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Risk regulation, trade and international law: debating the precautionary principle in and around the WTO

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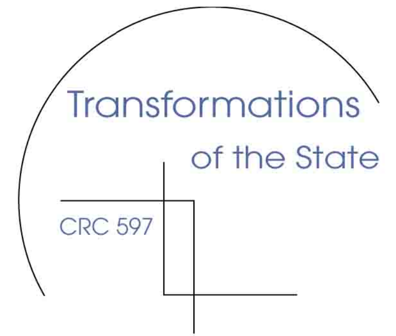

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Risk regulation, trade and international law: Debating the precautionary principle in and around the WTO

Christiane Gerstetter
Matthias Leonhard Maier

No. 18

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Risk regulation, trade and international law: Debating the precautionary principle in and around the WTO

ABSTRACT

The precautionary principle is one of the most contested principles in international law. In the context of trade regulation in particular, it has been a source of concern to those who fear that it might help to justify existing non-tariff barriers to trade or create additional ones. Proponents of the principle, in turn, argue that it is needed to fend off unwarranted health and environmental risks in situations where scientific uncertainty prevails, even if this works against the liberalisation of trade. In these contests the question of where and when the precautionary principle should be applied is inextricably linked to the question of what it means in the first place. Starting from the observation that consensus on a precise definition is missing both in legal-political practice and in academic scholarship, the present paper is concerned precisely with those practical interpretative contests which result from the principle's ambiguity. We focus on attempts to agree legally binding definitions in the context of international trade regulation. The core of the paper is an empirical analysis of debates on several specific aspects of the precautionary principle, which were at issue during the past decade in four different international institutions: the WTO dispute settlement, some of the WTO's political committees, the Codex Alimentarius Commission (in particular its Committee on General Principles), and the conference of states which negotiated the Cartagena Protocol on Biosafety. Differences and similarities among these institutions are then analysed in a comparative perspective, taking up various contested issues one by one. From our findings we derive a set of hypotheses regarding the conditions under which, and the legal or political pathways on which, the precautionary principle (and perhaps other abstract normative ideas of a similar type as well) can make a difference to the outcomes of international decision-making.

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Risk regulation, trade and international law: Debating the precautionary principle in and around the WTO*

1 Introduction

The international trading system, with the World Trade Organization (WTO) as its institutional core, is quite deliberately based on the single goal of removing barriers to the trans-border exchange of goods. While tariffs were for a long time the most significant barriers to trade, non-tariff barriers have now become much more important in many areas. Among non-tariff barriers to trade, the regulations that nation-states establish to protect the health and safety of humans and the natural environment ("risk regulation") potentially play a prominent role. Protective regulations as such are not necessarily at odds with WTO law. On the contrary, the legitimacy of domestic measures "necessary to protect human, animal or plant life or health" (Art. XX (b) GATT) is explicitly acknowledged. In order to prevent its protectionist abuse, however, domestic risk regulation is subject to a number of constraints or "disciplines" under WTO law. Since the conclusion of the Agreement on Sanitary and Phytosanitary Measures (SPS) at the end of the Uruguay Round of GATT negotiations, the requirement of scientific justification is central among these disciplines is (see in particular Art. 2.2, 5.1 SPS). In other words, what distinguishes a legitimate protective measure from illegitimate protectionism is, inter alia, that the former can scientifically be shown to counter a demonstrable risk.

Straightforward as it may be in principle, this system is based on a series of non-trivial presuppositions. Quite evidently, it presupposes the availability of relatively uncontested scientific knowledge. It is in cases where such knowledge is not available that the *precautionary principle* can come into play. Although this principle has been around for quite some time, its meaning is still ambiguous.[1] There are several seemingly simple definitions, often likening the precautionary principle to common-sensical notions such

* An earlier version of this paper was presented at the conference on "Legal Patterns of Transnational Social Regulation and International Trade", organised by Christian Joerges and Ernst-Ulrich Petersmann at the European University Institute, Florence, 24-25 September 2004. Our thanks to participants in the conference, in particular Theofanis Christoforou, as well as to our colleagues in the on-going research project on "Social Regulation and World Trade", namely Christiane Conrad, Ulrike Ehling, Christine Godt, Josef Falke and Christian Joerges for helpful comments, and to David Gerl for able research assistance.

[1] Environmental policy in Germany of the 1970s is frequently cited as the original source of the precautionary principle (e.g., Gehring and Cordonier Segger 2003: 2-3; O'Riordan, Cameron, and Jordan 2001a: 11; Woolcock 2002: 2-3); others point to Sweden as the principle's first institutional home (Löfstedt, Fischhoff, and Fischhoff 2002: 382; Sand 2000: 448). While its diffusion throughout many nations and international institutions may indeed have started in these places, at least some of its component ideas are no doubt much older.

as "better safe than sorry", or "look before you leap". Neither in the legal-political realm nor in academia, however, is a definition to be found which would be both precise and consensual. A reasonable working definition which takes into account (in brackets) some of the most important controversial aspects might go something like this: *Regulatory action (subject to certain constraints) should be allowed (or even prescribed) to counter risks to human health and the environment, even if (the nature and) the magnitude of this risk are not (yet) scientifically proven*. In the present paper we are concerned precisely with those interpretative contests which result from the precautionary principle's ambiguity, and which are aimed at legally binding definitions.[2]

A big part of these contests surrounding the precautionary principle revolves around seemingly arcane technical questions such as what specific kind of horticultural measures are suited to keep apple trees free from a particular bacterial disease; or whether a set of guidelines for the conduct of foodstuff risk assessment, developed by the subsidiary body of an international organisation most people have never even heard about (i.e., the Codex Alimentarius Commission – see below), should apply to that organisation only or also to its individual member states. Lurking behind these technical legal and natural-scientific issues, however, are core issues of contemporary debates on sovereignty and global governance, democracy and expertise, or the taming and enabling of economic globalisation. Thus the precautionary principle is sometimes considered as a tool for preserving – at least in cases of "scientific uncertainty" – nation-states' regulatory leeway, which tends to be increasingly narrowed by the dense web of rules constituting the multilateral trade system. At other times, the precautionary principle is understood – among both supporters and opponents – as attacking the very science "mantra" (Kerr 2003) which underlies the multilateral trade system's approach to social regulation. And the context in which resulting conflicts are settled is itself continuously evolving, insofar as nation-states not only decide on whether or not to apply the precautionary principle at home, but are also involved in various attempts to institutionalise (some version of) the principle in internationally, in the trade sector and beyond.

Especially in the context of on-going debates about the "international rule of law" and "legalization", it is important to remember that nation-states are not only the subjects of international law and thus the addressees of the "rule of law", to the extent that

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[2] As will be shown below, an important element of these struggles is the question of whether the idea of precaution should at all be considered a *principle* in the strict, legal sense. In a looser sense, however, the term "precautionary principle" is widely, although not universally, used to designate the idea(s) in question. For the sake of convenience, we follow this practice throughout the paper, but without wanting to take a position on its legal status. Wherever the latter is at issue, we will use more specific language to differentiate between the precautionary principle as an idea and as a legal principle.

it exists internationally, but also – along with other actors – its authors. They perform this role quite actively, fighting about the proverbial commata. This is certainly nothing new, but it has somewhat receded to the background in current discussions of “legalisation” in international relations, where there has on the whole been more attention to certain characteristics of international law than to the process by which it is created.[3] We ought thus not to look only at how an emerging rule of law might bind states in their external behaviour and whether this is desirable, but also at what role states play in bringing about this transformation. The fate of the precautionary principle in and around the WTO provides ample opportunities for the study of this intricate relationship.

We begin in the following section by offering a rough typology of existing research in legal and political science on the precautionary principle, so as to contextualise our own approach to the subject matter, the specifics of which are subsequently introduced (2.). The core of the paper is an empirical analysis of four trade-related international institutions and debates on various aspects of the precautionary principle therein (3.). Differences and similarities among these institutions are then analysed in comparative perspective, taking up various contested issues one by one (4.). Finally, we summarise our findings by way of submitting a few hypotheses to be explored in further research (5.).

2 THE APPROACH OF THIS PAPER IN THE CONTEXT OF EXISTING RESEARCH

The lack of consensus on the precautionary principle’s precise meaning makes analysis of its role in legal and political processes difficult, but at the same time also helps to raise scholarly attention – so we might conclude from the enormous amount of attention the precautionary principle has received in recent legal and social-science scholarship. Roughly, this literature can be divided into three broad strands (which are often combined in individual books and articles):

(1) An *abstract-analytical* strand which explores the logical and ethical foundations of the principle and the variety of interpretations it can meaningfully be given in theory (e.g., Godard 1997). From this variety of interpretations some authors have constructed a limited number of ideal-typical versions of the precautionary principle that can be classified according to the answers they give to a series of general questions (Applegate 2000; Sandin 1999). Comparing the precautionary principle to alternative principles of, or approaches to, risk regulation is another important theme in this strand (De Sadeleer 2002; Majone 2002; Morris 2002).

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[3] See Finnemore and Toope (2001) for related criticism of the legalisation literature (referring especially to Goldstein et al. 2000 and other contributions in that volume).

(2) A *normative* strand which criticises or advocates either the principle as such or specific interpretations of it. Wholesale rejection of the precautionary principle may be rare but it does exist (Adler 2002); more commonly particular – e.g., “strong” as opposed to “weak” – understandings of it are rejected as logically inconsistent or socially undesirable (Stewart 2002; Sunstein 2003; Van den Belt 2003). Also to this genre belongs a whole series of more favourable attempts at reducing the principle’s ambiguity and specifying its legal and institutional implications, be it in general (e.g., Tickner 1999) or for a particular area (Bohanes 2002; Peel 2004 for WTO law), in the latter case often at the explicit request of the political authorities (Renn et al. 2003 for the EC).

(3) An *empirical* strand which mostly looks for legal and political formulations of the principle in different places: what Fisher (2002) calls – and criticises as – “precaution spotting”. This is probably the broadest strand. It includes not only contributions which collect and compare emanations of the precautionary principle across policy areas, countries (various chapters in O'Riordan, Cameron, and Jordan 2001b) and regions (especially EC and US, see Christoforou 2004; Daemen 2003; König 2002; Prakash and Kollman 2003), levels of governance (Schroeter 2002; Scott and Vos 2002), or combinations of the above (De Sadeleer 2002; EEA 2002; Wiener and Rogers 2002). This strand also encompasses analyses which focus on the principle’s formulation in individual, more or less narrowly defined substantive and geographical areas.[4] In the legal literature, analysis of particular court decisions is also an important part of this strand.[5] A further variation of this theme is constituted by analyses of the principle’s diffusion from one jurisdiction, issue area or governance level to others (Cameron and Wade-Gery 1992; Freestone and Hey 1996; Jordan and O'Riordan 1999).

The approach we take in this paper falls into the third, “empirical” category. This is an important point to note, for it implies that we do not take a stance here on if or how the precautionary principle *should* be applied and interpreted, be it in general or in a particular context. Instead, we want to find out about how the principle is *in fact* employed by individual actors and reflected in international decisions. The scholarly literature on the principle abounds with controversies – as indicated by the absence of anything resembling even remotely a consensual definition. The question, then, is whether

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[4] Numerous examples could be cited for this latter category. By way of illustration, consider analyses of European GMO regulation and the role of the precautionary principle therein (Levidow 2001; Levidow, Carr, and Wield 2000; Scott 2003; Tait 2001).

[5] Commentaries on WTO jurisprudence are cited below, 3.1. On recent relevant decisions of the European Court of Justice and Court of First Instance see Segnana (2002), Ladeur (2003), MacMaoláin (2003), Dabrowska (2004) and Szawlowska (2004). Of course such analysis often feeds into the second, normative strand of the literature as well.

the controversies in the literature find a parallel in the “real world” of international legal and political practice. In addressing this issue we inevitably draw on the first, abstract-analytical strand of the literature as well, insofar as categories developed there are used to structure our discussion (most explicitly in Section 4). For example, we employ the commonly made differentiation of risk regulation into the stages of risk assessment, risk management and risk communication. To which of the first two stages the precautionary principle applies is one of the most prominent issues in the debates analysed below (see below, p. 35).

What we hope to add to the existing empirical literature is, on the one hand, greater attention to the controversies that surround the principle when applied in real-world interactions. It is these interactions that shape what the “precaution spotter” eventually gets to see.[6] Thus we look at political negotiations in various international fora on which we attempt to get a grip mainly by tracing the main controversies through the negotiating process. We also look at one judicial body, the WTO dispute settlement mechanism, focussing on the interpretation of relevant WTO norms it proffers and diverging interpretations advocated by WTO Members. On the other hand, by comparing relevant debates across several different international fora, we hope to lay the basis for subsequent work of a less descriptive and more explanatory kind. To this end, we will develop several hypotheses from the empirical material on which future research might build. In particular, they might serve to explore the institutional conditions under which the precautionary principle, and perhaps similar principled ideas in international law and politics as well, can help to deal with conflicts between free trade and social regulation.

The international institutions which we have selected for closer analysis are briefly introduced in the remainder of this section. Generally speaking, given its position at the centre of the international trading system, the WTO is an obvious forum to look at, but it is by no means the only one. WTO law is related to other international law by way of formal or informal relations, and what actors might not achieve in the WTO, they might try to achieve elsewhere. The existence of overlapping norms, belonging to the law of different international organizations and purporting to regulate the same subject matter, creates considerable legal uncertainty and political tensions. It seems, consequently, appropriate to not just focus on the WTO, but to take into account also developments in other fora that give rise to this kind of legal ambiguity. Put differently, if we want to

[6] We use the term “international debates” – in a very broad sense, to also include legal proceedings as well as the participation of supranational entities such as the WTO dispute settlement bodies and the European Commission – as an umbrella term for this kind of interactions. We also use the more specific term “international negotiations” where appropriate, i.e., where state (including EC) representatives interact with each other in the absence of a third-party adjudicator.

understand what happens to the rule of law across levels of governance, a focus on individual institutions or on particular international regimes is almost certainly insufficient. Institutional interactions and emerging "regime complexes" ought to be taken into account as well.[7]

More specifically, then, we have selected four fora for closer analysis, in all of which the precautionary principle was at least considered for being set on the agenda: (1) WTO dispute settlement as the judicial branch of the WTO, (2) several committees as part of the political branch of the WTO, and in addition two fora external to the WTO, one of them linked formally to WTO law, namely (3) the Codex Alimentarius Commission (CAC), and the other linked to the WTO by a more informal – and largely unresolved - legal relationship, (4) the Cartagena Protocol on Biosafety. We start by looking at that part of the WTO framework which has probably attracted most public attention: the *dispute settlement* (Section 3.1). Our focus there are the dispute settlement cases that are related to the precautionary principle. But of course the WTO does not only consist of the dispute settlement mechanism; it also has an infrastructure of political bodies. The political arm of the WTO, in contrast to the EC, does not have a competence for secondary legislation of its own and is thus much weaker than the dispute settlement.[8] Still, in these political bodies negotiations take place and relevant information is exchanged. We focus on several committees where negotiations with possible relevance for the precautionary principle took place, namely the *Committee on Trade and Environment* (CTE), the Committee on Sanitary and Phytosanitary Measures (*SPS Committee*) and the Committee on Technical Barriers to Trade (*TBT Committee*) (3.2). The CTE was brought into existence in the course of the GATT's Uruguay Round. Its mandate is to discuss the trade-and-environment nexus and the adequate role of the WTO therein.[9] In contrast to the CTE, the SPS and TBT Committees are both charged with administering the respective WTO Agreements and performing specific tasks assigned to them therein.[10] The analysis will be completed by a brief glance at discussions about the precautionary principle in other WTO committees.[11]

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[7] See Raustiala and Victor (2004) for the notion of "regime complexes". Institutional interaction (or "linkage", "interplay") more generally has recently been the subject of increasing attention in both legal and political science (Oberthür and Gehring 2003; Oberthür and Gehring 2004; Trachtman 2002; Young 2002).

[8] Which has lead to a good deal of criticism (see Bogdandy 2002: 266-280; Ehlermann 2002: 632-638).

[9] The mandate is contained in the Decision on Trade and Environment (http://www.wto.org/english/tratop_e/envir_e/issu1_e.htm). For the CTE's development see in more detail Ehling (2005).

[10] The TBT Committee is, for example, charged with granting exceptions to the TBT Agreement to developing countries (Art. 12:8), notification of TBT measures (Art. 15:2) and review of the Agreement (Art. 15:3). The SPS Committee has the mandate to coordinate harmonisation efforts with other international organisations (Art. 3:5

Afterwards we move further away from the “core” of the WTO and look at linkages with other international organisations whose law has or may have an impact on WTO law and vice versa. The first of these other organizations is the *Codex Alimentarius Commission* (CAC), the body set up jointly by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) in 1963 which is responsible for developing standards in the area of food safety (3.3). With the establishment of the WTO, the importance of these standards, which are not binding *per se*, has significantly increased: the SPS Agreement in its Art. 3:2 contains an incentive for WTO Members to design their national sanitary and phytosanitary standards in conformity with the CAC standards by stipulating a presumption that national (and regional) standards conforming to the CAC standards are consistent with WTO law. The standards of the CAC are, hence, formally related to WTO law. Thus, if the CAC incorporates the precautionary principle into its framework, this will have important repercussions on what sanitary measures precisely WTO Members might licitly take under WTO law.[12]

Finally, we look at the Cartagena Protocol on Biosafety, negotiated under the auspices of the UN Convention on Biological Diversity (CBD – 3.4). Although its connection with the WTO is much more indirect than is the case with Codex, the connection is nonetheless existent.[13] The relationship between WTO law and multilateral environmental agreements (MEAs) such as the Cartagena Protocol is still largely unresolved, at least on the political level.[14] Moreover, the WTO legal order is part of the larger international legal order, which has already influenced the way WTO law is interpreted and may further do so in the future (see Marceau 1999:108-139). The Cartagena Protocol

SPS), develop guidelines for the application of certain provisions of the agreement (Art. 5:5) and grant exceptions to developing countries (Art. 10:3).

11 Another forum we might have included in our analysis is the WTO’s Trade Policy Review Mechanism, another political body of the WTO. Precaution was occasionally an issue there, see the documents from the two most recent trade policy reviews of the EC, WT/TPR/S/72, WT/TPR/S/102 (both secretariat reports) and WT/TPR/M/72, WT/TPR/M/72/Add. 1, WT/TPR/M/102, WT/TPRM/M102/Add. 2 (minutes of the meeting, including the advance questions of other Members directed to the EC and the EC’s replies). Ultimately, however, the TPRM is not designed to produce any concrete policy outcome, but rather serves as a forum for enhancing transparency in trade policy, which makes it a less-than-ideal complement to our selection of fora.

12 See section 3.3 below for a more detailed description of the function of CAC standards under WTO law.

13 The connection between WTO and Cartagena Protocol is recognised and discussed in a substantial body of literature. In addition to citations in the text, see *inter alia* Isaac, Phillipson, and Kerr (2001), Chaytor, Palmer, and Werksman (2003), Winham (2003), Böckenförde (2004), Oberthür and Gehring (2005).

14 See the *status quo* of the discussions in the CTE, Summary Report on the Ninth Meeting of the Committee on Trade and Environment Special Session, 22 June 2004, TN/TE/R/9.

thus has the potential to influence the interpretation of WTO law with regard to measures concerning those genetically modified organisms (GMOs) to which it applies.

For each of these fora, we investigate what role the precautionary principle played, how successful proponents of the principle and its particular interpretations were in promoting their position, and in what way the precautionary principle is enshrined in the resulting decisions.In doing so, we will lay particular emphasis on controversies regarding specific aspects of the precautionary principle, rather than the principle as such. This reflects the observation, stated above, that strictly speaking there is no such thing as "the principle as such" – its meaning is the very subject, rather than a presupposition, of the debates we analyse. As we shall see, our focus on specific contested aspects also reflects the actual distribution of opinions in these debates, where fundamental opposition to the precautionary principle (whatever way it is defined) turns out to be less important than disagreement over how it should be understood, and where it should be applied.

The approach we take, which is to concentrate on officially stated positions and reasons, and a corresponding neglect of the "real" interests hidden behind such "rhetoric", might invite the objection that we miss out on what is actually driving relevant developments. E.g., one may suspect that the precautionary principle is advocated by the EC (the principle's main proponent internationally) not out of genuine concern for health and environment but so as to protect the ailing European biotechnology industry from American competitors (cf. Bailey 2002: 8), or because the European Commission considers it easier to pronounce a new regulatory philosophy than to fix institutional deficiencies that produce "regulatory failure" in the first place (Majone 2002). We take seriously such sceptical interpretations, insofar as we do not assume that state actors' official pronouncements are generally to be taken at face value. Nor do we believe, however, that "rhetoric" should generally be considered mere window-dressing without any significance for actual behaviour. Such an impoverished notion of rhetoric is of doubtful value in most social settings, if only because it has nothing to say about the conditions under which rhetoric is likely to work.[15] In the specific kinds of setting we are interested in, the rhetoric/reality dichotomy is even less useful, because (a) we are dealing with actors all of which can be assumed to have strategic capacities, rather than with a single strategic manipulator facing an easy-to-fool crowd; (b) we are specifically dealing with legal argumentation which, although it is of course commonly employed for all kinds of insincere purposes, is subject to specific constraints that make it hard to completely control its effects; and (c) the setting is already imbued with legal and non-legal norms of various sorts, which effectively prevents the merely strategic use of normative argu-

[15] For a richer understanding of "rhetoric" see Maier (2003, with further references).

ments (on this latter point see in a different context Schimmelfennig 2003). For our purposes, then, rhetoric in an important sense *is* reality – the reality of international debates aimed at producing legally binding decisions, in which both actors and observers are well-advised to take seriously *what* is being said, quite independently of *why* it is being said.

3 THE PRECAUTIONARY PRINCIPLE ON THE AGENDA OF TRADE-RELATED INTERNATIONAL INSTITUTIONS

Having stated the paper's basic approach and how it relates to existing research, we now turn to the empirical analysis, concerning the way the precautionary principle appears on the agenda of trade-related international institutions.

3.1 WTO dispute settlement

The forum that has gained most attention within academia and in the larger public is the dispute settlement mechanism of the WTO. The dispute settlement mechanism has, since its thorough re-modelling in the course of the Uruguay Round, dealt with several cases that touch upon issues of precaution. They all concern the interpretation of the SPS Agreement, which sets forth the conditions under which WTO Members might take measures to protect human, animal or plant health from certain risks. Four cases have been decided until today (WT/DS18 – *Australia-Salmon*; WT/DS26, 48 – *EC-Hormones*; WT/DS76 – *Japan-Agricultural Products*; WT/DS245 – *Japan-Apples*). A fifth one, the case on EC measures affecting the marketing of biotech products (WT/DS291-293), is still underway at the time of writing.[16]

Subject of our analysis is the interpretation that the dispute settlement bodies (with an emphasis on the Appellate Body) undertake concerning provisions and aspects of the agreement that are related to the precautionary principle and/or precautionary measures taken by WTO Members. We start with an analysis of Art. 5:7, which is – according to a common reading (Eggers 2001:5; Pardo Quintillán 1999:155) – *the* precautionary norm in the SPS Agreement, and afterwards proceed to look at other relevant aspects of the Agreement.[17]

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[16] The contents of the SPS Agreement and the factual background of most of these cases have been described elsewhere at considerable length – see for overviews of the SPS Agreement and the case law Iynedjian (2002), Landwehr (2000), Pauwelyn (2000) and Christoforou (2000). Studies on individual cases include: on the *Hormones* case Eggers (1998), Godt (1998), Goh and Ziegler (1998), McNiel (1998) and Neugebauer (2000); on the *Salmon* case Taylor (2000) and Thomson (2002); on the *Agricultural Products* case Whitlock (2002). The *Apples* case does not seem to have received much scholarly attention yet.

[17] Other analyses of the role of the precautionary principle under the SPS Agreement are Bohanes (2002), Eggers (2001), Hey (2000) and Scott and Vos (2002)

3.1.1 Art. 5:7 SPS Agreement

The dispute settlement bodies have found four requirements in Art. 5:7 that must be fulfilled cumulatively for justifying a measure under Art. 5:7.[18] The measure must be

(1) imposed with respect to a situation where relevant scientific information is insufficient and

(2) adopted on the basis of available pertinent information.

Furthermore, the WTO Member in question must

(3) seek to obtain the additional information necessary for a more objective assessment of the risk and

(4) review the measure accordingly within a reasonable period of time.

Until now, no country has ever successfully deployed Art. 5:7 for justifying a – provisional – SPS measure.[19] In both cases in which the interpretation of Art. 5:7 was at issue, *Japan-Apples* and *Japan-Agricultural Products*, the WTO adjudicators decided against the defendant.

Art. 5:7 is categorised by the adjudicators as a “qualified exemption”[20] from what could be called the science disciplines of the SPS Agreement.[21] More interesting than the overall character of Art. 5:7, however, is the way the different elements of Art. 5:7 are to be interpreted. A troubling point concerning the first of the four above-mentioned requirements is which are legitimate reasons for the insufficiency of scientific evidence under Art. 5:7. Theoretically at least two possible reasons are conceivable: A first possible reason (1) could be that simply no scientist has yet investigated the issue in question and thus data are not available, but could, in theory, be produced. A second reason (2) could be that there is no scientific evidence, because it is, given a certain state of science, impossible to produce such evidence on a certain matter, either at all or with satisfactory reliability. The categorisation is, of course, an analytical one. In practice

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[18] WT/DS76/R, para. 8.54; WT/DS245/AB/R, para. 176.

[19] The defendants have not invoked Art. 5:7 in all cases in which they potentially could have done so, though. For example, the EC in the *Hormones* case held the view that its hormone ban was not a temporary measure and hence did not want to rely on Art. 5:7; see WT/DS26/R/USA, paras. 4.239, 8.249.

[20] See WT/DS76/AB/R, para. 80. It is not entirely clear what legal consequences result from qualifying a norm as “exemption” rather than “exception”. Most likely the consequences are procedural in nature. According to Eggers (2001: 164-168), an exemption in contrast to an exception does not have to be invoked by the defending party for a Panel to base its findings on the norm.

[21] Both Art. 2:2 and 5:1-5:3 SPS deal with scientific justifications for SPS measures. As Art. 5:7 is directly referred to in Art. 2:2, it is primarily an exception to this norm. As Art. 5:1-5:3 can be seen as spelling out more in detail the scientific evidence requirement of Art. 2:2 it must also be conceived of as an exemption (to stick with the dispute settlement’s terminology) to those norms.

one will frequently not be able to unequivocally attribute the lack of scientific evidence to either of the two reasons.

The only case where the first requirement of Art. 5:7 was directly at stake is the *Apples* case. In this case, Japan had contended during the appeal proceedings that Art. 5:7 covered situations of “unresolved uncertainty”.[22] By this term, Japan meant an uncertainty that science was not able to resolve, despite accumulated scientific evidence.[23] It thus relied on reason (2). The Appellate Body rejected this argumentation.[24] Instead the Appellate Body clearly distinguished a situation of “scientific uncertainty” from one of “insufficiency of relevant scientific evidence.” Art. 5:7 only covers the latter one,[25] i.e., situations of type (1). This seems a clear enough *dictum*. The Appellate Body, however, then added in ambiguity by saying that insufficiency does not necessarily mean the absence of evidence, but it could also mean that available evidence is not *reliable*.[26] Thus, like the unsuccessful Japanese defendants, it used reason (2). It is therefore a task for the Appellate Body in future cases to clarify its standpoint. In order to arrive at its conclusions the Appellate Body relied on a textual method of interpretation, highlighting that Art. 5:7 did not speak of “scientific uncertainty”, but rather of insufficient scientific evidence.[27]

The second of the four conditions in Art. 5:7 has not played a major role in any of the cases so far. The third and fourth conditions in Art. 5:7 – regarding the need to seek additional information and to review the measure, respectively – were discussed in the *Agricultural Products* case. In this case, the defending party – once again, Japan – had itself not claimed to actively have sought additional information, but still the Panel emphasised that this could be done relatively easily.[28] Moreover, the Panel stated that a certain question on which the defending party claimed a lack of sufficient evidence had been at issue for 20 years, which it did not consider a reasonable period of time.[29] The Appellate Body supported this view of the Panel and said that what constituted a reasonable period of time depended on how easy it was to collect the additional information necessary for a review.[30] The reasonableness of a period of time might thus, it

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[22] WT/DS245/AB/R, paras. 33, 34.

[23] This the way the AB understood the concept in WT/DS245/AB/R, para. 183.

[24] WT/DS245/AB/R, para. 184.

[25] WT/DS245/AB/R, para. 184.

[26] WT/DS245/AB/R, para. 185, italics in the original text.

[27] WT/DS245/AB/R, para. 184.

[28] WT/DS76/R, para. 8.58.

[29] WT/DS76/R, para. 8.57.

[30] WT/DS76/AB/R, para. 93.

seems, be determined both in terms of an absolute time limit ("20 years is too long") and in relation to the difficulties the scientific research process meets with. As the term "reasonable" is an indeterminate term which demands the exercise of judgement by the adjudicators about the interests and rights at stake in the concrete case, it does not come as a surprise that the Appellate Body did not come to grips with this term by means of textual interpretation. Rather, it emphasised the malleability of the requirement in relation to the circumstances of individual cases. It established a kind of "the easier evidence is to find, the shorter the reasonable period" rule which can be conceived of a as a kind of balancing of the relevant interests at stake.

3.1.2 Other elements

Whether – and if so, how far – the significance of the precautionary principle reaches beyond Art. 5:7 under the SPS Agreement is not entirely clear. Dispute settlement proceedings deal with three interpretive aspects that have a bearing on what precautionary measures WTO Members might take under the SPS Agreement. The first concerns the status of the precautionary principle in international law and what legal consequences it might have for the interpretation of the SPS Agreement. The two further aspects were recognised by the Appellate Body as being reflections of the precautionary principle in the SPS Agreement: the right of WTO Members to choose for themselves an "appropriate level of protection" , and the way science and scientific evidence are conceptualised under the SPS Agreement.[31] We discuss each aspect in turn.

Status and scope of the precautionary principle

The status and scope of the precautionary principle and its significance for the interpretation of the SPS Agreement were brought to the dispute settlement agenda by the EC in the *Hormones* case.[32] The Appellate Body in this case refused to state – as the EC had claimed – that the precautionary principle was a general principle of international law and could thus guide the Members' risk assessment under Art. 5:1. At the same time, in an exercise of judicial self-restraint the Appellate Body made clear that it considered it neither prudent nor necessary to make such a statement about the status of the precautionary principle in international law.[33] It found that whatever the status of the precautionary principle in international law was, the principle could not override the explicit

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[31] See WT/DS/26, 48/AB/R, para. 124.

[32] WT/DS245/R, para. 5.34.

[33] The paragraph is remarkable, both because the Appellate Body makes it very explicit that it considers this move an issue of wisdom (rather than considering itself not competent for making a finding on the subject) and also because it is one of the very rare moments where the Appellate Body cites legal scholarship in a footnote (WT/DS26,48/AB/R, para. 123).

obligations contained in the SPS Agreement,[34] and it could not be used to justify measures otherwise inconsistent with the Agreement.[35] It can be doubted, however, whether this finding is as common-sensical an interpretation as the Appellate Body makes it look like. As far as the cited findings are an application of the rule that general principles of international law do not nullify treaty provisions unless they constitute *ius cogens*,[36] they are convincing. Whether the principle would overrule the explicit wording of a treaty norm, is, however, not the most troubling question.[37]

More interesting a point is whether the precautionary principle could provide guidance for the interpretation of norms which remain underdetermined in the SPS Agreement. If the Appellate Body had wished to use the principle as a tool to this end, it could have drawn on Art. 31:3 (c) of the Vienna Convention on the Law of Treaties (VCLT). This norm mandates that in the interpretation of a treaty any relevant rules of international law applicable in the relations between the parties shall be taken into account. A principle of international law might be one example of such law applicable in the relations between the parties.[38] The Appellate Body, however, does not follow this approach. One conceivable reason for the Appellate Body's refusal to use this option would be that the Appellate Body, contrary to what it stated explicitly, implicitly did make a decision that the precautionary principle was not a general principle of international law. Such a kind of self-contradictory interpretation should, however, not be lightly assumed. The alternative would be that the Appellate Body does not think that the norms of the SPS Agreement offer enough terminological indeterminacy for making use of the precautionary principle, or at least not a kind of indeterminacy which might be filled with the help of the precautionary principle. In sum, the Appellate Body neither awards the precautionary principle the status of a legally binding principle of international law (1) nor does it hold it to be relevant in the interpretation of the norms of the SPS Agreement (2). Whether (2) is a *sequitur* of (1) is, however, less clear.

A ramification of the Appellate Body's position on the lack of relevance of the principle is that it does not elaborate on the scope of applicability and its relation with risk assessment and risk management. There is, however, an additional reason for which the

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[34] WT/DS26,48/AB/R, para. 125.

[35] WT/DS26, 48/AB/R, para. 124.

[36] E contrario, this can be inferred from Art. 53 VCLT (see also Brownlie 2003:4; Shaw 1991: 851).

[37] Although there seem to be differing views about this, too. McGinnis (2003) puts forward normative arguments for why treaty provisions should be superior in general to customary international law, criticising Pauwelyn (2001).

[38] Marceau and Trachtmann (2002: 849); see also Woolcock (2002: 22) for the interpretative function of general principles of international law.

Appellate Body cannot talk about the applicability of the principle to either risk assessment or risk management. The Appellate Body has rejected the proposition that the common risk assessment/risk management divorce can be found in the SPS Agreement[39]. It found no textual reference to risk management in the legal text and thus facially rejects any such distinction. Whether this is also a rejection of the idea that a risk regulation process might be divided into different phases, each one guided by a different rationality, is less clear.[40] In any event, from the Appellate Body's stance follows with a compelling logic the formal restriction of the precautionary principle to the realm of risk assessment.

The right to choose the appropriate level of protection (ALOP)

The right of WTO Members to choose the appropriate level of protection as they wish is in the eyes of the Appellate Body an aspect of precaution to be found in the SPS Agreement.[41] This right would indeed amount to something like a green card for applying precautionary measures, if it could be exercised without further qualification or limits. In this case, a Member could set a level of protection at zero risk even where scientific uncertainties concerning causality and/or the magnitude of the risk existed. Taking into account that the precautionary principle permits or prescribes action where uncertainty about the occurrence of a damage prevails, this would clearly be a precautionary approach.[42]

Under the SPS Agreement things are, however, more complicated. The reason for this is that while choosing a *level* of protection is indeed a prerogative of WTO Members under the SPS Agreement, and their choices are not subject to judicial review, this is not true for the *measures* taken to reach this level of protection. The latter are subject to both the "science disciplines" in Art. 2:2, 5:1 and the "trade disciplines" in Art. 2:3, 5:5, 5:6. Although this might not put *de jure* limits to the right of Members to choose their appropriate level of protection, it clearly does restrict their options as to what measures they take to reach this level of protection. As taking measures is, however, what counts in a regulatory context, the right to choose a level of protection is not all too big an asset if not accompanied by a right to decide about the regulatory measures to be taken. In other words, while it might be true that Members have a right to choose their level of protection under the SPS Agreement and this is an aspect of precaution, they do

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[39] WT/DS26, 48/AB/R, para. 181.

[40] Many authors do assume that, in substance, the risk assessment/risk management separation is present in the SPS Agreement, too (see Bohanes 2002: 339; Landwehr 2000: 67; Nunn, in Robertson and Kellow 2001: 96; Walker 2003: 226).

[41] WT/DS26, 48/AB/R, para. 124.

[42] This point was in fact made by Japan in WT/DS246/AB/R, para. 36, albeit in the context of Art. 5:7.

not gain much from this as long as they are not entitled to also choose measures to practically secure that this level is reached.

To elaborate somewhat on this controversial point: It is a problematic assumption, in a regulatory context, that the right to choose a level of protection is separable from the measures taken to attain it. Let us compare the above formulated proposition

(1) “We exercise our right to choose a level of protection by setting the level of protection at x *and* hence we will take measure y.”

with a second one, formulated to the same end:

(2) “We choose level of protection x. X is the level of protection we reach by taking measure y.”

In the second proposition the level of protection x is inextricably linked to the measure y taken. Whereas proposition (2) is evidently perfectly possible from a strictly logical point of view, the important question in our context is whether any country would want to use it in its formulation of an ALOP. We are inclined to answer this question in the positive, especially in cases where a zero-risk level is the objective. Although this point might need further reflection and elaboration, we contend that the following statement is a meaningful one which real-world political actors might thus actually make: “We want to absolutely protect our population against the dangers arising from the use of substance A. Absolute protection means for us that we do want to exclude any damage, even the smallest one, resulting from the use of A. This absolute protection is precisely the protection that we reach when completely banning the use and imports of A.” There are, in other words, very likely situations in which a complete prohibition of a certain substance or practice plus effective enforcement is the only way of reaching the desired level of protection. In such cases, not being allowed to take the “one and only” measure implies at the same time not being able to choose the level of protection.[43]

What does all this mean for the idea that the right to set an appropriate level of protection is an aspect of precaution? Our thesis is that while it is theoretically possible to make this point, its practical relevance is very limited – due to the fact that right to choose a level of protection is itself a right from which WTO Members do not profit

[43] One might, and with due reason so, argue that in such a situation the SPS Agreement as interpreted by the dispute settlement bodies would not prevent a country from taking “the one and only” measure. The ruling of the AB in the *Asbestos* case that the “safe use” propagated by Canada was not a feasible alternative to a ban is as indicative of this as its finding in the *Hormones* case that the risks to be taken into account in a risk assessment may include risks arising from the real-world handling of a substance. Whether a measure is permissible does, however, not depend on the right of Members to choose a level of protection, but on the interpretation of the specific provisions (to which the “rhetoric” of the ALOP does not contribute). It is this rhetoric that we argue against as somehow misleading, not the outcome of conrete cases.

much in the end. Thus, it could be said that although it is uncontroversial between the WTO adjudicators and the Members that Members have a right to choose their level of protection and this an aspect of precaution, not much is gained from this in the end in terms of precaution.

Concept and role of science and scientific evidence

A final point of relevance to our discussion in this section is the conceptualisation of science and scientific evidence by the WTO adjudicators. How does this question relate to the precautionary principle? One of the basic conditions for applying the precautionary principle is the existence of scientific uncertainty. Now if a norm makes science the yardstick for certain regulatory measures, the way science is understood makes of course a giant difference. If one has a notion of science or of a scientific process as necessarily entailing a certain degree of uncertainty, the precautionary principle will turn into something like an eternal companion to any norm that makes science a decisive criterion. On the other hand, if one assumes the regular scientific case to be one where certainty prevails and clear-cut conclusions can be made, there is less room (or necessity) for a precautionary principle. This point is reflected in the dispute settlement cases, although science itself is hardly a topic. The issue is mainly dealt with in procedural terms, i.e. with regard to the question what scientific evidence is sufficient to warrant a finding by the adjudicators that a measure complies with the science disciplines of the SPS Agreement.

Two sub-aspects might be distinguished. First, the Appellate Body acknowledges that what standards are applied to the scientific evidence submitted is an aspect of precaution. It stated that when reviewing Members’ SPS measures and the evidence put forward to support them, Panels “should bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risk of irreversible, e.g. life-terminating, damage to human health are concerned.”[44] The message is that in cases of grave potential damage, Panels are to content themselves with less evidence (in a qualitative or quantitative sense) for holding a Member’s SPS measure to be consistent with WTO law. This implies that a lower degree of certainty is sufficient before measures might be taken. Similarly to what was observed above concerning the term “reasonable” in Art. 5.7 SPS, the Appellate Body interprets here the term “sufficient” in Art. 5.1 SPS as involving a “the more serious the risk, the less evidence is required” rule. Once more, this constitutes a kind of balancing-of-interests approach – probably owed again to the open and “evaluative” character of the treaty term to be interpreted.

[44] WT/DS26, 48/AB/R, para. 124.

Second, the Appellate Body is apparently of the view that science does not always come to monolithic conclusions and that different methods might be used to arrive at valid results. Thus in the context of the interpretation of Art. 5:1 SPS, the Appellate Body found that a measure could still be "based on" a risk assessment if its base is only a minority scientific view.[45] Again, this implies a lowering of the degree of scientific certainty that needs to exist before a measure can be enacted, and hence an element of precaution (Eggers 2001: 188). The Appellate Body also accepts that scientific investigation might have to take place beyond the narrow confines of a laboratory[46] and that it might express its result in both quantitative and qualitative ways.[47] Altogether, then, the Appellate Body's findings reflect rather broad, "sociologically" informed concepts of science and scientific evidence.

3.2 WTO Committees

Now we leave the judicial stage of the WTO and move to the political arena. The shortest formulation for reporting what happened in the WTO committees with regard to the precautionary principle would probably be a plain "nothing". The single most important move with regard to the precautionary principle came from the EC: In 2000, it submitted both the European Commission's *Communication on the Application of the Precautionary Principle* (in the following: the Communication)[48] and the *Resolution on the Use of the Precautionary Principle* of the December 2000 Nice European Council (henceforth: the Resolution)[49] to the SPS[50] and TBT[51] Committees and the CTE.[52] In the CTE, the issue was debated as part of the negotiations on "item 2", concerning the relationship between environmental policies relevant to trade and environmental measures with

45 WT/DS26, 48/AB/R, para. 194.

46 WT/DS/26, 48/AB/R, paras. 205, 206.

47 WT/DS18/AB/R, para. 124.

48 KOM (2000) 1 final. For an overviews of the Communication's contents see McNelis (2000). Further commentary and analysis is provided by Priess and Pitschas (2000), Majone (2002), Woolcock (2002) and Daemen (2003).

49 Annex II of Presidency Conclusions of the Nice European Council Meeting, 7, 8 and 9 December 2000 (No. 400/1/00). The European Parliament also dealt with the Communication, endorsing its overall thrust but in several instances going beyond what the Commission – or, for that matter, the Council – stated (Report A5-0352/2000, 23 November 2000). Reflecting the limited influence of the Parliament in external trade policy, its report was not officially considered in any of the WTO fora and is hence neglected in our analysis.

50 The Communication as G/SPS/GEN/168 and the Resolution as G/SPS/GEN/225.

51 The Communication as G/TBT/W/147 and the Resolution as G/TBT/W/154.

52 The Communication as WT/CTE/W/147 and the Resolution as WT/CTE/W/181.

significant trade effects and the provision of the multilateral trading system.[53] In the SPS Committee, the EC submissions came under the heading of "Implementation of the Agreement"[54], whereas in the TBT Committee they came simply under "Other Business".[55]

The objective of both EC documents is to clarify internally the manner of application of the precautionary principle by the Commission, but also to contribute to the international debate externally.[56] Both documents were – in the words of EC representatives – introduced to the WTO Committees to dispel fears about the use of the precautionary principle as a tool for protectionism.[57] They both use the same strategy of clarifying on the one hand the way the precautionary principle is applied within the Community, drawing thus attention to the internal legal obligations that bind the Community organs. At the same time they suggest certain interpretations of WTO law, aiming at keeping open regulatory space for WTO Members (read: the EC itself). The EC also made it clear that it saw precaution as a possible item for future negotiations within the WTO.

Altogether both documents did not receive too warm a welcome from the other WTO Members, although (partial) support was voiced by some countries.[58] Most Members, however, took a rather critical stance, for a variety of reasons.[59] One bone of contention was the alleged status of the precautionary principle as customary and cross-sectoral principle of international law. Several Members objected and pointed out that the principle had not reached this status yet and, if at all, needed to be formulated and applied in

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[53] See WT/CTE/M/24, paras. 78-87; WT/CTE/M/26, para. 59-89 and also WT/CTE/INF/5/Rev. 3.

[54] See G/SPS/R/18.

[55] See G/TBT/M/21; G/TBT/M/23, paras. 129-140.

[56] Communication, p. 6.

[57] See WT/CTE/M/26, para. 59; G/SPS/R/18, para. 2; G/TBT/M/21, para. 84.

[58] See the comments of Switzerland in G/SPS/R/21, para. 89, Norway in WT/CTE/M26, para. 69. Other countries verbally confirmed that they shared some common ground with the EC on precaution, but in substance raised objections so serious that these affirmations would rather appear to be some kind of lip-service or diplomatic courtesy. See comments of the US in WT/CTE/M/26, para. 75, of Australia, of Canada in G/TBT/M/21, para. 86.

[59] In addition to the conflicting views on certain aspects described in this section, a further point of dissent was the appropriate forum for discussing the issue. Regarding the TBT Committee, e.g., several Members did not think that the matter belonged on its agenda, see the comments made by Australia in G/TBT/M/24, para. 117; Chile in G/TBT/M/23, the US in G/TBT/M/23, para. 133; India in G/TBT/M/21, para. 87. Moreover, it should be noted that the issued was also framed/perceived by many Members as point of conflict between developed/developing countries, see Argentina in G/SPS/R/18, para. 10; Cameroon in G/SPS/R/19, para. 39. Concerns were voiced that the application of the precautionary principle would make it even harder for developing countries to access developed countries' markets.

a sector-specific way.[60] As to the role of science in decision-making, some countries shared the EC's approach that the precautionary principle belonged to the realm of risk management where decisions had to be taken in the light of scientific uncertainty.[61] O-ther Members felt less at ease with this conception, stressing that decision-making had to be science-based (as laid down in the SPS Agreement), and warned not to use the precautionary principle as a tool for loosening the tie between science and the regula-tory measures taken.[62]

Several Members also seemed concerned with what purpose the EC pursued with its submissions. They rejected what they saw as an attempt to alter the negotiated balance of the rights and obligations of the Members as well as trade and non-trade concerns set forth in the various agreements. Elements of precaution already inherent to the existing provisions were thus emphasised.[63] Altogether, the EC's input did not trigger any major discussions on the issue. Not surprisingly, it did not result in any concrete policy out-come, either.

The issue of precaution was also discussed in other WTO fora, related to the agricul-tural negotiations. The protocols of the Committee on Agriculture contain several refer-ences to precaution. Some deal of disagreement existed apparently about whether the issue should be at the hands of the Agriculture Committee or fell rather under the man-date of the SPS Committee.[64] In debates of the Trade Negotiations Committee several countries spoke in favour of progress in the agriculture negotiations and made it clear that they did not want debates about precaution to delay such progress. The feeling seems to have been that some countries used the issue unduly as a bargaining chip for the anyway intricate negotiations.[65]

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[60] Argentina in G/SPS/R/18, para. 10 and WT/CTE/M/26, para. 82; Hong Kong, China in WT/CTE/M/24, para. 85; India and Egypt in G/TBT/M/21, paras. 89 and 92; Mexico in G/SPS/R/18, para. 11; the US in WT/CTE/M26, para. 75; WT/CTE/M/24, para. 82 and G/TBT/M/23, para. 133.

[61] Switzerland in WT/CTE/M/26, para. 84 and Norway in para. 69 of the same document.

[62] Australia in G/TBT/M/24, para. 117 and WT/CTE/M/24, para. 81; Hong Kong, China in WT/CTE/M/24, para. 85.

[63] Australia in G/SPS/R/18, para. 4 and WT/CTE/M/26, para. 67; Bolivia in G/SPS/R/18, para. 7; Brazil in WT/CTE/M/26, para. 68 and G/TBT/M/23, para. 134; Canada in G/TBT/M/24, para. 115; Malaysia in WT/CTE/M/26, para. 80.

[64] See TN/AG/6, para. 28, a report which met with a considerable amount of criticism for including precaution among the debated issues, see Brazil in TN/AG/R/9, para. 25 and TN/C/M/11 as well as Australia in, Annex 2, p. 17 of the same document.

[65] See Australia in TN/C/M/3, para. 152 and Peru in TN/C/M/4, para. 17.

3.3 Codex Alimentarius – Committee on General Principles

The next forum which we look at is the Codex Alimentarius Commission (CAC). As we have stated above, the CAC is an example of a forum which is formally related to the WTO: The non-binding CAC standards do not form part of the WTO legal order directly. They are, however, incorporated into WTO law by virtue of Art. 3:2 of the SPS Agreement and Art. 2:4 of the TBT Agreement. Neither of those norms makes the CAC standards binding for the WTO Members, but both stipulate basically that WTO Members wishing to deviate from those standards need to justify such deviation. Whether a Member has or has not complied with this obligation is a matter open to review by the dispute settlement bodies. According to Art. 3:2 SPS, a national food-safety measure is presumed to be consistent with WTO law if it conforms to the CAC standards. A Member wishing to deviate from standards needs to justify this and fulfil additional requirements (Art. 3:3 and 5 SPS). These additional requirements, however, also must be fulfilled in cases where no relevant international standards exist. The function of the presumption in Art. 3:2 SPS is thus clearly to make it easier for WTO Members to justify SPS measures conforming to international standards in the light of WTO law. The situation where no international standard exists and the situation where a WTO Member does not enact its measures in conformity with these standards are, however, treated identically before WTO law (see also Iynedjian 2002: 70, 77). Thus, it could be said that the philosophy of the SPS Agreement is one of rewarding the good children, not of punishing the trouble-making kids by making deviations from the CAC standards extra-hard (see alsoPauwelyn 1999: 656).

This is, however, only one of the aspects of the relationship between WTO law and the Codex. Next to rewarding countries that design their SPS measures in conformity with the Codex standards, the SPS Agreement also obliges WTO Members in Art. 5:1 to take into account risk assessment techniques developed by the CAC when conducting food safety assessments. Thus, the development of risk assessment techniques allowing to apply precaution within risk assessment would also open a venue for WTO Members to exert precaution when taking measures that restrict the import of certain foodstuffs (on the relation of the precautionary principle to risk assessment see more specifically below, p. 35).

In our analysis of the Codex negotiations, we focus on the elaboration of *Working Principles for Risk Analysis for Food Safety* (in the following: the Principles).[66] There are two reasons for choosing precisely this text: the Principles are of importance in the development of Codex standards in general, and the issue of precaution was particularly

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[66] Issues with relevance for precaution were also discussed in other Codex bodies, such as the Committee on Food Hygiene and the Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology.

relevant for their development. The purpose of the Principles is to streamline the risk analysis process which takes place before a new Codex standard is agreed upon. The Principles are composed of sections on general aspects of risk analysis, risk assessment policy, risk assessment, risk management and risk communication. Each section contains guidelines of a more or less general nature for the respective stage of the risk analysis process.

We will on the next pages look at the negotiating process from the 22nd session of the Commission in 1997, where this text was debated for the first time, until its 26th session in 2003, where the Draft Principles were adopted for inclusion in the Procedural Manual, focussing on several controversial issues surrounding precaution which arose throughout this process. We will describe the main arguments brought forward and how the issue was settled.[67] Many issues were contested and, of course, opinions diverged on formulations but we will concentrate only on those problems, and their fate in the course of the negotiating process, that are closely related to the precautionary principle. We will also restrict the reproduction of comments to those made by governments and exclude those of NGOs and other international organisations, so as to secure comparability with the other fora where mainly countries' representatives are entitled to submit comments.

3.3.1 To refer or not to refer to the precautionary principle

The first controversial issue was whether a reference to the precautionary principle should be included into the Principles. Proponents of a reference to the precautionary principle argued that the inclusion of such a reference would augment consumers' trust in risk analysis[68] and also make clear that health protection was the primary objective of the CAC.[69] They also stressed that uncertainty was inherent to risk assessments, and

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[67] The analysis is based on the reports of the sessions of different CAC bodies, mostly the Committee on General Principles (CCGP) and preparatory documents such as drafts proposed by the Secretariat. Only from the 15th session of the CCGP (2000) onwards more extensive documentation is available from the Codex Website. For the 14th session some documents beside the report of the session can be obtained from ftp://ftp.fao.org. For the sessions before these only the reports of the sessions are available. When the CAC Secretariat prepares a document, it must, of course take into account the mandate given to it by a Committee or the Commission and the views that were given by Members and observes in written or orally. Still, at least some documents (e. g., CX/GP 00/3) leave the reader with the impression that the Secretariat enjoys quite a degree of autonomy when drafting and is willing to use it. It also sometimes takes the floor during sessions for giving its view on certain issues.

[68] ALINORM 01/33A, para. 61.

[69] See ALINORM 99/33A, para. 29; ALINORM 01/33, para. 49.

principles on risk analysis thus had to address these uncertainties anyhow.[70] A reference to the precautionary principle/approach was seen as the standard formulation for cases of uncertainty which consequently should also be used in Codex to avoid parallel terminologies and hence confusion.[71] The opponents of a reference to the precautionary principle voiced concern over the lack of clarity on the scope and content of the principle, especially in the area of food safety.[72] This might, as some worried, allow countries to use the precautionary principle to cause obstacles to trade and to deviate from their obligations under WTO law.[73] It was also feared that including reference to the precautionary principle might be a device for risk managers not to base their decisions on scientific risk assessments.[74] It is interesting that the rhetoric battle is not fought mainly along the lines of the legal status of the principle, an issue which is seldom touched upon.[75] Still, the approach/principle controversy also played a certain role.

In the first available draft,[76] a reference to precaution was contained in the section on *general aspects*.[77] This reference was maintained throughout the process and in the version included in the procedural manual.[78] It seems that a formulation as general as this one (without reference to a "principle") was something that all countries could live with.

3.3.2 Risk management and precaution

More controversial was a reference to the precautionary principle (or a precautionary approach) in the section on *risk management*. The debate has two interwoven strands: First, there is again the terminological problem of whether the precautionary principle should be recognised as *principle* and included as such into the text. This debate is related to a more substantive aspect: Several countries seem to have been anxious that including a reference to precaution/the precautionary principle/a precautionary approach

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70 One of the most common principles for addressing situations of scientific uncertainty is the precautionary principle, but of course those situations might be resolved without explicit reference to precaution, albeit following the logic of precaution. See for the argument ALINORM 01/33, para. 48.

71 See the comment by Norway in CX/GP 00/3-Add. 1, p. 9.

72 See ALINORM 99/33, para. 20; ALINORM 99/33A, paras. 32, 33; ALINORM 01/33, para. 47.

73 ALINORM 01/33A, paras. 61, 66.

74 See ALINORM 99/33A, para. 30.

75 One exception is ALINORM 01/33A, para. 61. From this paragraph it becomes clear, however, that for some countries favouring the inclusion of a reference, the inclusion itself seem to have been the important point, not the exact formulation as "principle" or "approach".

76 CX/GP 00/3.

77 Para. 5 reads: „The situations where scientific evidence is insufficient or negative effects are difficult to evaluate should be clearly identified, in order to ensure that adequate precaution is integrated in the risk analysis process.“

78 See para. 11. The formulation here is different from the initial one, but the reference to precaution still exists.

in risk management would make the whole risk-analysis process less science-oriented, loosening the ties between risk assessment and risk management. The question was, thus, how closely risk managers were to be bound to the result of a risk assessment process. Should they enjoy some extra-margin of discretion, deduced from the precautionary principle, for taking into account non-scientific factors (which could be reached through the precautionary principle)? Should mention of situations of scientific uncertainty be made at all in the Principles?

The first draft available contains only a bracketed reference to the “precautionary principle/ a precautionary approach” in the section on risk management, as no consensus had been reached in the prior session.[79] During the 14th CCGP session, the EC and some of its Member States underlined the need to address situations of insufficient scientific evidence in the section on risk management.[80] This was, however, contentious right away. During the 15th session two alternative versions were formulated, one of them referring to “precaution” only, the other one referring in a footnote to the precautionary principle.[81] The working group established for dealing with the issue in preparation for the next session agreed on one version that contained both a reference to precaution in the main text and the footnote, but marked it an open question whether this footnote should be deleted.[82] During the 16th session a major discussion took place.[83] In the end different versions were kept in the text[84] and it was decided to seek the advice of the Commission itself on how the CAC should proceed in cases where the risk assessment revealed scientific uncertainty on a certain matter.[85]

The Commission during its 24th session took a decision on this point[86] and at the same time restricted the scope of the Principles to application in the Codex framework.[87] This double decision had the effect of bringing the discussion about precaution in risk management to an end. The working group commissioned with the preparation of the 17th session of the CCGP agreed upon a proposal which did not contain any reference to precaution or the precautionary principle in either the text or a footnote in the section on

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79 CX/GP 00/3, para. 38 of the text and para. 38 of the draft.

80 ALINORM 99/33A, paras. 27-29.

81 ALINORM 01/33, Appendix III, paras. 34, 35.

82 See CX/GP 01/3 and ALINORM 01/33A, para. 54.

83 ALINORM 01/33A, paras. 32-34, 49-69.

84 ALINORM 01/33A, Appendix V.

85 ALINORM 01/33A, para. 72.

86 See below, next section.

87 See below, section 3.3.4.

risk management.[88] In this text and all following drafts,[89] the text that the Commission had proposed for dealing with scientific uncertainty can be found in the section on general principles (para. 10). In the section on risk management the text no longer contains any explicit reference to situations of scientific uncertainty or precaution, but para. 10 is mentioned in one of the paragraphs as providing guidance to risk managers (para. 29).[90] This situation remained unchanged until the inclusion of the Principles in the Procedural Manual.

3.3.3 Behaviour of the Codex in cases of insufficient evidence

A sub-aspect of the debate on precaution in risk management is the question whether Codex bodies should develop standards in situations of insufficient scientific evidence. To understand the different positions, it is important to recall that the function of a Codex standard under WTO law is to facilitate matters for governments wishing to take SPS measures.[91] Proponents of the idea that Codex should not elaborate any standards in cases of insufficient scientific evidence argued that global standards like the CAC standards should not be taken without an adequate scientific basis. Governments could act as second line of defence and still take necessary actions in the light of scientific uncertainty.[92] It was also pointed out that measures of only a provisional measure were not to be taken at Codex level which would also speak against any action at all with scientific uncertainty still present.[93]

The question seems to have come up for the first time during the 14th session of the CCGP. During this session France proposed that if the precautionary principle was not mentioned in the section on risk management, it should be set forth in the alternative that Codex should not adopt standards or other texts in cases of scientific uncertainty.[94] Until the 16th session of the CCGP the point was not debated as a separate issue; rather precaution in risk management in general was the topic. Only during the 16th session it emerged again.[95] The Committee decided in view of remaining disagreement to request the help of the Commission.[96] During its 24th session the Commission agreed on the

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88 CX/GP 02/3.

89 ALINORM 03/33, Appendix II; ALINORM 03/33A, Appendix IV.

90 ALINORM 03/33 Appendix II and ALINORM 03/33 A, Appendix IV, para. 29.

91 See above, first paragraph of section 3.3.

92 See the comment by Uruguay in ALINORM 01/33, para. 52; the comments of the US in CX/GP 00/3-Add. 5, p. 2.

93 See CX/GP 01/3-Add. 2, p. 9.

94 ALINORM 99/33A, para. 31.

95 See ALINORM 01/33A, paras. 62, 69.

96 ALINORM 01/33A, para. 72.

following clause: “When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such text would be supported by the available scientific evidence.”[97] This formulation was forthwith included in para. 10 of the Principles – in the section on general aspects, not under risk management.

3.3.4 Scope of the Principles

A further point for debate during the writing of the Principles was their scope. It was unclear whether the Principles were designed for application in the Codex framework alone or should also provide guidance to Member governments. For the latter case a decision needed to be made whether one version of the Principles was enough or both situations were so different that two sets of rules needed to be formulated. The mandate given to the CCGP by the 22nd session of the Commission simply requested the elaboration of principles for inclusion in the Procedural Manual; the title of the agenda item referred, however, to the application of risk analysis principles in the Codex.[98] As the later process would show, the mandate was not unambiguous.[99]

Advocates of elaborating two sets of Principles mainly pointed out that the situations of the Codex and Member governments were different.[100] Whereas governments – as last resort against health risks – might be compelled to act in order to protect their populations in certain instances, no such pressure was likely to arise in Codex which could always freely decide whether to elaborate a standard or not. It was also said that enlarging the scope of the principles would diminish prospects for reaching consensus.[101] No country seems, however, to have rejected categorically the elaboration of standards for application by governments.

Underlying the first available draft is the idea that the Principles will be applicable by both the Codex and governments.[102] In the CCGP session preceding this draft, the need for clarifying this point had already been recognised.[103] As the matter could not be settled until the 16th session, it was decided by the CCGP in this session to ask the Com-

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97 ALINORM 01/41, para. 81.

98 ALINORM 97/37, para. 164.

99 See for example ALINORM 01/33A, para. 59.

100 See ALINORM 01/33, para. 53 and CX/GP 00/3, paras. 47, 48.

101 CX/GP 01/3-Add. 2, pp. 9, 10.

102 See CX/GP 00/3, Section Scope, para. 1.

103 ALINORM 99/33, para. 18 and ALINORM 99/33 A, paras. 16, 24. Interestingly the Secretariat was the one to stress that the initial mandate given to the CCGP by the Commission only covered the elaboration of Principles applicable in the Codex framework, ALINORM 99/33A, para. 24.

mission to take the necessary decision.[104] The Commission in its 24th session came up with the Solomonic resolution that the CCGP should proceed to elaborate principles for application in the Codex framework with priority, but subsequently or in parallel work on principles offering guidance to governments.[105] Consequently, the CCGP split up its work process into two separate ones, with the one on the elaboration of Principles on risk analysis for application by governments still under way.[106]

3.3.5 Concepts of science, precaution and the proper role of science in risk analysis

A final aspect in our analysis of the debate are the diverging concepts of science that are reflected in the contributions made by the diverse actors involved in the making of the Principles. In contrast to what is true for the first four issues described above, this one was not as such a subject of explicit debate. Rather it underlies the different positions and only sometimes turns into concrete proposals. The prevailing understanding in the Codex negotiations seems to have been that uncertainty frequently occurs during scientific investigation. This is manifest for example in the existence of a section of the Principles on risk assessment policy. The idea that it is necessary to set guidelines for scientists on how to proceed in their research process to keep them from taking implicit normative decisions,[107] is starkly at odds with a concept of science according to which space for such normative decisions by individual scientists simply does not exist. That cases of scientific uncertainty are expected to occur, is also recognised in, among others, para. 10 of the Principles.

Although Codex negotiators thus seemed to be united by a similar overall approach towards science, details remained controversial. Two aspects are especially salient: First of all, the described controversy about the application of precaution in risk management can be understood as a conflict over how much uncertainty is regularly expected to remain after a risk assessment was performed, and hence how science-driven the whole process of risk analysis should be (see above, p. 22). Specifically, there was a debate about whether the whole process of risk analysis should be described as “science-based” or whether a reference to science should be included at least into the section on risk management. According to the protocol of the 13th session, several countries were of the opinion that the risk analysis process should be based on sound science.[108] The lack of unequivocal support for this position, however, led during the 15th CCGP session to the

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[104] ALINORM 01/33A, paras. 24, 71.

[105] ALINORM 01/41, para. 75.

[106] See the Report of the 20th session of the CCGP (2004), ALINORM 04/27/33A, paras. 37-43.

[107] On uncertainty in risk assessments and science policy as a reaction, see Walker (1998: 259-263).

[108] ALINORM 99/33, para. 19.

bracketing of the clause that risk analysis should be “soundly based on science” in the section on general aspects.[109] Equally a proposal made by the US during this session, to state that risk management should be grounded on a science-based risk assessment, did not gain the necessary support and was thus maintained only in brackets.[110] The issue was further debated during the 16th session. Consensus was reached that the bracketed clause was to be substituted by a reference to the *Statement of Principle concerning the Role of Science in the Codex Decision-making Process and the Extent to which Other Factors are Taken into Account*.[111] This Statement, which is part of the Procedural Manual, allows, in principle, the consideration of non-scientific factors in risk management while it is stated that this should not undermine the scientific basis of the risk analysis process. In the draft that served as preparation for the 17th session also the formulation that risk management should be grounded on scientific risk assessment was removed in favour of a reference to the Statement of Principle on the Role of Science.[112] With this, the text took its final shape which can also be found in para. 28 of the Principles in the final version included in the Procedural Manual.

A second question related to different concepts of science was how explicitly and how often the text should refer to controversies and dissent as part of science. The protocol of the 13th session mentions discussion about this point.[113] During the 15th session it was agreed to insert a reference to the existence of minority opinions.[114] This was rediscussed during the 18th session, but finally the hints to minority opinions in paras. 25 and 40 were maintained.[115] Other text proposals not included in the final version also reflect diverging views about what science has to offer in certain knowledge and how explicitly this should be recognised in the text. An example is the debate about enumerating different sources of uncertainty (which was finally rejected).[116]

3.4 Cartagena Protocol on Biosafety

We conclude our review of trade-related international debates and the role of precaution therein with an analysis of the Cartagena Protocol on Biosafety, the first binding inter-

[109] ALINORM 01/33, para. 15.

[110] ALINORM 01/33, paras. 33, 34 and para. 25 of the Draft Principles in the version from after the 15th session, ALINORM 01/33, Appendix III.

[111] ALINORM 01/33A, paras. 27, 28.

[112] Compare para. 32 of CX/GP 02/3, Appendix 2 with para. 25 of ALINORM 01/33, Appendix III.

[113] ALINORM 99/33, para. 22.

[114] ALINORM 01/33, para. 25.

[115] See ALINORM 03/33A, paras. 19, 26.

[116] See CX/GP 02/3, p. 51; ALINORM 03/33A, para. 26.

national agreement dealing with genetically modified organisms (GMOs).[117] The Convention on Biological Diversity (CBD), to which the Cartagena Protocol is a supplementary agreement, is part of the set of multilateral environmental agreements which were adopted at the 1992 UN Conference on Environment and Development, the Rio de Janeiro “Earth Summit”. In August 2004, the Convention had 188 Parties, including the EC as well as all of its current member states.[118] The handling and use of GMOs – in this context called “living modified organisms” (LMOs)[119] – are singled out in the Convention for treatment in a protocol, i.e., a binding international instrument that is separate from, but builds upon the Convention.[120] Work on a protocol began in the framework of the Ad Hoc Working Group on Biosafety (BSWG) in 1996. The role of the precautionary principle in the Protocol emerged as one of the main sticking points for the first time at the Extraordinary Meeting of the Conference of the Parties to the CBD (ExCOP) in Cartagena in February 1999 (Falkner 2002; Graff 2002). Not least for this reason the Protocol could be adopted only one year later, at the resumed ExCOP meeting in Montreal. Despite efforts by its opponents to persuade CBD Parties not to ratify the Protocol (e.g., Bailey 2002: 13; Phillips 2000: 74), it had received the required number of 50 ratifications in June 2003 and entered into force ninety days later. In the following subsections we take a closer look at individual contested issues concerning the precautionary principle and how they were resolved.

3.4.1 Reference to precaution

As indicated by the BSWG’s terms of reference, the desirability of some sort of reference to precaution in the Protocol appears to have been consensual as early as 1995.[121] The formulation there, however, leaves a wide range of possible ways of “taking into

[117] Compared to negotiations in the Codex and its subsidiary bodies, the history of the Cartagena Protocol is much better documented in various observers’ and participants’ reports (especially in Bail 2002), on which we can thus rely throughout most of this section.

[118] The United States, by contrast, is not a party to the CBD due to resistance against its ratification in Congress (Phillips 2000: 65). The US had observer status in the negotiations of the Cartagena Protocol but, like other GMO-exporting nations such as Canada and Argentina, has not ratified the Protocol either (Falkner 2004).

[119] The term “living modified organism” reflects arguments about the proper scope of a biosafety agreement (see below); specifically the USA insisted during CBD negotiations that only the final organism and not the process of genetic modification as such could possibly pose a risk to biodiversity (Marquard 2002: 289).

[120] On the origins of the Cartagena Protocol in the CBD and the history of negotiating the Protocol see Cosbey and Burgiel (2000), Bail, Falkner, and Marquard (2002), as well as Mackenzie et al. (2003: 1-5).

[121] The terms of reference for the BSWG provided that, inter alia: “The protocol will take into account the principles enshrined in the Rio Declaration on Environment and Development and, in particular, the precautionary approach contained in Principle 15” (Decision II/5, UNEP/CBD/COP/2/19, para. v).

account” the precautionary principle. Until relatively late in the negotiating process, the Parties appear to have cared about this issue much less than about the more specific issues discussed below (cf. Graff 2002, also on much of the following). When the question of whether – and if so, how – to explicitly anchor the precautionary principle in the Protocol finally emerged on the agenda, it was the so-called “Like-minded Group” of developing countries that pushed for a strong statement.[122] In particular, the Like-minded Group wanted references to the precautionary principle not only in the preamble and the article on objectives, but also in operational provisions relating to decision-making and risk-assessment procedures (Graff 2002: 412). On the other hand, the “Miami Group” of grain-exporting countries (Argentina, Australia, Canada, Chile, the US and Uruguay) was not only reluctant to adopt a protocol at all but also opposed any special recognition of the precautionary principle, should a protocol be adopted anyway. The EC initially took a mediating position between these two groups of countries. Between the Cartagena and Montreal conferences, however, the EC position appears to have developed in the direction of stronger support for the precautionary principle. At the end of the day, this position prevailed at least insofar as the Protocol does indeed refer to precaution in both its general and its specific parts (see more specifically below). On the other hand, it has also been argued that precautionary language in the Protocol remains “general, ambiguous, and qualified” (Safrin 2002: 626), and a closer look at individual contestable aspects of the precautionary principle is required for a more complete assessment.

3.4.2 Status

Regarding the status of the precautionary principle, the question of whether it should be regarded as principle or approach was among the sticking points during the negotiations (Mackenzie et al. 2003: 13). The Miami Group in particular argued that the Rio Declaration, to which the BSWG’s mandate refers, speaks of an “approach” with no precise legal meaning and content, and that hence no specific precautionary provisions were mandated for the Protocol (Graff 2002: 413). The outcome is something of a counter-intuitive mixture. On the one hand, reference to an “approach” rather than a “principle” is made in the section on objectives:

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[122] That fact that support of the developing world for the protocol was so strong may come as a surprise when contrasted to the WTO agricultural negotiations, during which the developing countries rather seemed to fear that some of the developed countries might unduly use precaution as a bargaining chip (see section 3.2 above). The difference probably has to do with the fact that GMOs are produced almost exclusively by corporations from developed countries but may well be sold also on developing countries’ markets. Developing countries were thus facing more costs than advantages if the precautionary principle was not included into the Cartagena Protocol, while they might have potential gains from keeping precaution off the WTO agenda.

> *“In accordance with the precautionary* approach *contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is […]” (Art. 1, emphasis added).*

On the other hand, the inclusion of specific precautionary provisions in the operational part would seem to confirm that precaution is something more than just an “approach” in the context of the Protocol.

An assessment of the status of precaution in the Cartagena Protocol is further complicated by its unclear relationship with certain provisions of WTO law, most notably those contained in the SPS Agreement. This lack of clarity is in part a corollary of the diverging opinions during the negotiation process. On the one hand, the Miami Group prevailed in having a “saving clause” inserted in the Protocol’s preamble, according to which

> *“this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements” (Recital no. 10).*

In the absence of such a clause, it was feared, “some nations [might] use [the Protocol] and its ‘precautionary language’ to justify import bans or other restrictions on LMOs without basing them on a scientific risk assessment” (Safrin 2002: 611). On the other hand, this clause is immediately followed by the assertion that

> *“the above recital is not intended to subordinate this Protocol to other international agreements” (Recital no. 11).*

What the inclusion of both clauses does in legal terms is not quite clear[123] and has been – along with the relationship of WTO law and the Protocol in general – the topic of a considerable amount of commentary and analysis. While some observers consider the two bodies of international law to be in tension with each other, even to represent “alternative paradigms” (Phillips 2000), others consider them to be quite compatible with each other (e.g., Safrin 2002).

3.4.3 Scope and measures

The scope of the Cartagena Protocol, and by implication of its precautionary elements, is restricted insofar as it only refers to GMOs and not to products containing them. Also the Protocol is mainly concerned with GMOs for “intentional introduction into the environment” of the importing party (Art. 7:1). The inclusion in the protocol of “living modified organisms intended for direct use as food or feed, or for processing” (LMO-FFPs) – which account for a much bigger part of trade in GMOs than those for release into the

[123] The pending dispute settlement case *EC – Measures affecting the marketing of biotech products* (WT/DS 291, 292, 293) might partially end this uncertainty, at least for practical purposes. The EC in its first submissions invokes the Cartagena Protocol as a justification for its measures concerning the marketing of GMOs.

environment – was long resisted by the grain-exporting countries organised in the Miami Group, and this issue was an important reason for the breakdown of the Cartagena negotiations (ENDS Daily, 24 Feb 1999). In the end LMO-FFPs were indeed included, but compared to GMOs intended for release into the environment, possibilities to set import restrictions are more limited in their case.

As mentioned above, in addition to the statement on objectives (and an almost identical formulation in the Preamble), the precautionary principle is also built into the operational parts of the Protocol, which considerably expands the scope of its application. In this context it is therefore appropriate also to touch upon the question of what kind of precautionary measures are foreseen. First, GMOs intended for release into the environment – including, most importantly for the time being, seeds – are subject to a an elaborate procedure of prior informed consent, called Advance Informed Agreement (AIA), the “backbone of the Protocol” (Cosbey and Burgiel 2000: 7) set out in Art. 8-10. In this procedure the prospective exporter is obliged to provide the intended importing country with extensive information (specified in Annex I to the Protocol), including a risk assessment report, before the first instance of importing any given GMO. The prospective importing country has a range of options for its reaction, including outright prohibition of the import. The crucial point with regard to precaution is that, according to Art. 10:6,

> *“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 [the Party of import] from taking a decision, as appropriate, with regard to the import of the living modified organism in question [...], in order to avoid or minimize such potential adverse effects.”*

Secondly, GMOs intended for use as food or feed or for processing (LMO-FFPs) are subject to a simpler procedure, which basically establishes a mechanism of multilateral information exchange through the so-called Biosafety Clearing-House (Art. 11). The Clearing-House Mechanisms provides exporters with information about relevant laws and regulations in countries of import, and it provides the latter with information about LMO-FFPs that are admitted for domestic use in exporting countries and hence may become subject to transboundary movement. Under the Biosafety Clearing-House procedure, the exporter does not have to wait for the importing country’s reply to its notification, but the latter ultimately retains the right to restrict the import of the organism in question in accordance with its domestic regulations (Art. 11:4). And, crucially, in reaching a decision on the import of an LMO-FFP, as in the case of other LMOs, Parties are entitled to take into account the precautionary principle; the formulation of Art. 10:6 is repeated verbatim in Art. 11:8.

Thirdly, the Protocol recognizes that some (developing and transition) countries may not yet have in place regulations pertaining to the import of LMO-FFPs. These countries are specifically required to conduct a risk assessment of the organism in question prior to deciding on its import or otherwise (Art. 11:6).[124] Requirements for such risk assessments are further specified in Annex III to the Protocol. Among the "General principles" there it is noted 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" (para. 4).*

The meaning of this paragraph is less than entirely clear, but it is read in at least parts of the literature as constituting a further instance of precautionary language in the Cartagena Protocol (Graff 2002: 418; Mackenzie et al. 2003: 13). If we go along with this interpretation, application of the precautionary principle extends to both risk assessment and risk management in the Protocol.

3.4.4 Triggers and limits

Having discussed the status and scope of the precautionary principle as enshrined in the Cartagena Protocol, as well as the precautionary measures which Parties are entitled to take, to complete the picture let us now briefly return to the relevant provisions and look at the "triggers" for precautionary measures, i.e., the conditions that must be fulfilled for such measures to be taken under the Protocol, and the limits imposed on the measures, i.e., the conditions specifying what kind of measures are regarded as legitimate in the Protocol. With regard to triggering factors, the threshold level is relatively low as far as the relevant kinds of damage are concerned.[125] Both Art. 10:6 and 11:8 refer to

> *"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".*

Unlike in the Rio Declaration, "threats of serious or irreversible damage" are not required in this formulation for precautionary action to be taken (as noted also by Eggers and Mackenzie 2000: 532). The EC is reported to have insisted on this less demanding formulation, so as to ensure that Parties retain the right to determine for themselves the acceptable level of risk and protection on a case-by-case basis (Graff 2002: 418). From the opposite point of view, in particular the last part of the formulation, concerning

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[124] Apparently it is assumed that in countries with pertinent domestic regulations in place, these regulations provide for a risk assessment to be conducted anyway.

[125] Sandin (1999) refers to this as the "threat dimension", to be distinguished from the "uncertainty dimension" of the precautionary principle (see also below, 4.2).

"risks to human health", has been criticised as alien to the "original" objectives of the CBD – the conservation of biodiversity – and as unduly expanding the scope for precautionary action (cf. Phillips 2000: 69). Again, this wording was introduced by the EC early on; it received support from many developing countries as well (Marquard 2002: 293).

Regarding the "uncertainty dimension" (Sandin 1999), on the other hand, the Cartagena Protocol does not appear to diverge significantly from the "mainstream" of relevant international agreements. It, too, presupposes "potential adverse effects" to be determined by way of scientific risk assessment, both in the case of LMO-FFPs (Art. 11:6, as cited above at note 124) and in the case of LMOs for release into the environment (Art. 10:1, referring to Art. 15 on risk assessment). While the requirement of a scientific risk assessment does not appear to have been controversial in the negotiations, there was disagreement over what kinds of knowledge would be relevant to the inference that uncertainty is given in a particular situation. The EC notably failed in its attempt to explicitly include uncertainty regarding the *existence* and the *nature* of potential adverse effects in addition to the *extent* of such effects, to which the Protocol now refers exclusively (Graff 2002: 416, 418). Implicitly, however, the current formulation can still be seen to cover also uncertainty regarding "the nature of" potential adverse effects – an interpretation which would seem to be confirmed by Annex III on risk assessment, which includes both identification and evaluation of potential adverse effects among the objectives of risk assessment (Graff 2002: 419).

Moreover, the Protocol significantly broadens the range of legitimate triggers of precautionary action insofar as it explicitly acknowledges "socio-economic considerations" (Art. 26) as legitimate reasons for restricting the import of LMOs, "especially with regard to the value of biological diversity to indigenous and local communities" (Art. 26:1). Insertion of this Article into the Protocol was a primary concern of the Like-minded Group of developing countries, who saw this matter as closely related to the precautionary principle (Khwaja 2002).

4 CONTESTED ASPECTS OF THE PRECAUTIONARY PRINCIPLE

In Section 3 we have seen how specific aspects of the precautionary principle are contested in different international settings, and how these contests are (temporarily) settled in the form of political agreements or legal rulings. In the present section we discuss our empirical findings with the help of an analytical framework which underlies much of the foregoing analysis, albeit not always explicitly. Building on several related efforts by other authors (inter alia, see Applegate 2000; Eggers 2001; Sandin 1999), this framework differentiates between two sets of issues that are potentially the subject of contestation: (1) the status and scope of applicability of the precautionary principle (including whether it should at all be labelled a "principle"), and (2) the factors triggering the

application of precautionary measures (including different concepts of science). For a series of more specific questions contained in these two sets of issues, below we review the extent to which they played a role in the different fora and with what results. We also point to some salient differences between the real-world negotiations and scholarly debate, without, however, aiming at a comprehensive comparison.

4.1 Status and scope of applicability

The questions of what status the precautionary principle has, both in legal and in more general terms, and at what stages in the risk-analysis process it should be applied, were debated in all of the bodies we have dealt with in one way or another. Several more specific issues were contested.

What role for the precautionary principle?

In logical terms, before one can talk about *how* the precautionary principle should be interpreted or applied, the question of *whether* it should be applied at all – in a given issue area and/or a particular jurisdiction – naturally poses itself. In practical terms, both are hard to disentangle, since answers to the question of the principle's general applicability at least partially depend upon particular interpretations.[126] The issue is further complicated by the fact that preferences may be couched in different languages. Lawyers or negotiators of an international treaty, proficient in the use of "legalese", will frequently express opposition to applying the principle by contending that it is not a legal principle at all (but may be – for example – "an approach") and should hence not be applied in a certain context. Academic observers may more freely reject the principle, by giving – for example – economic or moral reasons for their position (e.g., Stewart 2002). We find both kinds of language in the real-world debates and in the academic literature. In the WTO Committees, for example, actors have succeeded in keeping the principle from reaching high levels of salience, based on arguments other than legal ones. However, in real-world debates the "legalese" variant is generally more important than in the academic literature.

The legal literature, for its part, is deeply divided over the status of the principle in international law.[127] Mostly, of course, advocates of a stronger role of the precautionary principle will claim that it is a principle in the legal sense, whereas opponents will not.

[126] Witness especially the debate about "weak" and "strong" versions of the principle (Conko 2003; Stewart 2002; Van den Belt 2003). "Strong" versions are often rejected out of hand by authors who apply this distinction – but sometimes "weak" versions are rejected, too, insofar as they are deemed to be superfluous in comparison with more firmly established principles of decision-making.

[127] Cf. de Sadeleer (2002: 100, 318-9, affirming the precautionary principle's status as customary international law) with Wiener and Rogers (2002: 25). (see Schroeter 2002:26 with further references)

There are, however, also some commentators who claim that a precautionary “approach” is generally more organised and leaves less room for subjective elements in decision-making than the “principle”.[128] Still others downplay the difference between “principle” and “approach” altogether (see references in VanderZwaag 2002: 167). Frequently the debates about whether the precautionary principle should be applied were indeed fought along the lines of “principle” vs. “approach”. Outcomes vary among the different fora: from no decision at all on the matter, be it for lack of interest (WTO Appellate Body) or lack of agreement (WTO Committees), to a compromise referring to “precaution” plain and simple (CAC), to a preference for the “precautionary approach” (owed, however, mainly to the Rio Declaration – Cartagena Protocol). Notably, the precautionary principle *qua* “principle” is not recognised in any of the settings we have studied.

After all, one could say that the legal status of the principle did not play a decisive role in influencing outcomes. Rather, in the real-world debates the devil is in the details – and these details are not always discussed under the “precautionary” label. Even actors who refused to recognise the principle as principle were willing to discuss certain matters which could also have been discussed under the precaution label – for example, the role of science in decision-making or, as in the Codex, whether or not to set standards in case of scientific uncertainty.

How does the precautionary principle relate to WTO law?

A more specific question linked to both the precautionary principle’s legal status and its principled character (or lack thereof) is its relation to particular provisions of WTO law. This question was debated both in the WTO Dispute Settlement, where the Appellate Body denied the precautionary principle’s potential to guide the interpretation of the SPS Agreement, and in the CBD, where the issue of the “saving clause” generated much heat – and a legally ambiguous compromise solution.[129]

At what stage(s) of the risk-analysis process should the principle be applied?

As already indicated in the Introduction (p. 5), two of the stages risk regulation processes are commonly divided into are risk assessment (RA) and risk management (RM). How the precautionary principle relates to RM – the stage where the political decision about which measure to take is made – is not hard to see. With risk assessment – the

[128] The process of pesticide approvals in the US is cited as an example for a precautionary “approach”, the alleged difference being that product *must* be allowed on the market at the end of procedure unless environmental or health risks can be shown to exist according to scientific standards (Conko 2003: 642).

[129] See above, p. 30; on the relation between the Cartagena Protocol and WTO law more generally also Eggers (2001:265-286), Rivera-Torres (2003) and Stewart (2003).

“science-driven” part of risk regulation – the connection is not that easy to detect. The precautionary principle might, however, be seen to play a role in dealing with uncertainties arising in the course of scientific exploration already during the scientific process itself. Thus the setting of certain “science policies” (Walker 1998) which set forth default assumptions about modelling, extrapolation etc. might be conceived of as an application of precaution, where they require scientists to assume, e.g., a rather higher probability of a certain risk occurring or a larger potential damage.

The RA/RM distinction permeates international debates on the precautionary principle much more than one might expect on the basis of the scholarly literature, where most authors seem to take it for granted that RM is where the principle belongs.[130] Again, however, international outcomes vary – most markedly between the Codex Principles, which do not contain a specific reference to the principle in the context of either RA or RM, and the Cartagena Protocol, which contains such references in both contexts.

4.2 Triggering conditions

Perhaps the most broadly debated aspect of the precautionary principle concerns the conditions under which it should be applied to a particular problem. This aspect is described in the literature in terms of “triggers” or “thresholds”.

What exactly is meant by “scientific uncertainty”?

In the dominant view of the precautionary principle as belonging to the realm of risk management (as opposed to risk assessment – see above), it can be meaningfully invoked only if available scientific data are not sufficient for a formal risk assessment to be performed in the first place. This presupposes that a reasonably sharp line can be drawn between situations of sufficient and insufficient scientific information, respectively. Interestingly, in academic debates this presumption is challenged by both critics (Majone 2002: 104) and proponents (Fisher 2002: 9) of the precautionary principle. Within the realm of international law and politics, it is mainly the dispute settlement cases that touch upon this issue repeatedly. It seems fair to say, however, that a clear answer to the question of what kind of scientific uncertainty is necessary or sufficient for precautionary measures to be justified escapes even the WTO adjudicators – which is all the more remarkable because it is the very function of adjudicators to take decision of a yes/no (binary) type. In the political fora the issue is either not addressed in the first place (WTO Committees), or dropped off the agenda during the process (CAC), or simply restated in a close-to-tautological way (“lack of scientific certainty due to insuffi-

[130] Risk communication is generally considered as the third stage of the risk-analysis process, but apparently it is not seen as a potential field for precautionary action by either practitioners or academic observers.

cient relevant scientific information and knowledge" – Cartagena Protocol, Art. 10:6, 11:8).

How is "science" at large conceived of?

The challenge of operationalising "scientific uncertainty" is related to ambiguities in the notion of "science" at large. Most generally speaking, if science is seen as an enterprise where controversy is the rule rather than the exception, and where constructive contributions and normative decisions of the individual scientist are central to the results of scientific discovery, the results of a scientific investigation are always in a certain sense "uncertain". In this view, uncertainty could be said to be inherent in science. The scientific-uncertainty requirement will thus more often be fulfilled than not – which considerably enlarges the space for the application of the precautionary principle. Conversely, the closer the underlying conception of science comes to an understanding of science as – in a strong sense – *exakte Wissenschaft* (the precise, objective part of science), the less space is left for the application of the precautionary principle. Uncertainty would in this concept rather be seen as something which for contingent reasons might occur occasionally – as a shortcoming of disciplines which are generally capable of certain and true propositions. In both the WTO Dispute Settlement proceedings and the CAC negotiations these issues were touched upon. Obviously, they cannot be settled by way of judicial or political decisions in the same way as the other issues discussed. We can thus only note the distribution of the different conceptions of science in international debates, where both are clearly discernible but there is remarkably broad support for the first, "sociologically informed" understanding of science.

What is the role of "non-scientific" factors?

In addition to disputes about the meaning and the prevalence of scientific uncertainty, there is also a more fundamental debate about whether non-scientific considerations can and should play a role in triggering precautionary policies. The distinction between scientific and non-scientific triggers was a matter for debate in several international fora, especially in the CAC and Cartagena Protocol negotiations. The Protocol stands out in this regard, insofar as it explicitly allows for import restrictions to be based also on socio-economic considerations – even if it remains unclear to date what kind of specific considerations would actually pass the test of judicial review. The CAC Principles also allow for non-scientific factors to be taken into account, even if the scientific base of a standard is still emphasised as a sine-qua-non requirement.

5 When, where and how does the precautionary principle matter? Concluding hypotheses

Our analysis of the precautionary principle and its role in trade-related international debates suggests the following main conclusions:

(1) It is difficult but not impossible for opponents of the principle to counter its attraction and keep it off the agenda of international decision-making. Even those who oppose the principle as legal principle do not decline to discuss the issues which the precautionary principle is meant to address – sometimes using a different label altogether, sometimes preferring terms like "precautionary approach". Inside the WTO, and especially in its political bodies (as opposed to the dispute settlement), resistance appears to be stronger, or in any event more successful, than in the other institutional settings we have looked at (Codex Alimentarius Commission, Conference of Parties to the Biodiversity Convention). To the extent that the precautionary principle does become the subject of international debates, it is inevitably drawn into a process of increasing specification, regarding in particular its scope of application, the conditions that must be fulfilled for precautionary measures to be taken and – an aspect that we have not consistently pursued – the kind of measures that are considered appropriate.

(2) While the drive towards increasing specification appears to be inherent in all the different fora, the results of this process vary considerably across international institutions. This might be expressed in terms of the overall "precautionary content" of the agreements reached or decisions made. By this we mean the degree to which an international governance structure enables the states which are part of it to take precautionary measures, i.e. regulatory measures in the absence of scientific certainty, and under what conditions. With regard to our selection of cases we would consider the precautionary content highest in the Cartagena Protocol, moderate in the Codex Principles on Risk Analysis, moderate to low in the rulings of the WTO dispute settlement bodies, and lowest in the WTO Committees.

   a) The Cartagena Protocol is a remarkably precautionary piece of international law in three respects. First, it not only refers to precaution – if not *the* precautionary *principle* – in its preamble and section on objectives but, much more significantly, entitles Parties to restrict the import of GMOs in the face of scientific uncertainty about potential adverse effects they might have on the domestic environment or on human health. Secondly, the Protocol generally allows for import restrictions to be based also on socio-economic considerations, even if it remains unclear to date what kind of

specific considerations would actually pass the test of judicial review. And thirdly, even the Protocol’s provisions on risk assessment contain language which, although far from unambiguous, can be read as building an element of precaution into the process.

b) In the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, precaution has the status of an “inherent element”. Although this formulation falls short of adopting precaution as a principle, precaution still has a “systemic” status, being relevant to all processes of risk analysis. The action that the Principles prescribe for cases where evidence for a risk exists is, however, not that a standard ensuring a high level of protection be adopted, but rather that no standard be adopted at all. This, on the one hand, leaves countries the leeway to go for a high level of protection themselves, but also it does not urge them to do so. Both aspects together would make the precautionary content of the Principles rather seem moderate.

c) In the SPS Agreement, as interpreted by the Appellate Body, the precautionary principle is not a general principle and does not have any significance beyond specific formulations contained in the Agreement. The most important of these formulations, Art. 5.7 SPS, seems to be, however, quite limited in reach, given that it only covers provisional measures.

d) The WTO Committees, finally, have not even entered into serious negotiations concerning precaution, much less produced any agreement with significant precautionary content.

Overall, we might hypothesise that the more specific the risk that must be regulated – extreme cases in this respect: transboundary movement of a very specific category of products (Cartagena Protocol) vs. “trade and environment” as such (CTE) – and the more precise the mandate of the respective organisation to deal with it, the likelier is the institutionalisation of a relatively “strong” formulation of the principle.[131]

(3) The precautionary principle has not been recognised as principle in the legal sense in any of the fora we have looked at. This does not mean that specific aspects of it could not be found in the legal norms negotiated – on the contrary, we have described these aspects at some length throughout this paper.

[131] Of course, more contingent historical influences, such as the impact of the failed Seattle Ministerial Meeting of the WTO on the Cartagena negotiations (cf. Cosbey and Burgiel 2000: 13; Graff 2002: 414-5), may also have played a role. In and of themselves, however, these contingent factors are insufficient to explain the differences we observe between negotiations held in various international fora at about the same time.

The point is that negotiators in all of the fora we have looked at stopped short of referring to the “precautionary principle” *as such*. Instead they preferred to refer to an “approach” or to remain at the level of more concrete norms. Apparently international actors did not want to bestow the precautionary principle (in the non-technical sense) with the special dignity and the legal weight that a genuine legal principle might have – neither in particular institutional settings nor in the system of international law as a whole. The latter concern is reflected in the frequent use by opponents of the principle of the argument that it is not a recognised principle (in the legal sense) of international law.

(4) The precautionary principle is not recognised by all actors as a principle of international law, but still it has observable effects. It structures debates, and it is not easily banned from the agenda of risk regulation, although the way it is taken into account and moulded into treaty norms varies considerably. This resembles the function that some theorists ascribe to principles in a legal system: They secure that certain points of views or arguments are taken into account in a decision-making process without prescribing a specific final outcome (Alexy 1995; Dworkin 1981). The precautionary principle seems to fulfil a very similar function – even without being a legally binding principle.

Our observations thus call for further consideration of the conditions under which abstract normative ideas (“principles” in a wider sense) at the international level have certain kinds of effect. The comparative-institutional approach employed here has generated a number of plausible hypotheses in this regard. In future work it would be desirable for these hypotheses to be linked to others which can be derived from legal and political theory as well as from empirical research in other areas. Also it would probably prove fruitful to supplement the comparative perspective, which looks at different international institutions one by one, by systematic consideration of different kinds of institutional interaction. The dynamics we have analysed are entirely on the “micro-level”, so to speak, of individual negotiations and debates, whereas more “macro” processes at the inter-institutional level are neglected.[132] For practitioners such interaction is self-evident. Political and legal scientists recently have also increased their attention to inter-institutional relations on the international level (see above, note 7), but there remains much scope for interaction also between the disciplines.

[132] Theofanis Christoforou alerted us to this point.

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