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THE PRECAUTIONARY PRINCIPLE IN THE EUROPEAN UNION & ITS IMPACT ON INTERNATIONAL TRADE RELATIONS

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STEPHEN WOOLCOCK*

ABSTRACT

Although elements of precaution were used in the environmental regulation of various countries in the 1970s, including the United States, it has been the European Union that has emerged as the main proponent of the precautionary principle, both in European regulatory policy and in international agreements.

The precautionary principle must be considered as an important and enduring feature of European and increasingly international policies aimed at dealing with the risk to the environment as well as human, plant and animal health in instances where the level of risk is not insignificant and where there is scientific uncertainty.

Developed and applied originally in the field of environmental regulation, the precautionary principle has subsequently found application in other related policy fields such as human health, and is becoming an acceptable feature of – if not customary – international law.

Rightly or wrongly, the precautionary principle is also wrapped up in the current critique of "globalisation", because it promises wider, more democratic participation in decision-making concerning issues of central importance to the sustainability and risks associated with economic and technological development. Precaution provides those sceptical of established policy-making procedures with a case for opening the policy process to wider participation and greater transparency and democratic accountability.

The central issue with regard to the EU's application of the precautionary principle is whether it will form the basis for balanced policy that promotes sustainability and facilitates the growth of trade and investment. Or will it be used in an arbitrary fashion and simply wheeled out to justify controls on trade or investment that are dictated by commercial or political expediency?

Most of the concern expressed about EU policy relates to a number of trade disputes involving the United States. These include, in particular, the beef hormones case on which the WTO ruled against the EU ban on the grounds that

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it was inconsistent with Article 5(7) of the Agreements on Sanitary and Phytosanitary Measures. Precautionary measures taken by the EU were found to be inconsistent with the SPS agreement, which only allows for provisional measures based on precaution. The second case concerns genetically modified products where measures – taken by EU member states and the EU as a whole on the basis of precaution have also been challenged by the EU's trading partners. The EU's policy in these cases has not only been inconsistent with existing trade rules but also inconsistent in its application.

This inconsistency must be seen as a result of political expediency in the face of intense domestic pressure for a higher degree of precaution in risk management following a number of failures to provide sufficient protection for consumers and the environment. The latest and most significant failure concerned BSE (mad cow disease) where regulators withheld information on risk from consumers for largely commercial reasons, but the European Environment Agency has recently published a report listing a series of failures to protect the environment or human health over a period of the last 100 years.

The EU member states and European institutions have recognised the need to develop a clear and consistent approach to the use of the precautionary principle. This has resulted in a clearer statement on its application in the 2000 European Commission paper, which has subsequently been endorsed by member states and the European Parliament and in the revised food safety regime currently being implemented in the EU.

The European Union's motivation in pressing for the application of the precautionary principle in international trade and environmental agreements therefore results from the fact that the precautionary principle has been established as the guiding principle for environmental and food safety regulation *within* the EU. This is firmly anchored in treaty provisions introduced in 1991, and in the jurisprudence of the European Court of Justice. This establishment of the precautionary principle has come about because of the political pressure from consumers and voters who lack confidence in the existing regulatory regimes and are sceptical of the ability of science to find all the answers. It is therefore inaccurate and superficial to characterise the EU's insistence on the acceptance of the precautionary principle as a cover for protection. Trade issues arise because Europeans are demanding a higher degree of precaution than has been accepted by other governments.

The EU's insistence on the precautionary principle has also been characterised as a rejection of "sound science". This is also inaccurate or at least only part of the story. The EU's approach to risk analysis is not anti-science; rather, it argues that risk assessment should be science-based. The EU approach does, however,

place scientific risk assessment within a broader framework which also includes non-scientific value judgements of what is an acceptable risk for society. There is a widespread acceptance of scientific uncertainty in risk assessment and management. For this reason, the vast majority of countries accept the need for precaution as a legitimate element in risk analysis. This is, for example, reflected in its inclusion of a range of multilateral environmental agreements in the SPS agreement and in the current discussions on Principles of Risk Analysis in the Codex Alimentarius. Differences arise not over the use, but rather the degree of precaution, and how to ensure that the inevitable regulatory discretion associated with the use of precaution is not used to limit trade "unfairly".

Given the differences between public policy preferences between countries and regions, it is always going to be difficult to reach consensus on international standards governing what is acceptable risk. It is worth noting that standards-setting is as much a political as a scientific process with votes in the various relevant fora, such as Codex Committees, deciding on acceptable levels. Whilst there remains a need to continue work on international agreement on standards, the more likely policy approach to resolving tensions is agreeing on procedural criteria for the application of precaution. Such procedural criteria can help to ensure that discretion is not abused. This is the approach recommended in the recent draft on Principles for Risk Analysis within the context of work on the Codex Alimentarius. The proposed criteria include, for example, the requirement to continue efforts to improve scientific knowledge of the risks involved, proportionality, transparency, consistency, non-discrimination, the use of cost-benefit analysis and provision for reviews of risk-assessment decisions and measures taken to mitigate risk. These criteria have already found expression in the EU's policy guidelines and in other policy applications, such as in the new regulations on EU food safety.

One important difference between the EU and other countries is that the EU wishes to see "the" precautionary principle recognised in a wide range of international environmental and trade agreements. Other governments oppose this on the grounds that the international legal precedent that exists in environmental regulation is inappropriate for other policy fields. In other words, the EU wants "the" precautionary principle to cover all types of risk (environmental, food and animal health, etc.). This is consistent with EU practice. Other governments want to tailor the application of a precautionary approach to the specific policy area or risk.

Disputes between the EU and its trading partners over the application of the precautionary principle seem likely to continue and could become much more serious, if, for example, there is a WTO case brought over EU bans – or labelling

– of genetically modified products. The EU ban is influenced by genuine consumer and environmental concerns. They are not simply disguised protection. The EU's trading partners have equally deep-seated but divergent views on how to deal with risk and what role precaution should play in regulation. These divergent views have developed over a period of time and can be said to be structural in nature. The WTO dispute settlement will not be able to resolve problems created by such structural differences. What is needed is a wider international debate on the role of precaution with a view to finding some agreed procedural criteria or guidelines on how precaution should be applied.

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1. Introduction

This paper discusses the European approach to the precautionary principle and how this impinges on international trade relations. It starts by illustrating how the concept of the precautionary principle was developed in the European Union from the late 1970s onwards. Although the US and other countries have had elements of precaution in their environmental regulation, it is the EU that has developed and is promoting the wider application of "the precautionary principle" in international agreements.[1]

The paper then unpacks the elements that go to make up the precautionary principle in order to help understand what is involved. This shows that the application of the precautionary principle rests on three core conditions: a) regulatory non-action threatens to lead to non-negligible harm; b) there is a lack of certainty as to the cause and effects relationship; and that c) under such circumstances, regulatory inaction is not justified. In addition to these core conditions, there is a range of other elements that are associated with the use of the principle.

The paper illustrates how the precautionary principle has become a central feature of EU policy not just in the field of environmental regulation but also more recently in the field of human health/food safety. This fact, together with the rapid application of the precautionary principle in a range of regional, bilateral and multilateral agreements, means that like it or not a precautionary approach, if not "the" precautionary principle is here to stay.

Attention then turns to how differences over the application of a precautionary approach/principle can create difficulties in the international trading system and trade relations. The paper discusses the examples of the WTO (agreements on the Application of Sanitary and Phytosanitary Measures and the Technical Barriers to Trade), the Bio-safety Convention, and current work in the Codex Alimentarius.

[1] In the policy debate there is an important distinction between the term "the precautionary principle" and "a precautionary approach". As this paper will show, there is a growing body of jurisprudence and history associated with "the precautionary principle" largely derived from its application in the field of environmental regulation. A precautionary approach is different in the sense that these precedents set with regard to "the precautionary principle" are not considered to be applicable.

2. The Origins of the Precautionary Principle

Although elements of precaution can be found in the US and British environmental regulation in the 1970s, it has been the European Union that has emerged as the main proponent of the principle since the 1980s. Indeed, having provided the model for early European environmental regulation, the United States now finds itself in the position of trying to resist European pressure to apply the precautionary principle in international agreements. The application of the precautionary principle in the Biosafety Protocol[2] and the EU's use of precaution as grounds for regulating and limiting the importation of genetically modified crops[3] are two recent examples of such tensions.

There are a number of reasons why the precautionary principle has assumed an important role in both domestic and international policy and why it is here to stay. The first is that the EU, as a major player in international trade and environmental regime formation has adopted the approach in its risk analysis and is championing its use in international agreements. In the late 1970s and early 1980s it was the Federal Republic of Germany that played an important role in developing and promoting the use of the precautionary principle within the EU. Germany policy was driven by a deep-seated concern about the impact of acid rain on its forests, global warming and the pollution of the North Sea. At that time there was no scientific consensus on the impact of acid rain on the environment. Sweden had thrust acid rain onto the agenda at the UN Environment Conference in Stockholm in 1972. The Long Range Transport of Air Pollutants (LRTAP) study had linked acidification in Scandinavia with sulphur dioxide (SO2) emissions, but the link was still contested within the scientific community in part due to firm resistance from countries, such as the United Kingdom, to any regulation requiring expensive flue gas cleaning of major SO2 polluters. The German philosophy at the time was summed up in the 1976 Environment Report of the Federal Government:

> Environmental policy is not fully accomplished by warding off imminent hazards and the elimination of damage that has occurred. Precautionary environmental policy requires furthermore that natural resources are protected and demands on them are made with care.[4]

[2] See Robert Falkner, "Regulating biotech trade: The Cartagena Protocol on bio-safety", International Affairs, Volume 76, No. 2, April 2000.

[3] See Grant Issac, Shondeep Banerji and Stephen Woolcock, "Trade policy and food safety", Consumer Report, The Consumer Association, London 2000.

[4] Quoted in O'Riordan et al., Reinterpreting the Precautionary Principle, Cameron and May, 2001.

The precautionary principle was therefore used in support of tough regulations requiring expensive de-sulphurisation practices, because although trees were dying there was at that time no clear causal link to SO2 emissions. Once these measures had been introduced in national regulation, Germany industry joined with environmental groups and other NGOs in pressing for the introduction of controls across Europe. Similarly tough environmental regulations were applied to address CO2 emissions and the pollution of the North Sea through the dumping of sewage sludge containing heavy metals.

The German approach to precaution was a pretty robust one as indicated in the Federal German government's report on environmental policy in 1984:

> The principle of precaution (Vorsorge) commands that damages done to the natural world…should be avoided in advance and in accordance with opportunity and possibility. Precaution further means the early detection of dangers to health and the environment by comprehensive, synchronised… research… [It] also means acting when conclusively ascertained understandings by science is not yet available.[5]

A broad consensus, at least on the use of precaution in environmental policy, appears to have developed in Germany, despite the fact that this resulted in increased costs for industry. Support for the approach and tough environmental regulation *per se* was probably German industry making virtue out of necessity. German industry was willing to accept that it had little option but to embrace improved environmental standards and that in doing so it could strengthen its international competitive position by being first to develop more environmentally sustainable technologies. This consensus on the need to adopt more environmentally sustainable technologies and production has been called "ecological modernisation". In other words the potential conflict between growth and environmental aims was overcome through support for modernisation that would replace old polluting technologies and products with new ones and thus promote growth whilst improving the environment. It is not clear what link there is between ecological modernisation and the precautionary principle. The introduction of less polluting technologies can clearly be encouraged by regulation aimed at minimising or preventing known risk. In Europe there is concern that an excessive degree of precaution will have a chilling effect on investment in new technologies. This is particularly the case with biotechnology.

Throughout the 1980s the European Union moved progressively towards tougher environmental protection and a wider application of the precautionary principle.

[5] See Albert Weale, The New Politics of Pollution, Manchester University Press, 1992.

In this Germany was a leading proponent, but there was growing support among other member states of the EU that were equally influenced by the strength of the environmental arguments shaped by effective environmental NGO lobbying. Some countries resisted the trend for reasons of principle and expediency. Environment policy in Britain was – and to a lesser degree continues to be – more influenced by sound science, and during the 1980s the British government resisted tougher EU environmental regulation of S02 emissions and the dumping of sewage sludge in order to keep the costs for UK industry down. The case was even made that the winds and tides that prevailed in British weather patterns resulted in easy natural dispersal of pollution and thus gave British industry a comparative advantage compared to industrial locations such as the Rhine valley where natural dispersal was slow. Although Britain was able to delay the introduction of tougher environmental regulation it was not able to stop the trend in EU policy. Subsequently British policy has also shifted towards more environmentally friendly policies, but it still includes a more ready acceptance of cost benefit analysis as a factor in shaping regulatory policy more than is the case in other EU member states like Germany. The 1999 statement by the new Labour Government on the precautionary principle illustrates how the British position has moved towards the EU consensus:

> The precautionary principle means that it is not acceptable just to say "we can't be sure that serious damage will happen, so we'll do nothing to prevent it". Precaution is not just relevant to environmental damage – for example, chemicals, which may affect wildlife may also affect human health. At the same time precautionary action must be based on objective assessments of the costs and benefits of action. The principle does not mean that we only permit activities if we are sure that serious harm will not arise, or there is proof that the benefits will outweigh the possible risks… There are no hard and fast rules on when to take action: each case has to be considered carefully... transparency is essential... Decisions should be reviewed to reflect better of risk as more evidence becomes available (DETR, 1999, quoted in O'Riordan).

The shift in UK policy is also symptomatic of the progressive application of the precautionary principle in the EU during the 1980s and 1990s. The first piece of EU legislation adopting the precautionary principle was the 1979 Directive on the testing of new chemicals. But this has been followed by many more applications of precaution in the total of 500 pieces of legislation in the field of the environment up to 2000 (Haig, 2000). Paradoxically, the model used for the Directive on new chemicals in 1979 was US legislation, but by the 1990s the EU was ahead of the US in its application of the precautionary principle. The

Maastricht Treaty revision of the founding treaty of the EU enshrined environmental protection, including the use of the precautionary principle as one of the central policy objectives of the EU. See below.

A second reason why the precautionary principle has been brought to the forefront of debate in recent years has been the steady extension of the use of the principle from the environment into other related policy fields such as human, animal and plant health. This wider use of the precautionary principle has gone hand in hand with the general trend towards a convergence of environmental regulation and other policy areas, such as trade policy, as the aim of integrating environmental objectives into other policies domains became more and more accepted. In this respect the EU position has tended to be to seek to establish that "the" precautionary principle shall be applied in all instances, whereas the governments of other countries, such as the United States, appear to wish to tailor the use of precaution to the specific policy area.

The link with food safety and trade has in particular, thrown up cases such as the beef hormones, when the EU introduced a ban on certain hormones in beef in 1988 on the grounds that these could be carcinogenic. In 1998 the EU also banned the use of four antibiotics in animal feed (virginiamycin, bacitracin zinc, tylosin phosphate and spiramycin) on the grounds that such use of antibiotics risked promoting resistance to antibiotics in humans and thus reducing their effectiveness. Finally, a number of EU member states have banned to sale of certain genetically modified crops and the EU suspended further approvals of GM products and proposed mandatory labelling of GM products in food, on the grounds that genetically modified products represent a risk to the environment and consumers.[6] The GM cases concern a significant volume of trade and could create very serious trade tensions between the EU and the major agricultural exporters including in particular the United States. In all cases precaution has played a role in the sense that the level of risk and how such risk should be managed has been an issue of contention.

Animal rights issues or broader ethical issues related to, for example, the use of human genetics seem likely to be further areas in which the precautionary principle will find application. Developments in science continue to offer new technologies and new products with significant benefits but also a potential impact on the environment and human health. At the same time, there remains, as in the past, a level of uncertainty about the impact of these products. This, combined with the links between environmental policy and other policy areas,

[6] In July 2001, the European Commission proposed two Directives: one on traceability and labelling of GMOs and products produced from GMOs and one on the regulation of GM food and feed.

such as in the case of the treatment of GMOs, seems likely to ensure that there will be continued pressure for methods developed in environmental policy such as the precautionary principle to be applied in other policy areas.

A third reason why precaution has been brought to the fore in recent years is that it is wrapped up in the debate on sustainability. Sustainability must be seen as a wider concept than environmental protection and one that involves a politicisation of decision-making in the fields of environmental regulation, food safety and other issues linked to sustainable production and consumption. Sustainability is in turn linked to a wider agenda concerning the participation of consumers, the public and above all civil society NGOs in the decision-making processes. The desire for sustainable development reflects a deep scepticism that science has all the answers and thus a suspicion of decisions on risk assessment or risk management based on "sound science". The case is made that science-based decisions are not without normative biases and that as a result the assessment of risk should be open to wider participation, so that societal norms and values can be integrated into the risk assessment process.

There is also a suspicion of the risk management decisions taken by regulatory agencies or governments. Established channels of decision-making have been challenged as unaccountable. Experiences such as with the handling of the BSE issue in Britain and elsewhere have at best shown that regulators and politicians have not reflected public concern about the potential impact and at worst that regulators and politicians sought to keep information about risk from the public for reasons of commercial interest of producers. Episodes such as the BSE fiasco have therefore led to a fundamental undermining of public confidence in the established – predominantly science-based – risk assessment and management procedures within Europe. There has therefore been increasing pressure for greater transparency and decision-making and for greater participation in the decision-making process. Conventional democratic channels are rejected in favour of activism by a range of civil society NGOs, including consumers and other groups, but especially environmental NGOs. As the definition or application of the precautionary principle is inevitably political, these pressures for wider participation will have a bearing on its application.

3. The Concept of the Precautionary Principle

Before going any further it is important to have a clearer idea of what the precautionary principle is. This section discusses the various elements that make up the precautionary principle. From the outset it should be pointed out that discussing the elements does not get us anywhere nearer an operational criteria for determining non-negligible risk and thus justifying regulatory intervention. Nor will this discussion provide answers to the question of what degree of

intervention is needed. But a greater understanding of what are generally seen to be elements of the precautionary principle should help us understand it better, even if it results in a more sophisticated level of confusion.

The essence of the precautionary principle is that it provides "the philosophical authority in a rational yet chaotic age to take public policy or regulatory decisions about the protection of the environment or human health in the face of scientific uncertainty, or worse, ignorance".[7] Alternatively, the precautionary principle provides the basis for "acting in advance of scientific proof of harm to address uncertain but potentially significant risks".[8] The precautionary principle involves some shifting of the balance in the debate about regulatory intervention away from inaction to action by regulators in the face of a lack of reasonably convincing scientific evidence. This is best illustrated by Cameron's broad definition that the precautionary principle "stipulates that where the environmental [or other] risks being run by regulatory inaction are in some way uncertain but non-negligible, regulatory inaction is unjustified".[9]

As Cameron argues these definitions lead one to three key questions in the debate of what constitutes the precautionary principle:

- How does one determine whether non-negligible risk exists and its extent?
- Assuming this is possible what regulatory action is justified? and
- How should the thresholds for risk and costs of non-action be determined, in other words who makes the decisions?

3.1 Determining Non-Negligible Risk

There is inevitably a spectrum of risk assessment. At the one (environmental) end of the spectrum, there is non-negligible risk in all cases, since new products of processes will always have some impact. At the other end of the spectrum non-negligible risk is heavily qualified by benefits and action constrained by the potential costs in terms of lost production and economic benefits. Clearly a definition which includes everything in non-negligible risk is not much help. The position adopted by, for example, the European Commission in its 2000 paper on the precautionary principle falls between these two extreme positions. The Commission's paper is discussed below.

Risk can be seen as consisting of two elements: the *probability* that an event will

[7] James Cameron, "The precautionary principle in international law", in O'Riordan et al., p. 113.

[8] Jorden and O'Riordan, 1999.

[9] Cameron, op cit., p. 116.

occur and the *seriousness* of that event for the environment and human health. For example, one could postulate that the probability of a major nuclear accident resulting in the release of significant levels of radioactive material is lower than a road accident involving a petrol taker in which petrol is spilt leading to pollution of water courses by carcinogenic benzene in the petrol. The nuclear accident would however be much more serious and affect far more people than a localised spill of petrol. [10] Thus, whilst science may be able to develop some theories on the probability of an event, it may not be able to assess the seriousness of the impact, which will be shaped by other factors such as how close the tanker crash is to a water source and whether that water source is important in public water supply. Alternatively scientific uncertainty may be present in the calculation of the probability of an event whilst the seriousness may be more easy to predict. There may of course be uncertainty with regard to both elements.

In the literature and debate on risk, there is a general distinction between *risk assessment, risk management and risk communication*. Science-based approaches have tended to be given greater emphasis in risk assessment even if other social or environmental factors figure more in risk management. The work of the Codex Alimentarius on Principles of Risk analyses this distinction between risk assessment, risk management and risk communication. The European Commission employs this approach in its 2000 paper on the precautionary principle, and envisages that precaution has greater application in risk management than risk assessment.[11] It has also been argued that one of the major differences between the US approach and the European approach to risk is that whilst both approaches provide a central role for science in risk assessment, the US also uses sound science as the basis for risk management, whereas the EU does not.[12] Such a distinction is helpful as a broad generalisation only since the distinctions between risk assessment, management and communication are less clear cut in practice.[13]

[10] This is not an especially good example since there is scientific evidence that both nuclear leaks and benzene represent a risk. The issue involved here is therefore prevention of dangerous levels of exposure rather than precaution in the fact of uncertainty.

[11] European Commission, Communication from the European Commission on the Precautionary Principle, 2000, p. 10.

[12] Grant Isaac, Regulatory regionalism in transatlantic trade relations: The case of agricultural biotechnology, PhD dissertation, London School of Economics, February 2001.

[13] Risk communication is concerned with transparency and with an interactive dialogue between those responsible for risk analysis (assessment and management) and stakeholders (i.e. consumers, industry and the academic/research community).

In practice, rules such as those of the WTO provide for provisional precautionary measures to be taken while further research is undertaken in order to be able to make a comprehensive assessment of risk. But before provisional measures can be taken there must be an initial identification of risk. This raises the particular difficulty of deciding what criteria should be used to make such identification. Some would argue that such initial identification of risk should use scientific knowledge. The proponents of precaution argue that this is inadequate.

3.2 Deciding on What Action Should Be Taken

Assuming it is possible for risk assessment to determine that non-negligible risk exists, how does one decide on the degree of regulatory intervention? Again it is possible to define a spectrum of possible policy objectives to guide decision-makers. This spectrum ranges from avoidance of irreversible harm [to the environment] to action to protect the environment regardless of the worth of any product or process to mankind. If the latter policy objective were chosen, it would require a higher degree of precaution or tough regulation aimed at significantly constraining the production of the product concerned or quite possibly an outright ban. If irreversible harm is selected as the policy objective, then it is possible to envisage lower levels of precaution and a greater use of cost-benefit analysis. For example, in the examples of German and British policy on acid rain discussed above, Germany pursued a higher level of precaution than the British.

Broadly speaking therefore the precautionary principle says that where there is uncertainty, there is a high cost of inaction. As with the risk assessment, however, there are dangers associated with high levels of precaution. There could be high economic costs of regulatory intervention, which might, for example, undermine the competitive position of the European industry compared with producers elsewhere. There may also be high political and economic costs, for example, in the interruption of trade relations between the EU and US through the introduction of high degrees of precaution in the regulation of genetically modified foods. There may also be political costs in high degrees of precaution in the sense that if these are not born out by subsequent experience and reasonably definite scientific conclusions, risk managers may be embarrassed and thus less likely to apply the precautionary principle in the future. In other words, “crying wolf” or appearing to overreact to a potential risk may undermine the credibility of the precautionary principle. Decision-makers might then be more reticent about acting in the future when there is a genuine need to act. Against these points it is argued that the absence of harm to the environment or human health does not negate the value of precaution.

If measures are thought necessary, there is also the question of how long they

should be used. In other words should measures be time-limited, subject to review after a specified period. Or must the duration of any provisional precautionary measure depend on the particular characteristics of the case in hand and the difficulties in gaining sufficient scientific evidence?

3.3 How to Set the Thresholds for Risk and Costs of Non-Action

Under the precautionary principle as applied in Europe, science does not have all the answers; therefore, thresholds must inevitably be set in a *political process*. The precautionary principle thus legitimises public institutions to take decisions. This does not mean that science is not important. As the European Commission paper on the precautionary principle stresses, science is essential in risk assessment and every avenue must be pursued in the search of firm scientific evidence. But science may have no answers to offer, or may have only conditioned answers. Scientific analysis requires data that may not be available or is unreliable. It is also argued that scientific judgements inevitably contain subjective value judgements of what constitute harm or damage to health or the environment, so that scientific processes have to be subject to appropriate public appraisal. As noted above, there is today a high level of mistrust of the suitability of conventional forms of democratic accountability to provide this appraisal.

In other words, when it comes to the question of how decisions are taken in the application of the precautionary principle, the final decisions on thresholds and the costs of non-action are taken in a political process, not simply by accepting the view of science. Furthermore in the current climate of disaffection with the ability of conventional channels of democratic decision-making to make such decisions, there is pressure for direct inclusion of civil society. The position in the United States can be contrasted with that in Europe in the sense that the findings of the science-based risk assessment tend to play a decisive role in risk-management decisions. There is also more consumer confidence in this approach in the US than in Europe.

3.4 Equity

To accept that decisions on risk thresholds are subjective and determined by political processes means that judgement will inevitably vary from location to location. For example, a developing country may place more emphasis on economic growth and less on environmental damage or potential health risks than a developed economy with high *per capita* incomes. The application of the precautionary principle therefore raise questions concerning how the costs of, for example, pollution abatement should be shared.

The application of the precautionary principle therefore appears to call for a

greater level of international cooperation, including means of ensuring that the costs of environmental protection are shared, than under a regime in which "objective" science determined policy. These equity considerations add to the pressure to deal with environmental issues on a regional or global level because of the existence of physical externalities (i.e. cross-border pollution or global commons issues).

3.5 The Burden of Proof

Under conventional environmental law and regulation the burden of proof tends to be placed upon those who seek to regulate or prohibit a product or process, because they believe their health or the environment is being damaged. This is often a significant hurdle, especially when assessments of harm of damage are based on scientific evidence. If there is no scientific evidence of damage, then one cannot prove the need for regulation. But scientific evidence is expensive to obtain and producers often control access to the necessary data.[14] This is not the case in medicines, where the producers of new active substances must prove they are both effective and safe from adverse side effects. Food safety regulation comes somewhere in between these two ends of the spectrum.

The precautionary principle eases the burden of proof on those seeking to impose controls. If there is no need to prove scientifically that there is a non-negligible risk that a product or process damages health or the environment, then it is easier to make the case for regulation. Indeed, if high levels of precaution are envisaged in legislation; it may reverse the burden of proof, placing it upon those seeking to introduce new processes or products.

4. The Application of the Precautionary Principle by the European Union

So far this paper has discussed the elements of the precautionary principle in general terms. This section looks at how the EU has applied the principle and in particular how the application of the precautionary principle in the EU is likely to impact upon the EU's trading partners.

The precautionary principle is now an integral part of European policy with regard to the environment and other policy areas such as food safety. As noted above the precautionary principle is now anchored in the Treaty (on European Union) (Art. 174):

> Article 174(2) Community policy on the environment shall aim at a high

[14] The position with drugs and food additives is that companies seeking to introduce new products have to show that these are safe.

> level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the Precautionary Principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter pays.

Despite the fact that the reference to the precautionary principle appears in the article of the treaty dealing with Community environmental policy, the precautionary approach has been interpreted as being applicable to other areas of policy, such as food safety, health and safety. This interpretation relies in part on Art. 6 of the treaty, which states:

> Environmental protection requirements must be integrated into the definition and implementation of the Community policies and activities referred to in Article 3 [the creation of a customs union and single market] in particular with a view to promoting sustainable development.

In its ruling in the joined BSE cases (C-157/96 and C-180/96), brought by the British government to challenge the implementation of a ban on British beef by the European Commission on the grounds that the sale of beef still constituted a risk to health despite the regulatory measures adopted by the British, the ECJ ruled that the precautionary principle does not just apply to environmental legislation but also measures aimed at protecting human health. In the BSE case, the ECJ also confirmed that the precautionary principle can be used as grounds for banning the sale of a product:

> Where there is uncertainty as to the existence or extent of risks to human health [the British government naturally argued that measures introduced in the UK were sufficient to ensure food safety], the institutions may take protective measures without having to wait until the reality and seriousness of the risk become fully apparent.

This position by the ECJ has been subsequently confirmed in a number of decisions of the Court of First Instance (the preliminary court which deals with more straight forward cases in order to ease the burden on the European Court of Justice). This was the shown in cases T-70/99 and T-199/96, which also confirmed that the precautionary principle could be used to protect consumer health. The latter of these cases confirmed the view that health takes precedence over economic considerations. The European Commission has also applied the precautionary principle in its White Paper and draft legislation on food law, a

position that is fully supported by the European Parliament.[15]

There would therefore appear little doubt that the precautionary principle has been established as an integral part of EU regulatory policy. The question that remains, is how has it been applied to date and how will it be applied in the future? With regard to this paper it is also important to ask how the principle will be applied in instances where other countries will be affected, such as in the application of the precautionary principle in cases that have an important bearing on market access to the EU. The EU policy on the application of the precautionary principle in regional or multilateral agreements will also be of considerable importance to the EU's main negotiating partners. Is the precautionary principle the basis for a balanced approach to EU policy that promotes sustainability and facilitates the growth of trade and investment? Or is it an arbitrary concept that is wheeled out to justify controls that are dictated by commercial or political expediency?

4.1 The Application of the Precautionary Principle in EU Trade Policy

Most of the concern about the use of the precautionary principle in the EU is based on a number of trade disputes involving the United States. These include, in particular, the beef hormones case, which went before the World Trade Organisation (WTO) dispute settlement, the action by a number of EU member states and the EU on the sale of genetically modified products, and the EU ban on the use of certain antibiotics in animal feed as growth promoters.

Without going into these in any great depth, it is reasonable to say that these cases do not reflect the balanced and consider application of the precautionary principle in the EU. The beef hormone case concerns a ban imposed in 1988, before the EU got very far in applying the precautionary principle. US beef exporters believed that the EU ban was arbitrary and had protectionist intent, because US beef had been found to be safe in the US, on the basis of a sound science test. But the US could not challenge the EU ban until the introduction of the WTO Agreement on Sanitary and Phytosanitary measures in 1995. Existing GATT provisions under Art. XX provided considerable discretion for the EU to ban without any ruling from the GATT. The SPS Agreement, as will be discussed below, provides for precaution in so far as it allows for temporary controls or bans when scientific evidence is inadequate (Art. 5(7) SPS). The EU ban was however a permanent ban, so it could not benefit from the SPS provisions on precaution. The rest of the SPS agreement is geared to science-

[15] See European Commission, White Paper on General principles of Food law in the European Union, COM 99 719 final.

based risk assessment including reference to (science-based) standards set by the relevant international standards bodies, such as the Codex Alimentarius. In other words rules and thinking on precaution have evolved considerably since the EU ban on beef hormones. Reference to the precautionary principle in the case of the beef hormones ban could therefore be seen as a means of justifying a policy that was at odds with existing WTO rules, but which was in place when the WTO rules were changed.

The same might be said for the case of genetically modified products. A 1990 Directive by the EU laid down provisions concerning GM products, including elements of precaution, but this was adopted before public awareness and suspicion of traditional methods of risk assessment had been aroused by such cases as BSE. Approvals began under the 1990 Directive, but strong reaction from consumers and environmental organisations led to national governments taking unilateral action that was inconsistent with the EU rules. As the action of EU member states is at odds with EU law, it is difficult to say that they are consistent with a balanced European approach to precaution.

4.2 The European Commission's Paper

What of future EU application of the precautionary principle? In February 2000 the European Commission produced a position paper on the precautionary principle, setting out how it envisages the principle being applied. This was produced with the participation of all Directorates General of the Commission, including those concerned with environmental and consumer affairs, as well as those concerned with industry and trade. At the time of publication the paper was presented as merely a contribution to the ongoing debate on the application of the precautionary principle within the EU in all policy areas. The Commission's paper has, however, been subsequently endorsed in a Resolution of the EU Heads of State and Government at the June 2001 European Council and the European Parliament.

The Commission paper argues that the EU, like other members of the WTO, has the right to set standards of protection for the environmental and human animal and plant health at the levels it wishes. This is dictated by the EU treaty provisions which require the EU to develop high standards of environmental and consumer protection. The EU is not just about opening markets; it also has objectives in social and environmental policies. At the same time the Commission seeks in its paper to develop an approach to precaution that will avoid recourse to the precautionary principle as a disguised form of protectionism.

The Commission approach breaks down the process of dealing with risk into various phases. First of all it presumes that potential hazards are identified in new

projects or processes. Following this there is the division between risk assessment risk management and risk communication.

4.3 Risk Assessment

A science-based approach is seen as central to the risk assessment stage. The Commission argues that scientific investigation including the use of statistical data to assess probability provides the essential base for dealing with risk. Risk assessment is broken down into four stages:

1. *Hazard identification* which means identifying the biological, chemical or physical agents that may have adverse effects, such as through observation of damage to health or the environment
2. *Hazard characterisation*, which seeks to establish the causal relationship between the use or release of the products concerned and harm;
3. *Appraisal of exposure*, which is the evaluation of the probability of exposure to the product under investigation; and
4. *Risk characterisation*, which is the (quantitative or qualitative) estimation of the probability and severity of any adverse effects.

It stresses, however, that where scientific uncertainty exists, the exact nature of this uncertainty should be made clear to policy-makers that have the responsibility of making decisions. If scientific evidence shows reasonable grounds for concern, then normal preventative measures should be taken to reduce risks. In other words, the Commission supports the use of a prudential approach for dealing with known risks. Where scientific knowledge is inadequate, there should be research commissioned in order to help fill gaps. The EU has also initiated work in the European Scientific Technology Observatory on the concept of scientific uncertainty in order to better understand the nature of scientific methods. In other words the Commission sees science as playing an essential role in dealing with risk. The EU approach to precaution is not anti-science.

4.4 Risk Management

Whilst science has its proper role, the Commission paper stresses that judging what is and what is not an acceptable risk for society is an “eminently political responsibility”. In other words when it comes to risk management, science cannot be expected to able to make judgements on what is and what is not an acceptable risk, especially when there is a lack of scientific certainty.

In terms of what action should be taken to deal with risk, the Commission stresses that taking no action forms part of a logical approach to the

precautionary principle. Nor need the action when taken, always be in the form of legally binding measures or Directives in the case of the EU. The suitable course of action may be to commission further research into the effects of the product or process, or simply to inform the public of the potential risk from use of the product. If legislation is required this will in the EU be subject to review by the European Court of Justice. The ECJ can also review and rule on any act of the EU institutions, including recommendations or other measures short of proposing legislation. The Commission sees this as a guarantee against arbitrary decisions.

4.5 Guidelines for Regulatory Measures

The Commission paper sets out a number of guidelines for measures taken on the basis of the precautionary principle. These draw on existing guidelines found in EU law and practice as well as in international trade rules. Generally these guidelines seek to limit the danger of the abuse of discretionary policy decisions. These principles are:

- *Proportionality*. Any measure should not be out of proportion to the risk entailed and should not aim at zero risk. At the same time the Commission argues that whilst the ban on the use of a product may not be proportionate, there may in certain cases be not alternative. The Commission also stresses that proportionality must take account of long term developments and should not, for example, result in risks being shifted onto future generations. Here the Commission appears to wish to aim for a point somewhere in the middle of the spectrum between a total ban and inaction, but the wording provides scope for total bans all the same.
- *Less restrictive measures*. When selecting the level of regulatory intervention less restrictive measures (than prohibition) should be given consideration, for example, reductions in exposure, tighter controls, provisional limits, replacement with alternative products or (non binding) recommendations. The "less trade restrictive" wording is a little unclear here and is weaker than the use of the "least trade restrictive measure" favoured in trade agreements.
- *Non-discrimination*. In line with standard EU and international economic law it is proposed that any measure should be non-discriminatory. In other words products should be treated the same regardless of their "geographical origin". But the Commission paper clearly does not mean that any measure should respect national treatment for like products as set out in the WTO rules.
- *Consistency*. When measures are taken to deal with risk with regard to one product or policy area these should whenever possible be consistent with policies pursued in other cases. Such consistency will reduce the degree of

uncertainty for producers and make regulation or action more predictable. Here as in other respects the Commission paper follows the SPS agreement, which calls for consistency.

- *Benefits and costs of action.* Before taking any action there should be a cost-benefit analysis covering both economic and non-economic factors as well as both long and short term costs ad benefits. The efficacy of different options for action should also be considered, so that other things being equal the most effective measures are taken. But as the treaty states, health takes precedence over economic considerations.
- *Continued examination of scientific developments*. The life of any measure should be determined by the status of scientific knowledge. In other words if science is able to clarify risk or show that risk is less than was originally anticipated, then the measure should be modified or revoked. The Commission seems to argue that it is inappropriate to place time limits on any action. This is again in line with the SPS agreement. However the later includes reference to the need for scientific justification for a measure being found within a reasonable period of time.

4.6 Burden of Proof

The Commission paper also addresses the question of burden of proof, pointing out that under existing practice for drugs, pesticides and food additives, prior approval is required. This means that the burden of proof is on those wishing to introduce the new products to show that they do not risk harming consumers or the environment. This means that is it business that must pay for the collection of scientific evidence.

For other products or in other cases, consumers, individuals or public authorities have to fund research if they wish to prove that the product is not safe. The Commission clearly entertains the view that there should be an easing of the burden of proof on consumers or environmental lobbies wishing to prove that a product is not safe. The introduction of a degree of precaution would, of course, have this effect.

4.7 Assessment

It is fair to say that the EU to date has not been especially consistent in its application of the precautionary principle to issues concerning international trade, such as in the food safety cases. The lack of a developed body on principles with regard to the application of the precautionary principle to certain policy areas has made it possible to argue that the EU is simply using precaution as a means of justifying what are in fact decisions based on political or commercial

expediency.

The EU is therefore committed to the application of the precautionary principle. One area in which this will be of considerable importance for the EU's trading partners is that of food safety.

4.8 The Application of Precaution in New EU Food Safety Provisions

The guidelines for the application of the precautionary principle discussed above are general to all applications in the EU. As mentioned above, the EU's application of the precautionary principle was developed in the field of environmental regulation. In recent years it has also found wider application in food standards. One reason for this has been the shift in consumer views and especially consumer confidence in the established, largely science based risk analysis procedures, as a result of cases such as the BSE crisis. In order to restore confidence in European food safety regulation, the EU is in the process of a comprehensive restructuring of food safety legislation and regulatory procedures. This restructuring was set out in a White Paper on Food Safety,[16] and was followed by draft implementing legislation, which is currently in the final stages of being adopted by the EU member states and the European Parliament.[17] [18]

The revamped approach to food safety regulation in the EU uses the well established distinction between risk assessment, which will be the responsibility of the new European Food Authority in cooperation with national regulatory authorities, risk management, which will at EU level remain the responsibility of the European institutions, namely the Council of Ministers and European Parliament with some powers delegated to the European Commission, and risk communication, where both the Commission and European Food Authority appear to have a role.

European food safety regulation will continue to be based on scientific advice that will be provided to the EU institutions by the European Food Authority. The existing scientific committees that advised the EU policy-makers will be

[16] White Paper on Food Safety, Com (1999) 719 final.

[17] See Proposal for a Regulation of the European Parliament and Council laying down the general principles and requirements of food law, establishing the European Food Authority (EFA) and laying down procedures in matters of food safety. Com (2000) 714 of November 2000.

[18] The establishment of the European Food Authority was held up because it was one of a number of new institutions, whose location had to be decided at the Laeken European Council in December 2001. The location of the EFA in Helsinki as was expected was frustrated by Italy which sought to have it located in Parma.

integrated into the EFA and will come under the general guidance of a Scientific Steering Committee of the EFA. One of the rationales for establishing the EFA was that more research was needed at an EU level on food safety issues and more effective scientific co-operation among national expert bodies (undertaken within the Scoop), which the EFA will also promote. Research at the EU level is also funded in the research frameworks.

The EU is therefore seeking to put more effort into strengthening the scientific assessment of risk, but the EU approach as set out in the White Paper and subsequent legislation, also provides for "other legitimate factors" to be taken into account in the decision making process. These include, for example, reference to the environment, animal welfare, sustainable agriculture and consumer expectations. None of these factors could be expected to be covered in any substantial fashion in conventional scientific assessment methods. Art. 7 of the Regulation laying down the general principles and requirements of European food law (see above) states that the precautionary principle may be used in risk management:

> Art. 7 (1) In those specific circumstances where, following an assessment of available pertinent information a risk to health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.
>
> Art. 7 (2) Measures adopted on the basis of paragraph 1 shall be proportional and no more restrictive of trade than is required to achieve the high level of health protection chosen by the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

The application of precaution here applies to intra-EU trade although the same criteria are inevitably likely to be applied to imports into the EU. The EU approach to food safety regulation therefore fully embraces the precautionary principle and as such is in line with both public opinion in the EU as well as the jurisprudence of the ECJ. Art. 7 (1) leaves a good deal of scope for non-scientific factors to be considered, including in the initial identification of possible risk. Both paragraphs stress that the European Community (EU) has chosen high standards of protection for health and food safety. Whilst

precautionary measures are to be provisional, there is a good deal of discretion with regard to the length of time needed to gather more scientific information. This contrasts with the aims of some of the EU's trading partners to set reasonably tight time scales.

In addition to the wording of the Regulation, there is of course the guidelines on interpretation of the precautionary principle set out in the Commission communication of January 2000, and subsequently endorsed by the European Council (in a resolution of Heads of State and Government in June 2001) and the European Parliament.

The EU's approach to precaution has been shaped by a range of factors. Experience in the field of environmental regulation has been important as noted above. There have also been some systematic studies of the use or non-use of precaution in past cases of risk to the environment and health. For example, a study of 12 cases of harm or potential harm to the environment and health over the past century was undertaken by the European Environment Agency. The conclusions reached in this study have to a large extent been incorporated into EU policy. For example, the EEA study argues for the need for continuous monitoring of the long-term effects of exposure to potentially harmful substances and for research to help plug the gaps in knowledge. These approaches are incorporated into the EU's approach to food safety. The separation of responsibilities for risk analysis and the regulation of a sector was a lesson that was painfully learned in the case of BSE. The EEA study also points to the need to acknowledge uncertainty in science and for "lay" (i.e. non-expert) inputs into judgements of risk. These are core elements in the EU's interpretation of the precautionary principle as set out in the European Commission's 2000 report.[19]

[19] The full list of recommendations from the European Environment Agency are as follows: 1) Acknowledge and respond to ignorance, as well as uncertainty and risk, in technology appraisal and public policy-making. 2) Provide adequate long-term environmental and health monitoring and research into early warnings. 3) Identify and work to reduce blind spots and gaps in scientific knowledge. 4) Identify and reduce interdisciplinary obstacles to learning. 5) Ensure that real world conditions are adequately accounted for in regulatory appraisal. 6) Systematically scrutinise the claimed justifications and benefits alongside the potential risks. 7) Evaluate a range of alternative options for meeting needs alongside the option under appraisal, and promote more robust, diverse and adaptable technologies so as to minimise the costs of surprises and maximise the benefits of innovation. 8) Ensure use of "lay" and local knowledge, as well as relevant specialist expertise in the appraisal. 9) Take full account of the assumptions and values of different social groups. 10) Maintain regulatory independence from interested parties while retaining an inclusive approach to information and opinion gathering. 11) Identify and reduce institutional obstacles to learning and action. 12) Avoid "paralysis" by analysis" by acting to reduce potential harm when there are reasonable grounds

5. The Precautionary Principle in International Law

If the precautionary principle is finding application in the European Union, what is the position in other countries, and what use is made of the principle in bilateral, regional or multilateral agreements? This is an important question because the widespread adoption of the principle in both practice and law could have important implications for policy and trade relations. It would also suggest a need for efforts to reach agreed interpretations of the principle.

5.1 The Precautionary Principle as part of the Body of International Law

Although the precautionary principle only emerged in international (environmental agreements) agreements in the 1980s it has had a meteoric rise.[20] Surveys of the application of the principle show a large and growing number of multilateral, regional and bilateral agreements use it or the concepts embodied in the precautionary principle. The first multilateral environment agreement to include the concept was the 1985 Vienna Convention on Ozone Depleting Substances, which included a reference to precaution in its preamble. At a regional level the Ministerial Declaration of the Second International Conference on the Protection of the North Sea stated that:

> 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 scientific evidence.[21]

The Bergen Declaration of the United Nations Economic Commission for Europe on sustainable development is another clear expression of the principle in a European agreement. This states:

> 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 threat of serious irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.

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for concern. See European Environment Agency, Late lessons from early warnings: The precautionary principle 1896-2000, Environmental Issue Report No. 22, Earthscan Publications, 2002.

[20] James Cameron, "The precautionary principle in international law", in O'Riordan et al. (2001).

[21] Quoted in European Commission (2000), Annex II.

Regional or bilateral agreements outside of Europe have also made use of the concept of precaution even if they did not make explicit reference to a precautionary principle, e.g. agreements between the US and Canada on water quality in the Great Lakes.

Multilateral agreements on the environment (MEAs) soon picked up and employed the same sort of wording. Probably the most significant step was in the Rio Declaration of the United Nations Conference on Environment and Development (UNCED) which states in Principle 15 that:

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

Similar provisions were included in the preamble of the Convention Biodiversity of 1992 and in the principles of the Convention on Climate Change of 1992. Furthermore aspects of precaution can now be found in the rules governing international trade, such as in the Agreement on Sanitary and Phytosanitary Measures of the WTO and the Cartagena Protocol on Biosafety which regulates trade in living modified organisms (LMOs) (or biotech products), see below. This has provoked a debate on whether the precautionary principle has now become part of the body of international environmental law or indeed an aspect of customary law. The significance of the latter is that when a principle becomes part of customary international law is may be applied in the interpretation of any relevant international agreement even if the parties to that agreement have not explicitly committed themselves to applying the principle.

5.2 The Precautionary Principle as Customary Law

In his discussion of the role of the precautionary principle in international law, Cameron argues that the precautionary principle, because of its widespread application in international environmental and trade agreements, does indeed form part of the body of international environmental law and that a good case can be made for it being treated as customary law.[22] Cameron uses the application of the precautionary principle in this range of agreements, as well as case law, as grounds for arguing that precaution is burgeoning towards becoming part of customary international law. The case law also comes from the international and regional levels. For example, the International Tribunal for the Law of the Sea

[22] See James Cameron, "The Precautionary Principle in International Law", in O'Riordan et al. (2001).

applied the precautionary principle in the bluefin tuna case. This case involved a claim by Australia and New Zealand that on the grounds of precaution, unilateral experimental fishing of bluefin tuna by Japan was inconsistent with Japan's obligations under the Law of the Sea.

At a regional level the European Court of Justice has accepted precaution as grounds for allowing trade restrictions under Art. 36 EEC, i.e. on trade within the EU. For example, in the Danish brown bee case, which involved a ban on the importation of a non-native species of bee to the Laeso Island in Denmark, it was argued by Denmark that this would threaten the native Laeso brown bee. [23] There was no scientific proof that the native bee would be threatened, but the ECJ accepted the case for a ban based on precaution:

Cameron also argues that all these applications of the precautionary principle have a number of common elements, namely that they are all based on the recognition that: a) regulatory non-action threatens to lead to non-negligible harm; b) a lack of certainty as to the cause and effects relationship exists; and that c) under such circumstances, regulatory in-action is unjustified. The widespread application of these common principles therefore enables a case to be made that the precautionary principle is customary international law.

Such legal arguments are likely to become more important in the future, but for the moment the issue is still undecided. Indeed, in the beef hormones case the Appellate Body of the WTO did not accept the argument of the European Community, supported by the World Wildlife Fund for Nature (WWF), that the precautionary principle was part of customary law and should therefore be accepted as grounds for limiting imports of beef containing growth hormones.[24]

6. The Precautionary Principle and Trade Relations

6.1 The WTO

The preamble to the WTO contains a reference to the objectives of the organisation that includes "sustainability", although this is included in a range of objectives including expanding the production and trade in goods and services. This has been used by proponents of the principle to argue that WTO rules should be modified to allow for a greater degree of precaution than is currently the case.

Perhaps the most important part of the WTO with regard to recent actions

[23] European Court Reports II 3051 (1996).

involving the precautionary principle has been the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS agreement) adopted with the WTO in 1995. The SPS agreement allows Member governments of the WTO to take SPS measures provided the measures taken are "based on scientific principles" (Art. 2 (2) SPS). As noted above the approach of the SPS agreement is squarely science based, except:

> where relevant scientific evidence is insufficient, [when] a Member [government] may *provisionally* [emphasis added] adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organisations as well as from the sanitary and phytosanitary measures applied by other members. In such circumstances Members shall seek to obtain the additional information necessary for a more objective assessment of the risk and review the sanitary or phytosanitary measure according within a reasonable period of time (Art. 5(7) SPS).

It is this Art. 5 (7) which, according to the Appellate Body of the WTO [in the beef hormones case] contains elements of the precautionary principle. Having said this there remains considerable scope for ambiguity in the agreement. For example, does the reference to information from relevant international organisation mean that the safety of a product that conforms with Codex Alimentarius standards, as the US beef does, is not uncertain? Equally, does the reference to "measures applied by other members" mean that if other countries find the product safe there cannot be scientific uncertainty surrounding the product?

The SPS agreement contains a list of the factors that should be taken into account when assessing risk including: scientific evidence; relevant inspection techniques, sampling and testing methods; prevalence of specific diseases or pests; relevant ecological or environmental conditions etc. It is not clear whether this is an exclusive list. Art. 5(2) SPS calls for an evaluation of the costs of any SPS measuring, including loss of production to be considered in assessing risk. Art. 5(4) calls for measures that "minimise the effects on trade" and Art. 5(6) the use of SPS measures that are not more trade-restrictive than required to achieve "the appropriate level of sanitary or phytosanitary protection". So Art. 5(7) must be seen in the context of this generally much more restrictive set of conditions on the use of SPS measures to limit trade.

A key test case in the interpretation of the SPS agreement with regard to the interpretation of Art. 5 was the beef hormones case. As noted above the EU argued that the precautionary principle was customary international law and should therefore be applied in the WTO and specifically in the SPS agreement.

This case was made in part because of the general weakness of the EU's case under the SPS agreement, but it reflects the EU's policy on the role of the precautionary principle as an instrument with very wide application. As pointed out above, Art. 5 (7) allows for provisional measures to be taken when there is inadequate scientific knowledge. In the case of the EU ban on growth hormones in beef, the ban was permanent and had not been based on any systematic scientific risk assessment. The US was therefore able to argue that the SPS agreement provides for action when there is insufficient evidence, but that the EU ban was neither provisional nor based on any scientific assessments.

Regardless of the substance of the case, the beef hormone case is interesting in the sense that the Appellate Body did find some evidence that Art. 5 (7) contains elements of a precautionary. The discussion on the elements of the precautionary principle would indeed appear to support this position.

In the Australian Salmon case the Appellate Body of the WTO interpreted other articles of the SPS agreement, including Art. 5(2) on what is involved in risk assessment. This case involved an Australian ban on the importation of fresh salmon from Canada on the grounds that this could result in the entry of certain pests present in Canada. Here the Appellate Body found that this included identification of the potential pest, the likelihood of the pest entering a country in the absence of SPS measures, as well as the likelihood of this being prevented with SPS measures in place, in other words the effectiveness. A comparison of these elements with the discussion of what constitutes the precautionary principle above again shows that there are clearly common elements.

In the Japanese apples case, which involved a US complaint against Japan on the testing of different varieties of apple, the Appellate Body also began to define what constitutes "sufficient" scientific evidence and in particular the nature of the link between scientific evidence and a specific SPS measure. For example, general scientific data may not be sufficient to justify SPS measures when the impact of a pest may vary between varieties of a product.

This discussion of the current interpretation of the SPS agreement suggests that it does provide scope for some degree of precaution. At the moment however there is no consensus between the major WTO Members on this issue. The EU favours the application of precaution, as illustrated in the Commission's Communication of February 2000.[25] The US position, at least that of the federal government, is that science-based approaches should determine risk assessment and much of risk management. The US sees the EU approach to precautionary

[25] The Commission argues that its approach is consistent with the SPS Agreement. There are areas, however, where this is likely to be challenged.

principle as a cover for arbitrary decisions, especially given that the EU stresses the role of political decisions. The US views such political decisions that are not subject to due process as liable to capture by vested interests. Although the WTO Appellate Body may have some scope to interpret the SPS provisions, it is unlikely to wish to rule on an issue that remains one of considerable contention between the two major WTO members.

In terms of trade relations the potential for a dispute over genetically modified products is therefore the source of some concern. GM products are of much greater economic significance in transatlantic and other trade than, for example, beef. In the case of beef hormones there was an international standard developed in the Codex Alimentarius. As noted above this was determined by a largely science based approach, which proponents of precaution would argue failed to adequately account for societal concern of potential harm. In the case of genetically modified products, however, there is no international standard. Although a Codex committee has been working on the issue for some time, it is still some way from reaching any agreement, for the reason that the parties to discussions in the Codex are the same as those in the general debate about the use of precaution with regard to GM products. With both sides firmly wedded to their respective positions the scope for compromise is limited. Under these conditions a ruling by the WTO on such a sensitive issue could be damaging to the organisation and the trade regime in general, since it would undermine support for the WTO in one of the major members.

In short a resolution to the differences over the use of precaution in the SPS agreement will require some convergence between the existing EU and US positions. A precondition of such a convergence is a clear understanding of what is meant by precaution. This condition has not been satisfied to date, although the European Commission paper has contributed to a clearer understanding of the EU position.

6.2 The Technical Barriers to Trade Agreement

Although of less direct concern to the application of the precautionary principle the TBT agreement of the WTO is likely to be important for trade issues concerning environmental and health issues. The TBT Agreement requires non-discrimination between *like products* in the application of *mandatory* regulation or *labelling* of health and safety issues, voluntary standards and conformance assessment measures. As such it has been important in tackling a range of technical barriers to trade, especially those in industry and manufacturing. The TBT agreement envisages that Members of the WTO will wish to set different standards of protection. So mandatory regulations can be adopted provided these do not discriminate between like products.

The like product clause creates a difficulty with regard to environmental issues in that there is no scope for differentiation between products with regard to the method of production. In short products produced in a non-sustainable fashion must be treated the same way as products produced using sustainable methods of production. With regard to the case of GM products the question that arises is whether TBT Agreement allows for discrimination between "natural" or non-GM products and GM products that are *substantially equivalent* to non-GM products.[26]

One means of dealing with differences between the standards of protection and precaution between countries is to provide labels, so that consumers know what they are buying and can exercise their right practice "sustainable consumption". In other words they can freely choose not to buy products that originate from GM crops.[27] There are a number of difficulties with this apparently elegant solution. As it stands the TBT agreement prohibits mandatory labelling schemes which discriminate between products according to how they are produced. Thus the proposed EU mandatory-labelling scheme for GM products could be at odds with the TBT Agreement. Voluntary labelling schemes are not subject to binding TBT disciplines. Voluntary schemes are covered by a non-binding Code of Conduct for voluntary standards and labelling bodies. But European consumers do not appear to be satisfied with voluntary labelling schemes. They want something that has the force of law and can thus be properly enforced. There is also some lack of clarity over whether public but voluntary schemes, such as the eco-labelling schemes developed in a number of European countries (such as the Blue Angel in Germany and the White Swan in Sweden) are subject to TBT disciplines or not. Some exporting countries consider that they should be subject to full TBT disciplines. The EU has sought to include clarification of this and other elements of the TBT and SPS agreements in the WTO as part of any future multilateral trade round.

6.3 The Bio-Safety Convention

The 1992 Convention of Biodiversity called for the establishment of biosafety-related regulations to deal with the risks to biodiversity associated with the release

[26] The WTO treats products as like products unless differences in production or processing methods are embodied in the product itself. This raises the question of whether GM products, such as GM soya oil is chemically different from non-GM soya oil. If it is not, then the TBT agreement prohibits any measure that discriminates between the GM and non GM oil.

[27] Labelling can be very effective. Even without a formal labelling regime for GM based products, consumer preferences have had a real impact on the willingness of North American farmers to plant GM crops for fear that these will not find export markets in Europe.

of living modified organisms (LMOs) resulting from biotechnology. In March 2001 the Cartagena Protocol on Bio-safety was adopted under the auspices of the Convention on Bio Diversity. As noted above the Cartagena Protocol provides for the application of the precautionary principle, despite the resistance to this from the so-called Miami group of countries exporting that have high percentages of GM crops and LMOs in their agricultural exports.

The centrepiece of the Bio-safety protocol is the system of Advanced Informed Agreement Procedure in which importing countries are informed in advance of the arrival of LMOs in any shipment. Under the Protocol states then have the right to refuse to allow the importation of the LMOs when, according to the standards prevailing in the importing country, the LMO poses a threat to the bio diversity of the country concerned. Two forms of LMOs are possible: one is the form that will be released into the environment, such as when seeds or other living organisms are imported, and LMOs in food. In the latter case, it is argued that these pose no threat for the environment. As a result LMOs in food are not subject the provisions of Advance Informed Agreement Procedure. Many European consumers appear to feel strongly that there are also food safety issues and have lobbied hard for at least labelling of products that originate from GM crops.

The major issue for trade relations is, of course, that if each party to the agreement has the right to deny access to imports on the basis of national standards and the Protocol provides for the application of the precautionary principle, does the Bio-safety Protocol prevail over the WTO provisions or vice versa? The Bio-Safety Protocol provides for the application of a permanent ban based on the precautionary principle, whereas the SPS agreement provides for a much more restricted form of precaution for a transition period only.

There would seem to be a clear clash here between different international agreements. Savings clauses were negotiated to address this issue, but these do not resolve the long-term problem of one agreement adopting the precautionary principle and the other (the WTO) not or only partially. The Bio-Safety Protocol reads:

> This Protocol shall not be interpreted as implying a change in the rights and obligations of a party under an existing international agreement.

According to this sentence, the rights of the members under the WTO are not affected. In other words the more science based provisions of the SPS and the non-discrimination between like products under the TBT agreement prevail. In the next paragraph of the Protocol however, it reads:

> The above recital is not intended to subordinate this Protocol to other

international agreements.

which reads that the Bio-Safety Protocol prevails over the WTO.[28]

The conclusion from these examples, of how the precautionary principle can affect international trade and trade agreements, would appear to be that there is no option but to find some consensus on the application of the precautionary principle. The concept lies at the heart of differences in risk assessment and risk management and thus differences over the interpretation of a number of key trade and environment agreements.

6.4 Work in the Codex Alimentarius

The Codex Alimentarius has played an important role in defining food safety standards and as such played a decisive role in disputes such as the beef hormone case. The Codex is also at the centre of efforts to find an agreed interpretation or application of the precaution principle or a precautionary approach in issues related to food safety and health.[29] In 2000 the Commission of the Codex Alimentarius considered a draft proposal on Codex Working Principles for Risk Analysis. This was discussed in 2000 but without any consensus being reached. One of the main reasons for a lack of consensus was the inclusion in the draft of wording covering the use of precaution/the precautionary principle. The aim of the new Working Principles was accepted by all Codex members, namely that risk analysis in Codex should be aimed at "protecting the health of consumers while at the sae time ensuring fair practices in food trade".[30] There was also agreement to consider the draft Working Principles.

Differences were apparent from the beginning on the broad approach to risk analysis. For example, the US argued for wording that would ensure that risk analysis was "soundly based on science", while the EU and Consumers International, saw science as an important but not the only element in risk

[28] See Gary Sampson, "Bio-technology and trade issues in the WTO", paper presented at the Seminar on European Trade Policies, Sweden Trade Council, Stockholm, 11 August 2001.

[29] There is sensitivity about terminology here. Issues related to consumer health could be interpreted to include environmental issues, which is what consumer organisations generally wish. A narrower definition of food safety could help to maintain a distinction between the use of precaution in food safety and the wider use of the precautionary principle in environmental regulation, which is what the food industry and processors want.

[30] For the draft Working Principles for Risk Analysis and the comments on the draft from various national delegations and interested parties, see Report of the 24th Session 2-7th July 2001 of the Joint FAO/WHO Food Standards Programme.

analysis. The Codex draft supported the distinction between three phases of risk analysis: namely risk assessment, risk management and risk communication. Broadly speaking there was also support for the view that risk assessment was essentially science based and risk management could provide scope for other legitimate factors to be considered. The 2000 draft stressed the need to separate assessment and management in order to ensure the scientific integrity of the assessment process. The debate on the draft showed, however, that clear-cut distinctions were not possible and that assessment and management must be seen as interactive. The provisions on risk communication stressed the need to have effective communication with all interested parties. In subsequent discussions this was clarified as including consumers, industry and the academic community.

The draft Working Principles reflected what appeared to be a broad consensus on the three elements of risk analysis. For example, risk assessment should be undertaken by independent assessors and suitable measures should be taken to ensure their independence. Four steps in risk assessment were identified. These were equivalent to those in the European Commission's 2000 White Paper, namely hazard identification, hazard characterisation, exposure assessment and risk characterisation. Furthermore there seems to have been agreement that risk assessment must specify areas of uncertainty and that these should be clearly indicated to risk managers and interested parties.

According to the draft the responsibility for resolving the impact of uncertainty lies with the risk manager and that guidelines should be developed for which legitimate non-scientific factors should or can be included in risk management. It is with regard to the coverage of precaution that agreement on the draft seemed to cease. There were two alternative proposals included in the draft text (at para 34) on when precaution would be justified. The first paragraph was considered to be broadly consistent with the wording of Art. 5(7) of the SPS Agreement in the WTO and was therefore favoured by the national delegations from many agricultural exporting countries as well as the food processing industry. The second proposed paragraph sought to go somewhat beyond the SPS definition. This stated:

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

The draft then went on to provide, in paragraph 35 a number of criteria relating to

the decision to use precaution and the measures to be adopted that would help to achieve the objective of protecting human health without restricting trade. Paragraph 35 stated:

In such situations [as defined in para 34] the following criteria should be taken into account to ensure the consistency and transparency of the decision process:

- the decision to use precaution follows the identification of a] specific risk is identified in a preliminary risk assessment or evidence to support a risk exists, but cause and extent are un-known due to gaps in scientific data;
- [measures] should be proportional to the potential extent of risk based on available scientific data;
- [there should be a]transparent explanation of the need for measures to be taken;
- decisions [to apply precaution] should be consistent with those taken in similar circumstances;
- decisions should be provisional and subject to ongoing and transparent review involving interested stakeholders;
- information should continue to be gathered;
- there should be an examination of the full range of options [including costs benefit analysis] and the effectiveness of each measure, before action is taken.

Again the EU approach as set out in the 2000 Communication is consistent with these criteria. It should be no surprise therefore that the EU endorsed the draft Working Principles favouring the wording in para 34 (b) and that in para 35. The United States made various proposals to modify the wording including, for example, that the initial hazard identification should be by "available scientific information". This, of course, would place the emphasis on scientific evidence, so that precaution would be applicable to the degree that the nature and extent of the risk was uncertain. The US along with most other Codex delegations, consumers and industry that provided comments on the draft broadly supported para 35 as a step towards defining the criteria for the application of precaution, but put cost benefit analysis at the top of the list rather than at the bottom.

Comments from various national delegations and interests illustrated that there was still much scope for differences over the draft. For example, would it apply to the Codex or to the application of risk analysis by governments/risk analysts, should precautionary action be time limited; how should the vital preliminary risk assessment be carried out and on what basis? Following submissions from the various national delegations and interests work continued in a Working Party chaired by France. This convened in December 2001 to consider a revised draft

and will meet again in April 2002. A range of differences separate the parties in these discussions, but underlying these appears to be a broad distinction between those who wish to see the precautionary principle applied in food safety (the European union and consumer organisations) and those who wish to insulate food safety regulation from the historical precedents set through the application of the precautionary principle in environmental regulation (the US, other agricultural exporters and the food processing industry). For the latter group the WTO SPS Agreement provides a more attractive model, although it is recognised that it would be useful to have agreed criteria on how to apply precaution. This is especially the case with regard to the decision process to be followed.

7. Conclusions

This paper leads to the following conclusions:

- The precautionary principle has emerged as a philosophy on which to base policy because: a) science has continued to produce new products and processes but cannot prove with an degree of certainty that European consumers find acceptable, that these products do not represent more than an acceptable risk to the environment or human health; b) consumers and environmental and other civil society NGOs are seeking more sustainable forms of production and consumption; and c) have become increasingly sceptical of the ability of science and established channels of democratic decision-making to decide what is an acceptable risk.
- Europe has been the origin and main promoter of "the precautionary principle" in the field of environmental regulation.
- The precautionary principle has now been extended from environmental regulation to include other areas of EU policy, such as in particular food safety and has been anchored in the body of EU law and practice.
- The precautionary principle (and perhaps "the precautionary principle") has also found application to some degree at least in a wide range of multilateral and regional environment agreements as well as within the WTO, and precaution is accepted in the Codex Alimentarius. Some form of precaution is therefore here to stay.
- Trade tensions can be expected to persist, however, because there remain important ambiguities in international agreements concerning the degree of precaution that can be used. There are clear conflicts between different international agreements, such as the WTO and the Bio-Safety Convention. There are also differences of view over whether it is appropriate or feasible to use one precautionary principle for all policy areas. The EU tends to favour

this approach, whereas the United States and others are resisting the application of the precautionary principle as developed for environmental policy to other policy areas, such as food safety.

- The EU is pushing for the inclusion of "the precautionary principle" in the interpretation of the WTO SPS Agreement and in the Codex work on principles for risk analysis. At issue is not whether some form of precaution will be included in the rules and guidelines emerging from these regimes, but with what interpretation of precaution.
- Some EU applications of the precautionary principle have been less than coherent and have probably been shaped by political expediency. The EU has now adopted a set of criteria to be used when applying the precautionary principle, which are largely in line with the existing international norms that exist.
- Given the nature of international economic interdependence (globalisation) and the linkages that exist between environmental and food safety issues, there is a pressing need to develop more extensive criteria for the application of precaution or the precautionary principle.
- Risk varies from case to case so it is difficult to see how a single comprehensive definition of precaution can be of much use. At issue is the development of a set of procedural norms and principles that can be employed to ensure that decisions taken in risk analysis, especially in risk management, are transparent, proportionate or non-discriminatory and subject to some form of review, to ensure that the discretion that is inevitably associated with the application of precaution is not abused as a means of trade protection.

8. An Agenda for Future Research

The issue of a precautionary approach or principle is central to a range of important issues of considerable importance to the way international regimes handle regulatory policy issues. There are ongoing debates in the WTO on the interpretation and scope of application of the SPS Agreement. There are discussions in the Codex Committees on Principles of Risk Analysis. There remains an open clash between the Bio-Safety Protocol and the WTO and between the WTO and other multilateral environmental agreements, such as the Kyoto Protocol, which contain provisions on precaution. In all these issues the role of the European Union will be crucial, because it is the main supporter of the use of the precautionary principle.

Within Europe there are new regimes in the field of food safety and the regulation of GMOs. How the EU evolves domestically will inevitably shape its position in

international negotiations. In order to fully understand the nature of the wider international disputes, it is essential to have a full understanding of how the "domestic" regulatory structures have evolved. In the case of the EU there is therefore an opportunity to observe the reform of the regulatory structures.

The focus of future research should therefore be on how the structure of European regulatory policy in the fields of the environment, food and consumer protection is evolving. In particular it will be important to assess whether and if so how the EU applies a uniform approach to precaution across all relevant policy areas.

The EU process can not only shape international negotiations; it is also shaped by them. There is clearly a good deal of synergy between the development of the EU position on precaution in 2000 and the work in international fora, such as the relevant Codex committees and the Codex Commission itself. It would therefore be interesting to assess the interaction between the EU and international processes.

Beyond this EU-focused approach, to research there remains much work on the outstanding issues mentioned above. The highly technical and complex nature of the issues makes it difficult for all but a few specialists to understand the nature of the debates. This remains the case notwithstanding the genuine efforts by governments to promote "transparency". There is therefore a case to be made for independent observation of the debates in bodies such as the Codex and the publication of clearly written but competent assessments of the issues, so that a wider constituency can understand the issues and the positions of the main interests.

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