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Joint Working Party on Trade and Environment**UNCERTAINTY AND PRECAUTION: IMPLICATIONS FOR TRADE AND ENVIRONMENT**

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FOREWORD

This report, prepared in response to a mandate from the Joint Working Party on Trade and Environment at its meeting in May 2000, addresses the use of precaution in situations of scientific uncertainty in the context of trade and environment.¹ In accordance with the mandate, the study reviews the objectives related to precaution that 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 sections.²

The first chapter deals with the *meanings and objectives of precaution*. It examines the concept of precaution in the framework of environmental protection and provides brief overviews of how precaution is reflected in national laws and international environmental instruments.³ It further presents selected provisions of WTO agreements and WTO jurisprudence that may be relevant to measures taken to protect the environment in the context of scientific uncertainty. These overviews are further developed in Annexes I to III.

The second chapter describes a number of *measures, steps and tools* to identify and evaluate risks and to manage such risks in situations of insufficient scientific certainty about potential environmental damages. It provides a selection of examples of how such tools are set out in international instruments and have been implemented by OECD Member countries.

The third chapter addresses some *issues for discussion* emerging from the previous chapters. These issues include precaution and science, transparency and consultation, the costs of precaution and the concerns of developing countries with regard to precaution.

The report is published under the responsibility of the Secretary-General.

¹ This paper generally uses the term "precaution" rather than "precautionary principle" and "precautionary approach", both of which appear in legal texts and in the literature. Where legal texts or literature using the latter terms are referred to, and where they appear in Member countries' contributions to this paper, the terms are left unchanged. The use of one or the other term in this paper is without any implication as to its interpretation. For an explanation of the different terms used to address the concept of precaution, see E. Hey (1991), *The Precautionary Concept in Environmental Policy and Law: Institutionalising Caution*, Georgetown International Environmental Law Review, 303-18, page 304.

² The mandate specified 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.

³ 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.

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I. MEANINGS AND OBJECTIVES OF PRECAUTION

The concept of precaution

A number of cases of serious environmental degradation have changed the perception of environmental protection, not only within governments, but also in society at large. The depletion of the ozone layer and other natural resources; the extinction of species of fauna and flora; pollution of even 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.

This has led to the notion that not only *known* risks, but also *potential* risks to the environment and human health may need to be addressed; when there is a rational basis for concern, when their nature or magnitude is uncertain, and when a causal link with a certain action or process is not fully established. The use of precaution can be described as anticipating environmental harm by taking measures, as appropriate, to avoid it, or by choosing the least environmentally harmful activity. This notion of precaution is based upon the assumption that in certain cases, scientific certainty, to the extent it is obtainable with regard to environmental issues, may be achieved too late to provide effective responses to environmental threats.⁴

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 further raised awareness of the desirability of anticipatory action. 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.

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.⁵ Explicit references to the use of precaution in situations where full scientific evidence about the possible environmental consequences of an action or inaction is not available have become more

⁴ P.S. Rao (1998), *First Report on prevention of transboundary damage from hazardous activities*, International Law Commission, 50th session, page 19, www.un.org/law/ilc/index.htm.

⁵ The "assimilative capacity of the environment" has been defined as the capacity of relevant environmental media to tolerate disturbance due to anthropogenic inputs without unacceptable harm. According to some analysts, this approach assumes that science can accurately predict threats to the environment, and provide a technical solution to mitigate such threats once they have been accurately predicted; that there will remain sufficient time to act; and that acting at this stage will result in the most efficient utilisation of scarce financial resources. The use of precaution is based on an entirely new set of assumptions, including the vulnerability of the environment, the limitations of science to accurately predict threats to the environment, and the availability of alternative, less harmful processes and products. O. McIntyre and T. Mosedale (1997), *The precautionary principle as a norm of customary international law*, *Journal of Environmental Law*, Vol 9, N.2, page 222, based on E. Hey (1991).

frequent over the past years. Decisions taken in such circumstances have increasingly come under public scrutiny.⁶

There is a variety of formulations of precaution, both in national legislation and in international instruments. On the one hand, this may be due to the fact that the use of precaution is context-specific and there is no formulation that suits all situations. It may further lead to the conclusion that there is no uniform understanding of the meaning of precaution.⁷ The most widely agreed and often referenced formulation is that contained in Principle 15 of the Declaration on Environment and Development adopted in 1992 (Rio Declaration):

“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.”

Elements of precaution

Exercising precaution in the context of environmental protection may be desirable in situations where two factors concur: the existence of a *risk*,⁸ i.e. where potentially hazardous effects deriving from an action, product or process have been identified, and *lack of scientific certainty* on the effect on human health and the environment of such an action, product or process, or on the extent of potential damage. The essence of precaution is that once a risk warranting action has been identified, the lack of full scientific certainty should not prevent action to protect the environment.⁹ Identifying a potential risk and the level at which scientific evidence is sufficient to justify the adoption of measures are factors that vary from case to case, and so does the appropriate action to be taken in such circumstances. A very remote risk or a slight degree of scientific uncertainty about a possible causal link between an action and potential damage would be unlikely to require the same type of action as, for example, a high risk combined with great lack of scientific evidence about a potential damage.

The use of precaution cannot be limited to approving an action or process, or prohibiting it, but implies managing various levels of risk and uncertainty, and taking the appropriate measures at each level. For example, in the field of fisheries, there generally exists some level of harvesting at which there is little

⁶ For more detailed research, see O. Godard (2000), *Politiques d'environnement et règles du commerce international: le principe de précaution sur la ligne de fracture*, Ecole polytechnique, page 3, and P. Kourilsky and G. Viney (1999), *Le principe de précaution*, page 26 ss.

⁷ P.S. Rao (1998), page 21.

⁸ 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 World Bank (1997), *Environmental Assessment Sourcebook*, www.worldbank.org.

⁹ The EC Communication on the Precautionary Principle (2000), deals in detail with the question of "factors triggering recourse to the precautionary principle", pages 13 ss, www.europa.eu.int/comm/index_en.htm. For a detailed discussion on these factors, see D. Freestone, E. Hey (1996), *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*. See also J. Cameron (1999), *The Precautionary Principle*, in G. P. Sampson, B. Chambers, eds., *Trade, Environment and the Millenium*, page 242.

or no scientific uncertainty that can be sustained, and, at the opposite, some level at which there is little uncertainty regarding the damage to stocks due to excessive harvesting. Between these two extremes there is a zone of uncertainty about the consequences of harvesting activities, which calls for adequate measures, including, where necessary, the use of precaution.¹⁰ Further, a risk may vary depending on the level of an activity, with the risk growing as the activity increases (e.g. harvesting of natural resources), and on the interrelation with other actions or processes (e.g. fisheries and marine pollution).

Invoking precaution in situations where one of these two elements is missing, e.g. where there is no risk, or the risk is very negligible, or where there is a perceived risk for which there is no scientific basis, may be seen as a misuse, or abuse, of the concept. Such abuse could lead to undesired consequences, such as imposing disproportionate costs on society and business, stifling technological innovation, or creating unjustified trade barriers.

The use of precaution in environmental protection

It is not always possible, when looking at either national regulations or international instruments dealing with environmental protection and damage prevention, to draw a clear line between environmental and health issues, since both are closely related.¹¹ The use of precaution has been part of health and food regulation for years.¹² It has also become recognised as an important element of environmental protection in national regulatory systems. For example, precaution has been a feature of the U.S. regulatory system for over 100 years, and has always been inherent in the *process* of developing measures to protect the environment, rather than stated as a principle. Germany is often quoted as being the first country to have explicitly introduced the notion of precaution for environmental protection in its regulatory system, in the 1970s. The concept of precaution has also been gradually introduced in international environmental instruments.

The availability of a high level of scientific certainty as to the effects on the environment of an action or an accumulation of actions contributes to adopting the appropriate measures aimed at preventing harm to the environment. 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.¹³ Illustrations of the significance

¹⁰ As an example, the 1995 Code of Conduct for Responsible Fisheries recommends that States should apply a precautionary approach widely to conservation, management and exploitation of marine living resources. In implementing the precautionary approach, States should 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 distribution of fishing mortality and the impact of fishing activities, including discards, on non-target and associated or dependent species, as well as environmental and socio-economic conditions (Article 7.5). See also FAO (1996), *Technical Guidelines for responsible fisheries, Precautionary approach to capture fisheries and species introduction*.

¹¹ 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, 1996, paragraph 29. This paper focuses on precaution in the context of environmental protection and will not deal specifically with health or food safety issues.

¹² For a description of the use of precaution in OECD Member countries' food safety regulations, see OECD (2000a), *Compendium of national food safety systems and activities*, www.oecd.org/EN/documentation/0,,EN-documentation-32-nodirectorate-no-no-no-32,00.html.

¹³ T. Tietenberg (2000), *Environmental and Natural Resource Economics*, page 49.

of scientific uncertainty are the depletion of the ozone layer and global warming. In both cases, first steps 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 problem.

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 retained.¹⁴ 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. They may have been due, in some cases, to 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.

Dissatisfaction with such outcomes, both among decision-makers and the general public, increased public information about environmental damage, 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 that, in certain circumstances, it may be appropriate, or necessary, to exercise precaution in environmental protection, and to take appropriate action even before full scientific certainty regarding potential damage to the environment is available.

The obligation to prevent harm to the environment and the concept of precaution

The “no harm principle”, as 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) provides that:

"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."

This principle has remained highly influential in the subsequent development of law and practice in environmental matters. In its advisory opinion on the Legality of the Threat or Use of Nuclear Weapons, the International Court of Justice considered that "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."¹⁵ According to some analysts, the principle, as it has been applied in some international agreements, requires States to do more than make reparation for environmental damage, namely, to take suitable measures to prevent and limit environmental damage¹⁶.

¹⁴ See in this context A. Nollkaemper (1996), *What you risk is what you value*, in D. Freestone, E. Hey eds., op. cit, page 74.

¹⁵ International Court of Justice, Legality of the Threat or Use of Nuclear Weapons, 1996 (Request by the UN General Assembly for an advisory opinion), paragraph 29, www.icj-cij.org.

¹⁶ P.W. Birnie and A.E. Boyle (1992), *International Law and the Environment*, pages 91- 92. These authors cite as examples the Vienna Convention for the Protection of the Ozone Layer, the MARPOL Convention, the London Convention on the Prevention of Marine Pollution by Dumping of Wastes and other Matter, the UN Convention on the Law of the Sea and the ECE Convention on Environmental Impact Assessment in a Transboundary Context.

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 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 scientific 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 can be regarded as key to ensuring sustainable development.

Precaution in international environmental instruments

Precaution is a subjective term: the acceptable level of risk and the level of protection to address that risk varies, both among individuals and different societies. In addition, differences in regulatory approaches are likely to result in different applications of precaution aimed at addressing risks. In the face of uncertainty about the possible harmful consequences of an action, or of inaction, decisions are therefore often taken on a case-by-case basis, in the framework of a specific context. It is difficult to determine in advance in which situations it is prudent to exercise precaution and to provide concrete guidance on the appropriate measures. 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 are specific to the framework of each instrument, and the implementation of adequate measures needs to be adapted to each particular context.

While references to precaution that appear in international instruments are generally addressed to governments, over the last few years a number of instruments have been adopted which recommend the use of precaution by individuals or enterprises. A recent example can be found in the OECD Guidelines for Multinational Enterprises, which encourage enterprises "consistent with the scientific and technical understandings of the risks, where there are threats of serious damage to the environment, taking also into account human health and safety, not [to] use the lack of scientific certainty as a reason for postponing cost-effective measures to prevent or minimise such damage".¹⁷ 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", as well as the Business Charter for Sustainable Development, sponsored by the International Chamber of Commerce, which includes a reference to the precautionary approach.¹⁸

Examples of references to precaution in international environmental instruments are provided in Annex I.

¹⁷ The Guidelines for Multinational Enterprises are annexed to the 1976 Declaration on International Investment and Multinational Enterprises, revised in 2000, www.oecd.org/oecd/pages/home/displaygeneral/0,3380,EN-home-93-3-no-no-no-93,00.html.

¹⁸ The Business Charter for Sustainable Development formulates the precautionary approach as "not to use the lack of full scientific certainty as a reason for postponing cost effective measures to prevent or minimise damages to the environment". J. Adams (1999), *Foreign Direct Investment and the Environment: the role of voluntary corporate environmental management*, in OECD, *Foreign Direct Investment and the Environment*.

Environmental protection, scientific uncertainty, precaution and WTO Agreements

The preamble to the Marrakesh Agreement establishing the World Trade Organisation (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”.¹⁹

Several WTO Agreements contain provisions on measures to protect human health and the environment: the General Agreement on Tariffs and Trade (GATT), the Agreement on Technical Barriers to Trade (TBT Agreement), and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).²⁰

Among these instruments, only the SPS Agreement refers specifically to circumstances where measures are taken on a provisional basis in cases where relevant scientific evidence is insufficient. 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). It requires Members, in assessing risk, to “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” (Article 5.2). 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” (Article 5.7).

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).

The provisions of the SPS Agreement have been interpreted in various disputes brought under the WTO dispute settlement mechanism. These cases deal with health and food safety issues and not specifically with environment; they are, however, mentioned in this paper to the extent that the findings of

¹⁹ In its interpretation of Article XX of the GATT, and making reference to the objective of sustainable development in the preamble of the WTO Agreement, the Appellate Body has 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”. United States- Import Prohibition of Certain Shrimp and Shrimp Products (Shrimp-Turtle case, WT/DS56/AB/R), paragraphs 153 and 155 of the Appellate Body report; www.wto.org/english/tratop_e/dispu_e/dispu_e.htm.

²⁰ Other WTO Agreements also contain references to measures to protect the environment, such as the General Agreement on Trade in Services (GATS) and the Agreement on Agriculture; however, they seem less relevant for the purposes of this study and are therefore not dealt with here; www.wto.org/english/docs_e/legal_e/legal_e.htm

the Appellate Body are relevant to a better understanding of the use of precaution and the role of science in the implementation of precautionary measures.²¹

Both the GATT and the TBT Agreement include provisions on measures taken by Members to protect human health and the environment. Unlike the SPS Agreement, they do not specifically refer to situations in which there is lack of scientific evidence. This does not imply, however, that measures taken out of precaution are not consistent with the GATT or the TBT, unless obligations under the agreements are violated.

Relevant excerpts from WTO reports, in particular those where the Appellate Body interprets Article 5.7, are set out in Annex II below. Annex II also contains references to provisions in the GATT and the TBT, as well as WTO jurisprudence related thereto, which may be of relevance in a discussion on scientific uncertainty and precaution.

Precaution in the laws of OECD countries

In all OECD countries, precaution is regarded as an integral part of risk analysis in the food safety area.²² With few exceptions, precaution has found its way into national environmental legislation and practice, and an increasing number of OECD countries specifically address the issue of scientific uncertainty and the use of precaution in their laws.

Examples of legislation of OECD Member countries addressing scientific uncertainty and precaution are provided in Annex III of this paper.

The status of precaution in international law

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 a principle of international environmental law.²³ Various international and regional tribunals have seen cases dealing with measures

²¹ These cases are: the case based on complaints by the United States 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); and the case based on a complaint by the United States regarding measures taken by Japan to test and confirm the efficacy of the quarantine treatment for each variety of agricultural products (Japan-Varietals case).

²² OECD (2000 a). 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; www.oecd.org/EN/documentation/0..EN-documentation-32-nodirectorate-no-no-no-32,00.html.

²³ It is not the purpose of this paper to contribute to this debate. Numerous articles and studies deal with the legal status of precaution, such as D. Freestone and E. Hey (1996), J. Cameron and J. Abouchar (1996), *The Status of the Precautionary Principle in International Law*, in D. Freestone, E. Hey, op. cit, page 37; J. Cameron (1991), *The Precautionary Principle: a fundamental principle of law and policy for the protection of the global environment*, Boston College International and Comparative Law Review, page 1; P. Kourilski and G. Viney (1999); P. Martin-Bidou (1999), *Le principe de précaution en droit international de l'environnement*, Revue Générale de Droit International Public, L. Lucchini (1999), *"Le principe de précaution en droit international de l'environnement: ombres plus que lumières"*, Annuaire français de droit international, XLV, O. McIntyre and T. Mosedale (1997), *"The precautionary principle as a norm of customary international law"*, Journal of Environmental Law, Vol 9 N. 2; and EC (2000).

that have been characterised as precautionary: the International Court of Justice,²⁴ the WTO Appellate Body,²⁵ and the European Court of Justice.²⁶ None of these tribunals has clarified the legal status of precaution, nor confirmed the existence of a precautionary principle as a principle of international law.

²⁴ Case concerning the Gabčíkovo-Nagymaros Project (Hungary/Slovakia), Decision of 25 September 1997.

²⁵ Hormones case, paragraph 123 of the Appellate Body report.

²⁶ Judgements of 5 May 1998, cases C-157/96 and C-180/96.

II. EXERCISING PRECAUTION

Decision-making in situations of risk and uncertainty

The outcome of most human activities cannot be accurately predicted, and for many environmental problems it is not possible to state with certainty what consequences a particular policy or action will have.²⁷ Essential elements of precautionary approaches are the existence of a risk of a potential damage, and the scientific uncertainty linked either to the probability of such damage to occur, to the potential scope of such damage, or to both.

Risk analysis plays an important role in the decision-making process in situations of uncertainty. Risk analysis consists of three inter-related components: risk assessment, risk management and risk communication.²⁸ There is no agreed view on the role of precaution in the process of risk analysis. The EC for example considers that precaution is particularly relevant to the management of risk.²⁹ For the United States, precaution is a feature of both risk assessment and risk management, in other words, inherent throughout the risk analysis process.

Measures, steps and approaches to apply precaution

Most measures taken out of precaution are aimed at, or contribute to, preventing damage to the environment, public health and safety; and conserving natural resources. The use of precaution may be necessary in deciding whether and how to regulate in cases when scientific evidence is insufficient to determine with adequate certainty that such damage will effectively occur or to what extent it may occur. Precaution is exercised in the context of specific situations, and no generally agreed guidance exists on when to apply precaution, "how much" precaution is necessary in a given situation, or which measures are the most suitable ones.

A variety of tools, measures and steps, aimed at addressing situations of risk and scientific certainty in different situations are available to decision-makers, through different regulatory processes. While most of them are not specifically, or exclusively, precautionary, they may be relevant to support decisions taken in situations of scientific uncertainty, and to the use of precaution.³⁰ In practice, a combination or succession of several tools is generally put in place. These measures, steps and approaches can be roughly divided into two broad categories: those aimed at *identifying, evaluating and assessing* a risk, and those aimed at *managing and controlling* such risk.

²⁷ OECD (1995), *The economic appraisal of environmental projects and policies, a practical guide*, page 139.

²⁸ OECD (2000 a), page 6.

²⁹ EC (2000), page 2

³⁰ According to the European Commission, recourse to precaution does not necessarily mean adopting final instruments designed to produce legal effects that are open to judicial review. 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 (2000), page 16.

Identification, evaluation and assessment of risks

Decision-makers 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. A variety of tools are available for assessing risk that provide important information to decision-makers. These tools may also include co-operation, research and exchange of information, which may all be used to increase information relevant to assessing, evaluating and monitoring risk.

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, or whether to submit approval to certain conditions. That is the purpose of procedures requiring the prior approval, or prior informed consent, of an authority before an action can proceed. Similarly, risk can be addressed by certain information that accompanies a product, for example in documentation or on labels.

Risk assessment

Risk assessment involves the identification of potential environmental adverse effects or hazards, and determining, when hazard is identified, the probability of it occurring.³¹ There is no universal definition of risk assessment: A variety of definitions exist, which depend on the context and circumstances in which the assessment of risks is carried out.

Risk assessment has been seen in OECD literature 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 values.³²

Risk assessment is an essential element in food safety policies. The Codex Alimentarius has developed the following definition of risk assessment for use in the food safety context: risk assessment is a scientifically based process consisting of (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment, and (iv) risk characterisation.³³

In the SPS Agreement, risk assessment is defined as "the evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages of feedstuffs."³⁴

³¹ OECD (2000 b), *Report of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology*, page 18; www.oecd.org/EN/documentation/0,,EN-documentation-529-nodirectorate-no-no-no-32,00.html.

³² OECD (1995), page 141.

³³ OECD (2000 a), page 6.

³⁴ Annex A, paragraph 4 of the SPS Agreement.

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.³⁵

A number of international environmental instruments are the result of collective risk assessment that preceded or accompanied the negotiation. Some include provisions for risk assessment. The procedures for assessing risk vary from agreement to agreement: some include provisions for a collective risk assessment carried out by the Parties to the convention, while others require a risk assessment to be undertaken by an individual (e.g. the exporter of certain goods). Under the Convention on International Trade of Endangered Species of Wild Flora and Fauna (CITES), the inclusion of new species in the relevant Appendixes is done after a decision by the Parties, based on a collective evaluation of risks. Similarly, the Convention on Persistent Organic Pollutants (POP Convention) provides for scientific screening criteria, a collective risk assessment and risk management evaluation whereby a scientific committee will examine a proposal to add a chemical to the relevant annexes. The Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (PIC Convention) provides for procedures for banned or severely restricted chemicals. These procedures include review, by a Chemical Review Committee, of information provided in notifications of Parties on final regulatory action regarding such chemicals.³⁶ The information to be provided includes indication of whether the final regulatory action was taken on the basis of a risk evaluation, and if so, information on such evaluation. The Cartagena Protocol on Biosafety (CPB) contains guidance on the risk assessment to be conducted under the Protocol before a decision on import is made.³⁷

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 certain environmental protection measures.

Risk assessment in the UK

In the UK, the Interdepartmental Liaison Group on Risk Assessment (ILGRA) has been created with the objective of helping to secure coherence and consistency within and between policy and practice in risk assessment as undertaken by the UK Government, and helping to disseminate and advance good practice. ILGRA is currently developing policy for consistent application of the Precautionary Principle

³⁵ 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. World Bank (1997).

³⁶ Final regulatory action in the sense of the PIC Convention means an action taken by a Party that does not require subsequent regulatory action by that Party, the purpose of which is to ban or severely restrict a chemical.

³⁷ Annex III of the CPB.

across Government Departments. Further, through ILGRA each Government Department is committed to developing its own risk assessment strategy.³⁸

*Risk assessment for GMOs in Norway*³⁹

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.⁴⁰

Environmental Impact Assessment

Closely related to the concept of risk assessment is that of environmental impact assessment (EIA), a procedure for evaluating the likely impact of a proposed activity on the environment.⁴¹ EIA 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 impacts.⁴² EIAs have been seen as important tools for supporting precaution by providing information and identifying areas of uncertainty.⁴³

Environmental hazard and risk assessment in World Bank projects

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, like for example in the case of a potential release of

³⁸ Information provided by the UK. The risk assessment strategy of the UK Department of Trade and Industry can be found at 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".

³⁹ Different Member countries have different preferences for terms which describe *products of modern biotechnology*. The United States, for example, suggests using the terms *genetically engineered products*, *biotech products* or *products of biotechnology*. In this report the term "*transgenic organisms*" is used. The term "*living modified organism*" (*LMO*) is also used in certain sections of this report. This is the term that is used in the Cartagena Protocol on Biosafety. See in this regard OECD (2000 b). Where Member countries have used the terms "*genetically modified organisms*" or "*GMOs*" in their contributions to this report, these terms have been left unchanged.

⁴⁰ Information provided by Norway.

⁴¹ Article 1.6 of the 1991 Convention on Environmental Impact Assessment in a Transboundary Context.

⁴² OECD (1999 a).

⁴³ In the case brought in 1995 by New Zealand before the International Court of Justice "Request for an examination of the situation in accordance with paragraph 63 of the Court's 1974 judgement in the case concerning nuclear tests (New Zealand vs France)", New Zealand argued, in its written submissions, that France should have carried out an environmental impact assessment to satisfy, *inter alia*, the requirements of the precautionary principle as stated in French law. See also E. Hey (1992), page 315 for a discussion on the relevance of environmental impact assessment as one possible measure to institutionalise caution.

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:

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.

What is the range and magnitude of these adverse impacts? What number of people or 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.

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.⁴⁴

Research

In a context of scientific uncertainty, follow-up activities such as research and scientific monitoring can be seen as an essential complement to precautionary approaches. 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 (Basel Convention), the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol), and the POP Convention. At national level, governments also have a role to play in encouraging 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.

Monitoring complements research and international co-operation, and can be considered critical to the application of precaution; the feedback provided by monitoring allows for better informed future decisions.⁴⁵ According to one analyst, as a component of a precautionary policy, monitoring procedures should be used mainly as a safety mechanism for detecting possible mistakes in the implementation of the measures adopted, instead of serving as a mere indicator that regulatory measures should be initiated.⁴⁶

The French Committee for Prevention and Precaution

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

⁴⁴ World Bank (1997).

⁴⁵ According to the EC Council Resolution on the Precautionary Principle, paragraph 21, "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."

⁴⁶ E. Hey (1991), page 316.

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, and GMOs. The Committee has carried out research on these topics and issued recommendations.⁴⁷

International co-operation

Often, environmental damage is due not to one single action, but to an accumulation of, or synergies between, 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, it can be achieved through international co-operation.

International co-operation can take a variety of forms, and includes accepting binding commitments, e.g. 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, often forms an important part of international co-operation. The CPB, for example, has put in place a Biosafety Clearing House, in order to facilitate the exchange of scientific, technical, environmental and legal information on living modified organisms.⁴⁸

International co-operation for the protection of the seas

An example of precautionary action through international co-operation on a regional scale is the concerted action of the 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 into the marine environment.⁴⁹ 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 confirmed.⁵⁰

The North Sea has been subject to eutrophication, oil pollution, pollution by hazardous substances and chemicals, and radioactive substances for many years. 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 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 and bans on the use of tributyl tin.

Prior Informed Consent

In order to be able to control potentially damaging actions, such as trade in dangerous substances, decision-makers need to be provided with sufficient information before deciding whether a certain action may proceed and if so, under which circumstances. In the context of trade, prior informed consent (PIC) is

⁴⁷ Ministère de l'aménagement du territoire et de l'environnement, *Comité de la prévention et de la précaution. Rapport d'activité (1996-1998)*.

⁴⁸ Article 20 of the CPB.

⁴⁹ *The North Sea. An Integrated Ecosystem Approach For Sustainable Development*, www.odin.dep.no.

⁵⁰ L.D. Mee (1996), *Scientific Methods and the Precautionary Principle* in D. Freestone, E. Hey, op. cit., page 109.

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, PIC procedures have been agreed at the international level.

For example, PIC procedures are envisaged in the Basel Convention, in the PIC Convention and in the CPB. These agreements place the responsibility for providing adequate information on the product to be imported onto the exporting Party.

The Advance Informed Agreement Procedure under the CPB

Under the CPB, the Advance Informed Agreement (AIA) Procedure applies prior to the first intentional transboundary movement of 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. Among the information that must be provided, is a previous and existing risk assessment report, consistent with the requirements fixed in the Protocol.⁵¹ 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. 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, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of an LMO, to avoid or minimise such potential adverse effects.⁵²

Approval Procedures

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, the import of certain products, the discharge or emission of substances, etc.) is approved by the competent authorities. Approval procedures are an essential element in the marketing of, for example, chemicals and pesticides.

Approval procedures for pesticides in the United States

In the United States, the Federal Insecticide, Fungicide and Rodenticide Act requires pre-market approval or 'registration' of new pesticides. The registration process involves the submission of a substantial body of data on potential health and environmental effects, including toxicology studies in animals and environmental fate studies. A new pesticide can legally not be used until the Environmental Protection Agency (EPA) reviews the data and determines that the pesticide will not pose unreasonable risks, and meets applicable health, safety and environmental standards established under U.S. law. Older pesticides are subject to re-registration reviews and to requirements for additional data when new concerns

⁵¹ Annex I of the Protocol sets out the information required in notifications; Annex III describes the requirements of risk assessments.

⁵² The AIA procedure is described in Articles 7 ss of the Protocol.

arise. In addition, the Toxic Substances Control Act requires prior notification to EPA before other new chemical substances are manufactured.⁵³

Discharge permits in Norway

The precautionary principle is applied in the Norwegian system for discharge permits according to the Pollution Control Act regulating the direct release of chemicals into the environment. The pollution authorities give emphasis to the precautionary principle when deciding on permits of certain industrial discharges, e.g. when considering the uncertainties that may exist regarding potential environmental effects of the discharges.⁵⁴

Identification requirements

Identification requirements, such as classification, labelling, and documentation, 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. Governments generally regulate a process directly, for example through approval requirements, and not indirectly through information measures, such as labelling. Thus, labelling and other information requirements can be seen as complements to risk management decision making, but not as a substitute for it.

Labelling can be compulsory or voluntary. Labelling is generally compulsory when the good in question risks causing a damage (for example, radioactive material) or being damaged (for example, live animals), if it is improperly handled. Sometimes, instead of labels, authorities require products to be accompanied by detailed documentation on the characteristics of and risks related to the product.

A number of MEAs contain identification and documentation requirements aimed at informing the authorities of the importing country of the contents of the shipment characteristics. Examples are the Basel Convention,⁵⁵ the PIC Convention,⁵⁶ and the CPB.⁵⁷

⁵³ Information provided by the United States.

⁵⁴ Information provided by Norway.

⁵⁵ 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.

⁵⁶ 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.

⁵⁷ Article 18 contains detailed provisions on the handling, transport, packaging and identification of living modified organisms.

GMO labelling in Australia, New Zealand and Japan

The Australia-New Zealand Food Standards Council (ANZFSC) agreed in July 2000 to implement mandatory labelling for GM foods where novel GM material is present in the final product. Implementation will be based on detectability /testing or a verifiable paper audit trail. The measures came into force in December 2001.⁵⁸

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

In the Austrian Chemicals Act, the precautionary principle is explicitly mentioned in connection with the duty to classify chemicals: “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.”⁵⁹

Management and control of risks

Once risks have been identified, decision makers must make a determination as to whether and how to manage such risks. Precaution may enter into such decisions in situations when an action or activity has been identified as potentially causing damage.

Governments may determine 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 to ensure that an activity remains within the limits of known risks; thereby excluding, or at least limiting, the possibility of potentially dangerous uncontrolled situations.

Certain measures go further to limit or reduce the scope of a potentially damaging activity; these include bans, prohibitions, quotas, and moratoria.

Risk management

If risk assessment identifies a potential hazard or adverse effect, measures may be taken to minimise or mitigate it. This is known as risk management.⁶⁰ There are many definitions of risk management, which depend on, among other things, the context in which risk management is carried out.

For Codex Alimentarius, which deals with risk management in the food safety area, it is the process, distinct from risk assessment, of weighing policy alternatives. This is made in consultation with all the interested parties, taking into consideration risk assessments and other factors for the health

⁵⁸ Information provided by Australia.

⁵⁹ Information provided by Austria.

⁶⁰ OECD (2000 b), page 18.

protection of consumers, and, if needed, selecting appropriate prevention and control options.⁶¹ The World Bank refers to 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 risk.⁶²

Risk management plans for GMOs in Switzerland

In Switzerland, the precautionary principle has to be taken into account for the deliberate release of GMOs into the environment. Once a risk assessment has been carried out, 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 GMOs with similar risks, adequate with respect to the cost/benefit ratio and public acceptance, and adapted by the applicant in case new scientific knowledge becomes available. Authorisation for the release of GMOs 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 sufficiently.⁶³

Standards and limits

Standard setting has been described as the confluence of science and policy determination.⁶⁴ By setting a standard, decision-makers establish what is the limit of an acceptable level of pollution, or, where scientific evidence is insufficient, of acceptable risk of pollution or of environmental damage. Standards and limits include, for example, minimum quality standards or maximum tolerable contamination levels (thresholds, 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, and maximum permissible standards of waste emission.⁶⁵

International standards set under conditions of uncertainty are closely related to the issue of different perceptions of risk. Countries differ in their tolerance of risk and of the types of measures needed to reduce such risk. Internationally agreed standards can be seen as setting 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 United States pesticide regulation

In the United States, 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

⁶¹ OECD (2000 a), page 7.

⁶² World Bank (1997).

⁶³ Information provided by Switzerland.

⁶⁴ B. A. Weintraub (1992), *Science, International Environmental Regulation, and the Precautionary Principle: Setting Standards and Defining Terms*, New York University Environmental Law Journal, page 12.

⁶⁵ P. Sands (1999), *Transnational Environmental Law. Lessons in Global Change*, page 31.

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 different “margin of safety” factor only if the Agency has reliable data indicating that a different factor will be safe for infants and children.⁶⁶

Reduction targets for chemicals in Norway

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.⁶⁷

Restrictions, bans, quotas and moratoria

Production, use and trade restrictions aim at limiting the potentially damaging effects of a product. Bans prohibit an activity, or the production and/or trade of a product, and thereby aim at eliminating the problem at its root. This type of measure is the most extreme, since it sets the tolerance for risk at zero.

A number of MEAs impose production, use and trade restrictions or prohibitions. The Montreal Protocol 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 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. Under the POP Convention, Parties have committed to prohibit and/or take the measures necessary to eliminate the production, use, import and export of certain chemicals.

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 Convention on Future Multilateral Co-operation in the Northwest Atlantic Fisheries and the Convention for the Conservation of Southern Bluefin Tuna.

Moratoria are temporary bans of an activity, including trade with certain goods. For example, moratoria can be used in fisheries conservation, to allow for stocks to recover.⁶⁸ When moratoria have been

⁶⁶ Information provided by the United States.

⁶⁷ Information provided by Norway.

⁶⁸ Some analysts cite the decision on a moratorium on commercial whaling under the 1946 International Convention for the Regulation of Whaling by the International Whaling Commission as an example of the application of the precautionary principle in a wildlife context. Regulations on quotas under the Convention must be based on scientific findings. The Scientific Committee of the International Whaling Commission has adopted a caution policy to achieve this, based on the view that scientific information and population theory is so uncertain that catch quotas could not safely be set for any species. Some countries however think that certain stock and species could still be taken without risk. P.W. Birnie and A.E. Boyle (1992), page 455.

used in cases of uncertainty about the potential consequences of an activity, programmes for further research have generally accompanied them.⁶⁹

Bans on certain chemical products in Norway

In Norway, the precautionary principle is applied in decisions concerning individual substances, as in the legislation banning ozone-depleting substances covered by the Montreal Protocol and in the national regulation banning the use of phthalates in toys and products for children under three years of age. The decision to restrict the use of phthalates was taken because of the possible endocrine effects of these substances. In 1996, the Norwegian authorities adopted the goal to phase out by 2000 certain endocrine disrupters (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. The prohibition of CFCs as aerosol propellant in spray cans was implemented in 1980. At that time, evidence of the decomposition of the ozone layer was not generally acknowledged and the prohibition was based on the precautionary principle.⁷⁰

Prohibition of activities related to endangered species in the United States

In the United States, 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. It also seeks 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.⁷¹

Fishing quotas in Canada

In 1997, the Scientific Council of the North Atlantic Fisheries Organisation (NAFO) recommended that the yellowtail flounder stock (in the designated areas, “3LNO”) could be re-opened in 1998 with a total allowable catch (TAC) of 4,000t. It also specified a number of management conditions for re-opening the fishery. The NAFO implementation plan included a statement of management objectives, harvest strategies and reference points, conservation measures, 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.⁷²

⁶⁹ See 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.

⁷⁰ Information provided by Norway.

⁷¹ Information provided by the United States.

⁷² Information provided by Canada.

III. THE USE OF PRECAUTION IN THE CONTEXT OF TRADE AND ENVIRONMENT: ISSUES FOR DISCUSSION

Introduction

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.”⁷³ This chapter describes some of the issues raised by the relationship between environmental measures taken in situations of scientific uncertainty, including measures based on precaution, and international trade obligations. 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 deals, in particular, with the following subjects, all of which are closely inter-related:

Precaution and science. Science is inherent to the assessment of risk, and to the exercise of precaution. By pointing at a significant environmental risk, it may provide sufficient basis to trigger the adoption of appropriate measures, including the use of precaution. In some cases, there may not be sufficient scientific evidence to support a concern of one country that a particular risk exists, and this may raise trade conflicts. Sometimes, the conflict may occur because doubts are raised *whether* sufficient scientific grounding has been sought to support a given measure. Another source of potential conflict is that opinions may differ on whether, and to what extent, other factors than science could be considered relevant when adopting precautionary measures.

Transparency and consultation. Transparency, consultation and communication with the public are increasingly incorporated into decision-making processes. When deciding on measures based on scientific uncertainty, the acceptance of risks by society and groups within a society are important factors to be considered. Decision-makers are confronted with the difficulties of adequately taking into account such views, which may often diverge.

The costs of precaution. Precautionary measures have a cost, including opportunity costs. The decision to allocate costs to one or other party in a process - industry or government, importer or exporter - can have important implications, including trade impacts.

Developing countries' concerns regarding precaution. Developing countries have expressed concerns about the possible trade impacts of developed countries' exercising precaution. Developing countries often find they lack the capacity to adapt quickly to environmental, health and safety measures adopted by developed countries or within the context of international agreements. Furthermore in situations where full scientific certainty about a possible environmental risk is lacking, developing

⁷³ Gasoline case, paragraph 30 of the Appellate Body report, reiterated in the Shrimp-Turtle case, paragraph 186 of the Appellate Body report.

countries may face particular difficulties in adopting adequate measures in compliance with international commitments and obligations.

Precaution and science

The role of science in the decision-making process

It is generally recognised that a zero risk does not exist, and decision-makers are not expected to ensure a totally risk free environment. They are however expected to take decisions in situations of scientific uncertainty. Decision-making under scientific uncertainty in the area of environmental protection has been described as choosing the appropriate 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 measures.⁷⁴ To avoid such pitfalls 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 process.⁷⁵

A science-based assessment of risks and the application of precaution can be considered complementary: if a scientific evaluation reveals a high degree of uncertainty, decision makers need to decide on whether precautionary measures are necessary, and what the appropriate measures are.⁷⁶ In other words, the use of available scientific and technical information underlies informed policy decisions. 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 provide, precaution may figure in the decision-making process.⁷⁷

⁷⁴ OECD (1995)

⁷⁵ 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.

⁷⁶ The Vienna Convention for the Protection of the Ozone Layer is an example of the important role science plays in allowing 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. See *International Agreements*, background paper for the Fifth Annual World Bank Conference on Environmentally and Socially Sustainable Development.

⁷⁷ For further details on the debate between sound science and the precautionary principle, see P. Hardstaff (2000), *Science and Precaution in the Trade Regime*, Presentation to the RIIA Conference on Sustainability, Trade and Investment, www.riia.org; K. von Moltke (1996); and D. Freestone, E. Hey (1996).

Science and assessment of risks

There is no general agreement on whether the assessment of risks is a purely scientific process, or whether, and to what extent, other factors may be taken into account when assessing a risk.⁷⁸ The question of the factors which need to be considered in an assessment of risk has also been examined in the context of trade disputes. In the Hormones case, which was a health-related and not an environmental 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 further elaborated on this point in its report when it said: "To the extent that the Panel intended to refer to a process characterized by systematic, disciplined and objective enquiry and analysis, that is, a mode of studying and sorting out facts and opinions, the Panel's statement is unexceptionable. However, 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, we believe that the Panel is in error".⁷⁹ The Appellate Body further recalled that "some of the kinds of factors listed in Article 5.2 such as "relevant processes and production methods" and "relevant inspection, sampling and testing methods" 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. 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 strictly controlled conditions, but also risk to 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."⁸⁰

Concerns have been expressed by the business community that the application of precautionary measures which are not based on sound science, or sufficiently supported by scientific evidence, may, *inter alia*, “threaten economic interests, add significant transaction costs and distract resources from better understanding and resolving the environmental issues in dispute.”⁸¹ Similar concerns have been expressed by representatives of both developed and developing countries.⁸² 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. 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. Concerns have also been voiced in relation to

⁷⁸ J. Pauwelyn (1999), *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*.

⁷⁹ Hormones case, paragraph 187 of the Appellate Body report. The Appellate Body upheld the Panel's finding that the EC measures were inconsistent with the requirements of Article 5.1 of the SPS Agreement, but modified the Panels' interpretation by holding that Article 5.1. read in conjunction with Article 2.2. requires that the results of the risk assessment must sufficiently warrant the SPS measure at stake.

⁸⁰ 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.”

⁸¹ See BIAC’s statement on “*Sound Science and the Precautionary Approach*” submitted at the consultation with the OECD Trade Committee in February 2001, www.biac.org

⁸² These concerns are reflected, *inter alia*, in the summary records of discussions on precaution in international forums, such as the CTE (meetings of 5-6 July 2000 [WT/CTE/M/24] and 13-14 February 2001 [WT/CTE/M/26]), and the Codex Alimentarius Committee on General Principles (meeting of 23-27 April 2001 [ALINORM 01/33]).

potential economic and trade impacts of precautionary measures: political or economic needs, 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

While science provides a vital input to 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 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 solution. Science plays an important role in *analysing and assessing* a risk and in informing decision-makers about alternative approaches and the potential consequences of actions taken, but *management* of that risk and balancing the different factors in play is the responsibility of decision-makers.⁸³

A further problem is that science may not provide a single answer: it may give very different answers to the same question, and scientists are often able to provide equally sound arguments in support of divergent theories. Moreover, science is not immune from political and economic interests. A key question for policy makers, therefore, is which science to rely on as a basis for their decisions. The question cannot be solved by distinguishing between publicly funded research, and privately sponsored research. The former can make a real contribution, either by countering the dominance of industry research in some fields, or complementing it. But the latter may be considered as equally valuable and has played an important role in international environmental policy developments, as, for example, in the evolution of the ozone regime.

Scientific uncertainty can often derive from a lack of scientific consensus. The CPB acknowledges this difficulty and states, in the Annex dealing with risk assessment, that "Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk".⁸⁴

The WTO Appellate Body has also accepted that divergent scientific opinions may be considered in a risk assessment. In the *Hormones* case it said: "We do not believe that a risk assessment has to come to a monolithic conclusion that coincides with the scientific conclusion or view implicit in the SPS measure. The risk assessment could set out both the prevailing views representing the "mainstream" of scientific opinion, as well as the opinions of scientists taking a divergent view. Article 5.1 does not require that the risk assessment must necessarily embody only the view of a majority of the relevant scientific community. In some cases, the very existence of divergent views presented by qualified scientists who have investigated the particular issue at hand may indicate a state of scientific uncertainty. Sometimes the divergence may indicate a roughly equal balance of scientific opinion, which may itself be a form of scientific uncertainty. In most cases, responsible and representative governments tend to base their legislative and administrative measures on "mainstream" scientific opinion. In other cases, equally responsible and representative governments may act in good faith on the basis of what, at a given time,

⁸³ The current debate over transgenic organisms provides an example of divergent approaches, based on available scientific research. While some 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 transgenic organisms has not been sufficiently established, and that precaution is therefore still necessary. A. Laudon and C. Noiville (1998), *Le principe de précaution, le droit de l'environnement et l'OMC*, page 68.

⁸⁴ CPB, Annex III, paragraph 4.

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, especially where the risk involved is life-threatening in character and is perceived to constitute a clear and imminent threat to public health and safety. Determination of the presence or absence of that relationship can only be done on a case-by-case basis, after account is taken of all considerations rationally bearing upon the issue of potential adverse health effects".⁸⁵

Precaution and scientific innovation

One way to avoid a risk from an action is to refrain from such action. However, risk avoidance may in some cases pose obstacles to scientific and technological 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 from the benefits of new scientific and industrial developments. Striking the balance between these interests is without doubt one of the most difficult issues in relation to scientific innovation (e.g. in the field of nuclear power), and is currently at the heart of the debate on genetic engineering. On the other hand, precautionary measures may stimulate 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

That environmental precautionary measures may often be provisional - regardless of whether they are taken in the context of a particular international agreement or obligation - is linked to the fact that the environment is not a static but an evolving system. New and unexpected consequences can arise, due, for example, 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 uncertainties.⁸⁶ Similarly, situations evolve and precautionary measures which were warranted at some point in time may prove to be no longer necessary in the light of new developments and scientific evidence.

Some analysts 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 provable.⁸⁷ 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 terms.⁸⁸

⁸⁵ Hormones case, paragraph 194 of the Appellate Body report. Further details of the Appellate Body ruling on the Hormones case can be found in Annex II of this report.

⁸⁶ 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 led to the adoption of precautionary measures with regard to these risks, following the recommendations of the Committee for Prevention and Precaution.

⁸⁷ Justice L. Stein AM (1999), *Are Decision-makers too cautious with the precautionary principle?*, page 3; K. von Moltke (1996), page 98; and P. Hardstaff (2000), page 5.

⁸⁸ K. von Moltke (1996), page 99.

Article 5.7 of the SPS Agreement provides that “in cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information (...)” and that “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.”

Transparency and consultation

Uncertainty about a potential serious risk generates concerns and any action or inaction of decision-makers in such situations comes under increased public attention. In addition, the growing 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 risk.⁸⁹

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 transparency may be particularly important in the field of food safety, recent experience has shown that it is also essential in other areas, including environmental protection. Transparency and consultation can identify people's risk tolerance or averseness, provide information and draw attention to particular problems, explain and disseminate scientific information to the public in an accessible and understandable manner, allow for inputs from populations which may be more familiar with a particular environmental problem than decision-makers, provide a platform for discussion of alternatives, etc.

Adopting precautionary measures with respect to the environment often implies imposing a cost to society in the present 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 process.⁹⁰ Generally, there are divergent views within society, and balancing these also requires attention. Views may differ with regard to short-term risks, such as a threat of a potential damage that might occur in the immediate or near future, and long term risks, which may affect, or not, future generations. Further, risk perceptions may vary over time. 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 decision.⁹¹

⁸⁹ 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.

⁹⁰ E. Hey (1991), *The precautionary approach and the London Dumping Convention*.

⁹¹ OECD (1995), page 146.

Non-governmental organisations see public participation as an important element in the decision-making process in situations of uncertainty.⁹² 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 issues such as the impacts of new technologies, the adoption of environmental measures and their impacts on trade, etc.⁹³

Some governments have emphasised the importance of transparency and involvement of the public in situations of lack of scientific certainty concerning environmental or health risks, where it may be appropriate to exercise precaution. In the United States, for example, it is a general *obligation* to take decisions in a framework of transparency and consultation. The EU Council Resolution on the Precautionary Principle adopted in Nice in December 2000 considers "that civil society must be involved and special attention must be paid to consulting all interested parties as early as possible". It 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"⁹⁴. In Canada, the government has issued, in September 2001, a public discussion document outlining a Canadian perspective on what is the precautionary approach, why is it important, when it does apply, and how is it applied. The document, entitled "A Canadian Perspective on the Precautionary Approach/Principle", outlines broad guiding principles, reflecting current Canadian practices, to support consistent, credible and predictable policy and regulatory decision making when applying the precautionary approach/principle. It states that "where the public has low tolerance for serious or irreversible harm characterized by scientific uncertainty, a different approach to public engagement is required. Specifically, these situations necessitate a greater degree of transparency, clearer accountability and increased public involvement in decision making to minimize controversy and confusion and help maintain public trust".⁹⁵

The costs of precaution

Balancing risks and costs

It is not easy to determine the cost of risk prevention or minimisation, including the adoption of precautionary measures, and many different factors enter into play. These could include, among others, the costs to industry (e.g., strict risk assessment and safety requirements before a product or activity is approved), the costs to governments (e.g., putting in place adequate control and monitoring mechanisms), the costs to consumers (e.g., higher prices due to higher production costs), etc. Further, there may be

⁹² 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 require a mechanism to identify the preferences of the society. *EEB position on the precautionary principle*, 1999, www.eeb.org. Similarly, according to the "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". The Wingspread Statement was adopted in January 2000 by an international group of scientists, government officials, lawyers and labour and environment activists.

⁹³ An example, provided by France, is the Citizens Conference on GMOs held in 1998.

⁹⁴ www.europarl.eu.int/summits/nice2. This consideration is also reflected in EC (2000).

⁹⁵ The discussion paper can be found at www.dfait-maeci.gc.ca/tna-nac/prec-discussion-e.pdf. A note on the cover of the document specifies: "The principles expressed in this document should not be considered to be the official position of the Government of Canada or of federal departments and agencies. They are for discussion purposes only."

opportunity costs (e.g. the use, or excess of use, of precaution may prevent development of beneficial new products and technologies, which, although presenting a risk, would have other benefits for society). It is also important to consider the cost of inaction - the costs of not implementing adequate precautionary measures - including the impacts on the environment, and the cost - and related risks - of alternative measures (e.g., air pollution created from burning of animal carcasses to prevent the spread of disease). The possible liabilities incurred by decision-makers in cases of damages need also be considered.⁹⁶

A further difficulty is to find the right balance between acceptable risk and acceptable costs. Decision-makers have to take into account, and weigh, the concerns of those who have to bear the costs involved in measures aimed at limiting a risk, and those benefiting from such measures. The greater the uncertainty regarding a risk, the more difficult it is to find such a balance.⁹⁷

Another factor to be considered is the degree to which societies, or groups within a society, are ready to pay to avoid a certain risk. Experience shows that a group can regard certain risks as being unacceptable, even if the probability of damage is very remote, whereas other risks are more easily accepted.⁹⁸ For example, some can accept, or be indifferent, to a relatively high mortality rate of certain species, but may be ready to accept a higher cost for the protection of others. Moreover, a society is not homogeneous, and the different levels of risk tolerance and preferences of groups within a society need to be balanced.

Allocating the burden of proof

The decision of who should bear the burden of proving that an activity does, or does not, go beyond a certain threshold of risk, is of importance from a legal and economic point of view: requiring regulators to prove that an activity could be harmful before imposing measures could 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 (e.g. the costs of measures to prevent a damage, of testing, administrative processes, etc.), though they may be justified to protect human health, or prevent environmental damage, are likely to affect the activities of enterprises.⁹⁹

⁹⁶ On the issue of liabilities incurred by decision-makers, the work by the International Law Commission on the subject "International Liability for Injurious Consequences arising out of Acts not Prohibited by International Law" may be of relevance. The *First Report on Prevention of Transboundary Damage from Hazardous Activities* (A/CN.4/487/Add.1, International Law Commission, 50th session, 1998), prepared in connection with the above work, by P. S. Rao, Special Rapporteur, examines i.a. "the principle of precaution", page 19, www.un.org/law/ilc/index.htm.

⁹⁷ 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 reduced. See EC (2000) and E. Rehbinder (1994), *The precautionary principle in an international perspective*, page 100.

⁹⁸ 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.

⁹⁹ In EC (2000), page 22, the Commission considers 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."

According to some analysts, precaution, or the principle of precaution, suggests that where there is an identifiable risk of serious or irreversible environmental harm, for example extinction of species, widespread toxic pollution, or major threats to essential ecological processes, it may be appropriate to place the burden of proof - and therefore, to impose the costs - on the person or entity proposing the activity that is potentially harmful to the environment.¹⁰⁰ Some analysts have also suggested that allocating the burden of proof to the potential polluter may also be more efficient, since normally the latter is best placed to provide any information about the effects of his activity. In this regard, a distinction should be made between assigning the burden and costs of proving safety of a product or action that is newly introduced (e.g. a new chemical product), and situations where a product or action has been authorised and unforeseen risks emerge at a later stage. In such situations, it may not be possible or feasible to have the potential polluter bear the full costs. It has also been argued that 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 activities.¹⁰¹ In any event, whether the costs are borne by regulators or producers, they are often, eventually, passed onto taxpayers and consumers.

Decisions concerning the allocation of the burden of proof can also have trade implications. 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 may be challenged by potential exporters, and which can negatively impact the economy of the importing country.

In some countries, national legislation requires proof from the person wishing to introduce a substance into the environment, or carrying out a project, that such substance or project is not damaging for the environment. For example, in the United States, 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.¹⁰² The Swedish 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 countries.¹⁰³

Developing countries' concerns regarding precaution

Many developing countries have adhered, or are Parties, to international instruments in which precaution is embedded, both in the field of environmental protection (e.g. the Rio Declaration) and in the

¹⁰⁰ See P.S. Rao (1998), page 19, citing the *Final Report of the Export Group Workshop on International Environmental Law aiming at Sustainable Development*, UNEP/IEL/WS/3/2/p. 16, and OECD (1995), *Environmental principles and concepts*, www.oecd.org/EN/home/0,,EN-home-486-nodirectorate-no-no-no-8,00.html.

¹⁰¹ B.A. Weintraub (1992), page 15.

¹⁰² 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 United States.

¹⁰³ P. Sands (1999), *Transnational Environmental Law, Lessons in Global Change*, page 132 s.

area of trade (e.g. the SPS Agreement). Some have also incorporated precaution in their legislation or practice.¹⁰⁴

However, developing countries may face particular problems in relation to precaution, the implementation of appropriate measures in such situations, and their potential impacts on trade. These concerns are linked, *inter alia*, to the fact that there may be differing levels of acceptable risk in developed and developing countries.¹⁰⁵ One concern is that developing countries may see their exports affected by precautionary measures taken by developed countries. Developing countries have, in numerous forums, expressed their fears that environmental protection measures (including precautionary measures) adopted by developed countries may in fact be disguised protectionist trade measures, and that “precaution” might be abused to the detriment of their exports.¹⁰⁶

Another concern is that the assessment of risks and the adoption of adequate measures can be very costly, and may therefore be out of the reach of poorer countries. Developing countries may lack the capacity and the resources to adequately assess risks which may be necessary to the adoption of precautionary measures, and which may be required to comply with requirements under international instruments. Though many international instruments take into account the particular difficulties that developing countries may face, the difficulties in practice remain.¹⁰⁷ On the other hand, developed countries have expressed concerns that lack of capacity in developing countries to carry out an appropriate assessment of a risk, or to properly manage or monitor a potential situation of risk (such as the import of products requiring careful handling or controls) may lead to the application of excessive caution, and the adoption of measures that may be regarded as disproportionate to the risk involved.¹⁰⁸ The issue of capacity also relates to the fear of arbitrary action: scientists in some developing countries may find it hard to keep up with developments in areas such as environmental and health protection. If they have not been involved in the discussions that lead up to an environmental measure being taken, they may question the justification of such measure, and worry that other ones could arrive with little forewarning or consideration of developing countries' concerns.

¹⁰⁴ For example, the Act on Prevention of Risks derived from the Use of Biotechnology of Peru 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.

¹⁰⁵ For example, pest control needs may vary, leading to different decisions about permitting the use, or regulating the level of use, of certain pesticides. Conditions of pesticide use in developing countries may lead them to refuse products that can be safely used in industrialised countries where protective equipment is more widely available and more likely to be used.

¹⁰⁶ P. Sands (1999), pages 130-1, describes developing countries' concerns about the inclusion of references to precaution in the Rio Declaration and the CPB. 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 (see footnote 82).

¹⁰⁷ 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 treatment (Articles 9 and 10 of the SPS Agreement). 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.

¹⁰⁸ The prohibition by a country of the release or use of products that have not been tested in other countries could be seen as an example of precaution based on lack of capacity to carry out appropriate tests by the country itself. See in this regard the section on the precautionary principle of the Peruvian Act on Prevention of Risks derived from the Use of Biotechnology, dealing with living modified organisms.

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 the national and the international level.¹⁰⁹

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, and providing technical and financial assistance to address the impact of measures taken by developed countries, are possible contributions to further assist developing countries and to increase their confidence.

¹⁰⁹ For example, the UNCTAD/UNEP Capacity Building Task Force on Trade, Environment and Development, www.unep-unctad.org/cbtf/index.htm.

ANNEX I

PRECAUTION IN INTERNATIONAL ENVIRONMENTAL INSTRUMENTS

This Annex describes different approaches to precaution in selected international environmental instruments. It includes, in the Appendix, relevant excerpts from these instruments.

Emergence of precaution in international environmental instruments

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, 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 scientific 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.

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 policies.¹¹⁰

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. Several instruments for the conservation of specific marine regions and species have endorsed the concept of precaution.¹¹¹

The 1985 Vienna Convention for the Protection of the Ozone Layer (Vienna Convention) has been considered by some analysts to be 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 conventions.¹¹² The Vienna 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

¹¹⁰ See the 1974 OECD Declaration on Environmental Policy and the 1979 OECD Declaration on Anticipatory Environmental Policies.

¹¹¹ For example, the Agreement for the Implementation of the Provisions of UNCLOS relating to the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks and the FAO Code of Conduct for Responsible Fisheries.

¹¹² R. E. Benedick (1991), *Ozone Diplomacy*, A. Laudon and C. Noiville (1998), page 8; and P. W. Birnie and A. E. Boyle (1992), page 406. The 1989 Basel Convention has also been interpreted as adopting a precautionary approach; see OECD (1999 b), *Trade measures in Multilateral Environmental Agreements*, page 98.

relationship being established. 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 exist.

Environmental instruments with specific references to precaution

Numerous multilateral and regional environmental instruments make specific reference to the use of precaution, one of the first being the Ministerial Declaration of the Second International Conference on the Protection of the North Sea (1987). Other examples are the Rio Declaration on Environment and Development (UNCED, 1992), Agenda 21, the UN Framework Convention on Climate Change (UNFCCC, 1992), the Convention of Biological Diversity (CBD, 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 (CLRTAP, 1979), the Agreement for the Implementation of the Provisions of 1982 UNCLOS relating to the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks (SFS Agreement, 1995), the Protocol on Persistent Organic Pollutants (1998), and, most recently, the Cartagena Protocol on Biosafety to the Convention of Biological Diversity (CPB, 2000), and the Convention on Persistent Organic Pollutants (POP Convention, 2001).

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 will supersede the London Dumping Convention amongst parties to both instruments once it enters into force, includes reference to the precautionary approach.

Instruments providing guidance on the implementation of precaution

Some environmental instruments take a step further, and provide guidance on how to apply precaution in a particular situation. The 1982 UN World 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."

Other instruments providing specific guidance are the Bamako Convention on the Ban of Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes within Africa (Bamako Convention, 1991) and the UNFCCC. The Resolution to CITES, adopted in 1994 by the Conference of the Parties (Fort Lauderdale Resolution), provides that "by virtue of the precautionary principle... Parties shall act in the best interest of the conservation of the species..." and provides specific guidance on precautionary measures to be taken in specific circumstances. The SFS Agreement provides that "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".

Some instruments also take account of economic considerations. Article 15 of UNCED refers to "cost-effective measures". The UNFCCC 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."

Elements of precaution in international environmental instruments

Risk

Under most international environmental instruments, the risk that calls for precautionary action is the existence of a threat of an environmental damage, the formulation of which varies in the different instruments in question.

Many instruments refer globally to a "threat" of environmental damage (e.g. UNCED), 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).

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).

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" (CBD), "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" (CPB).

Lack of scientific certainty

A number of international instruments refer to "lack of full scientific certainty" (for example, the Declaration on Sustainable Development in the ECE Region, Rio Declaration, UNFCCC, Protocol on the Further Reduction of Sulphur Emissions). Most of them do not, however, specify what such scientific uncertainty refers to. Some 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, to uncertainty with regard to the release of substances which may cause harm "without awaiting for scientific proof regarding such harm" (Bamako Convention). The SFS Agreement provides that "States shall be more cautious when information is uncertain, unreliable or inadequate" and specifies that "the absence of adequate scientific information shall not be used as a reason for postponing or failing to take conservation and management measures."¹¹³

¹¹³ Article 6.2 of the Convention.

Appendix: References to precaution and precaution-related language in selected international environmental instruments¹¹⁴

Multilateral Environmental Agreements

***Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol, 1987)*¹¹⁵**

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 (UNFCCC, 1992)

Article 3

Principles

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. (...).

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

Article 2

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.

¹¹⁴ Instruments marked with * are not in force yet. The full text of the instruments mentioned in this Appendix can be found at www.unep.ch/conventions/; www.untreaty.un.org/English/treaty.asp; www.sedac.ciesin.org/entri/texts-home.html. The text of OECD legal instruments can be found at webdomino1.oecd.org/horizontal/oecdacts.nsf.

¹¹⁵ Protocol to the 1985 Vienna Convention on the Protection of the Ozone Layer.

Convention of Biological Diversity (CBD, 1992)

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 (...).

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)*Article 3

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.¹¹⁶

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 (SFS Agreement, 1995)*Article 5General principles

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:

(a) adopt measures to ensure long-term sustainability of straddling fish stocks and highly migratory fish stocks and promote the objective of their optimum utilization;

¹¹⁶ 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).

(b) ensure that such measures are based on the best available scientific evidence available and are designed to maintain or restore stocks at levels capable of producing maximum sustainable yield, as qualified by relevant environmental and economic factors, including the special requirements of developing States, and taking into account fishing patterns, the interdependence of stocks and any generally recommended international minimum standards, whether sub-regional, regional or global;

(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 adequate scientific information shall not be used as a reason for postponing or failing to take conservation and management measures.¹¹⁷

Cartagena Protocol on Biosafety to the Convention of Biological Diversity (CPB, 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.

¹¹⁷ 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."

Article 10. 6

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism 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.¹¹⁸

Annex III, paragraph 4

Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

Convention on Persistent Organic Pollutants (Stockholm, 2001)*

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.

Article 8

7. If on the basis of the risk profile conducted in accordance with Annex E, the Committee decides:

(a) That the chemical is likely as a result of its long-term environmental transport to lead to significant adverse human health and/or environmental effects such that global action is warranted, the proposal shall proceed. Lack of full scientific certainty shall not prevent the proposal from proceeding (...).

9. The Committee shall, based on the risk profile referred to in paragraph 6 and the risk management evaluation referred to in Paragraph 7(a) or paragraph 8, recommend whether the chemical should be considered by the Conference of the Parties for listing in Annexes A, B and/or C. The Conference of the Parties, taking due account of the recommendations of the Committee, including any scientific uncertainty, shall decide, in a precautionary manner, whether to list the chemical, and specify its related control.

¹¹⁸ Similar text is contained in Article 11.8.

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 Convention, 1991)

Article 4.3

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, 1992)

Article 2

General obligations

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.

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 (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 de Janeiro, 1992)

Principle 15

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.¹¹⁹

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.

¹¹⁹ Annex 4 of the Resolution lists a number of “precautionary measures.”

7.5 Precautionary approach¹²⁰

7.5.1. 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.

7.5.2. In implementing the precautionary approach, States should 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 distribution of fishing mortality and the impact of fishing activities, including discards, on non-target or associated or dependent species, as well as environmental and socio-economic conditions.

¹²⁰ Paragraphs 7.5.3-5 contain detailed guidance on implementation of the precautionary approach.

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.

OECD Environmental Strategy for the 1st Decade of the 21st Century¹²¹

When designing policies for environmental sustainability which operationalise these criteria countries should apply precaution as appropriate in situations where there is lack of scientific certainty.¹²² 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.

¹²¹ The Strategy was adopted by OECD Environment Ministers on 16 May 2001; www.oecd.org/pdf/M00001000/M00001182.pdf.

¹²² The "criteria for environmental sustainability" referred to in this paragraph are: *regeneration, substitutability, assimilation, avoiding irreversibility*.

ANNEX II PRECAUTION AND SELECTED WTO AGREEMENTS

Precaution and the SPS Agreement

The SPS Agreement sets forth specific disciplines for sanitary and phytosanitary measures for the protection of human, animal or plant life or health among which are that 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).

The provisions of the SPS Agreement have been interpreted in various recent disputes brought under the WTO dispute settlement mechanism (the Hormones case, the Salmon case, and the Japan-Varietals case). In each of these cases, the measures were found inconsistent with the SPS Agreement, because there was no scientific basis for the measures, or because there was no risk assessment, or because there was no rational relationship between the risk assessment and the measure.

In the Hormones case, the EC Commission invoked the precautionary principle to justify a ban on the import of Canadian and U.S. meat derived from cattle to which growth hormones had been administered. The three parties involved - the EU, the United States and Canada - maintained different positions with regard to the legal status of precaution. The WTO Appellate Body summarised these positions as follows¹²³: "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*".¹²⁴

¹²³ Hormones case, paragraph 121 of the Appellate Body report.

¹²⁴ 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, general principles of law are, in principle, applicable to all countries. Principles of customary international law are generally applicable to all countries, except consistent dissenters. For a detailed description of the sources of international law, see I. Brownlie (1990), *Principles of public international law*, pages 1 ss. See also J. Cameron (1991), page 1.

In its report, the Appellate Body examined the relevance of precaution, or the precautionary principle, in the interpretation of the SPS Agreement¹²⁵:

“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.¹²⁶ 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.¹²⁷

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

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

¹²⁶ Footnote 69 of the Appellate Body report: "Authors like P. Sands, J. Cameron and J. Abouchar, while recognizing that the principle is still evolving, submit nevertheless that there is currently sufficient state practice to support the view that the precautionary principle is a principle of customary international law. See, for example, P. Sands, *Principles of International Environmental Law*, Vol I (Manchester University Press 1995), p.212; J. Cameron, "The Status of the Precautionary Principle in International Law, in J. Cameron and T.O'Riordan (eds.), *Interpreting the Precautionary Principle*" (Cameron May, 1994), 262, p. 283; J. Cameron and J. Abouchar, "The Status of the Precautionary Principle in International Law", in D. Freestone and E. Hey, (eds.), *The Precautionary Principle in International Law* (Kluwer, 1996) 29, p. 52. Other authors argue that the precautionary principle has not yet reached the status of a principle of international law, or at least, consider such status doubtful, among other reasons, due to the fact that the principle is still subject to a great variety of interpretations. See for example, P. Birnie and A. Boyle, *International Law and the Environment* (Clarendon Press, 1992), p. 98; L. Gündling, "The Status in International Law of the Precautionary Principle" (1990), 5:1,2,3 *International Journal of Estuarine and Coastal Law* 25, p. 30; A deMestral (et.al), *International Law Chiefly as Interpreted and Applied in Canada*, 5th ed. (Emond Montgomery, 1993), p. 765; D. Bodansky, in *Proceedings of the 85th Annual Meeting of the American Society of International Law* (ASIL, 1991)p. 415. "

¹²⁷ Footnote 70 of the Appellate Body report: "In (*Case concerning the Gabčíkovo-Nagymaros Project*, the International Court of Justice recognized 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...". However, we note that the Court did not identify the precautionary principle as one of those recently developed norms. It also declined to declare that such principle could override the obligations of the Treaty between Czechoslovakia and Hungary of 16 September 1977 concerning the construction and operation of the Gabčíkovo/Nagymaros system of Locks. See *Case concerning the Gabčíkovo/Nagymaros Project* (Hungary/Slovakia), I.C. J. Judgement, 25 September 1997, paras 140, 111-114. Not reported in the I.C. J Reports but available on internet at <http://www.icj-cij.org/idecis.htm>."

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 Agreement*.”

In the Japan-Varietals case, the Appellate Body considered that “Article 5.7 operates as a *qualified* exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence. An overly broad and flexible interpretation of that obligation would render Article 5.7 meaningless”.¹²⁸ It further noted Japan's argument that the requirement in Article 2.2 not to maintain an SPS measure without scientific evidence should be interpreted in the light of the precautionary principle and restated its position in the Hormones case that “...the precautionary principle finds reflection in the preamble, Article 3.3 and Article 5.7 of the *SPS Agreement* and that this principle has not been written into the *SPS Agreement* as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of the Agreement.”¹²⁹

The Appellate Body further analysed the requirements which provisional SPS measures “Article 5.7 of the *SPS Agreement* sets out four requirements which must be met in order to adopt and maintain a provisional SPS measure. Pursuant to the first sentence of Article 5.7., a Member may provisionally adopt an SPS measure if this measure is

- (1) imposed in respect of a situation where “relevant scientific information is insufficient”; and
- (2) adopted “on the basis of available pertinent information”.

Pursuant to the second sentence of Article 5.7 such a provisional measure may not be maintained unless the Member which adopted the measure:

- (1) seek(s) to obtain the additional information necessary for a more objective assessment of risk; and
- (2) review[s] the ... measure accordingly within a reasonable period of time.

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.”¹³⁰

The Appellate Body further considered: “What constitutes a “reasonable period of time” has to be established on a case-by-case basis and depends on the specific circumstances of each case, including

¹²⁸ Japan-Varietals case, paragraph 80 of the Appellate Body report.

¹²⁹ Japan-Varietals case, paragraph 81 of the Appellate Body report.

¹³⁰ Japan-Varietals case, paragraph 89 of the Appellate Body report.

the difficulty of obtaining the additional information necessary for the review *and* the characteristics of the provisional SPS measure.”¹³¹

It also stated 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. However, Article 5.7 states that the additional information is to be sought in order . to allow the Member to conduct "a more objective assessment of risk". Therefore, the information sought must be germane to conducting such a risk assessment...”¹³²

In relation with the concept of "risk" used in the SPS Agreement, the Appellate Body has considered, in the Hormones case, 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.”¹³³

Precaution and the GATT

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. Article XX provides that nothing in the Agreement shall prevent Members from adopting or enforcing measures that are “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.”

While GATT provisions have been interpreted in several disputes related to trade restricting measures to protect human health and the environment,¹³⁴ so far, none of them have been interpreted in decisions specifically based on the precautionary nature of an environmental measure.¹³⁵

In interpreting Article XX of the GATT, the WTO Appellate Body stated that “WTO Members have a large measure of autonomy to determine their own policies on the environment (including its

¹³¹ Japan-Varietals case, paragraph 93 of the Appellate Body report.

¹³² The Appellate Body agreed with the Panel that Japan "did not seek to obtain the additional information necessary for a more objective risk assessment" and that it had not reviewed its varietal testing requirement "within a reasonable period of time". It therefore found the measure by Japan not justified by Article 5.7. Japan-Varietals case, paragraphs 92-3 of the Appellate Body report.

¹³³ Hormones case, paragraph 187 of the Appellate Body report.

¹³⁴ 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).

¹³⁵ A. Laudon and C. Noiville (1998), page 59, provide an interpretation of precautionary measures under the GATT and the TBT Agreement. See also J. Cameron (1991), page 257.

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.”¹³⁶ Similarly, in the 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.”¹³⁷

With regard to the role of science in relation to Article XX (b), 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 opinion. A Member is not obliged, in setting health policy, automatically to follow what, at a given time, may constitute a majority scientific opinion.”¹³⁸

In the Shrimp-Turtle case, the Appellate Body 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.”¹³⁹ In the United States-Gasoline case, the Appellate Body has also considered that the GATT “is not to be read in clinical isolation from public international law.”¹⁴⁰

Precaution and the TBT Agreement

The TBT Agreement, which covers mandatory technical regulations, voluntary standards, and conformity assessment procedures, 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 levels 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...”.

Other provisions of the TBT Agreement that may be relevant to a discussion on precaution are Articles 2.2 and 2.3. 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 risks 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 risks, relevant elements of consideration are, inter alia, available scientific and technical information, related processing technology or intended end-uses of products”. Article 2.3. provides that technical regulations “shall not be maintained if the circumstances or objectives giving rise to their adoption no longer exist or if the changed circumstances or objectives can be addressed in a less trade-restrictive manner.”

¹³⁶ United States-Gasoline case, pages 29-30 of the Appellate Body report.

¹³⁷ Measures affecting asbestos and asbestos containing products (hereafter “Asbestos case”), paragraph 168 of the Appellate Body report .

¹³⁸ Asbestos case, paragraph 178 of the Appellate Body report.

¹³⁹ Shrimp-Turtle case, paragraph 129 of the Appellate Body report.

¹⁴⁰ United States-Gasoline case, page 17 of the Appellate Body report.

ANNEX III

PRECAUTION IN ENVIRONMENTAL LEGISLATION OF OECD MEMBER COUNTRIES

This Annex provides examples of how precaution is embedded in environmental legislation of OECD Member countries. It is largely based on contributions from Member countries.¹⁴¹

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*.

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 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.

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.

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

¹⁴¹ To the extent possible, the wording of these contributions has been kept unchanged; editorial changes have been made where necessary.

¹⁴² Contribution from Australia.

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 degradation and promotes and reinforces enforceable pollution prevention approaches.”¹⁴³

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 the 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.¹⁴⁴

Japan adopted a Basic Environment Plan in 1994, which outlines comprehensive and long-term government policies for environmental conservation¹⁴⁵. The New Basic Environment Plan, which revises the 1994 plan, was adopted in 2000. Four concepts are considered to be the basic guidelines for environmental policies: the Polluter-Pays Principle, Eco-efficiency, the Precautionary Approach, and Environmental Risk. In regard to the precautionary approach, the Plan states that, for certain environmental issues, some irreversible problems and serious long-term impacts have been discovered. As of yet the mechanisms related to their causes, as well as their full impacts on the environment have not been determinable, due to lack of scientific knowledge. In such critical situations, the Plan provides that a precautionary approach will be undertaken as soon as possible, even if sufficient scientific evidence is still being gathered to support the existence of the problem itself, and that no excuses will be made for the postponement of countermeasures, such as stating the lack of complete scientific evidence.¹⁴⁶

In Korea, the National Assembly passed in February 2001 an Implementation Act for the Cartagena Protocol on Biosafety. The Implementation Act sets forth procedures and criteria to accommodate the Protocol into the Korean legal system. As the centrepiece of the accommodation efforts among many government agencies with differing policy priorities, the precautionary approach is read into the Korean Implementation Act as follows: "The 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 does not explicitly include “lack of scientific certainty” as a crucial factor needed to facilitate application of the precautionary principle set out in the Protocol. However, the precautionary approach accommodated in the Protocol was well taken into account in introducing the Implementation Act. Taking an inclusive approach based on the Protocol, the Implementation Act reflects the spirit of the precautionary approach of the Protocol.¹⁴⁷

¹⁴³ Contribution from Canada.

¹⁴⁴ Contribution from the Czech Republic.

¹⁴⁵ Outline of the Basic Environment Plan, Ministry of the Environment, Japan.

¹⁴⁶ The Basic Environment Plan (tentative translation), December 2000 www.env.go.jp

¹⁴⁷ Contribution from Korea.

Mexico's Wildlife Act, adopted in 2000, provides that the authorities in charge of wildlife management have to apply the principles set out in the General Act of Ecological Balance and Environmental Protection and that, in no case, lack of scientific certainty can be used as an argument to postpone the adoption of efficient measures for the conservation and management of wildlife.¹⁴⁸

The "Environment 2010 Strategy" of New Zealand sets out the Government's vision, principles and goals for the environment to the year 2010. It establishes the framework within which central and local government and the private sector can develop their own policies and plans. The Strategy contains 11 principles developed by the Government for integrating environment, society and economy, one of which is "applying the precautionary principle". One of the goals listed in the strategy is to take precautionary actions to help stabilise atmospheric concentrations of greenhouse gases in order to reduce risk from global climate change.¹⁴⁹

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 conducted in an ethically and socially justifiable way, in accordance with the principle of sustainable development and without detrimental effects on health and environment. The importance of applying the precautionary principle in the implementation of this Act was emphasised in the bill presenting it to Parliament.¹⁵⁰

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."¹⁵¹

Precaution is an essential element of the regulatory system of the United States.¹⁵² Rather than stated as a principle, precaution has been inherent in the *process* of developing measures to protect the environment. 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 United States has applied precaution in a number of domestic laws to protect the environment. For example, it provided an early legislative response to ozone layer issues. In 1977, the United States proposed under TSCA to ban CFC's as propellants in non-essential spray cans. Later that year, the United States 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

¹⁴⁸ www.semarnat.gob.mx

¹⁴⁹ Ministry for the Environment, New Zealand, www.mfe.govt.nz/management/2010

¹⁵⁰ Contribution from Norway.

¹⁵¹ Contribution from Switzerland.

¹⁵² 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).

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 layer.¹⁵³

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 2000.¹⁵⁴ 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 incorporated references to precaution in their legislation.

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 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.¹⁵⁵

Belgium has included a reference to the precautionary principle in the 1999 Federal Act for the Protection of the Marine Environment in Belgian Maritime Waters: "When carrying out activities in maritime areas, the users of such areas and the Government shall take into account the preventive action principle, the precautionary principle, the principle of sustainable management, the polluter-pays principle and the restoration principle... The precautionary principle implies that preventive measures must be taken when there are justified reasons to fear pollution of maritime areas, even in the absence of a definite proof of a causal link between the introduction of substances, energy or materials in maritime areas and the damaging effects." The 1995 Decree on Environmental Policy of the Flemish Region provides, in the section on objectives and principles that "environmental policy aims at a high level of protection, based on an evaluation of the different social activities. It is based on the precautionary principle, the principle of preventive action, the principle that environmental degradation must be primarily prevented at the source, the standstill principle and the polluter pays principle."¹⁵⁶

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

¹⁵³ Contribution from the United States. The term environment used in this contribution broadly includes health, safety, and the conservation of natural resources.

¹⁵⁴ The report by the European Environment Agency (2002), "*Late lessons from early warnings: the precautionary principle 1896-2000*", examines "how the concept of precaution has been applied - or not - by policy makers over the past century when addressing a broad range of hazards linked to public health and the environment in Europe and North America" (news release of 10 January 2002). www.org.eea.eu.int/documents

¹⁵⁵ Contribution from Austria.

¹⁵⁶ Contribution from Belgium.

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 which allows to take measures based on the likely impact of pollution on the physical surroundings.¹⁵⁷

The Environmental Protection Act of Finland, which came into force in March 2000, is based on a number of principles, described as: the prevention or the restriction of damages to a minimum - caution and precaution principle; the application of the best available technology (BAT); the best practice from the perspective of the environment (BEP); and the polluter-pays principle.¹⁵⁸

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 cost.¹⁵⁹

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 care.¹⁶⁰ 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.

Italy applies the precautionary principle also to national legislation not covered by Community Law. Recently approved environmental legislation (Framework Act on Electro Smog, February 2001) refers specifically to the precautionary principle, whereas existing food legislation generally calls upon, but does not specifically address the principle. The Framework Act on Electro Smog mentions the precautionary principle in Article 1 (Objectives) amongst the guiding principles for the application of precautionary measures during risk management and control. The Act sets standards beyond which certain activities are not allowed, while the remaining activities must stay within the limits of an acceptable risk. In this way, occurrence of potential damage situations is limited. Following the entry into force of the above mentioned legislation, other, similar environmental measures, which explicitly refer to the precautionary principle, have been drafted. They are currently under the attention of the Parliament for approval.¹⁶¹

The new environmental legal system in Poland is based on principles listed in the Rio Declaration on Environment and Development, notably, the precautionary principle, the polluter-pays principle and the sustainable development principle. The Environmental Protection Law of 2001 provides that whoever undertakes an activity the negative impact of which has not been fully recognised, shall,

¹⁵⁷ Contribution from Denmark.

¹⁵⁸ Ministry for the Environment of Finland www.vyh.fi

¹⁵⁹ "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).

¹⁶⁰ J. Cameron and J. Abouchar (1996), quoting K. von Moltke, *The Vorsorgeprinzip in West German Environmental Policy*, 12th report of the Royal Commission on Environmental Pollution, HMSO, 1988.

¹⁶¹ Contribution from Italy.

applying precaution, undertake all possible preventive measures. The National Environmental Policy declares the precautionary principle as being one of the key principles of environmental policy and indicates that this principle requires undertaking appropriate measures already when there is a reasoned possibility for risk, without having to have full scientific evidence for it.¹⁶²

The Environmental Code of Sweden, which came into force in 1999, codifies the main existing environmental acts. It is aimed at promoting sustainable development and asserts the precautionary principle, the polluter-pays principle, the product choice principle and principles regarding resource management, the eco-cycle and suitable localisation of activities and measures.¹⁶³

¹⁶² European Eco-Forum (2001), Implementing Rio Principles in Europe: participation and precaution. Pre-publication final text version

¹⁶³ Ministry for the Environment of Sweden www.internat.naturvardsverket.se

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