The Operationalization of the Precautionary Approach in International Environmental Law Treaties – Enhancement or Façade Ten Years After Rio?

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I. Introduction

The 1992 United Nations Conference on Environment and Development (UNCED) marked the full emergence of the precautionary approach[1] in international law.[2] At that time, prominent authors saw the following decade as critical in the refinement and operationalization of the approach.[3] While the relevant documents of the 2002 Earth Summit in Johannesburg did not add any further essence to the issue but only reiterated what had been declared ten years before,[4] the status of the precautionary approach has been formally further strengthened within that period. In addition to the fact that the approach has been reaffirmed in virtually every relevant international agreement dealing with environmental protection and uncertainty of risks since 1992[5], it has also taken a centerstage in a number of inter-

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[1] Among lawyers and practitioners in international law, the precautionary language is used for two different aspects. First, the approach is described to ensure that the mere lack of scientific knowledge about risks cannot justify a failure to take appropriate precautions. This aspect is also enshrined in Principle 15 of the Rio-Declaration on Environment and Development. Second, the approach is used to stress the precautionary exploitation of natural resources (see R. Wolfrum, Precautionary Principle, in: Beurier/Kiss/Mahmoudi (Eds.), New Technologies and Law of the Marine Environment, 1999, 207, with reference to the 1994 Convention on the Conservation and Management of the Pollock Resources in the Central Bering Sea). Under this aspect, the precautionary approach is equivalent to the meaning of sustainable use. This paper focuses on the first aspect of the precautionary approach.

[2] J. Cameron/J. Abouchar, The Status of the Precautionary Principle in International Law, in: Freeston/Hey (Eds.), The Precautionary Principle and International Law – The Challenge of Implementation, The Hague 1996, 51; D. Freestone/E. Hey, Origins and Development of the Precautionary Principle, in: Freeston/Hey (Eds.), The Precautionary Principle and International Law – The Challenge of Implementation, The Hague 1996, 3; J. Cameron, The Precautionary Principle in International Law, in: O'Riordan/Cameron/Jordan, Reinterpreting the Precautionary Principle, London 2001, 115.

[3] Cameron/Abouchar, *supra* note 2, 52.

[4] General Assembly Resolution A/C.2/57/L.83; World Summit on Sustainable Development – Plan of Implementation, paras. 22 and 103; The Johannesburg Declaration on Sustainable Development, para. 8 (documents available under <http://www.earthsummit2002.org>).

[5] Cameron, *supra* note 2, 115; see the list of relevant international environmental agreements, in: D. Katz, The Mismatch between the Biosafety Protocol and the Precautionary Principle, in: Georgetown International Environmental Law Review (2001), 951 et seq.

national discussions and disputes on trade, the environment, and human health and has even become – according to some authors[6] – the *Leitmotiv* of European and Commonwealth environmental law and policy.

However, despite its growing presence in international law and although often regarded as a principle of international law or even part of customary international law, there is still considerable controversy over how to articulate or define a precautionary principle of law. A single universally shared version of the principle does not exist. Besides, the general understanding of the precautionary concept that, in case of scientific uncertainty, it is better to err on the side of safety by regulating too stringently, rather than too leniently[7], the precautionary principle is worded differently almost each time it is articulated.[8] Some writers have counted 14 different versions of the principle in international environmental law documents[9] and not all of the different approaches do easily co-exist with one another.[10] This vagueness surrounding the precautionary principle provides ample room for disagreement and does not particularly further its legal standing. Not surprisingly, the precautionary principle is often framed in non-binding terms as part of the preamble or the objectives provision of a treaty.

For a number of reasons, the Cartagena Protocol on Biosafety[11] can be seen as the central global environmental agreement with regard to the precautionary ap-

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[6] E. Fisher, Is the Precautionary Principle Justiciable?, in: Journal of Environmental Law 2001, 315; R. Macrory, "Editor's Foreword", Journal of Environmental Law 1997, 219.

[7] See S. Shapiro, Keeping the Baby and Throwing Out the Bathwater: Justice Breyer's Critique of Regulation, in: Administrative Law Journal 1995, 732: "When a regulator makes a decision under conditions of uncertainty, there are two possible types of error. The regulator can overregulate a risk that turns out to be insignificant or the regulator can underregulate a risk that turns out to be significant. If the regulator erroneously underregulates, the burden of this mistake falls on those individuals who are injured or killed and their families. If a regulator erroneously overregulates, the burden of this mistake falls on the regulated industry which will pay for regulation that is not needed." However this balance may disregard the positive effects of technical achievements for the society that were stopped by overregulation.

[8] N. Myers, Debating the Precautinary Principle, 2000, 1 (available under <http://www.sehn.org/ppdebate.html>).

[9] D. Vanderzwaag, The Precautionary Principle in Environmental Law and Policy: Elusive Rhetoric and First Embraces, in: Journal of Environmental Law and Practice 1999, 355 et seq.; see also K.R. Foster/P. Vechhia/M.H. Repacholi, Science and the Precautionary Principle, in: Science 288 (2000), 979; J. Tickner/C. Raffensperger/N. Myers, The Precautionary Principle in Action – A Handbook, Windsor 1999 (available under <http://www.biotech-info.net/handbook.pdf>).

[10] See for the inconsistency of "strong" and "weak" precautionary language: E. Soule, Assessing the Precautionary Principle, Harvard Colloquium: Biotechnology in the Global Economy: Science and the Precautionary Principle, 22-23 September 2000 (available under <http://www.cid.harvard.edu/cidbiotech/comments/comments73.htm>); similiarly: J. Morris, Defining the Precautionary Principle, Harvard Colloquium, Harvard Colloquium: Biotechnology in the Global Economy: Science and the Precautionary Principle, 22-23 September 2000 (available under <http://www.cid.harvard.edu/cidbiotech/comments/comments79.htm>); M. Iynedjian, Le principe de précaution en droit international public, in: Droit International de Sciences Diplomatiques et Politiques 2000, 253, with further approaches for defining in note 16; similar Foster/Vecchia/Repacholi, *supra* note 9, 979; Myers, *supra* note 8; J. Bohanes, Risk Regulation in WTO Law: A Procedure-Based Approach to the Precautionary Principle, in: Columbia Journal of Transnational Law 2002, 331.

proach.[12] First, it is one of the few international agreements that do not only include precautionary language in some of its provisions, but also reflect the idea of precaution through their composition and structure as such: The Protocol's combination of import control and risk assessment allows for the early assessment and decision on a potential risk;[13] second, it contains four different wordings of the precautionary approach in four different sections[14] of the Protocol; and third, it has been hailed as the first inclusion of the precautionary principle in the operational part of a global environmental agreement.[15] The comprehensive integration of the precautionary approach is especially noteworthy since the aim of the Protocol is not to reduce or phase out chemical substance like pesticides, pollutants or halons that may be replaced by other less hazardous substances without severely disrupting international trade over the time. Instead, it addresses a product that is the outcome of one of the key technologies of the new century whose continuing development has an essential economical impact for industrialized nations competing with each other in becoming the preferential place for future investment in this technology.[16] Additionally, the Protocol's objective is to ensure an adequate level of protection in the field of the safe transfer, handling and use of LMOs with a spe-

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[11] 39 ILM 1027 (2000). On June 13, 2003, the 50th country ratified the Protocol, starting a 90-days countdown to the agreement's entry into force (11. September 2003).

[12] See the comment of Klaus Töpfer, Executive Director of UNEP, on the occasion of the 50th ratification of the Biosafety Protocol: "The Cartagena Protocol institutionalises the precautionary approach [...]", in: Treaty on international trade in GMOs to become law – the Cartagena Protocol on Biosafety will enter into force in September, press release, UNEP, available under: http://www.biodiv.org/doc/press/pr-2003-06-13-bs-01-en.pdf.

[13] In this way P.T. Stoll, Controlling the Risks of Genetically Modified Organisms: The Cartagena Protocol on Biosafety and the SPS Agreement, in: Yearbook of International Environmental Law 2000, 98.

[14] Preamble, objectives provision, operational provisions, Annex III.

[15] L. Graff, The Precautionary Principle, in: Bail/Falkner/Marquard (Eds.), The Cartagena Protocol on Biosafety – Reconciling Trade in Biotechnology with Environment and Development?, London 2002, 417. A. Gupta, Advanced Informed Agreement: A Shared Basis for Governing Trade in Genetically Modified Organisms?, in: Indiana Journal of Global Legal Studies 2001, 276. Although Article 2 (2)(a) of the Paris Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR Convention) already applies the precautionary principle in an operational provision, the OSPAR-Convention has to be considered a regional and not a global one. See H.J. Priess/C. Pitschas, Protection of Public Health and the Role of the Precautionary Principle under WTO Law: A Trojan Horse Before Geneva's Walls?, in: Fordham International Law Journal 2000, 527 et seq.

[16] The use of biotechnology in the agricultural sector has produced a growing number of genetically modified organisms and products from them. The rapid diffusion from transgenic crops illustrates the pace at which biotechnology is transforming the commercial landscape. The potential ecological effects of such a use became the focus of widespread debate at national and international levels. As a reflection of the need to regulate potential risks posed by transnational transfers of genetically modified organisms, efforts have been made since the middle of the 1990's to negotiate a Biosafety Protocol. After five years of discussion, on January 29, 2000, ministers and senior officials from over 130 governments finalized a legally binding agreement setting out procedures in the field of safe transfer, handling and use of living modified organisms (LMOs) that may have an adverse effect on biodiversity. See M. Böckenförde, Das Biosafety-Protokoll und seine Auswirkungen auf das System der Welthandelsordnung (forthcoming), Einleitung, I.

cific focus on transboundary movement.[17] It regulates international trade in LMOs without being another side-agreement of the WTO but originating from a treaty of international environmental law, the Convention on Biological Diversity.

Hence, being – as part of the Protocol – on the frontline of trade and environment disputes, a deeper analysis of the different facets of the precautionary approach in the Protocol may help to evaluate the *status quo* of the precautionary principle in international law ten years after Rio and mirrors best its progress and the set-backs of the last decade.

Firstly, this paper introduces therefore the precautionary language of the Protocol on its different levels and in its different wordings. It then argues, secondly, that the operationalization of the precautionary principle just went half way; the pertinent provisions on a decision-making level only allow governments of the member states, in cases where sufficient evidence of risk exists, to take precautions, if there is a lack of certainty about the extent of those risks. But they do not permit governments to take appropriate precautions where lack of scientific knowledge about the nature of a risk still exists. As a consequence, Article 10 (6) CPB and Article 11 (8) CPB rather correspond to Articles 5.1-6 of the SPS-Agreement than to Article 5.7 SPS. This will bring the author to the conclusion that the so called first operationalization of the precautionary principle in an international environmental treaty is rather a façade than an enhancement of the principle in international law although measures taken on the basis of Article 10 (6) CPB may be nevertheless very effective.

II. The Different Facets of the Precautionary Approach in the Biosafety-Protocol

1. The Different Levels on which the Precautionary Approach is Addressed within the Protocol

The Protocol's objective is to ensure an adequate level of protection in the field of safe transfer, handling and use of LMOs. It is mainly achieved by the application of the Advanced Informed Agreement (AIA) procedure. The central principle permeating throughout the AIA-procedure is the right of the importing country to refuse the transboundary movement of the regulated goods on the basis of a decision making process.[18] Pursuant to the idea of an agreement, the AIA-procedure consists of two subsequent elements: First, the party from which an LMO is exported for the first time must provide advanced notice to the importing party; second, the importing party then has the right to permit, subject to conditions, or to deny permission to import the LMO as long as the decision is based on the proce-

[17] Article 1 CPB.

[18] R. Falkner, Regulating Biotech Trade: the Cartagena Protocol on Biosafety, in: International Affairs 76 (2000), 308.

dures set out in the Protocol. These procedures require an initial assessment of risk at the national level under international procedural discipline.[19]

On both levels, the level of assessing a risk according to Article 15 and Annex III, and the level of taking a decision based on the results of the outcome of the risk assessment pursuant to Article 10 (1) and Article 10 (6) CPB-parties are authorized and/or obliged to apply the precautionary approach. Hence, in the Protocol, the precautionary principle is applied as a "risk assessment tool" and as a "risk management tool". Furthermore, the precautionary approach is placed in its traditional positions, in the Protocol's preamble and also in the objectives provision. According to Article 1 CPB, parties to the Protocol are obliged to adhere to the precautionary approach as set out in Principle 15 of the Rio Declaration while implementing the Protocol's objective.

Not only does the Biosafety Protocol embody the precautionary approach at different levels as demonstrated above, it also offers different variations of the precautionary principle. This becomes apparent if the principle is split into its several elements.[20] Central themes are: the type of uncertainty that is required in the scientific community[21], the level of risk that justifies precautionary action[22] and the action to be taken if a situation triggers this level of risk; others are either additional requirements or accompanying obligations that have to be met in order to apply the principle in a legal manner.

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[19] Stoll, *supra* note 11, 99.

[20] See Stoll, ibid., 115; Katz, *supra* note 5, 956.

[21] The Helsinki Convention on the Protection and Use of Transboundary Watercourses and International Lakes requires in this respect: "[...] the release of hazardous substances shall not be postponed on the ground that scientific research has not fully proved a causal link between those substances, on the one hand, and the potential transboundary impact, on the other hand"; The Convention on Biological Diversity (CBD) and the Framework Convention on Climate Change (FCCC) require "lack of full scientific certainty [...]".

[22] The CBD requires for example a "threat of significant reduction or loss of biological diversity" (preamble) whereas the FCCC requires "threats of serious or irreversible damage" (Article 3 (3)) and the Helsinki Convention requires in Articles 1 (2), 2, 5a for example a "significant adverse effect on the environment".

Table 1. The different wordings of the precautionary approach in the Biosafety-Protocol

The precautionary approach of Principle 15 of the Rio Declaration, incorporated in the Biosafety-Protocol through Article 1 CPB and the recital 4 of the preamble	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.
The precautionary approach in the operative part of the Protocol (Article 10 (6) and 11 (8) CPB)	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 the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.
The precautionary language of Annex III No. 4 CPB	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.
The precautionary approach of Annex III No. 8 (f) CPB	Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

a) The precautionary approach as part of the preamble and the objectives provision

As is common in many other environmental agreements[23], the Biosafety Protocol introduces precautionary language in its preamble and objectives provision. However, whereas most of these treaties do not oblige their parties to adhere to the precautionary approach by framing it in non binding terms[24], the Protocol does so. Article 1 CPB requires the objective of the Protocol to be "in accordance with the precautionary approach" thereby making explicit reference to Principle 15 of the Rio Declaration. The text of Principle 15 is kept in strict words: "[...] lack of full scientific certainty s h a l l not be used [...]". So far, the obligatory wording of Principle 15 had not much legal relevance, since the principle itself was part of the Rio

[23] See for instance the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, 28 ILM 649 (1989); the Convention on Biological Diversity, 31 ILM 818 (1992); Rotterdam Convention on Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, 38 ILM 1 (1999).

[24] See for example the wording in the Preamble of the CBD, where "[...] lack of scientific uncertainty should not be used [...]" or in Article 3 FCCC where "[t]he Parties should take precautionary measures [...]; P r i e s s / P i t s c h a s, *supra* note 15, 527.

Declaration on Environment and Development that is regarded as non-binding soft law.[25] However, as part of the body text of an international agreement, the legal impact of the strict wording is not softened by the legal status of the original declaration. Hence, through its incorporation in the body text of the Protocol, Principle 15 has gained a mandatory character which applies to the Protocol in its entirety.[26] As a consequence, each provision of the Protocol has to be implemented from the specific perspective of the precautionary approach as set out in Principle 15. The spirit of the precautionary approach may insofar require a restrictive application of exception clauses in the Protocol (simplified procedure, Article 13 CPB; regional agreements, Article 14 (3) CPB), or may have some impact on the relationship to non-parties.

Of specific interest in the given context is the effect Article 1 CPB may have on the precautionary language on the decision-making level in Article 10 (6) or Article 11 (8) CPB. Once the criteria contained in Article 10 (6) CPB are met, a party "shall not be prevented from taking [an appropriate] decision". In other words, Article 10 (6) CPB provides the right of a party to take a specific measure, e.g. to restrict imports. It was suggested by some scholars[27] that this right to act in Article 10 (6) CPB would be influenced by Article 1 CPB (Principle 15), thereby becoming a duty to act, if the stricter criteria of Principle 15 were met.[28] This idea was based on the ground that Principle 15 contains an obligation to act in case of "threats of serious or irreversible damage".[29] According to this author's view, it does not. Principle 15 only states that once the qualified threat has been identified, cost effective measures to prevent environmental degradation shall not be postponed with the argument of scientific uncertainty. However, there may be other valid reasons for a government not to take action; Principle 15 does not generally preclude a government in the given situation of remaining passive.

But Article 10 (6) CPB may be guided through Article 1 CPB with regard to the action that may be taken if a situation triggers the pertinent level of risk (potential adverse effects). According to Article 10 (6) CPB, a party then has the right to take

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[25] To the non-binding character of soft law in environmental law see: U. Beyerlin, Umweltvölkerrecht, Munich 2000, 64-66; P. Sands, Principles of International Environmental Law, Manchester 1995, 103; more general on the status of soft law in a hierarchy of norms on an international level: U. Beyerlin, "Prinzipien" im Umweltvölkerrecht – ein pathologisches Phänomen?, in: Cremer/Giegerich/Richter/Zimmermann, Tradition und Weltoffenheit des Rechts – Festschrift für Helmut Steinberger, Berlin 2002, 31-61.

[26] M. Herdegen/T. Spranger, Internationale Praxis Gentechnikrecht, Heidelberg, 17th suppl. August 2001, Protokoll über die biologische Sicherheit, 6 et seq.

[27] N. Bernasconi-Osterwalder, The Cartagena Protocol on Biosafety: A Multilateral Approach to Regulate GMOs, in: Brown-Weiss/Jackson (Eds.), Reconciling Trade and Environment, 2001, 706.

[28] The required type of uncertainty in Principle 15 of the Rio Declaration is "lack of full scientific certainty" whereas Article 10 (6) CPB asks only for a "lack of scientific certainty". The levels of the risk that justifies precautionary action are also different levels: While Principle 15 requires "threats of serious or irreversible damage", Article 10 (6) CPB needs "potential adverse effects" to trigger precautionary action.

[29] Bernasconi-Osterwalder, *supra* note 27, 706.

a decision "as appropriate, [...] in order to avoid or minimize such potential adverse effects". To determine the meaning of "as appropriate" in this context, reference may be taken from Article 1 (Principle 15) which stresses the cost-effectiveness of precautionary measures.

b) The precautionary approach as part of the risk assessment pursuant to Annex III

Before designing a precautionary measure pursuant to Article 10 (6) CPB, "potential adverse effects" have to be identified. They are to be identified and evaluated by a risk assessment[30] that the parties are obliged to undertake prior to taking decisions on import.[31] The assessment is to provide a "recommendation as to whether or not the risks are acceptable or manageable [...]".[32] Annex III lists a number of specific obligations concerning the methodology and "points to consider" which must be included in a risk assessment.[33] Precautionary language can be found in various parts of Annex III. Annex III No. 4 describes the meaning of "lack of scientific knowledge" or "lack of scientific consensus" within the risk assessment. As stated before, the risk assessment is meant to identify risks in the sense of potential adverse effects of LMOs on the conservation and sustainable use of biological diversity in the likely potential receiving environment.[34] Annex III Nr. 4 clarifies that "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." In other words, as risk is a function of two variables – the probability of an impact and its magnitude – insufficient knowledge with regard to one or both factors should not be a valid basis in determining whether there is a risk. Hence, Annex III Nr. 4 emphasizes the difference between the absence of evidence (of a risk) and the evidence of absence.[35] The first one must not be the ground from which the second one is deduced. The precautionary approach installs the parameters of how to interpret scientific information for (scientific) statements on the basis of certain risk (in form of potential adverse effects[36]) that trigger justifiable recourse to precautionary measures on the level of decision-making (Article 10 (6) CPB). Thereby the precautionary approach becomes an integral part of a

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[30] Annex III No. 1.

[31] Article 15 (2) CPB. Implicitly, the decision has to be based on the outcome of such a risk assessment. See Graff, *supra* note 15, 418; Böckenförde, *supra* note 16, ch. II. C. III. 1. c).

[32] Annex III No. 8 (e).

[33] For a detailed introduction of the requirements in Annex III see Stoll, *supra* note 11, 94.

[34] Annex III No. 1.

[35] Economic & Social Research Council, The Politics of GM food, 1999, 7; P.T. Saunders, Use and Abuse of the Precautionary Principle, London 2000 (available under: <http://www.biotech-info.net/precautionary-use-and-abuse.html>).

[36] Annex III No. 1 introduces the term of potential adverse effects into the risk assessment and determines that the task of a risk assessment is their identification and evaluation. Insofar unclear Stoll, *supra* note 11, 99.

science based risk assessment. To that end, Annex III is a testimony against the dichotomy of sound science and precaution.[37]

Another element of precaution can be found in Annex III Nr. 8 (f) which addresses the question of how to proceed in cases of uncertainty regarding the level of risk.[38] Annex III Nr. 8 (f) does not refer to scientific uncertainty and the remedies suggested in order to overcome the uncertainty gives the impression that this section focuses on appropriate strategies of how to manage the risk in cases where the dimension of the assessment's outcome is not yet fully clear.[39] "Level of risk" may then be understood as the different dimensions of technological risk (ubiquity, reversibility, delay, persistence, mobilization potential)[40] that have to be taken into account.

c) The precautionary approach as part of the decision-making procedure

Article 10 (6) CPB and Article 11 (8) CPB are often regarded as the innovative part of the Protocol with regard to the precautionary approach, explicitly allowing states to take precautionary action in reaching their decision on imports of LMOs. As mentioned before, these provisions are celebrated as the first operationalization of precautionary language in a global international environmental agreement. But once divided into its different elements, the ambivalence of that approach becomes apparent. The necessary degree of scientific uncertainty within the scientific community seems to be – *prima facie* – lower than in Principle 15 of the Rio Declaration. Instead of "lack of full scientific certainty" Article 10 (6) CPB and Article 11 (8) CPB only require "lack of scientific certainty". However, the attached limitation of the relevant kind of "lack of scientific certainty" restricts the effect of the provisions considerably. Pursuant to Article 10 (6) CPB and Article 11 (8) CPB, such lack of certainty must be due to "insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects". Hence, the

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37 A. Sterling, On Science and Precaution in the Management of Technological Risk, Brussels 1999, 38; H. Meyer, Precise Precaution versus Sloppy Science – A Case Study. Third World Network Briefing Paper (available under: <http://www.cqs.com/sloppyscience.htm>); L. Levidow, "Sound Science" as Ideology, Harvard Colloquium: Biotechnology in the Global Economy: Science and the Precautionary Principle, 22-23 September 2000 (available under: www.cid.harvard.edu/cidbiotech/comments/comments91.htm); P.L. Bereano, Politics, Sound Science and the Precautionary Principle. Harvard Colloquium: Biotechnology in the Global Economy: Science and the Precautionary Principle, 22-23 September 2000 (available under: <www.cid.harvard.edu/cidbiotech/comments/comments92.htm>); C. Erben, Das Vorsorgegebot im Völkerrecht, part III. ch. X. I. (forthcoming).

38 For the text of Annex III No. 8 (f) see Table 1.

39 Annex III No. 8 (f) suggests to address the uncertainty by requesting further information on the specific issue of concern or by implementing appropriate risk management strategies and/or monitoring LMOs.

40 "Ubiquity" refers to the geographical extent of a risk, "reversibility" to the potential of restoration, "delay" to the latency of manifestation, "persistance" to the duration of harm and "mobilization potential" to the political sensitivity: See WBGU (German Government's Advisory Council on Global Change), Welt im Wandel: Strategien zur Bewältigung globaler Umweltrisiken, Heidelberg 1999.

scientific uncertainty that justifies precautionary action is not related to the nature of an adverse impact, but only to its extent. This emphasis on the extent of an adverse impact has to be interpreted as requiring prior scientific evidence of the existence of an adverse impact before precautionary action can legitimately be taken.[41]

A legal analysis utilising Article 31 of the Vienna Convention on the Law of Treaties (VCLT) supports such a reading. According to Article 31 (1) VCLT, 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".

The ordinary meaning of the term "extent" carries a notion of quantity. Hence, in order to determine the "extent" of an impact, the question of its existence had to be answered in a positive way before. It seems that the negotiating groups were aware of this quantitative limitation of the term extent. The original proposal of what later became Article 10 (6) CPB was tabled by the EU delegation in Montreal during a joint meeting of the contact group on commodities and trade-related issues. It included reference to "the existence of" and the "nature of" potential adverse effects, but this reference was dropped owing to an objection from the Miami group.[42]

The context in which Article 10 (6) CPB is embedded does not require a different understanding to the one provided by the ordinary meaning. It also conforms to the pattern of the risk assessment set out in Annex III of the Protocol. As mentioned above, the risk assessment process has to be distinguished from the risk management process. In the former, scientific results about potential adverse effects are identified, evaluated and interpreted, in the latter, political decisions are taken. Article 10 CPB determines what kind of decision may be taken on the basis of a certain outcome of the risk assessment. Hence, if, as a result of the risk assessment, a potential adverse effect has been identified, but there is lack of scientific knowledge about its extent, the parties may take, according to Article 10 (6) CPB, any decision "in order to avoid or minimize such potential adverse effects". If, however, as a result of the risk assessment, a potential adverse effect has not been identified due to lack of scientific knowledge, parties must not take recourse to Article 10 (6) CPB but may decide pursuant to Article 10 (3)(d) CPB to extend the specified pe-

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[41] Stoll, *supra* note 13, 99; L. Stökl, Das Verhältnis multilateraler Umweltschutzabkommen zum WTO-Recht, dargestellt am Beispiel des Biosafety-Protokolls, in: Aussenwirtschaft 2001, 349; Cameron, *supra* note 2, 141; A. Gupta, Precautionary Decision-Making under the Cartagena Protocol on Biosafety. Harvard Colloquium: Biotechnology in the Global Economy: Science and the Precautionary Principle, 22-23 September 2000 (available under: <www.cid.harvard.edu/cidbiotech/comments/comments84.htm>); other scholars regard the precautionary approach in Article 10 (6) CPB as "fairly strong", but do not discuss the meaning of the term "extent" in the given context: K. Buechle, The Great, Global Promise of Genetically Modified Organisms: Overcoming Fear, Misconceptions, and the Cartagena Protocol on Biosafety, in: Indiana Journal of Global Legal Studies 2001, 298; S. Charnovitz, The Supervision of Health and Biosafety Regulation by World Trade Rules, in: Tulane Environmental Law Journal 2000, 300.

[42] Graff, *supra* note 15, 416.

riod by a defined period of time. The mere fact that some lack of scientific certainty does not yet allow the application of Article 10 (6) CPB is no sign of inconformity between the risk assessment and the risk management process.[43]

The narrow version the precautionary approach gives in Article 10 (6) CPB is also in line with the Protocol's objective and purpose, as laid out in Article 1 CPB. The objective of the Protocol "is to contribute to ensuring an adequate level of protection [...] for the conservation and the sustainable use of biological diversity [...]". This language includes elements of a compromise and does not intend to guarantee the highest level of protection. Hence, the moderate precautionary approach corresponds to this part of the objectives provision. Further, Article 1 CPB states that the objective of the Protocol has to be in accordance with the precautionary approach of Principle 15 of the Rio Declaration. It therefore may be argued that the precautionary approach in Article 10 (6) CPB has to be of at least the same strength as the one in Article 1 CPB. As discussed above, the precautionary wording in Article 1 CPB (Principle 15 of the Rio Declaration) differs from that in Article 10 (6) CPB.[44] It sets higher standards for triggering precautionary action and only allows for cost-effective responses. Article 10 (6) CPB, instead, applies a narrower scope that focuses only on the extent of certain effects. Despite the strong interpretative influence of Article 1 CPB on the other provisions of the Protocol, it has no legal power to change their clear meaning.[45] Instead, Article 10 (6) is to be considered the more specific norm that prevails in case of incompatibility. However, although both versions do not provide a common basis for precautionary action[46], their overall level of protection should be compatible.[47]

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[43] Within the methodology of the different steps of a risk assessment, Annex III (8) (d) is the step, where Article 10 (6) CPB comes into play. Annex III (8) (d) reads: "An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized." At this stage, adverse effects are identified, but the overall risk is yet unclear. Under such circumstances, Article 10 (6) CPB may be applied.

[44] *Supra*, note 28.

[45] See A.D. Mc Nair, Law of Treaties, Oxford 1961, 365 with regard to treaty interpretation: "The words "interpret", "interpretation" are often used loosely as if they included "apply, application". Strictly speaking, when the meaning of the treaty is clear, it is "applied", not "interpreted". Interpretation is a secondary process which only comes into play when it is impossible to make sense of the plain terms of the treaty, or when they are susceptible of different meanings." See also E. U. Petersmann, From the Hobbesian International Law of Coexistence to Modern Integration Law: The WTO Dispute Settlement System, in: Journal of International Economic Law 1998, 189; D. Simon, L'interprétation judiciaire des traités d'organisations internationales, Paris 1981, 83.

[46] Unless it is argued that lack of full scientific certainty in the case of qualified threats of damage requires already sufficient knowledge on the existence of potential adverse effects.

[47] Some authors distinguish between "uncertainty" that generally refers to situations in which harm is probabilistic in nature, but for which a probability distribution is known or may be assigned and "true uncertainty" where even the probability of harm is not known. Whereas the precautionary approach in Article 10 (6) CPB refers to the first type of uncertainty, the precautionary principle is generally discussed with reference to the second type of uncertainty. One could therefore argue that Article 10 (6) CPB only includes a "2nd class" precautionary principle. See S. Charest, Bayesian Approaches to the Precautionary Principle, in: Duke Environmental Law and Policy Forum 2002, 267 et seq.

2. Article 10 (6) CPB as a Reflection of the Delayne Clause in International Law

The quality of the precautionary approach in Article 10 (6) CPB and Article 11 (7) CPB reflects a structure that allows for the implementation of the Delayne clause for LMOs "in order [...] to avoid potential adverse effects on the conservation and sustainable use of biological diversity". The Delayne Clause is a strict legislative pronouncement enacted by the US-Congress in the late 1950's: If a substance is found to be carcinogenic, the substance must be prohibited.[48] The Clause seems to express the unequivocal judgment that consumers should not be exposed to food ingredients known to cause cancer, regardless of the benefits the ingredients might provide or the magnitude of the risk that they might present.[49] This zero tolerance-policy has survived the last century, at least for food additives and colour additives, although advances in technology have provided the capability to detect even the minutest traces of carcinogens that many believe do not pose a significant risk to the public. But the attempt of the Food and Drug Administration (FDA) to read a *de minimis* exception into the Delaney Clause was turned down by US-Courts.[50]

Article 10 (6) CPB forms the international legal basis for national governments to enact regulations similar to the Delayne Clause, but with respect to the conservation of biological diversity. What kind of decision may be taken on the basis of Article 10 (6) can be illustrated with three LMO-related scenarios that are presently discussed in the scientific literature. The most prominent example is the harm of the monarch butterfly through transgenic pollen[51], followed by reports on

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[48] S.B. Mastrostefano, The Delaney Clause: Still No De Minimis Exception, in: George Washington Law Review 1989, 1307.

[49] R.A. Merrill, FDA's Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaption to Scientific Progress?, in: Yale Journal on Regulation 1988, 2.

[50] See *Public Citizien v. Young*, 831 F. 2d 1108 (D.C. Cir.).

[51] In a first study, Monarch Butterfly larvae were placed on milkweed leaves, which had Bt-pollen put on them in the laboratory in a similar density as found on milkweed leaves near cornfields. Less than half of the larvae reared on transgenic, pollen-dusted leaves survived, compared to larvae reared on leaves dusted with non-transgenic pollen. Because the Bt protein is targeted at corn borer pests, not Monarchs, these results could mean that Bt may harm unintended pests such as monarchs. J.E. Losey/L.S. Rayor/M.E. Carter, Transgenic Pollen Harms Monarch Butterflies, in: Nature 399 (1999), 214; L.C.H. Jesse/J.J. Obrycki, Field Deposition of Bt-transgenic Corn Pollen: Lethal Effects on the Monarch Butterfly, in: Oecologia 125 (2000), 241; summarizing: J.E. Losey/J.J. Obrycki/R.A. Hufbauer, Impacts of Genetically Engineered Crops on Non-Target Herbivores: Bt-Corn and Monarch Butterflies as a Case Study, in: Letourneau/Burrows (Eds.), Genetically Engineered Organisms, Boca Raton 2001, 151 et seq.; there is, however, considerable controversy over this study: Further studies, conducted at more environmentally likely levels of pollen, seemed to confirm this result (A.R. Zangerl *et al.*, Effects of Exposure to Event 176 Bacillus Thuringiensis Corn Pollen on Monarch and Black Swallowtail Caterpillars under Field Conditions, 98 Proc. Nat'l Acad. Sci. U.S. Am. 11908-11912 (2001) available under: <http://www.pnas.org/cgi/content/full/98/21/11908>), though the majority of a more recent group of studies commissioned by the U.S. Department of Agriculture suggests that the threat to monarchs is quite limited: R.L. Hellmich *et al.*, Monarch Larvae Sensitivity to Bacillus Thuringiensis-Purified Proteins and Pollen, 98 Proc. Nat'l Acad. Sci.

the negative impact of genetically modified Bt-corn in soil[52], and other negative non target effects[53]. In all three cases, scientific data been published in peer-reviewed scientific reports in internationally recognized journals, indicating the presence of a risk. Although highly controversial and not unanimously shared, the published data is sufficient to trigger the threshold criteria of Article 10 (6) CPB. As shown above, lack of scientific consensus in these questions is not a preventive criteria for the identification of potential adverse effects.[54] Severe doubts about the significance of those risks for the conservation of biological diversity also fail to hinder the application of Article 10 (6) CPB. As those three examples underscore, the focus on the extent of potential adverse effects alone does not always have a limiting factor for the actual applicability of that provision.[55] Hence, despite Article 10 (6) CPB's not containing a strong precautionary language, it may become a very effective tool to regulate trade in LMOs. Of course, the mere fact that Article 10 (6) CPB enables for the application of the Delayne Clause, does not oblige parties to complay with it in the often critizised inflexible manner. Instead, they may, or, depending on the interpretation of the term "as appropriate" in Article 10 (6) CPB, even have to acknowledge other factors to avoid the anomaly prompted by the Delaney Clause.[56]

III. The Compatibility of Article 10 (6) CPB With Article 5.1-6 SPS

It has become a common exercise of scholars analysing the Biosafety-Protocol to test its compatibility with pertinent provisions of WTO law, most prominently with those of the SPS-Agreement.[57] In search for potential conflicts, the precau-

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U.S. Am. 11925-11930 (2001) (available under http://www.pnas.org/cgi/content/full/98/21/11925); K.S. Oberhauser *et al.*, Temporal and Spatial Overlap between Monarch Larvae and Corn Pollen, 98 Proc. Nat'l Acad. Sci. U.S. Am. 11913-11918 (2001) (available under: <http://www.pnas.org/cgi/content/full/98/21/11913>; J.M. Pleasants *et al.*, Corn Pollen Deposition on Milkweeds in and Near Cornfields, 98 Proc. Nat'l Acad. Sci. U.S. Am. 11919-11924 (2001) (available at <http://www.pnas.org/cgi/content/full/98/21/11919>).

[52] D. Saxena/S. Flores/G. Stotzky, Insecticidal Toxin in Root Exudates from Bt corn, in: Nature 402 (1999), 480; G. Stotzky, Release, Persistence, and Biological Activity in Soil of Insecticidal Proteins from Bacillus Thuringiensis, in: Letourneau/Burrows, *supra* note 49, 187-222; D. Saxena/S. Flores/G. Stotzky, Bt Toxin is Released in Root Exudates from 12 Transgenic Corn Hybrids Representing three Transformation Events, in: Soil Biology & Biochemestry 2002, 133-137.

[53] A. Hillbeck/M. Baumgartner/M.F. Padrout/F. Bilger, Effects of Transgenic Bacillus Thuringiensis Corn-Fed Prey on Mortality and Development Time of Immature Chrysoperla Carnea, in: Environmental Entomology 27, 480-487. A. Hilbeck, Transgenic Host Plant Resistance and Non Target Effects, in: Letourneau/Burrows, *supra* note 49, 167 et seq.

[54] Annex III (4).

[55] See Stökl, *supra* note 39, 347.

[56] As a result of the Delaney Clause, although carcinogenic substances are banned, non-carcinogenic yet toxic color additives with higer quantitative risk assessment may be allowed on the market. See Mastrostefano, *supra* note 48, 1309.

tionary approaches of Article 10 (6) CPB and Article 5.7 SPS are often seen as counterparts. However, taking the above analysis seriously, Article 10 (6) CPB corresponds more favorably with Article 5.1-6 SPS than to Article 5.7 SPS.[58]

1. Article 10 (6) CPB and Article 5.7 SPS – an Unequal Pair

a) Aim and purpose of the SPS-Agreement

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) is part of the law of the World Trade Organization (WTO). The SPS Agreement applies to all sanitary and phytosanitary measures that may, directly or indirectly, affect international trade. Its perspective is that of a trade agreement, not a health agreement. Its intention is to prevent interference in the trade of goods through the enactment of arbitrary and discriminatory SPS measures by national governments. The SPS Agreement does not create any substantive sanitary or phytosanitary measures *per se*. Instead, the agreement sets forth a number of general procedural requirements to ensure that a sanitary or phytosanitary measure is in fact a scientifically-based protection against the risk asserted by the member imposing the measure, and not a disguised barrier to trade. [59] The SPS Agreement applies a threefold approach in order to address conflicts arising from divergent policies in risk-related areas: harmonization[60], mutual recognition[61] and a coordination

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[57] Stoll, *supra* note 13; Katz, *supra* note 5; T.P. Stewart/D.S. Johanson, A Nexus of Trade and Environment: The Relationship Between the Cartagena Protocol on Biosafety and the SPS Agreement of the World Trade Organization, in: Colorado Journal of International Law and Policy 2003, 1-52; R. Howse/J. Meltzer, The Significance of the Protocol for the WTO Dispute Settlement, in: Bail/Falkner/Marquard (Eds.), The Cartagena Protocol on Biosafety – Reconciling Trade in Biotechnology with Environment and Development?, London 2002, 482-495; Charnovitz, *supra* note 39, 271-302; S. McCaffrey, Biotechnology: Some Issues of General International Law, in: The Transnational Lawyer 2001, 91-102; Priess/Pitschas, *supra* note 15; Stökl, *supra* note 55; A.H. Qureshi, The Cartagena Protocol on Biosafety and the WTO – Co-Existence or Incoherence?, in: International and Comperative Law Quarterly 2000, 835-855; Bernasconi-Osterwalde, *supra* note 27; S. Safrin, Treaties in Collision? The Biosafety Protocol and the World Trade Organization Agreements, in: American Journal of International Law 2002, 606-628.

[58] See Erben, *supra* note 37, part II. ch. VIII. II. 3. to the relation between the precautionary and Art. 5.1 SPS.

[59] Although the preamble to the SPS takes note of a desire by governments to improve human, animal, and plant health, the SPS targets only the overuse of national health regulation. The agreement contains no minimum standard for food safety or for applying science to the food production process. In other words, although a government can violate the SPS Agreement by using poor science to impose food safety regulation, a government can not violate the SPS Agreement if it neglects science by failing to impose adequate food safety regulation. See Charnovitz, *supra* note 39, 276; Böckenförde, *supra* note 16, ch. III A. V. 1.; R.H. Steinberg, Trade-Environment Negotiations in the EU, NAFTA, and WTO: Regional Trajectories of Rule Development, in: American Journal of International Law 1997, 238.

[60] The SPS Agreement encourages governments to establish national SPS measures consistent with certain relevant international standards, guidelines, and recommendations as specified in Annex A (3). Where national measures conform with the relevant standards, guidelines, and recommendations, they

of national risk policies pursuant to Article 5 SPS.[62] This third approach is relevant for the issue at hand and is surveyed below.

b) The role of the precautionary approach in Article 5.7 SPS

Whereas the Protocol's perspective is to provide the importing party with adequate protection from adverse effects of biological diversity through imported LMOs, the SPS Agreement focuses on the protection of the exporter from arbitrary regulations imposed by the government of an importing country. Similarly, the intention of the precautionary approach differs: Article 5.7 SPS provides a qualified exemption from the general requirement that SPS measures are to be based on sufficient scientific evidence.[63] However, this right to take SPS measures in the absence of sufficient scientific evidence requires nevertheless the presence of "available pertinent information" on which the measure is to be based. The twofold emphasise on a limited period of time ("provisionally" and "within a reasonable period of time") as well as the obligation "to seek to obtain the additional information" and to "review the [...] measures accordingly" seems to indicate that Article 5.7 SPS should only be invoked if some temporary extension is needed within the exercise of a risk assessment in order to further justify existing scientific information "more objective[ly]"; but it does not allow the taking of a final precautionary measure on the risk management level until further clarification or knowledge arises. Hence, the provisional character of Article 5.7 SPS is closer to the first part of Annex III (8) (f) read together with Article 10 (3) (d) CPB than to Article 10 (6) CPB.[64] This interpretation seems to be confirmed by the Appellate Body which stated that the precautionary principle had not been written into the SPS Agreement as a ground

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will be deemed necessary for protecting human, animal, or plant life and presumed to be consistent with the relevant provisions of the SPS Agreement and of GATT 1994. As far as LMOs are concerned, the three organizations referred to by the SPS Agreement have not yet produced pertinent standards, guidelines or recommendations.

61 In the absence of international standards, the SPS Agreement in Article 4 envisages a recognition of the standards of exporting states, provided that the "exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary and phytosanitary protection". In cases where states are reluctant to recognize foreign standards as equivalent or where they intent to introduce a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, their national SPS measures are to be established or coordinated pursuant to Article 5 SPS.

62 See Stoll, *supra* note 11, 103.

63 Article 5.7 SPS reads: "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 measures accordingly within a reasonable period of time".

64 Annex III (8) (f), first part, reads: "Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issue of concern". Article 10 (3) (d) CPB allows to extend the period of 270 days by a defined period of time.

for justifying a measure that otherwise violates the SPS Agreement.[65] It indicates that Article 5.7 SPS should only apply when time runs short within the course of a risk assessment in which some pertinent information was already made available. However, as misinterpreted by most of the authors analyzing the SPS-Agreement, Article 5.7 SPS does not oblige the one member alone to take the provisional measure to "seek to obtain the additional information necessary" but addresses all members (plural) together.[66] In contrast, a decision taken by Article 10 (6) CPB does not have a time limited element.[67] It applies on the risk management level where final decisions are taken. The Protocol does not distinguish between decisions pursuant to Article 10 (3) CPB or Article 10 (6) CPB once they are made. Consequently, there is no separate obligation to obtain additional information or to review a measure. Article 12 (1) CPB allows but does not oblige a party of import to review and change a decision "in the light of new scientific information on potential adverse effects", regardless of whether it is based on Article 10 (6) CPB or not. Only if it has been informed by an exporting party or a notifier that "a change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based", or that "additional relevant scientific or technical information has become available"[68], will further activities have to be taken by the importing party. But again, this is valid for all decisions taken within Article 10 CPB.

1. Articles 5.1-6 SPS as Equivalent of Article 10 (6) CPB

a) The decision-making process of Articles 5.1-6 SPS

Article 5 SPS defines a number of requirements for national SPS measures, including one that states ensure that, pursuant to Article 5.1 SPS, such measures are based on a risk assessment that conforms to the procedural and substantive requirements set out in the agreement and that provide a rational basis for the SPS measure contemplated by a state.[69] Article 5.2 SPS enumerates a number of aspects to be

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[65] WTO Appellate Body Report, EC Measures Concerning Meat and Meat Products, WT/DS26/AB/R at para. 124.

[66] See for example all the authors listed in note 57; according to this author's knowledge only one scholar refers correctly to an obligation of the members of the Agreement: C. Lucas, Stellungnahme des Ausschusses für Industrie, Außenhandel, Forschung und Energie für den Ausschuss für Umweltfragen, Volksgesundheit und Verbraucherpolitik zu der Mitteilung der Kommission über die Anwendbarkeit des Vorsorgeprinzips (KOM(2000) 1 – C5-0143/2000 – 2000/2086 (COS)).

[67] One author has suggested to read the term "as appropriate" in Article 10 (6) in a time limiting way similar to the one in Article 5.7 SPS. See Stökl, *supra* note 39, 350.

[68] Article 12 (2) (a) and (b) CPB.

[69] A risk assessment carried out in accordance with the SPS Agreement has to (i) identify the adverse effects on human health and, if any such adverse effects exist, (ii) evaluate the potential or probability of occurrence of these effects (see WTO Appellate Body Report, Australia – Measures Affecting Importation of Salmon, WT/DS18/AB/R). By doing so, risk assessment techniques devel-

considered in the risk assessment, including "available scientific evidence" as the most prominent element. Economic factors have to be taken into account as part of the assessment with regard to risks to animal or plant life or health.[70] The risk assessment structure provided by Article 5 SPS has been further elaborated upon by WTO panels and the Appellate Body. According to the Appellate Body, a Member is not required to conduct its own risk assessment but can defend its measure by relying on an assessment conducted by another member or an international organization.[71] Furthermore, the risk assessment does not have to be based on views representing the mainstream.[72] A proper risk assessment does also not need to establish a "minimum magnitude of risk"[73] but it has to find evidence of an "ascertainable" risk.[74] It will not be sufficient for governments to impose regulations simply on the basis of the "theoretical" risk that underlies all scientific uncertainty.[75]

Once such an ascertainable risk has been identified, a WTO member is free to determine its appropriate level of protection as long as the other requirements are respected. In other words, the result of the risk assessment does not necessarily dictate a specific SPS measure, but leaves the determination of the appropriate level to each member state.[76] Hence, a member state may decide that the level of risk it is

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oped by international organizations as well as a number of substantive criteria provided in Article 5 SPS have to be taken into account. See Stoll, *supra* note 11, 105.

[70] Article 5.3 SPS.

[71] WTO Appellate Body Report, EC Measures Concerning Meat and Meat Products, WT/DS26/AB/R at para. 190.

[72] Ibid., at para. 194: "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. The risk assessment could set out both prevailing views 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 qualified scientists who have investigated the particular issue at hand may indicate a state 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 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. Determination of the presence or absence of that relationship can only be done on a case-by-case basis, after account is taken of all considerations rationally bearing upon the issue of potential adverse health effects."

[73] WTO Appellate Body Report Australia – Measures Affecting Importation of Salmon, 20.10.1998, WT/DS18/AB/R, at para. 124.

[74] Ibid.

[75] Ibid., at para. 125; WTO Appellate Body Report, EC Measures Concerning Meat and Meat Products, WT/DS26/AB/R at para. 187.

[76] See explicitly *supra* note 70, para 199: "... [T]he level of protection deemed appropriate by the Member establishing a sanitary measure is a prerogative of the Member concerned and not of a panel or of the Appellate Body"; J. Pauwelyn, An Overview of the WTO agreements on health and technical standards and their impact on communication, in: Zeitschrift für das gesamte Lebensmittelrecht 2000, 849; R. Howse/P.C. Mavroidis, Europe's Evolving Regulatory Strategy for GMOs – The Issue of Consistency with WTO Law: Of Kine and Birne, in: Fordham International Law Jour-

willing to accept is "zero risk". This interpretation of Article 3.3 SPS and Article 5.1, 5.6 SPS is confirmed by the Appellate Body[77] and does correspond to the intention of the US-delegation during the negotiations of the SPS-Agreement to find a wording that allows for the survival of the Delayne Clause under the new WTO regime.[78] The selected appropriate level of protection then has to conform to the requirements of Article 5.5 and Article 5.6 SPS. According to Article 5.6 SPS member states "shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility".[79] It is important to keep in mind that those trade related requirements only have to be considered within a chosen level of protection. If a member decided to follow a "zero risk" policy, a ban may very often be the sole way to achieve it. Article 5.5 SPS contains a more intricate concept of non-discrimination and is probably one of the most controversial SPS-rules. It amounts to a duty on states to ensure some consistency in SPS-related areas of national policy that may have an impact on trade[80], requiring a member "to avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade". In other words, if an LMO and an alien species pose the same risk to the biodiversity of one country (i.e. through outcrossing), but only LMOs are restricted, there may be a violation of Article 5.5 SPS.[81]

b) Parallels between Articles 5.1-6 SPS and Article 10 (6) CPB

By comparing Article 5.1-6 SPS with Article 10 (6) CPB some remarkable consistency becomes apparent. Both provisions need the evidence of an "ascertainable"

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nal 2000, 323; J.H. Barton, Biotechnology, the Environment, and International Agricultural Trade, in: Georgetown International Environmental Law Review 1996, 101; V.R. Walker, Keeping the WTO from Becoming a "World Trans-science Organization": Scientific Uncertainity, Science Policy, and Factfinding in the Growth Hormones Dispute, in: Cornell International Law Journal 1998, 268; Böckenförde, *supra* note 16, ch. III V. 3. c) dd).

[77] WTO Appellate Body Report Australia – Measures Affecting Importation of Salmon, 20.10.1998, WT/DS18/AB/R, at para. 125; WTO Appellate Body Report, EC Measures Concerning Meat and Meat Products, WT/DS26/AB/R at para. 186.

[78] D.E. McNiel, The First Case under the WTO's Sanitary and Phytosanitary Agreement: The European Union's Hormone Ban, in: Virginia Journal of International Law 1998, 124 et seq.; R.M. Millimet, The Impact of the Uruguay Round and the New Agreement on Sanitary and Phytosanitary Measures: An Analysis of the U.S. Ban to DDT, in: Transnational Law & Contemporary Problems 1995, notes 120, 124, 133.

[79] A footnote to Article 5.6 states: For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.

[80] Stoll, *supra* note 11, 107; Charnovitz, *supra* note 39, 283.

[81] For more details see the Guidelines to Further the Practical Implementation of Article 5.5, issued by the SPS-Commission (G/SPS/15).

risk, but do not require precise knowledge on the extent of the potential adverse effects. Once such a risk is identified, governments are free to set their appropriate level of protection, including a zero-risk policy as known from the Delayne Clause. The decision taken is final; there is no obligation for further inquiry or review. The additional requirements of Articles 5.5 and 5.6 SPS could be read into the "as appropriate" requirement of Article 10(6) CPB. This conclusion backs the statement of the Appellate Body that the precautionary principle "finds reflection" in Article 5.7, but does not exhaust the relevance of the precautionary principle for the SPS-Agreement.[82]

IV. Conclusion

This article has shown that the first operationalization of the precautionary approach in an international environmental agreement is rather a façade than an enhancement of the precautionary principle. It only allows for precautionary measures with regard to the extent of a risk but not with respect to its nature. However, within that scope, no further restrictions are made with respect to time limitation or obligation of review, although the term "as appropriate" may require some additional tests (i.e. consistency, proportionality, etc.). When analyzing the different elements of the precautionary approach in Article 10 (6) CPB its proximity to Articles 5.1-6 SPS becomes apparant. Despite its "weak" precautionary approach Article 10 (6) CPB allows parties to the Protocol to protect their citizens from the potential adverse effects resulting from LMOs that are presently discussed in the scientific literature. It remains to be seen whether the second decade after Rio creates an environmental agreement that operationalizes precautionary language including the existence or nature of potential adverse effects.

[82] WTO Appellate Body Report, EC Measures Concerning Meat and Meat Products, WT/DS26/AB/R at para. 124.