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UNCERTAINTY AND PRECAUTION: IMPLICATIONS FOR TRADE AND ENVIRONMENT

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This draft study has been prepared in response to the mandate from the Joint Working Party on Trade and Environment at its meeting in May 2000. It has been revised in the light of comments and contributions from Delegations, after the discussion of the draft study at the meeting of the JWP in November 2000. The JWP is invited to discuss the draft study in view of its finalisation and declassification, and to decide whether further work should be undertaken on the basis of the issues suggested at the end of the study.

Contact person: Cristina Tébar Less ENV/GSP: Tel. (33-1) 45 24 18 51; Fax (33-1) 45 24 78 76;
Email: cristina.tebar-less@oecd.org

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INTRODUCTION

1. This paper, prepared in response to a mandate from the Joint Working Party on Trade and Environment at its meeting in May 2000, addresses the implications of uncertainty and precaution for trade and environment. According to the mandate, the study reviews the objectives related to precaution which appear in national and international instruments, gives concrete examples of the use of precaution, and sets out the key issues arising for trade and environment from the two previous sections¹.

2. The first chapter deals with the *meaning and objectives of precaution*. It examines the concept of precaution in the framework of environmental principles, describes precautionary approaches as formulated in international environmental instruments, and provides an overview of the status of precaution in national and international law². It further analyses how WTO Agreements deal with environmental protection in the context of scientific uncertainty.

3. The second chapter provides *examples of measures* that decision-makers apply in situations of uncertainty about a potential environmental damage. It describes both measures set out in international instruments and adopted in national practice, including measures with potential trade effects, and gives examples of the implementation of such measures.

4. The third chapter deals with a number of *issues for discussion* emerging from the previous chapters and which are of relevance for the debate on the implications of uncertainty and precaution for trade and environment. These issues include the role of science, transparency and consultation, the costs of precaution and the concerns of developing countries with regard to precaution. .

5. Annexes I and II provide an overview of references to precaution in international environmental agreements, and in OECD Member countries legislation, respectively. Annex III includes an overview of WTO provisions and jurisprudence on science and risk assessment.

¹ The mandate provided that the study should be based on existing material, including the draft UNEP study dealing with precaution. However, since the UNEP study is currently under revision, this paper does not include references thereto. The mandate further specified that the study should not deal with food safety issues.

² The term international environmental instruments is used to designate both binding instruments – multilateral environmental agreements (MEAs) - and non-binding instruments, such as Declarations, Recommendations, Resolutions, etc.

I. MEANING AND OBJECTIVES OF PRECAUTION

The concept of precaution

6. A number of developments over the last years have changed the perception of environmental protection, not only within governments, but also in society at large. The depletion of the ozone layer, evidence of climate change caused by greenhouse gas emissions, the extinction of species of fauna and flora, pollution of the most remote eco-systems, as well as increasing health problems related to environmental pollution are examples of damages that were not prevented in time.

7. This has led to the notion that not only *known* risks, but also *potential* risks to the environment and human health need to be addressed, even when their nature or magnitude is uncertain, and when a causal link with a certain action or process is not fully established. Further, the fact that certain actions carried out in the past only show their disastrous effects after many years, often due to an accumulation of relatively minor impacts, has raised awareness for the need of anticipatory action. Rapid technological progress, and the increasing dissemination of new and innovative industrial products and processes have also been seen as calling for increased caution, at least as long as the potential damaging effects of such processes and products on human health and the environment are not sufficiently known.

8. It is generally recognised that the use of precaution in the context of environmental protections is called for when two factors concur: the existence of a *risk*³ (i.e., where potentially hazardous effects deriving from an action, product or process have been identified) and *lack of certainty* on the effect of such action, product or process, or on extent of a potential damage (i.e. circumstances where scientific evaluation does not allow the risks to be determined with sufficient certitude). The essence of precaution is that once a risk has been identified, the lack of scientific proof should not be invoked as a reason for not taking action to protect the environment⁴. Risk and uncertainty can thus be regarded as “triggering factors” or preconditions justifying a decision to take precautionary action, and to establish what are the most appropriate measures to prevent, limit or minimise the potential damage.

³ According to the World Bank, “*Hazard denotes a property (of substances, microorganisms, and so on) or a situation that in particular circumstances could lead to harm. If these circumstances occur, they result in adverse consequences. Risk is a function of the probability (or frequency) of a hazard occurring, and the magnitude of the consequences; risk therefore represents the likelihood of a potential hazard being realised*”. See Environmental Assessment Sourcebook, World Bank, 1997.

⁴ D. Freestone, E. Hey, *Origins and Development of the Precautionary Principle*, page 13, in D. Freestone and E. Hey, eds., *The Precautionary Principle and International Law. The Challenge of Implementation*, 1996,. See also J. Cameron, *The Precautionary Principle*, in G. P. Sampson, B. Chambers, eds., *Trade, Environment and the Millenium*, 1999, page 242.

The use of precaution in environmental protection

9. Acting with precaution is attempting to prevent a damage, which may have occurred in the absence of that attempt. In other words, precautionary action to protect the environment can be seen as a preference to err on the side of caution, rather than assuming that the assimilative capacity of the environment will be able to absorb a potential damage. The use of precaution when taking decisions in situations where full evidence about the possible environmental consequences of an action or inaction is not available has therefore become more frequent, and such decisions have increasingly come under public scrutiny⁵.

10. Preventing harm to the environment is best achieved where there is a high level of certainty as to the effects on the environment of an action or an accumulation of actions. However, for many environmental problems, it is not possible to state with certainty what consequences a particular policy or action will have, either because scientific evidence is not available, or because scientific estimates are imprecise or incomplete. Illustrations of the significance of scientific uncertainty are the depletion of the ozone layer and the global warming problem. In both cases, decisions to prevent further damage were taken when the very serious implications of these problems were noticed, without awaiting scientific certainty about the exact causes and the extent of the problem⁶.

11. Some decisions concerning the environment may lead to constraints on an activity (industrial, agricultural, recreational or other), limiting the otherwise beneficial effects of these activities. The ideal policy response is one that preserves the environmental amenity while still allowing the benefits of the activity to be retained⁷. Such balance however, is not always possible. Often, decisions have not been sensitive enough to environmental concerns, and serious, sometimes irreversible, damage has been allowed to occur. This may have been based, in some cases, on simple disregard for the environment; but sometimes, decisions have been taken because there was no or insufficient evidence that an activity would cause environmental damage, or that the damage would be as important as it turned out to be.

12. Dissatisfaction with such outcomes, both among decision-makers and the general public, increased public information about environmental damages, growing awareness of the potential risks of human activities and unexpected cumulative effects, as well as the irreversibility of certain environmental damages, have led to a change in the balancing of factors in decision-making. There is now a growing recognition of the need to apply precaution in environmental protection, and to act before full certainty on the links between an action or inaction and a potential damage to the environment, or the extent of such potential damage, is available.

13. It is not always possible, when looking at either national regulations or international instruments dealing with environmental damage prevention, to draw a clear line between environment and health issues, since both are closely related⁸. The use of precaution has been part of health and food regulation for

⁵ For a more detailed research into these factors, see Olivier Godard, *Politiques d'environnement et règles du commerce international: le principe de précaution sur la ligne de fracture*, Ecole polytechnique, February 2000, page 3 and P. Kourilsky and G. Viney, *Le principe de précaution*, 1999, page 26 ss.

⁶ T. Tietenberg, *Environmental and Natural Resource Economics*, 2000, page 49.

⁷ See in this context André Nollkaemper, *What you risk is what you value*, in D. Freestone, E. Hey eds, page 74.

⁸ For the purposes of this paper, the term environment will be understood as also encompassing human health. This understanding is based on the definition of environment by the International Court of Justice: "*The environment is not an abstraction but represents the living space, the quality of life and the very health of human beings, including generations unborn*". Advisory Opinion of the International Court of Justice on the legality of the threat or use of nuclear weapons, paragraph 29.

many years and has now also become generally recognised as an important element of environmental protection, both in national regulatory systems and in some international instruments, even though in many instances no specific references to “precaution” appear in the relevant texts.

Precaution in the context of environmental protection

The obligation to prevent harm to the environment

14. The overwhelming majority of international conventions are based on the principle that environmental degradation should be prevented by avoiding pollution or nuisance, rather than waiting for it to occur, and then trying to counteract its adverse effects⁹. This principle of customary international law, known also as the “no harm principle” has been formulated in the 1972 Stockholm Declaration of the UN Conference on the Human Environment (Principle 21) and the 1992 Rio Declaration on Environment and Development (Principle 2):

“States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental and developmental policies, and the responsibility to ensure that activities within their jurisdiction and control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction”.

15. This principle has remained highly influential in the subsequent development of law and practice in environmental matters. It is the basis for most multilateral environmental agreements, and is also reflected in numerous OECD instruments dealing with environment¹⁰. Whereas older formulations of the “no harm” principle, have dealt only with transboundary harm, the existence of the general obligation of States to ensure that activities within their jurisdiction and control respect the environment of other States or of areas beyond national control is now part of the corpus of international law relating to the environment. The principle, as it has been applied in international lawmaking, requires States to do more than make reparation for environmental damage, namely, to take suitable measures to prevent and limit environmental damage¹¹.

Prevention and precaution

16. While the concept of harm prevention is well established in national and international law, that of precaution has only more recently entered into the public debate. The distinction between both terms in current language is clear: prevention can be defined as “*keeping something from occurring or stopping from doing something*”, precaution, as “*a measure taken in advance to avert possible harm, or caution*”

⁹ A. Kiss, *The Rights and Interests of Future Generations and the Precautionary Principle*, page 26, in D. Freestone and E. Hey, eds., op. cit.

¹⁰ Since 1971, the OECD has adopted several dozens of instruments in the field of environment. OECD instruments can take different forms. *Decisions* are legally binding instruments; *Recommendations* are not legally binding but are submitted to Members for consideration in order that they may, if they consider it opportune, provide for their implementation; *Declarations*, which set out relatively precise policy commitments, are solemn texts negotiated in the framework of the OECD and adopted at high level, generally by Ministers.

¹¹ P.W. Birdie, A.E. Boyle, op.cit. pages 91- 92.

*employed beforehand*¹². In practice however, when it comes to applying concrete measures, especially in the field of environmental protection, this difference is less evident.

17. The environment is very complex, and it is often impossible to determine with full certainty whether an action will cause damage, or what the extent of such damage will be. It is therefore often difficult, if not impossible, to draw a line between an action taken in the light of uncertainty about a potential harm, and an act aiming at the prevention of a more or less known, harmful, consequence. Both have the same objective: to avoid or minimise possible damage to the environment. As well as prevention, precaution is necessary to avert environmental damages that would otherwise be borne by future generations. In this sense, both precaution and prevention are key to ensuring sustainable development.

Precaution in international environmental instruments

Evolution of precaution as formulated in international instruments

18. Precaution is a subjective term: some individuals are more cautious than others when facing a risk, as are governments when deciding on policies to avert risks. Similarly, the acceptable level of risk and the level of protection to address that risk varies, both among individuals and different societies. It is therefore difficult to determine in advance in which situations the use of precaution is called for, and to provide concrete guidance on measures to put precaution in practice. This also implies that in the face of uncertainty about the possible harmful consequences of an action, decisions are often taken on a case-by-case basis, in the framework of a specific context.

19. Over the last years, States have attempted to better define, and agree on, situations which justify the use of precaution for the purposes of environmental protection, and on the measures to put precaution in practice. These attempts are reflected in a number of international environmental instruments, which can be seen as collective efforts to anticipate and tackle environmental problems.

20. When looking at precaution in international environmental instruments, a rough distinction can be made between three different approaches. First, some instruments do not explicitly refer to precaution, but are based on a situation where, to prevent a potential serious damage for which scientific certainty is lacking, countries have chosen to act with precaution. Second, a number of instruments make reference to precaution, without, however, providing any guidance on how to apply it in practice. Finally, some instruments provide guidance on measures that should, or could, be taken to implement precaution¹³.

21. Environmental instruments address a variety of problems: protection of natural resources, fisheries management and conservation, air pollution, water pollution, climate change, etc. Although the general objective of precaution is to protect human health and the environment, it seems difficult, given the diverse objectives of environmental instruments and the various approaches to precaution, to provide a single, overarching definition of precaution. The objectives of precaution therefore need to be examined in the framework of each instrument, and the implementation of precautionary measures needs to be adapted to each particular context.

22. The most widely used formulation of precaution is that contained in Principle 15 of the Declaration on Environment and Development adopted in Rio in 1992 (Rio Declaration):

¹² Random House Webster's College Dictionary.

¹³ Examples of these different approaches are provided in Annex I.

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

24. While references to precaution appear in international instruments are generally addressed to governments, over the last years a number of instruments have been adopted which recommend the use of precaution by individuals or enterprises. A recent example is the *OECD Guidelines for Multinational Enterprises*, in which enterprises are encouraged¹⁴. Further examples are Principle 7 of the UN Global Compact, under which the UN Secretary General asks world business to “support a precautionary approach to environmental challenges”, and the Business Charter for Sustainable Development, sponsored by the International Chamber of Commerce, which includes a reference to the precautionary approach: not to use the lack of full scientific certainty as a reason for postponing cost effective measures to prevent or minimise damages to the environment¹⁵

The legal status of precaution in international law: overview of the current debate

25. Much has been written about the legal status of precaution, and numerous studies have analysed whether the existing body of law and jurisprudence reflects the existence of a precautionary principle, and whether the use of precaution is a principle of international law, or of international environmental law¹⁶.

26. The legitimacy of the use of certain precautionary measures has also been invoked before various international tribunals: the International Court of Justice¹⁷, the International Tribunal for the Law of the Sea¹⁸, the WTO Appellate Body¹⁹ and the European Court of Justice²⁰. None of these tribunals has accepted the challenge of clarifying the legal status of precaution, nor has any confirmed the existence of a precautionary principle as a principle of international law.

27. The main streams in the current debate on the status of precaution in international law are those reflected in the positions maintained by the EU, the US and Canada respectively in the dispute on EC measures concerning meat and meat products (Hormones case). The WTO Appellate Body summarised as

¹⁴ The Guidelines for Multinational Enterprises are annexed to the 1976 Declaration on International Investment and Multinational Enterprises, revised in 2000.

¹⁵ J. Adams, *Foreign Direct Investment and the Environment: the role of voluntary corporate environmental management*, in *Foreign Direct Investment and the Environment*, OECD 1999

¹⁶ It is not the purpose of this paper to contribute to this debate. Numerous articles and studies deal with the legal status of the precautionary principle, such as the *Communication from the EC Commission on the Precautionary Principle*, 2000, D. Freestone and E. Hey, op. cit., Cameron and Abouchar, op. cit., J. Cameron, *The Precautionary Principle: a fundamental principle of law and policy for the protection of the global environment*, Boston College International and Comparative Law Review, 1991, page 1, P. Kourilski, G. Viney, op.cit., Pascale Martin-Bidou, *Le principe de précaution en droit international de l'environnement*, Revue Générale de Droit International Public, 1999-3.

¹⁷ Case concerning the Gabcikovo-Nagymaros Project (Hungary/Slovakia), Decision of 25 September 1997.

¹⁸ International Tribunal for the Law of the SEA; Southern Bluefin Tuna Cases, New Zealand v Japan; Australia v. Japan, Requests for provisional measures, Order of 27 August 1999. The order has subsequently been withdrawn.

¹⁹ Hormones case, WT/DS26/AB/R, WT/DS48/AB/R, paragraph 123 of the Appellate Body report.

²⁰ Judgements of 5 May 1998, cases C-157/96 and C-180/96.

follows the positions of the three parties in that dispute²¹: “*The basic submission of the European Communities is that the precautionary principle is, or has become, “a general customary rule of international law” or at least “a general principle of law” (...). The United States does not consider that the “precautionary principle” represents customary international law and suggests it is more an “approach” than a “principle”. Canada, too, takes the view that the precautionary principle has not yet been incorporated into the corpus of public international law, however, it concedes that the “precautionary approach” or “concept” is “an emerging principle of law” which may in the future crystallise into one of the “general principles of law recognised by civilised nations within the meaning of Article 38(1) c) of the Statute of the International Court of Justice*”²².

Precaution in the laws of OECD countries

28. In all OECD countries, precaution is regarded as an integral part of risk analysis in the food safety area²³. With few exceptions, precaution has found its way into national environmental legislation, and an increasing number of OECD countries specifically address the issue of uncertainty and precaution in their laws.

29. In some countries, precaution appears as a principle or as an approach informing environmental measures. In others, the use of precaution is formulated as an obligation for the government and the implementing authorities. Others do not refer to precaution *per se*, but have adopted provisions and implemented measures to deal with situations in which precaution is called for. Some examples of legislation of OECD Member countries incorporating the concept of precaution are provided in Annex II of this paper.

Precaution in trade agreements

Precaution in the Agreement on the Application of Sanitary and Phytosanitary Measures

30. Several WTO Agreements contain provisions on measures to protect human health and the environment, but only the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) refers specifically to measures taken in cases of uncertainty²⁴.

²¹ Hormones case, paragraphs 121-122 of the Appellate Body report

²² International custom, as evidence of a general practice accepted as law, and general principles of law recognised by civilised countries are, together with treaties, sources of international law. Whereas treaties apply only to countries which are parties to them, international custom and general principles of law are, in principle, applicable to all countries. For a detailed description of the sources of international law, see Ian Brownlie, *Principles of public international law*, pages 1 ss. See also J. Cameron, op. cit., page 1.

²³ *Overview of national food safety systems and activities* (SG/ADHOC/FS(2000)5/FINAL). More detailed information on how precaution is implemented in food safety decisions in each OECD country can be found in SG/ADHOC/FS(2000)5/ANN/FINAL.

²⁴ This section will focus on three agreements: the General Agreement on Tariffs and Trade (GATT), the Agreement on Technical Barriers to Trade (TBT) and the Agreement on the Application of Sanitary and Phytosanitary (SPS) measures. Other WTO Agreements containing references to measures to protect the environment are the General Agreement on Trade in Services (GATS) and the Agreement on Agriculture. These agreements seem less relevant for the purposes of this study and are therefore not included in the analysis.

31. The SPS Agreement sets forth specific disciplines with which sanitary and phytosanitary measures are developed and maintained: “*Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health provided such measures are not inconsistent with the provisions of this Agreement*” (Art 2.1 and Preamble), that they are “*applied only to the extent necessary to protect human, animal or plant life or health*”, are “*based on scientific principles*” and “*are not maintained without sufficient scientific evidence*” (Article 2.2), “*do not arbitrarily or unjustifiably discriminate between Members*”, and are “*not applied in a manner which would constitute a disguised restriction on international trade*” (Article 2.3).

32. Article 5 establishes the obligation for Members to ensure that their sanitary and phytosanitary measures are based “*on an assessment, as appropriate to the circumstances, of the risk to humans, animal or plant life or health*” (Article 5.1)²⁵. Article 5.7 deals with situations in which there is lack of scientific certainty: “*In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary and phytosanitary measures on the basis of available pertinent information, including that from the relevant international organisations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measures accordingly within a reasonable period of time*”.

33. The above provisions, in particular Article 5.7, have been interpreted in various recent disputes brought under the WTO dispute settlement mechanism: the cases based on complaints by the US and Canada regarding the EC's prohibition of meat and meat products derived from cattle to which certain hormones had been administered (Hormones case), the case based on a complaint by Canada regarding Australia's prohibition on the importation of salmon from Canada (Salmon case)²⁶, and the case based on a complaint by the US regarding measures taken by Japan to test and confirm the efficacy of the quarantine treatment for each variety of agricultural products (Agricultural products case)²⁷.

34. In the report on the Hormones case the Appellate Body examined the relevance of the precautionary principle in the interpretation and the SPS Agreement²⁸:

“The status of the precautionary principle in international law continues to be the subject of debate among academics, law practitioners, regulators and judges. The precautionary principle is regarded by some as having crystallised into a general principle of customary international environmental law. Whether it has been widely accepted by Members as a principle of general or customary international law appears less than clear. We consider, however, that it is unnecessary, and probably imprudent, for the Appellate Body in this appeal to take a position on this important, but abstract, question. We note that the Panel itself did not make any definitive finding with regard to the status of the precautionary principle in international law and that the precautionary principle, at least outside the field of international environmental law, still awaits authoritative formulation”.

²⁵ Article 5 further describes the factors that Members shall take into account in the assessment of risks (paragraphs 2-3), and recalls that Members should take into account the objective of minimising negative trade effects, shall avoid arbitrary or unjustifiable distinctions in the levels of protection to be appropriate in different situations and ensure that measures are not more trade-restrictive than required to achieve the appropriate level of protection (paragraphs 4-6).

²⁶ WT/DS18/AB/R.

²⁷ WT/DS76/AB/R.

²⁸ In the Hormones case, the EC Commission invoked the precautionary principle to justify its ban on the import of Canadian and US meat treated with growth hormones.

It appears to us important, nevertheless to note some aspects of the relationship of the precautionary principle to the SPS Agreement. First, the principle has not been written into the SPS Agreement as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of that Agreement. Secondly, the precautionary principle indeed finds reflection in Article 5.7 of the SPS Agreement. We agree, at the same time, with the European Communities, that there is no need to assume that Article 5.7 exhausts the relevance of a precautionary principle. It is reflected also in the sixth paragraph of the preamble and in Article 3.3. These explicitly recognise the right of members to establish their own appropriate level of sanitary protection, which level may be higher (i.e., more cautious) than that implied in existing international standards, guidelines and recommendations. Thirdly, a panel charged with determining, for instance, whether “sufficient scientific evidence” exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned. Lastly, however, the precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation in reading the provisions of the SPS Agreement.

We accordingly agree with the findings of the Panel that the precautionary principle does not override the provisions of Articles 5.1 and 5.2 of the SPS Agreement²⁹“.

35. In the report of the Agricultural products case, the only case so far where a defendant argued that its measure was a provisional one, the Appellate Body, analysed the four requirements which provisional SPS measures under the first sentence of Article 5.7 must meet: “... a Member may provisionally adopt an SPS measure if this measure is (1) imposed in respect of a situation where relevant scientific information is insufficient”, and (2) adopted on the basis of available pertinent information. Pursuant to the second sentence of Article 5.7 such a provisional measure may not be maintained unless the Member which adopted the measure: (3) seek(s) to obtain the additional information necessary for a more objective assessment of risk, and (4) review(s) the ... measure accordingly within a reasonable period of time”.

36. The Appellate Body further emphasised that “these four requirements are clearly cumulative in nature and are equally important for the purpose of determining consistency with this provision. Whenever one of these four requirements is not met, the measure at issue is inconsistent with Art 5.7”³⁰. As to what constitutes a “reasonable period of time” to review a measure, the Appellate Body points out that this “has to be established on a case-by-case basis and depends on the specific circumstances of each case, including the difficulty of obtaining the additional information necessary for the review and the characteristics of the provisional SPS measure”³¹.

Precaution in the GATT and the TBT Agreement

37. Both the GATT and the TBT Agreement include provisions on measures taken by Members to protect human health and the environment. They are, however, silent on use measures applied in cases of scientific uncertainty and on the use of precaution.

²⁹ Hormones case, paragraphs 123 to 125 of the Appellate Body report.

³⁰ Agricultural products case, paragraph 89 of the Appellate Body report.

³¹ Agricultural products case, paragraph 93 of the Appellate Body report.

38. Trade measures adopted by WTO Members under the GATT must conform with general trade principles: most-favoured-nation (Article I of the GATT), national treatment (Article III), the general elimination of quantitative restrictions (Article XI). A limited number of exceptions to these principles are foreseen. Under Article XX, countries are allowed to take measures “*necessary to protect human, animal or plant life or health*”(paragraph b), or “*relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production and consumption*” (paragraph g). In accordance with the “chapeau” of Article XX, any such measures must not be applied “*in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade*”.

39. The TBT Agreement, which aims at ensuring that technical regulations and standards do not create unnecessary obstacles to trade, recognises in the Preamble that no country should be prevented from taking “*measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health, of the environment... at the level it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade...*”. Under Article 2.2, Members are to ensure that “*technical regulations are not prepared, adopted or applied with a view or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risk non-fulfilment would create. Such legitimate objectives are, inter alia, ... protection of human health or safety, animal or plant life or health, or the environment. In assessing such risk, relevant elements of consideration are, inter alia, available scientific and technical information, related processing technology or intended end-uses of products*”.

40. While these provisions have been interpreted by the competent dispute settlement bodies in several disputes related to trade restricting measures to protect human health and the environment³², so far, none of these provisions have been interpreted in decisions on disputes involving the use of precautionary, environmental measures. WTO jurisprudence interpreting developments in environmental protection in relationship with the above provisions and other relevant WTO texts, might however be relevant when considering the application of precautionary measures and their compliance with the GATT and the TBT Agreement³³.

The relationship between developments in environmental protection and the WTO Agreements

41. The preamble to the Marrakesh Agreement establishing the WTO provides that the WTO has the objective of “*raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world’s resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance them and for doing so in a manner consistent with their respective needs and concerns at different levels of economic development*”.

³² United States-Standards for Reformulated and Conventional Gasoline (United States-Gasoline case, WT/DS2/9); United States- Import Prohibition of Certain Shrimp and Shrimp Products (Shrimp-Turtle case, WT/DS56/AB/R); European Communities- Measures Affecting Asbestos and Asbestos-containing Products (Asbestos case, WT/DS135/AB/R).

³³ Anne Laudon and Christine Noiville in *Le principe de précaution, le droit de l' environnement et l'OMC*, 1998, consider that among the WTO Agreements, the GATT and the TBT are the “*least unfavourable to precautionary measures*”, page 59 ss. See also J. Cameron, op. cit., page 257.

42. The WTO Agreements aim at liberalising access to markets on a non-discriminatory basis. They seek to ensure fair and equal competitive conditions for market access, and predictability of access for all traded goods and services³⁴. While the purpose of these agreements is to limit measures that could hamper free trade, within the established rules, the general obligations of the Agreements may affect the availability of certain measures to protect the environment.

43. According to the WTO Appellate Body: “*Members are free to adopt their own policies aimed at protecting the environment as long as, in so doing, they fulfil their obligations and respect the rights of other Members under the WTO Agreements*”³⁵. In interpreting Article XX of the GATT, the WTO Appellate Body has stated that “*WTO Members have a large measure of autonomy to determine their own policies on the environment (including its relationship with trade), their environmental objectives and the environmental legislation they enact and implement. So far as concerns the WTO, that autonomy is circumscribed only by the need to respect the requirements of the General Agreement and the other covered agreements*”³⁶. Similarly, in the recent report on “Measures affecting asbestos and asbestos containing products” (hereafter “Asbestos case”) the Appellate Body stated: “*It is undisputed that WTO Members have the right to determine the level of protection of health that they consider appropriate in a given situation*”³⁷.

44. The TBT specifies in the Preamble that a country should not be prevented from taking measures necessary for the protection of human, animal or plant life or health, of the environment “*at the level it considers appropriate*”. Some countries consider that taking measures even before full knowledge about a potential damage exists -i.e., precautionary measures, is an appropriate level of protection, and a number of them have incorporated this concept in their legislation³⁸.

45. Both the GATT and the TBT Agreement allow for exceptions to general trade rules, subject to certain conditions. The TBT Agreement requires such a technical regulation not to be “*more trade-restrictive than necessary to fulfil a legitimate objective*”, the protection of the environment being one of such objectives. The GATT requires a measure to be “*necessary to protect human, animal or plant life or health*” or “*relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production and consumption*”. Contrary to the SPS Agreement, both the GATT and the TBT Agreement are silent on the need that measures be science-based. Under Article 2.2. of the TBT Agreement, a country is required to take account of the risk non-fulfilment (of a legitimate objective) would create. In assessing such risk, relevant elements of consideration are, *inter alia* “*available scientific and technical information, related processing technology or intended end-use of products*”. In other words, scientific information is one, but not the exclusive element to be considered. The GATT does not refer to scientific or other considerations on which a measure under Article XX b) or g) would need to be based.

46. The debate on the relationship between measures taken pursuant to MEAs and WTO rules is still ongoing, as is likewise the debate on the relationship between environmental principles or emerging approaches to environmental protection - such as the use of precaution -, and WTO rules. On the other

³⁴ UNEP/IISD, *Trade and Environment; a handbook*, 2000, page 26.

³⁵ United States-Gasoline case, paragraph 30 of the Appellate Body Report, reiterated in the Shrimp-Turtle case, paragraph 186 of the Appellate Body Report.

³⁶ United States-Gasoline case, pages 29-30 of the Appellate Body report.

³⁷ Asbestos case, paragraph 168 of the Appellate Body report

³⁸ See Annex II

hand, the Appellate Body has, in recent decisions, taken into account developments in environmental protection³⁹.

47. For example, in the Shrimp-Turtle case, it noted that “*the words of Article XX (g) ‘exhaustible natural resources’ were actually crafted more than 50 years ago. They must be read by a treaty interpreter in the light of contemporary concerns of the community of nations about the protection and conservation of the environment. While Article XX was not modified in the Uruguay Round, the preamble attached to the WTO Agreement shows that the signatories to that Agreement were, in 1994, fully aware of the importance and legitimacy of environmental protection as a goal of national and international policy*”⁴⁰.

48. With reference to the objective of sustainable development in the preamble of the WTO Agreement, the Appellate Body further said that “*this preambular language must add colour, texture and shading to our interpretation of the agreements annexed to the WTO Agreement, in this case, the GATT 1994. ... It is proper for us to take into account, as part of the context of the chapeau, the specific language of the preamble to the WTO Agreement*”⁴¹. The Appellate Body further quoted the statement by the International Court of Justice that “*where concepts embodied in a treaty are “by definition evolutionary”, their interpretation cannot remain unaffected by the subsequent development of law...An international instrument has to be interpreted and applied within the framework of the entire legal system prevailing at the time of the interpretation*”. The Appellate Body noted, however, that “*the Court did not identify the precautionary principle as one of those recently developed norms*”⁴².

49. In the Hormones case, the Appellate Body referred to a decision of the International Court of Justice in which the precautionary principle had been invoked: “*In the case concerning the Gabčíkovo-Nagymaros Project (Hungary/Slovakia), the International Court of Justice recognised that in the field of environmental protection... new norms and standards have been developed, set forth in a great number of instruments during the last two decades. Such new norms have to be taken into consideration, and such new standards given proper weight*”⁴³.

³⁹ The Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) provides that “*...the dispute settlement system ... serves to preserve the rights and obligations of the Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of the DSB cannot add or diminish the rights and obligations provided in the covered agreements*” (Article 3.2 of the (DSU). This has been interpreted to include the Vienna Convention on the Law of Treaties (United States-Gasoline), which states that treaties must be interpreted in the light of any “*relevant rules of international law applicable between the parties.*”

⁴⁰ Shrimp-Turtle case, paragraph 129 of the Appellate Body report.

⁴¹ Shrimp-Turtle case, paragraphs 153 and 156 of the Appellate Body report.

⁴² Hormones case, footnote 70 of the Appellate Body report, with a quotation from the ICJ Advisory Opinion in Namibia - Legal Consequences, (1971) ICJ Reports, page 31.

⁴³ Hormones case, footnote to paragraph 123 of the Appellate Body report. In the case brought before the International Court of Justice (ICJ) by Hungary against Slovakia, Hungary invoked the precautionary principle, to justify its impossibility of complying with the 1977 Treaty on the Construction and Operation of the Barrage System, entered into with Czechoslovakia. In its decision, the Court did not make any reference to the principle, but stated: “*The Court is mindful that, in the field of environmental protection, vigilance and prevention are required on account of often irreversible character of damage to the environment and of limitations inherent in the very mechanism of reparation of this type of damage. Throughout the ages, mankind has, for economic and other reasons, constantly interfered with nature. In the past, this was often done without consideration of the effect upon the environment. Owing to new scientific insights at to growing awareness of the risk for mankind - for present and future generations - of*

50. The Appellate Body has further considered that the GATT “*is not to be read in clinical isolation from public international law*”⁴⁴.

51. In this context, it may also be useful to recall the emphasis that the Appellate Body put on the need to solve global environmental problems through international co-operation, and not through unilateral measures. The Appellate Body quoted, in particular, the report of the WTO Committee for Trade and Environment, forming part of the Report of the General Council to Ministers on the occasion of the Singapore Ministerial Conference, which supported and endorsed “*multilateral solutions based on international co-operation and consensus as the best and most effective way for governments to tackle environmental problems of a transboundary or global nature. WTO Agreements and multilateral environmental agreements are representative of efforts of the international community to pursue shared goals, and in the development of a mutually supportive relationship between them, due respect must be afforded to both.*”⁴⁵.

pursuit of such interventions at an unconsidered and unabated pace, new norms and standards have been developed, set forth in a great number of instruments during the last two decades. (...)”

⁴⁴ United States-Gasoline case, page 17 of the Appellate body report.

⁴⁵ Shrimp-Turtle case, paragraphs 167 ss of the Appellate Body report.

II. MEASURES OF PRECAUTION

Types of precautionary measures, steps and approaches

52. Chapter I has shown that there are different definitions of, and approaches to precaution, both in national and international instruments. Precautionary measures are applied in the context of specific situations, and no generally agreed guidance exists on when to apply precaution, nor “how much” precaution is necessary in a given situation. Most measures of precaution are measures aiming at or contributing to preventing damage to the environment, their particularity being that they are applied in the absence of full certainty that such damage will effectively occur. Instruments dealing with precaution provide for a variety of measures and steps, aimed at addressing the different elements of precaution in a variety of situations. Precautionary measures address these various elements and situations in different ways. In practice, a combination or succession of several measures is generally put in place. These measures, steps and approaches can be divided into two broad categories: those aimed at *identifying, evaluating and assessing* a risk, and those aimed at *managing and controlling* such risk. Each of these categories includes a number of different measures, steps and approaches.

Identification, evaluation and assessment of risks

53. Essential elements of precautionary approaches are the existence of a risk of a potential damage, and the uncertainty linked either to the probability of such damage to occur, or to the potential scope of such damage, or both. Decision-makers however need a certain amount of information about the potential consequences of a product, process or activity in order to take the necessary measures to prevent or minimise any damages linked thereto. Measures to address this need are those to assess the risk and the potential environmental impact of an activity, as well as measures to manage and monitor such risks. They include risk assessment and, as a complementary tool, environmental impact assessment. Precautionary approaches are often accompanied with measures that seek to identify the impacts of a product, process or activity on the environment, and the possible solutions to address its damaging consequences. These measures include co-operation, research and exchanges of information.

54. To adequately address a risk, it is essential for decision-makers to have advance knowledge of concrete actions or situations which may cause a damage, and to be able to decide whether to authorise or approve them, before the potentially damaging action occurs. This is the purpose of procedures requiring the prior approval, or prior informed consent of an authority before an action can proceed. Similarly, by accompanying a product with certain information - for example, through labels- controls and measures to prevent a risk relating to the product can be put in place.

Measures to identify, evaluate and assess risks

Risk assessment

55. The outcome of most human activities cannot be accurately predicted, and human interventions in nature are particularly prone to uncertainty. As knowledge about these activities improves, the uncertainty about future outcomes can be expressed in terms of the probability of them happening. In this case, it can be said that “uncertainty has been converted into risk”, and in this context, risk has been described as measurable uncertainty⁴⁶.

56. Risk assessment has been defined as the *process* of converting uncertainty into risk. It entails three main steps: analysing the initiating event and the pathways through which the effect occurs; specifying the size and severity of the risk; and estimating probabilities and expected values⁴⁷.

57. Another definition is that of the Codex Alimentarius: risk assessment is a scientifically based process consisting of (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment and (iv) risk characterisation⁴⁸. Risk assessment is an essential element in food safety policies.

58. The World Bank defines risk assessment as a combination of risk estimation and risk evaluation. The technique of risk assessment may be used to assess the relative costs and benefits of a situation, development proposal or regulatory approach.⁴⁹

59. Many international environmental instruments are the result of collective risk assessment which preceded or accompanied the negotiation, and several international agreements include provisions for risk assessment. The procedures for risk assessment vary from agreement to agreement, some include provisions for a collective risk assessment carried out by the Parties to the Convention, others require a risks assessment to be undertaken by an individual (e.g., an exporter of certain goods). Under CITES, the inclusion of new species in the relevant Annexes is done after a decision by the parties, based on a collective evaluation of risks. The lists of hazardous wastes in the Basel Convention reflect an international risk assessment as well. Similarly, the draft Convention on Persistent Organic Pollutants provides a collective risk assessment whereby a committee will examine a proposal to add a chemical to the relevant annexes. The Convention on Prior Informed Consent Procedure for Certain Hazardous Chemicals and

⁴⁶ *The economic appraisal of environmental projects and policies, a practical guide*, OECD 1985, page 139.

⁴⁷ OECD 1985, op. cit., page 141.

⁴⁸ *Overview of national food safety systems and activities*, SG/ADHOC/FS(2000)5/Final, page 6. On the four components of risk assessment, see also the EC Communication on the precautionary principle, page 14 and Annex III.

⁴⁹ Some concepts related to risk assessment are defined as follows by the World Bank: “*Hazards* refers to sources of potential harm, whereas *risk* considers frequency and severity of damage from hazards. A risk assessment involves evaluating actual and perceived risks at the basis for decision-making. *Hazard* denotes a property (of substances, microorganisms, and so on) or a situation that in particular circumstances could lead to harm. If these circumstances occur, they result in adverse consequences. *Hazard assessment* is thus the identification of hazards, their potential receptors (people, natural resources, plants or animals) and the determination of the consequences. *Risk* is a function of the probability (or frequency) of a *hazard* occurring, and the magnitude of the consequences; *risk* therefore represents the likelihood of a potential hazard being realised. *Risk estimation* involves identifying the probability of harm occurring from an intended action or accidental event. *Risk evaluation* determines the significance of estimated risks, including risk perception (involving subjective appreciation and judgement), which will more often than not bear little relation to a statistical probability of damage. Environmental Assessment Sourcebook, World Bank, 1997.

Pesticides in International Trade first requires that two Parties take final regulatory action with regard to a chemical before the Committee set up by the Convention assesses whether the chemical should be added to Annex A, and thus be subject to measures to reduce or eliminate releases. The Protocol on Biosafety contains guidance on the risk assessment that importers of LMOs may require the exporter to carry out.

60. At the national level, many countries require risk assessment in the areas of health and food safety, e.g. for the introduction of new drugs, food additives, etc. A number of countries also require risk assessment prior to the adoption of environmental protection measures.

Risk assessment in the UK

61. *In the UK, the Interdepartmental Liaison Group on Risk Assessment (ILGRA) has been created with the objective to help secure coherence and consistency within and between policy and practice in risk assessment as undertaken by the UK Government and help disseminate and advance good practice. ILGRA is currently working on a Government Declaration on risk. Further, through ILGRA each Government Department is committed to developing their own risk assessment strategy⁵⁰.*

Risk assessment for GMOs in Norway

62. *Under the Norwegian Gene Technology Act, deliberate release of GMOs may only occur subject to approval. All GMOs are evaluated on a case by case basis, and a product is only approved when there is no risk of detrimental effects on health or the environment. Significant emphasis is placed on whether the release represents a benefit to the community and a contribution to sustainable development. Between 1997 and 2000 six GMO products have been prohibited because they contain antibiotic resistance genes, which may represent a major risk to human and animal health. The probability of gene transfer to pathogenic bacteria is likely to be small. If this was to happen, however, it could contribute to the serious problem of antibiotic resistance. Even though the main cause of antibiotic resistance is the use of antibiotics, the possibility that resistance genes in genetically modified products may reinforce this undesirable development cannot be excluded. The overall conclusion, based on a scientific assessment and the precautionary principle resulted in prohibiting the six products containing antibiotic resistance genes. The prohibitions have not met with formal reactions from the trade community or other countries.*

Environmental Impact Assessment (EIA)

63. Closely related to the concept of risk assessment is that of environmental impact assessment, a procedure for evaluating the likely impact of a proposed activity on the environment⁵¹. Environmental impact assessment is essentially a planning tool aimed at identifying the adverse environmental consequences of a proposed action, so that those approving a project are fully informed of its potential

⁵⁰ Information provided by the UK. The risk assessment strategy of the UK Department of Trade and Industry can be found under www.dti.gov.uk/about/risk_assessment.htm. In relation with precaution, the strategy provides that "... the Department supports the Precautionary Principle, i.e., the view that it is not desirable, when considering risks which appear to be significant, to delay action until there is absolute scientific certainty. In practical terms, this means acting on estimates of the risks (and therefore the benefits of reducing those risks and the cost for society of not doing so) which are towards the upper end of any range of uncertainty."

⁵¹ See Article 1.6 of the 1991 Convention on Environmental Impact Assessment in a Transboundary Context

impacts⁵². While EIAs are not, *per se*, precautionary measures, they can be seen as an important tool for supporting a precautionary approach by providing information and identifying areas of uncertainty.

Environmental hazard and risk assessment in World Bank projects

64. Many types of development supported by the World Bank involve environmental risk. For example, dam construction or remedial action to clean up pollution may pose risks to human health or the natural environment. Under such conditions, the potential environmental impacts are often subject to uncertainties. Where these uncertainties are significant, for example, in the case of a potential release of toxic material in a densely populated area, a quantitative assessment of hazards and risks may be appropriate. The techniques of hazard and risk assessment have been developed to help determine the degree of uncertainty associated with development activities. These techniques may be used independently from or in support of environmental assessment (EA) and environmental audit, which they complement. In the context of World Bank development projects, risk assessment deals with three basic questions:

1. What can go wrong? What impacts might affect human health and the natural environment, and what are the reasonable project scenarios (cause and effect) that might result in damage to health, the environment or the financial viability of the project.

2. What is the range and magnitude of these adverse impacts? What number of people of geographical area could be affected, what is the maximum credible accident that could occur during the lifetime of the project, and what are the risks of routine operations.

3. How likely are these adverse consequences? With what frequency might they occur, what evidence is available to judge their likelihood, and what data are available.

*The first two questions are addressed in EAs, the third question is addressed by risk assessment*⁵³.

Measures and approaches to increase knowledge on a product, process or activity

Research

65. Precaution is used when sufficient knowledge on the consequences of an action is not available. Research seeks to obtain, increase or improve knowledge on a subject and is therefore essential to complement precautionary approaches⁵⁴.

66. Numerous international environmental instruments contain provisions for international research programmes, such as the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, the Montreal Protocol on Substances that Deplete the Ozone Layer, the draft Convention on Persistent Organic Pollutants, etc. At national level, governments also have a role to play to encourage the acquisition of new knowledge and research, or focusing research programmes on specific issues. The credibility of scientific research may also be strengthened through government efforts to ensure independent funding, transparency, impartiality in the selection of members of research teams, etc.

⁵² *Foreign Direct Investment and the Environment*, OECD, 1999.

⁵³ Extract from *Environmental Hazard and Risk Assessment*, Environmental Assessment Sourcebook, World Bank, 1997.

⁵⁴ According to the EC Commission, the decision to fund a research programme or even the decision to inform the public of the possible adverse effects of a product or procedure may themselves be inspired by the precautionary principle; EC Communication on the Precautionary Principle, page 16.

The French Committee for Prevention and Precaution

67. In 1996, the French Ministry for the Environment established the “Committee for Prevention and Precaution”, aimed at assisting the Ministry in founding its policies on the principles of prevention and precaution and in filling the gaps between research and scientific knowledge on the one hand, and regulatory action on the other. The Committee is composed of experts chosen so as to cover the areas of competence of the Ministry for the Environment. Among the priority topics of research with which the Committee has been entrusted are dioxins and pesticides; health impacts of climate change, genetically modified organisms etc. The Committee has carried out research on these topics and issued recommendations⁵⁵.

International Co-operation

68. Often, environmental damage is due not to one single action, but to an accumulation, or synergies of a multitude of actions. Therefore, co-ordinated action among potential “co-polluters” is often essential to prevent or minimise environmental damage. At the national level, this is often achieved through regulation imposing certain measures or prohibiting certain actions or procedures. At the international level, this can be achieved through international co-operation.

69. International co-operation can take a variety of forms, and includes accepting binding commitments, by agreeing to certain behaviour, taking part in common programmes or projects, etc. Exchanging information, e. g., on national practices or results of research programmes, is often part of international co-operation. The Biosafety Protocol for example has put in place a Biosafety Clearing House, in order to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms and to assist Parties in implementing the Protocol⁵⁶.

70. Monitoring complements research and international co-operation, and can be considered critical to the application of precaution. The EC Council Resolution on the Precautionary Principle provides that “decisions taken in accordance with the precautionary principle should be reviewed in the light of developments in scientific knowledge, and, to that end, the impact of such decisions should be monitored and additional research conducted in order to reduce the level of uncertainty”⁵⁷.

International co-operation for the protection of the seas

71. An example of precautionary action through international co-operation on a regional scale is the concerted action of the 18 Contracting Parties to the Mediterranean Action Plan with regard to the tributyl tin content of anti-fouling marine paint, one of the most toxic substances ever introduced intentionally to the marine environment⁵⁸. The contracting parties decided to put into effect control measures before receiving any conclusive results as to the danger of this paint to marine habitats. Subsequently the harm to the environment of tributyl tin was confirmed⁵⁹.

⁵⁵ Comité de la prévention et de la précaution. Rapport d'activité 1996-1998. Ministère de l'aménagement du territoire et de l'environnement.

⁵⁶ Article 20 of the Biosafety Protocol.

⁵⁷ EC Resolution on the Precautionary Principle, paragraph 21.

⁵⁸ *The North Sea. An Integrated Ecosystem Approach For Sustainable Development*, www.odin.dep.no.

⁵⁹ L.D. Mee, *Scientific Methods and the Precautionary Principle* in D. Freestone, E. Hey, eds., op. cit., page 109.

72. *The North Sea Conference sought to protect the North Sea from potentially damaging substances, even where there was scientific uncertainty on the effects of such substances. The North Sea has been subject to eutrophication, oil pollution, pollution by hazardous substances and chemicals, and radioactive substances for many years. The countries that joined this conference realised the importance of co-operation in order to achieve their environmental goals. The types of measures taken include: bans on the dumping and incineration of waste at sea, reduction of inputs of nutrients by 50%, cessation of all inputs of hazardous substances within one generation (by the year 2020), bans on the dumping of offshore installations, bans on the use of tributyl tin.*

Measures of consent and approval, and identification requirements

Prior Informed Consent

73. Controlling potentially damaging actions, such as trade in dangerous substances, requires that decision-makers be provided with sufficient information to decide whether a certain action may proceed and if so, under which circumstances. In the context of trade, prior informed consent (PIC) is a procedure that requires the prior, informed, written consent from transit countries and from the country of import. To avoid creating unnecessary barriers to trade on certain goods, without diminishing the importing countries' ability to be aware of potential dangers, prior informed consent procedures have been agreed at the international level.

74. Prior informed consent procedures are provided for in the Basel Convention on the Control of Transboundary Movements of Hazardous Waste and their Disposal, the Protocol on Biosafety and CITES. More recent examples are the 1998 Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade and the Protocol on Biosafety. These agreements are driven in part by the recognition that, often, developing countries do not have the infrastructure and capacity to control their borders adequately. Hence, these agreements place the responsibility, e.g., to provide adequate information on the product to be imported, onto the exporting Party.

The Advanced Informed Agreement Procedure under the Protocol on Biosafety

75. *The Advanced Informed Agreement (AIA) Procedure, provided for in the Protocol on Biosafety, applies prior to the first intentional transboundary movement of certain living modified organisms (LMOs) for intentional introduction into the environment of the Party of import. Under this procedure, the Party of export must notify or require the exporter to ensure notification to the competent authorities of the country of import, of certain information concerning the exporter and the LMO concerned. Among the information that must be provided is a risk assessment report, carried out in compliance with the requirements fixed in the Protocol⁶⁰. On the basis of the information contained in the notification, the Party of import can within a specified period, approve the import, prohibit it, request additional relevant information, or inform the notifier of an extension of the period. Where there is lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a LMO on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risk to human health, the AIA allows the Party of import to take a decision, as appropriate, with regard to the import of an LMO, to avoid or minimise such potential adverse effects⁶¹.*

⁶⁰ Annex I of the Protocol sets out the information required in notification; Annex II describes the requirements of risks assessments.

⁶¹ The AIA procedure is described in Articles 7 ss of the Protocol.

Approval Procedures

76. Approval procedures take the form of a series of requirements that need to be satisfied before an action (such as introduction of a new product on the market, or the import of certain products) is approved by the competent authorities. Approval procedures are an essential element in the marketing of chemicals, food and food additives, and pharmaceuticals.

Approval procedures in the US

77. *In the US, in such areas as pesticide, food additive, drug, and medical device safety, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA) require that products be reviewed and approved before they can be marketed. Consistent with statutory obligations, the United States prohibits the use or import of these products unless the regulatory authorities are satisfied that the product meets health, safety and environmental requirements. In addition, the Toxic Substances Control Act (TSCA) requires prior notification to EPA before other new chemical substances are manufactured⁶².*

Identification requirements

78. Identification requirements, such as classification and labelling, serve to provide information on the properties of a product, thereby alerting interested parties (e.g., authorities, consumers, workers handling the product) about its potential risks. A labelled, or otherwise identified product can be handled with specific care, or be subject to special controls, thereby diminishing the potential risks that uncontrolled handling could entail.

79. Labelling can be compulsory or voluntary. Labelling is generally compulsory when the good in question is or is perceived to be more damaging than a similar one or risks causing a damage (for example, radioactive material) or being damaged (for example, live animals), if improperly handled. Sometimes, instead of labels, authorities require products to be accompanied by detailed information on the characteristics and risks of the product. Voluntary labelling reflects the choice of consumers to be informed about its specific characteristics, or about the way in which it has been produced (e.g., recyclable containers, organic food, etc.)⁶³. Such labelling schemes provide consumers with additional information about a product and empower them to make choices according to their own interests⁶⁴.

80. A number of MEAs contain identification requirements aimed at informing the authorities of the importing country of the contents of the shipment characteristics. Examples are the Protocol on Biosafety⁶⁵, the Convention on Prior Informed Consent Procedure for Certain Hazardous Chemicals and

⁶² Examples provided by the US

⁶³ The Consumer's Choice Council's *Activist Handbook on Genetically Modified Organisms and the WTO*, by Mathew Stilwell and Brennan Van Dyke, (Center for Environmental Law) contains a discussion on GMO labelling and the precautionary principle. www.consumerscouncil.org.

⁶⁴ Steve Charnovitz, *The Supervision of Health and Biosafety Regulation by World Trade Rules*, Tulane Environmental Law Review, Summer 2000.

⁶⁵ Article 18 contains detailed provisions on the handling, transport, packaging and identification of living modified organisms.

Pesticides in International Trade⁶⁶ and the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal⁶⁷.

GMO labelling in OECD countries

81. *The Australia-New Zealand Food Standards Council (ANZFSC) agreed in October 1999 to implement mandatory labelling for genetically modified foods and products where GM characteristics are present and detectable in the final product. Implementation will be based on detectability/testing or verifiable paper audit trail⁶⁸. Japan requires labelling for certain products containing GMOs both produced domestically and imported. Labelling is required for those products for which GMOs are among the top three raw materials and/or account for more than five percent of the total weight.*

Classification of chemicals in Austria

82. *In the Austrian Chemicals Act, in connection with the duty to classify chemicals, the precautionary principle is explicitly mentioned: "The principle of precaution is to be observed when classifying substances and preparations. If - when applying the classification principles referred to in paragraph 2 - there are reasonable grounds to suspect the presence of a hazardous property within the meaning of § 3 paragraph 1, the substance or preparation is to be classified according to this hazardous property as a precautionary measure."⁶⁹*

Management and control of risks

83. Precaution is called for in situations where an action or activity has been identified as potentially causing damage. Once risks have been assessed, decision makers are called to manage such risks.

84. Certain measures aim at limiting a potentially damaging action, or reducing its scope. Examples of such measures are bans, prohibitions, quotas and moratoria.

85. Governments can fix the level of risk or damage that they are able or willing to accept, by setting standards, beyond which an activity is not allowed. Standards help ensuring that an activity remain within the limits of known risks, thereby excluding, or at least limiting, the possibility of uncontrolled, potentially dangerous situations.

Risk management

86. Risk management has been defined by Codex Alimentarius as the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessments and other factors for the health protection of consumers, and for the promotion of fair trade

⁶⁶ Under Article 13, each Party shall require that both chemicals listed in Annex III and chemicals banned or severely restricted in its territory are, when exported, subject to labelling requirements that ensure adequate availability of information with regard to risks and/or hazards to human health or the environment, taking into account relevant international standards.

⁶⁷ Under Article 4.7. b), each Party shall require that hazardous wastes and other wastes that are to be the subject of a transboundary movement be packaged, labelled, and transported in conformity with generally accepted and recognized international rules and standards.

⁶⁸ The measures will come into force in December 2001. Information provided by Australia.

⁶⁹ Example provided by Austria.

practices, and if needed, selecting appropriate prevention and control options⁷⁰. Risk management has been seen as an essential component of risk analysis, together with risk assessment and risk communication⁷¹.

87. According to the World Bank, which sees risk management as the process of implementing decisions about accepting or controlling risks, based usually on cost-benefit analysis, risks may be controlled through the application of technology, procedures or alternative practices. The iterative nature of risk management requires that control technologies or alternative practices be re-evaluated for associated risk⁷². Where full scientific evidence related to a potential damage is not available, risk managers are often called to apply precaution.

Risk management plans for GMOs

88. *In Switzerland, the precautionary principle has to be taken into account for the deliberate release of genetically modified organisms into the environment. Once a risk assessment has been carried out, and taking into account uncertainties relating to lack of specific scientific knowledge, the applicant for such release has to define a risk management plan to prevent possible damage to human health and the environment. The measures defined in the risk management plan have to be based on the precautionary principle and must fulfil the following criteria: they have to be proportionate to the degree of safety necessary; comparable to measures required for releases of genetically modified organisms with comparable risks; adequate with respect to the cost/benefit ration and public acceptance, and adapted by the applicant in case new scientific knowledge becomes available. Authorisation for the release of genetically modified organisms in field trials or as products has to be based on the risk management plan and can only be denied in case human health and the environment cannot be protected sufficiently⁷³*

Measures prohibiting or limiting a potentially damaging action or process

Bans and prohibitions

89. Bans prohibit an activity, or the production and/or trade of a good. This type of measure is one of the most straightforward ones, since it aims at eliminating the problem at its root. When evaluating the effectiveness of this type of measures, it is necessary to take account, where appropriate, of the potential harm of the *current* or *substitute* practice or good.

90. Several MEAs impose bans. The Montreal Protocol on Substances that Deplete the Ozone Layer establishes legal obligations to limit the use and production of specific chemicals based on calculations of their ozone-depleting potential and imposes trade restrictions on imports and exports with non-parties. The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, allows trade with hazardous wastes only under certain conditions, which include the unavailability of suitable disposal facilities in the country of generation. It recognises that any State has the sovereign right to ban the entry or disposal of foreign hazardous wastes and other wastes in its territory. The import and export of hazardous wastes from non-Parties is prohibited, unless it is subject to an agreement or arrangement the provisions of which are no less environmentally sound, or compatible with the environmentally sound management of hazardous wastes under the Basel Convention.

⁷⁰ SG/ADHOC/FS(2000)5/FINAL, page 7.

⁷¹ EC Communication on the Precautionary Principle.

⁷² Environmental Assessment Sourcebook, World Bank, 1997.

⁷³ Example provided by Switzerland.

Bans on CFCs

91. *In Norway, the prohibition of CFCs as aerosol propellant in spray cans was implemented in 1980. At that time, knowledge about the decomposition of the ozone layer was not generally accepted and the prohibition was based on the precautionary principle. Similarly, the Norwegian authorities adopted as a goal in 1996 to phase out by 2000 certain endocrine disruptors (alkylphenols and etoxylates), suspected to cause serious damage to health and the environment. This goal has been set even though sufficient scientific proof to establish a cause-effect relationship is not available*⁷⁴

Prohibition of activities related to endangered species

92. *In the US, the 1973 Endangered Species Act (ESA) seeks “to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved [and] to provide a program for the conservation of such endangered species and threatened species.” An endangered species is defined as “any species which is in danger of extinction throughout all or a significant portion of its range,” and a threatened species as “any species which is likely to become an endangered species throughout all or a significant portion of its range.” A determination that a species is endangered triggers the imposition of statutory restrictions upon activities that may threaten it, such as taking, selling, exporting and importing. For threatened species, the Secretary of the Interior (for most marine species, the Secretary of Commerce) issues regulations defining activities that are prohibited. In addition, each federal agency must ensure that any proposed action “is not likely to jeopardize the continued existence” of any listed species*⁷⁵.

Quotas

93. Quotas do not prohibit an activity, but impose a quantitative restriction. This type of measures is generally used in the conservation of natural resources, in particular, in the area of fisheries. Quotas are found in MEAs such as CITES, the 1978 Convention on Future Multilateral Co-operation in the Northwest Atlantic Fisheries and the 1993 Convention for the Conservation of Southern Bluefin Tuna (CSBT Convention).

Quotas on fishing stocks

94. *In 1997, the Scientific Council of NAFO (North Atlantic Fisheries Organisation) recommended that the yellowtail flounder stock (in the designated areas, “3LNO”) could be re-opened in 1998 with a TAC (total allowable catch) of 4,000t. It also specified a number of management conditions for re-opening the fishery that were consistent with the precautionary approach. The NAFO implementation plan includes a statement of management objectives, harvest strategies and reference points, conservation measures, and research and monitoring. By this time, Canada had developed some experience in applying more stringent conservation measures on stocks which were not under moratorium. These measures were aimed at promoting a solid assurance of management control. Canada also recognised that setting a TAC is only the first step in reopening a fishery. In all cases where a reopening was recommended, a number of management conditions were specified. These conditions were imposed to ensure control of the fishery, protection of the stock against over-exploitation, and gathering of additional information about stock status*⁷⁶.

⁷⁴ Example provided by Norway.

⁷⁵ Example provided by the US.

⁷⁶ Example provided by Canada.

Moratoria

95. Moratoria are temporary bans of an activity, including trade with certain goods. Moratoria are used e.g., in fisheries conservation, to allow, i.a., for stocks to recover. Moratoria are also called for in cases of uncertainty about the potential consequences of an activity, and are in such cases generally accompanied by programmes for further research⁷⁷.

Moratorium on the use of driftnets

96. *The UN Resolution on “Large scale pelagic drift net fishing and its impact on the living marine resources of the world’s oceans and seas”, which recommends a moratorium on driftnet fishing has been considered to be precautionary in two separate fashions⁷⁸. Firstly in that it proposes action to address a serious threat to the environment while there is still some scientific uncertainty as to the impacts of driftnet fishing. Secondly the moratorium shifts the burden of proof onto those with the intention of continuing the practice described under the moratorium to demonstrate that their actions will not have an unacceptable impact on the conservation of living marine resources.⁷⁹*

Standards and limits

97. Standard setting has been described as the confluence of science and policy determination⁸⁰. By setting a standard, decision-makers establish what is the limit of an acceptable level of pollution, or, where scientific evidence is insufficient, of risk of pollution or of environmental damage. Standards and limits include for example minimum quality standards or maximum tolerable contamination levels (threshold, safety standards) for specific environmental resources such as air and water or for consumption resources such as food and feedstuffs; minimum quantity standards for non-renewable resources and for those renewable resources which have a critical zone below which depletion becomes irreversible; maximum permissible standards of waste emission, etc.⁸¹

98. International standards set under conditions of uncertainty are closely related to the problem of different perceptions of risk. Countries differ in their perception of risk and of the types of measures needed to reduce such risk; internationally agreed standards set an acceptable level of risk to all the parties. International agreements and recommendations often contain provisions specifically indicating that Parties can take more stringent measures, or implement them more quickly, than agreed.

Thresholds in US pesticide regulation

99. *In the US, in establishing maximum residue levels for pesticides that have “threshold” levels below which no effects would be expected, the Federal Food, Drug, and Cosmetic Act directs EPA to apply an additional ten-fold safety factor “to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children.” EPA may use a*

⁷⁷ See in this regard the OECD Recommendation on Principles concerning Coastal Management C(97)161(Final), which recommends a moratorium on certain types of developments in coastal zones which could have irreversible adverse effects on the environment.

⁷⁸ UN Resolution 44/225.

⁷⁹ D. Freestone and E. Hey, op. cit. , page 5 ss.

⁸⁰ Bernard A Weintraub, *Science, International Environmental Regulation, and the Precautionary Principle: Setting Standards and Defining Terms*, New York University Environmental Law Journal 1992, page 12.

⁸¹ Peter H. Sand, *Transnational Environmental Law. Lessons in Global Change*, 1999, page 31.

different “margin of safety” factor only if the Agency has reliable data indicating that a different factor will be safe for infants and children. In addition, the law requires EPA to consider available information on potential variability among major identifiable population groups in terms of sensitivity to pesticide effects, when making safety determinations as to permissible residue levels in food⁸².

Reduction targets for chemicals in Norway

100. In Norway, the precautionary principle is taken into account when setting quantified reduction targets related to the goal of protecting human health and the environment. The Government has adopted a priority list that specifies goals to phase out or substantially reduce emissions of some twenty or so chemical substances and groups of substances within certain time limits. For some substances, reduction targets have been set where there is substantial uncertainty regarding the degree of risk that the substances pose for human health or the environment.

⁸² Example provided by the US.

III. IMPLICATIONS OF PRECAUTION FOR TRADE AND ENVIRONMENT: ISSUES FOR DISCUSSION

Introduction

101. Numerous national and international environmental instruments incorporate the concept of the use of precaution in situations of uncertainty. Trade agreements also seem to leave room for precautionary approaches. However, there are differing views on how adequately existing instruments and arrangements and the jurisprudence associated with these instruments, address the relationship between precaution and international trade. Sometimes, precautionary measures can affect or be seen to affect, international trade thus creating conflicts between the need to protect the environment and the principles of free trade⁸³.

102. This chapter describes some of the issues raised by the relationship between precaution and international trade. It does not attempt to solve the existing conflicts or divergence of views, but intends to provide some background information to stimulate further discussion of these issues. It will in particular deal with the following subjects, all of which are closely inter-related:

103. *The role of science.* Science is inherent to the assessment of risk. On the one hand, by showing that there is a potential, serious environmental problem, it may provide sufficient basis to trigger protective measures. On the other hand, it does not always provide enough proof on the link between the cause and its consequences or their extent, and therefore, to fully justify the need or scope of precautionary measures. This may raise conflicts, when measures taken by a country affect trade, and where the scientific basis for such measures is challenged by other countries. Opinions may differ on whether, and to what extent other factors than science could be considered relevant in adopting precautionary measures.

104. *Transparency and consultation.* When deciding on measures based on uncertainty, the perceptions and acceptance of risks by society are also important factors for decision-makers. Transparency, consultation and communication with affected parties are increasingly incorporated in decision making processes.

⁸³

In its Communication on the Precautionary Principle, the EC considers that where action is deemed necessary, measures based on the precautionary principle should be, *proportional* to the chosen level of protection, *non-discriminatory* in their application, *consistent* with similar measures already taken, based on an *examination of the potential benefits and costs* of action or lack of action, *subject to review* in the light of new scientific data, and *capable of assigning responsibility* for producing the scientific evidence necessary for a more comprehensive risk assessment. It explains the requirement of non-discrimination to mean that “*comparable situations should not be treated differently and different situations should not be treated in the same way, unless there are objective grounds for doing so. Measures taken under the precautionary principle should be designed to achieve an equivalent level of protection without invoking the geographical origin or the nature of the production process to apply different treatments in an arbitrary manner*”. EC Communication on the Precautionary Principle, pages 4 and 19.

105. *The costs of precaution.* Precautionary measures have a cost, and the decision to allocate this cost to one or other party in a process – e.g., industry or governments, importer or exporter, can have important implications, including trade implications.

106. *Developing countries' concerns regarding precaution:* Developing countries are likely to have particular difficulties, on the one hand, to cope with the potential trade impacts of precautionary measures taken by other countries, and on the other hand, to adopt precautionary measures themselves.

Precaution and science

The role of science in the decision-making process

107. All human activities have an impact on the environment, and often, that impact can be negative. In many cases, threats to the environment are the result of complex processes with origins which are difficult or impossible to identify. By the time these impacts become visible, significant, sometimes irreversible, changes have taken place.

108. Decision making under uncertainty in the area of environmental protection consists in choosing the right measures while avoiding certain pitfalls, such as adopting measures which are ineffective or even more damaging than inaction, taking them at the wrong time, or taking measures whose cost outweighs the benefits they are intended to achieve, rather than adopting cost-effective measures⁸⁴. To avoid such pitfalls and to make sound decisions, decision-makers require as much information as possible on the potential consequences of an action or inaction. The contribution of science, to help assess the potential impacts of an action is therefore essential to the decision-making process⁸⁵. Though they do not take the final decisions, scientists are deeply implicated in the processes of environmental policy formation⁸⁶.

109. The assessment of risks using sound science, and the application of precaution can be considered complementary: once scientific evaluation has been completed, and if such evaluation reveals a degree of uncertainty, decision makers need to decide on whether precautionary measures are necessary, and what the appropriate measures are⁸⁷. In other words, precaution underlies the use of available scientific and technical information to make informed policy decisions, and can be seen as an option for decision-makers

⁸⁴ *Dealing with Uncertainty*, OECD, 1991 [ENV/EC/ECO (91) 12].

⁸⁵ At the OECD Environment Committee meeting at ministerial level held in 1991, Ministers “reaffirmed that the precautionary principle will guide their approach when confronted by threats of serious or irreversible environmental damage”...and “agreed on the central role that science plays in environmental decision-making, and that OECD governments should strengthen their efforts to support and encourage the international science community to assess environmental risks to human health and natural ecosystems...” SG/Press(91)9, paragraph 38.

⁸⁶ Konrad von Moltke, “*The relationship between policy, science, technology, economics and law in the implementation of the precautionary principle*”, in D. Freestone, E. Hey, op.cit., page 98.

⁸⁷ The Vienna Convention for the Protection of the Ozone Layer is an example of the importance of science to allow decision-makers to adopt preventive measures in the light of uncertainty. After scientists first realised that certain chemicals pose a threat to the ozone layer, extensive efforts were undertaken to measure the seriousness of the problem. Subsequently, scientists tackled the underlying causes by finding alternative chemicals that could replace ozone-depleting substances. Acknowledging the dominant role of science is key in assessing how the international community has responded to the threat of ozone depletion and in drawing lessons that might be applicable to other environmental issues *International Agreements*, background paper for the Fifth Annual World Bank Conference on Environmentally and Socially Sustainable Development.

when science does not provide the necessary or adequate knowledge about a potential damage, or when there are divergent scientific opinions that cast a doubt over the certainty they can provide⁸⁸.

Science and assessment of risks

110. One of the most controversial issues in the debate on risk, uncertainty and precaution is the role of science in the assessment of risks. As seen in chapter I of this paper, some international instruments require that decisions taken in cases of uncertainty be based on science (e.g. the SPS Agreement). Other instruments (including the GATT and the TBT Agreement, and various MEAs) do not include such requirement. Further, there is no general agreement on whether the assessment of risks is a purely scientific process, or whether other factors, such as consumer concerns, cultural or moral preferences and societal value judgements may be taken into account when determining a risk⁸⁹.

111. In the Hormones case, the Panel held that that a risk assessment required by Article 5.1 of the SPS Agreement is a “*scientific process aimed at establishing the scientific basis for the sanitary measure a Member intends to take*”. The Appellate Body rejected this view, to the extent that the Panel “*purports to exclude from the scope of a risk assessment in the sense of Article 5.1, all matters not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences*”⁹⁰. The Appellate Body further recalled that some of the factors listed in Article 5.2 are “*not necessarily or wholly susceptible of investigation according to laboratory methods of, for example, biochemistry and pharmacology. Furthermore, there is nothing to indicate that the listing of factors that may be taken into account in a risk assessment of Article 5.2 was intended to be a closed list*”⁹¹. A summary of findings of the Appellate Body on science and risk assessment is set out in Annex III.

112. Concerns have been expressed, i.a. by the business community, that the application of precautionary measures which are not based on sound science, or sufficiently supported by scientific evidence, may i.a., “*threaten economic interests, add significant transaction costs and distract resources from better understanding and resolving the environmental issues in dispute*”⁹². One position in this debate is that precaution must be exercised as part of a science-based approach to regulation, not as a substitute for such an approach; and that while different countries may choose their own levels of protection and a variety of policy considerations can inform such decisions, there must be some rational basis for concern based upon available pertinent information when exercising precaution. Similar concerns have been voiced in relation with potential economic trade impacts of precautionary measures: political or economic needs,

⁸⁸ For a more detailed discussion of the debate *between sound science and the precautionary principle*, see P. Hardstaff, Science and Precaution in the Trade Regime, Presentation to the RIIA Conference on Sustainability, Trade and Investment, March 2000, and K. von Moltke, op. cit., D. Freestone, E. Hey, op.cit.

⁸⁹ J. Pauwelyn *The WTO Agreement on Sanitary and Phytosanitary Measures as applied in the first three disputes, EC-Hormones, Australia-Salmon and Japan-Varietals* 2(4) *Journal for International Economic Law*, 1999.

⁹⁰ Hormones case, paragraph 187 of the Appellate Body report.

⁹¹ Hormones case, paragraph 187 of the Appellate Body report. Article 5.2 of the SPS provides: “*In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest-or disease free areas; relevant ecological and environmental conditions; and quarantine and other treatment.*”

⁹² See BIAC’s statement on “*Sound Science and the Precautionary Approach*” submitted at the consultation with the OECD Trade Committee in February 2001.

perceived or non-science based fears etc. should not be a substitute for a science-based approach. It has also been said that economic and political interests should not be triggers of precautionary measures, though they may be elements in the broad application of precaution as a general concept.

The limits of science

113. While science is necessarily part of international environmental management it is important to separate what science can do from what it cannot. Science can help define a problem and often, it can help to determine the appropriate solutions. But science alone cannot decide on whether to seek a solution in the first place, or how to define an acceptable solution⁹³. Science may be able to provide knowledge, for example, to establish indicative standards, but it cannot conduct the political balancing necessary to set the actual threshold, nor to decide on the concrete measures that are necessary to achieve such standards. In short, science can help in *analysing and assessing* a risk, but the *management* of that risk and balancing the different factors in play is the responsibility of decision-makers. Science however has also a role in risk management, in providing information about alternative approaches and on the potential consequences of actions taken by decision-makers.

114. The current debate over GMOs provides an example of the limits of science in the general evaluation of a risk. While certain countries consider that research carried out over the past 15 years has not confirmed the initially suspected risks on the environment and human health from such organisms, and therefore precautionary measures can now be lifted, others consider that the harmlessness of GMOs has not been sufficiently established, and that precaution is therefore still necessary⁹⁴.

115. A further problem is that science does not provide a single answer: science may give very different answers to the same question, and scientists are often able to provide equally sound arguments in support of divergent theories. Science can be influenced by political and economic interests. A key question for policy makers is therefore which science to use. The question cannot be solved by distinguishing between research funded publicly, and privately sponsored research. Public funding for research and targeting of public funds for research both can have a real contribution to make to counter the dominance of industry research in some fields, or to complement it. But industry funded research has also played an important role in international environmental policy developments, for example, in the evolution of the ozone regime.

116. Scientific uncertainty can often derive from a lack of scientific consensus. The Protocol on Biosafety takes account of this difficulty and states that “*Lack of ... scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk*”⁹⁵. The WTO Appellate Body has also accepted that there may be divergent scientific opinions, and considers that “*in some cases, the very existence of divergent views presented by qualified scientists ... may indicate a roughly equal balance of scientific opinion, which may itself be a form of scientific uncertainty...*”⁹⁶.

⁹³ Decisions taken by scientists within the bounds of scientific methods are important and may have a significant impact on the final result. For example the outcome of a risk assessment will largely depend on starting assumptions.

⁹⁴ Anne Laudon and Christine Noiville, op. cit., page 68.

⁹⁵ Biosafety Protocol, Annex II, paragraph 4.

⁹⁶ Hormones case, paragraph 194 of the Appellate Body report.

Precaution and scientific innovation

117. One way to avoid a risk from an action is to refrain from undertaking such action. However, this may in some cases be an obstacle to scientific development, and consequently, to innovation and progress. Decision-makers are not expected to ensure a totally risk-free environment in the broadest sense, but to balance the different interests and risks related thereto. Preventive, and where necessary, precautionary measures should avoid or minimise risks without however stifling innovation nor preventing society to benefit from new scientific and industrial developments. Striking the balance between these interests is without doubt one of the most difficult issues in relation with scientific innovation (e. g., in relation with nuclear power), and is currently at the heart of the debate on genetically modified organisms and genetic engineering. On the other hand, precaution can also promote innovation by fostering the development of alternatives to potentially dangerous products, processes or activities. For example, action to prevent depletion of the ozone layer has promoted the use of innovative alternatives to CFCs.

Evolution of scientific knowledge

118. As described in Section I above, Article 5.7 of the SPS Agreement allows that “*in cases where relevant scientific evidence is insufficient, a Member [may] provisionally adopt sanitary and phytosanitary measures on the basis of available pertinent information (...). In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time*”.

119. Some authors criticise the fact that the SPS Agreement introduce the notion that Members may “*provisionally*” adopt measures in cases of insufficient scientific evidence. They question the capacity of science to provide full certainty about the environmental consequences of an action and argue that full scientific certainty is neither achievable nor provable⁹⁷. Others argue that science rarely provides clear proof of major environmental impacts because the environment is too complex to be comprehensively described in strictly scientific terms⁹⁸. The environment is not a static but an evolving system, and new, unexpected consequences can arise due to an accumulation of impacts, or synergies between various impacts. Therefore, situations which at some point seemed scientifically fully or sufficiently assessed may develop and raise new uncertainties⁹⁹.

Transparency and consultation

120. While it is generally recognised that, when adopting precautionary measures, science and scientific risk assessment play a fundamental role in the decision-making process, it has also been maintained that such decisions should be taken in a framework of transparency and openness towards those concerned¹⁰⁰.

⁹⁷ Justice L. Stein AM, *Are Decision-makers too cautious with the precautionary principle*, at Lawlink, page 3, K. von Moltke, op.cit., pg 98; P. Hardstaff, op. cit., page 5.

⁹⁸ K. von Moltke, op. cit., page 99.

⁹⁹ An example, provided by France, is the development of measures concerning dioxines. While at a certain time, knowledge about the environmental impacts of dioxines allowed to determine the known risks, and to adopt preventive measures, further research has revealed new risks of imprecise magnitude and severity. This has lead to the adoption of precautionary measures with regard to these risks, following the recommendations of the Committee for Prevention and Precaution.

¹⁰⁰ See i.a., the EC Council Resolution on the Precautionary Principle.

121. Uncertainty about a potential serious risk generates fear and any action or inaction of decision-makers in those situations comes under increased public attention. In addition, the increasing influence of civil society on decision-making processes reinforces the need to take into account public concerns at early stages of the decision-making process, and to keep the public informed of developments in a given situation and measures taken to address a risk¹⁰¹.

122. Transparency at all levels is also essential to prevent wrong or exacerbated perceptions of a risk, as opposed to an objective risk, assessed on the basis of scientific evidence. While for the general public this may be particularly important in the field of food safety, as recent experience has shown, it is also essential in other areas, including risks to the environment.

123. Adopting precautionary measures implies imposing a cost to society now in order to avoid the possibility of degradation in the future. Assumptions about the costs society is willing to accept in return for a better-protected and preserved environment therefore play an important role in the decision-making process¹⁰². Generally, there are divergent views within society, and balancing these also requires attention. Canvassing the views of the parties whose interests are affected by a project or a concrete measure allows gauging the degree of risk averseness amongst stakeholders, and allows accommodating such averseness in the final decision¹⁰³.

124. In its “Communication on the Precautionary Principle”, the EC Commission says that decision-makers need to be aware of the degree of uncertainty attached to the results of the evaluation of the available scientific information. Judging what is an “acceptable” level of risk for society is an eminently political responsibility. Decision-makers faced with an unacceptable risk, scientific uncertainty and public concerns have a duty to find answers. Therefore, all these factors have to be taken into consideration. The EC Council Resolution on the Precautionary Principle calls on Member States and the Commission to “*ensure that the public and the various parties involved are informed as fully as possible about the state of scientific knowledge, the issues at stake and the risks to which they and their environment are exposed*”¹⁰⁴.

125. Non-governmental organisations see public participation as an important element in the decision-making process in situations of uncertainty. The European Environmental Bureau (EEB) for example considers that there is a considerable degree of subjectivism in choosing for a risk averse or a risk friendly approach, different within and between different societies. Decisions on the acceptability of technologies and activities, as well as on the intensity of their control cannot be defined by “sound science” alone, but requires a mechanism to identify the preferences of the society¹⁰⁵. Similarly, according to the

¹⁰¹ The OECD Recommendation on the Use of Economic Instruments in Environmental Policy [C(90)177/FINAL] provides guidelines for the implementation of such instruments, some of which also seem pertinent for measures adopted in situations of uncertainty. For example, to increase the acceptability of instruments it recommends to disseminate information to target groups concerning aspects of the instrument (or measure) that may affect them, to conduct consultations with target groups concerning the application of such instruments, and to make timely announcements of these instruments.

¹⁰² E. Hey, *The precautionary approach and the London Dumping Convention*, 1991.

¹⁰³ *The Appraisal of Environmental Projects and Policies, a practical guide*, OECD, 1995, page 146.

¹⁰⁴ See also EC Commissioner David Byrne, “Address on the Precautionary Principle in the domain of human health and food safety”; www.europa.eu.int

¹⁰⁵ EEB position on the precautionary principle, 1999, <http://www.eeb.org>.

“Wingspread Statement on the Precautionary Principle”, the “*process of applying the Precautionary Principle must be open, informed and democratic and must include potentially affected parties*”¹⁰⁶.

126. The studies undertaken by the OECD on transparency and consultation in trade and environment reflect that OECD Members are increasingly keeping society informed and involving the public in the decision-making process, including on issues such as the impacts of new technologies (such as biotechnology), food safety, adoption of environmental measures (including precautionary measures) and their impacts on trade, etc.¹⁰⁷

The costs of precaution

Balancing risks and costs

127. Theoretically, environmental risks can be minimised so as to approach the level of zero; however, the costs of attaining this goal increase disproportionately. Finding the right balance between acceptable risk and acceptable costs is not easy, and decision-makers have to weigh the different concerns, as well as the attached costs. The greater the uncertainty of a risk, the more difficult it is to find such balance. It has been suggested that the measures taken for the implementation of precaution should be proportionate to the degree and extent of the risk to be reduced¹⁰⁸.

128. A further factor that should be considered is the degree to which society is ready to pay to avoid a certain risk. Experience shows that society sees certain risks as being unacceptable, even if the probability of damage is very remote, whereas other risks are more easily accepted¹⁰⁹. For example, society can accept or be relatively indifferent to a relatively high mortality rate of certain species, but is ready to accept a higher cost for the protection of others. These different perceptions can lead to imposing costs on certain sectors and not on others.

129. The 1991 OECD paper “Dealing with Uncertainty” examines the economic aspects of precautionary environmental approaches by comparing two different strategies, one focusing on “precaution”, the other one on “research”¹¹⁰. It tries to provide a response to the dilemma of whether action should be taken in complete ignorance of what the outcome will be and then, in the light of the actual

¹⁰⁶ The Wingspread Statement was adopted by an international group of scientists, government officials, lawyers and labour and environment activists, in January 2000 <http://www.ratical.org>.

¹⁰⁷ An example, provided by France, is the Citizens Conference on GMOs held in 1998.

¹⁰⁸ EC Communication on the Precautionary Principle, E. Rehbinder, *The precautionary principle in an international perspective*, 1994, page 100.

¹⁰⁹ Speed limitations are an example of divergent levels of acceptance of a risk: in spite of evidence that speed increases the risk and severity of road accidents, speed limitations are set at very different levels in different countries.

¹¹⁰ Dealing with Uncertainty, ENV/EC/ECO(91)12, prepared for the Group of Economic Experts of the Environment Committee, was an exploratory study in the framework of the OECD project on “Economics of Sustainable Development”. The study shows that the “precautionary strategy” and the “research strategy” are compatible with an economic analysis, but that the choice between them depends on the margin of uncertainty. If there is a large degree of uncertainty, it may be premature to react too quickly to a hazard whose existence has not yet been clearly established, but if the margin of uncertainty has narrowed, the precautionary principle or approach is justified on economic grounds. See also *The Appraisal of Environmental Projects and Policies*, a practical guide, OECD, 1995, which dedicates a chapter to “Uncertainty and Risk”, page 139.

outcome, think about the best strategy to be adopted, or whether one should first try to reduce the margin of uncertainty before committing major funds to pollution control. The analysis undertaken in the study shows that it is necessary to start and continue research as long as the probability of anti-pollution measures being successful seems slight, and to initiate such measures when the probability of their not being successful has become slight. It would be unwise to wait until there is absolute certainty before taking anti-pollution measures, but it would also be unwise to commit large funds on the basis of inadequate data. The cost of research, and getting information to reduce uncertainty should be kept in mind, and should not be allowed to become an end in itself but should be commensurate with the expected benefits¹¹¹.

Allocating the burden of proof

130. It has often been argued that the precautionary principle, or simply, applying precaution in the face of uncertainty, implies shifting the burden of proving that an action is not damaging to the environment to the potential “polluter”. Such a shift usually becomes necessary when there is lack of access to crucial information. Shifting the burden of proof may also be more efficient, since normally the potential polluter is best placed to provide any information about the effects of his activity. Regulators will rarely have the ability and the resources to undertake the scientific testing necessary to investigate practices or to license all potentially harmful substances or activities¹¹².

131. The decision of who should bear the burden of proof in relation with decisions based on precaution is of importance from a legal point of view, but it is also a question of economic justice: requiring regulators to prove that an activity could be harmful before imposing measures would mean shifting the costs of collecting evidence of such damage to the regulator, and thus to society at large, rather than the potential polluter. On the other hand, where the burden of proof is allocated to the polluter (e.g. the producer), the costs of precaution, though justified to protect human health, or prevent environmental damage, can, on the other hand, affect the activities of enterprises (by imposing costly measures to prevent a damage, or prohibiting certain activities)¹¹³. Similarly, requiring the exporter to provide evidence that a product does not entail a risk that is unacceptable to the importing country can have trade impacts, which potential exporters might challenge.

132. In some countries, national legislation requires proof from the person wishing to introduce a substance in the environment, or carrying out a project, that such substance or project is not damaging for the environment. For example, in the US, as a precautionary action to guard against possible harms from products in this class, pesticide producers or any person interested in maintaining a pesticide tolerance have the burden of proving that their products and any resulting residues in food meet the safety standards established by the regulatory agency charged by law with regulating pesticides..¹¹⁴. The Swedish

¹¹¹ OECD, 1995, op. cit, page 151.

¹¹² Weintraub, op. cit., page 15.

¹¹³ In its Communication on the precautionary principle, the EC Commission indicates that “action taken under the head of the precautionary principle must in certain cases include a clause reversing the burden of proof and placing it on the producer, manufacturer or importer, but such an obligation cannot be systematically entertained as a general principle. This possibility should be examined on a case-by-case basis when a measure adopted under the precautionary principle, pending supplementary scientific data, so as to give professionals who have an economic interest in the production and/or marketing of the procedure or product in question the opportunity to finance the necessary research on a voluntary basis. EC Communication, page 22.

¹¹⁴ The Federal Food, Drug, and Cosmetic Act (FFDCA) provides that any pesticide residue on foods “shall be deemed unsafe” and therefore cannot be distributed in commerce unless a tolerance or tolerance

Environment Protection Act of 1969 introduced the concept of environmentally hazardous activities, for which the burden of proof is flatly reversed, i.e., the regulatory authorities do not have to demonstrate that a certain impact will occur, instead, the mere risk, if not remote, is to be deemed enough to warrant protective measures or a ban on the activity. This is also reflected in the legislation of other Nordic countries¹¹⁵.

133. Some international environmental instruments place the burden of proof on the party wishing to engage in a potentially environmentally damaging activity. One example is the moratorium on large-scale driftnet fishing recommended in UN Resolution 44/225. The moratorium was agreed on the basis that those who would seek to continue the practice of driftnet fishing had to demonstrate, “*using statistically sound analysis*”, that measures had been taken “*to prevent the unacceptable impact of such fishing practices and to ensure the conservation of the living resources of that region*”¹¹⁶.

134. A recent example is the Biosafety Protocol, which has been interpreted to allocate the burden of proof on the exporter to establish the harmless nature of a living modified organism¹¹⁷. While it requires the party of import to ensure that risk assessments be carried out, including in cases where precautionary measures are taken, it specifically allows the importer to require that the exporter carry out risk assessments and/or require exporters to pay for risk assessments¹¹⁸. The final decision on whether to authorise the import remains with the importing authority¹¹⁹.

Developing countries’ concerns regarding precaution

135. Many developing countries are Parties of international instruments in which precaution is embedded, both in the field of environmental protection (e.g. the Rio Declaration, subscribed by a large majority of countries in the world) and in the area of trade (e. g. the SPS Agreement). Some have also incorporated precaution in their legislation or practice¹²⁰.

136. However, developing countries may face particular problems in relation to uncertainty and precaution, and the measures called for in such situations. One concern is that developing countries may see their exports affected by precautionary measures in developed countries. Developing countries have, in numerous forums, expressed their fears that environmental protection measures (including precautionary

exemption has been issued– i.e., a default zero approach, where in the absence of a tolerance or exemption, zero residues are permitted on foods. In the case of chemicals regulated under the Toxic Substances Control Act (TSCA), EPA is explicitly authorised to regulate individual “new” chemicals in the absence of “sufficient information to permit a reasoned evaluation of the health or environmental effects” of the chemical, where EPA finds there is a likelihood of significant or substantial human or environmental exposure. Example provided by the US.

¹¹⁵ Peter Sand, *Transnational Environmental Law, Lessons in Global Change*, 1999, page 132 s.

¹¹⁶ UN Resolution 44/225, *Large scale pelagic drift net fishing and its impact on the living marine resources of the world’s oceans and seas*, discussed by D. Freestone, E. Hey, op. cit., page 260.

¹¹⁷ A. Cosby and S. Burgiel, op. cit., Peter Hardstaff, op. cit., page 3.

¹¹⁸ Article 15.2 and 3.

¹¹⁹ The issue of the burden of proof in disputes under WTO Agreements will not be dealt with in this paper.

¹²⁰ For example, the Act on Prevention of Risks derived from the Use of Biotechnology of Perú has a chapter on the precautionary principle. The Forestry Act of Bolivia includes, among the fundamental principles on which the Act is based, the precautionary principle.

measures) adopted by developed countries may be in fact disguised protectionist trade measures, and suspect that “precaution” might be abused in detriment of their exports¹²¹.

137. Another concern is that the assessment of risks and the evaluation of the need for precautionary measures, can be very costly, and may therefore be out of reach for poorer countries. Developing countries may lack the capacity and the resources to adopt precautionary measures, and to ensure that such measures comply with requirements under international instruments. Though many international instruments take account of these concerns¹²², the difficulties in practice remain. This may render the adoption of such measures, including those related to recommendations in, or commitments under international environmental obligations, as well as precautionary measures related to imports, especially difficult for these countries.

138. A number of initiatives have been put in place to assist developing countries in addressing these difficulties. Multilateral and regional development banks play an important role in assisting countries in complying with their obligations under international environmental instruments. Specific programmes have been launched to help developing countries acquire the necessary capacity to efficiently address trade-environment-development issues at both national and international level¹²³.

139. Increased transparency and communication on environmental measures taken by developed countries, sharing the results of scientific research and other scientific information, facilitating the assessment of risks related to new activities and processes, providing technical and financial assistance to developing countries to address the impact on their economy of measures (including precautionary measures) taken by developed countries, etc. are possible contributions to further assist developing countries, and to increase their confidence.

¹²¹ See Peter Sands, *The Precautionary Principle; a European Perspective*, op. cit., pages 130-1 for a description of developing countries' concerns about the inclusion of references to precaution in the Rio Declaration and the Biosafety Protocol. See also the summary records of the meetings of the WTO Committee on Trade and Environment held in July 2000 and February 2001, at which precaution in the context of trade and environment was discussed.

¹²² The SPS Agreement recognises the difficulties of developing countries in the preamble: “*Developing country Members may encounter special difficulties in complying with the sanitary or phytosanitary measures of importing Members, and as a consequence in access to markets, and also in the formulation and application of sanitary and phytosanitary measures in their own territories...*” and contains specific provisions on technical assistance and special and differential treatment¹²². These provisions allow the SPS Committee to grant developing countries specified, time-limited exceptions from the Agreement, taking into account their financial, trade and development needs. Other WTO Agreements also deal with developing countries' situation, but nothing is specifically provided for with regard to the difficulties that developing countries may encounter when facing situations of uncertainty and having to justify environmental precautionary measures in trade disputes.

¹²³ For example, the UNCTAD/UNEP Capacity Building Task Force on Trade, Environment and Development.

Issues for discussion and further work

140. This section suggests a number of issues for discussion and possible further work on uncertainty and precaution in the trade and environment context. The JWP is invited to consider these issues and decide whether and how it could develop work on any of them.

Precaution and science

141. Should the relationship between measures taken in situations of scientific uncertainty and the provisions of trade agreements be further analysed, with special focus on the evolving role of science?

142. Considering the divergences of views among countries on decision-making in situations of uncertainty (e.g., on the factors to be taken into account in the assessment of risks on which precautionary environmental measures should be based), would it be helpful to carry out analytical work with a view to supporting the development of good practices or guidelines for government decisions related to precaution?

Transparency and consultation

143. Are current mechanisms on transparency and consultation with civil society in OECD Member countries and in international forums adequate to address situations of uncertainty and risk leading to the adoption of precautionary measures, or should new mechanisms be developed?

The costs of precaution

144. In view of the broad range of measures that can be taken at national and international level to address situations of uncertainty and risk, and considering that relatively little evidence seems to exist on the economic and trade impacts of such measures, should work be carried out to examine the effective and potential impacts of such measures, including their costs and the costs of alternative measures?

145. Should the allocation of the burden of proof in the context of precautionary measures, and its potential economic and trade impacts be further examined?

Developing countries' concerns

146. How could assistance be provided to help developing countries, first, to better understand and address the impacts of precautionary measures adopted by developed countries, and second, to develop the necessary capacity to adopt precautionary measures themselves, in compliance with their international commitments?

ANNEX I - PRECAUTION IN INTERNATIONAL ENVIRONMENTAL INSTRUMENTS

1. This Annex provides a description of the emergence of precaution in international environmental instruments and an overview of the elements of precaution, as described in such instruments. It further includes relevant extracts from selected international instruments dealing with uncertainty and precaution.

Emergence of precaution in international environmental instruments

2. While environmental instruments normally aim at tackling situations which cause, or can in all likelihood cause, environmental damage, they also address, more or less explicitly, of situations where the potential environmental consequences of an action are uncertain. Several international environmental instruments negotiated in the 1970s and 1980s were adopted on the basis of a certain degree of uncertainty about potential, serious environmental damage. Though they make no specific reference to precaution or its different elements, the approach taken by these instruments can be described as precautionary in nature.

3. The OECD was one of the first international organisations to deal with global environmental issues. Some of the earliest instruments adopted by the OECD, or in the framework of OECD meetings (such as Declarations adopted at meetings at Ministerial level), take a precautionary approach by advocating anticipatory policies¹²⁴.

4. The protection of the seas and the management of fisheries are among the first areas in which governments agreed to adopt precautionary approaches, in view of increasing, serious damages due to an accumulation of damaging human interventions. Though the 1982 United Nations Convention on the Law of the Sea (UNCLOS) does not explicitly refer to the use of precaution, it has been interpreted as adopting a precautionary approach¹²⁵. Similarly, several conventions for the protection of specific marine regions have endorsed the concept of precaution¹²⁶.

¹²⁴ See the 1974 OECD Declaration on Environmental Policy and the 1979 OECD Declaration on Anticipatory Environmental Policies.

¹²⁵ See Southern Bluefin Tuna Cases, *New Zealand v Japan; Australia v. Japan*, Order of 27 August 1999. New Zealand and Australia argued that Japan, had breached several provisions of the United Nations Convention of the Law of the Sea (UNCLOS) “*having regard to the precautionary principle.*” Though in its Order for provisional measures, the Tribunal did not explicitly refer to the precautionary principle, several of the judges did so in their separate opinions. One of the judges considered that “*it cannot be denied that UNCLOS adopts a precautionary approach*”. The Order was subsequently withdrawn.

¹²⁶ See D. Freestone and E. Hey, *Origins and development of the precautionary principle*, in D. Freestone, E. Hey, eds, op. cit., pages 5 ss., for a description of the introduction of precaution in instruments dealing with the protection of the marine environment and fisheries management.

5. The 1985 Vienna Convention for the Protection of the Ozone Layer has been cited as being one of the clearest examples of the implicit adoption of a precautionary approach in an international agreement. The Convention was negotiated and adopted after scientific research had led to indications that human action was depleting the ozone layer at an alarming pace, but without a clear causal relationship being established. It is considered as being one of the first international environmental instruments to perceive the need for preventive action in advance of firm proof of actual harm, and in that sense it is indicative of the emergence of a more “precautionary” approach than had been typical for earlier pollution conventions¹²⁷. The Vienna Convention thus represents the first effort of the international community formally to address a risk before essential links between human activity and the environmental damage were proven to exist¹²⁸.

6. While the Vienna Convention was groundbreaking in many senses, it remains that it was basically a framework for action, without much practical guidance, and which required further international agreement on concrete measures. Such agreement was reached a few years later, with the Montreal Protocol on Substances that Deplete the Ozone Layer, adopted in 1987 and subsequently amended several times. The Montreal Protocol was among the first international agreements expressly advocating a precautionary approach¹²⁹.

Environmental instruments with specific references to precaution

7. The most often referenced formulation of precaution is that contained in Principle 15 of the 1992 Rio Declaration on Environment and Development: “*In order to protect the environment, the precautionary approach shall be widely applied by States according to their capability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation*”.

8. This, or similar formulations have been incorporated, or referred to in numerous multilateral and regional environmental instruments such as the UN Framework Convention on Climate Change (1992), the Convention of Biological Diversity (1992) the Convention on the Protection and Use of Transboundary Watercourses and International Lakes (1992), the Convention for the Protection of the Marine Environment of the North East Atlantic (OSPAR Convention, 1992); the Convention on the Protection of the Marine Environment of the Baltic Sea Area (1992) the Protocol on the Further Reduction of Sulphur Emissions (1994) to the Convention on the Long Range Transboundary Air Pollution (1979); the Protocol on Persistent Organic Pollutants (1998) to the Convention on the Long Range Transboundary Air Pollution (1979), and, most recently, the Protocol on Biosafety to the Convention of Biological Diversity (2000) and the draft Convention on Persistent Organic Pollutants, to be signed in Stockholm in May 2001.

9. In addition, several instruments have been amended to, *inter alia*, specifically incorporate provisions on precaution, such as the Resolution on the Application of the Precautionary Approach to Environmental Protection within the Framework of the London Dumping Convention, adopted in 1991. The 1996 Protocol to the Convention, which once it enters into force will supersede the London Dumping Convention, includes reference to the precautionary approach. The 1994 Resolution to the 1973

¹²⁷ P. W. Birnie, A. E. Boyle, op. cit., page 406.

¹²⁸ R. E. Benedick, *Ozone Diplomacy*, 1991, page 45.

¹²⁹ The 1989 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal has also been interpreted as adopting a precautionary approach. See *Trade measures in Multilateral Environmental Agreements*, OECD 1999, page 98.

Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) provides that the Parties shall apply the precautionary principle.

Instruments providing guidance on the implementation of precaution

10. Some environmental instruments take a further step, and provide guidance on how to apply precaution in a particular situation. The 1982 UN Charter for Nature, for example, is straightforward on how to deal with lack of certainty regarding the potential effects of an activity: “*Activities which are likely to pose a significant risk to nature shall be preceded by an exhaustive examination (...), where potential adverse effects are not fully understood, the activities should not proceed.*”

11. Other instruments providing specific guidance are the 1991 Bamako, the 1992 Framework Convention on Climate Change the 1995 Agreement relating to the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks, the Protocol on Biosafety which provides for the use of a precautionary approach and contains detailed provisions on how to carry out risk assessments to identify and evaluate the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity

12. A number of instruments provide for a whole range of measures which can be considered precautionary in nature, or part of part of a precautionary approach: research programmes, exchanges of scientific information, prior approval or consent procedures, etc. These include e.g. the Montreal Protocol on Substances that Deplete the Ozone Layer, Framework Convention on Climate Change, as well as the already mentioned Protocol on Biosafety and the draft Convention on Persistent Organic Pollutants.

Elements of precaution in international environmental instruments

Risk

13. Under most international environmental instruments, the risk that triggers precautionary action is the existence of threat of a - more or less serious - environmental damage. The threshold of risk varies greatly in the different instruments.

14. Many instruments refer globally to a “*threat*” of environmental damage (for example, the Rio Declaration on Environment and Development), others invoke “*reasonable grounds for concern*” (Convention for the Protection of the Marine Environment of the North East Atlantic) or “*reasons to assume that substances... may create hazards...*” (Convention for the Protection of the Marine Environment of the Baltic Sea).

15. The references to the type of *damage* vary from a reference to a threat of “*irreversible adverse effects*” (OECD Recommendation on Principles concerning Coastal Management), “*serious and irreversible damage*” (Protocol on the Further Reduction of Sulphur Emissions), “*serious or irreversible damage*” (Rio Declaration), and “*potentially damaging impacts*” (Ministerial Declaration at the Third International Conference on the Protection of the North Sea).

16. Other instruments do not refer to a damage as such, but to “*significant harm to the environment*” (OECD Recommendation on Integrated Pollution Prevention and Control), to “*harm to humans and the environment*” (Bamako Convention), to a “*potential transboundary impact*” (Convention on the Protection and Use of Transboundary Watercourses and International Lakes), a “*threat of significant reduction or loss of biological diversity*” (Convention on Biological Diversity), “*substances that may bring about ...hazards to human health, living resources and marine ecosystems, damage amenities or interfere with other*

legitimate uses of the sea” (Convention for the Protection of the Marine Environment of the North East Atlantic), or “*the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity...taking also into account risks to human health*” (Protocol on Biosafety).

Lack of certainty

17. While the duty of preventing damage to the environment is based on a known risk, the notion of precaution is based on “lack of certainty”. Most instruments refer, more specifically, to “*lack of full scientific certainty*” (Declaration on Sustainable Development in the ECE Region, Rio Declaration on Environment and Development, Framework Convention on Climate Change, Protocol on the Further Reduction of Sulphur Emissions). A majority of instruments do not specify what such scientific uncertainty refers to. Some are more precise in this regard, and refer to the establishment of a “*causal link*” (Convention on the Protection and Use of Transboundary Watercourses and International Lakes, Declaration of the Second International Conference on the Protection of the North Sea); others refer to uncertainty with regard to the release of substances which may cause harm “*without awaiting for scientific proof regarding such harm*” (Bamako Convention). The Protocol on Biosafety refers to lack of scientific certainty regarding “*the extent of the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity*”. The Agreement relating to the Conservation of Straddling Fish Stocks and Highly Migratory Fish Stocks provides that “*States shall be more cautious when information is uncertain, unreliable or inadequate*” and specifies that “*the absence of scientific information shall not be used as a reason for postponing or failing to take conservation and management measures*”

Action and measures of precaution

18. Few instruments refer to a precise “action” that the combination of risk and uncertainty would trigger. Some refer to “*action to control input from [dangerous] substances*” (Declaration of the Second International Conference on the Protection of the North Sea), others to “*action to avoid potentially damaging impacts*” (Declaration of the Third International Conference on the Protection of the North Sea), “*action to avoid the potential transboundary impact of the release of hazardous substances*” (Convention on the Protection and Use of Transboundary Watercourses and International Lakes), “*precautionary measures to control equitably total global emissions*” (Montreal Protocol), or “*precautionary measures to anticipate, prevent or minimise the causes of climate change and mitigate its adverse effects*” (Framework Convention on Climate Change).

19. Other instruments provide that scientific uncertainty should not be used as a reason for postponing either “*measures to prevent environmental degradation*” (Rio Declaration), “*measures to avoid or minimise... a threat*” (Convention on Biological Diversity) or “*actions which are justified in their own right*” (Agenda 21, Chapter 35). The Protocol on Biosafety is more precise and provides that lack of full scientific certainty shall not prevent a party “*from taking a decision as appropriate with regard to the import of living modified organisms... in order to minimise... potential adverse effects*”.

20. In a number of instruments the use of precaution is regarded as a tool for environmental management. According to Agenda 21, “the precautionary approach should provide a basis for policies relating to complex systems that are not yet fully understood and whose consequences and disturbances cannot yet be predicted”¹³⁰. A 1994 Resolution taken by Parties to CITES, provides that “by virtue of the

¹³⁰ Chapter 35, paragraph 35.2.

precautionary principle... Parties shall act in the best interest of the conservation of the species...”. Finally, the 1995 Agreement relating to the conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks provides that “States shall apply the precautionary approach widely to conservation, management and exploitation of straddling fish stocks and highly migratory fish in order to protect the living marine resources and preserve the marine environment”.

Economic considerations

21. When recommending not to postpone action where there are threats of damage to the environment, some instruments also take account of economic considerations. Article 15 of the Rio Declaration refers to “*cost-effective measures*”. Some instruments have taken on this reference. For example, the Convention on Climate Change specifies that “*policies and measures to deal with climate change should be cost-effective so as to ensure global benefits at the lowest possible cost*” and the Protocol on the Further Reduction of Sulphur Emissions indicates that “*precautionary measures to deal with emissions of air pollutants should be cost-effective*”. The Montreal Protocol recommends “*taking into account technical and economic considerations*”; while the Bamako Convention simply refers to “*appropriate measures...*”. The OECD Recommendation on Water Resource Management Policies recommends governments to ensure that “*the costs of control are not highly disproportionate in view of the potential risks imposed on society.*”

Selected international instruments with reference to uncertainty and precaution¹³¹

Multilateral Environmental Agreements

Montreal Protocol on Substances that Deplete the Ozone Layer (1987; Protocol to the 1985 Vienna Convention on the Protection of the Ozone Layer)

“*The Parties to this Protocol...*

Determined to protect the ozone layer by taking precautionary measures to control equitably total global emissions of substances that deplete it, with the ultimate objective of their elimination on the basis of developments in scientific knowledge, taking into account technical and economic considerations and bearing in mind the development needs of developing countries”.

UN Framework Convention on Climate Change (1992)

“The Parties should take precautionary measures to anticipate, prevent or minimise the causes of climate change and mitigate its adverse effects. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures, taking into account that policies and measures to deal with climate change should be cost-effective so as to ensure global benefits at the lowest possible cost”

¹³¹ Instruments marked with * are not in force yet.

Convention of Biological Diversity (1992)¹³²,

“The Contracting Parties ...

Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimise such a threat (...)”.

Convention on the Protection and Use of Transboundary Watercourses and International Lakes (1992)

“In taking the measures referred to in paragraphs 1 and 2 of this article the Parties shall be guided by the following principles:

(a) The precautionary principle, by virtue of which action to avoid the potential transboundary impact of the release of hazardous substances shall not be postponed on the ground that scientific research has not fully proved a causal link between those substances on the one hand, and the potential transboundary impact on the other hand”.

Protocol on the Further Reduction of Sulphur Emissions (Oslo, 1994) to the Convention on the Long Range Transboundary Air Pollution (Geneva, 1979)

“The Parties...

Convinced that where there are threats of serious and irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures taking into account that successful measures to deal with emissions of air pollutants should be cost-effective”.

Protocol to the Convention on the Prevention of Marine Pollution by Dumping of Wastes and other Matter (1996, London Dumping Convention, 1972)¹³³

“In implementing this Protocol, Contracting Parties shall apply a precautionary approach to environmental protection from dumping of wastes or other matter whereby appropriate preventive measures are taken when there is reason to believe that wastes or other matter introduced into the marine environment are likely to cause harm even when there is no conclusive evidence to prove a causal relation between inputs and their effects”.

¹³² The Decision on Alien Species that Threaten Ecosystems, Habitats or Species, adopted by the Conference of the Parties of the Convention on Biodiversity in May 2000 includes a list of “Interim guiding principles for the prevention, introduction and mitigation of impacts of alien species”, the first of which recommends adopting a precautionary approach. It provides that “*given the unpredictability of the impacts of biological diversity of alien species, efforts to identify and prevent unintentional introduction as well as decisions concerning intentional introductions should be based on the precautionary approach. Lack of scientific certainty about the environmental, social and economic risk posed by a potentially invasive alien species or by a potential pathway should not be used as a reason for not taking preventive action against the introduction of potentially invasive alien species. Likewise, lack of certainty about the long term implication of an invasion should not be used as a reason for postponing eradication, containment or control measures*”.

¹³³ This provision, contained in the section on “General obligations” is an almost literal transcription of a provision of the Resolution on the Application of the Precautionary Approach to Environmental Protection within the Framework of the London Dumping Convention (1991).

Agreement for the Implementation of the Provisions of the United Nations Convention on the Law of the Sea of 10 December 1982 relating to the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks (1995)*

“In order to conserve and manage straddling fish stocks and highly migratory fish stocks, coastal States and States fishing on the high seas shall, in giving effect to their duty to co-operate in accordance with the Convention: (...)

(c) apply the precautionary principle in accordance with Article 6

Article 6 “Application of the precautionary approach”

1. “States shall apply the precautionary approach widely to conservation, management and exploitation of straddling fish stocks and highly migratory fish stocks in order to protect the living marine resources and preserve the marine environment.

2. States shall be more cautious when information is uncertain, unreliable or inadequate. The absence of scientific information shall not be used as a reason for postponing or failing to take conservation and management measures¹³⁴.

Protocol on Biosafety to the Convention of Biological Diversity (2000)*

The Parties to this Protocol...

“Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development.”

Article 1

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Article 10

¹³⁴

Paragraph 3 provides guidelines for implementing the precautionary approach and provides that States shall: “(a) improve decision-making for fishery resource conservation and management by obtaining and sharing the best scientific information available and implementing improved techniques for dealing with risk and uncertainty; (b) apply the guidelines set out in Annex II and determine, on the basis of the best scientific information available, stock-specific reference points and the action to be taken if they are exceeded; (c) take into account inter alia, uncertainties relating to the size and productivity of the stocks, reference points, stock condition in relation to such reference points, levels and distributions of fishing mortality and the impact of fishing activities on non-target and associated or dependent species, as well as existing and predicted oceanic, environmental and socio economic conditions; and (d) develop data collection and research programmes to assess the impact of fishing on non-target and associated or dependent species and their environment, and adopt plans which are necessary to ensure the conservation of such species and to protect habitats of special concern”.

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 on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that party from taking a decision, as appropriate, with regard to the import of living modified organisms in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects”*¹³⁵.

Draft Stockholm Convention on Persistent Organic Pollutants¹³⁶

Preamble

“The Parties to this Convention...

Acknowledging that precaution underlies the concerns of all the Parties and is embedded within this Convention...”

Objective

“Mindful of the precautionary approach as set forth in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Convention is to protect human health and the environment from persistent organic pollutants”

Regional Environmental Agreements

Convention on the Ban of Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes within Africa (Bamako, 1991)

“The Adoption of Precautionary Measures:

(f) Each Party shall strive to adopt and implement the preventive, precautionary approach to pollution problems which entails, inter-alia, preventing the release into the environment of substances which may cause harm to humans or the environment without waiting for scientific proof regarding such harm. The Parties shall co-operate with each other in taking the appropriate measures to implement the precautionary principle to pollution prevention through the application of clean production methods, rather than the pursuit of a permissible emissions approach based on assimilative capacity assumptions.”

Convention for the Protection of the Marine Environment of the North East Atlantic (OSPAR Convention, Paris, 1992)

“The Contracting Parties shall apply:

(a) the precautionary principle, by virtue of which preventive measures are to be taken when there are reasonable grounds for concern that substances or energy introduced, directly or indirectly, into the marine environment may bring about hazards to human health, harm living resources and marine ecosystems, damage amenities or interfere with other legitimate uses of the sea, even when there is no conclusive evidence of a causal relationship between the inputs and the effects”.

¹³⁵ Article 11, which deals with procedures for living modified organisms intended for direct use as food or feed, or for processing, contains a similar text in paragraph 8.

¹³⁶ To be signed in Stockholm in May 2001.

Convention on the Protection of the Marine Environment of the Baltic Sea Area (1992)*“Fundamental principles and obligations*

The Contracting Parties shall apply the precautionary principle, i.e., to take preventive measures when there is reason to assume that substances or energy introduced, directly or indirectly, into the marine environment may create hazards to human health, harm living resources and marine ecosystems, damage amenities or interfere with other legitimate uses of the sea even when there is no conclusive evidence of a causal relationship between inputs and their alleged effects”.

Declarations, Resolutions and other non-binding instruments***Ministerial Declaration of the Second International Conference on the Protection of the North Sea (London, 1987)***

“(…) In order to protect the North Sea from possibly damaging effects of the most dangerous substances, a precautionary approach is necessary which may require action to control inputs of such substances even before a causal link has been established by absolutely clear evidence”.

Ministerial Declaration at the Third International Conference on the Protection of the North Sea (The Hague, 1990)

“The participants... will continue to apply the precautionary principle, that is to take action to avoid potentially damaging impacts of substances that are persistent, toxic and liable to bioaccumulate even where there is no scientific evidence to prove a causal link between emissions and effect”

Ministerial Declaration on Sustainable Development in the ECE Region (Bergen, 1990)

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

Ministerial Declaration at the Second World Climate Conference (SWCC), 1990

“In order to achieve sustainable development in all countries to meet the needs of present and future generations, precautionary measures to meet the climate challenge must anticipate, attack, or minimise the causes of, and mitigate the adverse consequences of, environmental degradation that might result from climate change. Where there are threats of serious and irreversible damage, lack of full scientific certainty should not be used as a reason for post-postponing cost-effective measures to prevent such environmental degradation. The measures adopted should take into account different socio-economic contexts”.

Declaration on Environment and Development (Rio Declaration, 1992)

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

Agenda 21 (1992)

Chapter 17, paragraph 17.21

“A precautionary and anticipatory rather than a reactive approach is necessary to prevent the degradation of the marine environment. This requires, inter alia, the adoption of precautionary measures, environmental impact assessment, clean production techniques, recycling, waste audits and minimisation, construction and/or improvement of sewage treatment facilities, quality management criteria for handling of hazardous substances, and a comprehensive approach to damage impact from air, land and water. Any management framework must include the improvement of coastal human settlements and the integrated management and development of coastal areas”.

Chapter 35, paragraph 35.3

“In the face of threats of irreversible environmental damage, lack of full scientific understanding should not be an excuse for postponing actions which are justified in their own right. The precautionary approach should provide a basis for policies relating to complex systems that are not yet fully understood and whose consequences and disturbances cannot yet be predicted”.

Resolution of the 9th Conference of the Parties, Criteria for Amendment of Appendices I and II (Fort Lauderdale, 1994) , Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES, 1973)

“Recognizing that by virtue of the precautionary principle, in cases of uncertainty, the parties shall act in the best interest of the conservation of the species when considering proposals for amendment of Appendices I and II;

Resolves that when considering any proposal to amend Appendix I or II the Parties shall apply the precautionary principle so that scientific uncertainty should not be used as a reason for failing to act in the best interest of the conservation of the species”¹³⁷.

Code of Conduct for Responsible Fisheries (1995)

General Principles

6.5. States and subregional and regional fisheries management organisations should apply a precautionary approach widely to conservation, management and exploitation of living aquatic resources in order to protect them and preserve the aquatic environment, taking account of the best scientific evidence available. The absence of adequate scientific information should not be used as a reason for postponing or failing to take measures to conserve target species, associated or dependent species and non-target species and their environment.

Management framework and procedures

States should apply the precautionary approach widely to conservation, management and exploitation of living aquatic resources in order to protect them and preserve the aquatic environment. The absence of adequate scientific information should not be used as a reason for postponing or failing to take conservation and management measures.

¹³⁷

Annex 4 of the Resolution lists a number of “precautionary measures”.

OECD instruments and texts

Recommendation on Principles concerning Coastal Management (1976)

“In certain coastal zones, pending evidence on environmental impacts of proposed projects, it may be necessary to take conservation steps by temporarily preventing certain types of development which could possibly have irreversible adverse effects on the environment. Such a moratorium could be lifted when evidence is available that the project can be developed in harmony with environmental protection”.

Recommendation on Water Resource Management Policies: Integration, Demand Management and Groundwater Protection (1989)

“Appendix: Guidelines for improved protection of groundwater resources. Section VII: Dealing with Uncertainty

Because currently available information will rarely resolve all uncertainties in decision-making for groundwater management, policies should encourage precautionary decisions, particularly with the most valuable of vulnerable aquifers. Policy should also provide for effective interim protection measures to proceed concurrently with any further research, and should include planning strategies that allow flexibility in implementation.

When control measures are set under conditions of substantial uncertainty, a general assessment should be made to ensure that the costs of control are not highly disproportionate in view of the potential risks imposed on society”.

Recommendation on Integrated Pollution Prevention and Control (1990)

“Appendix: Guidance on integrated pollution prevention and control. Essential Policy aspects

Certain policies, common to all aspects of environmental protection, are essential to an effective integrated approach. These include that (...)

d) the absence of complete information should not preclude precautionary action to mitigate the risk of significant harm to the environment”.

Recommendation on Integrated Coastal Zone Management (1992)]

“Considering that Environment Ministers reaffirmed that the precautionary principle will guide their approach when confronted by threats of serious irreversible environmental damage, i.e., that lack of full scientific certainty will not be used as a reason for postponing measures to prevent environmental degradation...”

OECD Guidelines for Multinational Enterprises [Annex I to the Declaration on International Investment and Multinational Enterprises(2000)]

“Enterprises should...

Consistent with the scientific and technical understanding of the risks, where there are threats of serious damage to the environment, taking also into account human health and safety, not use the lack of full scientific certainty as a reason for postponing cost-effective measures to prevent or minimise such damage.”

Draft OECD Environmental Strategy for the 1st Decade of the 21st Century¹³⁸

“When designing policies for environmental sustainability which operationalise these criteria [regeneration, substitutability, assimilation, avoiding irreversibility] countries should apply precaution as appropriate in situations where there is lack of scientific certainty. Principle 15 of the Rio Declaration on Environment and Development of 1992 includes the precautionary approach, and precaution has subsequently been addressed by various Multilateral Environmental Agreements (MEAs), such as the Framework Convention on Climate Change, the Convention on Biological Diversity and its Protocol on Biosafety, the Convention on POPs, etc. Policies and measures for environmental sustainability should also be implemented in a cost-effective manner, and contribute to the full and consistent application of the Polluter Pays and User Pays Principles.”

¹³⁸

To be adopted by OECD Environment Ministers on 16 May 2001.

ANNEX II - PRECAUTION IN THE LEGISLATION OF OECD MEMBER COUNTRIES

1. This Annex provides examples of how precaution is embedded in legislation of OECD Member countries. It is largely based on contributions from Member countries. To the extent possible, the wording of these contributions has been kept unchanged; editorial changes have been made where necessary.

2. The Canadian Environmental Protection Act (CEPA) adopted in 1999 provides that the government shall “*exercise its powers in a manner that protects the environment and human health, applies the precautionary principle that, where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental and promotes and reinforces pollution prevention approaches*”¹³⁹.

3. Precaution is an essential element of the regulatory system of the United States¹⁴⁰. A regulatory agency may take precautionary action where there is a rational basis for concern based upon available pertinent information. Precaution must be exercised as part of a science-based approach to regulation, not a substitute for such an approach. The U.S. has applied precaution in a number of domestic laws to protect the environment. For example, the US provided an early legislative response to ozone layer issues. In 1977, the US proposed under TSCA to ban CFC’s as propellants in non-essential spray cans. Later that year, the U.S. amended its Clean Air Act to authorize the Administrator of the EPA to regulate “any substance... which in his judgement may reasonably be anticipated to affect the stratosphere, especially ozone in the stratosphere, if such effect may reasonably be anticipated to endanger public health or welfare.” This amendment also specifically authorized EPA to finalize the 1977 TSCA proposed rule on spray cans. These measures constituted a domestic legal response to the possibility of adverse impacts on the stratospheric ozone layer at a time when significant uncertainty remained regarding the actual effect of CFC’s or other substances on the ozone layer¹⁴¹.

4. In Australia, the Precautionary Principle is incorporated into various environment-related policies and legislation at the Federal, State and local government levels, including the *Great Barrier Reef Marine Park Act 1975*, the *Natural Heritage Trust Act 1997* and the *Environment Protection and Biodiversity Conservation Act 1999*.

5. The Precautionary Principle is a key consideration under the *Environment Protection and Biodiversity Conservation Act 1999*. An objective of this Act is to promote ecologically sustainable

¹³⁹ Contribution from Canada.

¹⁴⁰ Precaution has figured in the U.S. Government domestic legislation since early in the 1900’s (e.g., 1906 Federal Food, Drug and Cosmetic Act (FFDCA), amended 1938, 1954, 1958, 1962, 1993, 1997; 1906 Federal Meat Inspection Act; Federal Plant Pest Act; 1995 U.S. Department of Agriculture Regulation 1512; 1996 Food Quality Protection Act - FQPA- Amending the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and FFDCA).

¹⁴¹ Contribution from the US. The term environment used in this contribution broadly includes health, safety, and the conservation of natural resources.

development (s.3(1)(b)). The principles of ecologically sustainable development are provided in the Act (s.3A) and include the Precautionary Principle. The Act states that “The precautionary principle is that lack of full scientific certainty shall not be used as a reason for postponing a measure to prevent degradation of the environment where there are threats of serious or irreversible environmental damage” (s.391). Under the Act the Minister must take account of the Precautionary Principle in making key decisions about the assessment of and whether to approve actions which are likely to have a significant impact on matters of national environmental significance. Matters of National Environmental Significance include World Heritage properties, Wetlands of international importance, listed threatened and migratory species, nuclear actions, the Commonwealth marine area, together with the other matters to which Part 3 of the Act applies - Commonwealth land and Commonwealth actions.

6. The Act also stipulates that the Minister must take into account the Precautionary Principle in relation to other matters, specifically the draft of decisions listed in s.391 of the Act. The specified decisions include those related to the conservation of threatened species and ecological communities, listed migratory species, whales and other cetaceans, and listed marine species; recovery plans, threat abatement plans, and wildlife conservation plans; and the management of World Heritage properties, Biosphere reserves, Commonwealth reserves and wetlands of international importance.

7. The application of the Precautionary Principle is an explicit requirement of much legislation at the State and Territory level. It is further implied through references to ecologically sustainable development. For example, in one particular State, a major mining proposal was refused development approval on the grounds that the unknown risks to the environment of a significant, nationally listed wetland could only be avoided by refusing the proposal. Also the *Local Government Act 1993* requires “councils, councillors and council employees to have regard to the principles of ecologically sustainable development in carrying out their responsibilities”¹⁴².

8. In 1992, the Treaty of Rome establishing the European Communities was amended to specifically include the precautionary principle among the principles on which Community policies on the environment would be based. In early 2000, the EC Commission issued a “Communication on the precautionary principle”, the broad lines of which were endorsed by the EC Council’s Resolution on the Precautionary Principle, adopted in Nice in December 2000. The principles laid down in the Treaty and subsequent Acts, such as the Council Resolution, are the basis for EU Member’s environmental legislation, and some of them have recently incorporated references to precaution, or the precautionary principle or approach in their legislation.

9. Germany started making specific reference to precaution in its environmental legislation in the 1970s, by providing that environmental policy is not fully accomplished by warding off imminent hazards and the elimination of damage which has occurred; precautionary environmental policy requires furthermore that natural resources are protected and demands on them made with care¹⁴³. The Federal Immission Control Act requires installations to be established and operated in a manner that takes precautions to prevent harmful effects on the environment, in particular through the use of state-of-the-art emission control measures. The Reunification Treaty of 1990 incorporates the precautionary principle, the polluter pays principle and the principle of co-operation among others, as the basic guidelines for environmental policy in both the Bund and the Länder.

¹⁴² Contribution from Australia.

¹⁴³ James Cameron and Juli Abouchar, *The Status of the Precautionary Principle in International Law*, in D. Freestone, E. Hey, op. cit, page 37 quoting Konrad von Moltke, *The Vorsorgeprinzip in West German Environmental Policy*, 12th report of the Royal Commission on Environmental Pollution, HMSO, 1988.

10. France modified its Rural Code in 1995 to provide that the absence of certainty, taking into account current scientific and technical knowledge, must not delay the adoption of effective and proportionate measures aiming at preventing a risk of serious and irreversible damage to the environment, at an economically acceptable cost¹⁴⁴.

11. In Austria, the precautionary principle is explicitly mentioned as one of the guiding principles in the Act on Genetic Engineering. Precaution is also embedded in the Austrian Chemicals Act (1996). The objective of the Austrian Chemicals Act 1996 as stated in § 1 corresponds to the precautionary approach: “§ 1. (1) The objective of the Federal Act is the precautionary protection of human health and the environment from direct or indirect harmful effects which may be caused by the manufacture and marketing, acquisition, use or waste treatment of substances, preparations or articles.” In accordance with this objective and to the precautionary approach there is a duty to register new substances (§5). The Minister for the Environment is obliged to take precautionary action by general or special regulations, including bans and restrictions of certain dangerous chemicals. These can be seen as applications of the precautionary approach.

12. In Denmark, several pieces of legislation incorporate the notion of precaution. Although the concept of precaution itself is not mentioned in these Acts, they do reflect the essence of the precautionary principle, i.e., that measures are allowed in case of possible risks to human beings or the environment, even if available scientific information is incomplete. References to precaution appear in Government comments accompanying these texts. Examples are the 1991 Act on Gene Technology, which provides for measures in cases of risks of undesirable effects; the 1996 Act on Chemicals, which allows measures to be taken in relation to the sale or use of chemical products provided such measures, on the basis of available investigations or experience, are suspected to present hazards to health or the environment; and the 1998 Environmental Protection Act allows to take measures based on the likely impact of pollution on the physical surroundings.

13. In Switzerland, the precautionary principle is explicitly mentioned in the Federal Act relating to the Protection of the Environment of 1983, revised in 1997. It provides that early preventive measures are to be taken in order to limit effects which become harmful or a nuisance. The precautionary principle is further incorporated in a number of environmental policies, and is, for example, the guiding principle of pollution control. In this regard, the Act relating to the Protection of the Environment provides that “*irrespective of existing environmental pollution, as a precautionary measure, emissions shall be limited as much as technology and operating conditions will allow, provided that this is economically acceptable*”¹⁴⁵

14. Norway adopted a Gene Technology Act in 1993. The purpose of this Act is to ensure that the production and use of genetically modified organisms is part of an ethically and socially justifiable way, in accordance with the principle of sustainable development and without detrimental effects on health an environment. The importance of applying the precautionary principle in the implementation of this Act was emphasised in the bill presenting it to Parliament¹⁴⁶.

¹⁴⁴ “L’absence de certitudes compte tenu des connaissances scientifiques et techniques du moment, ne doit pas retarder l’adoption de mesures effectives et proportionnées visant à prévenir un risque de dommages graves et irréversibles à l’environnement à un coût économiquement acceptable” (Code Rural, Article L200).

¹⁴⁵ Contribution from Switzerland.

¹⁴⁶ Contribution from Norway.

15 In the Czech Republic, despite the fact that the precautionary principle is not explicitly mentioned in any of the Laws or Ministerial Decrees, it was taken into account during drafting and adoption of a number of Acts, such as the Act on Chemical Substances and Preparations, the Act on Genetically Modified Organisms, the Act on Prevention of Serious Accidents Caused by Dangerous Chemical Substances. It is also taken into account in current proposals such as the draft Act on Wastes, the draft Act on Air and the draft Act on Packaging.

16. In some countries, the concept of precaution, or the precautionary principle or approach, is unknown in the legislative system. This is, for example, the case of Korea. As a consequence, Korea encountered certain difficulties when implementing the Protocol on Biosafety, which refers to precaution in several provisions. The Korean National Assembly passed in February 2001 an Implementation Act for the Cartagena Protocol on Biosafety. The Implementation Act sets forth procedures and criteria required in accommodating the Protocol into the Korean legal system. As the centerpiece of the accommodation efforts among many government agencies with differing policy priorities, the precautionary principle is read into the Korean Implementation Act as follows: The relevant government agency is authorised to prohibit or restrict importation or production of LMOs (including organisms as defined in section 2) which fall under any of the following descriptions: (1) LMOs that pose, or have potential to pose, a threat to the health of the general public, preservation of biodiversity and its sustained usage; (2) Organisms that have been produced through mutation with LMOs as listed in section 1, (3) LMOs that have, or have potential to exert, a socio-economically negative impact in light of the value of domestic biodiversity. This provision fails to include “lack of scientific certainty” as a crucial factor needed to facilitate application of the precautionary principle, as set out in the Protocol. This discrepancy between the Protocol and its Implementation Act renders the precautionary principle still a moot point in the Korean legal system¹⁴⁷.

¹⁴⁷

Contribution from Korea.

ANNEX III - SCIENCE AND RISK ASSESSMENT IN WTO AGREEMENTS AND JURISPRUDENCE

1. Paragraph 4 of Annex A of the SPS Agreement sets out the treaty definition of risk assessment. According to this provision, there are in fact two types of risk assessment, one being “*the evaluation of the likelihood of entry, establishment or spread of a pest or diseases within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied and of the associated potential biological and economic consequence*”, the other one “*the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuff.*”

2. In the Salmon case, where the first type of assessment was of relevance, the Appellate Body considered that a risk assessment must *identify* the diseases whose entry, establishment or spread a Member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these diseases; *evaluate the likelihood* of entry, etc., as well as the associated potential biological and economic consequences; and to do so *according to the SPS measures that might be applied*¹⁴⁸. The Appellate Body further considered that evaluating the “likelihood” of entry, etc. of a disease was not to evaluate the mere “possibility”, but the “probability” of entry etc., and associated biological and economic consequences. It further specified that it was not sufficient to evaluate “*some*” likelihood, but “*the*” likelihood, and conceded that the likelihood could be expressed *quantitatively or qualitatively*¹⁴⁹.

3. In the Hormones case, where the second type of assessment was relevant, the Panel interpreted this provision to mean that a risk assessment is a scientific process aimed at establishing the scientific basis for the sanitary measure a Member intends to take. The Appellate Body however disagreed with this interpretation and said that “*it is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strict controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die*”¹⁵⁰.

4. Article 5.2 of the SPS Agreement describes the factors that should be taken into account in a risk assessment: “*In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods, relevant inspection, sampling and testing methods, prevalence of specific diseases or pests, existence of pest-or disease free areas; relevant ecological and environmental conditions; and quarantine and other treatment.*”

¹⁴⁸ Salmon case, paragraph 121 of the Appellate Body report.

¹⁴⁹ Salmon case, paragraphs 123 and 124 of the Appellate Body reports.

¹⁵⁰ Hormones case, paragraph 187 of the Appellate Body report.

5. The Appellate Body has interpreted the above provision in the sense that “there is nothing to indicate that the listing of factors that may be taken into account in a risk assessment of Article 5.2 was intended to be a closed list”¹⁵¹

6. The Appellate Body has also specified that the kind of risk evaluated in a risk assessment under the SPS Agreement must be “*an ascertainable risk; theoretical uncertainty is not the kind of risk which ... is to be assessed.*”¹⁵². It further said that there is no requirement for a risk assessment to establish a “*certain magnitude or threshold level of degree of risk*”¹⁵³.

7. On the quantification of risk to be assessed, the Appellate Body said that “there is no requirement under Article XX(b) of the GATT 1994 to quantify, as such the risk to human life or health. A risk may be evaluated either in quantitative or qualitative terms.”¹⁵⁴

8. As regards the relationship between the measure and the risk assessment, the Appellate Body said that “*the results of the risk assessment must sufficiently warrant, that is to say, reasonably support, the SPS measure at stake*”, in other words, that there had to be a “*rational relationship between the measure and the risk assessment*”.¹⁵⁵

9. The Appellate Body has further considered who must carry out the risk assessment and considered that “Article 5.1 [of the SPS Agreement] does not insist that a Member that adopts a sanitary measure shall have carried out its own risk assessment. It only requires that the SPS measure be “based on an assessment, as appropriate for the circumstances. The SPS measures might well find its objective justification in a risk assessment carried out by another Member or international organisation”¹⁵⁶.

10. On the level of scientific evidence, the Appellate Body said that a risk assessment does not need to “*come to a monolithic conclusion that coincides with the scientific conclusion or view implicit in the SPS measure. The risk assessment could set out both the prevailing view representing the mainstream of scientific opinion, as well as the opinions of scientists taking a divergent view. Article 5.1 does not require that the risk assessment must necessarily embody only the view of a majority of the relevant scientific community. In some cases, the very existence of divergent views presented by qualified scientists ... may indicate a roughly equal balance of scientific opinion, which may itself be a form of scientific uncertainty. In most cases, responsible and representative governments tend to base their legislative and administrative measures on “mainstream” scientific opinion. In other cases.... [they] may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources. By itself, this does not necessarily signal the absence of reasonable relationship between the SPS measure and the risk assessment...*”¹⁵⁷.

11. Closely related to the above are the findings in the Asbestos case, where the Appellate Body said that: “*In justifying a measure under Article XX(b) of the GATT 1994, a Member may also rely, in good faith, on scientific sources which, at the time, may represent a divergent, but qualified and respected*

¹⁵¹ Hormones case, paragraph 187 of the Appellate Body report.

¹⁵² Hormones case, paragraph 186 and Salmon case, paragraph 125 of the Appellate Body reports.

¹⁵³ Hormones case, paragraph 186, confirmed in Salmon case, paragraph 124 of the Appellate Body reports.

¹⁵⁴ Asbestos case, paragraph 167 of the Appellate Body report; see also footnote 48 to paragraph 186 of the Appellate Body report in the Hormones case.

¹⁵⁵ Hormones case, paragraph 193 of the Appellate Body report.

¹⁵⁶ Hormones case, paragraph 190 of the Appellate Body report.

¹⁵⁷ Hormones case, paragraph 194 of the Appellate Body report.

*opinion. A Member is not obliged, in setting health policy, automatically to follow what, at a given time, may constitute a majority scientific opinion.*¹⁵⁸

12. In cases where sufficient scientific evidence is not available, the Appellate Body has said that neither Article 5.7 nor any other provision of the SPS agreement “*sets out explicit prerequisites regarding the additional information to be collected or a specific collection procedure. Furthermore, Article 5.7 does not specify what actual results must be achieved; the obligation is to seek to obtain “additional information ... to allow the Member to conduct a more objective assessment of risk. Therefore, the information sought must be germane to conducting such a risk assessment.*”¹⁵⁹

¹⁵⁸ Asbestos case, paragraph 178 of the Appellate Body report.

¹⁵⁹ Agricultural products case, paragraph 92 of the Appellate Body report.