Conventional Argument" (27 January 2000).

⁹⁰DSU, Articles 1.1 and 3.2, sentence 1.

⁹¹See, the analysis in Part 2, I B.

⁹²The United States, the major trading nation in GMOs, are prevented from becoming a party to the protocol, because they have signed, but not ratified the Convention on Biological Diversity. See Convention on Biological Diversity, Articles 28 and 29.

have raised concerns that the relevant provisions of the *Cartagena Protocol* clash with Article 5.7 of the *SPS Agreement*.⁹³

If there was a conflict between the *Cartagena Protocol* and Article 5.7 of the *SPS Agreement* in that the former "overrides" the latter, the new environmental treaty could not be considered in WTO dispute settlement proceedings.⁹⁴ Yet, the Preamble to the *Cartagena Protocol* envisages a "mutually supportive" relationship between both sets of rules, which suggests that there is no conflict, but that cross-fertilizations could occur.⁹⁵

This chapter focuses on one single, discreet question: What is the legal effect of the new right to precaution contained in the *Cartagena Protocol* in adjudicating a trade conflict on GMOs? At this juncture, the discussion of the specific relationship between a precautionary principle and the *SPS Agreement* meets the long-festering debate on trade and environment.

This warrants a brief consideration of the relationship between the *Cartagena Protocol* and the *SPS Agreement* with a view to the specific issues of multilateral environmental agreements in Part I.

Part II, titled "no conflict", takes a closer look at Articles 5.7 of the *SPS Agreement* and the relevant provisions on the taking of precautionary measures under the *Cartagena Protocol* in order to examine whether they clash or not. It argues that there is no conflict, but that cross-fertilizations have already taken place at the level of the negotiations.

⁹³Phillips, Peter W.B./Kerr, William A., "The WTO Versus the Biosafety Protocol for Trade in Genetically Modified Organisms", 34(4) *Journal of World Trade* (2000), pp. 63-75, at 72.

⁹⁴*SPS Agreement*, Article 11(3). The question what would happen, if a Panel started adjudicating a dispute and then suddenly finds that the *Cartagena Protocol* supersedes the *SPS Agreement* as applicable law is academically interesting, but moot, since, as argued below, there is no legal conflict between both sets of rules.

Part III of this chapter, titled "cross-fertilizations", picks up the GMO hypothetical which could not be resolved solely with Article 5.7 of the *SPS Agreement*, and offers some tentative suggestions about the possible impact of the *Cartagena Protocol* in a future WTO dispute on GMOs.

I. THE RELATIONSHIP BETWEEN THE *CARTAGENA PROTOCOL* AND WTO LAW

The relationship between the *Cartagena Protocol* and WTO law was one of the major sticking points in the negotiations.⁹⁶

C. THE PREAMBULAR LANGUAGE OF THE *CARTAGENA PROTOCOL*

The *Biodiversity Convention* itself contains a savings clause generally subordinating it to other international agreements.⁹⁷ Following the proposals of the Cairns Group, the Draft *Cartagena Protocol* contained a similar provision regarding the relationship with other international agreements.⁹⁸ However, the parties could not agree on a savings clause, but chose to address the relationship between trade and environment agreements in three preambular paragraphs. The Preamble to the Protocol provides in relevant part:

⁹⁵Eggers, Barbara/Mackenzie, Ruth, "The *Cartagena Protocol* on Biosafety", 3 JIEL 525 (2000), at 541.

⁹⁶ See generally, Eggers, Barbara/Mackenzie, Ruth, "The *Cartagena Protocol* on Biosafety", 3 JIEL 525 (2000), pp. 525-543; Phillips, Peter W.B./Kerr, William A., "The WTO Versus the Biosafety Protocol for Trade in Genetically Modified Organisms", 34(4) *Journal of World Trade* (2000), pp. 63-75.

⁹⁷Article 22 (1) of the *Biodiversity Convention* provides: "The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause serious damage or threat to biological diversity."

⁹⁸Article 31 of the Draft Protocol on Biosafety, titled "Relationship with other international agreements", provided: "The provisions of this Protocol shall not affect the rights and obligations of any Party to the Protocol deriving from any existing international agreement to which it is also a Party, except where the exercise of those rights and obligations would cause serious damage or threat to biological diversity." See UNEP/CBD/ExCOP/1/L.2/Rev.1, available at <<http://www.biodiv.org/excop1.html>> (visited 20 January 2000).

Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,

Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,

Understanding that the above recital is not intended to subordinate this Protocol to other international agreements.⁹⁹

This language which has been taken from the Preamble to the 1998 *Rotterdam Convention*¹⁰⁰, does not contain a clear conflict rule within the meaning of Article 30.2 of the *Vienna Convention* because the second and third recital cancel each other out. By contrast, the words "mutually supportive", and "shall not be interpreted" as well as the non-subordination language, seem to suggest that trade-related provisions of environmental treaties are increasingly negotiated with a view to WTO law and that any conflicts could be avoided by harmonious interpretation, so that both agreements can apply cumulatively.

B. WTO LAW: EMERGING CONDITIONS FOR "MUTUAL SUPPORTIVENESS" AND "DEFERENCE" TO MEAS

The relationship between WTO law and multilateral environmental agreements has been specifically addressed in the Committee on Trade and Environment (the "CTE") as well as in the Appellate Body Report *United States – Shrimp* and a growing body of literature. The following section cannot revisit the rich and long-going debate on that subject¹⁰¹ but briefly reviews where the law stands now on the part of the WTO.

⁹⁹CPB, 9th-11th preambular paragraph.

¹⁰⁰*Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade*, done at Rotterdam, 10 September 1998, not yet in force, 38 ILM 1.

¹⁰¹See for example the works of Jackson, John H.: *World Trade Rules and Environmental Policies: Congruence or Conflict?* Washington and Lee Law Review, 268

1. The CTE

The Committee on Trade and Environment (the "CTE") is called upon to identify the relationship between the provisions of WTO law and trade measures pursuant to multilateral environmental agreements.¹⁰² Despite several rounds of stocktaking exercise, the CTE discussions on linkages between multilateral environmental agreements and WTO law have not yet advanced to an agreement clarifying their relationship.¹⁰³ The report of the CTE to the Singapore Ministerial Conference endorsed:

multilateral solutions based on international cooperation and consensus as the best and most effective way for governments to tackle environmental problems. WTO agreements and multilateral agreements (MEAs) are representative of efforts of the international community to pursue shared goals, and in the development of a mutually supportive relationship between them, due respect must be afforded to both.¹⁰⁴

Aiming at "institutional coherence" and "legal certainty" for the use of environmental measures taken pursuant to an MEA when challenged by a non-party in a WTO dispute settlement, the CTE currently discusses several concepts of "mutual supportiveness" and "deference" between WTO law and MEAs.¹⁰⁵ The most elaborate is

Vol. 49 (1992), pp. 1227-1259. *Hilf*, Meinhard, "Freiheit des Welthandels contra Umweltschutz?", NVwZ 2000, pp. 481-600; *Mavroidis*, Petros C.: Trade and Environment after the Shrimps-Turtles Litigation, *Journal of World Trade* 34 (1) 2000, pp. 73-88; *Petersmann*, Ernst-Ulrich, "Trade and Environmental Protection: The Practice of GATT and the European Community Compared", in *Cameron, James/Demaret, Paul/Geradin, Damien*, "Trade & The Environment: The Search for Balance", London, 1994, pp. 147-181.

¹⁰²Decision on Trade and Environment.

¹⁰³Committee on Trade and Environment, Report of the Meeting held on 5-6 July 2000, WT/CTE/M/24, 19 September 2000.

¹⁰⁴Report of the Committee on Trade and Environment, WT/CTE/1, 12 November 1996, para. 171, section VII of the Report of the General Council to the 1996 Ministerial Conference, WT/MIN(96)/2, 26 November 1996.

¹⁰⁵Committee on Trade and Environment, Report of the Meetings held on 5-6 July 2000. WT/CTE/M/24, see in particular pages 1-4.

the one by Canada advocating a "principles and criteria approach to MEAs" in WTO disputes where not both disputants are parties to the MEA.¹⁰⁶ Panels should then consider the following qualifying principles: (i) is the MEA open to all countries; (ii) the MEA reflects broad-based international support; (iii) the provisions specifically authorizing trade measures should be drafted as precisely as possible; (iv) trade with non-parties is permitted on the same basis as trade with Parties when non-parties have equivalent levels of environmental protection; and (v) negotiators have explicitly considered the criteria developed by the WTO for the use of trade measures in MEAs.¹⁰⁷

In short, the WTO on its part has not clarified the link between its provisions and MEAs. However, relevant decisions and the current negotiations also reflect the approach of "mutual supportiveness" and Members strive to resolve the party/non-party issue.

2. WTO Jurisdiction

In *United States – Shrimp* the Appellate Body already moved far ahead. Its interpretation of Article XX of the GATT 1994, suggests the following three effects of multilateral environmental agreements on WTO law.

First, the Appellate Body interpreted Article XX of the GATT 1994 with reference to several multilateral environmental agreements including the *Biodiversity Convention*.¹⁰⁸ In that decision, the Appellate Body referred to Article 31.3(c) of the *Vienna Convention* for the first time.¹⁰⁹ Yet, the Appellate Body has not applied the requirement that a norm must be "applicable" in the relations between the parties strictly, but explicitly noted that not all parties to the

¹⁰⁶*Ibid.*

¹⁰⁷*Ibid.*

¹⁰⁸Appellate Body Report, *United States – Shrimp*, para. 130.

¹⁰⁹*Ibid.*, para. 158.

dispute had signed and ratified these conventions.¹¹⁰ It read the term "exhaustible natural resources" evolutionary as comprising "living turtles", so as not to prevent WTO Members from protecting living resources as prescribed by several current environmental treaties. To buttress this interpretation, the Appellate Body referred to the principle of effectiveness of treaty interpretation¹¹¹, and to the Preamble of the *WTO Agreement* as well as the Decision of Ministers at Marrakesh to establish a permanent Committee on Trade and Environment, where the Ministers took note of the *Rio Declaration on Environment and Development*".¹¹²

Thus, the case law of the Appellate Body suggests that WTO law can be interpreted in the light of multilateral environmental agreements.

Secondly, the Appellate Body referred to the *Inter-American Convention on the Protection and Conservation of Sea-turtles*, where American States agreed to take "appropriate and necessary measures" for the protection, conservation and recovery of sea turtle populations and their habitats within such party's land territory" but also provided that, in implementing these measures, the parties shall act in accordance with their obligations under the *WTO Agreement*.¹¹³ The Appellate Body noted the

"juxtaposition of (a) the consensual undertakings to put in place regulations providing for, inter alia, use of TED jointly determined to be suitable for a particular party's maritime areas, with (b)

¹¹⁰*Ibid.*, footnotes 110, 111, and 113. See also, para. 168. This is a very significant methodological development. In *United States – Tuna*, the GATT Panel stressed that only treaties to which all GATT Contracting Parties are Members can be used under Article 31(3)(c) of the *Vienna Convention*. See, Report of the Panel, *United States – Restrictions on Imports of Tuna ("Tuna/Dolphin II")*, DS29/R (unadopted), dated 16 June 1994, para. 5.19.

¹¹¹Appellate Body Report, *United States – Shrimp*, para. 131.

¹¹²*Ibid.*, para. 154.

¹¹³*Inter-American Convention*, Articles IV and XV.

the reaffirmation of the parties' obligations under the WTO Agreement", which suggest that the parties to the Inter-American Convention together marked out the equilibrium line".¹¹⁴

This suggests that the Appellate Body might defer to a negotiated solution, where Members, in a "consensual undertaking", tackle a trade and environmental conflict through an agreement which takes account of their obligations under WTO law.

Thirdly, to support that turtles are an "exhaustible natural resource", the Appellate Body referred to the list of species threatened with extinction in Appendix 1 of CITES.¹¹⁵ This suggests that the fact-finding carried out under multilateral environmental agreements could be considered in WTO dispute settlement proceedings.

3. Literature

Only few scholars still attempt to resolve the relationship between WTO law and multilateral environmental agreements by applying the rules of conflict set forth in Article 30 of the *Vienna Convention*, i.e., *lex posterior*, and the *lex specialis* rule.¹¹⁶ As *Hilf* cautioned, rules of conflict do not produce viable results, because it cannot depend on historically adventitious decisions to ratify a treaty or not, which one supersedes the other.¹¹⁷ According to him, savings or trumping clauses are not adequate to decide a conflict, but only a mutual influence can lead to useful results.¹¹⁸

¹¹⁴Appellate Body Report, *United States – Shrimp*, para. 170.

¹¹⁵*Ibid.*, para. 132.

¹¹⁶See, *Wold*, Chris, "Multilateral Environmental Agreements and the GATT: Conflict and Resolution? 26 Environmental Law, 841 (1996) at 910 and 913.

¹¹⁷*Hilf*, Meinhard, "Freiheit des Welthandels contra Umweltschutz?", NVwZ 2000, at 481.

¹¹⁸*Ibid.*, at 484. A concept of cross-fertilization of norms has also been successful under European Community Law. See, *Hilf*, Meinhard, "Die Organisationsstruktur der Europäischen Gemeinschaften" (Berlin, Heidelberg, New York: Springer, 1982), at 224.

Marceau set out a comprehensive analysis of the relationship between WTO law and norms of general international law, with a particular focus on multilateral environmental agreements.¹¹⁹ She argued that, under Article 31.3(c), WTO panels and the Appellate Body are required to "take into account" a broad range of "non-WTO" legal instruments.¹²⁰

Going through the different elements of Article 31.3(c), she supported the broad approach of the Appellate Body in interpreting the term "applicable in the relations between the parties" not to require that all Members of the WTO, or all parties to the dispute are also parties to that agreement. In further developing this approach, she argued that even were only one party to the dispute is a party to the multilateral agreement, it could be taken into account, if the convention is a "subset of all the parties to the treaty under interpretation" and open to all WTO Members.¹²¹ This approach should be in line with the text of Article 31.3(c) of the *Vienna Convention*, and required by the presumption against conflict and the principle of effectiveness of treaty interpretation. In applying her approach to multilateral environmental agreements, she distinguished "six main situations". Depending on the two possibilities whether both disputants are also parties to the agreement or only one disputant, in both situations, the disputed measure might either be: (1) required by an MEA; (2) not required, but explicitly permitted; or (3) taken in furtherance of the goals of an MEA.¹²² Of interest for the precautionary principle is the situation where a party of the *Cartagena Protocol* makes use of its right to precaution, i.e., a trade measure permitted by the MEA. In that respect, *Marceau* argues that where

¹¹⁹*Marceau*, Gabrielle, "A Call for Coherence in International Law – Praises for the Prohibition Against 'Clinical Isolation' in WTO Dispute Settlement", 33 (5) *Journal of World Trade* 87 (1999).

¹²⁰*Ibid.*, at 128.

¹²¹*Ibid.*, at 124 and 125.

¹²²*Ibid.*, at 129.

both parties to the dispute are also parties to the WTO, the principle of effectiveness of treaty interpretation would require that a trade restriction explicitly permitted by an MEA could be presumed to satisfy the requirements of Article XX of the GATT 1994.¹²³ Even, where only one disputant is party to the environmental treaty, the permission of a measure is still relevant as a "rule applicable in the relations between the parties", and can be used to interpret Article XX of the GATT 1994, albeit having less value.¹²⁴

4. Comment:

The relationship between "trade and biosafety" is complex and still evolving. Although it is too early to determine the link between the *Cartagena Protocol* and WTO law, a few points can be made with respect to the possible role of the *Cartagena Protocol* in WTO dispute settlement proceedings.

First, WTO law and jurisdiction appears to support the concept of "mutual supportiveness" as reflected in the Preamble of the *Cartagena Protocol*, i.e., that a harmonious reading of trade and environmental agreements would allow their cumulative application.

Following *United States – Shrimp*, a multilateral environmental agreement can be used to interpret the ambiguous provision of Article XX of the GATT 1994. There appears to be no reason why the *Cartagena Protocol* could not be used to interpret Article 5.7 of the *SPS Agreement*. The underlying rationale for evolutionary treaty interpretation that the GATT was crafted 50 years ago, when environmental protection was not an issue, also applies to the *SPS Agreement* which was negotiated before the conflicts on GMOs arose.

¹²³*Ibid.*, at 131.

¹²⁴*Ibid.*, at 133 and 134.

(a) An Emerging solution for the party/non-party issue?

The party/non-party issue might become less dramatic for the *Cartagena Protocol*. The case law of the Appellate Body and the current negotiations in the CTE, as well as the literature suggest that environmental conventions can be used for the interpretation of WTO law even where both disputants are signatories or parties to an agreement. In that respect, three core conditions can be distilled: An environmental treaty must: (i) be open to Membership to all WTO Members, (ii) enjoy broad-based support; and (iii) must have been negotiated with a view to WTO law.

Is this approach, which transgresses the traditional requirement of Article 31.3(c) of the *Vienna Convention* in line with Article 3.2 of the DSU and the *pactis tertiis nec nocent nec prosunt* rule?¹²⁵ There are no valid counter-arguments. First, a mere interpretation of WTO law in light of other international treaties does not unduly restrict the rights of WTO Members who have chosen not to become a party to an agreement, because the MEA would not be treated as binding obligation. Both in *United States – Shrimp*, as well as in *European Communities – Hormones*, the Appellate Body carefully analyzed whether the text of the WTO obligation requires and permits the interpretation in light of another norm. As regards the precautionary principle, the Appellate Body does not accept consideration of an outside norm which would "override" the text of the *SPS Agreement*. Moreover, panels and the Appellate Body retain flexibility in the extent to which they use such outside norms on a case-to-case basis.¹²⁶

Three good arguments support the new approach. First, the principle of effectiveness of treaty interpretation, which also forms part of the customary rules of treaty interpretation referred to under Article 3.2 of the DSU, requires that WTO law is not interpreted so as

¹²⁵*Vienna Convention*, Articles 34 ff.

¹²⁶*Marceau*, above, n. 115, at 126.

to invalidate provisions under other international treaties.¹²⁷ The decisive argument, however, might be the reference to the objective of sustainable development in the Preamble to the *WTO Agreement* as well as the decision to establish the CTE, where WTO Members explicitly supported the tackling of global environmental problems through MEAs.

The Seattle Ministerial Meeting has brought to light the need but also the limits of the WTO in dealing with environmental problems. As noted by the Appellate Body in *United States – Shrimp*, a negotiated agreement may mark out the line of equilibrium between trade and environmental goals.¹²⁸ The *Cartagena Protocol* illustrates that MEAs are more dynamic and better equipped for finding inventive solutions to complex problems. At the same time, they offer expertise which might absolve WTO dispute settlement proceedings from difficult fact-finding exercises. If WTO adjudicators would not take account of MEAs when interpreting WTO law, there would be no incentives for Members to negotiate such agreements.

(b) The *Cartagena Protocol*: A Model Treaty for Mutual Supportiveness and Legal Certainty?

When applying these emerging criteria to the *Cartagena Protocol* it appears that it would be a model treaty to fulfil the conditions for cross-fertilizations even in a dispute involving the United States of America. The *Cartagena Protocol* is open to Membership to all WTO Members. It has been negotiated with a view to WTO law. Finally, it enjoys broad based support. The United States have participated in the negotiations as active observer. They

¹²⁷The principle of effective treaty interpretation reflects the general rule of treaty interpretation, pursuant to which a treaty be interpreted to give meaning and effect to all the terms of the treaty. The principle also mandates that a treaty not be interpreted so as to invalidate provisions under other treaties. See, *Jennings*, Sir Robert/Watts, Sir Arthur (eds.): *Oppenheim's International Law*, Vol. I Peace, Parts 2 To 4 (9th edition, Burnt Mill, Harlow, Essex: Longman), at 1280-1281 with further references.

¹²⁸Appellate Body Report, *United States – Shrimp*, para. 170.

have endorsed the final deal and declared that they would abide by it.¹²⁹ In the CTE, the United States welcomed the adoption of the *Cartagena Protocol* and stated that it would provide for the environmental objectives of the Protocol to be met, while not unduly interfering with international trade.¹³⁰ It advised that the discussions during the negotiations on precaution had addressed the issue of which controls to insert to ensure against abuse of a concept that was still in its infancy, but that work was needed to articulate how to implement this concept.¹³¹

(c) A remaining Conflict between the Precautionary Principles?

While the statement of the United States nourishes hope that the party-non party problem of the *Cartagena Protocol* can be resolved, it also points to the remaining crucial question of a possible conflict between the right to take a precautionary measure under the *Cartagena Protocol* and the differing obligations under Article 5.7 of the *SPS Agreement*. As repeatedly emphasized by the Appellate Body, an outside precautionary principle cannot "override" the provisions of the *SPS Agreement* and where there is a conflict, Article 11.3 of the *SPS Agreement* provides that it steps back with the consequence that the dispute cannot be adjudicated by WTO Panels.

D. SUMMARY

The Preamble to the *Cartagena Protocol* does not contain a clear conflict rule towards WTO law. The words "mutually supportive", and "shall not be interpreted", as well as the non-subordination language, seem to suggest that trade-related provisions of environmental treaties are increasingly negotiated with a view to

¹²⁹Phillips, Peter W.B./Kerr, William A., "The WTO Versus the Biosafety Protocol for Trade in Genetically Modified Organisms", 34(4) *Journal of World Trade* (2000), pp. 63-75, at 68.

¹³⁰CTE, Report of the Meeting held on 29 February – 1 March, Note by the Secretariat, WT/CTE/M/23, 5 April 2000.

¹³¹*Ibid.*

WTO law and that conflict could be avoided by harmonious interpretation, so that both agreements can apply cumulatively.

From the part of the WTO, the relationship with the *Cartagena Protocol* has not been clarified. WTO law and jurisdiction appears to support the concept of "mutual supportiveness" as reflected in the Preamble of the *Cartagena Protocol*, i.e., that a harmonious reading of trade and environmental agreements would allow their simultaneous existence.

The party/non-party issue appears to become less dramatic, because the Appellate Body does not apply the requirement spelled out by Article 31.3(c) of the *Vienna Convention*, whereby an outside norm must be "applicable in the relations between the parties" strictly. This approach is well founded in the principle of effectiveness of treaty interpretation and the consensus between WTO Members, as reflected in the Preamble to the *WTO Agreement* and the work of the CTE, that environmental problems should be tackled by multilateral environmental agreements. The analysis of the case law, work of the CTE and the literature allowed to distil three emerging conditions under which the provisions of MEAs can be considered in WTO disputes even if one of the disputants is not a party to the MEA. These are that the agreement must: (i) be open to Membership to all WTO Members; (ii) enjoy broad-based support; and (iii) must have been negotiated with a view to WTO law. At face value, the *Cartagena Protocol* appears to fulfil these conditions. The participation of the United States in the negotiations as well as its later statements indicate that they support the Protocol. However, these also reflect that specifically the issue of precautionary measure might cause conflicts.

This points to the crucial issue of whether the provisions of the *Cartagena Protocol* spelling out the right to precaution would conflict with Article 5.7 of the *SPS Agreement*, and would thus be barred

from being considered in WTO dispute settlement proceedings for "overriding" the obligations under the *SPS Agreement*.

II. NO CONFLICT...

Picking up from this question, the following section takes a close look at the precautionary principle as set forth in the *Cartagena Protocol* and Article 5.7 of the *SPS Agreement*. Some have raised concerns that the provisions for precautionary measures clash.¹³² Others argue that they are on their face compatible.¹³³ When comparing the respective provisions of the *SPS Agreement* and the *Cartagena Protocol*, one rather notes similarities than differences. In particular, both treaties require that an import measure be based on a risk assessment.¹³⁴ The Protocol uses almost equal language than the *SPS Agreement* by requiring, for example, that an import decision must be based on "available scientific evidence in order to identify and evaluate the possible adverse effects of LMOs" and "a risk assessment carried out in a scientifically sound manner".¹³⁵

The overview of the *Cartagena Protocol* in Part 1, §1 II of this thesis has shown that six of its provisions deal with precaution and scientific uncertainty.¹³⁶ Thus, the devil might be in the detail. The following two sections first compare the relevant provisions of the *Cartagena Protocol* and the *SPS Agreement* and then analyze whether there is a conflict.

¹³²Phillips, Peter W.B./ Kerr, William A., "The WTO Versus the Biosafety Protocol for Trade in Genetically Modified Organisms", 34(4) *Journal of World Trade* (2000), pp. 63-75.

¹³³Eggers/Mackenzie, above n.61, at 540.

¹³⁴See, Article 15(1) and Annex III *CPB*, on the one hand and Articles 2.2, 5.1, and Annex A.4 of the *SPS Agreement* on the other. Although not subject to the AIA procedures, decisions on the import of LMOs for food or feed or for processing are also subject to a risk assessment requirement. See, Article 11(1) read together with Annex II (j) of the *CPB*.

¹³⁵*CPB*, Article 15.1.

¹³⁶*CPB*, 4th preambular paragraph, Articles 1, 10.6, 11.8, and Annex III.4 and 8(f).

A. A COMPARISON OF THE RIGHTS TO PRECAUTION

Before taking a careful look at the relevant provisions governing precautionary measures, it is worth to cite them again in full.

Article 5.7 of the *SPS Agreement* provides:

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

The *Cartagena Protocol*, in its Preamble and Article 1 refers to Principle 15 of the *Rio Declaration*. However, its operative provisions governing import restrictions in situations of scientific uncertainty, i.e. Articles 10.6 and 11.8 of the CPB provide in relevant part:

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism [...], in order to avoid or minimize such potential adverse effects.

While the general risk assessment principle in Annex A III.4 of the CPB requires a neutral approach to scientific uncertainty, Annex AIII. 8(f) of the CPB stipulates:

Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Article 12 of the CPB, titled "Review of decisions" provides:

1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risk to human health, review and change a decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.

2. A party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:

- (a) A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based; or
- (b) Additional relevant scientific or technical

information has become available.

3. The party of import shall respond in writing to such a request within ninety days and set out the reasons for its decision.

4. The Party of import may, at its discretion, require a risk assessment for subsequent imports.

1. Triggering Factors

When comparing the triggering factors for a precautionary measure, the Protocol appears to set a higher threshold than the *SPS Agreement*: While Article 5.7 of the *SPS Agreement* requires that "relevant scientific evidence is insufficient", the Protocol employs the terms "lack of scientific certainty regarding the extent of potential adverse effects", which is "due to insufficient relevant scientific information and knowledge". The fact that the Protocol only requires insufficient scientific *information* whereas Article 5.7 says that scientific *evidence* must be insufficient, does not cause a difference, because the relevant substantive requirement of Article 5.7 is that the measure be based on "available pertinent *information*".¹³⁷

The minimum requirement that there be some scientific information regarding a risk under Article 5.7 of the *SPS Agreement*, is reflected, but not explicitly spelled out in Articles 10.6 and 11.8 of the CPB.¹³⁸ However, when reading these provisions together with

¹³⁷Article 5.7 of the *SPS Agreement* requires, in addition, that a Member bases its measure on information including that from relevant international organizations and other Members. Such a requirement is lacking in Article 10(6) of the CPB. However, as found, in chapter 3, the text under Article 5.7 is merely illustrative. Moreover, the Protocol, in general, provides for information exchange. Thus, this does not seem to be a relevant difference.

¹³⁸Only when insufficient scientific information regarding the *extent* of a potential adverse effect causes a lack of scientific certainty, the Protocol allows a precautionary measure. This implies that there is some information indicating the *existence* of an adverse effect.

the risk assessment requirement in Annex A.III 8(f) of the CPB¹³⁹, the Protocol is stricter than Article 5.7, because it requires "specific issues of concern".

2. Procedural Obligations

By contrast, the Protocol appears to set less stringent procedural obligations: First, under the *Cartagena Protocol*, the precautionary measure does not have to be adopted "provisionally", as required by Article 5.7 of the *SPS Agreement*. Second, while Article 5.7 spells out an obligation to actively seek to obtain the additional information necessary for a more objective assessment of risk and review the measure accordingly within a reasonable period of time, the *Cartagena Protocol*, under Article 12, only sets forth an obligation to review *upon request* of the Party of export or the notifier when additional relevant information has become available, or a change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based. Thus, under, the *Cartagena Protocol*, the country of import can wait passively until new information on LMOs becomes available, and the importer requests a review of the measure.

Third, this "mini-review" obligation does not even apply to decisions taken in the food safety sector, because Article 12.2 of the CPB explicitly only applies to decisions taken under the AIA procedure according to Article 10 of the CPB.

Fourth, the *Cartagena Protocol* explicitly permits the country of import to require the exporter to carry out the risk assessment. More specifically, although obliging the country of import to "ensure that risk assessments are carried out", it may require the exporter to "carry out the risk assessment" and specifies that the "cost of risk assessment shall be borne by the notifier if the Party of import so

¹³⁹This is required by Articles 15.1 and 11.1 read together with Annex II(j) of the CPB.

requires".¹⁴⁰ This stands in stark contrast to the obligation under Article 5.7 of the *SPS Agreement*, whereby the Member taking the provisional measure must seek the additional information.

In sum, while, overall, the language of Article 5.7 of the *SPS Agreement* and Articles 10.6 and 11.8 of the *Cartagena Protocol* illustrates that the Protocol has been negotiated with a view to the *SPS Agreement*, four procedural conditions on the taking of a precautionary measure are less burdensome under the *Cartagena Protocol* than under Article 5.7 of the *SPS Agreement*.

B. NOT MUTUALLY EXCLUSIVE

According to the general international law presumption against conflict, two provisions only conflict if they are "mutually exclusive".¹⁴¹ This concept is also employed by the Appellate Body.¹⁴² The Appellate Body, when dealing with possible conflicts between WTO agreements has further elaborated the notion of conflict: A "difference" only exists where two provisions, e.g. the provisions of the DSU and the special and additional rules of the *Anti-Dumping Agreement* "cannot be read as complementing each other". Moreover, a conflict is only given "in a situation where adherence to the one provision will lead to a violation of the other provisions".¹⁴³ In other words, differing obligations are only "mutually exclusive" when "Members could not comply with the obligations resulting from both Agreements at the same time or that WTO Members are

¹⁴⁰CPB, Article 15(2) and (3).

¹⁴¹Jenks, Wilfried, "The Conflict of Law-Making Treaties, The British Yearbook of International Law, B.Y.I.L., at 425 (1953); Jennings, Sir Robert/Watts, Sir Arthur (eds.), "Oppenheim's International Law", Vol. I Peace, Parts 2 to 4 (9th edition, Burnt Mill, Harlow, Essex: Longman), at 1280; Sinclair, Ian, "The Vienna Convention on the Law of Treaties", (2nd edition Manchester: Manchester University Press, 1984), at 97.

¹⁴²Appellate Body Report, *United States – Shrimp*, para. 128.

authorized to act in a manner that would be inconsistent with the requirement of GATT rules."¹⁴⁴

Both, Article 5.7 of the *SPS Agreement* and Articles 10.6 and 11.8 of the CPB provide for a right to take a precautionary measure. Thus, they do not set forth mutually exclusive obligations in the sense of requirements.

They only impose differing conditions on the taking of a precautionary measure. These are stricter under the *SPS Agreement* than under the Protocol. However, WTO Members and Parties to the Protocol can comply with both sets of rules by simply following the stricter conditions. The *Cartagena Protocol* does not authorize its parties to act in a manner inconsistent with Article 5.7 of the *SPS Agreement*. This is clarified in the Preamble which interdicts that the Protocol be "interpreted as implying a change in the rights and obligations of a Party under any existing international agreements." Thus, the Protocol does not diminish the stricter conditions for provisional measures under Article 5.7 of the *SPS Agreement*.

C. SUMMARY

The triggering factor for a precautionary import restriction under the *Cartagena Protocol* is stricter than provided by the *SPS Agreement*, while its procedural obligations are less burdensome than Article 5.7 of the *SPS Agreement*. More specifically, a measure is not bound to be provisional and must not automatically be reviewed after a reasonable period of time, but only upon request of the exporter who

¹⁴³Appellate Body Report, *Guatemala – Anti-Dumping Investigation Regarding Portland Cement from Mexico* ("Guatemala – Cement"), WT/DS60/AB/R, adopted 25 November 1998, para. 65.

¹⁴⁴Panel Report, *European Communities – Regime for the Importation Sale and Distribution of Bananas* (WT/DS27/R/USA), adopted 25 September 1997, para. 7. 161. See also *Indonesia – Certain Measures Affecting the Automobile Industry*, WT/DS54, 55, 59 & 64/R, adopted 23 July 1998, (*Indonesia-Automobiles*), para 14.99, where the Panel compared Article III:2 of the GATT and the *SCM Agreement*, and argued that the *SCM Agreement* does not deal with taxes on products as such but rather with subsidies to enterprises, so that oth provisions are at most concerned with different aspects of the legislation.

submits new information. However, there is no "conflict" between both provisions in that they are "mutually exclusive". Applying the nuanced notion of conflict developed by the Appellate Body, one finds that both agreements only permit, but do not require certain precautionary measures. Adherence to the stricter conditions set by the *SPS Agreement* would not violate the less stringent conditions under the *Cartagena Protocol*. The preambular language of the Protocol clarifies that it shall not be interpreted so as to authorize a deviation from the stricter WTO law provisions.

III. ... BUT CROSS-FERTILIZATION

The lack of conflict between the *Cartagena Protocol* and the *SPS Agreement* does not prevent future disputes on whether GMOs pose risks or not. However, it opens the way for cross-fertilizations. WTO adjudicators would face difficult legal and factual questions when applying Article 5.7 of the *SPS Agreement*. This section offers some suggestions how "cross-fertilization" between precautionary principles under the *Cartagena Protocol* and the *SPS Agreement* could work in practice. Picking up from the hypothetical which was difficult to resolve when only relying on Article 5.7 of the *SPS Agreement*, this section explores how the "jointly determined line of equilibrium" looks like.

A. THE HYPOTHETICAL REVISITED

Exporter E wishes to sell *Bt* maize seeds in developing country D. D refuses its consent under the *Cartagena Protocol on Biosafety*. It points to the Monarch Butterfly study and estimates that one of its tropical Emperor butterflies in a million might be adversely affected by *Bt* maize pollen. Moreover, older studies indicate that the long-term effects of GMOs can only be fully assessed after 100 years. To avoid any adverse effects on its centers of genetic diversity, D wants to take a long term ban.

E challenges the measure in WTO dispute settlement proceedings and argues that it is at odds with both, Articles 2.2 and 5.7 of the *SPS Agreement*. All new laboratory and field tests suggest that *bacillus thuringiensis* is safe. D has not sought to obtain information of how *Bt* maize affects its emperor butterfly or "center of genetic diversity". D contends that it has no financial means to carry out such specific studies and argues that it is up to E to show that his product is safe.

B. LEGAL CROSS-FERTILIZATIONS: THE LINE OF EQUILIBRIUM

First, the Protocol clarifies the important practical issue of who has to carry out and pay for scientific studies. The *Cartagena Protocol* explicitly distinguishes between the obligation of the party of import to "ensure that a risk assessment is carried out" and the possibility to "require the exporter to carry out the risk assessment". Moreover, Article 15.3 of the CPB provides that the "cost of risk assessment shall be borne by the notifier if the Party of import so requires". Such a distinction is not made in the *SPS Agreement*, albeit the text allows for its interpretation in that way, which was indicated by the Panel in *Japan – Agricultural Products*.¹⁴⁵

When WTO adjudicators apply the "mini-rational relationship" test under Article 5.7, i.e. whether the ban has been taken "on the basis of available pertinent information" they are faced with the difficult decision whether the older and less specific information of D is pertinent against the available data from laboratory or field studies carried out by E. The very existence of the Protocol could acknowledge potential adverse effects of LMOs, and that LMOs may, as a class be treated differently from traditional organisms. The Protocol particularly recognizes the possible adverse effects of LMOs on centres of origin and centres of genetic diversity.¹⁴⁶ While these general guidelines might work in favour of D, the rather hidden provision of Annex III.8(f) of the CPB which requires the country of import to "request further information on specific issues of concern" might indicate that a precautionary import restriction on LMOs cannot rely on general allegations that the biodiversity is endangered.

¹⁴⁵See, above Part 2, § 2, III, B.

¹⁴⁶CPB, Preamble, 7th paragraph.

Moreover, the requirement to consider monitoring the living modified organism in the receiving requirement could be invoked against long-term bans.

However, as regards the reasonable time for review, the Protocol does not use the term "provisional", thus supporting the dropping of this element in the Appellate Body jurisdiction on Article 5.7 of the *SPS Agreement*. Moreover, the fact that the review obligation under Article 12 of the *CPB* is only triggered by a request of the exporter where he has new scientific evidence, suggests that the reasonable time might be longer and is only bound by the evolving scientific knowledge on GMOs. In short, there are several possibilities how WTO law could take account of the *Cartagena Protocol* to tailor a biotechnology specific interpretation of Article 5.7 while not impairing the rights and obligations of WTO Members

C. TOWARDS COOPERATIVE FACT-FINDING

Where a WTO panel is left in doubt whether information regarding a one in a million risk for a butterfly is "pertinent" according to Article 5.7 of the *SPS Agreement*, it could refer to the "fact-finding" carried out under the Protocol. The *Cartagena Protocol* has adopted a "precautionary" negative listing approach, whereby initially all LMOs are subjected to the Advance Informed Agreement procedure. Article 7.4 of the *Cartagena Protocol* provides that "the advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health."

In *United States – Shrimp*, the Appellate Body referred to the positive list of endangered species under CITES.¹⁴⁷ Similarly, Panels might, when in doubt, refer to the negative list of LMOs deemed not to pose risks of adverse effects by the Parties to the Protocol. In turn, with regard to LMOs that are not "negative-listed", there could be a presumption that scientific evidence on the potential effects of these LMOs is still insufficient and that a measure is based on available pertinent information. Over the long run, these references to "outside" fact-finding could develop towards a cooperative fact-finding procedure, as already envisaged between the International Plant Protection Convention and WTO dispute settlement proceedings.¹⁴⁸

IV. FROM CAUSE TO CURE? - ISSUES AND CHALLENGES

The precautionary principle is reflected in Article 5.7 of the *SPS Agreement*, the WTO filter for scientific uncertainty. That safeguard is still an "accordion-like concept". The trade conflicts on hormone-treated beef and GMOs have spurred WTO Members to jointly refine the precautionary principle. A fascinating process of legal cross-reflections between WTO law and "outside" norms which take account of Article 5.7 of the *SPS Agreement*, but further refine the limits of precaution without hazarding the mutual rights and obligations of WTO Members can now take place.

Is the precautionary principle developing from cause to cure? There should be no illusions. Even the most accurately defined precautionary principle would be open to abuse. The cultural, economic and scientific factors which incensed trade conflicts will remain and trigger new rows with the advent of novel technologies or unexpected diseases. Constitutional issues of global governance

¹⁴⁷ Appellate Body Report, *United States – Shrimp*, para. 132.

¹⁴⁸ See, Article XIII of the IPPC, providing that in case of disputes a Committee of Experts prepares a report under the IPPC, which might then "also be submitted, upon its request, to the competent body of the international organization responsible for resolving trade disputes".

remain, in particular, the question: Who determines whether a risk is genuine? The consumer? A national authority, or the WTO? The nuanced links between the *SPS Agreement* and other international organizations might, over the long run, develop towards cooperative fact-finding procedures, where the WTO dispute settlement mechanism can build upon the facts determined elsewhere. For the time being, the new process-oriented element in the precautionary principle might allow panels to gradually pay more and more deference to Members who follow them, and to mark out the line of equilibrium between precaution and precautionism.

SUMMARY OF ARGUMENTS AND CONCLUSIONS

The precautionary principle is a red rag in international trade relations. Originally developed in environmental law, it was invoked by the European Communities in several trade conflicts arising from hormone-treated beef or genetically modified organisms (GMOs). Agricultural exporters fiercely protest against this "phony concept" and the United States and Canada maintain that no internationally agreed definition of a precautionary principle exists but, at best, a precautionary "approach" which varies from context to context. The Appellate Body pointed to the crux of the precautionary principle in international trade relations when holding that "at least outside the field of international environmental law, [it] still awaits authoritative formulation". The lack of a clear definition invites suspicions that the principle might be abused for protectionist purposes. Moreover, the Appellate Body emphasized that WTO law has its own specific filter to deal with scientific uncertainty in Article 5.7 of the *Uruguay Round Agreement on the Application of Sanitary and Phytosanitary Measures* (the "SPS Agreement"), in which the precautionary principle "finds reflection". The negotiations of the *Cartagena Protocol on Biosafety* (the "Cartagena Protocol") and the *Draft Codex Working Principles for Risk Analysis* (the "Codex Principles") put the spotlight on the links between the precautionary principles contained therein and the SPS Agreement.

This thesis has analyzed the key legal issues arising from the precautionary principle in WTO law. Below are all findings and conclusions of my thesis, as developed in the course of my analysis.

1. The precautionary principle is enshrined in several continental European legal orders. A closer look at the roots of the precautionary principle in German law shows that it emanates from protective duties of the government. It marks the point at which a risk becomes unacceptable and justifies interference with markets. While, e.g., the United States, use a "catch-all" concept of risk, the legal term precaution (*Vorsorge*) was developed to delineate, on a spectrum of different degrees of risk, an

acceptable risk from a merely residual risk. The precautionary principle itself is not defined in German statutory law, but courts have carved out triggering factors, i.e. a remote possibility of risk, even if only supported by minority opinions, and limiting factors, including the principle of proportionality. Apart from India, most common law jurisdictions have not articulated a precautionary principle. However, comparative analyses have concluded that most of them, e.g., the system of the United States, are "precautionary in nature", in particular in the area of health and food safety.

2. The European Communities are currently the chief promoter of the precautionary principle. It is recognized in the *EC Treaty* for the area of environmental protection. However, in the field of human health and food safety, where the European Communities took "precautionary measures" it is not yet articulated. As a partial response to the trade conflicts regarding hormone-treated beef, GMOs, BSE, and antibiotics, Community institutions are currently striving to formulate the first over-arching and general articulation of the precautionary principle. The triggering factors, e.g., "reasonable grounds for concern" or that "the desired level of protection could be jeopardized" are still oscillating. They reflect the low thresholds of risk which justified the European Community measures regarding GMOs, BSE and antibiotics, where it was sufficient that adverse effects on human health could not be "excluded" or "ruled out". A mere consumer threshold is not envisaged and, indeed, all contentious measures of the European Communities, although responding to consumer fears, were taken with a view to scientific evidence. The limiting factors include necessity, regulatory consistency, and the principle of proportionality, which does not allow a "zero risk" policy, but permits the prevention of long-term adverse effects. A significant legal development are the process-oriented steps to be followed, including an evaluation of the risk, identification of topics for further research and transparency.

3. The adoption of the *Cartagena Protocol* as well as the negotiations of the *Codex Principles* indicate an emerging consensus at the international level that precaution is necessary, but that clear limits need to be placed on its use to avoid disguised protectionism. The *Cartagena Protocol* recognizes a right to precaution in its operative provisions and sets forth specific and detailed conditions governing import restrictions on GMOs, including the review of precautionary measures. As regards human health and food safety, a precautionary principle is currently being negotiated under the Codex Alimentarius Commission. Albeit not yet defined, some emerging features of a precautionary principle for food safety could be distilled. The threshold of risk triggering a protective measure is lower than in environmental protection, albeit not aiming at zero risk. Pure consumer concerns cannot justify interference with markets. Other than in the area of environmental protection, there is a trend towards a reversal of the burden of proof. The new precautionary principles are more "process-oriented". They require governments to evaluate the risk, review the measures and involve foreign stake-holders. Thus, in the field particularly relevant for international trade, the precautionary principle is now "close to authoritative formulation".

4. The WTO faces the flip-side of the precautionary principle. As the guardian of liberal trade, it has to deal with the allegation of exporters that precautionary measures result in disguised protectionism of inefficient agricultural markets. According to *Sykes*, even health and environmental measures which apply indistinctly to imported and domestic goods, might result in "regulatory protectionism", if they disadvantage foreign producers "in a manner unnecessary to the attainment of some genuine non-protectionist regulatory objective". A welfare economic analysis of the two examples of GMOs and hormone-treated beef indicates, that the measures taken by the European Communities would be protectionist, *if* there was no genuine risk. However, the crux of uncertain risks is that the determination of whether preventive measures would be "dead-weight" costs can only be made after a risk has manifested itself, as illustrated, e.g., in the BSE crisis. The theory of public choice would explain the trade conflicts of hormones and GMOs with diverging consumer values and risk aversenesses which

result in time intervals between governmental responses and differing degrees of market intervention. While the precautionary principle itself only tackles the balancing of human health and environment versus domestic economic interests, the WTO needs to balance national regulatory choices with the economic interests of foreign firms.

5. The long-festering trade conflict arising from the ban on hormone-treated beef showed that the "accordion-like concept" of the "like" product test under Article III:4 of the GATT 1947, coupled with the exception under Article XX of the GATT 1947, could not grasp the difficulties of scientific uncertainty. The *SPS Agreement* takes a different approach. It uses a right-limit technique. Members may choose their own appropriate level of protection, but must comply with a set of seven obligations, including a science test, a harmonization requirement, a necessity test, an obligation to ensure regulatory consistency and transparency. As indicated by the Appellate Body, Members enjoy an autonomous "right to precaution" in the form of a right to determine the appropriate level of protection or "acceptable level of risk", which may be higher than that implied in international standards, and even be zero risk. The determination of the appropriate level of protection is a "prerogative" of each Member and cannot be second-guessed by WTO panels. Thus, Members are free to decide how much risk they want to accept, e.g. the death of one woman in a million or one butterfly in a million.

6. Whether the precautionary principle finds reflection in WTO law depends on the conditions for the taking of precautionary measures. This term which is more and more used when discussing trade measures that pose particular problems of scientific uncertainty, can be defined as measure taken pursuant to the precautionary principle to protect human, animal, and plant life or health, or the environment, which is taken in situations of scientific uncertainty and may directly or indirectly affect trade. To ensure a precise analysis of the conditions for precautionary measures, further fine-tuning is necessary. First, distinctions can be made between differing degrees of scientific uncertainty. GMOs, involve a high degree of scientific uncertainty, i.e., short term data stand against a few controversial studies

and a bunch of "what if...?" questions. More evidence has been gathered on the effects of hormones, where scientists rather disagree which inferences to draw from existing data. Second, there are considerable differences between "old" pre-Uruguay Round measures, where Members were scientifically idle, e.g. in *Japan – Agricultural Products*, and recent measures taken in the antibiotic cases or Hormones II, which refer to scientific evidence in their Preambles and are labeled provisional, or temporary. Third, trade practitioners use the term "emergency measures" for situations like the BSE crisis, where governments react quickly to the release of scientific findings. Finally, the issue of "mixed measures" has been risen where governments pursue several different legislative goals, e.g. protection of health and consumer concerns and market stabilization in the first Hormones Directive.

7. The chief limits of precaution are set by the obligations under Articles 2.2, 5.1 and 5.7 of the *SPS Agreement* which, according to the Appellate Body, are "essential for the maintenance of the delicate and carefully negotiated balance in the *SPS Agreement*, between the shared, but sometimes competing, interests of promoting international trade and of protecting health". The basic obligation under Article 2.2 of the *SPS Agreement* to ensure that a measure is "not maintained without sufficient scientific evidence" is applied by using a rational relationship test. This concept has been criticized as "we no it when we see it stance". The analysis of the full case law bearing on the rational relationship test, debunked the myth that Article 2.2 of the *SPS Agreement* implies a "sound scientific evidence" standard. The Appellate Body correctly permitted the consideration of minority views as opposed to the preponderance of scientific thinking. This reflection of the precautionary principle not only applies to human health, but has also been extended to animal and plant life or health. The hot debate about the requirements for the consideration of minority views is overstated. The Appellate Body correctly applies a standard whereby the "quantity and quality" of the scientific evidence counts. The minimum standards for sufficient scientific evidence are that studies must be specific and systematic. They must come from qualified and respected sources, and be authored by scientists who have, themselves

investigated the issue at hand. Moreover, few experimental data is not sufficient, in particular if it is not free of error. These further conditions can be legally buttressed by the text of Annex A.3, the relationship between Article 2.2 and 5.7, and the purpose of the *SPS Agreement* to prevent countries from using "stone-wall strategies" by giving "general declarations" rather than "explanations" for their measures.

8. The specific obligation under Article 5.1 of the *SPS Agreement* requires that a measure be "based" on an "assessment of the risk". The notion of risk assessment is defined under Annex A.4, which provides different conditions depending on whether a risk is "food-borne" or "pest or disease related". The *SPS Agreement* does not prescribe a certain notion of risk. Governments may take account of consumer concerns albeit only *together* with scientific evidence when assessing adverse effects on human, animal or plant life or health. Thus, those precautionary measures which respond to a mixture of health and consumer concerns can still meet the risk assessment requirement under Article 5.1 of the *SPS Agreement*. A risk must be "ascertainable" as opposed to "theoretical" uncertainty, i.e. speculations which are not verifiable by using scientific methods. This notion of risk does not diminish the spectrum of risks reflected in the precautionary principle.

9. However, there is a paradoxon created by the case law of the Appellate Body which may cause insecurity whether the *SPS Agreement* sets a minimum threshold of risk higher than the ones established by the precautionary principle. On the one hand, the Appellate Body stressed the difference between the requirement in Annex A.4 to evaluate the "likelihood" versus "potential" of adverse effects by interpreting it as "probability" versus "possibility". On the other hand, the Appellate Body emphasized that no minimum magnitude of risk is required. To square this, it can be argued that the obligation to evaluate risks and to provide sufficient scientific evidence is purely process-oriented. WTO Panels are only called upon to examine whether a Member has *assessed* the risk, but not whether there *is* a *risk*. More specifically, Members must assess and evaluate the "potential" respectively "likelihood" of adverse effects, but can determine

what is a "potential" or "likelihood". Yet, the procedural obligations under Annex A.3 are strict. The Appellate Body requires Members to specifically evaluate the adverse effects arising from a certain substance. "Some evaluation" and reference to "uncertain elements" is not enough. Although a recent DSU Article 21.5 Panel adopted a less stringent reasonable confidence and objectivity standard, this obligation might, *de facto* create a significant hurdle for most precautionary measures

10. Indeed, the analysis of the hypotheticals under Articles 2.2, and 5.1 of the *SPS Agreement* suggests that, although the rational relationship test leaves room for manouvre, the hurdle of sufficiently specific and systematic evidence, supported by experimental data might not be taken by most precautionary measures. A moratorium on imports of GM foods, for example, which is based on the Monarch Butterfly study, might be turned down for not specifically scrutinizing the effects of all GMO imports on human health. As regards the Hormones II measure, it would be difficult to decide whether the new data on oestradiol 17 β are sufficiently specific and free of errors so as to stand against the existing body of scientific evidence which concludes that the administration of hormones is safe when following a good husbandry practice. The fact that the European Communities have based their implementation measure with respect to the five remaining hormones on Article 5.7 by only prohibiting them provisionally illustrates the relevance of the safeguard for scientific uncertainty.

11. There is much confusion regarding the legal nature of Article 5.7. Other than Article XX of the GATT, it is not titled "general exception". It has been characterized as exception, exemption, derogation, and autonomous right. The Appellate Body calls it a "*qualified* exemption". The interpretation of the provision in its context suggests that Article 5.7 is not an exception. Thus, the burden of proof does not automatically shift to the respondent and it does not have to be interpreted narrowly. Article 5.7, like other safeguards, under the ATC or Article 3.3 of the *SPS Agreement*, transgresses the traditional distinction between obligations and exemptions. The term "exemption" stems from taxation law. WTO law uses the concept, e.g. in Article II of the GATS when allowing Members to maintain, on a

temporary basis, measures that violate the MFN obligation. This suggests that an exemption excludes certain measures from the reach of an obligation, while an exception justifies a violation of an obligation.

12. The four-pronged test for Article 5.7 of the *SPS Agreement* set forth by the Appellate Body requires that "a provisional measure must be (1) imposed in respect of a situation "where relevant scientific information is insufficient"; and (2) adopted "on the basis of available pertinent information". According to the second sentence, a Member may not maintain a provisional measure unless it (3) seeks to "obtain the additional information necessary for a more objective assessment of risk" and (4) reviews the "measure accordingly within a reasonable period of time". These elements are cumulative in nature, i.e. a Member must comply with all of them when taking a precautionary measure. That test reflects the ordinary meaning of Article 5.7 of the *SPS Agreement* but for the element "provisionally" which has flown into the overarching term "provisional measure".

13. The entrance requirement of Article 5.7 of the *SPS Agreement* denotes its scope of application. The term "cases in which relevant scientific information is insufficient" is co-extensive to Article 2.2 of the *SPS Agreement*, i.e. all measures which fall through the first hurdle of the science test are generally eligible for the mechanism under Article 5.7.

The decisive triggering factor for a provisional measure is that it is adopted "on the basis of available pertinent information". To date, there is no case law on this element. A contextual analysis of the first sentence of Article 5.7 suggests that it might imply a "mini-risk evaluation" obligation to carry out a "less objective assessment of risk" which evaluates some information that triggers a specific and researchable scientific hypothesis about a risk for human, animal or plant life or health and identifies the remaining uncertainties. The term "on the basis of" might be interpreted as a "mini-rational relationship" test. It would be another "we know it when we see it test". In particular at both ends of the spectrum of scientific uncertainty, it

would be difficult to delineate "pertinent information" from "theoretical risks" and "sufficient scientific evidence".

14. Whether the requirement to "seek to obtain additional information necessary for a more objective assessment of the risk" entails an obligation of the importing country to provide and pay for scientific studies is unclear. In line with WTO jurisdiction, one could arguably distinguish between (i) the obligation to show that a product is safe in pre-marketing approval and quarantine proceedings (ii) the obligation to ensure that a measure has been based on a risk assessment and (iii) the burden of proof in WTO dispute settlement proceedings. The text of the *SPS Agreement* can be used to support that WTO law does not change the precautionary principle whereby a producer has to prove that a new product is safe. As regards the question "what" kind of information must be sought, the Appellate Body ruled that such information must be "germane" to "conducting a more objective assessment of the risk". Thus, building on the information and scientific hypothesis which warrants the provisional measure, further evidence must be sought which allows the Member to carry out a risk assessment pursuant to Article 5.1 of the *SPS Agreement*. To fulfil these conditions, the information to be sought must be specific.

15. The term "provisionally" has raised much concern that Article 5.7 of the *SPS Agreement* would only justify a limited amount of measures which are explicitly applied on an interim or temporary basis, e.g. the emergency measures in the BSE cases, but does not cover the whole range of precautionary measures, in particular measures affecting biotechnology products, where long term risks are suspected. Disputants and scholars keep suggesting certain time limits up to 20 years to flesh out the element "provisionally". The case-to-case test developed by the Appellate Body does not explicitly include the element "provisionally", but measures the reasonable period of time according to the "specific circumstances of the case" the "difficulty of obtaining the additional information necessary" and the "characteristics of the provisional" measure. This test reflects the wording of Article 5.7 read in light of the negotiating history. Clear time-

limits as set for provisional safeguard or anti-dumping measures or as spelled out in Article 21.3(c) of the DSU cannot be given for Article 5.7 of the *SPS Agreement* because scientific evidence is constantly evolving and the outcome of the scientific process is unpredictable. Yet, drawing on limited experience from the DSU 21.3(c) arbitration in *European Communities - Hormones*, it should be possible to measure how long it might take scientists to obtain the additional information in an individual case. The case-to-case test developed by the Appellate Body permits emergency measures such as those taken in the BSE crisis, or temporary bans, e.g., a two year moratorium on GMOs. Long-term bans on GMOs and *Hormones II* are difficult to appraise. The term "provisionally" would disallow *de facto* permanent bans which are disguised as "provisional measure". *Hormones II* poses the interesting question whether a permanent ban can be turned into a provisional one. Considering the relationship between Article 5.7 and Article 21.5 of the DSU it can be argued that, as long as new information exists which warrants further research, a never-ending "spiral of new science" under Article 5.7 might be preferable to a never-ending "spiral of retaliation and carousel retaliation".

16. Testing the Article 5.7 filter with the hypotheticals shows that it produces relatively good results for "model" provisional measures, e.g. the emergency actions taken in the BSE cases. The procedural requirements under Article 5.7 second sentence work well to catch blatant cases of "scientific idleness", i.e. most "old" measures, where imports have been blocked for years on the basis of scientific assumptions. However, at both ends of the spectrum, i.e. *Hormones II* and the "what if..?" questions involved in the biotechnology cases, WTO adjudicators, when faced with new measures, might be forced to "determine" whether Members have adopted the measures "on the basis of available pertinent information". Although the interpretation of the requirement gave some guidance on the application of this possible mini-rational relationship test, WTO adjudicators might well come down on both sides. Thus, the conditions for the taking of precautionary measures are not clear. When looking back, the accordion-like concept of the "like-product" test, coupled with the exception

under Article XX of the GATT, has, in the end been replaced by another accordion, albeit with fewer keys.

17. Where the substantive tests boil down to the assessment of scientific information on a case-to-case basis, the rules on fact-finding play a crucial role. The scientific facts involved in trade conflicts about precautionary measures are complex and highly disputed. The burden of proof is the first important determinant. The analysis of the case law with a view to identifying how much proof is necessary to make a *prima facie* case of inconsistency with Articles 2.2, and 5.1 of the *SPS Agreement* indicates that it is easier to make a *prima facie* case of inconsistency than to refute it. The precise standard of proof varied between the mere absence of scientific evidence regarding MGA, which was enough to show that no risk assessment existed in *European Communities – Hormones*, and *Japan – Agricultural Products*, where the Appellate Body set the bar higher to ensure that to prove a violation of Article 2.2, mere allegations that there is no scientific evidence are not enough. Important for precautionary measures is the question, whether a successful *prima facie* case shifts the burden of proof in the strict sense, i.e. the risk of non-persuasion in situations where the evidence is in equipoise. Here, the case law of the Appellate Body created some uncertainty. However, it can be argued that the *prima facie* case, as generally in international law, only shifts the burden of evidence.

18. Although Article 5.7 of the *SPS Agreement* transgresses the distinction between general obligations and exceptions, by operating as "qualified exemption", the general burden of proof under the *SPS Agreement* is applicable to that provision. As indicated in WTO jurisdiction, the complaining country must make a *prima facie* case that the conditions for a provisional measure are not fulfilled. The use of presumption techniques, following Article 5.8 of the *SPS Agreement*, as well as the general obligation to disclose information under Article 13.1 of the DSU can ensure that neither party can withhold information to the detriment of the other disputant.

19. The point up to which WTO adjudicators may second-guess national risk determinations is not marked by a clear standard of review in the *SPS Agreement* as incorporated in Article 17.6 of the *Anti-Dumping Agreement*. The Appellate Body applies Article 11 of the DSU as standard of review, requiring panels to make an objective assessment of law and facts. As regards the interpretation of most legal concepts under the *SPS Agreement*, e.g., risk and risk assessment, the Appellate Body has paid a considerable degree of legal deference towards Members. Problematic is the second-guessing of factual determinations. Here, the standard of review developed by the Appellate Body is rather a standard of appellate review. Apart from "wilful distortions" of facts and "egregious errors" factual determinations of the panel fall outside the scope of appellate review.

The assessment of the facts in the first SPS cases was heavily criticized for re-doing the national risk assessment. When taking a closer look at what the panels did in all four SPS rulings, there appears to be a clear difference between early cases and the more recent *Australia – Salmon 21.5* decision. As regards the "old" measures, the defendants only gathered evidence after the measure was challenged. This evidence was then re-evaluated by the Panel. In *Australia – Salmon 21. 5*, however, Australia carried out a risk assessment following the requirements of Article 5.1 and Annex A.4. The 21.5 Panel employed a "reasonable confidence" standard after verifying that Australia had followed the steps prescribed in Annex A.3. Whether this standard would be upheld by the Appellate Body and could develop into a reasonableness standard similar to the one set forth by Article 17.6 of the *Anti-Dumping Agreement* would depend on further refinement of the process of risk determinations, in particular under Article 5.7 of the *SPS Agreement*. National standards of review cannot be transplanted. However, the new process-oriented precautionary principles negotiated under the Codex Alimentarius Commission might mark the "trade-off" between national responsibility for food safety and cooperation between the WTO Members.

20. The development of new precautionary principles in the *Cartagena Protocol on Biosafety* and the Codex Alimentarius Commission puts the

spotlight on the link between these norms and WTO law. Observers have expressed concerns that the new precautionary principles might be a "slippery slope" towards eroding the science based mechanism of the *SPS Agreement*. The *SPS Agreement* envisages a more nuanced relationship to "outside" norms than other WTO agreements. First, Article 3.2 of the DSU directs WTO adjudicators to "clarify the existing provisions of [the covered] agreements in accordance with customary rules of interpretation of public international law". Second, the *SPS Agreement* incorporates standards, guidelines and recommendations of relevant international organizations as the basis of harmonization or risk assessment techniques (Articles 3.1, 3.2, 3.3, 5.1 and Annex A.3 of the *SPS Agreement*). Third, Article 11.3 of the *SPS Agreement* contains a savings clause regulating possible conflicts with other international agreements by stipulating: "Nothing in this Agreement shall impair the rights of Members under other international agreements, including the right to resort to good offices or dispute settlement mechanisms of other international organizations or established under any international agreement."

21. The Appellate Body, in *European Communities – Hormones* and *Japan – Agricultural Products*, consistently held that the precautionary principle cannot be a "ground for justifying SPS measures that are otherwise inconsistent with the obligations of the Members set out in the *SPS Agreement*". This is in line with Articles 3.2, 7.2 and 11 of the DSU and Article 11.3 of the *SPS Agreement*, whereby "outside" principles cannot form the legal basis of a WTO dispute, but can only have an interpretative function pursuant to Article 31.3(c) of the *Vienna Convention*.

22. The interpretative function of the precautionary principle in the *SPS Agreement* has been generally acknowledged by the Appellate Body, but consistently rejected *in casu*. When carefully analyzing the reasoning in *European Communities – Hormones* and *Japan – Agricultural Products*, three main reasons stand out why the Appellate Body has refused to read Articles 2.2 and 5.1 in the light of the precautionary principle. First, this would have broadened the scope of these provisions to the detriment of Article 5.7 of the *SPS Agreement*, which would have "overridden" the text

of the *SPS Agreement*. The ruling in *United States – Shrimp* has shown that an "outside" rule can only be considered if both are not "mutually exclusive" i.e. conflict. This correctly reflects Article 31.3(c) of the *Vienna Convention* which is a principle of harmonious treaty interpretation whereby the governing treaty, i.e. WTO law, retains the primary role. Second the Appellate Body exercised jurisdictional self-restraint towards the International Court of Justice by declining to determine the status of the precautionary principle in international law. Third, even assumed that, as argued, the precautionary principle in the form of Principle 15 of the *Rio Declaration*, has attained the status of a customary rule of international law, it would have had no relevant content for a dispute under the *SPS Agreement* relating to food safety. This reasoning is in line with the conditions set forth by Article 31.3(c) of the *Vienna Convention*. However, it does not exclude a reading of Article 5.7 of the *SPS Agreement*, which is ambiguous and needs clarification in the light of norms which provide relevant guidance on the subject matter. A general precautionary principle applying to all subject matters, i.e. both environment and health as well as all geographical areas of application does not (yet) exist. Of the specific precautionary principles identified in Part 1 of the thesis, only the (still to be negotiated) *Codex Principles* in the area of food safety and the *Cartagena Protocol*, which relates to GMOs would be relevant norms within the meaning of Article 31.3(c) of the *Vienna Convention*.

23. Precautionary Principles can become incorporated standards in the *SPS Agreement*. A precautionary principle developed under the Codex Alimentarius Commission would, upon its adoption, automatically attain the status of a privileged standard according to Article A.3(a) of the *SPS Agreement*. Other than suggested by Charnovitz, the *Cartagena Protocol* does not meet the requirements set out by Annex A.3(d) of the *SPS Agreement* to become an incorporated standard, because its subject-matter is or might be covered by the Codex and the IPPC. Even if the respective scopes and roles of these organizations will be clarified after a period of alignment, the *Cartagena Protocol* would first need to be identified by the SPS Committee through a consensus decision.

24. The *Codex Principles* could have an useful interpretative effect on both, Articles 5.1 and 5.7 of the *SPS Agreement*. They do not prescribe a certain measure and can, therefore, not form the basis of harmonization under Article 3 of the *SPS Agreement*. However, they could, arguably, have effect through the obligation under Article 5.1 "taking into account risk assessment techniques developed by the relevant international organizations". Where the definition of risk assessment does not provide further guidelines, these standards can refine the obligations, for example the rules for the choice of experts, could contribute to resolving the issue of minority opinions. However, the real treasury lies in the "criteria" set forth for precautionary measures, more specifically, the conditions for a "preliminary risk assessment". These could refine the hazy obligation under Article 5.7 of the *SPS Agreement* and further the elaboration of processes which are the precondition for paying more deference towards Members in the assessment of risks.

25. The *Cartagena Protocol* is not an amicable settlement between the United States and other WTO Members regarding their trade conflicts on GMOs. However, it sets forth detailed provisions governing precautionary measures in the area of biotechnology, where the WTO mechanism does not produce predictable results. A conflict between precautionary import restrictions under the Protocol and the *SPS Agreement* was one of the major sticking points in the negotiations. The Protocol does not use a savings or trumping clause to regulate its relationship with WTO law, but envisages a "mutually supportive" relationship between "trade and environment agreements". It mandates that the Protocol "shall not be *interpreted*" as implying a change in the obligations under other international agreements, albeit not being "subordinated" to them. This suggests that the relationship between WTO law and this environmental treaty has advanced to a stage beyond conflict, where both sets of rules can apply cumulatively and cross-fertilizations are possible by interpreting WTO law in the light of the Protocol and *vice versa*.

26. WTO law and jurisdiction support the concept of "mutual supportiveness". The Appellate Body, in *United States – Shrimp* already

moved far ahead by allowing cross-fertilizations at three levels: First, where a term, e.g., "exhaustible natural resources" in Article XX(g) of the GATT 1994 is ambiguous, it can be interpreted "evolutionary" with a view to multilateral environmental agreements as long as the texts are not "mutually exclusive". Second, the Appellate Body referred to the fact-finding under a multilateral environmental agreement. Third, it noted that a "jointly determined solution" can mark out the "line of equilibrium". The legal hurdle to be taken by the *Cartagena Protocol* in a WTO dispute involving the United States, who, although having participated in the negotiations and openly endorsed their outcome, are not likely to become a party, might be less dramatic than sometimes suggested. The Appellate Body, in *United States – Shrimp*, did not apply the requirement that a norm of international law must be "applicable in the relations *between the parties*" to be taken into account in the treaty interpretation under Article 31.3(c) of the *Vienna Convention*, strictly, but referred to the principle of effectiveness of treaty interpretation. An emerging consensus on the party/non-party issue in the CTE supports this approach although the precise conditions are not fixed yet. Because the *Cartagena Protocol* is open to Membership to all WTO Members, enjoys broad-based support including the United States, and has been negotiated with a view to WTO law, it might fulfil the conditions set by Article 3.2 of the DSU read together with Article 31.3(c) of the *Vienna Convention*, to be taken into account by WTO adjudicators when interpreting Article 5.7 of the *SPS Agreement* in a GMO dispute *if* the precautionary principle of the Protocol does not "override" Article 5.7 of the *SPS Agreement*.

27. Precisely the provisions on the precautionary principle in the *Cartagena Protocol* have raised concerns that there might be a conflict between the Protocol and the *SPS Agreement*. The devil is in the detail, because six provisions of the Protocol govern the taking of precautionary measures. A careful comparison of the respective obligations concerning import restrictions on LMOs under the Advance Informed Agreement Procedure (10.6 of the CPB) as well as for LMOs declared to be used directly as food or feed, or for processing (11.8 of the CPB), with Article 5.7 of the *SPS Agreement* indicates that the Protocol has been negotiated

with a view to Article 5.7. As regards the triggering factor for a precautionary import restriction, the *Cartagena Protocol* not only uses similar concepts but is even stricter than Article 5.7 of the *SPS Agreement*, because Annex A.III.8(f) of the CPB requires Members to identify "specific issues of concern". By contrast, although Article 12 of the CPB sets forth review obligations similar to the ones contained in Article 5.7, second sentence of the *SPS Agreement*, these are less burdensome than Article 5.7 of the *SPS Agreement*. More specifically, under the Protocol, a measure is not bound to be provisional and must not automatically be reviewed after a reasonable period of time, but only upon request of the exporter who submits new information. For the area of food safety, no review obligations have been included into the Protocol.

28. Despite the legal differences there is no "conflict" between the respective provisions of the *Cartagena Protocol* and the *SPS Agreement*. Applying the general international law notion of conflict, whereby two provisions must be "mutually exclusive", which has also been adopted by the WTO Appellate Body in *United States – Shrimp*, one can argue that both agreements only permit, but do not require certain precautionary measures. They only differ in the conditions placed upon the right to precaution. However, adherence to the stricter conditions set by the *SPS Agreement* would not violate the less stringent conditions under the *Cartagena Protocol*. The preambular language of the *Cartagena Protocol* clarifies that it shall not be interpreted so as to authorize a deviation from the stricter WTO law provisions. Finally, as analyzed above, Article 5.7 of the *SPS Agreement* sets forth broad case-to-case tests, which have, e.g., dropped the term "provisionally" and might allow WTO panels to come down on both sides.

29. States have gone beyond *legal* conflict between trade and biosafety. However, disagreements about restrictions on GMOs will continue. Because the United States, as major trading nation in biotechnological products, are legally prevented from becoming a party of the Protocol until they have ratified the *Biodiversity Convention*, it is realistic to expect that trade conflicts will be brought to the WTO dispute settlement proceedings.

The final section has explored several ways of how Panels could refer to the *Cartagena Protocol* when resolving a case under Article 5.7 of the *SPS Agreement*. First, the provisions of the *Cartagena Protocol* clarify the practically and financially important issue of the burden to provide evidence under Article 5.7 of the *SPS Agreement* by distinguishing more carefully between the obligation to "ensure that a risk assessment is *carried out*" and the obligation "to *carry out* the risk assessment and to pay for the studies" which, according to the Protocol, can be placed on the exporter. As regards the element "on the basis of available pertinent information", the *Cartagena Protocol* works in favour of exporters. Although generally acknowledging concerns that centers of genetic diversity might be adversely affected by LMOs, the Protocol requires the country of import to identify "specific issues of concern". By contrast, through the omission of the "provisionally" element, the Protocol might influence the determination of the "reasonable period of time" for review under Article 5.7 of the *SPS Agreement* in favour of the country of import.

Most importantly, where left in doubt, WTO adjudicators could refer to the fact-finding carried out under the Protocol, i.e. they could refer to the negative list of LMOs deemed not to pose risks of adverse effects by the Parties to the Protocol. With regard to LMOs that are not "negative-listed", there could be a presumption that scientific evidence on the potential effects of these LMOs is still insufficient and that a measure is based on available pertinent information.

30. The thesis concluded that the precautionary principle is developing from cause to cure. The trade conflicts on hormone-treated beef and GMOs have spurred WTO Members to jointly determine its boundaries. A fascinating process of legal cross-reflections between WTO law and "outside" norms which take account of Article 5.7 of the *SPS Agreement*, but further refine the limits of precaution without blurring the mutual rights and obligations of WTO Members is taking place. Yet, there should be no illusions. Many issues and challenges remain. Even the most accurately defined precautionary principle would be open to abuse. The cultural, economic and scientific factors which incensed trade conflicts endure and

will trigger new rows with the advent of novel technologies or unexpected diseases. The hormone conflict has highlighted many constitutional issues of global governance, in particular the question: Who determines whether a risk is genuine? The consumer? A national authority, or the WTO? The nuanced links between the *SPS Agreement* and other international organizations and conventions might, over the long run, develop towards cooperative fact-finding procedures, where the WTO dispute settlement mechanism can build upon the facts determined elsewhere. For the time being, the new process-oriented element in the precautionary principle might allow panels to gradually pay more and more deference to Members who follow them, and assist them in marking out the line of equilibrium between precaution and precautionism.

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