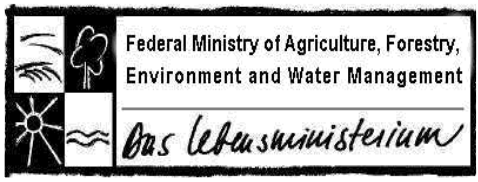
ELISABETH FREYTAG, THOMAS JAKL,
GERHARD LOIBL, MICHAEL WITTMANN (Ed.):

THE ROLE OF PRECAUTION IN CHEMICALS POLICY

The Precautionary Principle in Existing Law
The Rationality of Precaution
The Future of Precaution in Chemicals Policy

Conference

Diplomatic Academy Vienna
Thursday Nov. 15 and Friday Nov. 16, 2001



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INTRODUCTION

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Federal Minister of Agriculture, Forestry,
Environment and Water Management,
Austria

The Conference held on "The Role of Precaution in Chemicals Policy" dealt with one of the most important and possibly the most debated-on principle of environmental politics.

In its essence, the precautionary principle justifies early action in the case of scientific uncertainty in order to prevent potential harm to human health and the environment. In terms of environment policy, to act with foresight, in a cautious way, is just good practice. It does mean nothing else but simply striving for being "better safe than sorry".

It is our common experience, that human activities may cause risks of severe or irreversible damages. Concerning such potential negative impacts, policy-makers are challenged to decide whether to take preventive measures or not especially in cases of blurred scientific evidence. Applying the precautionary principle is the political and legal answer for decision-makers to deal with potential risks in the absence of full scientific proof in order to avoid being late.
This principle is fundamental to numerous multilateral agreements and treaties. The majority of these instruments is dealing with environmental problems such as water pollution, climate change, ozone layer depletion, biodiversity loss, hazardous chemicals and the transfer of genetically modified organisms.

In particular within the area of Chemicals policy, the need for precautionary action is evident and urgent.
A large number of man-made chemicals was released into the environment, is still being and will inevitably be released during the near future. There are several cases of chemicals having been considered to be safe that due to their persistent nature manifested environmental harm in areas, which were not part of their initial assessment.

Let me just mention those chemicals, which are responsible for depletion of the ozone layer or the emerging group of Endocrine Disruptors. In terms of chemicals-policy beside the toxicological effects especially this property of persistence urges precautionary action.

Currently, international environmental politics offer many different notions of the precautionary principle. However, its scope, the triggering factors for its application and the operationalisation of the precautionary principle are being developed on a case by case basis. Therefore it is especially important for chemicals policy to have clear prevailing conditions for transparent precautionary measures.

The new European Chemicals Policy will be – and this is my firm belief and position - a milestone in this respect. This framework is being developed on the basis of more than three decades of experience. Europe's Environment ministers together with the Commission, the European Parliament and a broad range of stakeholders have backed this process with a strong and clear commitment with regard to precaution.

For the past few years, negotiations on international agreements and treaties in the field of environmental politics have been dominated by the discussion about the application of the precautionary principle or the precautionary approach.
With the recent adoption of the Cartagena Protocol on Biosafety, and the Stockholm Convention on Persistent Organic Pollutants the operational use of the precautionary principle became one of the key components of multilateral agreements.

One important document in this respect is the European Commission's Communication on the application of the precautionary principle.

According to this opinion, taking precautionary action in an accepted and justified way, is inevitably linked with scientific background and transparent decision-making. Otherwise there will always be the notion of having taken unjustified measures or having created possible barriers to trade. That brings us to the tricky conclusion that policy makers need profound knowledge about the scientific uncertainty triggering precautionary measures. In other words: we have to be sure about what we do not know for sure. That does not make life easier.

At the same time, the EC Communication provides the starting point for a new and broader discussion on the issue of precaution.
The current debate on the precautionary principle raises a broad series of questions such as environmental, consumer-, economic development- and trade-related considerations.

Policy makers will have to apply the precautionary principle within this context. It is therefore the goal of this conference to shed some light on questions like the following:

What is the scope and the legal status of the precautionary principle, both at international and national level?

Which circumstances justify or demand precautionary actions?

How can we make the precautionary principle operative?

Do we need guidelines on the application of the precautionary principle at an international level?

What kinds of tools are needed for implementing precautionary action?

I believe, that it is the duty of environmental policy to allow for a quick and efficient diffusion of current knowledge and to promote the exchange of views with the ultimate goal of a common understanding and a common sense in this area.

This of course was the central motivation for convening this conference.

It brought together representatives of international organizations, European institutions, NGOs, industry, trading organizations, consumers' associations, scientists and authorities from twenty-eight countries, in order to learn about discuss on and develop policy strategies for applying and implementing precaution.

I am convinced, that this conference can be seen as a major step into this direction.

FOREWORD

ERNST SUCHARIPA
Director of the Diplomatic Academy of Vienna

The Diplomatic Academy of Vienna is not only a training institute for international professions with a European and beyond that, global outreach. The Academy also serves as an international meeting place to discuss various aspects of foreign policy and international issues.

One of the focal points in our activities is the issue of sustainability including environmental diplomacy and negotiations.

We were therefore particularly pleased that the Austrian Ministry of Agriculture, Forestry, Environment and Water Management chose the Academy as the venue for its important conference on the Role of Precaution in Chemicals Policy, an issue which is widely debated in national and international environmental politics.

We are glad to publicize the proceedings of this event in our series of Favorita Papers.

I wish to thank the organizers of the workshop for the excellent cooperation we enjoyed and for their assistance, both intellectually and financially, in making this publication possible.

CONFERENCE CONCLUSIONS BY THE CHAIRS

GERHARD HAFNER, THOMAS JAKL & GERHARD LOIBL

➢ The main goal of the Conference was to discuss the current status of the Precautionary Principle in law and to scrutinize its further application in the area of chemicals policy. The Conference did not aim at establishing a particular definition of the Precautionary Principle, which would apply in general. It discussed – based on recent international and regional practice – the status and application of the Precautionary Principle. The starting points of the discussions were examples of the formulation and application of the precautionary principle in different areas of environmental policy. The Precautionary Principle was understood both as underlying political guideline and as an element of the decision-making processes, used by all relevant actors.

- No conflicting or contradicting understanding concerning the triggering factor for the application of the Precautionary Principle (uncertain risk) was identified.

- A crucial item, which was raised in the presentations, related to the consequences of triggering this principle: if the circumstances for the application of Precaution are given, do they require subsequent measures? The answer does of course depend on the relevant legal background of each case. In any case at least continued monitoring and even increased awareness were required.

- In case of a legal framework, having PRECAUTION as inherent PRINCIPLE – as is the case for the EU framework in particular with regard to chemicals - the mandatory character is widened to a remarkable extent. The application of the Precautionary Principle in this respect directly mandates adequate risk reducing measures.

- In order to increase the legal certainty of the application of the precautionary principle, in particular to ensure compliance with WTO rules, it was underlined that the circumstances under which the Precautionary Principle will trigger action should be elaborated; the measures based on the Precautionary Principle need adequate specification in order to permit the operation of a transparent compliance regime.

- In this context, other principles of international environmental law, such as the principles of prevention and sustainable development have to be taken into

consideration. The factors, which allow the application of the Precautionary Principle, should be adequately specified.

- Within the context of chemicals policy it was postulated that rather than trying to elaborate the Precautionary Principle in a general manner, priority should be given to the establishment of transparent and effective implementation systems, confining possible disputes to a limited area or to specific chemicals.

- Lack of certainty - as an agreed precondition for precautionary action - could lead to phasing out of substances or uses but could at the same time hamper substitution by alternatives because their properties are often even less well documented. There was broad consensus that pre-marketing measures ensuring the availability of an adequate set of information were seen as the prerequisite for overcoming this deadlock.

- Ideally, the Precautionary Principle is incorporated into a legislative context that sees to generate adequate data prior to production and marketing of a chemical or a product.

- There was broad agreement that there is no contradiction or inherent conflict between science and precaution. Moreover, the conference came to the conclusion that precautionary decision-making had to be embedded into a transparent process, ensuring the involvement of stakeholders thus allowing for optimised exchange of information and decision-making. A transparent system open for all inputs – including those from scientists – increases the quality of decisions taken.

- Science can contribute to identify elements of qualitative or quantitative uncertainty and thereby contribute to sound decision-making.

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THE ROLE OF PRECAUTION IN CHEMICALS POLICY

Conference Programme

Thursday Nov. 15th and Friday Nov. 16th 2001, Vienna

Venue: Diplomatic Academy Vienna, Favoritenstraße 15 a, A-1040 Vienna, Austria

OPENING
WILHELM MOLTERER, Federal Minister for Agriculture, Forestry, Environment and Water Management, Austria

FIRST SESSION: THE PRECAUTIONARY PRINCIPLE IN EXISTING LAW
Chair: GERHARD HAFNER, International Law Commission

The Precautionary Principle in International Law
GERHARD LOIBL, University of Vienna

How has the issue of precaution arisen in the World Trade Organisation?
ERIC WIJKSTROM, World Trade Organisation, Geneva

The Precautionary Principle and public health aspects
MARCO MARTUZZI, World Health Organisation, Rome

The Precautionary Principle in European Law
THEOFANIS CHRISTOFOROU, European Commission

Examples of national implementations of the Precautionary Principle
Health and environmental legislation
LUDWIG KRÄMER, European Commission

The Precautionary Principle in National Chemical Policies in the EU

Netherlands
JAN VAN DER KOLK, Ministry VROM, Directorate-General for Environmental Protection, Netherlands

Sweden
EVA SANDBERG, Ministry of the Environment, Sweden

United Kingdom
PETER HINCHCLIFFE, Department of the Environment, Transport and the Regions, United Kingdom

SECOND SESSION: THE RATIONALITY OF PRECAUTION
Chair: GERHARD LOIBL, University of Vienna

Late Lessons from Early Warnings – some implications for Chemicals Policy
DAVID GEE, European Environment Agency, Copenhagen

Substitution and Precaution - both on Principle?
JAN AHLERS, Federal Environment Agency, Berlin

Science and the rationality of Precaution
Andrew Stirling, University of Sussex

Elements of precautionary decision-making according to the EU communication
WYBE DOUMA, Asser Institute, The Hague

Precautionary assessment - a framework for integrating science, uncertainty and preventive public policy
JOEL TICKNER, Lowell Center for Sustainable Production, Massachusetts

THIRD SESSION: THE FUTURE OF PRECAUTION IN CHEMICALS POLICY
Chair: THOMAS JAKL, Federal Ministry for Agriculture, Forestry, Environment and Water Management, Austria

Trade-off Analysis as a replacement for Cost-benefit in regulatory decision making
The role of regulation in shifting the focus from risk to technological options
NICHOLAS A. ASHFORD, Massachusetts Institute of Technology

Precaution, Clean Production and the Preventive Strategy
TIM JACKSON, University of Surrey

Precautionary decision-making in product developing and marketing
VERONIQUE SCAILTEUR, Procter-Gamble, Brussels

Precaution in the Future European Chemicals Policy
JEAN-FRANCOIS VERSTRYNGE, European Commission, Brussels

The New Chemicals Strategy of the EU (White Book) and the Precautionary Principle
How far does the White Book follow the precautionary approach? What could be improved?
DAVID SANTILLO, Greenpeace Research Laboratories, Exeter

POPs and the Precautionary Principle
JIM WILLIS, UNEP, Geneva

THE PRECAUTIONARY PRINCIPLE IN INTERNATIONAL LAW

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1. Introduction

In the last years the precautionary principle has become one of the most discussed and – also - disputed principles of international environmental law and policy making. Numerous international fora have put their attention to the meaning and effects of the precautionary principle for international environmental decision-making. The United Nations Environment Programme (UNEP), the International Law Commission (ILC), the World Trade Organisation (WTO), the Organisation of Economic Cooperation and Development (OECD), the European Union as well as numerous international negotiating committees (e.g. the international negotiating committee elaborating the Cartagena Protocol on Biosafety and the international negotiating committee elaborating an international legal instrument on Persistent Organic Pollutants) have discussed and analysed the precautionary principle. Moreover the precautionary principle has been raised in proceedings before international judicial bodies, such as the International Court of Justice (ICJ), the International Tribunal for the Law of Sea (ITLOS) and the Appellate Body of the World Trade Organisation.

The precautionary principle or – as it is also referred to – the principle of precautionary approach has been first introduced in the first half of the 1980ies in the discussions concerning the protection of the North Sea.[1] It seems that the first explicit appearance of the precautionary principle in an international instrument is the Declaration of the Second International North Sea Conference on the Protection of the North Sea.[2] Since then the precautionary principle – the origins are to be found in the German *Vorsorgeprinzip*[3] – have been incorporated in numerous international (environmental) treaties and international instruments.

2. The precautionary principle in treaties and other international instruments

Since the mid 1980ies the precautionary principle has found its way in a large number of international instruments. Already in 1985 the Vienna Convention for the Protection of the Ozone Layer "recognized" in its preamble the "precautionary measures" taken at the national and international level.[4]

The 1990 Bergen Ministerial Declaration on Sustainable Development in the ECE Region[5] was the first international instrument to treat the principle as one of general application which was linked to sustainable development. Para. 7 of the Bergen Declaration reads:

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

This provision of the Bergen Ministerial Declaration served as the basis for Principle 15 of the Rio Declaration which reads as follows:

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

Since 1992 the precautionary principle has been included in a number of international environmental treaties – either restating Rio Principle 15 verbatim or referring to precautionary approach or principle. Both the 1992 United Nations Framework Convention on Climate Change[6] and the 1992 Convention on Biodiversity[7] - which were both opened for signature at the Rio Conference - refer to the precautionary principle/approach. Other treaties which have incorporated the precautionary principle are the 1991 Bamako Convention on the Ban of Imports into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes within Africa or the 1992 Helsinki Convention on the Protection and Use of Transboundary Watercourses and International Lakes.

Furthermore, the precautionary principle has been endorsed in international instruments dealing with the protection and preservation of the marine environment, e.g. the 1992 Convention on the Protection of the Marine Environment of the Baltic Sea or the 1992 Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR Convention) or the 1995 Agreement for the Implementation of the Provisions of the United Nations Convention on the Law of the Sea of 10 December 1982 relating to the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks.[8]

The latest international environmental treaties which include the precautionary principle/approach are the 2000 Cartagena Protocol on Biosafety[9] and the 2001 Stockholm Convention on Persistent Organic Pollutants[10].

Article 1 of the Cartagena Protocol - entitled objective - refers to Principle 15 of the Rio Declaration.[11] Furthermore, Article 10, which determines the procedure a Party is to apply to decide whether to permit or prohibit the import of a "living modified organism", establishes the precautionary principle as a basis for decision-making.[12] Moreover, Article 11 determines in its para. 8 states that the precautionary principle has to be applied in regard to the "procedure for living modified organisms intended for direct use of food or feed, or for processing".[13]

Similar provisions may be found in the Stockholm Convention on Persistent Organic Pollutants. Article 1 – entitled objective – refers to Article 15 of the Rio Declaration.[14] Furthermore, Article 8 of the Convention - which sets out the procedure for listing of chemicals in the annexes to the Convention to be followed by the Persistent Organic Pollutants Review Committee - states that the precautionary principle/approach is to be applied.[15]

Thus, one may conclude, that the precautionary principle/approach has been accepted as a rule of international law. Has it become a rule of customary international law as a number of academics have stated and as has been claimed by some States, or, are those correct who claim that the application of the precautionary principle is limited to treaties which explicitly refer to the precautionary principle ?

3. Is the precautionary principle a rule of customary international law ?

Over the last years it has been argued by a large number of authors that the precautionary principle has become a rule of customary international law. They base their argument on the fact that numerous international instruments refer to the precautionary principle/approach as contained in the Rio Declaration and argue that this is evidence of the broad support it has received in recent years. On the other hand it has been argued that the principle/approach is not yet a rule of customary international law as it is "too vague" to be regarded as a rule of rule. But this controversy does not mean that it is not a useful tool for environmental regulation and that it has a status in international law. As may been seen from other principles of international law, such as Principle 2 of the Rio Declaration which states that "States may use their resources according to their own environmental and developmental policies, but have the responsibility not to cause damage to the environment of other States", it is important

that they are referred to when a decision is taken, rather than to decide on their status as a rule of international law, if they lack precise contents. As it has been argued by numerous authors "principles serve as guidelines, rather than imposing concrete obligations." In regard to the precautionary principle it has been argued that it states reasons in the direction of precaution, yet do not necessitate one particular decision that would guarantee total protection. It is in the very nature of principles of international law that uncertainties about their application and even their contents remain.

In the Nuclear Test Cases 1995 (New Zealand v. France)[16] the precautionary principle had been raised by New Zealand as an argument to stop underground nuclear tests. The Court did not take up this argument in its order[17], but reference was made to the precautionary principle in the dissenting opinions of two judges. Judge Weeramantry pointed out that the precautionary principle is "gaining increasing support as part of the international law of the environment"[18] and Judge Palmer[19] stated "the norm involved in the precautionary principle has developed rapidly and may now be a principle of customary international law relating to the environment"[20].

The precautionary principle was also referred to in the Gabikovo-Naygmoros Case between Hungary and Slovakia[21] before the International Court of Justice which concerned the building of dams on the river Danube. Although Hungary had argued along the lines of the precautionary principle as a justification for not implementing the project as set out in the treaty[22], the Court did not address this issue.

The International Tribunal of the Law of the Sea has referred to the precautionary principle/approach in the Southern Blue Fin Tuna Cases between Australia and New Zealand on the one side and Japan (Provisional Measures).[23] Australia and New Zealand sought emergency provisional measures to compel Japan to stop the Experimental Fishing Programme for Southern Blue Fin Tuna in the Southern Oceans. The Tribunal ruled that the parties …

> *" … should act with prudence and caution to ensure that effective conservation measures are taken to prevent serious harm to the stock of southern blue fin tuna" and that "Australia, New Zealand and Japan shall each refrain from conducting an experimental fishing programme."*[24]

Thus, ITLOS held that "the Parties should act with prudence and caution to ensure that effective conservative measures are taken to prevent serious harm to the stock of southern blue fin tuna." The order is to be seen as the first application of the precautionary principle/approach by an international court. As one commentator put it: "Even if ITLOS only urged "caution" on the parties, it did oblige them also to suspend

possible damaging activities despite the presence of scientific uncertainty. This is a classic application of precautionary methodology." [25]

In the most recent case before the ITLOS – the MOX Plant Case between Ireland and the United Kingdom[26] – Ireland argued that "the precautionary principle is now recognised as rule of customary international law, that […] is binding upon Ireland and the United Kingdom, and that it is of singular importance for the provisional measures phase of this case. The precautionary principle is a free-standing obligation which binds the United Kingdom but which it has failed to apply, and it is a principle applicable to the interpretation of each and every provision of LOSC upon which Ireland relies, including the interpretation and application of "urgency" under Article 290 (5) LOSC."[27] Furthermore, Ireland submitted that the inevitability of irreparable prejudice to the right of Ireland to insist upon these preconditions to the commissioning of the plant, if the plant is commissioned before a ruling on the merits of its claim, is obvious. Ireland further submits that the precautionary principle might usefully inform the assessment by the Tribunal of the urgency of the measures it is required to take in respect of the operation of the MOX plant."[28]

In its order, dated 3 December 2001, did not grant provisional measures as requested by Ireland, but prescribed that – considering prudence and caution - Ireland and the United Kingdom shall cooperate.[29]

As Judge Wolfrum stated in his separate opinion, "Ireland could not, for several reasons, rely on the precautionary principle or approach in this case even if it were to be accepted that it is part of international customary international law." If the tribunal would have followed Ireland's argument it would have had to decide on the merits, thus going beyond the scope of provisional measures.

These examples underline that the precautionary principle is taken into account by international judicial bodies, although yet no answer has been given whether it has become part of customary international law.

4. The contents of the precautionary principle and its application

The principle states that lack of scientific certainty in cases of serious or irreversible damage shall not be used as an excuse to postpone cost-effective measures to prevent environmental degradation. Thus, the principle entails acceptance of the fact that restrictions must be placed on activities which are likely to have significant negative impacts on the environment, even if science is unable to predict accurately what these

impacts will be. It does not, as many fear, provide an absolutist prohibition of such activities – it mandates "measures" – cost effective measures – the appropriateness of which will vary from case to case. The significance of the precautionary approach is that it should initiate a decision-making process in which the onus of proof is on those who wish to continue exploitation, rather than as usual on those in favour of conservation. In the international context that means that a State undertaking a certain activity has to provide evidence that it is not harmful to the environment.

One of the main issues to be resolved in the future is the question of "lack of scientific certainty". The interpretation of this phrase as giving rise to the application of the precautionary principle has raised to numerous controversies between academics and practitioners. So far no rule has developed on the extent of scientific evidence to be provided to trigger the precautionary principle/approach.

Moreover, it should be noted that the precautionary principle/approach has been worded differently in the various instruments – as has been demonstrated above. Thus, one could argue that it would hardly be possible to find a general description of the precautionary principle, but should rather concentrate on its application in different fields of environmental law and policy. E.g. Principle 15 of the Rio Declaration makes reference to "cost-effective measures" to be taken, whereas other instruments do not include these words. The effect of these words on the precautionary approach has not been discussed in detail, but is seems that it restricts its application in certain situations.

These different formulations have to be borne in mind, when discussed the implications of the precautionary principle/approach on the operational basis. But the precautionary principle should not be seen as a stand-alone principle. It has to be seen in the wider context of international environmental law and policy. In making the precautionary principle/approach operational other Rio principles are of relevance. I would just like to point out the most important ones – which have also been described as "indirect precautionary measures":

- *Principle 11* which requires that environmental legislation is enacted. It requires that procedures and institutions are in place to deal with issues as they arise, rather than in an ad hoc response mode.

- *Principle 19* on prior and timely notification of relevant information regarding transboundary impacts. The 1997 Convention on the Non-navigational Uses of International Watercourses, the 1998 Rotterdam PIC-Convention and the 1989 Basel Convention on Transboundary Movement of Hazardous Wastes and Their Disposal contain provisions on notification.

- *Principle 17* on Environmental Impact Assessment. It requires that projects are screened for environmental proposes. The 1991 Espoo Convention, the 1974 Nordic Convention and the Operational Directives of the World Bank and other financial institutions require such a procedure.

- *Principle 10* on Participation and Access to Information.[30]

5. Concluding Remarks

The precautionary principle/approach has explicitly been included in an increasing number of treaties and other international instruments in recent years. It is found in treaties dealing with the protection of the ozone layer, biodiversity or waste management. Although, this wide acceptance underlines its importance as a guideline for international environmental law and policy, its implications are still vain.[31]

It has been accepted as a guideline for decision-making, but so far its contents has not been described in a manner that would harden the precautionary principle in a generally applicable standard for all policy areas. As the evolution of the precautionary principle and fisheries law has demonstrated it has become an essential part of policy-making in this field and has served as a most important tool in ensuring sustainable fisheries policies.

In order to overcome criticism about its vagueness and therefore possible arbitrary application it would need to be formulated in a more precise way. It seems to me that a general description of the precautionary principle/approach might be a very far-a-way task, but in certain areas of international environmental law such a description will take place. The Cartagena Protocol and the POPs Convention are two international instruments which will lead to more specific terms on the application of the precautionary principle/approach in these two area: biosafety and chemicals safety. Such a case-to-case approach will help to overcome the uncertainties surrounded the precautionary principle. Furthermore, it should not be overlooked that its close relationship with other Rio Principles will be of vital assistance in making the precautionary principle work. Environmental impact assessment procedures, early notification and warning to other states, emergency assistance as well as access to information will help to elaborate the precautionary principle and overcome some of its current weaknesses.

NOTES AND REFERENCES

[1] For the origins and the evolution of the precautionary principle see David Freestone, The Precautionary Principle, in: Robert Churchill/David Freestone (eds.), International Law and Global Climate Change (1991), pp. 21. Cf. James Cameron/Juli Abouchar, The Status of the Precautionary Principle in International Law, in: David Freestone/Ellen Hey (eds.), The Precautionary Principle and International Law – The Challenge of Implementation (1996), pp. 29; P. K. Rao, International Environmental Law and Economics (2002), pp. 99.

[2] The participants of the Second Conference stated that they accepted that „...in order to protect the North Sea from possible 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 absolute clear scientific evidence." (Paragraph VII, London Declaration, London, 1987).
Furthermore, the Declaration called upon States to „accept the principle of safeguarding the marine ecosystem of the North Sea by reducing emissions of substances that are persistent, toxic and liable to bioaccumulate at source by the use of the best available technology and other appropriate measures. This applies especially when there is reason to assume that certain damage or harmful effects on the living resources of the sea are likely to be caused by such substances, even where there is no scientific evidence to prove a causal link between emissions and effects (the principle of precautionary action)." (Paragraph XVI (1), London Declaration, 1987). Cf. David Freestone/Ellen Hey, Origins and Development of the Precautionary Principle, in: David Freestone/Ellen Hey (eds.), The Precautionary Principle and International Law – The Challenge of Implementation (1996), p. 5.
See also Patricia Birnie/Alan Boyle, International Law and the Environment (1992), pp. 95.

[3] Cf. Lothar Gündling, The Status of International Law of the Principle of Precautionary Action, in: David Freestone/T. Ijlstra (eds.), The North Sea Perspectives on Regional Environmental Co-operation (1990), pp. 23.

[4] Preambularparagraph 5 reads:
"Mindful also of the precautionary measures for the protection of the ozone layer which have already been taken at the national and international levels". As similar provision is found in the Preamble of the Montreal Protocol on Substances that Deplete the Ozone Layer (preambularparagraph 8).

[5] Text is reprinted in Robin Churchill/David Freestone (eds.), International Law and Global Climate Change (1991), pp. 344.

[6] Article 3 para. 3 reads:
„The Parties should take precautionary measures to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects. Where there are threats of serious irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures, taking into account that policies and measures to deal with climate change should be cost-effective so as to ensure global benefits at the lowest possible cost. To achieve this, such policies and measures should take into account different socio-economic contexts, be comprehensive, cover all relevant sources, sinks and reservoirs of greenhouse gases and adaptation, and comprise all economic sectors. Efforts to address climate change may be carried out cooperatively by interested Parties."

[7] Preambularparagraph 9 reads:
„Nothing also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat."

[8] On the precautionary principle and fisheries see Dolliver Nelson, The Development of the Legal Regime of High Seas Fisheries, in: Alan Boyle/David Freestone (eds.), International Law and Sustainable Development – Past Achievements and Future Challenges (1999), pp. 113; and David Freestone, International Fisheries Law since Rio: The Continued Rise of the Precautionary Principle, in: Boyle/Freestone (eds.), op. cit., pp. 135.

[9] ILM 39 (2000), 1027 ff.

[10] ILM 40 (2001), 532 ff.

[11] Article 1 of the Cartagena Protocol reads:
„In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, and specifically focusing on transboundary movements."

[12] Article 10 para. 6 reads:
„Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects."

[13] Article 11 para. 8 reads:
„Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects."

[14] Article 1 of the POPs Convention reads:
„Mindful of the precautionary approach as set forth in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Convention is to protect human health and the environment from persistent organic pollutants."

[15] Article 8 para. 7 (a) states that if on the basis of the risk profile the Committee decides „that the chemical is likely as a result of its long-range environmental transport to lead to significant adverse human health and/or environmental effects such that global action is warranted, the proposal shall proceed. Lack of full scientific certainty shall not prevent the proposal from proceeding.". The decision whether a chemical is to be listed in the annexes is to be taken by the Conference of the Parties „in a precautionary manner" (Article 8 para. 9).

[16] Request for an Examination of the Situation in accordance with para. 63 of the Court's Judgement of December 1974 in the Nuclear Tests (New Zealand v. France) Case, ICJ-Reports 1995, pp. 288.

[17] Order dated 22 September 1995, ICJ-Reports 1995, pp. 288.

[18] Dissenting Opinion of Judge Weeramantry, ICJ-Reports 1995, p. 342.

[19] Judge Palmer had been the ad-hoc Judge on behalf of New Zealand. Dissenting Opinion of Judge Sir Geoffrey Palmer, ICJ-Reports 1995, pp. 381.

[20] ICJ-Reports 1995, p. 412, para. 91 (d).

[21] ILM 37 (1998), 162 ff. (Case concerning the Gabikovo-Nagymaros Project (Hungary/Slovakia)).

[22] See Para. 97 of the ICJ-Judgement which reads: "Finally, Hungary argued that subsequently imposed requirements of international law in relation to the protection of the environment precluded performance of the Treaty. The previously existing obligation not to cause substantive damage to the territory of another State had, Hungary claimed, evolved into an erga omnes obligation of prevention of damage pursuant to the "precautionary principle". On this basis, Hungary argued, its termination was "forced by the other party's refusal to suspend work on Variant C."

[23] ILM 38 (1999), pp. 1624.

[24] ILM 38 (1999), pp. 1624, at pp. 1634

[25] David Freestone, Caution of Precaution: "A Rose By Any Other Name …"?, Yearbook of International Environmental Law 10 (1999), pp. 25, at 32.

[26] The MOX Plant Case (Ireland v. United Kingdom), Request for provisional measures by Ireland, www.itlos.org.

[27] See Request for Provisional Measures and Statement of Case of Ireland, 9 November 2001, para. 97.

[28] Para. 148.

[29] The merits of the case will be heard by an arbitral tribunal in accordance with Annex VII of the Law of the Sea Convention.

[30] Cf. The Josphine Onoh Memorial Lecture on 1 May 2001 given by Prof. David Freestone at the University of Hull.

[31] Cf. Lada Soljan, The General Obligation to Prevent Transboundary Harm and its Relation t Four Key Environmental Principles, Austrian Review of International and European Law 3 (1998), pp. 209, at pp. 214.

THE ORIGINS, CONTENT AND ROLE OF THE PRECAUTIONARY PRINCIPLE IN EUROPEAN COMMUNITY LAW

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I. Introduction

The precautionary principle is about scientific uncertainty. It permits and in some cases requires the regulatory authorities to take action or adopt measures in order to avoid or reduce risk to health, the environment or in the workplace. The precautionary principle is "a statement of common sense"[2] that allows the competent regulatory authorities "to err on the side of safety"[3] in case of uncertainty.

The European Commission, after a relatively long period of gestation, issued on 2 February 2000 a *Communication on the Precautionary Principle* (European Commission, 2000). The *Communication* has four aims: to outline the Commission's approach to using the precautionary principle, to establish Commission guidelines for applying it, to build a common understanding of how to assess, appraise, manage and communicate risks that science is not yet able to evaluate fully, and to avoid unwarranted recourse to the precautionary principle as a disguised form of trade protectionism. The *Communication* also sought to provide an input to the ongoing debate on this issue, both within the Community and internationally, since relevant international law and approved agreements and conventions are part of Community law and, thus, influence the development and application of the precautionary principle in the Community and its Member States.

The Commission's *Communication* was endorsed by the December 2000 Nice European Council *Resolution*, which called on the Commission to: systematically apply its guidelines on the conditions for use of the precautionary principle, making allowance for the specific features of the various areas in which they may be implemented, and to incorporate the precautionary principle, wherever necessary, in drawing up its legislative proposals and in all its actions. The work of the Community institutions on the precautionary principle, including the numerous resolutions of the European Parliament and the active participation of non-governmental organisations, intensified an already lively public debate that was influenced by the recent food and health crises and the on-going debate on biotechnology and genetically modified products both at national, Community and international level.

This paper provides a brief but critical account of the history, content and role of the precautionary principle in European Community (EC) law, with particular reference to recent developments in administrative practice, legislation and case law by the relevant Community institutions. It responds also to some criticism and comments in the literature on the Commission's *Communication* on the precautionary principle.

II. The origins of the precautionary principle: an issue of substance or formality?

The basic duty of governments to act cautiously or to err on the side of safety has been a long-standing principle in the legal systems of several countries and the Member States of the Community in the area of public health protection. Moreover, the basic elements of the precautionary principle, that is uncertainty, risk and lack of direct causal link, have been applied, consciously or unconsciously, since public health was threatened from diverse technological sources (European Commission, 2002; EEA, 2001), or the "scientific revolution" in general (de Sadeleer, 1999; Hermite and David, 2000; Kuhn, 1970).

The application of precaution against actual or potential harm to public health is a generally observed practice in nearly all major jurisdictions (de Sadeleer, 1999; UNEP draft paper, 2001; Raffensperger and Tickner, 1999). The same can also be observed from the long-standing regulatory systems, both at national and Community level, concerning pre-marketing approval requirements for medicinal products, veterinary drugs, pesticides, contaminants, additives and other substances (European Commission, 2000; de Sadeleer, 2001). The specific allocation of the burden of proof in the pre-marketing approval process and in the context of litigation further demonstrate the above general proposition about the origins of the precautionary principle (European Commission, 2000).

For example, the European Court of Justice (ECJ) had ruled in the early 80s that:

> "*In so far as there are uncertainties in the present state of scientific research with regard to the harmfulness of a certain additive, it is for the Member States, in the absence of full harmonization, to decide what degree of protection of the health and life of humans they intend to assure, in the light of specific eating habits of their own population…*".[4]

This case law recognised the right of cautious Member States to block imports in their territory on grounds of threats to human health. The only condition under which they

were permitted to do so was scientific uncertainty with regard to the harmfulness of a product.

More recently, the judgment of the ECJ in the *BSE* case is based on the finding that *"at the time when the contested decision was adopted, there was great uncertainty as to the risks posed by live animals, bovine meat and derived products".*[5] Again the ECJ underlined uncertainty as a necessary element for the application of precaution.

The term "*precautionary principle*" has been coined in the 80s in the area of national and international environmental protection for a number of reasons. First, increasing environmental damage was observed that could not be clearly attributed to a specific agent or source of contamination or pollution. This created overall scientific uncertainty, which could not be tackled on the basis of the old principle that allowed intervention only in situations of full scientific knowledge and established causality (Von Moltke, 1988; Bodansky, 1991; O'Riordan and Cameron, 1994; Sands, 1995; Freestone and Hey, 1996; Noiville, 2000). This fact explains the specific reference made to the lack of clear and direct causal link between the measure and the observed damage that is found in particular in the early international environmental agreements and conventions that contain an explicit reference to precaution. The progressive recognition of the precautionary principle has made such specific reference to lack of direct causal link increasingly rare in the more recent international agreements and conventions, and it has practically been abandoned in the latest ones.

Second, the theory that the limits of the assimilative capacity of the environment had been reached incited the regulatory authorities to tackle scientific uncertainty and the lack of economic incentives for the private sector to take the necessary steps to reduce or eliminate pollution at the source. Third, the absence of a prior consent and approval procedure for a large number of potentially harmful agents and activities in the area of environmental protection may have also played a role in the development of the precautionary principle. Fourth, the progressive maturity and diffusion of environmental sensitivity and consciousness introduced a normative dimension about the need to protect the environment as such, in addition to avoiding harm to public health indirectly through environmental exposure.

It appears, therefore, that national environmental legislation and international agreements and conventions have actually borrowed from the area of health and transferred into the area of environmental protection the basic rationale of the precautionary principle, that is to err on the side of caution in case of scientific uncertainty. Contrary to conventional wisdom, therefore, the true origin of the

precautionary principle is not in the area of environmental protection, although the term as such appears to have been formally used for the first time in this area of law.

The above proposition is supported by the Court's reasoning in the *BSE* case, where it explained the basis of its decision relating to the Commission's precautionary action as follows:

> *"That approach is borne out by Article 130r(1) of the EC Treaty, according to which Community policy on the environment is to pursue the objective inter alia of protecting human health. Article 130r(2) provides that that policy is to aim at a high level of protection and is to be based in particular on the principles that preventive action should be taken and that environmental protection requirements must be integrated into the definition and implementation of other Community policies".* (at paragraph 64)

III. Definition, content and application of the precautionary principle in Community law

1. Definition

Article 174(2) of EC Treaty, as modified by the Maastricht Treaty, provides that the "*Community policy on the environment shall aim at a high level of protection ... It shall be based on the precautionary principle*...". At the time of amending the Treaty to insert an explicit reference to the precautionary principle in the area of environmental protection, certain definitions of the precautionary principle existed in national laws and secondary Community legislation, including international agreements and conventions to which the Community was a party (e.g., Second North Sea Convention, 1987; OSPAR, 1992; Rio Declaration, 1992; Convention on Trans-boundary Watercourses and International Lakes, 1992). Moreover, as explained above, the principle has already been applied in the area of public health protection since a long time ago. The EC Treaty, however, rightly did not provide a definition of the precautionary principle.

The difficulty of providing a generally applicable and universally acceptable definition of the precautionary principle stems not from any uncertain or imprecise nature of its basic rationale but, rather, from the fact that its application is context and case-specific, that is it depends on the level of risk a society considers acceptable for a specific substance or activity at a given moment in time (i.e. the so-called chosen level of health

or environmental protection). The level of risk considered unacceptable sometimes varies between no (or zero) risk and small, significant, serious or irreversible risk. It should be noted that although the acceptable level of risk can be defined both in qualitative or quantitative terms, in practice it is never expressed in a precise quantitative manner (e.g., 1 in 1.000.000 risk of death). However, there is no doubt that even a qualitative expression (e.g., significant or serious risk, etc.) of the acceptable level of risk includes or implies the chosen level of health or environmental protection. It follows that identifying uncertainty, risk and lack of direct causal link in a risk assessment does not automatically lead to the application of the precautionary principle, as the potential harm may be considered to be acceptable to the regulatory authorities and the public in a specific case or compatible with the chosen level of health or environmental protection established by statute.

For those reasons, it is submitted that the following passage from the Court's judgment in the *BSE case* contains all the necessary elements of a general definition of the precautionary principle that can be applied in all areas of Community law:

> *"Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent".*[6]

The above passage lays down three basic conditions that may trigger consideration and application of the precautionary principle in Community law: uncertainty, risk, and lack of direct causal link. These will be explained in more detail below.

For the sake of completeness, it should also be noted that the ECJ referred explicitly to the precautionary principle in the recent *Maize Seeds* case, where it stated that:

> "*Observance of the **precautionary principle** is reflected …in the right of any Member State…provisionally to restrict or prohibit the use/or sale on its territory of a product which has received consent where it has justifiable reasons to consider that it constitutes a risk to human health or the environment".*[7]

It is important to note that Directive 90/220, and in particular Article 16 thereof which was at bar in the above case, did not contain an explicit reference to the precautionary principle. Moreover, its legal basis is not an environmental policy provision but Article 100A (now Article 95) of the EC Treaty, which is normally used for general internal

harmonisation measures Yet, this did not prevent the Court from making the important finding that reflection of the precautionary principle is to be found in the right of each Member State to restrict imports in case of scientific uncertainty and possible risk to health or the environment. The Court said:

> *"It must be added that the system of protection put in place by Directive 90/220, in particular by Articles 4, 12(4) and 16, necessarily implies that the Member State concerned cannot be obliged to give its consent in writing if in the meantime it has new information which leads it to consider that the product for which notification has been received may constitute a risk to human health and the environment.*[8]

2. Basic conditions for the application of the precautionary principle in Community law

a) Scientific uncertainty

Scientific **uncertainty** is the essence of the precautionary principle. From a formal point of view, scientific uncertainty should be distinguished from risk and situations of ignorance (Stirling, 1999; EEA, 2001).

Scientific uncertainty exists when there is no adequate theoretical or empirical basis for assigning possibilities to a defined set of outcomes. In the strict sense, even if there is relatively high confidence about the possible set of outcomes, there is no basis to confidently assign probabilities to these outcomes (Stirling and Mayer, 2000a). As it will be seen below, this may be because of the novelty of the substance or activity concerned or because of complexity or variability in their context (Stirling, 1999; Stirling, 2000b). Moreover, uncertainty may relate to qualitative or quantitative elements of the analysis.

In the context of a risk assessment, scientific uncertainty should be distinguished from **risk**. Risk is a function of at least two variables: the likelihood (or probability) of an adverse effect and its severity or magnitude (Codex Alimentarius Commission, 2000). A formal definition of risk, therefore, is a condition under which it is possible to describe the possibilities (or probabilities) of occurrence of nearly all possible outcomes, and their magnitude. In practice, in the context of a risk assessment uncertainty and risk are frequently inextricably linked.

Uncertainty should also be distinguished from the condition formally known as **ignorance**, where some of the possible outcomes, at the time of assessing the activity or substance, are completely unknown or unknowable and, thus, fail entirely to be assessed (EEA, 2001). Although distinguishable, uncertainty and ignorance may co-exist in a risk assessment and this can further increase the potential for error in the degree of confidence regarding the existence of harm to health, the environment or in the workplace.

In conclusion, the basic legal definition of scientific uncertainty reflects the potential for error inherent in science and scientific information. As the Commission's *Communication* has pointed out, varying degrees of scientific uncertainty may result from information that is insufficient, inconclusive or contradictory, that is from lack of knowledge or a state of controversy on existing data or lack of some relevant data that render problematic an estimation of the adverse effect on health, safety in the workplace or harm to the environment (European Commission, 2000). However, when uncertainty is properly analysed and explained throughout the risk assessment, this should normally provide the competent regulatory authorities with a sufficient scientific basis on which they can take their decisions. That is the reason for which it is validly claimed that the precautionary principle is firmly based on science.

b) Risk, risk assessment and lack of direct causal link

The term *adverse effect* is used to describe harm, hazard, damage or some other kind of undesirable loss or impairment to health or the environment. The term *adverse effect* is from the regulatory point of view preferable to the other terms used because it can capture optimally any type of unwanted effect. The concept of health is defined in the constitution of the WHO as *"a state of complete physical, mental and social well-being that does not consist only in the absence of illness or infirmity"*. The ECJ referred explicitly to the above definition and concluded that a broad interpretation should be given accordingly to the concept of health in EC law.[9]

There are different ways of assessing risk to health, the environment or in the workplace and international practice in this regard is far from being coherent. In the Community legal order, regulatory action is nearly always based on a risk assessment of the highest possible quality. Nearly any substance or technological activity that may potentially have an adverse effect or impact on health, the environment or the safety in the workplace are subject to a risk assessment requirement and detailed provisions exist on how to conduct such an assessment, especially in the areas of dangerous substances, medicinal products,

food additives, contaminants, pesticides, GMOs, product standard- setting procedures, and environmental impact assessment.

As explained earlier, past experience has shown that lack of evidence establishing direct causal link between an activity, process or substance and an identified risk has always been at the root of applying precaution. There are obviously limits to knowledge at any given moment in time. Moreover, there are risks that can be caused by multiple, confounding factors that sometimes take time to materialise. The mistake has been made in several cases in the past of requiring scientific certainty before deciding to take restrictive or protective action (EEA, 2001; Raffensperger and Tickner, 1999). There are normally two reasons that had lead to such a regulatory attitude in the past. First, a positivist view of science, considering it to be a powerful and neutral tool capable of predicting risk and causality. This has been demonstrated to be wrong in several cases, because the experts' judgments appear to be prone to many of the same mistakes and biases as those of the general public, particularly when experts are forced to go beyond the limits of available information and data and rely on assumptions and intuition (Fischhoff et al., 1981; Slovic, 1987; Slovic, 1997). Second, existing risk assessment methodologies are inherently biased in favour of avoiding over-inclusive regulatory measures (i.e. the inclination is to avoid false positives) for fear of imposing undue costs on technological progress and on society (Breyer, 1993; Cranor, 1993; Graham, 1996; EEA, 2001; Funtowicz et al., 1992).

Because uncertainty and lack of causality normally undercut the ability to prove negligence in litigation, it would be legally inappropriate and wrong to require scientific certainty before allowing action to be taken to protect health or the environment (Wiener, 2001). As it has rightly been argued, studying uncertainty and causality to death often results in the death of those the regulatory authorities are supposed to protect (Infante, 1987; Infante, 2001).

Research has demonstrated that risk means more to people than the expected number of fatalities based on probabilistic quantitative assessments, which is the usual way experts assess risk (Fischhoff et al., 1981; Slovic, 1987). Indeed, the perception people have of risk is wider than that of experts and reflects a number of legitimate concerns (e.g. familiarity with risk, catastrophic potential, irreversibility of harm, threat to future generations, risk control possibilities, voluntariness of exposure, etc.), which are frequently omitted from an expert risk assessment (Fischhoff et al., 1981; Fischhoff et al., 1978; Slovic et al. 1985; Slovic, 1987). It follows from the preceding analysis that risk management measures, instead of trying to scientifically patronise the consumers, should take into account their legitimate concerns or the public's perception of risk, as

opposed to mere consumer (commercial) preference or choice that can be addressed by other more appropriate type of measures, such as labelling.

c) Acceptable level of risk, proportionality and cost-benefit analysis

Detailed studies of expressed consumer preferences indicate that people tend to view current levels of risk as unacceptably high for most activities and substances. Studies have also shown that the gap between perceived and desired risk levels suggests that people are not satisfied with the ways in which the market and regulatory authorities have balanced risks and benefits (Slovic et al., 1980; Slovic, 1987). Therefore, being able to define accurately the acceptable level of risk (or chosen level of health or environmental protection) is fundamental in risk management and the application of the precautionary principle. In simple terms, therefore, the objective is to discover *how safe is safe enough* for the people.

It is generally agreed that defining the level of acceptable risk is a normative decision that belongs to the democratically elected and accountable institutions of a state. Regulation of risk entails taking important decisions about how much health and safety people wish and can afford. As this touches upon the basic functions and mission of a democratic system of government, that is to protect *inter alia* the life and health of its people and the environment, decisions about the level of acceptable risk cannot be made by unaccountable scientific or other kind of experts. It follows that in any democratic system of government the electorate must have an opportunity for the final say about which risks it will bear and which benefits it will seek to obtain.[10] This is essentially the reason for which in the Community legal system, as in many other systems, the opinions of technical and scientific committees are of advisory nature only.[11] This also explains the fact that the work of all international standard-setting bodies on substances, agents, activities or processes is voluntary and non-binding, unless the parties to an international agreement or convention have clearly and explicitly renounced of their autonomous right to set their level of protection or the level of risk considered acceptable by its people. [12]

As a general rule, people and regulatory authorities normally pursue policies that seek to avoid risk to health or the environment, unless this becomes clearly a burden too high on them or the society to bear (Slovic, 1987). Pursuing zero risk policies, therefore, are not uncommon in any legal system, and the right to choose a zero level of risk has been upheld explicitly both by national and international courts and tribunals.

Equally, the fact that in our technologically complex society there are multiple sources of risk, including risks to which people voluntarily expose themselves, does not cancel out the legitimate objective to aim, whenever possible, for a zero risk level of health or environmental protection. Arguments have also been made in favour of adopting a detailed cost–benefit analysis in nearly all risk management decisions in the European Community, based *inter alia* on the multi-risk nature of our world and on reasons of efficient allocation of resources. These arguments are not only misconceived and flawed but also potentially dangerous. First, because voluntary exposure to risk by *some* must not enter into any type of balancing exercise against unintended, involuntary exposure to the same or other type of risks by *other* people. Contrary to what Wiener and Majone seems to suggest, the fact that people face multiple sources of risk in our society is not as such an argument in favour of a balancing exercise (Wiener, 2001; Majone, 2001). Second, the right to life and health is the most fundamental of all human rights, which implies that no restriction should in principle be placed on it without proper consideration. Indeed, as a matter of principle, reasons of justice, fairness and morality militate against a balancing exercise based on broad considerations of efficient allocation of resources (Dworkin, 1987; Rawls, 1999; Sen, 1986; Nussbaum, 2000). Third, the Court of Justice has held several times that, in a risk management and balancing exercise, considerations of health should take precedence over economic or commercial considerations.[13]

Unlike the situation in US law, there is no general guideline in Community law that obliges the regulatory authorities to analyse systematically the economic impact or cost of risk management measures. However, risk management does play an important role in improving the overall well-being of the Member States and their citizens in the Community and, for that reason, there is no barrier in the conduct of studies by the regulatory authorities, whenever feasible, in order to measure and report upon the economic impact of their decisions, so as to inform themselves and the public. Indeed, the regulatory authorities in the Community sometimes make, consciously or unconsciously, gross estimates of first level, direct cost and benefits analysis of their decisions. However, considerations of the level of economic impact or cost from adopting a future precautionary action do not play a decisive role in the determination *whether* to adopt a measure, but only in the actual *choice* or *design* of the measure to be taken.

In the Community legal order it is the principle of proportionality that is used to check the balance between the health or environmental objective pursued and the restrictive effects of the precautionary measure. It follows that the principle of proportionality in

risk management decisions in the Community requires tailoring the measures to the chosen level of health or environmental protection.

IV. Science, precaution and the courts

It is important to note that risk-averse societies are likely to be reluctant to trade a chosen high level of health protection for unpredictable uncertainty of possible harm. The problem of understanding and defining uncertainty in the context of a risk assessment can, therefore, be large, complex and nearly intractable, unless the analysis is structured into small and simpler concepts for each stage and component of the risk analysis. It follows that it is of paramount importance for risk assessors to explain in detail any kind of scientific uncertainty they encounter in every step of their analysis and the techniques, assumptions and values they employ to eliminate or reduce it. Residual uncertainties, however, are most likely to remain when there is lack of pertinent scientific knowledge or ignorance, despite the efforts employed by scientists to reduce the potential for error (Stirling, 1999).

Precaution can, therefore, be applied both by the scientists completing the risk assessment, on the basis of science policy guidelines that can be issued to them only by the risk management authorities, as well as by the regulatory authorities themselves who have to draw the necessary regulatory implications. Both risk assessors and risk managers attribute at any given moment in time different subjective values to available scientific data, the risks and the nature of possible adverse effects. Precaution applied by scientists in a risk assessment does not, therefore, eliminate the need to allow also risk managers to apply precaution to the same agent, activity or process when taking regulatory action. Risk assessors' *technical* precaution (when modelling and interpreting evidence and data) is, therefore, distinguishable from the risk managers' *regulatory* precaution (when taking normative regulatory action).

Dealing with scientific uncertainty becomes an issue when it is institutionalised in a democratic decision-making process, because regulators and judges are obliged to make decisions, sometimes within short time limits, even when scientific evidence in a risk assessment is inconclusive. Moreover, whereas judges are only required to control the discretion of the regulatory authorities in solving a specific legal dispute (but not the underlying basis of scientific uncertainty), the regulatory authorities' main cause of concern is the potential effects on health, the environment or in the workplace from the uncertainty and risk. The difficult decision to take, therefore, rests ultimately with the regulatory authorities that are accountable to the public.

It should also be noted that in the Community legal system, the objective of any risk management measure should be to achieve a "high level" of health or environmental protection.[14] One of the means to achieve this objective is the mandatory requirement to base the measure or action on the precautionary principle. [15] This requires that appropriate consideration should be given to the interaction between the level of acceptable risk and the obligation to err on the side of safety in case of scientific uncertainty. Therefore, the precautionary principle in the Community legal system plays an important role in that it provides the means to the regulated or potentially affected natural or legal persons to control, if necessary by means of action before the courts, the way risk management institutions take their normative decisions when evaluating scientific uncertainty and risk as well as in the way they balance costs and benefits. That is why the precautionary principle in genuine situations of scientific uncertainty should not only allow but in certain cases can *oblige* the regulatory authorities to err on the side of caution when this is necessary to achieve the chosen level of human, animal or plant life or health or environmental protection. This is *one* of the three functions performed by the precautionary principle, that is to put constraints on the decision-making process and on normative regulatory discretion. This entails both *ex ante* and *ex post* control of measures taken to regulate risk.

V. The specific problem of allocating the burden of proof

The EC and other countries that apply a prior approval procedure (or prior marketing authorisation) for certain products, substances or processes place the burden of proving safety or lack of harm on the applicant manufacturer or operator (burden of proof = burden of producing evidence + burden of persuasion). The candidate products, substances or processes are deemed to be dangerous unless and until the interested manufacturer carries the necessary scientific work and succeeds in demonstrating to the satisfaction of the authorities the *safety* or *lack of harm,* compared to the level of acceptable risk of their products, substances, processes or activities. As already explained, the chosen level of protection does not have to be fixed in advance in the statute but may be decided on a case-by-case basis. The quantum of evidence required is an empirical question and may vary from case to case. As the Commission's *Communication* has suggested, measures based on the precautionary principle can be adopted when there are "reasonable grounds for concern" or when there are "valid reasons to consider" that there may be a risk.

The standard of proof applied by courts when reviewing cases may also vary between application of the preponderance test, the proof beyond reasonable doubt test, or the

clear and convincing test, etc. In Community law in the context of products or substances requiring prior approval to be marketed, the standard of proof is clearly on the manufacturer who must usually demonstrate safety ”adequately or sufficiently”, which is a test comparable to the proof beyond reasonable doubt test applied in common law jurisdictions.

The general guideline in EC law is to aim for a ”high level” of health or environmental protection (e.g., Article 3(1)(p), Article 152(1) and Article 174(2) of EC Treaty). But how high is high enough is not always obvious. For this reason, the level of acceptable risk may need to be further specified in concrete cases. For instance, in the USA the level of acceptable risk in a number of sectors is fixed by statute and may vary from no (or zero) risk to significant risk or unreasonable risk, etc., while in some other cases the level of acceptable risk may be fixed at the time of taking a specific measure and can be subject to judicial interpretation (Sunstein, 2001). As explained before, in such cases the function of the precautionary principle is to *compel* action when the risk assessment shows that the risk from authorising the substance, process or activity is likely to exceed the chosen level of acceptable risk.

There appears to exist also a general *default rule* that places the burden on the regulatory authorities to demonstrate the existence of a risk. As explained above, this should imply only a relatively low threshold of producing evidence and burden of persuasion (especially in case of emergency or safeguard measures), otherwise there would be a real risk of defeating the very purpose of applying the precautionary principle. Nevertheless, even in cases where no prior authorisation procedure is applied, regulations may place, on a case by case basis, upon the final users or the public authorities the burden of demonstrating the existence of a risk from a product, process, activity or project. Here, despite the opposition by some authors (e.g., Wiener, 2001), the application of the precautionary principle is particularly important (EEA, 2001). In cases of established scientific uncertainty and lack of direct causal link, there may be a need to take a specific regulatory measure to reverse the burden of producing evidence and the burden of persuasion upon the producer, manufacturer, importer or economic operator in general (e.g. long used chemicals, etc.), when this is necessary to meet the chosen level of healthy or environmental protection. This is another of the three functions of the precautionary principle, that is *to compel* the adoption of protective regulatory measures which are likely to satisfy the necessity test more easily. This approach is also in conformity with the necessity test as laid down in several international environmental agreements and conventions and in the international trade rules of the WTO Agreements.

VI. Status of the precautionary principle in international and Community law: principle, approach or rule?

The principle according to which responsible governments should act on the basis of precaution when there is scientific uncertainty in order to achieve the chosen level of health protection is so widely and universally accepted that is now in the process of becoming, or has already crystallised as, a rule of customary international law in the areas of health and environmental protection. Consequently, some divergence in the terminology used (i.e. principle or approach or measure) in the various international conventions and agreements is of no legal significance as such.

Striped of all its peripheral/functional elements, the precautionary principle is essentially about scientific uncertainty. In accordance with generally accepted theory of international law, it can therefore be argued that the precautionary principle, understood in that sense, has already become a principle or customary rule of international law, because all the requisite elements of *usus* and *opinio necessitatis* exist and have been met with quite strong, consistent and widespread acceptance. Any differences in the formulation of the principle in the available definitions relate rather to its peripheral/functional elements, like what should be the nature or extent of risk identified, the need to conduct a risk assessment or a cost/benefit analysis before taking the measure, etc, which do not as such affect the core and basic rationale of the principle (that is scientific uncertainty, risk and lack of clear causal link).

In any case, in Community law the precautionary principle has the status of a mandatory treaty principle (Article 174(2) of EC Treaty, as modified by the Maastricht Treaty). The Community regulatory authorities (and those of the Member States acting in the area of Community law) are *obliged* to consider the application of the precautionary principle *when this is necessary to achieve the already chosen level of health or environmental protection*. But the level of protection does not have to be chosen necessarily in advance nor in an abstract manner in all cases. As explained, it may be decided on a case by case basis at the time of taking a specific regulatory measure. [16] In this latter type of cases, a requirement to apply *consistency* in the choice of the level of protection could provide some means of controlling the discretion, which the regulatory authorities normally enjoy in the design and application of precautionary measures.

The question about the status of the principle in international law is not without interest, however, as the successful invocation of the principle in the context of an international agreement or convention will depend not only on the text of the agreement under

consideration but also on the principle's status in international law (interpretative and/or overriding functions). It follows that the normative value of the precautionary principle in national or international law, from the recognition of the principle as a customary rule of international law, would be to compel *ex ante* and *ex post* consideration and application of precaution when this is necessary to achieve the chosen level of health, safety or environmental protection, even when the relevant legal provisions of an agreement or conventions make no explicit or implicit reference to it.[17]

VII. Conclusion

Every society is free to choose the level of acceptable risk to health or the environment. The precautionary principle provides a basis both to the regulatory authorities and the regulated natural or legal persons to ensure that this democratic societal choice is achieved. First, it *enables* and sometimes *obliges* the regulatory authorities to take action when there is scientific uncertainty and risk but direct causal link cannot be established. This is the most important normative function of the principle. Second, the precautionary principle sometimes entails placing the burden of proof on the applicant manufacturer to demonstrate safety or that the level of acceptable risk will not be exceeded. Third, the precautionary principle also enables the affected persons to control, if necessary by means of action before the courts, the exercise of regulatory discretion in risk management. These are the three basic normative functions the precautionary principle performs in Community law.

The precautionary principle is firmly based on science because its application is warranted only when uncertainty is scientifically established. As it reflects also a principle of common sense, that is to err on the side of caution in case of uncertainty, the normative force of the precautionary principle both in Community law and international law should not be denied. In the European Community, considerations of health or environmental protection take precedence over economic considerations. Therefore, the precautionary principle is a legal norm which can be deployed to ensure that the societal values and choices on health and environmental protection in the Community are fulfilled.

REFERENCES

Applegate J.S. (2000): *The Precautionary Preference: An American Perspective on the Precautionary Principle*, 6 Human & Ecological Risk Assessment 413.

Arrow K. (1963): *Social Choice and Individual Values*.

Bodansky D. (1991) : *Scientific Uncertainty and the Precautionary Principle*, Environment, 4 September 1991.

Bourdieu P. (2001): *Science de la science et réflexivité*.

Breyer S. (1993): *Breaking the Vicious Circle – Toward Effective Risk Regulation.*

Cranor C.F. (1993): *Regulating Toxic Substances – A Philosophy of Science and the Law.*

De Sadeleer N. (1999) : *Les Principes du Polluer-Payer, de Prévention et de Précaution.*

De Sadeleer N. (2001): *Le statut juridique du principe de précaution en droit communautaire: du slogan a la règle*, CDE 91.

Dworkin R. (1987): *Taking Rights Seriously* (corrected 5th impression).

Environmental Protection Agency (EPA) (1995): *Science Policy Council – Guidance for Risk Characterization*.

European Commission (2000): *Communication on the Precautionary Principle*.

European Council (2000): *Resolution on the Precautionary Principle*.

European Environment Agency (EEA) (2001): *Late Lessons from Early Warnings: The Precautionary Principle 1896-2000.*

Fischhoff B. et al., (1978): *How Safe Is Safe Enough? A Psychometric Study of Attitudes Towards Technological Risks and Benefits*, 9 Policy Science 127.

Fischhoff B. et al., (1981): *Acceptable Risk.*

Funtowicz S., Ravetz J. (1992): *Three Types of Risk Assessment and the Emergence of Post-Normal Science*, in S. Krimsky and D. Golding (eds.), *Social Theories of Risk*, pp. 251-273.

Godard O. (ed.) (1997): *Le principe de précaution dans la conduite des affaires humaines.*

Graham J.D. (1996): *Making Sense of Risk: An Agenda for Congress*, p. 183, in *Risks, Costs, and Lives Saved: Getting Better Results from Regulation*, (R.W. Hahn ed., 1996).

Hermite M-A., David V. (2000)*: Evaluation des risques et principe de précaution*, 239 Petites Affiches 13.

Infante P.F. (1987): *Benzene Toxicity: Studying a Subject to Death*, 11 Am. J. Ind. Med. 599-604.

Infante P.F. (2001): *Benzene: An Historical Perspective on the American and European Occupational Setting*, p. 38-51, in European Environment Agency (EEA) (2001): *Late Lessons from Early Warnings: The Precautionary Principle 1896-2000.*

Kourilsky P. et Viney G. (2000): *Le Principe de Précaution*.

Kuhn T. (1970): *The Structure of Scientific Revolution.*

Louviere (2001)

Luce R. and Raiffa H. (1957): *Games and Decisions.*

Majone G. (2001): *The Precautionary Principle and Regulatory Impact Analysis* (mimeo available with the author).

Molak V. (1997): *Fundamentals of Risk Analysis and Risk Management.*

Morgan M., Henrion M., Small M. (1990): *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis*.

National Research Council (1994): *Science and Judgment in Risk Assessment.*

Noiville C. (2000): *Principe de précaution et gestion des risques en droit de l'environnement et en droit de la santé*, 239 Petites Affiches 39.

Noiville C., de Sadeleer N. (2001): *La gestion des risques écologiques et sanitaires a l'épreuve des chiffres – Le droit entre enjeux scientifiques et politiques*, R.D.U.E 389.

OECD (2000): Joint Working Party on Trade and Environment, *Uncertainty and precaution: implications for trade and environment,* COM/ENV/TD(2000)114, 20-21 November 2000.

O'Riordan T. and Cameron J. (eds.) (1994): *Interpreting the Precautionary Principle*.

Otsuki T., Wilson J.S., Sewadeh M. (2001): *A Race to the Top? A Case Study of Food Safety Standards and African Exports.*

Raffensperger C. and Tickner J. (eds.) (1999): *Protecting Public Health and the Environment – Implementing the Precautionary Principle*.
Sands Ph. (1995): *Principles of International Environmental Law I.*
Sen A. (1986): *On Ethics and Economics*.
Slovic P. et al., (1985): *Characterizing Perceived Risk, in Perilous Progress: Managing the Hazards of Technology*, Ch. 5, p. 105 (Robert W. Kates et al. (eds.)).
Slovic P. (1987): *Perception of Risk*, 236 Science 280-285.
Stirling A. et al., (1999): *On Science and Precaution in the Management of Technological Risk*.
Stirling A. and Mayer S. (2000a): *Precautionary Approaches to the Appraisal of Risk: A Case Study of a Genetically Modified Crop*, 6 Int. J. Occup. Environ. Health 342.
Stirling A. (2000b): *Sciences et risques: aspects theoriques et practiques d'une approach de precaution*, p. 73-103, in Zaccai E. and Missa J.N. (2000): *Le principe de precaution – signification et cosequences*.
Sunstein C.R. (2001): *Cost-Benefit Default Principles*, 99 Michigan Law Rev. 1651.
US Statement of Administrative Action for WTO/SPS Agreements (1994): 103d Congress, 2d Session, H.D. 103-316 (27.9.1994).
UNEP (2000): *The Legal Implications of the Precautionary Principle for Multilateral Trade Rules*. (A draft paper commissioned from the Center for International Environmental Law, 24.3.2000, available with the author).
Walker V.R. (2001): *Some Dangers of Taking Precautions Without Adopting the Precautionary Principle: A Critique of Food Safety Regulation in the United States*, 31 ELR 10040.
Walker V.R. (1991): *The Siren Songs of Science: Toward a Taxonomy of Scientific Uncertainty for Decionmakers*, 23 Connecticut L. Rev. 567 (1991).
Wiener J. B. (2001): *Precaution in Multi-Risk World* (mimeo available with the author)
Zaccai E. et Missa J.N. (eds.) (2000): *Le Principe de Précaution – Significations et Conséquences.*

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NOTES

[1] All views are strictly personal.

[2] Decision in *Leatch v. National Parks and Wildlife*, Land and Environment Court of New South Wales, (1993) 81 L.G.E.R.A. 270, per Stein, J.

[3] Decision in *Pacific Northwest Venison Producers v. Smitch*, 1994 U.S. App. LEXIS 6028 (20 F.3rd 1008), per Skopil, Jr.

[4] See, e.g., Case 174/82, *Sandoz BV* [1983] ECR 2445 at paragraph 16 (emphasis added); Case 227/82, *Van Bennekom* [1983] ECR 3883; and Case 178/84, *Commission v Germany (Beer case)* [1987] ECR 122.

[5] Judgment of 5 May 1998, Case C-157/96, *BSE* [1998] ECR I-2211, at paragraph 62, thus linking explicitly the protective measure to uncertainty and the chosen level of health protection.

[6] Judgment of 5 May 1998, Case C-157/96, *BSE* [1998] ECR I-2211, at paragraph 63, repeated in subsequent judgments.

[7] Judgement of 21 March 2000, Case C-6/99, *Greenpeace v. France* [2000] ECR I-1651, at paragraph 44. See also the judgment of the EFTA Court in Case E-3/00, *EFTA Surveillance Authority v. Norway*, paragraphs 30-31, of 5 April 2001.

[8] Case C-6/99, supra, paragraph 45.

[9] Case C-84/94, *U.K. v. Council* [1996] E.C.R. 5755, at paragraph 15.

[10] That is essentially the reason for which decisions about the acceptable level of risk to human, animal or plant life or health or the environmental are made at the lowest possible level of social organisation and should be based on reflective public judgments as expressed in public arenas. See, e.g., E. Anderson, *Value in Ethics and Economics*, 1993. Indeed, this is the rationale on which the exceptions in Articles 30 and 95(4), (5) and (6) of the EC Treaty are based, except where Community law has harmonised to a substantial extent the field of activity and, consequently, pre-empted national regulatory action, as is the situation for instance in the area of measures based on Articles 37 or 152(4)(b) of the Treaty. See, e.g., Case 68/86, *UK v. Council* [1988] ECR 855; and Case C-331/88, *Fedesa* [1990] ECR I-4023. The same rationale applies to the exceptions laid down in Article XX(b) of GATT 94, but the theory of pre-emption does not apply in the WTO legal system.

[11] See, e.g., Case C-120/97, *Upjohn* [1999] ECR I-223, at paragraph 47. See also Case C-405/92, *Armand Mondiet* [1993] ECR I-6133, at paragraph 31.

[12] In the US legal system, this has been explained very accurately in the Statement for Administrative Action for the WTO Agreements as follows:

> *"The SPS Agreement thus explicitly affirms the right of each government to choose its level of protection, including a "zero risk" level if it so chooses. A government may establish its levels of protection by any means available under its law, including by referendum. In the end, the choice of the appropriate level of protection is a societal value judgment. The Agreement imposes no requirement to establish a scientific basis for the chosen level of protection because the choice is not a scientific judgment".*

See *US Statement of Administrative Action for WTO/SPS Agreements (1994):* 103d Congress, 2d Session, H.D. 103-316, p. 745 (27.9.1994).

[13] See, e.g., Order in case C-180/96R, *UK v. Commission* [1996] ECR I-3903, at paragraph 93; Order in case C-76/96R, *Farmers' Union* [1996] ECR I-3903, at paragraph 105; Case C-183/95, *Affish* [1997] ECR I-4315, at paragraph 43; Order of 15.9.98 in Case T-136/95R, *Industria del Frio Auxiliar Conservera v. Commission* [1998]ECR II-3301, at paragraph 58; Orders of 30.6.99 in case T-13/99R, *Pfizer* [1999] ECR II-1961, at paragraph 171, and in case T-70/99R, *Alpharma* [1999]ECR II-2027, at paragraph 152.

[14] See Articles 3(1)(p), 95(3), 152(1), 153, and 174(2) of the EC Treaty.

[15] The term "*to base on*" should be interpreted to impose a *rational relationship* between, on the one hand, the measure taken to protect health or the environment and, on the other, the identified risk and uncertainty.

[16] In addition to the cases already discussed in the text, the Community applied, explicitly or implicitly, the precautionary principle in a number of concrete cases, leading to a high or sometimes zero level of risk policy. The following is not an exhaustive list of the cases: hormones in beef, BSE, pesticides in baby food, prohibitions of carbadox and olaquindox as feed additives, phthalates in toys, BADGE, BFDGE and NOGE materials used as additives, rBST, HCFCs, certain antibiotics in animal feed, contaminated mushrooms, asbestos, PCBs, certain GMOs, etc.

[17] As is the case, for instance, in Article XX.b of GATT 94 and in Article 2.2 of the TBT Agreement.

PRECAUTION, THE PROTECTION OF HEALTH AND THE ENVIRONMENT, AND THE FREE CIRCULATION OF GOODS WITHIN THE EUROPEAN UNION

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I. The precautionary principle in EU Law

The European Union (EU)[2] is not a State; it therefore may act only where the EC Treaty allows it to do so. Action at EU level must be in conformity with a number of principles that are laid down in the EC Treaty, among which subsidiarity and the proportionality principle (Article 5 EC Treaty) are of particular relevance. Product legislation is in particular based on Articles 37 (agricultural matters), 95 (product standards to ensure the free circulation of goods within the EU) and 175 (environmental matters) EC Treaty. The borderline between the three provisions is not entirely clear, despite a number of judgments by the Court of Justice[3]. Normally, chemical legislation is based on Article 95, though there are exceptions: thus, the authorisation[4] and ban[5] of agricultural pesticides is based on Article 37, the ban of ozone-depleting substances on Article 175[6].

The precautionary principle is only mentioned in the environmental chapter of the EC Treaty, together with the principle of prevention[7]. However, as Article 6 EC Treaty requires that environmental protection requirements "must be integrated into the definition and implementation of the Community policies and activities", and as precaution and prevention undoubtedly are part of the environmental protection requirements, Community action in the areas of agriculture, trade or transport are to take due account of the precautionary and prevention principle. The Court of Justice recognised this interpretation in two important cases concerning the export ban for British beef which the European Commission had decided in order to combat the BSE(mad-cow) disease. Against the argument, that such a ban was illegal, because the precise cause of that disease was not yet known, the Court stated[8]:

> *"Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent. That approach is borne out by Article 130r(1)* (now Article 174(1) L.K.) *of the EC Treaty, according to which Community policy on the environment is to pursue the objective inter alia of protecting human health. Article 130r(2)*

(now Article 174(2) L.K.) provides that that policy is to be based in particular on the principles that preventive action should be taken and that environmental protection requirements must be integrated into the definition and implementation of other Community policies".

To what extent Community policies and specific actions are based on the principles of precaution and prevention is first of all a question of political will and determination of Community institutions. This question will not be discussed here, as the contribution refers to national, not to Community legislation; suffice it to state that the EU is allowed to base its policies and specific actions on these principles taking, of course, due account of other requirements of the Treaty such as the principle of proportionality.
It follows from the repartition of powers laid down in Article 5 EC Treaty[9] that under EU law, Member States may do whatever they want in the area of health and environmental legislation. They are limited in this power by the provisions of the EC Treaty itself and by the secondary legislation which was adopted in pursuance of that Treaty. For the sake of clarity, a distinction is made of situations where the Community has enacted secondary legislation, i.e. directives or regulations, and situations where it has not legislated.

II. National precautionary legislation once the EU has legislated

1. Where the Community has dealt with a specific environmental or health issue, these provisions prevail over differing national provisions; this is established case law[10] and is logical: if the national rules were to prevail the Community provisions would not apply throughout the European Union, but only in those parts of it, where no national rule existed. Furthermore, national legislation could, at any time, limit the application of EU law by introducing new rules and thus cause an element of uncertainty which provision was to be applied in a given moment.
This prevailing character of Community law was the subject of considerable controversies over the last thirty years. In particular those Member States that were interested in pursuing a more precautionary or preventive policy or a policy that aimed at ensuring better protection of health, safety and the environment felt that they were impeded by the Community to give optimum protection to their citizens and to their environment. Thus, when the EC Treaty was amended in 1987 and an environmental chapter was introduced, a provision was inserted stipulating that Community measures for the environment adopted on the basis of the present Article 175 EC Treaty did "not prevent any Member State from maintaining or introducing more stringent protective measures"; however, these measures had to be compatible with the EC Treaty[11]. As

regards the Treaty provision on the free circulation of goods, a provision was added which allowed Member States to "apply", for health or environmental reasons, more stringent national provisions than those that had been decided at Community level. This provision raised academic controversies, whether "apply" meant "continue to apply" or also included the possibility to adopt new provisions. A new Treaty amendment of 1999 clarified that Member States were also allowed, subject to very strict conditions, to introduce new measures and thus to opt out of the Community system[12]. No such derogation clause was introduced into other Treaty provisions, in particular not into Article 37 EC Treaty.
It follows from these provisions that Member States' possibilities to adopt provisions, also by virtue of the precautionary or preventive principle, are different and depend on which Treaty provision the Community measure was based.

2. Member States' possibilities are largest, where the Community legislation was based on Article 175 EC Treaty. Member States then may adopt legislation which is based on the precautionary principle without having to explain or justify their approach. Where, for instance, the Community legislation provides that HCFCs shall no longer be produced after 31 December 2025[13], any Member State may, by virtue of Article 176 EC Treaty, provide for such a ban already as of an earlier date. Where the Community has limited the sulphur content of certain fuels by virtue of a directive that was based on Article 175[14], any Member State may, at any moment, further reduce this sulphur content. It is clear, though, that the further requirement of Article 176, according to which the measure must be compatible with the Treaty, also requires that the national measures respects the proportionality principle and therefore does not go beyond the objective which the Member States intends to achieve.

3. Member States' possibilities for legislative action are much more reduced, where the Community measures was based on Article 95 EC Treaty, as follows from the wording of that provision. The reason for this is that the Community measure adopted under that provision aims at harmonising the national legislation, establish common provisions for the circulation of goods within the European Union and ensure that a level playing field for these products exists throughout the Union. Consequently, deviations from the common standard must constitute an exception; while it is common ground that the environment is different in the different parts of the region and Articles 174 to 176 EC Treaty do not aim at "harmonising" the environment, the rationale of Article 95 is that where product standards were considered to be in need of being harmonised, such standards should be as uniform as possible and, as a rule, not provide for derogations.
Under this perspective, thus, the derogation of Article 95(5) - Article 95(4) will be mentioned below - is the exception which applies where a uniform Community

provision meets a specific "new", hitherto unknown, environmental situation in a specific Member State. It is significant that not even human health considerations would allow to recur to this provision, as the Treaty starts from the assumption that human health issues are equal or equivalent all over the European Union. And it is not surprising to find that until end 2001, all attempts by Member States to use Article 95(5), were rejected by the Commission[15].

Normally, the requirement of "new scientific evidence" would exclude that national legislation, based on the precautionary principle could be justified under Article 95(5). Indeed, the general ponderation which product-related measure should be taken in view of the uncertainty of the product's effects on the environment is supposed to have been taken into consideration when the EU legislation was made, as this legislation had to aim at a high level of environmental protection (Article 95(3)). This author cannot think of a concrete, realistic example, where national legislation, based on the precautionary or preventive principle, could be thought to comply with all requirements of Article 95(5), though much might depend on how the Court of Justice will finally interpret the different conditions.

Community legislation on the classification, packaging and labelling of chemical substances[16] and preparations[17] provides for total harmonisation of national legislations[18]. Thus, national deviating measures are only allowed under the narrow conditions of Article 95 EC Treaty; furthermore, as the legislation on chemical substances had been adopted on the basis of Article 94, not even this possibility exists as regards the classification, packaging and labelling of chemical substances.

In 1983 and 1985, EU legislation restricted the marketing and use of asbestos fibres and of products containing containing such fibres[19]. As a number of Member States considered this legislation not far-reaching enough, nine of them adopted legislation which prohibited the marketing and use of asbestos altogether. The Commission did not take any action against these States, but accepted that the free circulation of asbestos which respected the restrictions of the earlier legislation was made impossible. Finally, in 1999, EU legislation was passed that altogether prohibited asbestos[20].

4. Where Community product-related legislation is based on other provisions than Articles 175 or 95 EC Treaty, there is no provision in the Treaty which allows Member States to adopt more stringent or otherwise different provisions. It is not either possible to apply Article 176 or 95(4) and (5) in such cases, as both provisions are exceptions and must therefore be interpreted and applied restrictively; Article 6 EC Treaty is of no help. It should, however, be noted that Member States are only prevented from adopting legislative measures in those cases, where the Community really has legislated. For example, the EU-wide ban of certain pesticides only concerns the specific pesticides that are expressly enumerated[21], therefore, Member States remain free to ban other

pesticides which have not been banned by the Community, be it for preventive and precautionary or for other reasons.
If one looks generally to the provisions of the EC Treaty, it has to be underlined that wherever Member States are entitled to adopt legislative measures which deviate from EU legislative measures - Articles 176 and 95(4) and (5) - these measures are not requested to be provisional measures. They are not either requested to be preceded by a risk analysis or a risk assessment and are not limited to any risk of an irreversible damage. The only Treaty provision which comes close to such requirements is Article 95(10) which allows that Community legislation may contain a safeguard clause[22]. However, such a safeguard clause allows Member States to deviate from existing Community legislation to meet a specific emergency situation. The safeguard measures which have a practice in Community legislation of some thirty years, do not respect existing Community legislation because they have to solve a sudden, unforeseen problem that cannot be dealt with by existing Community provisions. Safeguard measures therefore are provisional by nature. They thus must not be confounded with national legislation which is based on the precautionary or the prevention principle; such legislation is not "provisional" nor does it intend to disregard the existing EU provisions.

III. National precautionary legislation in the absence of EU legislation

1. Where the Community has not adopted legislation for the protection of health or the environment, Member States are, in principle, free to adopt those measures which they consider appropriate. As regards product-related measures, Member States must respect Article 28 EC Treaty which prohibits quantitative restrictions on imports and all measures having equivlent effect; from this general provision, Article 30 allows a derogation on grounds of, among others, "the protection of health and life of humans, animals and plants". Jurisprudence of the Court of Justice which is not to be presented in detail here, has allowed Member States to adopt measures to protect health or the environment beyond the enumeration of Article 30[23], provided that such measures are not discriminating and are proportionate to the objective that was pursued with the measure.
The academic discussion on the construction and limits of Member States' power to adopt environmental or health legislation need not presented here. There is consensus, though, that a case-by-case examination is necessary to weigh the national environmental legislation against the Community interest, laid down in Article 30, in the free circulation of goods; protectionism remains protectionism even if it is practised under the auspices of health or environmental protection. Therefore, the national

measure has to be examined whether it is necessary and whether it is capable of reaching the desired environmental or health objective. In order to ensure that a proper balance was struck, the EU introduced a control system[24], requiring that national legislation which was capable of affecting products had to be notified, in a draft form, to the Commission which, in turn, sent it to all other Member States. The notification set a standstill period in motion, during which the national draft was checked whether it was capable of impairing the free circulation of goods. As the sanctions for omission to notify were very severe - the national legislation which was adopted without having followed the notification procedure was not enforceable[25] - all national product-related legislation undergoes a Community scrutiny as to its compatibility with the rules on the free circulation of goods.

2. Within these limits, thus, the reversed "Cassis-de-Dijon-Principle" applies[26]: in the absence of EU-legislation, Member States are free to adopt environmental or health measures which they wish, as long as such measures are proportionate and not discriminating. As it is irrelevant, why Member States legislate, they thus may base their legislation on precautionary or preventive considerations. Some examples may illustrate how these aspects were handled in the past:
A number of Member States banned some chemical substances or even products from their territory: Denmark banned metal cans for refreshment drinks, Italy phosphates from detergents, Austria polybromated biphenyls (PBB), Germany lead capsules for alcoholic beverages, Netherlands mercury in thermometers and lead capsules for alcoholic beverages, Denmark and Netherlands lead in ammunition; in 1999, Denmark even went so far as to prohibit lead use almost completely. All these cases were accepted by the European Commission and all other Member States as being compatible with the provisions on the free circulation of goods.
In 1988, the Court had to deal with a Dutch ban of a pesticide "Improsol" which was in use in other Member States. The Court found that pesticides constituted significant risk to the health of humans and animals and to the environment and stated: "It is therefore for the Member States for the Member States in the absence of full harmonization of the in this matter, to decide at what level they wish to set the protection of the life and health of humans"; it thus considered the Dutch ban to be legal[27].
Sweden prohibited the use of trichloroethylen, allowing some possibilities for granting exceptions of that ban. The Court of Justice held that the substance was known to be dangerous to humans and the environment and that Sweden was thus entitled to provide for such a ban; the proportionality principle was in any way respected, as there was the possibility to grant derogations from the ban[28].
More examples could be given. The point which is made here is that in the absence of EU legislation, Member States may themselves ban or restrict the use of substances or

products, provided that the limits drawn up by the EC Treaty, as interpreted by the Court of Justice are respected. The discretion of Member States is the greater, the more a substance is known to be dangerous to humans or the environment. In particular, where a substance has already been classified, for instance by Directive 67/548, to be in one way or the other dangerous, Member States are entitled to take those preventive or precautionary measures which they consider adequate to protect humans or the environment. There is no provision in EU law which would oblige them to make a risk assessment of such a substance prior to taking legislative action; even Directive 98/34 only requires them to notify the results of any risk assessment where such data are available[29].

3. It thus appears that Member States have a considerable amount of discretion to take action with regard to those substances which are toxic, bioaccumulative or persistent; already in 1976, the EU - in order to reduce the discharge of substances into water - established a (incomplete) list of dangerous substances which was composed according to these three substances[30] which could be a first line of orientation. Furthermore, one might think of heavy metals and of substances which are classified as carcinogenic or teratogenic. It would hardly be objectionable, under EU rules of law, if such substances were prohibited from being used at least in all those cases, where they could technically - economic considerations are normally not relevant - be substituted by substances that do not belong to the above-mentioned categories. And again, there is no provision in EU law which would require that the substituting substance has been the subject of a risk assessment of its own.

The precautionary or prevention principle applies in cases of scientific uncertainty. For most of the above-mentioned substances, there is scientific certainty that they are dangerous to humans or the environment; what is uncertain is their effect on the environment, i.e. on human health, fauna and flora, soil, buildings, water, atmosphere, climate and so on. To take a concrete example: the effect of cadmium in landfills is largely unknown and has hardly ever been researched. It is thus perfectly compatible with the precautionary principle that cadmium-containing batteries which form about eighty percent of all cadmium in landfills, are forbidden, as landfills are their normal disposal path, as collection and recycling only give poor results and as they can technically be replaced by less harmful batteries.

At several occasions, the proportionality principle was interpreted by the Court of Justice[31]. However, in no case has the Court requested that the national legislation only allowed provisional measures by Member States, that there should be a risk of serious or irreversible damage or that the national legislation be preceded by a risk assessment. It is clear, though, that changing circumstances may require that the measures which were taken, are amended also. Where, for instance, scientific evidence demonstrates that

a substance which was considered harmful, is not harmful, national legislation would have to take account of such a development; but this does not mean that the national measure, right from its beginning, must be a provisional measure. Furthermore, if at a later stage the EU decides to harmonise legislations and the EU measure does not attain the same level of protection, the national legislation may, under the conditions of Article 95 (4) be maintained and continue to be applied.

IV. Member States' consumer protection legislation

If one looks into Member States' legislation on consumer protection to examine how the precautionary or prevention principle was considered in that legislation, one will first have to realise that Member States have the full, sovereign power of acting. They do not need, therefore, an explicit authorisation in a national statute law which allows them to take action in the case of a risk. Another marked feature of national legislation is that it was reviewed in the early 1990s, subsequent to the adoption of Directive 92/59 on consumer product safety which fixed EU-wide requirements for the safety of consumer products[32]; a parallel directive on environmental safety of products does not exist, though some of the national provisions also include the environment in the scope of the legislation.

A typical example for national legislation may be the Danish Act on product safety of 1994[33] which defines what a safe product is and which then allows public authorities to take preventive measures in order to ensure that only safe products are marketed and to take measures to ensure that unsafe products that have been marketed, no longer present a safety risk. Similarly, the Danish Act on chemical substances and products in its version of 1993[34] aims at preventing damage to human health or the environment and contains a number of provisions to prevent such damage; in other cases, the administration may take measures to prevent such damage from occurring.

The Austrian Act on product safety 1994[35], the Belgian Act on consumer safety 1994[36], the Spanish Decree on product safety of 1996[37], the German Act on product safety of 1997[38], the General Product Safety Regulations 1994 (United Kingdom)[39], the Warenwet (Netherlands)[40] all establish that products may not present a danger for human health; they empower the competent authorities to take the necessary preventive and other measures to ensure that only safe products are marketed and generally state that regulatory action may be taken where the competent authorities consider this necessary in order to prevent damage.

Of particular interest may be the Swedish Environmental Code of 1998[41], as it is the most recent of the different national provisions that address issues of product safety and as it tries to bring together elements of consumer protection and of environmental

protection. The Code is very largely based on the concept of preventing damage or detriment to human health and the environment and mentions the necessity to take precaution at several occasions (in particular Chapter 2, Sections 3, 5, 9, Chapter 13, sections 11, 14, Chapter 14, section 17). It imposes a general obligation on manufacturers, importers or traders to take the necessary precautionary or preventive measures in order to avoid risks to human health or the environment and require them to "avoid using or selling chemical products or biotechnical organisms that may involve risks to human health or the environment if products or organisms that are less dangerous can be used instead. The same requirement shall apply to goods that contain or are treated with a chemical product or a biotechnical product" (Chapter 2 section 6). The omission to respect this substitution principle is punishable as an offence (Chapter 29 section 3).

Generally, it can be stated that the possibility for national competent authorities to take action - either by way of regulation or on a case-by-case basis - in order to prevent damage to human health by products, exists in practically all Member States . To what extent Member States make use of this possibility, is less a question of law but of political determination. Not all national legislation expressly mentions the protection of the environment as being capable of being endangered by products, though this often might be implicit. Once more, the measures which the competent national authorities might undertake, are designed to be proportionate to the risk of damage involved. Nowhere is there any consideration of provisional measures, of the prior making of a risk assessment or of the possibility to act only in cases where there is a threat to an irreversible or serious damage.

V. Conclusions

1. Where the EU has adopted product-related legislation on the basis of Article 175 EC Treaty, Member States may, for precautionary or preventive reasons, adopt more stringent environmental provisions, provided that these provisions are not discriminating and are proportionate to the objective pursued.

2. Where the EU has adopted product-related legislation on the basis of Article 95 EC Treaty, Member States may maintain previously existing more protective legislation or introduce new stricter legislation only under the conditions laid down in Article 95. The conditions for new legislation appear so strict that this possibility is rather theoretical.

3. Where the EU has adopted product-related legislation on another basis of the EC Treaty, in particular on the basis of Article 37 EC Treaty, Member States may not adopt more protective national legislation, not either for reasons of precaution or prevention.

4. Where a specific substance or product has not yet been the subject of EU legislation as regards its marketing or use, Member States may adopt provisions that is based on the precautionary principle or that aims to prevent damage to humans or the environment. Such national legislation has to be notified, at draft stage, to the European Commission. It may not discriminate and must be proportionate to the objective pursued.

5. Member States' legislative discretion is the greater, the greater the scientific consensus is that the substance in question is dangerous to humans or the environment. As regards toxic, bioaccumulative and persistent substances, furthermore also heavy metals, carcinogenetic and teratogenic substances, Member States have practically no legal barrier for action; their action depends on their political will.

6. Where Member States take action, they are not obliged to execute beforehand a risk assessment, or only to take provisional measures or only to act where there is a risk of serious or irreversible damage.

7. National legislation frequently allows competent authorities to take preventive or precautinary action in cases of risk of harm to humans or to the environment, either on a case-by-case basis or generally; the decision which measure to take is left to the competent authorities.

8. There is an EU directive on consumer product safety. A corresponding EU directive on the environmental safety of products does not exist.

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NOTES AND REFERENCES

[1] The author only expresses his personal opinion.

[2] The term "European Union" is used throughout this contribution, though the original EC Treaty of 1958 established the "European Economic Community". The term "European Union" only exists since 1993; it was introduced by a Treaty amendment which provided for the creation of a

European Union, to underline the political objective of the European Community and to take account of and further promote economic and political integration of the Member States. The European Union - unlike the European Community which continues to exist as one of three "pillars" of the European Union - does not have legal personality; therefore, environmental and other legislation is adopted by the European Community (EC), not by the European Union(EU).

[3] See Court of Justice, cases C-62/88, ECR 1990, p.1527; C-300/89, ECR 1991, p.I-2867; C-70/88, ECR 1991, p.I-4561; C-155/91, ECR 1993,, p.I-939; C-405/92, ECR 1993, p.I-6133; C-187/93, ECR 1994, p.I-2857; C-164/97 and 165/97, ECR 1999, p.I-1139.

[4] Directive 91/414, OJ EC 1991, no.L 230, p.1.

[5] Directive 79/117, OJ EC 1979, no.L 33 p.36.

[6] Regulation 2037/2000, OJ 2000, no.L 244 p.1.

[7] Article 174 (2) EC Treaty: "Community policy on the environment shall..be based on the precautionary principle and on the principles that preventive action should be taken.."

[8] Court of Justice, cases C-157/96, ECR 1998, p.I-2211, paras 63-64; C-180/96, ECR 1998, p.I-2265, paras 99-100; it is to be noted that the English version of the judgments refers to "preventive action", whereas the German version mentions the "Grundsätze der Vorsorge und Vorbeugung".

[9] Article 5 EC Treaty: "The Community shall act within the limits of the powers conferred upon it by this Treaty and of the objectives assigned to it therein.."

[10] Court of Justice, cases 6/64, ECR 1964 p.1265; 106/77, ECR 1978, p.629; C-213/89, ECR 1990. p.I-2466; C-184/89, ECR 1991, p.I-297.

[11] Article 176 EC Treaty.

[12] See Article 95 EC Treaty: " ... (4) If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 30, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.
(5) Moreover, without prejudice to paragraph 4, if, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provision as well as the grounds for introducing them."

[13] Regulation 2037/2000 (no.5 supra), Article 3(3).

[14] Directive 1999/32, OJ EC 1999, no.L 121 p.13.

[15] Decisions 1999/836, OJ EC 1999, no.L 329 p.100(Germany, mineral wool); 2000/509, OJ EC 2000, no.L 205, p.7 (Belgium, organostannic compounds); 2001/570, OJ EC 2001, no.L 202 p.37 (Germany, organostannic compounds).

[16] Directive 67/548, OJ EC 1967, no.L 196 p.1 with subsequent amendments.

[17] Directive 1999/45, OJ EC 1999, no.L 200 p.1.

[18] Court of Justice, case C-278/85, ECR 1987, p.4069 (as regards Directive 67/548).

[19] Directive 83/478, OJ EC 1983, no.L 263 p.33; in considerant 2 of this Directive, it is stated "prevention is the best way of protecting human health": it is submitted that the same is true for the protection of the environment. Directive 85/610, OJ EC 1985, no.L 375 p.1.

[20] Directive 1999/77, OJ EC 1999, no.L 207 p.18.

[21] Court of Justice, cases C-125/88, ECR 1989, p.3533; C-293/94, ECR 1996, p.I-3159.

[22] Article 95 (10) EC Treaty: "The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 30, provisional measures subject to a Community control procedure".

[23] The landmark case for this jurisprudence was 120/78, ECR 1979, p.649 ("Cassis de Dijon"); the landmark case for national environmental measures was C-302/86, ECR 1988, p.4607 ("Danish bottles").

[24] Directive 98/34, OJ EC 1998, no.L 204 p.37.

[25] See Court of Justice, case C-194/94, ECR 1996, p.I-2201.

[26] See for more details L.Krämer, EC Environmental Law, 4th ed.London 2000, p.75 et seq.

[27] Court of Justice, case 125/88 (note 20 supra).

[28] Court of Justice, case C-473/97, ECR 2000, p.I-5681.

[29] Directive 98/34 (note 22 supra), Article 8(1).

[30] Directive 76/464, OJ EC 1976, no.L 129 p.23, annex I.

[31] See most recently Court of Justice cases C-157/96 and C-180/96 (note 7 supra) and C-473/97 (note 26 supra).

[32] Directive 92/59, OJ EC 1992, no.L 228 p.24.

[33] Lov om produktsikkerhed, nr.364 of 18 May 1994.

[34] Lov om kemiske stoffer og produkter, lovbelkendtgoerelse nr.583 of 9 July 1993.

[35] Bundesgesetz zum Schutz vor gefährlichen Produkten (Produktsicherheitsgesetz 1994).

[36] Loi relative à la sécurité des consommateurs of 9 February 1994.

[37] Decreto Real 44/1996 of 19 January 1996.

[38] Gesetz zur Regelung der Sicherheitsanforderungen an Produkte und zum Schutz der CE-Kennzeichnung vom 22.April 1997

[39] The General Product Safety Regulations 1994, Statutory Instruments 1994 No.2328.

[40] Warenwet (Stb.1935, 793) zoals deze laatstelijk is gewijzigd bij de wet von 21 april 1988, Stb.358.

[41] Miljöbalk of 11 June 1998, SFS 1998:808.

CHEMICALS POLICY, PRECAUTIONARY PRINCIPLE AND PRACTICE. VIEWS OF A POLICY MAKER.

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Summary

The precautionary principle as adopted in Rio de Janeiro, 1992, is interpreted in many different ways, from absolute safety to absolute proof of unsafety before taking measures. The balance of 'Rio' is often overlooked.
In practical life, the principle is not often fully applied, as a full justification is almost always required before a decision is taken or is maintained in a court case, and lack of knowledge or uncertainty is seldom accepted as justification. Examples from the chemicals area in the European Union are given.
The current EU policy and practice for chemicals are not in line with a reasonable interpretation of the precautionary principle, and the proposed revision is not fully clear in this respect. Many thousands of chemicals are on the market without any health or safety or environmental information in the public domain, and probably also with the manufacturers. The White Paper of the EU does not foresee clear sanctions when this situation continues. 'No data, no market' is apparently still a bridge too far. Meanwhile, industry continues to support full risk assessment, by governments, as a pre-requisite to any measure. Some NGO's tend to expect something close to absolute certainty - some even without the use of experimental animals- also to be given by governments, before a substance should be allowed to enter the market.
In the view of the Dutch government and its chemicals policy, a practical application of the precautionary principle implies that, at relatively short notice, manufacturers screen all chemicals for their potential harmful effects on man and ecosystems and take appropriate steps to ascertain that their products are only used, throughout the chain, in applications where they do not pose a serious risk. Authorities establish the framework for this, and see to its proper implementation. Stricter controls are necessary for more hazardous chemicals, general rules may be sufficient for low-hazard products.
Without any data however, the only way of precaution is a market ban.

I. Introduction

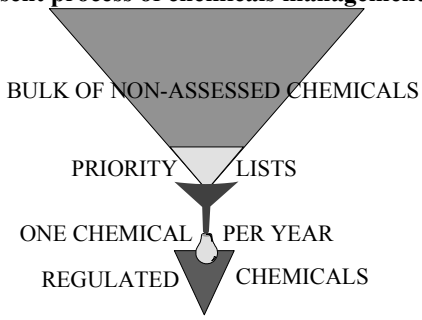
Many thousands of chemicals are currently on the market in the European Union. Of these, several thousands are HPVC’s, chemicals produced or marketed in volumes of

thousand tonnes or more per producer per year. A recent survey by the European Chemicals Bureau[1] showed, that for only 14 % of these HPVC's a full base set of data as required for new chemicals is available. For about 50% of these chemicals, there is no data, at least in the public domain. For the many thousands of chemicals produced in lower quantities, the situation with regard to public availability of data is certainly not better. Industry gives two contradicting reactions to this situation. At on side, it is stated that all relevant data are available with industry, at the other side it is maintained that producing the relevant data is not feasible within the almost two decades foreseen in the White Paper[2] of the European Commission of March 2001. In the meantime, surveys of MSDS's (material safety data sheets) from industry show that more than 50% contains serious misinformation[3].
Based on this lack of relevant data, one cannot expect that adequate measures to protect human health and the environment are taken by producers or downstream users, both professional and private.

II. Current European Union Policy and Practice

The current policy distinguishes between so-called new and existing substances, those being put on the market for the first time before 1980 or after that year and therefore included or not in the inventory of existing substances (EINECS)[4].
For new substances, a notification prior to marketing is required, including the submission of a base set of data. The notification part of the system functions reasonably well, the measures however that may be needed on basis of this information are taken in an extremely slow pace. In reality, any measure is taken years after the market introduction of a substance and therefore cannot be considered precautionary.
For 'existing substances', which represent far above 90 % of current market volume, there is European Union legislation for classification and labelling, but no systematic review with regard to potential effects on health or the environment. Priority lists have been established for a very limited number of substances which are considered to have the highest priority for review and potential regulatory action. In this system, almost all of the workload for reviewing data and performing a hazard and risk assessment is on Member States and European Commission. The review process in itself is extremely complicated, the speed with which regulatory action is taken, based on these reviews, is even slower. Globally speaking, the system delivers an output of one regulated chemical per year (fig. 1).

Figure 1:
Present process of chemicals management



Since the inception of the programme on existing substances in the early nineties, extensive guidance has been developed for performing the assessments, including not only the procedures for assessment of hazards, exposure, risk, but also of alternatives and cost-benefit and risk-benefit analysis of a substance and its potential alternatives. In this process, the whole workload and the full burden of proof on potential risk for health or the environment is on the authorities. The role of industry is limited to providing, on request, available information. Industry is however fully represented on the expert committees that discuss the assessments and potential relevant measures.

Once a potential measure has been proposed by the European Commission, decision making by Member States and Commission is again very detailed and slow.

The whole process is procedure driven rather than safety driven, it requires important resources, mainly coming from a limited number of Member States, and is not giving adequate and quick response to any concern that society may have on a specific chemical or group of chemicals.

Innovation, which is considered a cornerstone of the European Union's economy, is not served by such a slow process of decision making.

III. The Precautionary Principle in the current situation

The Precautionary Principle as adopted in Rio de Janeiro in 1992 is relatively clear in itself, but leaves a number of questions unanswered, such as: What level of proof is necessary before considering action? Who has to proof? When is damage considered serious or irreversible?

Currently, the European Union system for chemicals assessment is fully based on risk assessments to be performed by governments, and therefore, by definition is not precautionary, as proof needs to be given of serious risks before a measure can be

proposed and adopted. This is reflected in the way industry is insisting that full risk assessment remains the basis of the EU policy and instruments, also when implementing the policy review as outlined below. As an example, reference is made to a statement by the chairman of the Chemicals Industry Association before the British House of Lords in September 2001 (figure 2).
The Precautionary Principle has also been reflected in the Nice Treaty of 2000. It may therefore be used in new policies and instruments proposed by the European Commission and adopted by the European Council of Ministers.

Figure 2:
The precautionary principle according to CIA

Quote of a statement before the House of Lords, September 2001, by Mr Steel, Chairman CIA:

"Where there is absolute common agreement that a particular chemical was entering the environment with all these negative (i.e. P+B+T) effects, there is no way the chemical industry would fight that something be done about that."

IV. Some examples of current decision making

IV.1. *Azo-dyes and textile*
Since many years it is known that azo-dyes do present carcinogenic risks. A reason why several Member States have taken action against their application in textiles and other consumer products. Since two years, Member States are discussing a proposal of the European Commission to limit their use EU-wide. Detailed discussions include in particular the scope of the directive, such as inclusion of second hand clothing and carpets, therefore postponing protection of health of consumers until finally agreement is reached. Important resources are being spent on this dossier, and therefore not available for other urgent work, which shows very significant delays.

IV.2. *Brominated flame retardants.*
A company started production of a brominated flame retardant in the course of 2001. The substance is listed on EINECS, but no information on its hazards to health or the environment is available. As the substance is related to brominated flame retardants with know hazards and risks, the Dutch government decided a provisional ban until such time that the company had given reasonable proof of the absence of serious effects

for this substance. The proposed ban was notified to the European Commission and Member States, who replied that this proposed ban was unjustified, as the authorities had not proven beyond reasonable doubt that the substance does indeed present such effects. A reasoning based on analogy with known harmful substances is not considered adequate to this effect.

V. Review of the European Union Chemicals Policy

Starting in 1999, important discussions have taken place in the European Union with regard to a full review of the current policy and its implementation (fig. 3). This has resulted in the previously mentioned White Paper of the European Commission in February 2001 and Conclusions of the Council of Ministers in June 2001[5]. These contain the main lines that guide the European Commission in its current work of elaborating proposals for the implementation of the new policy. Given the kind of discussions currently taking place, it is too early to see to what extent the future European policy and its instruments for implementation will reflect a reasonable interpretation of the precautionary principle. However, the main decision making is still closely linked to full risk assessments, which is contrary to decisions based on 'lack of full scientific certainty' according to 'Rio'.

It will take another three to four years before the new policy has been translated into instruments adopted by the Council of Ministers and the European Parliament and implemented in the relevant legislation of the Member States. In the meantime, European Commission and Member States may adopt an approach that is much more in line with the fundamental thinking of the White Paper and the Council Conclusions than the current practice, including elements of a more precautionary approach. Clear sanctions, which are not yet proposed in the White Paper, are essential for the system.

Figure 3:
Process reviewing chemicals policy EU

- Council of Ministers discussions 1998-1999
- CEU: White Paper, February 2001
- Council of Ministers Conclusions June 2001
- Start of work on implementation September 2001

And in The Netherlands

- SOMS Tripartite co-operation started in 1998
- Cabinet statement: Note SOMS, March 2001
- Interim report on screening criteria December 2001

VI. The Dutch Strategy on management of Substances (SOMS)

Simultaneously to the European Union process, and in close conjunction, a Dutch programme (Strategy on Management of Substances, SOMS) is being carried out, that has resulted in a strategy paper in March 2001[6], adopted by the Dutch Parliament in June 2001 and an interim report on screening criteria in December 2001[7]. The Dutch strategy puts the main responsibility for the assessment on industry, within a clear framework by authorities and independent validation, combined with transparency of the process and public availability of all relevant information.

An important part of the policy is that producers or importers have the obligation to screen their chemicals on basis of all available information, including the use of models and QSAR's, for relevant endpoints for health and environment before January 2003 and have this screening independently validated and the information made publicly available before January 2005. The screening criteria for this have been adopted by the Dutch government in December 2001. Linked to the criteria are measures that have to be taken, in principle, for substances that on basis of the screening are of high concern (figure 4). Substances may therefore only be used, either directly, or incorporated in a preparation or a product, according to the boxes in the matrix. 'No, unless' implies that exceptions can be made based on adequate data and safety measures, 'yes, if' implies, that the substance may be used for the type of use indicated, provided certain risk reduction measures have been taken.

This approach would avoid the kind of detailed discussions that currently take place in the EU framework, such as the example mentioned under IV.a. above.

VII. Precautionary Principle and adequate distribution of responsibilities

In order to be able to apply a more precautionary approach in the new EU policy it is necessary to clearly define the respective responsibilities of industry, both producers and downstream users, and of government authorities, including the European Commission. Although the White Paper gives more responsibility to industry, this is essentially an obligation to provide information to the authorities, who still have the burden to proof potential or even real harmful effects to man or environment. This implies, that any action is in principle taken after the event may have occurred, which is contrary to precaution. A real precautionary approach would imply a self assessment by industry prior to marketing a substance. This assessment needs to consider the various uses for which a substance is marketed and the relevant exposures for man and potential environmental releases, i.e. before they have been able to cause a risk. In that sense the

current EU policy for new substances only goes halfway, in that it requires information, but does not lead to agreed measures prior to marketing.
Therefore, it is necessary, that in any new system a direct and obligatory link is foreseen between potential effects and measures to control these effects. The Dutch policy contains such direct links, see figure 4.
Under such a system, only those chemicals that present serious hazards to man or environment would come under full public scrutiny. For low-level hazard chemicals, industry would, under the conditions of transparency and independent validation, be responsible for proper risk management, see figure 5. This approach is based on intrinsic properties of a substance in the first place, both for screening and priority setting, resulting in acceptable 'in principle' use categories and based on this acceptable risks. It is therefore a reversal of the current system, in which a full risk assessment with detailed uses is taking place as a first approach.

Figure 4:
General policy principles on acceptable use

Category of danger	*On site intermediates*	*Industrial use*	*Professional use*	*Consumer use*
Very high concern	**No, unless**	**No, unless**	**No**	**No**
High concern	**Yes, if**	**Yes, but**	**No, unless**	**No, unless**
Concern	**Yes, if**	**Yes, if**	**Yes, if**	**No, unless**
No concern	Yes	**Yes**	**Yes**	**Yes, if**
No data	**No, unless**	**No, unless**	**No, unless**	**No, unless**

Figure 5:
Future concept for chemicals management

VIII. Conclusion

The current EU chemicals policy does not reflect a precautionary approach. It is unclear to what extent the further elaboration of the proposed policy of the EU Commission's White Paper will incorporate such approach. The Council Conclusions of June 2001 are more explicit and would imply a more precautionary approach as the burden of proof is more clearly shifted to industry. In the meantime however, both European Commission and Member States continue their practice of putting the full burden of proof on authorities and disregarding the element of precaution. The Netherlands proposes an EU approach that is in line with the EU Council Conclusions and the European Commission's White Paper, but is more explicit in responsibilities, burden of proof and precaution.

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NOTES AND REFERENCES

[1] Public Availability of Data on EU High Production Volume Chemicals by Remi Allanou, Bjorn G. Hansen and Yvonne van der Bilt (European Commission – Joint Research Centre – European Chemicals Bureau, 1999.

[2] White Paper of the European Commission on Strategy for the future chemicals policy, COM(2001) 88 final, 16 February 2001.

[3] Material Safety Data Sheet Quality Survey, The Netherlands Inspectorate of the Environment, 23 May 2000.

[4] EINECS, European Inventory of Existing Commercial Substances, Official Journal C 146, 15 June 1990

[5] Conclusion on Chemicals Policy of the EU Environmental Council, 24 June 2001.

[6] Strategy On Management of Substances, Memorandum of the Netherlands Government, 16 March 2001.

[7] Implementation Strategy on Management of Substances, Progress Report of the Netherlands Government, 14 December 2001.

THE PRECAUTIONARY PRINCIPLE IN SWEDISH CHEMICALS POLICY

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I. Introduction

Although much has happened in the area of Swedish chemicals policy during the last 5 years, Sweden has a long tradition of an active and ambitious chemicals policy. Moreover, precaution has for a long time formed the basis for the chemicals legislation and the requirements for importers and manufactures. This means that already a scientifically based suspicion about risk, although not proven, is sufficient to warrant measures for risk reduction.

II. Earlier Legislation

Already in 1973 when the act on Products hazardous to health and to environment was adopted, the obligation of taking precautionary measures were included.

In 1985 the National Chemicals Inspectorate (KemI) was formed and the legislation was modernised as the Chemicals Products act, covering all chemical products, not only hazardous ones as before, was adopted. There was no change however related to the requirement of taking precautionary measures. In the act it was stated that: ”Anyone handling or importing a chemical product must take such steps and otherwise observe such precautions as are needed to prevent or minimise harm to human beings or to the environment. This includes avoiding chemicals products for which less hazardous substitutes are available. The Government or such authority as the Government may designate, may issue special regulations concerning precautions. In the bill to parliament, preceding the adoption of the act, the government pointed out that the available knowledge in many cases was not enough to assess, with reasonable security, if a chemical could give rise to a suspected harmful effect or not. According to the government this should lead to a use of, as far as possible, the principle that a substance should be considered having the suspected harmful effect, until otherwise proven.

III. Present legislation

As of 1 January 1999 a new act came into force. This act, the Environmental Code; amalgamated 15 old acts in the environmental field, some of those beings the chemical products act, the GMO act and the pesticides act.

The first part of the Environmental Code contains overall provisions. These include a chapter of General rules of considerations, which are in principle applicable to all areas of environmental law. Until then such rules had only been valid for specific areas, such as for the handling of chemicals. The rules of consideration must be observed by everybody, irrespective of any intervention on the part of public authority. The precautionary principle, which is the fundamental rule of consideration in the code, says that the mere risk of damage or detriment involves an obligation to take the necessary measures to combat or prevent adverse health and environmental effects. This rule applies to all operations that may be relevant to the objectives of the code.

All rules of consideration are to be applied in the light of benefits and costs. The costs for taking precaution must be reasonable.

Swedish environmental quality objectives – Environmental policy for a sustainable Sweden – the 1998 Bill
A couple of years ago (May 1999) the Swedish Parliament adopted 15 new environmental quality objectives to be reached within one generation (till 2020). These goals were based on the proposal from the committee for review of the chemicals policy and the Swedish EPA. They were presented to the Parliament in a bill called *Swedish environmental quality objectives – Environmental policy for a sustainable Sweden.*

In order to reach the goal most related to chemicals, *A non-toxic environment,* guidelines for a new chemicals policy was elaborated. This goal is also clearly linked to the commitments of Esbjerg and Sintra.

> ”*A non-toxic environment”. = The environment must be free from man-made substances and metals that represent a threat to human health or biological diversity. This means that the levels of substances that occur naturally in the environment must be close to background levels, while the levels of man-made substances must be close to zero.*

Looking back on the occurrence of hazardous chemicals in the environment, on unexplained biological effects in the environment and in humans, the government concluded in the bill that hazardous man-made substances should not be accumulated in

the environment. Preventing this is the only reliable way of avoiding adverse health and environmental effects. Such action is consistent with the precautionary principle. The government stressed in the bill that the precautionary principle, although already an essential element of chemicals policy, must be given a more significant role in the future. Chemicals policy must be based on a greater readiness among authorities and enterprises to act as soon as they suspect a risk for damage. Consequently, Sweden believes that greater attention must be paid to substances that can cause health and environmental hazards owing to their intrinsic properties. The guidelines on the new chemicals policy reflect this approach.

The approach to chemicals policy in Sweden contains guidelines how to achieve the environmental quality goal. This means that:

- New products introduced onto the market are largely free from
  - man-made organic substances that are persistent and liable to bioaccumulate, and from substances that give rise to such substances and
  - man-made substances that are carcinogenic, mutagenic and endocrine disruptive –including those which have adverse effects on the reproductive system.
- New products introduced onto the market are largely free from mercury, cadmium, lead and their compounds.
- Metals are used in such a way that they are not released into the environment to a degree that causes harm to the environment or human health.
- Man-made organic substances that are persistent and liable to bioaccumulate occur in production processes only if the producer can show that health and the environment will not be harmed. Permits and terms of the Environmental Code are devised in such a way as to guarantee this guideline.

The intention is that the guidelines should provide guidance for manufacturers' product development and serve as a goal for their chemical strategies.

A Chemical Strategy for a Non-Toxic Environment - the 2001 Chemicals Bill

As a follow-up to the on bill *Swedish environmental quality objectives* the Government presented a new Chemicals Bill to the Parliament in the beginning of February 2001. The proposals in this bill was based on the work by the Chemicals Committee which was set up to elaborate on the details from the guidelines adopted in the 1998 bill and to make proposals on how to proceed. In this bill interim targets and strategies for achieving the overall goal were proposed and the guidelines were defined more in detail. The Parliament adopted this bill in June 2001.

Interim target 1

By 2010 information must be available about the properties of all deliberately produced or extracted substances that occur on the market. Information about the properties of high-volume substances and other substances that are considered particularly dangerous that is obtained, for example, by screening tests, must be available earlier. The same information requirements will apply to both new and existing substances. By 2020 information should also be available, to the extent possible, about the properties of all unintentionally produced and extracted chemical substances.

Interim target 2

Health and environmental information about the content of dangerous substances should be supplied with products by 2010.

Interim target 3

Dangerous substances should be phased out as follows.

New products should, wherever possible, be free from:
- carcinogenic, mutagenic and reprotoxic substances by 2007 if the products are to be used in such a way that they are released into the environment;
- new organic persistent and bioaccumulative substances should be phased out as soon as possible and at the latest by 2005; (=they should not be allowed to be introduced on the market)
- other organic substances that are *highly* persistent and *highly* bioaccumulative should be phased out by 2010;
- other organic substances that are persistent and bioaccumulative should be phased out by 2015;
- mercury should be phased out by 2003 and cadmium and lead by 2010.

These substances should not be used in production processes unless the enterprise concerned can show that they do not present a risk to health and the environment.
Existing products that contain substances with the above-mentioned properties, or mercury, cadmium or lead, should be treated in such a way that these substances do not enter the environment.
The interim target relates to man-made substances or substances extracted from nature. It relates also to substances that give rise to substances with such properties, including substances that are deliberately produced.

Endocrine-disruptive, allergenic and neurotoxic substances, substances that are harmful to the immune system and other substances that may give rise to risks of the same magnitude to human health should be covered by the interim target. Strategies for implementation of the target and specification of criteria for the phase-out of these dangerous substances should be in place by 2005.

The guidelines take into account the fact that persistent and bioaccumulative substances always represent a potential risk to human health and the environment. Persistent substances can be transported over long distances by wind and currents or via trade. There is thus a risk of their spreading to sensitive environments where their effects are particularly serious. Carcinogenic, mutagenic or endocrine-disruptive (including reprotoxic) effects are so serious that substances with any of these properties must not be allowed to cause involuntary exposure. The metals mercury and lead are both very toxic and also bioaccumulative, which means that they can be absorbed by and accumulated in organisms. Cadmium can damage kidneys and bones. The present intake of cadmium is close to levels that may be harmful to human health.

The long period that is required to lower the concentrations of persistent substances in the environment makes it necessary to take action against these substances even if there is no specific information to indicate that they are toxic. It is sufficient if we know that a substance is liable to bioaccumulate.

Criteria for particularly dangerous substances
The terms used in the interim target are defined as follows:

highly persistent substances: substances that have a half-life of more than 26 weeks in simulation tests at a temperature of 20º C;

highly bioaccumulative substances: substances with a bioconcentration factor that is higher than 5,000;

persistent substances: substances that have a half-life that is longer than 8 weeks in simulation tests at a temperature of 20º C;

bioaccumulative substances: substances with a bioconcentration factor that is higher than 2,000.

The substances covered by the guideline on carcinogenic, mutagenic and reprotoxic substances should be those that are classified under category 1 or 2 in the Dangerous Substances Directive (67/548/EEC).

Interim target 4

The health and environmental risks associated with the production and use of chemical substances must be continuously reduced up to the year 2010 in accordance with indicators to be adopted by the competent authorities. The presence and use of chemical substances that complicate materials recycling operations must also be reduced during the same period.

Interim target 4 relates to substances that are not covered by interim target 3.

Interim target 5

Target values should be set by the competent authorities by 2010 for at least 100 selected chemical substances that are not covered by interim target 3. These target values will specify permissible concentrations in the environment or maximum concentrations to which humans may be exposed. The aim is eventually to adopt these values as environmental quality standards.

Many of the measures that must be taken in order to achieve the objective will involve changes at the EU level. Sweden has striven to ensure that the chemicals policy that has been presented by the EU Commission when implemented into a revised chemicals legislation will be an effective tool for addressing problems related to chemicals. But it is also considered that Sweden must not only wait for progress to be made in the EU before launching initiatives at the national level.

The Swedish Chemicals Policy is in particular focused on the elimination of the use of substances that are persistent and liable to bioaccumulate. This is considered necessary even if we do not have the full knowledge of the toxic properties of the chemical. History has also taught us that substances with these properties might give rise to harmful effects that are difficult to detect. Once such effects are found, the substance may be so spread in society and the environment that it is very complicated, if possible at all, to eliminate. An example of this is PCBs.

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THE ROLE OF PRECAUTION IN CHEMICALS POLICY – THE UK APPROACH

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Over the last few years, the UK has been carrying out and implementing a strategic review of its environmental policy on chemicals, with the aim of bringing it more into line with the precautionary principle. This paper explains why we carried out the review, and what we have done to implement it.

The challenges of chemicals policy are typically those of sustainable development. The economic benefits of having a strong chemicals industry and the undoubted social benefits of having a wide range of useful chemicals available to society must be balanced against the environmental harm resulting from the production and use of chemicals. Damage to the environment can arise from the production of raw materials for chemicals manufacture, the consumption of energy in their production and use arisings of problematic wastes, and the intrinsic hazards of chemicals (for example their toxicity). While a comprehensive analysis of the environmental challenge posed by a chemical would take all of these into account, for reasons which are often more political than scientific we tend to focus almost all of our attention and resources onto solving problems posed by just one -the intrinsic hazards of chemicals.

In the past, we have claimed that our approach to hazard management has been based on sound science and risk assessment. This approach requires comprehensive information, a rigorous assessment of the risks posed by the hazards of the chemical, and the implementation of appropriate control measures. In principle, this is an excellent way of managing risks, and is the basis of current European legislation. However, in practice it is extremely resource intensive, with the consequence that only a small proportion of the chemicals currently on the market have been subjected to this sort of analysis, and almost no information is available about the environmental fate and effects of the remainder.

In the EU, this approach is formalised in the Existing Substances Regulation. The UK's strategic review set out to see whether there were ways in which we could bypass the long decision-making process. We wanted to move swiftly towards control measures for chemicals which we felt were unacceptably hazardous, without the inevitable delays of a full risk assessment and subsequent EU legislation. This would mean having to

take decisions without the degree of full scientific certainty that we have formerly sought, but more in line with the Precautionary Principle.

The conclusions of our Review were published in December 1999[1]. The key areas where we saw need for improvement were in the availability of information on chemicals, the speed with which precautionary action could be taken on chemicals of concern, and the public openness and transparency of the whole process. We decided on a number of actions we would need to take in order to secure these improvements, and we have established a Chemicals Stakeholder Forum to oversee this process for us.

The Forum[2] is asked to advise Government on managing risks to the environment and to human health from chemicals entering the environment through commercial production and use. Its full terms of reference can be seen on its website. Its membership is drawn from representatives of industry, environmental, consumer and animal welfare special interests groups, trade unions, academia, and representatives of organisations most closely linked with the view of the general public.

The Forum is asked to consider chemicals and chemicals-related issues by the Government, by the stakeholders themselves (who are encouraged to bring issues to the table) and the general public, although we have yet to secure a fully satisfactory way of engaging the public. The Forum receives scientific advice both from its own members (some of whom are scientists) and from the Advisory Committee on Hazardous Substances, which has been constituted specifically for that purpose. We expect the Forum to provide information and advice to Government, the stakeholders and the general public both on generic chemical issues and on specific chemicals. More importantly we expect it to secure voluntary agreements with the chemicals industry to control problematic chemicals. We expect this process to lead to faster, bolder and more precautionary assessments of the hazards of chemicals based on slim information requirements, and leading to prompt precautionary action.

The sort of action we expect the Forum to consider and advise upon fall into four categories:

- Advice to Government, industry and the public. If there are concerns about a particular chemical, we expect industry to note the concerns and start taking appropriate commercial action. If there is general alarm about a particular chemical which the Forum feels to be unjustified, we are hoping that its representative and authoritative composition will make it a credible source of advice for the public.

- Where the Forum has reasonable grounds for concern about a chemical, even where the scientific evidence is not complete, we invite industry to enter into a voluntary agreement to restrict the production or use of the chemical. The voluntary agreement might be an informal undertaking, or might be a formal binding agreement with Government. In the event that the companies concerned are reluctant to take action recommended by the Forum, they need to bear in mind that the proceedings of the Forum are all fully public, without exception, and are being tracked by the press. We believe that in many cases this glare of publicity will be sufficient pressure to secure prompt action, but if not …

- … Legislation. We have of course provision for national legislation to control chemicals, but because of the single market nature of the EU legislation any national measures we took would be subject to EU review, a lengthy and resource intensive process without necessarily any guarantee of success. But national measures remain an option.

- Normally, however, we would try to convince our EU colleagues of the need for Community legislation and this is where we see the value of the on-going EU Review.

Although the Forum has not been meeting for very long it has already carried out a lot of the preliminary work necessary to meet its objectives. It has, in particular, decided on a first set of criteria that will be used for screening chemicals for special attention. These criteria can be found on the Forum's website, but, in line with the UK's Chemical Strategy and with the Council Conclusions on the EU Review of Chemicals Legislation they are based around consideration of the intrinsic hazards of the chemicals, particularly carcinogenicity, mutagenicity, reprotoxicity, persistence, bioaccumulation and toxicity. The Forum is also considering ways in which the success of the national strategy might be measured, in terms of reducing the risks from chemicals on the market, and is exploring better ways of engaging the public in the debate on chemicals. Recently, it has issued a challenge to industry on the rapid phase out of octylphenol, and nonylphenol and its ethoxylates - we are awaiting industry's response.

Other papers today are dealing in detail with the EU Review. Here, I shall merely emphasise the UK's enthusiasm for the Review, particularly as it was initiated during the UK Presidency in 1998. We believe that, carefully formulated, the REACH process will give good pragmatic regulatory backing to the voluntary process that we have already started nationally.

In conclusion, under our new UK approach we expect to screen chemicals rapidly against the criteria set out by the Chemicals Stakeholder Forum. In cases where we see delays in getting agreed EU action on chemicals that meet these criteria we will move quickly to secure appropriate restrictions on their production and use. In this way, we have overlaid a strong element of precaution on the sustainable development challenges of chemicals policy.

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NOTES

[1] The Sustainable Production and Use of Chemicals

[2] http://www.defra.gov.uk/environment/chemistrat/stakehol/index.hgm

LATE LESSONS FROM EARLY WARNINGS – SOME IMPLICATIONS FOR CHEMICALS POLICY

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Late Lessons from Early Warnings
The Precautionary Principle 1896 – 2000
An EEA Report

- ***Late Lessons*** provides guidance to future application of the precautionary principle, centred on case studies of past practice (incl. asbestos, BSE, PCBs, DES, hormones in beef, CFCs, radiation, Great Lakes, MTBE, antibiotics in animal feed, etc.)
- The case studies evaluate
  - –when early warnings became apparent
  - –the subsequent actions, or inactions
  - –the costs and benefits of actions or inactions and
  - –the lessons to be drawn from each

2 European Environment Agency

German 'Vorsorgeprinzip'

(precautionary principle) in Clean Air Act, 1974, with definition in 1984 Report on Clean Air containing 5 elements

- Early detection (**research** needed)
- If impacts could be irreversible, then act **before 'proof'**
- Reduce environmental burdens anyway
- Governments promote Clean Production (later 'eco-efficiency')
- Encourage convergence around pursuit of both **environmental and non-environmental (e.g. innovation, competitiveness, employment)** goals

3 European Environment Agency

The European Court of Justice has consistently defined the Precautionary Principle as follows:

'Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent'

E.g., judgement of 5.5.98, case C-157/96, National Farmers Union (BSE) (1998) ECR I-2211, para. 63, repeated in several other cases.

Health Takes Precedence over Economic Interests

'Whilst acknowledging the economic and social difficulties which may be caused by the application of the precautionary principle, the Commission cannot but recognise, in accordance with the case law of the Court, the paramount importance to be accorded to the protection of health, which must take precedence over economic considerations'.

See, on that point, the order e.g. in the Case C-180/96R United Kingdom v Commission (1996) ECR I-3903, para.93.

Lesson 1: ***Acknowledge and Manage 'risk', 'uncertainty' & 'ignorance'***

- **Risk: 'known' impacts; 'known' probabilities**
  e.g. **Asbestos** and cancers from 1965
- **Uncertainty: 'known' impacts; 'unknown' probabilities**
  e.g. **Antimicrobials** in animal feed from 1961-1999
- **Ignorance: 'unknown' impacts and probabilities –** source of **'surprises'**
  e.g. **CFCs** and ozone layer depletion 1930s-1974

Lesson 2: ***Long term monitoring and investigate'early warnings'***

- With a focus on key uncertainties and background parameters (e.g. persistence and bio-accumulation)
- Often over several decades…
- With prompt and targetted research
- And open to 'surprises'

Lesson 3: ***Distinguish*** *between* ***risk, uncertainty*** *&* ***ignorance***

- **Risks** are where both **outcomes** and their **probability of occurrence** are **"known"**
  - **Asbestos** and the 3 main diseases from 1965
- **Uncertainties** are where we believe **we "know" the potential outcomes**, but **not their probability**
  - Antimicrobials in animal feed from 1961-1999
- **Ignorance** where we don't know what we don't know and cannot anticipate "surprises"
  - **CFCs** and ozone depletion 1930s-1974

Lesson 4: ***Beware*** *of* ***'blind spots'***

- Maintain open minds on possible impacts... (the automated analysis of US satellite data on stratospheric ozone was set to reject real low values as spurious instrument error)
- ... and basic parameters (**MTBE** is a high-volume chemical whose persistence was initially downplayed by regulators)
- Involve all relevant experts (medical experts dominated the **asbestos** issue; vetinary experts dominated the **antimicrobials** issue)

Lesson 5: ***Take account*** *of* ***'lay knowledge'*** *&* ***'specialist expertise'***

- The problems of **benzene** and **asbestos**, were apparent to factory inspectors, workers, local doctors and residents well before being accepted by regulators
- John Dennis, a New York journalist, was documenting the harmful effects of **X-rays** a few years after their discovery in 1895
- But no one source of knowledge is necessarily "right"
  - Some **asbestos** workers pointed to the retired, healthy workers at the annual Christmas Party as evidence of the 'safety' of asbestos...

Lesson 6: ***Take account*** *of different* ***values*** *&* ***perspectives***

- Values are relevant to all elements of risk assessment / evaluation, management and communication, so involve stakeholders in each
- Values, prespectives and assumptions must be transparent
- Can help rebuild public trust in science and governance
- The Swedish farmer's decision to stop using **antimicrobials** was partly based on their and consumer values

Lesson 7: ***Maintain regulatory distance from interested parties***

- Regulators can come too close to interested parties and share their values, resulting in delayed action
  - Benzene was known to be a bone marrow poison in 1897
  - The respiratory effects of asbestos was known in 1898
  - Producers and regulators knew of the effects of PCBs on workers in the 1930s
  - Scientific committees on hormone growth promoters were reliant on industry data
  - For BSE, the economic consequences dominated UK government's early actions; etc.

Lesson 8: ***Assess, justify and account for all pros and cons***

- Including their distribution; and 'secondary' benefits and costs
- Include effects of innovation and technological change, as well as social impacts of technology choices
- Product prices to include full costs of production, use & disposal (the 'polluter pays principle')
- This maximises efficiency, stimulates innovation and minimises environmental and health burdens
- Precautionary costs should not greatly outweigh the benefits; **the proportionality principle**

Lesson 9: ***Evaluate*** *alternative* ***means of providing services***

- Substance 'monopolies' stifle innovation and substitutes eg. **Asbestos, CFCs**
- Better alternatives were available earlier but not widely used eg. for **antimicrobials, asbestos, radiation, CFCs,** etc.
- Alternatives analysis can stimulate substitutes
- The principle of substitution, now part of OSPAR's Strategy on Hazardous Substances requires a **comparative assessment of alternative means of providing services;** as does the EU Biocides Directive
- But use precaution, eco-efficiency and diversity with substitutes, too

Lesson 10: ***Avoid paralysis by analysis***

- **e.g. the Great Lakes case:**
- *Assessing and prioritising the impact of all activities, and their interactions, on all species can delay justifiable action on any one*
- *Action on* ***fish stocks*** *preservation was delayed by 'more research'…*
- *Specify what 'more research' means, eg. the 17 steps in the causal chain from antimicrobials in animal feed to antibiotic resistance in humans; who will fund it; how long will it take; and who or what gets the benefit of the doubt meanwhile ?*

Lesson 11: Act on ***Precautionary Principle to minimise risks and maximise innovation***

- Using levels of proof (e.g. 'balance of probabilities') that are appropriate to the consequences of being wrong
- Supported by reducing overall environmental burdens via 'eco-efficiency' and other means
- Using diverse, robust and flexible technological and social options
- Monitored for impacts and effectiveness

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European Environment Agency

SUBSTITUTION AND PRECAUTION – BOTH ON PRINCIPLE?

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Abstract

The principles of substitution and precaution are important elements of the European Union chemicals policy. They are seen as a constituent of the whole risk assessment and risk management process. An important prerequisite for an application of the precautionary principle is that a risk assessment has been performed, showing that the risk cannot be determined because of the insufficiency of underlying data. One goal of the EU white paper on a strategy for a future chemicals policy is to encourage the substitution of dangerous by less dangerous substances where suitable alternatives are available. The dilemma of applying both principles simultaneously is that due to the lack of information about the substitute an application of the precautionary principle would prevent its introduction. A way out of this dilemma would be the obligation for industry to deliver sufficient data for all relevant chemicals as proposed by the new REACH system of the EU. Other important possibilities to enforce substitution could be an assessment of chemicals in clusters according to structural similarities or identical uses, a better risk communication, publication of lists of non or less hazardous chemicals, which can be used for certain applications, financial support for promising substitutions and information about successful substitution. Moreover, non-chemical alternatives should be taken into account additionally. Examples from the current risk assessment and risk management work within the EU existing chemicals program illustrate some of these possibilities.

Key words: *substitution, precaution, existing chemicals, risk assessment, risk communication*

The EU Commission has recently published a communication with general guidance for the application of the precautionary principle (1). The precautionary principle is seen as a constituent of the whole risk assessment and risk management process. An important prerequisite for its application is that

- A risk assessment has been performed, showing that
- the risk cannot be determined because of the insufficiency of underlying data.
- The degree of uncertainty should be identified.
- Measures based on the precautionary principle have to be re-evaluated in the light of scientific progress (2).

The tools applied in the EU for risk assessment already use a number of precautionary elements. For instance, in exposure assessment data gaps are accounted for by default values or realistic worst case assumptions and in effects assessment lack of knowledge is reflected by assessment or safety factors in order to extrapolate the results of monospecies laboratory tests of varying quality in such a way that the structure and function of natural ecosystems is adequately protected. The precautionary principle is also evident in the proposals for a future risk assessment of the marine compartment. For the open sea persistent, bioaccumulative and very toxic substances shall be assessed on the basis of intrinsic properties.

The precautionary principle is also an essential in the White Paper of the European Commission on a strategy for a future chemicals policy, which states that under certain conditions decision-making must be based on precaution in order to prevent damage to human health and the environment (3). Another key element of the new strategy is to encourage the substitution of dangerous by less dangerous substances where suitable alternatives are available. The Commission expects that the increased accountability of down-stream users and better public information will create a strong demand for substitute chemicals that have been sufficiently tested and that are safe for the envisaged use.

The principles of precaution and substitution are particularly critical when applied as elements of risk assessment and management of existing chemicals, which represent about
99 % of the production volume of industrial compounds. In contrast to new chemicals they are already on the market and are used in a wide range of applications. Usually, each application requires a different substitute. If substitution is envisaged, alternative substances or methodologies have to be found. However, so far there are only a few cases in which the precautionary principle was integrated into the development of new products. Due to a lack of knowledge about the availability of substitutes, it is usually difficult to find a better alternative for a certain use or function of a chemical substance. In addition the large difference in data and documentation requirements between new and existing chemicals hampers the substitution of dangerous existing chemicals by safer new ones.

The following example may illustrate the dilemma surrounding precaution and substitution in the present situation:

Suppose evaluation on the basis of the precautionary principle suggests the substitution of a potentially dangerous chemical, which is released to the environment during use

(e.g. in offshore drilling), although it was not possible to carry out a complete risk assessment for this substance due to insufficient data. However, as is normally the case, the potential substitute has not yet been tested. Should we therefore apply the precautionary principle to the substitute, with the consequence that substitution is not possible for precautionary reasons?

It would seem that the only way out of this dilemma is the obligation for industry to deliver a minimum data set for all relevant industrial chemicals. In addition, new concepts, such as assessment on the basis of spatial range as proposed by Scheringer (4) as a kind of hazard indicator at exposure level or risk management on the basis of persistence and bioaccumulation, may be valuable tools to combine precaution and substitution.

These items have been integrated in the REACH system described in the "White Paper on the Strategy for a future Chemicals Policy". The registration and evaluation stages in the REACH system will lead to more basic data, making it possible to compare different substitutes. Authorisation is focused on certain applications of dangerous chemicals and down-stream uses are thus particularly taken into account. The authorisation of very hazardous chemicals for certain applications will lead to a large demand for less critical alternatives.

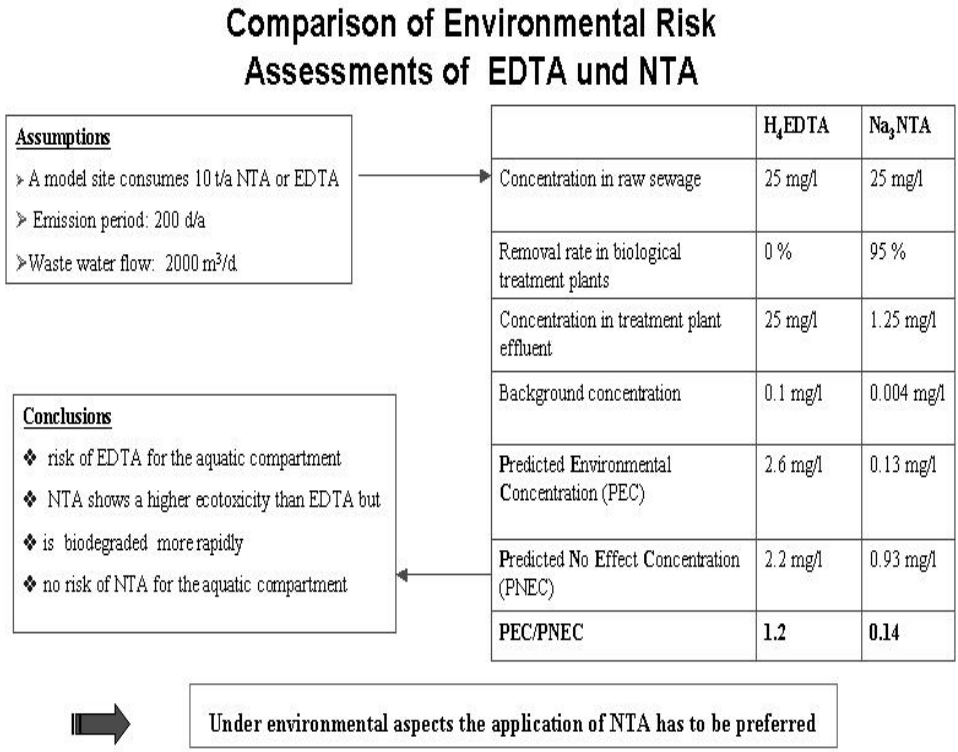
In addition to the need of a complete data set, an assessment of chemical substances in clusters according to structural similarities or identical uses (use clusters) would facilitate the application of the substitution principle. The use cluster approach means that all substances serving the same purpose (e.g. pickling) are subjected to a comparative assessment. It has the advantage that possible alternative products are assessed on the basis of identical criteria and that all stake-holders can be brought together (5). In general, assessing groups of chemicals enables the authorities to evaluate the consequences that would arise if a chemical of this group is used as a substitute for a regulated one for a certain application.

Examples from the current risk assessment and risk management work within the scope of the EU existing chemicals programmes are presented in the following to illustrate the possible advantages of these approaches. The examples are

- a comparative risk assessment of complexing agents (EDTA, NTA),
- risk assessment and risk management of short, medium and long chain chlorinated paraffins, and
- priority setting for fatty acid amines.

EDTA is on the first EU priority list, NTA on the third one. In both cases Germany serves as rapporteur. During risk assessment of EDTA it became apparent that it would be useful to perform a combined assessment of both substances as each is used as substitute for the other. Moreover, due to their special properties as complexing agents, it was necessary to develop guidance for the assessment of the whole group of complexing agents. Based on this it is possible to compare various complexing agents and choose the preferred substitute.

The following table compares the environmental risk assessments of EDTA and NTA. It is assumed that a model site uses 10 t/a complexing agent. In addition the normal default values of the EU TGD were applied. Under these conditions the concentration of



	H_4EDTA	Na_3NTA
Concentration in raw sewage	25 mg/l	25 mg/l
Removal rate in biological treatment plants	0 %	95 %
Concentration in treatment plant effluent	25 mg/l	1.25 mg/l
Background concentration	0.1 mg/l	0.004 mg/l
Predicted Environmental Concentration (PEC)	2.6 mg/l	0.13 mg/l
Predicted No Effect Concentration (PNEC)	2.2 mg/l	0.93 mg/l
PEC/PNEC	**1.2**	**0.14**

complexing agent in raw sewage will be 25 mg/l. As NTA undergoes biodegradation in a biological treatment plant and EDTA does not, a much lower predicted environmental concentration was obtained for NTA. Although NTA is more toxic than EDTA the

PEC/PNEC ratio is much lower. Therefore it was concluded that – due to the better biodegradation – under environmental aspects NTA has to be preferred and should substitute EDTA.

The second example is risk assessment and risk management of short, medium and long chain chlorinated paraffins. Short chain chlorinated paraffins are on the first EU priority list. It soon became obvious, that when regulated they may be substituted by medium or long chain paraffins. Therefore, UK found it necessary to perform risk assessments for all of them.

Prior to these EU activities, efforts had been ongoing in Germany to minimize environmental releases of chlorinated paraffins from metal working applications with the result, that in 1996 metal working industry stated that it had phased out virtually all chlorinated paraffins and a complete ban would pose no problems. Quite a number of reasons for the substitution of chlorinated paraffins in the metal working sector in Germany have been reported (6) such as

- Global policy issues to restrict use of hazardous substances
- Increasing disposal costs for chlorinated compounds
- Demands for general optimisation of plants and processes
- Direct or indirect influences of various regulatory instruments.

Due to these items the substitution process proved to be self-preserving, irreversible and net benefiting.

The third example is the priority setting of fatty acid amines. Tallow alkyl amine was on the second EU priority list with Germany as rapporteur. Starting the risk assessment it soon became obvious that the other fatty acid amines have similar properties and can substitute each other in several applications. Therefore the assessment of tallow alkyl amine was postponed for the moment and the most important other fatty acid amines were placed on the fourth priority for a combined risk assessment.

Often sufficient risk communication is an essential to enforce substitution. The willingness of down-stream users to apply a less risky alternative depends on the availability of information. Lists of chemicals with hazardous properties are available, but there are usually no lists of non or less hazardous substances, which can be used for certain applications. In addition the capability of down-stream users to assess the different alternatives has to be enhanced. The communication of examples of successful

substitutions proved to be quite encouraging, and last but not least the development of promising substitutions can be promoted by financial support.

On a recent workshop held in Hamburg in the context of a German R + D project on options for substituting hazardous chemicals through cooperation between industry, government and society (7) some additional considerations on precaution and substitution were discussed:

- Non-chemical alternatives should be included additionally in concepts of substitution. The aim must be to install an inherently safe application system not just inherently safe chemicals and
- For an enforcement of substitution we should not only trust on regulatory measures, but also on impulses from other stakeholders on the market.

Hopefully in future substitutions of dangerous chemicals as a consequence of an application of the precautionary principle will be much easier than nowadays. The overall outcome may be that substitution will enhance innovation.

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LITERATURE

(1) Communication from the Commission on the precautionary principle, COM 2000 (1)

(2) Ahlers J, Beulshausen T, Schwarz-Schulz B, Stolzenberg H-C: Anwendbarkeit des Vorsorgeprinzips – EU-Kommission und Bewertungspraxis, UWSF – Z. Umweltchem. Ökotox. 12,149-151 (2000)

(3) EU: White Paper – Strategy for a future Chemicals Policy, COM (2001) final

(4) Scheringer M, Hungerbühler K, Matthies M : The Spatial Scale of Organic Chemicals in Multimedia Fate Modeling – Recent Developments and Significance for Chemical Assessment, ESPR-Environ Sci&Pollut Res 8, 150-155 (2001)

(5) Ahlers J: The EU Existing Chemicals Regulation – A Suitable Tool for Environmental Risk Assessment and Risk Management? ESPR – Environ. Sci. & Pollut. Res. 6,127-129 (1999)

(6) Stolzenberg H-C: Risk Reduction in Germany for Chlorinated Paraffins used in Metalworking Fluids: Regulator's View on Triggers, Driving Forces, Perspectives, in: Organohalogen Compounds 47, 131-134 (2000), MS Denison and UC Davis eds.

(7) Von Gleich A, Ahrens A, Lißner L, Braun A: Gefahrstoff-Substitution – Innovation durch erfolgreiches Zusammenwirken von Wirtschaft, Staat und Zivilgesellschaft. UWSF-Z Umweltchem Ökotox 13, 267-268 (2001).

SCIENCE AND THE RATIONALITY OF PRECAUTION [1]

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I. Introduction

The 'precautionary principle' is becoming an increasingly prominent theme in the debate over technological risk. Many questions are raised over the implications for policy making. In particular, concerns have been expressed over the relationship between 'precautionary' and more traditional 'science based' approaches to decision making such as cost-benefit and risk analysis. Fears are sometimes raised that – unlike risk assessment – a 'precautionary approach' is too ambiguous and impractical to serve as a basis for real decision making, that it is somehow antagonistic to science and even that it threatens to stifle technological innovation and economic growth.

This paper takes a close look first at some of key conceptual issues bearing on this relationship between 'science' and 'precaution'. It is found that – far from being in tension – these two concepts might actually be seen as entirely consistent and even mutually reinforcing. The real distinction is found to lie between narrow 'risk based' concepts of regulatory appraisal and broader precautionary approaches. Turning to the practical implications, a series of key features are identified as characterising a precautionary approach to regulatory appraisal. An illustration is provided of one practical method which offers to address these imperatives and deliver an approach to regulatory appraisal which is at the same time both precautionary and scientifically robust.

II. The Scope and Complexity of Risk

Risk is a complex concept. Even under the most narrowly-defined of quantitative approaches, it is recognised that risk is a function of at least two variables – the likelihood of an impact and its magnitude. However, it is only very rarely the case that a series of technology, policy or investment options are seen to present only one form of hazard. Normally, the characterisation of risks associated with any individual option requires the consideration of a wide variety of disparate risks. In the energy sector, for example, risks can take forms including greenhouse gas emissions, radioactive wastes, heavy metals, persistent organic pollutants, soil erosion, thermal discharges, ambient noise, ecological disturbance or aesthetic intrusion in the landscape. Each of these risks

is manifest in a different way, with different physical, biological, social, cultural and economic connotations.

The conventional response in regulatory appraisal is to identify a single major yardstick of performance and seek to measure all the various aspects of risk using this as a metric. The chosen unit of measurement in conventional risk assessment is usually human mortality rates, although human morbidity is sometimes included. In some areas, the techniques of cost-benefit analysis are used to impose a common monetary metric on a wider range of impacts and render them comparable with the associated benefits. In this way, it is hoped that the multiplicity of risk magnitudes might usefully be reduced to a single key factor, thus apparently simplifying the process of appraisal. This process of reduction is an essential element in what is sometimes described as a 'science based' approach to the regulatory appraisal of risk.

Of course, one crucial consequence of this artificial narrowing and conflation of the full diversity of technological risks is effectively to exclude from consideration many classes of effect. For instance, it is clear that only a minority of the types of energy risks mentioned above is meaningfully addressed by a mortality, morbidity or monetary metric. Moreover, even with respect to the single issue of human health, risk is an inherently multi-dimensional concept. For instance, are exposures voluntary or controllable? Are they manifest as disease, injuries or deaths? How familiar are the risks? How immediately are they realised and how reversible once identified? To what extent are they concentrated in large events or dispersed in small routine incidents? How are they distributed across space, time and society? Mortality, and even morbidity, indices fail to capture these important contextual features.

Beyond this, further scope for divergent approaches to regulatory appraisal lies in the characteristics of the assessment process itself. Should appraisal take account of social, economic, cultural and ethical issues, as well as environmental and health factors? With respect to the more narrowly defined physical factors, to what extent should appraisal seek to address the potential additive, cumulative, synergistic and indirect effects associated with particular environmental and health risks? With how wide an array of potential alternatives should each individual technological or policy option be compared in appraisal? Should attention be confined simply to the implementation of the options concerned, or should it extend to their manufacture, processing, decommissioning and disposal, as well as to the various inputs (such as energy and materials) and associated risks at each stage? To what extent should the relative benefits of different options be taken into account in appraisal so that they can be offset against the associated risks?

In an ideal world, the appropriate response to factors such as these is easy to determine. All else being equal, the regulatory appraisal of risk should be as complete with respect to different classes and dimensions of risk and benefit and comprehensive with respect to different types of option. However, such aspirations provide only rather loose

operational guidance in the practical regulation of risk. Moreover, even were appraisal to be fully complete and comprehensive in some hypothetical sense, then there would still remain the problem of how the different aspects of risk should be framed and prioritised in analysis. For instance, what assumptions should be made about adherence to best practice in the various activities under appraisal? What relative priority should be attached to different effects such as toxicity, carcinogenicity, allergenicity, occupational safety, biodiversity or ecological integrity? What weight should properly be placed on impacts to different groups, such as workers, children, pregnant and breastfeeding mothers, future generations, disadvantaged communities, foreigners, those who do not benefit from the technology in question or even to animals and plants as beings in their own right? Even if they were practically feasible, objectives such as completeness or comprehensiveness do not assist in addressing issues of framing and prioritisation of this kind. No one set of assumptions or priorities may be claimed to be uniquely rational, complete or comprehensive.

It is here that we come to a classic and well-explored dilemma in the field of rational choice theory that underlies risk assessment and regulatory appraisal, but one that often seem to have been forgotten by those who aspire (or claim) for these techniques the status of 'sound science'. The disciplines of risk assessment, economics and decision analysis have developed no single definitive way of addressing the problems of comparing 'apples and oranges'. Even the most optimistic of proponents of rational choice acknowledge that there is no effective way to compare the intensities of preferences displayed by different individuals or social groups (Bezembinder, 1989). Indeed, even where social choices are addressed simply in relative terms, the economist Kenneth Arrow went a long way towards earning his Nobel Prize by demonstrating formally that it is impossible definitively to combine relative preference orderings in a plural society (Arrow, 1963).

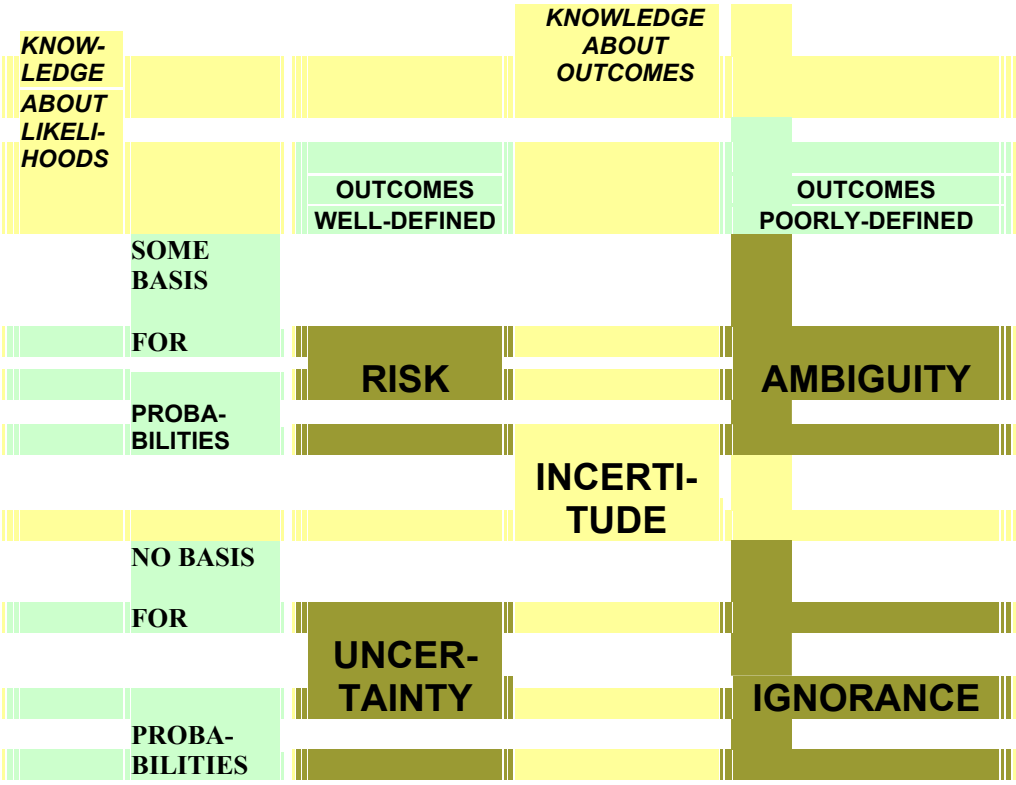
Put simply, the point is that "it takes all sorts to make a world". Different cultural communities, political constituencies or economic interests typically attach different degrees of importance to the different aspects of environmental risk and look at them differently. Within the bounds defined by the domain of plural social discourse, no one set of values or framings can definitively be ruled more 'rational' or 'well informed' than can any other. Even were there to be complete certainty in the quantification of all the various classes and dimensions of risk, it is entirely reasonable that fundamentally different conclusions over environmental risk might be drawn under different – but equally legitimate – perspectives. It is a matter of the science of risk assessment itself, then, that there can be no analytical fix for the scope, complexity and intrinsic subjectivity of environmental and health risks. The notion that there can be a single unambiguous 'science based' prescription in the regulatory appraisal of risk is not only naïve and misleading; it is a fundamental contradiction in terms.

III. The Depths of Incertitude

This problem may seem serious enough. Unfortunately, the difficulties encountered by the 'sound science' of risk assessment are even more intractable than this. Thus far we have considered only the issues associated with the characterisation of the 'magnitude' aspects of risk. What of the likelihoods? Here we come upon some profound limitations to the applicability and robustness of probabilistic approaches that are as seriously neglected in regulatory appraisal as are the difficulties discussed above concerning the comparison of magnitudes.

In economics and decision analysis, the well-established formal definition of risk is that it is a condition under which it is possible both to define a comprehensive set of all possible outcomes and to resolve a discrete set of probabilities (or a density function) across this array of outcomes. This is illustrated in the top left-hand corner of the diagram in Box 1. This is the domain under which the various probabilistic techniques of risk assessment are applicable, permitting (in theory) the full characterisation and ordering of the different options under appraisal. There is a host of details relating to this picture (such as those hinging on the distinction between 'frequentist' and 'Bayesian' understandings of probability), but none of these alter the formal scientific definition of the concept of risk.

BOX 1:
THE FORMAL DEFINITIONS OF RISK, UNCERTAINTY, AMBIGUITY AND IGNORANCE



The strict sense of the term uncertainty, by contrast, applies to a condition under which there is confidence in the completeness of the defined set of outcomes, but where there is acknowledged to exist no valid theoretical or empirical basis confidently to assign probabilities to these outcomes. This is found in the lower left-hand corner of Box 1. Here, the analytical armoury is less well developed, with the various sorts of scenario analysis being the best that can usually be managed (Funtowicz and Ravetz, 1990). Whilst the different options under appraisal may still be broadly characterised, they cannot be ranked even in relative terms without some knowledge of the relative likelihoods of the different outcomes.

Both risk and uncertainty, in the strict senses of these terms, require that the different possible outcomes be clearly characterisable and subject to measurement. The

discussion here has already made it clear that this is often not the case – the complexity and scope of the different forms of environmental risk and the different ways of framing and prioritising these, can all-too-easily render ambiguous the definitive characterisation of outcomes. This may be so, even where there is relatively high confidence in understandings of the likelihood that at least some form of impact will take place (top right corner of Box 1). An illustrative example here might be the prospects for regional climatic, ecological and socio-economic impacts arising from the human-enhanced greenhouse effect.

Where these problems are combined with the difficulties in applying the concept of probability, we face a condition which is formally defined as ignorance (bottom right corner of Box 1) (Loasby, 1976, Smithson, 1989, Wynne, 1992). This applies in circumstances where there not only exists no basis for the assigning of probabilities (as under uncertainty), but where the definition of a complete set of outcomes is also problematic. In short, recognition of the condition of ignorance is an acknowledgement of the possibility of surprises. Under such circumstances, not only is it impossible definitively to rank the different options, but even their full characterisation is difficult. Under a state of ignorance (in this strict sense), it is always possible that there are effects (outcomes) which have been entirely excluded from consideration.

Box 1 provides a schematic summary of the relationships between these formal definitions for the concepts of risk, uncertainty, ambiguity and ignorance. It is quite normal, even in specialist discussion, for the full breadth and depth of these issues to be rolled into the simple concept of 'risk' (and sometimes 'uncertainty'), thus seriously understating the difficulties involved. In order to avoid confusion between the strict definitions of the terms 'risk' and 'uncertainty' as used here, and the looser colloquial usages, the term 'incertitude' can be used in a broad overarching sense to subsume all four subordinate conditions. Either way, it is not difficult to see that it is the formal concepts of ignorance, ambiguity and uncertainty – rather than mere risk – which best describe the salient features of regulatory decision making in areas such as energy technologies, toxic chemicals and genetically modified organisms. Indeed, many of the most high profile technologically-induced 'risks' of recent years – such as stratospheric ozone depletion, endocrine disrupting chemicals and BSE, for instance – are all cases where the problem lay not so much in the determination of likelihoods, but in the anticipation of the very possibilities. They were surprises!

The crucial point is, that intractable uncertainties, ambiguities and ignorance are routinely treated in the regulatory appraisal of technology simply by using the probabilistic techniques of risk assessment. This treatment of uncertainty and ignorance as if they were mere risk effectively amounts to what the economist Hayek dubbed (in his Nobel acceptance speech) "pretence at knowledge" (Hayek, 1978). Far from displaying a respect for science in regulatory appraisal, the effect of such scientistic

oversimplification is actually to ignore and undermine the scientific principles on which risk assessment itself purports to be based. Given the manifest inapplicability – in their own terms – of probabilistic techniques under uncertainty and ignorance, this is a serious and remarkable error. The self-contradictions in aspirations to a 'science based' approach reliant on quantitative risk assessment, already noted in the last section, are thus further underscored and reinforced.

Why is it that pursuit of (and claims to) the definitive authority of 'science based' approaches continues to be so prominent in regulatory appraisal? It seems that the elegance and facility of probabilistic calculus has had a seductive effect on many risk analysts and their sponsors. This may be understandable, yet it is also curious. Despite the intractability of the condition of ignorance, there is no shortage of operational tactical and strategic 'precautionary' responses. Some specific features of these approaches will be reviewed in some detail later. For the moment, in the specific context of ignorance, the point is simply that there do exist practical alternatives to the use of probabilistic methods. For instance, there exists a variety of institutional procedures for including in the regulatory appraisal process a range of different scientific disciplines and people with pertinent professional and local knowledge and relevant socio-economic perspectives. By providing for the identification of a wider range of possibilities, this effectively helps to convert some part of the domain of ignorance into the more tractable condition of uncertainty. Here, techniques such as scenario and sensitivity analysis can also help systematically to characterise these neglected possibilities and explore their implications under different perspectives.

Beyond this, there are a series of broader strategies that may be employed and which will be returned to later. In particular, rather than focusing entirely on efforts to characterise the 'problem' (ignorance) attention can also be devoted directly at aspects of the 'solution'. Although the manifestations of ignorance are, by definition, not characterisable in advance, certain dynamic properties of the different options themselves can offer valuable ways of hedging against ignorance. Here properties such as flexibility, reversibility, resilience, robustness and adaptability are all potentially valuable (Stirling, 1999). Perhaps even more important, are the possible merits of deliberate diversification across a range of options. After all, it is a well-established matter of common sense that, when we don't know what we don't know, we don't put all the eggs in one basket! It may be that a persistent preoccupation with probabilistic methods has left these kinds of strategies unduly neglected in the regulatory appraisal of technological risk.

IV. Practical Consequences for Risk Assessment

The problems discussed so far – the multi-dimensionality of environmental and health risks and the conditions of uncertainty, ambiguity and ignorance – may all seem a little abstract and theoretical. It is perhaps also partly for this reason that they remain relatively neglected in the business of regulatory appraisal. Unfortunately, however, they have some important practical consequences that, though often concealed, hold profound implications for the interpretation of orthodox risk assessment results in all fields, extending from the regulation of energy options, through chemicals and industrial hazards to genetic modification technologies.

In all these areas, the typical response to these difficulties in regulatory appraisal is to reduce and simplify – focussing on those aspects that are either the most tractable or the most 'reasonable' under certain dominant perspectives. In this way, individual studies can construct a picture of environmental risks, which appears to be quite unambiguous and precise. The scale of the discrepancies only becomes evident on occasions when attention is extended to a series of different appraisal studies, each applying subtly different – but equally 'reasonable' and 'legitimate' – framing assumptions concerning the different dimensions of appraisal discussed here. When this takes place, it becomes clear that the apparent relative riskiness of different options can vary quite radically, depending on the framings and priorities attached to the 'hidden variables' during the process of appraisal.

Box 2 illustrates this by showing the results obtained in thirty two large scale risk assessments of eight different energy technologies conducted in industrialised countries over the past two decades. Here, environmental and health effects are characterised using the techniques of cost-benefit analysis as monetary 'external costs' expressed in standardised form per unit of electricity production (Stirling, 1997). This case is taken as an example because both the techniques employed, and this particular field of application, might arguably be seen as being among the most mature and intensively explored areas of application of comparative risk assessment. The picture is not specific to these techniques or this field. A similar pattern may be found in a variety of other regulatory fields, including transport, toxic chemicals and food safety. The same pattern is also evident in the underlying physical and mortality indices on which these monetary results are based. A number of salient features can be seen.

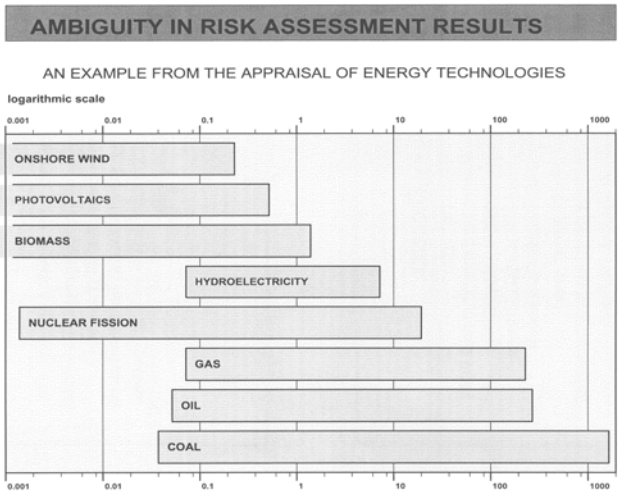
First, individual studies present their results with great precision – often as a single value rather than a range and sometimes expressed with as many as four significant figures (one part in ten thousand). Yet, the variability in the results obtained in the literature as a whole for any one option is radically larger. For instance, the uppermost values of the highest range assess the risks associated with coal power amount to the equivalent of some twenty dollars per kilowatt-hour of electricity production. The

lowest values of the bottom range in Box 2 are less than four hundredths of a cent per kilowatt-hour. The difference is more than four orders of magnitude – a factor of more than fifty thousand! Detailed analysis of the reasons for these discrepancies show that they do not arise as a result of any single factor. It is not a simple matter of some studies being more 'accurate' or 'reasonable' than others in any definitive sense. Instead, the variability is the cumulative consequence of the adoption of divergent assumptions and priorities concerning the whole range of the different 'dimensions of appraisal' identified in the preceding sections (Stirling, 1997).

The second crucial feature that is illustrated in Box 2 concerns the ambiguities in the ordering of the different options under appraisal. The lowest values obtained for the worst ranking option (coal) are lower than the highest values obtained for the apparently best ranking options (wind). Since the effect of the particular assumptions adopted in individual studies is to produce results at the high end of the overall range for some options but lower in the distributions for others, the overall picture yielded by the literature as a whole would accommodate virtually any conceivable ranking order for these eight options! By the judicious choice of framing assumptions, then, radically different conclusions can be justified for regulation.

This evident disjuncture between precision and accuracy in supposedly 'science based' risk assessment paints a rather negative picture. One of the first and most basic tasks in the management of risk is to construct some robust overall notion of the relative merits of the different options under consideration from the point of view of society as a whole. This then serves as a basis for regulatory intervention, market-based measures or investment initiatives. Where this cannot be achieved in any absolute (or even relatively robust) sense, then the value of appraisal lies in systematic exploration of the relationships between different assumptions in analysis and the associated pictures of the relative importance of different options. Where aspirations to the 'science-based' appraisal of risk lead to the assertion of the intrinsic authority of narrow risk assessment procedures, then these crucial exogenous factors typically remain unacknowledged and unexplored. In this event, the problem is not simply one of a lack of rigour concerning the theoretical contradictions noted in the previous sections. The difficulties are also very concrete and pragmatic. For, without a robust appreciation of the assumptions under which appraisal yields differing pictures of performance, serious questions must be raised over whether the associated results – no matter how confidently and precisely expressed – are of any practical policy use at all.

BOX 2
AMBIGUITY OF ORDERING IN RISK ASSESSMENTS (AN EXAMPLE FROM ENERGY TECHNOLOGIES)



V. 'Science' and 'Precaution' in the Appraisal of Risk

It is with increasing realisation of these practical and theoretical limitations to the value of orthodox risk assessment in regulatory appraisal, that interest is growing in complementary and alternative approaches. In particular, the 'precautionary principle' is becoming an ever more prominent feature of the regulatory debate on environmental risks and of national and international legislation (eg: O'Riordan and Cameron, 1993; Fisher and Harding, 1999; Raffensberger and Tickner 1999; Stirling, 1999, 2001; O'Riordan and Jordan, 2001; EEA, 2001). Although subject to a variety of different definitions, in the broadest of terms, a 'precautionary' approach acknowledges the difficulties in risk assessment by granting greater benefit of the doubt to the environment and to public health than to the activities which may be held to threaten these things. A host of different practical instruments and measures are variously proposed in different contexts as embodiments of a 'precautionary approach' or as means to implement a 'precautionary principle'. For present purposes, attention will concentrate on the way in which a precautionary approach offers a direct response to the practical and theoretical problems in regulatory appraisal which have been discussed so far.

One key theme in the current lively debate on these matters surrounds the frequent assertion (and sometimes assumption) that – whatever form it takes – a 'precautionary' approach to the management of environmental risk is somehow in tension with (or even antithetical to) the generally uncontroversial aspiration that regulatory decision making should be based on 'sound science'. Of course, this does not address the extent to which orthodox 'scientific' approaches such as comparative risk assessment may themselves be claimed to yield 'sound' results. The thrust of the discussion thus far has been to raise serious doubts over this. Nevertheless, the important question remains as to what exactly is the relationship between so-called 'science-based' and 'precautionary' approaches to the regulation of environmental risk?

A necessary starting point for this analysis is a clear characterisation of exactly what is meant by 'science' and 'precaution' in the context of decision making on environmental risk. Drawing on a wide literature, the table below displays some idealised attributes of scientific approaches to regulatory appraisal (Stirling, 1999a). In short, a scientific approach to the management of risk should, ideally and at minimum, be transparent in its argumentation and substantiation, systematic in its analytical methods, sceptical in its treatment of knowledge claims, subject to peer review, independent from special interests, professionally accountable and continually open to learning in the face of new knowledge. These aspirations may not always be realised, but they represent fundamental, and relatively uncontroversial, principles guiding any 'science-based' approach to regulatory appraisal.

Likewise, drawing on an equally extensive parallel literature, it is possible broadly to characterise the essential features of a 'precautionary' approach to the management of risk. In short, a precautionary approach involves the application of principles that 'prevention is better than cure', that 'the polluter should pay', that options offering simultaneously better economic and environmental performance should always be preferred ('no regrets'), that options should be appraised at the level of production systems taken as a whole and that attention should be extended to the intrinsic value of non-human life in its own right (a 'biocentric ethic'). In effect, this is variously taken to mean a certain humility about scientific knowledge and an acknowledgement of the complexity and variability of the real world. It implies recognition of the vulnerability of the natural environment and living organisms and the prioritising of the rights of those who stand to be adversely affected. It requires scrutiny of claims to benefits and justifications as well as risks and costs, with full account given to the available alternatives. Finally, a precautionary approach involves the adoption of long-term, holistic and inclusive perspectives in regulatory appraisal (Stirling, 1999b).

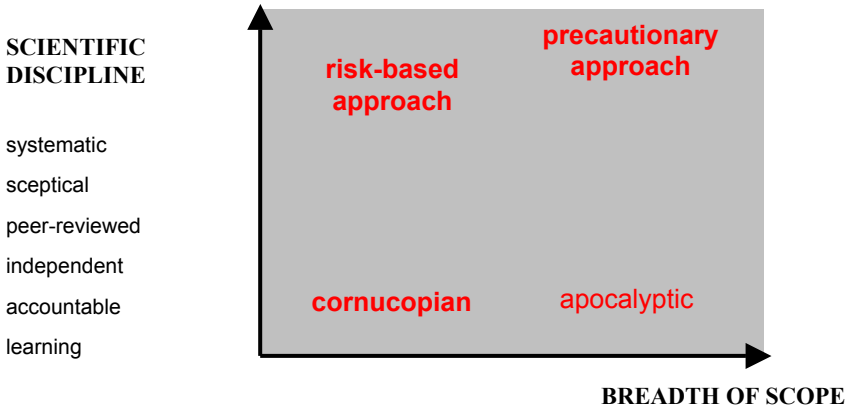
In many ways, these attributes of a 'precautionary' approach can be seen to concern different aspects of the breadth of the regulatory appraisal process. A 'broad' regime is one that takes account of a wide range of different types of impact, including qualitative

as well as quantitative issues and including indirect as well as direct effects. Likewise, a 'broad' framework accommodates a diverse array of different points of view (including, importantly, those of potential 'victims') and anticipates a wide range of possibilities in the face of uncertainty and ignorance. It extends consideration to the benefits and justifications associated with the introduction of the technology in question and examines a variety of alternative ways in which the benefits of a regulated technology might be realised at lower levels of risk. Taken together, these features constitute a more 'precautionary' approach because they increase the number and intensity of the constraints that any technological option must satisfy in order to be approved by the regulatory process, thus making it more difficult for certain innovations to pass through the regulatory 'filter'. At the same time, however, such measures might equally serve to encourage other technological innovations that might otherwise remain neglected.

What is interesting about this characterisation of 'precaution' in terms of the 'breadth' of the associated regulatory regime, is that it reveals an inherently consistent – and in many respects complementary – relationship between 'precaution' and 'science' in the management of technological risk. Accordingly, Box 3 distinguishes between different approaches to risk management based on the degree to which each embodies the respective characteristics of 'scientific appraisal' and 'breadth of framing' identified here.

BOX 3:

THE RELATIONSHIPS BETWEEN RISK, SCIENCE AND PRECAUTION



consider all **effects** — acknowledge possibility of **surprise**

compare **alternatives** — include many **perspectives**

account for **pros** as well as **cons** — take broad **social view**

reverse **onus of persuasion** — extend **research** and **monitoring**

Of course, both the 'broad'/'narrow' and the 'scientific'/'unscientific' dichotomies drawn here are highly stylised and simplified. However, the general picture revealed in Box 3 is at least richer and more realistic than the prevailing one-dimensional dichotomy between 'science' and 'precaution'. Taken together, the combination of these two dichotomies generates a fourfold array of idealised permutations. The adoption of a 'narrow' regime without reference to scientific understandings or disciplines in appraisal might be described as a permissive position. Taken to an extreme, this would amount to an entirely uncritical 'anything goes' approach to the regulation of technology of the kind associated with caricature 'cornucopian' visions of technological progress. Likwise, a broad-based regime might be similarly unscientific. The resulting restrictive position might be associated with a caricature 'apocalyptic' vision of technology. In the extreme, it would lead to a situation of paralysis under which no new technological innovation that offends in the slightest respect would ever be approved for deployment. The crucial point is that neither the 'permissive' (cornucopian) nor the 'restrictive' (apocalyptic) positions as defined here would be subject to challenge or reversal by the disciplines of scientific discourse associated with the vertical axis.

It is clear that neither the established procedures of risk regulation (based on relatively narrowly framed risk assessment methods) nor the emerging precautionary approach (based on broader perspectives and considerations) actually resemble these stylised 'permissive' or 'restrictive' caricatures. Existing risk assessment based regulation includes a host of effective checks and balances. It certainly does not necessarily provide for the uncritical approval of any new technology that may be developed. Likewise, even the most progressive formulations of a 'precautionary approach' are circumscribed in their scope, admit an incremental series of instruments and allow for regulatory approval under a host of favourable conditions. Both approaches are compatible – at least in principle – with the requirements of systematic methodology, scepticism, transparency, accountability, quality control by peer-review, professional independence and an emphasis on learning which are held here for the purposes of this discussion to be among the key aspirations of a 'science-based' approach.

It is at this point, that it is useful to return to the earlier discussion of the profound importance of the conditions of uncertainty, ignorance and multidimensionality in risk assessment. It was shown in the earlier sections that questions over the scope of appraisal, the plurality of different value positions and framing assumptions, the diversity of different anticipated possibilities and the degree of confidence placed in the available knowledge are all matters that are central to the 'scientific' status of the appraisal process. As was shown, it flows directly from the theoretical foundations of risk assessment, and cost-benefit analysis (and, indeed, all 'rational choice' approaches to decision-making on risk) that probabilistic approaches are inapplicable under strict uncertainty and ignorance. It also follows equally directly from these fundamental

theoretical principles that different priorities, framing assumptions and value systems cannot be definitively aggregated across different groups. For both these reasons, it is clear that there can be no analytical fix for the definitive ranking of different technology or policy options in the social appraisal of risk. All that can be done to maximise scientific rigour in appraisal is to ensure that the process is as broadly-based as possible in terms of the value systems and framing assumptions that are included and the options and possibilities that are addressed. Seen in this way, then, key elements of the 'breadth' of the regulatory regime themselves become issues of 'sound science' in the management of environmental risk, as well as institutional features of the wider regulatory regime. Precaution, conceived as a broadening of the regulatory appraisal process, is thus not just entirely consistent with science – it is a necessary pre-requisite for a truly scientific approach to the regulatory appraisal of risk. Indeed, precaution displays more robust claims to the status of sound science than does traditional narrow risk assessment!

VI. Some Practical Ways Forward

Although the potential benefits may be clear, it may at first sight seem rather ambitious to argue that the regulation of risks should in practice routinely extend attention to such a broad range of complex issues. How can any practical approach to regulatory appraisal be seen to display the properties such as humility, completeness, participation and the systematic consideration of the pros and cons of a range of options? Although it is obvious that there can be no one panacea, and that the appropriate response will vary from context to context, one final practical example may illustrate one way in which the appraisal of risk might realistically be broadened out to address all such considerations: the case of the 'multi-criteria mapping' (MCM) approach (Stirling, 1997, Stirling and Mayer, 1999, 2000, 2001).

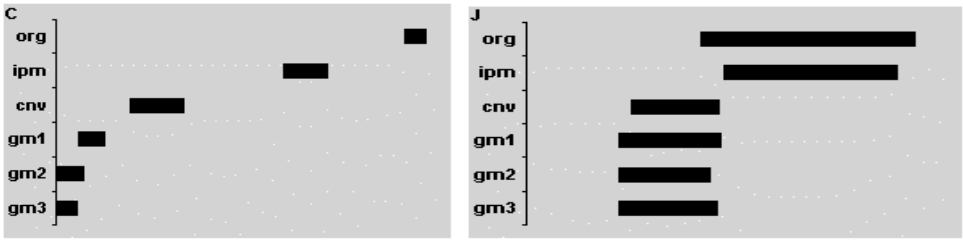
MCM employs techniques adapted from decision analysis. It involves iterative open-ended appraisal of an unlimited set of policy or technology options under an unconstrained array of evaluative criteria. Performance is characterised under each perspective on a numerical rating scale, with explicit attention to a wide range of pessimistic and optimistic assumptions. Criteria priorities are represented by numerical weightings. Specialised computer software generates graphic representations of option performance and permits comprehensive sensitivity testing, addressing key aspects of social contingency and potential surprise. Institutional ignorance is addressed by including different bodies of knowledge, societal ignorance by allowing explicit attention to properties like flexibility and portfolio diversity (Stirling, 1994; 1998; Stirling and Mayer, 2000). The technique can address issues of principle as well as

trade-offs. It can be employed in individual interview or small group settings to characterise different stakeholder viewpoints.

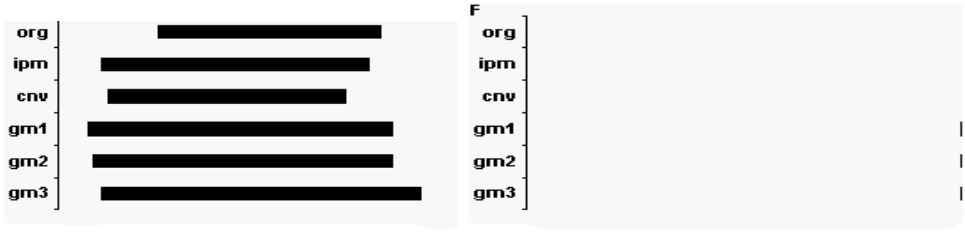
A stylised picture of the kind of results obtained from such an exercise is provided in Box 4. Each chart shows an appraisal of the relative performance of six different options for the production of oilseed rape (comprising, from top to bottom, organic farming, integrated pest management, conventional intensive farming and three different genetic modification strategies). The ten diverse viewpoints are grouped according to whether they represent government, industry, public interest or academic perspectives. The horizontal scale indicates overall performance, good (low risk) to the right, poor (high risk) to the left. The individual perspectives are not aggregated. The effect is to convey very graphically the full implications of variabilities due to divergent perspectives and the uncertainties due to different assumptions.

BOX 4:
DIVERGENT VIEWS OF RISKS OF DIFFERENT AGRICULTURAL OPTIONS

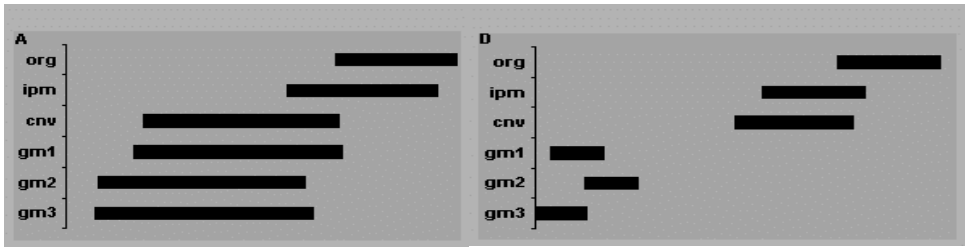
academic scientists

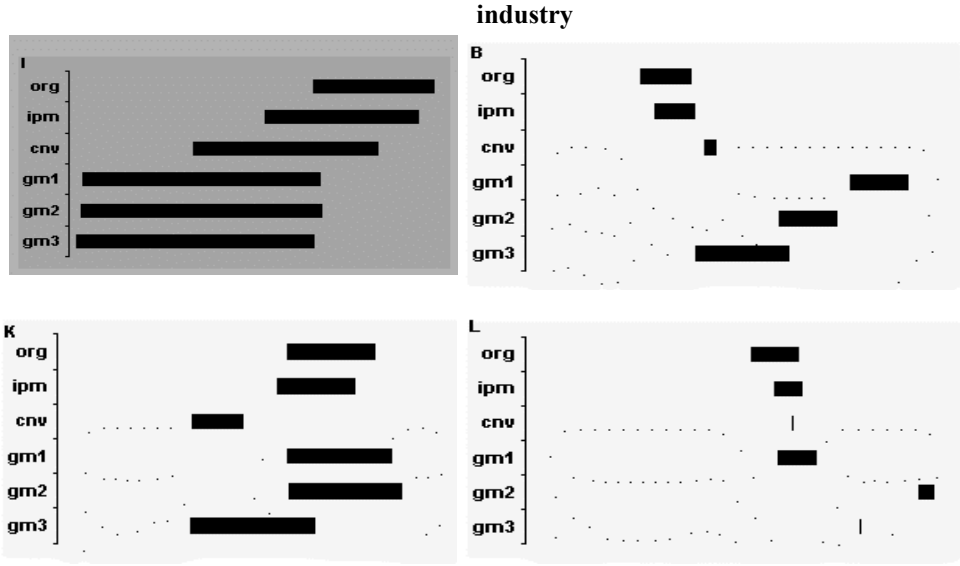


government advisers



public interest





Although like risk assessment MCM harnesses quantitative methods, these are used in a qualified 'conditional' fashion to explore and 'map' the consequences of different values and perspectvies rather than to prescribe the consequences of a particular set of assumptions. Attention is focused pragmatically on clear orderings of options generated under each perspective. Common ground can readily be identified, yielding conclusions that are all the more robust for being founded on detailed consideration of dissenting views. Yet, because no one prescription is made, this is achieved without sacrificing an appropriate degree of humility concerning the problems of ambiguity and ignorance. The freedom permitted in choosing and defining options, criteria, weightings, framing assumptions and 'pessimistic' and 'optimistic' scenarios, serve to address the intrinsic complexity, contingency and open-endedness in the social appraisal of risk. In short, an approach such as MCM can be claimed to address – at least in principle – all the key features of a broad-based precautionary approach in a form which can be practically implemented in realistic way.

VII. Conclusion

This paper has raised serious questions over the frequent assertion that 'precautionary approaches' to the appraisal of risk are somehow less scientific than conventional risk assessment. Indeed, the greater breadth of scope and the attention to diversity embodied in a precautionary approach may be seen as being more scientifically robust than the

relatively narrow and uncertainty-suppressing tendencies of supposedly 'science based' approaches like cost benefit analysis and risk assessment. The ostensible precision of conventional risk assessment can often conceal enormous ambiguity, thus both undermining policy effectiveness and infringing some of the basic principles of rational choice on which such 'science based' approaches are founded.

At first sight, the key requirements of a precautionary approach may seem somewhat daunting. Themes like humility over science, increased completeness of scope, attention to pros and cons, considering a range of alternatives, involving a diversity of disciplines and perspectives and greater emphasis on research and monitoring may seem to raise challenging operational and resource questions. But the practical example of multi-criteria mapping shows that, in principle at least, there is no reason to suppose that such aspirations need in any way be seen as unworkable, or even unduly onerous. In the end, the real value of more precautionary approaches to the appraisal of risk will lie in the benefits of encouraging less risky technologies, identified and deliberately fostered at an earlier stage in the innovation process.

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REFERENCES

Arrow, 1963 — K. Arrow, *Social Choice and Individual Values*, Yale University Press, New Haven

Bezembinder, 1989 — T. Bezembinder, Social Choice Theory and Practice, in C. Vlek and D. Cvetkovitch, *Social Decision Methodology for Technological Project,* Kluwer, Dordrecht EEA, 2001

Fisher and Harding, 1999 — E. Fisher, R. Harding (eds) *Perspectives on the Precautionary Principle*, Federation Press, Sydney

Funtowicz & Ravetz, 1990 — S. Funtowicz, J. Ravetz, *Uncertainty and Quality in Science for Policy*, Kluwer, Amsterdam

Hayek, 1978 — F. von Hayek, *New Studies in Philosophy, Politics, Economics and the History of Ideas*, Chicago University Press

Loasby, 1976 — B. Loasby, *Choice, Complexity and Ignorance: am inquiry into economic theory and the practice of decision making*, Cambridge University Press, Cambridge

O'Riordan & Cameron, 1994 — T. O'Riordan, J. Cameron, *Interpreting the Precautionary Principle*, Earthscan, London

O'Riordan & Jordan, 2001 — T. O'Riordan A. Jordan, *Reinterpreting the Precautionary Principle*, Cameron May, London

Raffensberger & Tickner 1999 — C. Raffensberger, J. Tickner (eds) *Protecting Public Health and the Environment: implementing the Precautionary Principle*, Island Press, Washington, 1999

Smithson, 1989	M. Smithson, *Ignorance and Uncertainty: emerging paradigms*, Springer, New York
Stirling and Mayer, 1999	A. Stirling S. Mayer, Rethinking Risk: a pilot multi-criteria mapping of a genetically modified crop in agricultural systems in the UK, SPRU, University of Sussex
Stirling and Mayer, 2000	A. Stirling, S. Mayer, Precautionary Approaches to the Appraisal of Risk: a case study of a GM crop, *International Journal of Occupational and Environmental Health*, 6(3), October-December
Stirling, 1994	A. Stirling, 'Diversity and Ignorance in Electricity Supply Investment: addressing the solution rather than the problem', *Energy Policy*, 22, 3
Stirling, 1997a	A. Stirling, Limits to the Value of External Costs, *Energy Policy*, 25(5).517-540
Stirling, 1997b	'Multicriteria Mapping: mitigating the problems of environmental valuation?', chapter in J. Foster (ed), *'Valuing Nature: economics, ethics and environment',* Routledge, London
Stirling, 1998	A. Stirling, Risk at a Turning Point?, *Journal of Risk Research*, 1(2) 97-110
Stirling, 1999	A. Stirling, On 'Science' and 'Precaution' in the Management of Technological Risk, report to the EU Forward Studies Unit, IPTS, Sevilla, EUR19056 EN
Stirling, 2001	A. Stirling, Risk, Uncertainty and Precaution: some instrumental implications from social science, in F. Berkhout, M. Leach, I. Scoones, (eds), Negoiating Change, Elgar, 2002
Wynne, 1992	B. Wynne, Uncertainty and Environmental Learning: reconceiving science and policy in the preventive paradigm, *Global Environmental Change*, 111-127

NOTES

[1] This paper draws on an earlier piece by A. Stirling and S. Mayer for the International Journal of Occupational and Environmental Health (2000)

COMMENTS ON THE COMMISSION'S COMMUNICATION ON THE PRECAUTIONARY PRINCIPLE

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I. Introduction

The EC codified the precautionary principle in 1993 by inserting it into Article 130R para 2 of the EC Treaty, next to the prevention principle. The Commission presented its Communication on the principle in the year 2000. Strange as this order might seem, it is to be preferred over the opposite line of action in some of the European Union's Member States. In the Netherlands, the idea that the quality of the general Environmental Management Act might be enhanced by laying down the precautionary principle in it was first encountered in the country's 1993 National Environmental Policy Plan.[1] By the end of the year 2001, the question whether to codify or not is still a point of investigation and further discussion.

In this contribution, it will be argued that the Communication forms a valuable contribution to the discussion on the precautionary principle. It fulfils a need for clarification on this controversial issue for the European Union itself, for the relationship between the European Union and its Member States and for the relationship between the European Union and third countries. At the same time, some points of concern remain. In the Communication, its fourfold aim is described as outlining the Commission's approach to using the precautionary principle, establishing guidelines for applying it, building a common understanding of how to assess, appraise, manage and communicate risks that science is not yet able to evaluate fully, and avoiding unwarranted recourse to the precautionary principle as a disguised form of trade protectionism. If the extensive list of detailed conditions before the principle is to be put into practice is applied too strictly, there is a risk that only the latter aim will be met.

II. The need for clarification

II.1. The European Union and its Member States

There are several reasons for clarification of the precautionary principle by the European Union. In the EU itself, the European Court of Justice has managed to set out precautionary lines of reasoning in its BSE case C-157/96 of 5 May 1998, to underline that the EC policy in accordance with Article 130R (now 174) para 2 *"is to aim at a*

high level of protection and is to be based in particular on the principles that preventive action should be taken and that environmental protection requirements must be integrated into the definition and implementation of other Community policies" and at the same time to disregard the precautionary principle in the same provision. In spite of the fact that the decision as such is in line with the precautionary principle, it is disquieting to learn that in a case that has every element of a precautionary decision, that very principle is left unmentioned five years after the principle was laid down in the EC Treaty.[2]

But there is more. The BSE case concerned the legality of EC measures. Traditionally, the ECJ has granted the Community a wide discretion where such measures are concerned, notably in the fields of agriculture and the protection of the environment. On the one hand, it is thus relatively easy for the Community to adopt precautionary measures. The ECJ only examines whether in doing so, the legislative has acted manifestly inappropriate having regard of the aim pursued. Is the measure vitiated by a manifest error or misuse of powers, or did the institutions manifestly exceed the limits of their discretion, the Court put it in Fedesa (where the ban on beef hormones was at stake),[3] Mondiet (on the legality of a driftnet ban)[4] and Bettati / Safety Hi-Tech (on the legality of a prohibition of HCHCs).[5] Thus, as long as the institutions stick to their duty to take a high level of protection as a basis for their action and apply the precautionary principle, the judiciary will not easily form an obstacle. On the other hand, if these same institutions decide not to follow a precautionary line of action, the judiciary will probably not be of much help. This implies for instance that the decisions of the Commission not to allow Belgium and Germany to ban the use of organostannic compounds as antifouling agents for all ships by 1 January 2003 as a precautionary measure – in line with IMO statements and meanwhile with an IMO decision – will be hard to challenge before the ECJ.[6]

Where precautionary measures adopted at the level of the Member States are concerned, the ECJ seems to be stricter. This is logical where such precautionary measures form an obstacle for the free movement of goods in the internal market, but the question then is whether the way in which the balancing of free trade and environment interests takes place in practice does justice to the precautionary principle. The ground thought is that Member States, in the absence of secondary legislation harmonising a particular area, are free to choose their protection levels. That was already determined at an early moment, for instance in the preliminary ruling on the Sandoz case.[7] At the same time, the ECJ did demand that the general Community rules (as explained by the Court) would be abided by, notably that Member States would prove that their measures were indeed necessary to reach the protection levels sought, and proportionate. If the latter test were to amount to a strict demand of 100% scientific proof, it is obvious that precautionary national measures would not stand a chance. In

Sandoz, the ECJ admitted itself that the degree of harmfulness of a particular food additive (namely certain vitamins) could not be determined with sufficient certainty, and that this left the Member States with a wide discretion. That discretion was limited however, the Court explained, where there existed a 'real need' for the additive in question (explained as a nutritional or technological need). If this was the case, a national precautionary measure would have to be considered as disproportional. The Dutch Council of State held that it was up to the Dutch authorities to prove that no such 'real need' existed, but came to the conclusion that this was aptly proven. Thus, in this case the national precautionary measures were possible.[8] In purely environmental protection cases it has to be awaited, whether the ECJ is willing to apply the necessity and proportionality test in a manner that does justice to the precautionary principle. This point will be returned to below, since it also concerns one of the conditions formulated by the Commission in its Communication.

Another need for clarification of the precautionary principle in the relationship between the EU and the Member States concerns the fact that at several instances the national judiciary has refused to apply the Community's precautionary principle.[9] From a narrow legal point of view this is acceptable: Article 174 addresses the Community, not individual Member States. The Nice Council conclusions did claim that the precautionary principle must also be applied by national authorities, but this political statement does not alter the text of Article 174. However, where the precautionary principle is reflected in EC directives (like for instance in the IPPC Directive), Member States are legally obliged to apply it and codify it in their national legislation. To stick with the Dutch examples, for the sake of convenience, if the Dutch claim that their above mentioned Environmental Management Act intends to implement the IPPC Directive, they will need to lay the precautionary principle down in that act - especially where the Council of State recently expressed that it was not willing to test an EMA decision allowing for polluting activities near the Wadden Sea against the precautionary principle, since this "does not constitute a principle codified in the EMA, nor a principle that the defendants within the margin of their discretionary freedom have inserted in their rules of evaluation".[10] The Communication discusses the way in which the Community itself is to apply the precautionary principle, but it would seem wise to also touch upon this aspect in future discussions.

II.2. The European Union and third countries

As far as the relationship between the EU and third countries is concerned, the trade disputes with the USA and Canada on *Beef hormones* showed several things.[11] First of all, it demonstrated that differences of opinion exist on the legality of the European ban on hormones: the Panels and Appellate Body declared that the ban was violating WTO

law, whereas the ECJ in Fedesa decided that the ban was legal under EC law. Secondly, the case demonstrated that a it is not yet accepted by all that the principle forms a ”general principle of international law” as the Communication claims, or a rule of international customary law.

The assertion made by the European Parliament in its Resolution that reference to precaution in international agreements "gives the precautionary principle the status of international customary law" whereas "its legal force needs to be strengthened in order to make it a norm in international law"[12] also raises some questions. The fact that the principle occurs in treaties could contribute to the coming into being of a rule of customary international law, but in itself does not form the proof for this. Furthermore, if the principle constitutes a rule of international customary law, it would seem to be a norm in international law already and there would be little left to strengthen in that respect.

Initial reactions from the USA to the Communication and from other countries to EC efforts of getting the topic on the agenda of Doha indicate that international consensus is not yet in reach. It also remains to be seen in which direction the discussions in the Codex Alimentarius will develop.[13] At the same time, a new potential trade conflict on precautionary EC measures with regard to GMO's might be on its way.

III. Selected elements

III.1. Lack of definition

One element missing in the Communication is a definition. The Commission claims that the absence of a definition does not necessarily lead to legal uncertainty, and that it is for decision-makers and ultimately the courts to flesh out the principle. The example of the ECJ and national cases referred to above showed that waiting for courts can lead to very meagre results in this respect. Although the Communication sets out many elements, it would have contributed to the discussion if the Commission had opted to include its own definition. An European definition might also prevent part of the criticism from the side of the United States of America, namely that there are so many different definitions and notions about precaution, that it is not possible to apply it widely. Hence, it should be referred to as an 'approach' rather than a 'principle'.

A European definition could be along the lines of the wording used in the second sentence of Principle 15 of the Rio Declaration, while omitting the elements of seriousness or irreversibility in order to circumvent discussions on whether a risk is really serious or not.

III.2. Scientific evaluation of risk

The Communication admits that ”when there are reasonable grounds for concern (...) and when at the same time the available data preclude a detailed risk evaluation, the precautionary principle has been politically accepted as a risk management strategy in several fields.” In spite of this assertion, the Communication demands that an attempt to complete as far as possible four *detailed* components of a risk assessment is to be performed. These include, as set out in an Annex, "estimations with regard to probability, frequency and severity of known or potential adverse environmental health effects liable to occur." Where possible, the scientific evaluation should "identify at each stage the degree of scientific uncertainty." This should be as complete as possible, where possible. Such requirements might stand in the way of a reasonable use of the precautionary principle. It seems hard or impossible to come up with degrees of scientific uncertainty. This element should therefore be applied in a manner that does justice to the precautionary principle.

III.3. Proportionality / cost-benefit analysis

Proportionality can be interpreted in different ways. The Communication demands that measures based on the precautionary principle must not be disproportionate to the desired level of protection. This looks like a least trade restrictiveness test. The Communication also demands that the measures must be tailored to the chosen level of protection, indicating a weighing of the potential benefits against the hindrances the measures will bring about. In practice, uncertainties with regard to the magnitude of potential risks will make it difficult to assess the proportionality of proposed action. This element should therefore not be applied too strictly. The same holds true for a cost / benefit test, where costs are relatively easy to calculate but benefits will be - per definition - more difficult to put into exact figures. The assertion made by the Commission that the examination of the pros and cons "cannot be reduced to an economic cost-benefit analysis" because it "is wider in scope and includes non-economic considerations" but that it "should include an economic cost-benefit analysis where this is appropriate and possible" indicates that especially in this respect, an open debate might prove to be very necessary in order to ensure that the potential damage to human health and the environment is given proper weight.

IV. Conclusions

Whether or not the Communication will allow for a reasonable use of the principle, or prevent the principle from performing the very function for which it was formulated will depend on the way in which the Community will apply the guidelines in concrete situations. As they are formulated now, a strict appliance of some of the guidelines in the Communication could make it difficult or even impossible to introduce precautionary measures. It should therefor be remembered that precaution stems from the German Vorsorge, which could be translated as taking care of the future. Precaution means erring on the side of caution in order to show we care about the future. It also means staying away from the boundaries where it is not sure that harmful effects will not occur. The Communication, much as it is to be welcomed for the reasons set out above, in some respects does seem to move us back in the direction of the very boundaries that the principle indicates to stay away from.

NOTES AND REFERENCES

[1] Second National Environmental Policy Plan (Nationaal Milieubeleidsplan 2), TK 1993-1994, 23 560, no. 2, at 181.

[2] Moreover, the Commission itself did not mention the principle in the export ban at issue.

[3] C-331/82 Fedesa [1990] ECR I-4023.

[4] C-405/92 [1993] ECR I-6133.

[5] C-341/95 and C-284/95 [1998] ECR I-4355 and I-4301 respectively.

[6] Commission Decision 2000/509, OJ 2000, L 205/7 and 2001/570, OJ 2001, L 202/37.

[7] C-174/82 [1982] ECR 2445.

[8] Council of State (Judicial Division), 14 November 1988, SEW 1990, 93 (note by Mortelmans).

[9] In the UK, the Duddridge case forms a well known example in this respect (R. v. Secretary of State for Trade and Industry, ex parte Duddridge and Others, [1995] EnvLR 151). A similar conclusion was reached by the Dutch Council of State (Administrative Law Division) in the case Stichting Waterpakt and Others v The Netherlands, 24 November 1999, nr. 98/1396, JM 2000/14 with note by Lambers.

[10] Council of State (Administrative Law Division) 12 May 2000, nr. E03.96.0068, AB 2000/395 with note by Freriks.

[11] WT/DS26/AB/R and WT/DS48/AB/R of 16 January 1998.

[12] EP Resolution on the Commission's Communication on the precautionary principle (COM(2000)1, point I.

[13] For further comments on this debate, see W.Th. Douma, How safe is safe? The EU, the USA and the WTO Codex Alimentarius debate on food safety issues, in: V. Kronenberger (ed.), The European Union and the international legal order: discord or harmony?, The Hague 2001, p. 181-197.

PRECAUTIONARY ASSESSMENT: A FRAMEWORK FOR INTEGRATING SCIENCE, UNCERTAINTY, AND PREVENTIVE PUBLIC POLICY

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I. Introduction

This paper presents a framework and set of procedures to implement the precautionary principle in environmental and health decision-making in the United States and elsewhere. The precautionary principle was developed to guide decision-makers where threats of serious harm existed, yet scientific evidence was insufficient to determine their specific type and magnitude.[1,2] While its interpretation and implementation have been debated in Europe for two decades, discussions about the principle are just beginning in the United States. Given substantial differences in the American environmental regulatory system, there is a need to translate precaution into a U. S. context. Precautionary Assessment can be a critical step towards infusing precaution as an overarching guide to environmental and health decision-making in the United States, overcoming some of the key barriers to its implementation in this country.[3,4]

The precautionary principle is conventionally understood to include two main components: action in the face of uncertainty; and placing the burden of proof on proponents of potentially harmful activities. These elements lead to interpretation of the precautionary principle as reactive, based on analyzing and responding to problems rather than proactively seeking solutions. This interpretation runs counter to its origins in the German Vorsorgeprinzip, which was meant to stimulate careful planning and innovation for job creation and sustainability.[5] Participants in the Wingspread Conference on the Precautionary Principle added two elements to restore the original spirit of the principle: assessment of alternatives and democratic decision-making structures.[6] These elements refocus environmental policy on seeking prevention opportunities and increase the information base and legitimacy of decision-making processes. Precautionary Assessment attempts to build all four components into administrative decision-making. It can be used to guide both public and private decisions.

II. The Fundamentals of Precautionary Assessment

Precautionary Assessment integrates prevention and care in environmental health policy. The goal is not to replace existing decision-making structures but rather to reorient them to support preventive, precautionary decisions. Central to this framework are flexibility, continuous feedback and learning, and a diverse portfolio of information, constituencies, and scientific and policy tools used in the decision-making process. This ”portfolio” or ”heuristic” approach focuses attention on the bulk of experience and understanding (e.g., of similar activities), in addition to the details of particular hazards. As such, it facilitates preventive decision-making on a chemical-by-chemical, activity-by-activity basis, as well as by broad categories of hazards.
Precautionary Assessment requires the following changes to current environmental health decision-making processes:

1. Precautionary Assessment redirects the questions asked in environmental decision-making. Instead of asking ”How safe is safe”; ”What level of risk is acceptable”; and ”How much contamination can a human (usually a healthy adult male) or ecosystem assimilate without showing any obvious adverse effects?” we must ask such questions as: ”How much contamination can be avoided while maintaining necessary values?”; ”What safer alternatives might achieve the desired goal?”; and "Do we need this activity in the first place?” In its simplest sense, Precautionary Assessment moves the focus from risks, which are highly uncertain and difficult to measure, to solutions to problems, for which we may have a greater certainty. It helps to partially avoid the all too common debates about whether the risk has been characterized accurately. In the end, the reasonableness of risk must be a function of the availability of alternatives to prevent harm.

2. Precautionary Assessment alters the basic assumptions of environmental and health decision-making. Rather than assume that specific substances or activities are safe until proven dangerous, Precautionary Assessment makes presumptions in favor of protecting the environment and public health under uncertainty. This places the responsibility for developing information, regular monitoring, demonstrating relative safety, analyzing alternatives, and preventing harm on those undertaking potentially harmful activities. It also facilitates government action to prevent harm and allows agencies to take action regarding potentially harmful activities. It lowers the amount and strength of evidence needed before preventive action can take place. Humans

and the environment, rather than a particular substance or action, receive the benefit of the doubt under scientific uncertainty and ignorance.

3. Precautionary Assessment modifies environmental decision-making to permit a more careful consideration of technologies and activities. For new activities, the framework establishes ”speed bumps,” which may slow but do not stop the development process. For example, a tiered permitting process (where the activity is allowed to proceed slowly as different types of evidence are presented) might be instituted for a new activity with poorly understood impacts. For both new and existing activities, Precautionary Assessment involves more careful, ongoing consideration of all available evidence on impacts and detailed analysis of the least hazardous ways to achieve a specific purpose. Evidence of potential harm from various disciplines, magnitude of potential effects, uncertainty, and availability of alternatives and preventive opportunities are considered together to determine precautionary courses of action. Often the availability of alternatives is sufficient reason to take preventive action, even if only a suspicion exists of potential impacts.

4. Precautionary Assessment expands the range of participants in risk decisions., Environmental decisions tend to be primarily policy decisions, due to high scientific uncertainty. They are also public decisions, affecting human health or public resources. The framework more effectively incorporates those potentially affected by substances and activities in the decision-making process. This requires transparent decision-making processes and structures for increasing citizen control in all phases of science and technology decisions.

5. The framework reconfigures the science used for public policy. Precaution needs to be embedded in all phases of science, including the research agenda. Incorporating the Precautionary Principle in environmental science requires an a priori commitment to taking care and providing information to inform preventive policy. This leads to changes not only to the questions asked but also to the methods of science. These changes include: broadening hypotheses to examine systems and cumulative and interactive effects of multiple stressors; a greater reliance on interdisciplinary approaches; the integration of critical qualitative and quantitative information; and more explicit discussion about uncertainties.[7, 8]

Precautionary Assessment incorporates some of the tools central to current environmental decision-making structures, such as risk assessment and cost-benefit

analysis, , but does not use them as the sole basis for decisions. Instead of using them to quantify ”acceptable” risks, decision makers can use them to quantify potential impacts, compare alternatives to an activity (or to establish priorities), and better understand trade-offs inherent in environmental decision-making.[9]

Precautionary Assessment provides a structural approach to agency priority-setting by ranking hazards based on evidence of harm, accumulated experience and understanding, and opportunities to prevent harm. By focusing on alternatives, it reorients agency attention to what can be done, rather than what cannot be done due to limited resources. This can result in efforts to establish goals for prevention and ”master plans” that array actions to be taken to achieve certain outcomes.

III. Applying Precautionary Assessment

Precautionary Assessment represents a framework and set of procedural steps designed to embed precaution in both the science and policy of environmental decision-making. It incorporates broad problem frame, thorough examination of alternatives, and an approach to science that expands the considerations, disciplines and constituencies involved in the collection and weighing of scientific evidence and ultimate decision-making process.

Precautionary Assessment incorporates a process flow that emphasizes flexibility. This is substantially different than the more rigid, formulaic four-step approach to risk-assessment and management set forward by the U. S. National Research Council[10], yet is consistent with approaches to sound decision-making proposed in many business texts.[11] There are four reasons why a process flow is more useful than the prescriptive rules currently used in environmental decision-making:

- Each decision is different--with different types of evidence, uncertainty, affected communities, and availability of alternatives.

- A more generalized approach permits a wider range of information to be used in the decision-making process and allows for more qualitative judgments in the face of uncertainty and complexity.

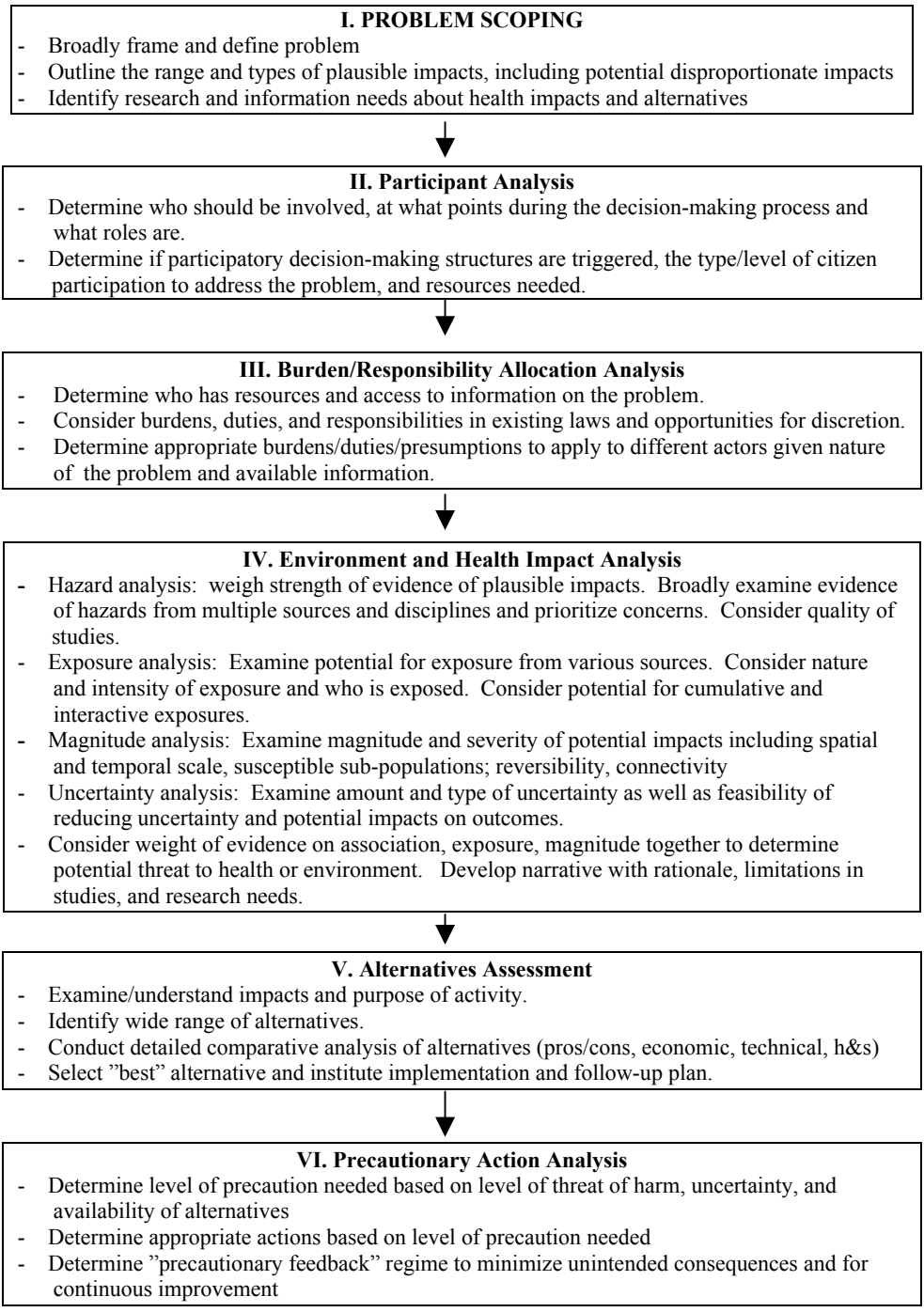
- A process flow does not oversimplify or narrow the decision-making process. Rather, it lays out a series of procedural steps that should be considered in all sound environmental and health decision-making processes.

- Since many environmental health decisions are made in the face of great uncertainty, yes/no or quantitative determinations are often not warranted by the available data and thus a broader range of options and considerations must be included.

A complete Precautionary Assessment would include all six of the procedural steps outlined in *Figure 1*. It is not necessary for each component to be completed in order and components may overlap or be repeated at several stages. However, it is clearly important to begin with a holistic definition of the problem as that will affect each of the following steps. While it may appear cumbersome, the process should be thought of as a heuristic device and normative considerations to guide sound, preventive environmental decision-making rather than an inflexible set of steps that must be completed in a particular way. In most cases, certain steps can be completed relatively quickly (e.g., Scoping, Participant Analysis, Burden Allocation). Depending on the nature of the problem and evidence other steps can be completed in a relatively rapid fashion, without extensive quantitative analysis. Often, steps can be bypassed or the extent of analyses reduced, as when strong evidence of safer alternatives exists or there is an established presumption of potential harm.

The order of steps in the process flow is similar to the progression of current environmental decision-making processes. The process flow is similar to one proposed by a 1975 U.S. National Research Council report, Decision Making for Regulating Chemicals in the Environment[12]. In that report, the panel recommended a generic procedure for decision-making on chemicals, acknowledging that there was no scientific formula for making such decisions.

Figure 1: The Steps of Precautionary Assessment



IV. Environmental and Health Impact Analysis

A centerpiece of Precautionary Assessment is the Environment and Health Impact Analysis (EHIA), in which the science of hazards and exposures is weighed. In this step, evidence of risks and uncertainties are examined to determine the possibility (and plausibility) of a significant health threat and the need for precautionary action. As many environmental risks are complex and highly uncertain, such an analysis must involve both the totality and individual pieces of the evidence for plausible indications of effects. The goal is to build a coherent picture of potential impacts--a "story." In Precautionary Assessment, this analysis is completed using a "research synthesis"[13] or weight of evidence approach. For example, in examining the health and environmental impacts of persistent and bioaccumulative substances in the Great Lakes, the U.S.-Canada International Joint Commission (IJC) defined the weight-of-evidence approach as follows:

The approach takes into account the cumulative weight of the many studies that address the question of injury or the likelihood of injury to living organisms. If, taken together, the amount and consistency of evidence across a wide range of circumstances and/or toxic substances are judged sufficient to indicate the reality or a strong probability of a linkage between certain substances or class of substances and injury, a conclusion of a causal relationship can be made.[14]

The IJC definition answers the question, "How and when do we know there is sufficient evidence or accumulated knowledge so that a reasonable person will conclude that policy makers should act?"

Experience on the U.S. Institute of Medicine's Committee on Agent Orange – where a research synthesis approach was used to determine whether an association existed between human exposure to herbicides used during the Vietnam War and dioxin contamination and adverse effects in humans - showed that when evidence is limited and uncertain, information is most appropriately presented in terms of categories of evidence rather than continuous, quantitative estimates of risk--although quantitative estimates may be integrated into the categories.[15] The Environment and Health Impact Analysis is a categorical approach.[16] Categorical presentations of evidence are supplemented by concise, yet detailed narratives describing the nature of evidence upon which the categories were determined (e.g., limitations in studies).

The categorical, or graded classification, approach has two important benefits over traditional "continuous" risk variable approaches for analyzing and presenting uncertain information. First, it provides greater accountability by providing clarity about the nature of the available evidence and choices in the analysis, instead of hiding behind a single number based on multiple assumptions which may be hidden. Numerical

determinations often ”crumple” information into a single value, losing track of nuances and qualitative details about that information. Further, by definition, the concept of ”risk” requires that probabilities of occurrence are fairly well understood, whereas in most environmental health decision-making available information and uncertainties do not allow for such precision.

Second, it opens up greater opportunities for prevention and intervention. Unpacking information on hazard, exposure, magnitude, and uncertainty, provides greater flexibility, understanding of the nature of potential impacts, and opportunities for preventive interventions in decision-making.

The Environment and Health Impact Analysis should include consideration of the wide range of sources of information and plausible harms and impacts identified during Problem Scoping. Who should conduct this analysis will depend on the nature of the problem (e.g., small localized decisions versus decisions on whole classes of substances). Evidence of potential impacts and uncertainties should be gathered from as diverse an array of disciplines and constituencies as possible, including: observational studies, worker case histories and case reports, toxicological studies, wildlife and domestic animal studies, cellular studies, ecological assessments, epidemiologic studies, community health studies, structure activity analyses, modeling, and monitoring. Impacts examined in the analysis should include human and ecosystem health impacts; acute and chronic effects; interactive and cumulative effects; direct and indirect impacts; and socio-economic, historical, and aesthetic impacts. Since the list of plausible impacts might be very large, it is useful to prioritize by impacts of greatest concern from a scientific and political point of view.

While the studies and other information should be evaluated for their quality--strength of the methods, questions asked, source, bias, confounding, and peer review--anecdotal information, including single case reports or case series, and ”lay” collected data should also be considered. If there are conflicts in the results and conclusions of individual studies, the strength of the studies becomes an important consideration in weighing evidence.

The *four steps* of Environmental and Health Impact Analysis include:

- *Hazard Analysis*: The purpose of this step is to understand the strength and quality of the evidence that there is or could be a detrimental effect. Studies and potential impacts are examined individually and as a whole. When possible, meta-analyses can be performed to provide more detailed information. Inherent properties in the activity or substance that could lead to adverse impacts are considered.

- *Exposure Analysis*: In this step, evidence of actual or potential exposure is gathered from various sources. The nature (direct, dispersive, controlled, closed-system) and intensity of exposure are analyzed as well as when and to whom exposure occurs, including the potential for cumulative and interactive exposures.
- *Magnitude Analysis*: In this step, evidence on the seriousness of potential impacts is examined, including: spatial and temporal scales of effects; potential catastrophic impacts; susceptible sub-populations; reversibility of adverse effects; and degree of connectivity of effects. When the potential magnitude of effects is large, weaker evidence provides a cause for concern.
- *Uncertainty Analysis*: This step includes both a qualitative and quantitative assessment of gaps in knowledge. Uncertainty should be analyzed broadly in terms of type (parameter, model, systemic, ignorance), sensitivity to changing assumptions, and feasibility of reducing uncertainty.

The results of these sub-analyses are combined into a final *Environment and Health Impact Analysis*. Here, the weight of the evidence of potential or actual harm for a particular hazard or group of hazards are be presented as one of five categories (based on analyses of hazard, exposure, and magnitude) and a concise, detailed narrative outlining the rationale for the categories, the evidence on which the determination was based, and other quantitative and qualitative considerations

The narrative should be clear about what is known, not known, and can be known about the threat (and suspected), limitations of scientific studies to understand the threat, and gaps in information, including research needs. The narrative should also indicate the extent to which uncertainty, and particularly ignorance, can be reduced through additional research. Quantitative evidence such as uncertainty analyses and quantitative assessments of risk should be included in this narrative and final categorical determination. The plausibility and probability of various outcomes should be considered. Finally, the strength of the evidence and categorical recommendation should be outlined. The analysis provides a determination, based on the weight of evidence, as to whether an activity is associated with or may cause harm, and the potential severity of that harm. While this research synthesis process is most applicable to determining whether there is enough evidence to take precautionary action on existing activities, it could also be applied to determining whether it is appropriate to restrict or otherwise act on new activities.

V. Alternatives Assessment

The other centerpiece of Precautionary Assessment is a thorough evaluation of alternatives to prevent or minimize harm. Alternatives assessment is the heart of the solutions-oriented approach of the precautionary principle, and central to sound, forward-looking environmental decision-making. This focuses decision-making attention on solutions and opportunities rather than simply the hazards associated with a narrow range of options.[17] In the end, acceptance of a risk must be a function not only of hazard and exposure but also of uncertainty, magnitude of potential impacts and the availability of alternatives or preventive options. Availability of a safer alternative can obviate the need for a costly, contentious, and potentially misleading quantitative risk assessment.

The goal of alternatives assessment is to identify and examine opportunities to prevent environmental health impacts from an activity. A secondary goal is to drive innovation toward more environmentally friendly and sustainable technologies, products, and practices. Thus, alternatives assessment should consider not only existing, easy and feasible options, but also those that can be developed – that are ”on the horizon.” Critics of the precautionary principle have argued that it paralyzes innovation and development of new technologies. However, the use of alternatives assessment in a precautionary context can embrace and encourage development of innovative, cleaner technologies. A thorough alternatives assessment may identify needs for cleaner technologies, which in turn can inform the planning of sustainable economic development activity.[18]

The most effective alternatives assessments start with a broad problem definition and address multiple risks at once (e.g., multiple chemicals, media, or facilities). Alternatives should be considered in terms of substitution, modifications to an activity that would prevent impacts (prevention opportunities), as well as stopping an activity or preventing its initiation. Alternatives assessments often have the most impact when undertaken early in a decision-making process – in the development phase.

Nonetheless, Alternatives Assessment requires tools to comprehensively analyze not only risks but also feasibility of alternative technologies and products. A variety of methodologies exist to evaluate technology and policy alternatives and to identify potential unintended consequences.[19] The steps of an alternatives assessment should include:

- Examination and understanding of the impacts and purpose of the activity. The purpose of this step is to better understand the ”service” that the activity provides (and whether that service can be provided in

a less damaging way), how hazardous materials are used (materials accounting); and potential impacts and benefits of the activity

- Identification of a wide range of options. Here, a diverse group of stakeholders should brainstorm a wide range of options that could lead to multi-risk reduction opportunities.
- Comparative analysis of alternatives. The goal of comparative options analysis is to thoroughly examine and compare technical feasibility and economic, environmental, and health and safety impacts and benefits from the existing or proposed activity and identified alternatives.
- Alternatives selection. The alternatives plan should contain an analysis of the selected alternative, how it will be implemented (including how barriers will be addressed) and a plan for follow-up, continuous improvement, and monitoring for potential adverse impacts.

VI. Precautionary Action Analysis

The last part of precautionary assessment is determining the appropriate course of action. This could be considered the ”risk management” phase of the decision process, yet it is fully integrated into all of the previous steps. Precautionary Action Analysis involves weighing the information gathered earlier to determine how much and what type of precaution should be taken. Policy tools for implementing precautionary action and preventing harm, ranging from further study to banning the activity, are chosen based on the severity of the risk, uncertainty involved, and availability of feasible alternatives. Finally, a feedback and monitoring scheme is developed to measure benefits and provide early warning of potential problems. The determination of actions is not based on a specific threshold for action but rather considers all of the available evidence in determining the most health-protective, yet reasonable, course of action. Precautionary assessment may also result in a decision that an activity is unlikely to cause harm or that its impacts would be minimal – in which case institution of a monitoring scheme may be the most appropriate action step.

The selection of actions will depend on the decision and may depend heavily on the legislation or regulation under which a particular activity is being addressed. The most preventive and flexible decisions will apply an array of actions. For example, prevention planning requirements (what are those?) could be combined with public right to know. Or a permitting process could be step-wise, contingent on testing and providing evidence of relative safety at each step. The final choice of actions should integrate all

the considerations--technical, political, social, ethical, and economic--that form part of sound environmental decision-making practices. It should also consider the ability to monitor for early warnings, adaptability, and ease of compliance/enforcement.

Some possible actions to apply precaution in chemicals policy, include: extended producer responsibility requirements, assurance bonding, pre-market review and study requirements; environmental impact statements, ecological taxes, right to know requirements, compensation for damages, and adaptive management. Two in particular merit more discussion:

- *Clean production and pollution prevention*. Clean Production and pollution prevention involve changes to production systems and products to reduce pollution at the source (in the production process or product development stage). This includes reducing the raw material, energy, and natural resource inputs (dematerialization) as well as reducing the quantity and harmful characteristics of toxic substances used (detoxification) in production systems and products[20, 21].

  The Massachusetts Toxics Use Reduction Act represents one concrete, effective application of pollution prevention and precaution. The Act encourages firms to identify ways to reduce their reliance on toxic substances rather than calculate acceptable emissions levels. Firms are required to understand how they use chemicals and for what purposes. They must then develop plans to reduce their waste and use toxic substances and measure progress. In the ten years following the Act, toxic chemical emissions have been reduced more than 80 percent; toxic waste, 57% percent; and toxics use, 40% percent, indexed for changes in manufacturing activity. Massachusetts firms have saved more than $15 million in the process, excluding unquantifiable benefits to health and the environment.[22]
- *Goal-setting and quality objectives*. Goal-setting involves the establishment of aggressive, preventive health goals and development of policies and measures to achieve those goals, while minimizing social disruption and unintended consequences (also known as ”backcasting”). Goal-setting focuses not on what futures are likely to happen but rather on how desirable futures can be obtained. Some categories of goals include: (1) goals for reducing exposures to hazardous substances; (2) goals for reductions in hazardous substances and activities; and (3) goals for reductions in the incidence of environmentally related diseases. It has been suggested that one might set a goal of reducing general population body burdens of broad classes of potentially toxic substances by 5 to 10% per year.[23] Such an effort is likely to have a positive health impact, even if it will probably never be possible to understand with

confidence all of the ways that mixtures of low concentrations of chemicals may affect health.

The chemicals policies of various European countries begin with a series of short and long term goals, including: phase-outs of the most dangerous substances, goals for reducing emissions, and goals for the collection of information. These goals are coupled with the establishment of ”red flags”, deterrent signals as to which substances and activities are undesirable – for example lists of chemicals of concern, research and development into alternatives, and flexible agreements with affected industry sectors to achieve goals (covenants).[24] The ”substitution” principle, which states that those handling chemical products must take all precautions necessary to prevent or minimize harm to humans or the environment, including avoiding chemical products for which less hazardous substitutes are available, is at the heart of many of these policies.[25]

Decisions made under a precautionary assessment should not be considered permanent, but part of a continuous process of increasing understanding and reducing overall impacts. Once precautionary actions have been chosen, follow-up and monitoring schemes for the activity should be developed. This type of feedback is critical to understanding the impacts of precautionary actions, as well as to provide early warnings of harm. It also stimulates continuous improvement in environmental performance and technological innovation. Follow-up tools include: periodic assessment, audit, or prevention planning requirements; regular reporting of environmental impacts (e.g., toxics use reporting); short- and long-term health and exposure monitoring; toxicological testing; and impact statements any time a major change is made to a product, process, or activity.

VII. Conclusion

Precautionary Assessment represents one tool for integrating precaution into administrative decision-making in the U.S. It incorporates a forward-looking, truly preventive approach, faithful to the original intent of the Vorsorgeprinzip, and can lead to greater innovation as well as better protection of human health and the environment. It provides a new role for scientific research and public policy that expands the constituencies, disciplines, and considerations involved in decision-making under conditions of uncertainty and complexity. However, broad implementation of the precautionary principle in the United States will require important changes in the conduct of environmental science and policy as previously noted, modifications in the

ways that courts review agency decisions, and new and reinvigorated political mandates for government agencies and businesses to act in a precautionary manner. Given increasing evidence of the impacts of toxic substances on health and ecosystems, public awareness and concern about these impacts, and growing discussions on the role of the precautionary principle in chemicals policy, these changes may well slowly be implemented in coming years.

NOTES AND REFERENCES

[1] Tickner, J. with C. Raffensperger. 2001. The American view on the precautionary principle. In Reinterpreting the Precautionary Principle, ed. O'Riordan, T, J. Cameron, and A. Jordan. London: Cameron and May.

[2] Raffensperger, C. and J. Tickner. 1999. Protecting Public Health and the Environment: Implementing the Precautionary Principle. Washington, DC: Island Press.

[3] Barriers to implementation of the precautionary principle in the United States include the inflexible, prescriptive of the American regulatory system and increasingly rigorous judicial review of agency decisions which results in the necessity for agencies to defend decisions quantitatively using a "rational" approach. See Tickner, J. 2000. Precaution in Practice: A Framework for Implementing the Precautionary Principle. Dissertation, Department of Work Environment, University of Massachusetts Lowell.

[4] Tickner and Raffensperger, 2001.

5 Boehmer-Christiansen, Sonja. 1994. The Precautionary Principle in Germany - Enabling Government. In Interpreting the Precautionary Principle, ed. Timothy O'Riordan and James Cameron: 31-60. London: Earthscan.

[6] See Raffensperger and Tickner, 1999

[7] For a more detailed discussion see, Kriebel, D, J. Tickner, et al. 2001. The Precautionary Principle in Environmental Science. Environmental Health Perspectives 109: 871-876.

[8] The Lowell Center for Sustainable Production, University of Massachusetts Lowell, hosted a September 2001 International Summit on Science and the Precautionary Principle where the integration of science in precautionary policies was discussed. A Summit statement, summary, and presentations are available at www.uml.edu/centers/lcsp/precaution

[9] See Tickner, 2000 for further discussion

[10] National Research Council. 1983. Risk Assessment in the Federal Government: Managing the Process. Washington, DC: National Academy Press.

[11] See Hammond, J, Keeney, R, and Raiffa, H. 1999. Smart Choices: A Practical Guide to Making Better Decisions. Cambridge, MA: Harvard Business School Publishing.

[12] National Research Council. 1975. Decision-Making for Regulating Chemicals in the Environment. Washington: National Academy of Sciences.

[13] Stoto, Michael. 2000. Research Synthesis for Public Health Policy: Experience of the Institute of Medicine. In Meta-Analysis in Medicine and Health Policy, ed. D. Stangl and D. Berry: 321-357. New York: Marcel Dekker.

[14] U.S.-Canada International Joint Commission. 1994. Applying the Weight of Evidence: Issues and Practice. U.S.-Canada International Joint Commission. Windsor, Ontario: International Joint Commission.

[15] Institute of Medicine. 1993. Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam. Washington, DC: National Academy Press.

[16] See Tickner, 2000 for further discussion. These categories are much like those used by the International Agency for Research on Cancer. Each of the four sub-analyses of Environmental and Health Impact Analysis have a set of categorical representations. For example, those used in Hazard Analysis include: Sufficient evidence of a hazard; limited/suggestive evidence of a hazard; inadequate/insufficient evidence to determine whether a hazard exists; and limited/suggestive evidence of no hazard

[17] O'Brien, Mary. 2000. Making Better Environmental Decisions: An Alternative to Risk Assessment. Cambridge, MA: MIT Press.

[18] Kriebel, D. and J. Tickner. 2001. Re-energizing Public Health Through Precaution. American Journal of Public Health, vol. 91, pp. 1351-1355.

[19] See Tickner, 2000.

[20] Jackson, T, ed. 1993. Clean Production Strategies. Boca Raton: Lewis Publishers.

[21] Geiser, K. 1999. Cleaner production and the precautionary principle. In, Protecting Public Health and the Environment: Implementing the Precautionary Principle, eds. Raffensperger, C. and J. Tickner: pp. 323-336. Washington, DC: Island Press.

[22] Massachusetts Toxics Use Reduction Institute. 1997. Massachusetts is Cleaner and Safer: Report on the Toxics Use Reduction Program. Lowell, MA: Massachusetts Toxics Use Reduction Institute. See also www.turi.org.

[23] Jackson R. Unburdening Ourselves. Silent Spring Review. Newton, MA: Silent Spring Institute; 1998, pp. 6-8. Available at www.silentspring.org.

[24] See Tickner, J. and P. Hoppin. 2000. Children's Environmental Health: A Case Study in Implementing the Precautionary Principle. International Journal of Occupational and Environmental Health, vol 6, pp. 327-334.

[25] Wahlstrom, Bo. 1999. The Precautionary Approach to Chemcials Management: A Swedish Perspective. In Protecting Public Health and the Environment: Implementing the Precautionary Principle, ed. Carolyn Raffensperger and Joel Tickner: 51-70. Washington, DC: Island Press.

IMPLEMENTING A PRECAUTIONARY APPROACH IN DECISIONS AFFECTING HEALTH, SAFETY, AND THE ENVIRONMENT: RISK, TECHNOLOGY ALTERNATIVES, AND TRADEOFF ANALYSIS

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In the United States, a precautionary approach has been applied in various ways in decisions about health, safety, and the environment for about 30 years, much longer than recent commentaries would have us believe, and earlier than the appearance of the 'Precautionary Principle' in European law[1]. In interpreting congressional legislation, the US courts have argued that federal regulatory agencies are required to err on the side of caution in protecting workers, and to protect public health from emissions to air with an ample or adequate margin of safety. One scholar seeks to make a distinction between a precautionary approach and the precautionary principle, asserting that "[w]ith rare exceptions, US law balances precaution against other considerations, most importantly costs" and hence is better described as a preference, rather than a principle[2]. I find this distinction superficial, or at least unhelpful, if not often inaccurate, and when understood within the context of Roman/Napoleonic-law based European legal systems preferring "codes' to court-based evolution of common law, a semantic rather than a real distinction. In the United States, in a series of industry challenges to regulations, courts acknowledged that even in the case where the scientific basis for a threat to health or the environment is not compelling, regulators have the discretion to 'err on the side of caution', without laying down a requirement to do so, although the directive to do so is often found in the enabling legislation of various regulatory regimes.

In this decade, the precautionary inclinations of the American and Anglo-Saxon jurisprudential systems, as well as codified expressions of the precautionary principle in German law, for example, have found their way into multilateral environmental agreements and international law. Principle 15 of the Declaration of the 1992 UN Conference on Environment and Development [the Rio Declaration] states: "In order to protect the environment, the precautionary approach shall be widely used by States according to their capabilities. Where there are threats of serious and irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." This is perhaps the best known statement of the precautionary principle, but the word 'approach' rather than 'principle' is used, and considerations of cost are certainly present in the phrases 'according to their capabilities' and 'cost-effective measures'. Nonetheless, it is a

principle – but one to be balanced in one way or another against other principles – no different than the situation in US law. Curiously, this statement of the principle is expressed in the negative: uncertainty should not be used to delay protection, rather than a statement that protection should be embraced deliberatively even in the face of uncertainty – a subtle but important distinction. The debate in Europe today is not whether the precautionary principle is a principle, but whether it trumps other international law, particularly the manner in which risk assessment is addressed and is relevant to trade law involving the World Trade Organization[3].

What brings the precautionary principle into sharp political focus today are (1) the fact that the nature of scientific uncertainty is changing and (2) the increasing pressure to base governmental action on more "rational" schemes, such as cost-benefit analysis and quantitative risk assessment, an embodiment of 'rational choice theory' promoted by the Chicago school of law and economics. The precautionary principle has been criticized as being both too vague and too arbitrary to form a basis for rational decision making. The assumption underlying this criticism is that any scheme not based on cost-benefit analysis and risk assessment is both irrational and without secure foundation in either science or economics. This paper contest that view and makes explicit the rational tenets of the precautionary principle within an analytical framework as rigorous as uncertainties permit, and one that mirrors democratic values embodied in regulatory, compensatory, and common law. Unlike other formulations that reject risk assessment, this paper argues that risk assessment can be used within the formalism of tradeoff analysis--a more appropriate alternative to traditional cost-benefit analysis and one that satisfies the need for well-grounded public policy decision making.

The recent crescendo of commentary on the legal application of the precautionary principle, following its increased incorporation into national and multilateral environmental agreements, has focused on situations in which there are significant uncertainties about the safety, health, and environmental effects of products, technologies, and other human activities. Where those uncertainties do not exist, it is often conceded – by default if not explicitly -- that cost-benefit analysis is an appropriate approach to designing policies. This paper will argue that the precautionary approach is a more fitting basis for policy even when large uncertainties do not exist, especially where the fairness of the distributions of costs and benefits of hazardous activities and products are a concern. Furthermore, it will offer an approach to making decisions within an analytic framework, based on equity and justice, to replace the economic paradigm of utilitarian cost-benefit analysis.

I. Elements of the Precautionary Principle

The application and discussion of the precautionary principle have focused on action to prevent, or refrain from contributing to, possible serious irreversible harm to health and the environment--whether on an individual basis or in terms of widespread environmental or health consequences. In particular, the precautionary principle has become embodied in regulations directed toward persistent and/or bioaccumulative toxic substances. Here it is worth reviewing the fact that the nature of uncertainty in the problems that now concern health, safety, and environmental regulators and advocates is changing. Formerly, concentrating on the magnitude of risks and their uncertainties -- in a probabilistic sense -- consumed the attention of the decision maker. Since better science would be expected to yield a better basis for decisions, it could be argued that risk management decisions should await its arrival. Today, problems of indeterminacy and ignorance increasingly characterize the risks we face[4]. It is no longer a question of waiting for the science to be developed. The limitations of 'knowing with greater accuracy' and 'not knowing what we don't know' attend – and will continue to attend in the foreseeable future -- modern day risks and confound so-called rational approaches to dealing with these hazards. The social concern with genetically modified organisms (GMOs) or with bioterrorism are examples. The proponents of GMO's deride social attempts to exercise caution over risks we cannot estimate or imagine, but who is arguing that taking precaution against terrorism is 'irrational'? Ought we expect 'consistency' in the management of highly uncertain (i.e., indeterminable or unknowable), possibly catastrophic risks? Perhaps a different theoretical framework is needed – one outside of deterministic choice theory.

I go one step further. The precautionary principle need not be restricted to cases of irreversibility or large uncertainty of effect. It might also be applied to mitigate a harm that is ultimately reversible--if reversing the damage could be more costly than preventing it. And what of the cases in which there are no uncertainties--for example, when we know that future generations will be harmed? Cost-benefit analysis is biased against investing heavily in the present to prevent such future harm, because of the use of discounting of cost and benefit streams over time. And there are many situations in which we are aware of our ignorance: for example, we know that only a very small percentage of all chemicals in commerce have been tested for toxic effects. In these cases, too, precaution is appropriate.

However, it is not the precautionary principle per se that is amenable to replacing cost-benefit analysis as a "decision rule" for action. Nor does the precautionary principle replace risk assessment. Attempts to establish a threshold of harm above

which the precautionary principle is triggered, for example, have been less than satisfactory. Rather, a precautionary approach or principle is most useful in guiding the selection of policies, and aiding in the establishment of priorities, in an attempt to deliver justice and fairness within a more appropriate framework that cost-benefit analysis. Precaution rightly focuses on uncertainty and irreversibility as two important factors, but others must be considered as well. A complete list of the important elements must include:

- the seriousness and irreversibility of the harm addressed;

- the societal distribution of possible costs and benefits of policies and technologies;

- the technological options for preventing, arresting, reversing, or mitigating possible harm; and the opportunity costs of selecting a given policy option.

- society's inclinations regarding erring on the side of caution and erring on the side of laxity;

Uncertainties in all these elements are relevant to the precautionary principle. Since most attention has been focused on the first, this paper will give special attention to the other three.

II. The Limits of Cost-Benefit Analysis in Addressing Distributional Concerns

During the past two decades, cost-benefit analysis has become the dominant method used by policy makers to evaluate government intervention in the areas of health, safety, and the environment. In theory, cost-benefit analysis of a policy option enumerates all possible consequences, both positive and negative; estimates the probability of each; estimates the benefit or loss to society should each occur, expressed in monetary terms; computes the expected social benefit or loss from each consequence by multiplying the amount of the associated benefit or loss by its probability of occurrence; and computes the net expected social benefit or loss associated with the government policy by summing over the various possible consequences[5]. The reference point for these calculations is the state of the economy in the absence of the government policy, termed the "baseline".

The mechanics of constructing a cost-benefit analysis can be seen with reference to Table 1, which presents a relatively disaggregated matrix of the various positive and

negative consequences of a government policy for a variety of actors. The consequences are first separated into economic, health and safety, and environmental effects, and those affected are organized into policy-relevant groups of actors, such as firms, workers, consumers, and "others". Initially, the consequences are represented in their natural units: economic effects are expressed in monetary units; health and safety effects are expressed in mortality and morbidity terms; and environmental effects are expressed in damage to eco-systems, etc. Economic analysis is used to evaluate monetary costs and benefits related to economic effects. Health and environmental risk assessments inform the entries in the last two columns of the matrix.

TABLE 1
Matrix of Policy Consequences for Different Actors

Group	**Economic Effects**	**Health/Safety Effects**	**Environmental Effects**
Producers	$C_{\$}$		
Workers	$C_{\$}$	$B_{H/S}$	
Consumers	$C_{\$}$	$B_{H/S}$	
Others	$C_{\$}$	$B_{H/S}$	$B_{Environment}$

All of the consequences of a candidate policy (or regulation) are described fully in terms of the times during which they occur. What traditional cost-benefit analysis does is translate all of these consequences into "equivalent" monetary units (since a dollar/euro in an earlier time period could be invested to earn interest over time) by discounting each to present value and aggregating them into a single dollar/euro value intended to express the net social effect of the government policy.

This poses two problems. One is the difficulty, even arbitrariness, of placing a monetary value on human life, health, and safety and a healthy environment. Another is that by translating all these consequences into equivalent monetary units, discounting each to present value (since a dollar/euro invested now is expected to earn interest over time), and aggregating them into a single dollar/euro value, the effects on the economy from investing now in future health, safety, and environmental benefits are weighted far more

heavily than those benefits that occur in the future, including those to future generations.

As a decision-making tool, cost-benefit analysis offers several compelling advantages. It clarifies choices among alternatives by evaluating consequences systematically. It professes to foster an open and fair policy-making process by making explicit the estimates of costs and benefits and the assumptions upon which those estimates are based. And by expressing all gains and losses in monetary terms, cost-benefit analysis permits the total impact of a policy to be summarized in a single dollar/euro figure. (Cost-effectiveness analysis relies on a benefit-to-cost ratio, rather than a net benefit calculus but otherwise shares the other weaknesses of a cost-benefit approach.)

This final step, however, may be stretching analytic techniques one step too far. An alternative approach, called tradeoff analysis, begins in the same way as does cost-benefit analysis, but does not aggregate like effects into a single benefit or cost stream, and it stops short of assigning monetary values to non-monetary consequences. Instead, all effects are described in their natural units. The time period in which each effect is experienced is fully revealed, but future effects are not discounted to present value. Uncertainties are fully described – all kinds of uncertainties – risk, probability distributions, and indeterminacy. It is pretty hard to know what we don't know, but confidence that we have fully described the world is a proxy. Tradeoffs between worker health or environmental improvements and costs to producers and consumers are made apparent, because the different cost and benefit elements are not aggregated.

Using tradeoff analysis, politically accountable decision makers could make policy choices in a transparent manner. Who bears the costs and who reaps the benefits from a policy option would not be hidden in a single, aggregate dollar/euro figure. Decisions would be based on accountability rather than accounting. Note that while cost-benefit is formulaic – i.e., a single figure of merit is sought for a policy/regulation such as the 'net benefit' or a 'benefit to cost ratio' – tradeoff analysis seeks to 'bound the set of not clearly incorrect, i.e., unfair decisions'. This has important implications for policy choices. Under a cost-benefit framework, one can easily demand prioritization of risk-reduction options based on the ranking of net benefits or cost-benefit ratios – with choices representing violations of the ranking being allegedly inconsistent or irrational. However, where large uncertainties exist, and the distributions of risks and benefits are of concern, there is no uniquely correct prioritization scheme or metric demanding 'consistency'. Advances in risk assessment techniques and economic analysis that takes technological innovation into account (see below) can narrow the uncertainties, but can never provide a unique best answer. That process ultimately has to reflect political,

social, and value judgments – preferably informed by public participation/stakeholder processes and transparent for all to see. Taking care to include concerns for effects, their uncertainties, and their distributional consequences – i.e., exercising precaution – to make responsible, accountable decisions is possible using tradeoff analysis, but not cost-benefit analysis.

III. Promoting Rational Technology Choices

One important element often left out of the traditional cost-benefit matrix has been the consideration of technological alternatives[6]. Regulatory agencies have a mixed history in making information about cleaner and safer technologies available and promoting their adoption. Agencies could help prevent pollution and accidents by helping firms to think about their technological options in a more formal and systematic fashion.

Options for technological change must be considered according to a variety of criteria, including economic, environmental, and health and safety factors. Identifying these options and comparing them against the technology in use is called Technology Options Analysis[7]. Unlike traditional technology assessment, Technology Options Analysis does not require absolute quantification of all the variables: one has only to demonstrate, in a comparative manner, that one technology is better or worse than another in performance, health, safety, ecological effects, and so forth. It is likely to be less sensitive to initial assumptions than, for example, cost-benefit analysis, and would enable industry and government to identify more creative cost-effective solutions. Government might require industries to undertake Technology Options Analysis, instead of traditional technology assessment focusing on technologies already existing within, or easily accessible to, the firm or industry. The latter would likely address only the technologies industry puts forward; it may thus miss the opportunity to identify and subsequently influence the adoption or development of superior technological options.

Once superior existing technologies--or technologies within easy reach--are identified, industries may be motivated to change their technology out of economic self-interest, or in order to avoid future liability. On the other hand, government might either force the adoption or development of new technology, or provide technical or financial assistance. Requiring firms to change technology can itself be a risky venture. Developing a new technology or adopting a technology new to a firm or industry introduces new uncertainties and financial risks. If this is done, policy should allow for error and accommodate industry for failures in bona fide attempts to develop new technologies, for example by allowing more time or sharing the financial risk.

Whichever route is taken by government, the precautionary principle requires the investigation of technology options for the development and adoption of cleaner and inherently safer (i.e., sustainable) technologies.

IV. Which Errors Are Worse?

Policy makers must address both uncertainty about (1) the nature and extent of health, safety, or environmental risks, and about (2) the performance of an alternative technology. First, they must choose whether to err on the side of caution or risk. With regard to the first type of uncertainty, two mistakes can be made. A "Type I" error is committed if society regulates an activity that turns out later to be harmless and resources are needlessly expended. Another error, a "Type II" error is committed if society fails to regulate an activity that finally turns out to be harmful[8]. A "Type III" error is said to occur when one provides an accurate [or precise] answer to the wrong problem[9].

Similarly, where uncertainty exists on the technology side, Type I errors can be said to be committed when society mandates the development or adoption of a technology which turns out to be much more expensive or less reducing of risks than anticipated, and resources are needlessly or foolishly expended. Type II errors might be said to be committed when, because of insufficient commitment of resources or political will, a significant missed opportunity is created by which society fails to force or stimulate significant risk-reducing technology. An important distinction between a cost-benefit approach and one based on precaution is that the former is 'risk-neutral' in the balancing of costs and benefits with their attendant uncertainties, and the latter reflects 'risk averseness' for some kinds of errors.

Value judgments clearly attend decisions whether to lean toward tolerating Type I or Type II errors with regard to both risk and technology choices. This is because the cost of being wrong in one instance may be vastly different from the cost of being wrong in another. For example, banning a chemical essential to a beneficial activity such as the use of radionuclides in medicine has potentially more drastic consequences than banning a nonessential chemical for which there is a close, cost-comparable substitute. It may be perfectly appropriate to rely on 'most likely estimates' of risk in the first case and on 'worst-case analysis' in the second. A Type II error on the technology choice side was committed in the case of the Montreal Protocol banning CFCs by creating a scheme by which DuPont and ICI, the producers of CFCs, were allowed to promote the

use of their own substitute, HCFCs, rather than adopt a more stringent protocol which would have stimulated still better substitutes.

Evaluating errors and deciding which way to lean is not a precise science. However, making those evaluations and valuations explicit within a tradeoff analysis will reveal the preferences upon which policies are based and may suggest priorities.

V. Further Grounds For Invoking The Precautionary Principle

Democratic decision making. The extent to which affected parties participate in identifying, evaluating, and selecting a protective policy may influence the acceptability of the policy. In the case of a possible, but highly uncertain harm, an equitable outcome may depend more on an equitable decision-making process than on a defensible argument about the technical correctness of an outcome based on existing information. The precautionary principle may be invoked to ensure a fair decision-making process, as much as to prevent harm.

Burdens of persuasion and proof. Part of the perceived fairness of the process involves the burden of persuasion--that is, the designation of which party has the burden of demonstrating or refuting a presumed fact. This is distinct from the burden of proof--a term referring to the strength of the evidence (data and information) needed to justify taking action. Both terms are relevant in formulation of the precautionary principle.

Much discussion has focused on cause-and-effect relationships between exposure/other events and harmful effects for which a high statistical confidence level or strength of association is traditionally required. To escape the rigors of these requirements, some proponents of the precautionary principle argue that the burden of persuasion should be shifted to the proponents of a potentially harmful technology. Opponents argue against so radical a shift, pointing out that negatives are harder to prove.

Of course, uncertainties of cause-and-effect relationships are by no means the only determinations to which the precautionary principle should be, or is applied. Others are (1) the complex sets of rights and duties embodied in so-called right-to-know including (a) the duty of potential wrong-doers to generate information, (b) the duty to retain information, (c) the duty to provide access to information to the potential victims of possible harm, and (d) the duty to warn the potential victims of possible harm; (2) providing funds to mitigate actual future harm to health or the environment; (3) compensating victims of unmitigated harm, and (4) the duty to prevent harm. The

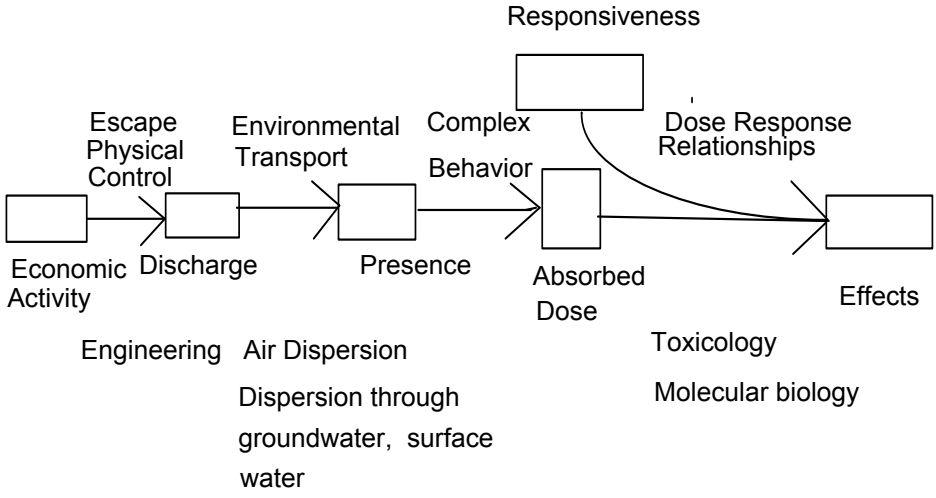
strength of the evidence required for these other, equally important factually-informed determinations may be much less than the traditional standard of proof in usual cause-and-effect determinations. [Much of the discussion of the precautionary principle focuses on cause and effect relationships for which a high statistical confidence level (p. 0.05) or strength of association is traditionally required in scientific publications. It should be remembered that the convention of requiring a p value no higher than 0.05 was an arbitrary historical choice. Critics of those wishing to invoke the precautionary principle by reducing the strength of causal proof would do well to remember this.] In addition, other ways of knowing besides statistical correlations might be pursued[10].

Other standards (burdens) of proof commonly invoked in public policy determinations include, in decreasing order of stringency: "strict liability for harm" (in the area of compensation, the "polluter pays principle" is sometimes invoked in statutory language or by the courts in fashioning equitable relief to victims), "clear and convincing evidence," "more probable than not" or "preponderance of the evidence," "substantial cause or factor," and "contributing factor." This "sliding scale" of evidentiary strength can be thought of as invoking the precautionary principle by expanding the "allowable possible error" in factual determinations. An alternative to shifting the burden of persuasion to another party is to lessen the burden of proof required to trigger an intervention to prevent or mitigate harm to health, safety, or the environment.

Also ignored by many commentators is the fact that burdens of persuasion often shift in the course of fact finding. Thus, depending on the nature of the intervention (notification, control, prevention, compensation, etc.), even if it is necessary for the regulator or potential victim initially to prove a [potential] harm, that proof is often not a high burden. A presumed fact (though a rebuttable presumption) might even be established by statute on the showing of certain other factual elements, such as the very existence of harm. Then, the burden of persuasion shifts to the intended regulated industry or alleged [potential] wrong-doer to refute the presumed or initially-established fact, often with a higher burden of proof. Legal injunctions against potentially harmful action are granted by the courts as equitable remedies. The commentators on the precautionary principle have often ignored a rich and important set of policy interventions or actions which are informed, but not dictated, by factual determinations. Regulatory agencies themselves--depending on their statutory mandates--are not bound by traditional burdens of proof. Further, reviewing courts usually give deference to factual findings by the agencies, as long as they stay within the "zone of reasonableness" defined by those mandates.

Where to Intervene. A precautionary approach should also address where control or regulation should be focused in the causal pathway the production or release of hazardous products or substances. The following figure provides a schematic of the possibilities. Waiting until ultimate health/ecological impacts are manifest is a much less precautionary approach than preventing the manufacture or use of potentially hazardous substances in the first place. The latter is described as cleaner and inherently safer production or pollution prevention and is in contrast to after-release or end-of-the-pipe control. Thus pollution prevention strategies are inherently precautionary in nature.

Figure 1
The Biological Impact Pathway



Source: N.A. Ashford, D. Hattis, E.M. Zolt, J.I. Katz, G.R. Heaton, and W.C. Priest, Evaluating Chemical Regulations: Trade-Off Analysis and Impact Assessment for Environmental Decision-Making Final Report to the Council on Environmental Quality under Contract No. EQ4ACA35. CPA-80-13, 1981. NTIS # PB81-195067.

VI. Precaution In Hindsight

It would be instructive to see how well we have fared with the implementation of the precautionary principle over the past 25 years. Scientific knowledge related to emerging health, safety, environmental, or public health problems began with a

suggestion--sometimes a mere whisper--that trouble was brewing. Those suggestions and whispers ultimately ripened into full-fledged confirmations that our worst fears were not only true; reality often exceeded those fears. Examples that come to mind include asbestos-related cancer and the toxic effects of benzene, lead, and Agent Orange--to name just a few.

The frightening, but enlightening, reality is that with few memorable exceptions, the early warnings warranted heeding and the early predictions were certainly in the right direction--even understated[11]. In retrospect, not only were all precautionary actions justified; we also waited far too long to take those actions.

Barry Commoner, in The Closing Circle, warned us to avoid exposures "not consonant with our evolutionary soup." Theo Colborn has assembled in Our Stolen Future striking examples of why this is so. Endocrine disrupting chemicals present an opportunity to act earlier, although some damage has already been done. Similarly, intervening now to prevent the next generation of developmentally or immunologically compromised, chemically intolerant persons, or otherwise chemically damaged individuals, many of them children, is both possible and necessary[12].

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NOTES AND REFERENCES

[1] de Sadeleer, Nicolas, Two Approaches of Precaution: A Comparative Review of EU and US Theory and Practice of the Precautionary Principle, Centre d'étude du droit de l'environment, Brussels, 2000.

[2] Applegate, John S. "The Precautionary Preference: An American Perspective on the Precautionary Principle" *Human and Ecological Risk Assessment* 6(3):413-443, 2000.

[3] Majone, Giandomenico, "The Precautionary Principle and Regulatory Impact Analysis" Manuscript, described as an expanded version of a paper submitted at the International Seminar on Regulatory Impact Analysis organized by Progetto AIR, Rome, 15 June 2001.

[4] Wynne, Brian, "Uncertainty and Environmental Learning," *Global Environmental Change*, June 1992, p. 111.

[5] Ashford, Nicholas A., "Alternatives to Cost-Benefit Analysis in Regulatory Decisions," *Annals of the New York Academy of Sciences*, Volume 363, April 30, 1981, pp. 129-137. See also Ashford, Nicholas A. and Caldart, Charles C. "Economic Issues in Occupational Health and

Safety,@ Chapter 5 in Technology, Law and the Working Environment, Revised Edition, Island Press, 1996, 641 pages.

[6] Ashford, Nicholas A., "The Importance of Taking Technological Innovation Into Account in Estimating the Costs and Benefits of Worker Health and Safety Regulation", in Proceedings of the European Conference on Costs and Benefits of Occupational Health and Safety 1997, The Hague, Holland, 28-30 May 1997, J. Mossink & F. Licher (eds.), 1998, pp 69-78.

[7] Ashford, Nicholas A. "An Innovation-Based Strategy for a Sustainable Environment," in Innovation-Oriented Environmental Regulation: Theoretical Approach and Empirical Analysis, J. Hemmelskamp, K. Rennings, F. Leone (Eds.) ZEW Economic Studies. Springer Verlag, Heidelberg, New York 2000, pp 67-107 (Proceedings of the International Conference of the European Commission Joint Research Centre, Potsdam, Germany, 27-29 May 1999.)

[8] Ashford, Nicholas A., "Science and Values in the Regulatory Process," in *Statistical Science*, Institute of Mathematical Statistics, Volume 3, Number 3, August 1988, pp. 377-383.

[9] Schwartz, S and Carpenter K. "The Right Answer for the Wrong Question: Consequences of Type III Error for Public Health Research" *American Journal of Public Health* 89:1175-1180, 1999.

[10] Josephson, John R. and Josephson, Susan G., Abductive Inference, 1996 Cambridge University Press, Cambridge, England, 306 pages.

[11] See, for example European Environmental Agency, Late Lessons from Early Warning: The Precautionary Principle 1896-2000, Environmental Issue Report No. 22, ISBN 92-9167-323-4, Copenhagen, Denmark 2002.

[12] Ashford, Nicholas A. and Miller, Claudia S., Chemical Exposures: Low Levels and High Stakes 1998, Second Edition, John Wiley Press, New York, 440 pages.

PRECAUTION, CLEAN PRODUCTION, AND THE PREVENTIVE STRATEGY

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I. Introduction

Clean (or cleaner) production is an approach to environmental management which aims to encourage new processes, products and services that are cleaner and more resource efficient. It emphasises a preventive approach to environmental management which attempts to minimise adverse risks over the lifecycle of products and services (Baas et al 1990, Jackson 1993, Misra 1995). There are strong historical and conceptual resonances between clean production and the precautionary principle. This paper argues that the precautionary principle not only motivates the search for preventive clean production strategies, but must also function as an operational guide for those strategies. In one sense, clean production is an operational response to the demand for precautionary action. In another sense, clean production represents a technological domain in which the lessons of the precautionary principle are as relevant as they are elsewhere.

One of the complexities associated with discussing the precautionary principle is that there are many definitions in several different forms. A useful categorisation of these different forms has been proposed by Wiener (2001) who offers three fundamentally distinguishable versions of the principle:

- *version 1*: uncertainty does not justify inaction;
- *version 2*: uncertain risk justifies action;
- *version 3*: shifting the burden of proof.

Wiener is critical of all three versions of the principle. He argues that Version 1 offers some useful insights into the management of environmental risk but is of limited usefulness, because it fails to specify what action should be taken in the face of inevitable uncertainty. Version 2 and 3, he claims, are both flawed because they fail to take account of so-called 'countervailing' risks. In the later sections of this paper, I shall examine this argument more closely and set out a case that Wiener has dismissed Versions 2 and 3 of the precautionary principle too lightly. I shall attempt to argue that Version 2 and more specifically Version 3 of the precautionary principle do in fact contribute valuable insights to environmental risk management. Nonetheless, his categorisation of the different versions of the principle provides a useful starting point

for my analysis, not least because Version 1 presents us with a clear historical link between the precautionary principle and the concept of clean production.

II. Version 1: Precaution versus the 'Permissive' Principle

Version 1 is probably the most familiar form of the principle and provides the basis for most formulations that exist in the language of international agreements. Principle 15 of the Rio Declaration, for example, is cast in precisely this form, as is Article 3.3 of the United Nations Framework Convention on Climate Change (FCCC), which declares that:

> *'Parties should take precautionary action to anticipate, prevent and minimise the causes of climate change and mitigate its adverse effects. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures.'*

Article 3.3 is also notable for linking the concept of precaution with that of prevention. Interestingly, the language of the FCCC suggests, counter to Wiener's criticism, what kind of action is required by precaution. This is a point to which I shall return later.

To the uninitiated observer, the linguistic construction of Version 1 may appear, at first sight, rather odd. Why should a principle be needed to urge policy-makers 'not to postpone' certain actions under certain conditions? Why should a principle be needed to articulate a relationship between scientific uncertainty and the timing of action? In the historical context the answer to these questions becomes clear: version 1 was needed precisely because the condition of scientific uncertainty had been used to justify not taking action to mitigate environmental risk, even in the presence of threats of serious or irreversible damage.

As an illustration, consider the example of industrial waste disposal into the marine environment. The dumping of wastes from the titanium dioxide (TiO_2) industry into the North Sea is a case in point. The TiO_2 industry produces white pigments which have been widely adopted as a safer alternative to the lead and zinc-based pigments used about 50 years ago. The product itself is non-toxic and is widely used as an additive in a variety of manufactured goods. However, the principal manufacturing route for TiO_2 in the 1970s and 1980s was a sulphate process which gave rise to a hazardous liquid wastestream with high acid and metal content. From quite early on, epidemiological studies of benthic communities in the German Bight (where acid wastes from the German TiO_2 industry were dumped) revealed that certain species of flatfish (limanda limanda) were suffering from an elevated risk of epidermal papilloma

(skin cancer) compared with neighbouring areas. By the early 1980s, impact studies established that chromium (one of the metals present in the TiO_2 wastes) was a prime suspect as causative factor for the disease (Dethlefsen et al 1993).

Thus, an accumulation of scientific evidence pointed to a link between the dumping of TiO_2 wastes and the occurrence of diseased dab. There was no disagreement that the wastes were potentially hazardous. There was no disagreement that elevated levels of disease were occuring in fish from areas where the wastes were dumped. There was no disagreement that elevated levels of chromium were to be found in dab from the disposal site. Nonetheless, and in spite of considerable opposition from environmental lobbies, dumping continued for twenty years, and for ten years after the first evidence of harm was identified. It continued precisely because it was not possible to demonstrate 'full scientific proof' of a causal link between the activity of dumping and the occurrence of diseased fish.

It is instructive to ask what exactly might have constituted full scientific proof of a causal link, in these circumstances. The truth is, as Dethlefsen et al (1993) argue, that unifunctional causality is almost impossible to establish in complex ecosystems. In fish, as in many other organisms, health is influenced by the level of immuno-competence of the organism, which is dependent in its turn on a complex matrix of parameters including food availability, ambient conditions, population composition, age, bacteria and viruses, and a host of potential pollutants including organo-chlorines, polyaromatic hydrocarbons and heavy metals. In one sense, this complexity should clearly warn us against seeking scientific certainty for individual causes; it is unlikely to be forthcoming. This lesson was lost however within a prevailing scientific paradigm which argued that it is possible to define and to calculate a specific 'assimilative capacity' for the marine environment – 'a property of the environment which measures its ability to accommodate a particular activity or rate of activity without unacceptable impact' (GESAMP 1990). This paradigm held tightly to the potential for scientific certainty regarding causality. Its response to uncertainty over cause-effect relations was to argue for more research before taking preventive action.

In the event, therefore, complexity became a part of the pretext for not interfering with current practice. Industry continued to lobby for 'scientific certainty'. Environmental groups campaigned furiously over pollution of the North Sea, dubbing assimilative capacity the 'permissive principle' (MacGarvin 1994). Policy-makers were faced with mounting evidence that disposal practices were having an impact on fish populations. The precautionary principle adopted in the Declarations of the First and Second North Sea Ministers Conferences of 1984 and 1987 broke this deadlock and led to a moratorium (and later a ban) on the dumping of industrial wastes in the North Sea.

Version 1 of the precautionary principle can be seen therefore as a quite specific response to a particular situation: in which the prevailing scientific model

demanded inaccessible levels of proof from complex systems with multi-functional causalities; and in which, in the absence of such proof, policy-makers and regulators were paralysed into inaction. In hindsight, it has become much clearer that the scientific model underlying this conflict was, if not confused, then at least an inadequate basis for policy-making. It is a 'scientific' insight (possibly a 'fact') that 'scientific certainty' of specific cause-effect relations is difficult if not impossible to establish in certain kinds of systems. What should we do when we are faced with this situation? It is patently absurd to argue, as those opposing the precautionary principle once did, that the absence of certainty should deter policy-makers indefinitely from taking action to avert potentially serious environmental harm. Version 1 of the precautionary principle responds to this absurdity.

III. Version 2: A Mandate for Prevention

Wiener accepts the insight offered by Version 1, but castigates its proponents for failing to identify what kind of action should be taken in the face of uncertainty. In one sense, this criticism is over-stated. Most incarnations of Version 1, with the possible exception of Principle 15 of the Rio Declaration, are articulated within a context which provides at least some indication of the kinds of actions which precaution demands.

Article 3.3 of the FCCC, cited above, typifies this situation. Though precaution is explicitly cast in the form of Version 1, the surrounding language indicates which actions policy-makers are being urged to take, namely those that will 'anticipate, prevent and minimise the impacts of climate change'. In the broader context of the Convention as a whole, and the community of knowledge within which the FCCC sits, it is fairly clear that the desired actions involve quite specific tasks: mitigating greenhouse gas emissions, reducing deforestation, improving sink capacities and so on. Subsequent deliberations under the Convention, including the Kyoto Protocol, specify the nature of these tasks quite precisely. Similar observations can be made about the Declarations from the North Sea Ministers conference. Thus, the distinction between Version 1 of the principle and Version 2 is, in practice, less significant than Wiener suggests. Implicitly at least, most Version 1 incarnations incorporate some indication of specific actions to be taken in the face of specific risks.

At the same time, however, it is clear that some forms of the precautionary principle go considerably further than this. For example, the Wingspread Statement (Raffensberger and Tickner 1999) includes the following recommendation:

> *'When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established.'*

A very early formulation of the precautionary principle put forward by the German Federal Interior Ministry in the 1970s (cited in Boehmer-Christiansen 1994) articulates the same general principle:

> *'The principle of precaution commands that the damages done to the natural world.. should be avoided in advance and in accordance with opportunity and possibility.'*

Uncertain risk justifies action, claims Version 2 of the precautionary principle. What is perhaps most striking about the Version 2 formulations cited above is not so much that they seek to mandate action (instead of simply removing the justification for inaction). Rather it is their generality; and it is precisely this generality which renders Version 2 problemetical in Wiener's view. Logically, Version 2 should be held to apply to all human activities, since all activity incurs uncertain risks. However, this means that the principle should also be applied to precautionary actions taken to address environmental risk. Wiener points out, correctly in my view, that actions taken to reduce particular 'target' risks, themselves incur a new set of uncertain risks – 'countervailing risks' – which logically speaking should also become the object for precautionary action.

An illustration of the problem of countervailing risk is provided by the historical case study examined in the previous section. Those pressing for continued dumping of industrial wastes in the marine environment pointed to the dangers of alternative disposal. Unguarded land disposal of TiO_2 wastes, for example, could pose threats to potable water supplies even more worrying than the threat of epidermal papilloma in limanda limanda. As the environmental lobby pointed out, however, the point here is that precaution at sea should not mean profligacy on land at all. Rather attempts should be made to reduce the waste arising at the source. In the case of TiO_2, source reduction of the wastes could be achieved through a combination of acid recyling and metal recovery. In general terms, it was argued, the alternative to disposal of wastes at sea was not land disposal, but the implementation of clean production strategies which reduced the need for any disposal of hazardous wastes (Baas et al 1990, MacGarvin 1989).

One of my arguments in this paper is that Version 2 of the precautionary principle, contrary to Wiener's objections, provides us with a quite clear indication of how we should proceed in the face of ubiquitous uncertainty relating to environmental risk. Specifically Version 2 provides us with a clear mandate for clean production,

defined as the 'continuous application of an integrated preventive environmental strategy to reduce risk' (UNEP 1992). Thus, my argument here is that clean production represents precisely what Wiener (2001) calls a 'risk-superior strategy for reducing multiple risks in concert.'

IV. Clean Production as Precautionary Action

The articulation of clean production as a precautionary strategy was echoed formally in the language of the Bamako Convention (1991) on the transboundary movement of hazardous wastes in Africa which declared that:

> *'Parties [to the Convention] shall cooperate with each other in taking appropriate measures to implement the precautionary approach to pollution prevention through the application of clean production methods.'*

The term 'clean production' itself was coined in May 1989 at a meeting of the UNEP Industry and Environment Office in Paris. The meeting defined clean production as a 'conceptual and procedural approach to production that demands that all phases of the lifecycle of a product or a process should be addressed with the objective of prevention or minimization of short and long-term risks to humans and to the environment' (Baas et al 1990). The terminology was later amended to 'cleaner production' on the recognition that no process or product chain could be expected to be entirely without environmental impact or potential adverse health effects. Cleaner production was supposed to indicate a progressive programme of improvements in the environmental performance of industrial processes and product systems. The most recent formal definition of the concept is the one contained in the UNEP Cleaner Production Declaration which defines cleaner production as 'the continuous application of an integrated, preventive environmental strategy applied to processes, products and services in pursuit of economic, social, health, safety and environmental benefits' (UNEP 2000).

The characterisation of clean production as a 'preventive' strategy provides perhaps the most fundamental distinction between this concept and earlier environmental management strategies. Preventive environmental management (Hirschhorn et al 1993, Hirschhorn and Oldenburg 1991) requires actions to be taken upstream, before environmental impacts occur. This is in contrast to more traditional environmental management strategies which tend to clean up pollution, as it were, after the fact. Preventive environmental management also distinguishes itself from end-of-pipe environmental management which attempts to 'prevent' the emission of specific

pollutants into a particular environmental medium by placing some kind of filter or treatment between the emission and the environment. Typically, end-of-pipe strategies risk pushing environmental problems from one medium to another rather than reducing the problem at the source. By contrast, the logic of prevention is to seek intervention at an earlier stage of the process in such a way that the polluting emission does not arise in the first place. Clean production is thus a 'directional' strategy: it looks as far as possible upstream in the societal network so as to take action at the source to avoid potential problems. The conversion of these guiding principles into an operational strategy is highly dependent on sector-specific and application-specific parameters and it is beyond the scope of this paper to go into this level of detail. Nonetheless it is possible to identify two main 'operational pathways' for clean production.

In the first place, the environmental risk associated with providing for human needs can be minimised by reducing the material flow through the processes, cycles and activities which provide for those needs. If this reduction in material flow is to occur without loss of service, ie without jeopardising the underlying needs, then this strategy implies the pursuit of efficiency improvements in the system. Efficiency improvement (Jackson 1996, Schmidt-Bleek 1993, von Weizsäcker et al 1997) is thus the first operational pathway of clean production. The second operational pathway is substitution. Specifically the 'substitution principle' aims for the progressive substitution of hazardous materials, products and activities with non-hazardous or less hazardous ones (Jackson 1996, Geiser 2001, Wahlström 1999).

Efficiency improvements include a variety of actions: simple good housekeeping actions and better materials handling at the process level; takeback, re-use and recycling strategies at the product level; and at the level of the economy as a whole, a general dematerialisation of economic services. A simple example of action at the process level is provided by the TiO_2 acid recycling process described above. These kinds of techniques emerged extensively from the 'pollution prevention' programmes in the 1970s and 1980s. Slogans such as 3Ms 'pollution prevention pays' (the 3P program) and the Chevron Corporation's 'Save Money and Reduce Toxics' (the SMART program) highlighted what has been a fundamental truth of corporate economics ever since the industrial revolution: reducing material input costs whilst maintaining output increases revenues and hence improves profitability. Put simply, resource efficiency improvements can be cost-effective (Jackson 1996, von Weizsäcker et al 1997, PIU 2001).

The second operational pathway – substitution of toxic or hazardous input materials – is less readily driven by economic goals, and therefore, not surprisingly, less common. A study of 29 organic chemical companies through the 1980s found that only around 10% of the reported actions involved substitution (Dorfman et al 1993). Those actions that did involve substitution were usually driven primarily by regulatory

pressures to reduce hazardous wastewater discharges or phase out the use of particular chemicals, a trend which appears to have intensified subsequently (Verschoor and Reijnders 2000). Nonetheless, such regulatory pressures can also provoke economic savings. For example a Monsanto plant which modified its product to substitute one kind of formaldehyde resin for another reduced its hazardous waste generation by 89%, saving the company around $60,000 annually.

Clearly, one of the issues for the substitution pathway is identifying which of the wide range of potential risks represent priority hazards. In the context of marine pollution, attention focused initially on substances which are persistent, toxic and liable to bioaccumulate. The logic was quite clear. Toxic substances cause harm to humans and other species. Persistent toxic substances hang around for a long time in the marine environment rather than becoming degraded into (potentially) less toxic forms. Persistent bioaccumulating substances hang around in the environment long enough to be taken up within the benthic food network and eventually reach the human food chain where humans become exposed to their toxicity. Thus, the identifiers of 'persistence', 'toxicity' and 'liability to bioaccumulate' are essentially proxy indicators of both hazard potential and exposure potential.

It is clear, however, that there are a number of other qualities that might provide proxy indicators of hazard and exposure potential. Carcinogenic, mutagenic and reprotoxic (CMR) chemicals, persistent organic pollutants (POPs), heavy metal pollutants, persistent synthetic compounds have all been singled as indicators of the need for priority attention in the context of various risk reduction initiatives. The EU White Paper on Chemicals Policy initially argued that most CMRs and POPs should be subject to the proposed REACH system of chemicals registration, evaluation and authorisation (EC 2000). Heated debates in the European Parliament ensued in which there were suggestions that the remit of the REACH system should be broadened to include all persistent and bioaccumulative substances, endocrine disrupters, sensitisers, and other weaker or disputed CMRs (ENDS 2001). The Swedish Chemicals Action Programme singled out 13 unwanted chemicals with properties including persistence, toxicity, syntheticity, and liability to bioaccumulate (Wahlström 1993, 1999).

It is worth noting that not all of the hazard and exposure identifier properties are required simultaneously before materials pose environmental or human health threats. The case of chlorofluorocarbons (CFCs) illustrates, for example, that both toxicity (as conventionally measured) and liability to bioaccumulate can be absent from the list of qualifiers, and yet the chemical can still indirectly pose a threat to both human health and the environment. CFCs were introduced as 'safe' substitutes for ammonia-based refrigerants, amongst other uses. They were believed to be safe not only for humans but also for other organisms. There was no evidence of bioaccumulation in any species or food chain. The dangers posed by CFCs arose partly from their persistence –

which enabled them to reach the stratospheric ozone layer without being degraded – and partly from an unforeseen chemical interaction between a synthetic compound and a particularly vital feature of the natural environment.

In fact, even persistence is no prerequisite for harm. Non-persistent or biodegradable substances can also be hazardous in the environment. Metabolites of certain polycyclic aromatic hydrocarbons (PAHs) have long been implicated in this respect (ICES 1987); DDE is a well-known carcinogenic metabolyte of DDT. To make matters worse, little information exists on the degradation products and metabolites of synthetic substances, and their environmental and health effects are often largely unknown. Synthetic compounds offer inherently unfamiliar and in some cases unquantifiable risks in the environment. Thus, there is a strong argument that a risk superior strategy should attempt to 'close the industrial loop' and aim for zero dissipation of synthetic chemicals into the environment (Geiser 2001).

There is a vital lesson here for risk reduction and chemicals policy. The suggestion is that it is possible (indeed risk superior) to structure risk reduction strategies such as clean production on the basis of a) a knowledge of the hazard potential of specific materials, products or activities and b) some kind of proxy indicator of exposure potential. This suggestion runs counter to conventional claims that risk reduction should proceed on the basis of detailed risk assessment procedures which include a comprehensive assessment of both hazard and exposure. Two specific factors militate against the conventional view: firstly, the sheer complexity associated with modelling exposure pathways, particularly for synthetic chemicals whose behaviour in the environment is inherently unpredictable; secondly the scope and scale implied by engaging in such a task for the 70,000 or so chemicals on or approaching the market today.

In summary, the precautionary strategy implied by clean production is to seek a progressive programme of risk reduction by a continual search for safer substitutes and more efficient (less materials intensive) ways of meeting human needs (Geiser 1999, Jackson and Marks 1999). Nonetheless, it is clear that clean production does not bypass and cannot afford to ignore the problem of countervailing risk. It is to this problem that we now turn.

VI. Clean Production and the Problem of Countervailing Risk

In general terms, a clean production intervention operates in the context of a specific target risk or set of target risks, say a particular toxic chemical, a range of material throughputs or a set of environmental emissions. No action taken to reduce the target risk, however, is entirely independent. Rather it stands within a complex causal

network of activities within the industrial economy. Thus, each such intervention will have a complex set of consequences, each of which may incur some kind of 'countervailing' risk. It is possible to identify three broad ways in which countervailing risks may arise in the context of clean production.

The first of these is what we might call the 'dilemma of substitution'. The substitution of one material, product or activity with another reduces the target risk but incurs a countervailing risk, namely the risk associated with using the new chemical or product, or carrying out the new activity. The assumption made within clean production is that the substituted activity is hazardous and the substituting activity is safe. The difficulty with this assumption is that the risk profile associated with the new activity is almost inevitably different from the risk profile associated with the earlier activity. Thus, it is not always easy to identify the existence of countervailing risk. Example of the failure to identify countervailing risk are provided by the cases of TiO_2 and CFCs discussed above. In both of these cases, the substances themselves were introduced at least partly to offset target risks associated with earlier materials (lead pigments and ammonia respectively). The countervailing risks associated with the new products were not picked up at the time the substitutes were introduced, in part because they occurred in different ways, at different parts of the product lifecycle.

The second broad category of risk associated with clean production strategies is what we might call 'transboundary leakage'. This refers to a situation in which the knock-on implication of addressing a particular target risk is to transfer risk across a geographical, economic or other system boundary. For example, a company invests in a new process technology that reduces its need for chlorinated organic solvents; however, the new technology requires electricity to run it. This electricity is generated off-site by a conventional coal-fired power station, and thus contributes a range of additional environmental emissions, which pose a new set of countervailing risks. Another example is provided by the situation in which policy measures (energy taxes, for example) are put in place to reduce energy consumption in the economy. The net effect of these measures is to reduce the energy intensity of the economy. One way of achieving this reduction is to keep the same economic structure, but improve the energy efficiency of all the processes. Another possibility is to induce a shift in the structure of the economy away from energy-intensive processes and towards less intensive ones. However, unless this shift is associated with a shift in patterns of consumption of final goods and services in the economy, the net effect may simply be to import more finished products from abroad. But overseas processes also contribute to global pollution, and in fact, the global burden from continuing consumption patterns might even increase, if production is less efficient or less well-regulated abroad. Thus, in this case, countervailing risks arise by exporting polluting processes across the system boundary.

Finally, countervailing risks arising from clean production strategies can be manifest in the form of opportunity costs, specifically the costs associated with the foregone benefits from existing practices. Generally speaking, these costs tend to be economic and social in character rather than environmental. So, for example, the removal of specific products or substance from the market generates a risk that the social benefits of that product or substance are also lost. Of course, it also generates the risk of lost revenues (and possibly lost jobs) in the particular sector whose profitability is based on the manufacture and sale of that substance or product. The example of the chlorine industry illustrates both these points.

Chlorine itself has been the focus of environmental campaign for a number of years (Thornton 1991). The chlorine industry has always defended itself by pointing to the benefits that chlorine provides, for example in providing clean potable water. Since chlorination of water supplies represents only about 1% of the chlorine market, however, this has never been a particularly strong justification for the industry as a whole. Recently, however, a recent advertisement for the industry highlighted the importance of PVC in medical uses (CIA 2002). 'Because blood bags have to be biodegradable,' claims the ad, 'they have to be made of PVC. So chlorine is essential to their manufacture. No chlorine, no blood bags, no life.' The final sentence of this claim may be hard to justify. However, this advertisement makes two things very clear. Firstly, some of the uses associated with toxic chemicals and substances are valuable to society and hard (although not in fact impossible) to substitute. Secondly, of course, the existence of this advertisement (and others like it) makes abundantly clear that the producers of those chemicals and substances face lost revenues if their products are banned. These are also opportunity costs. They represent countervailing risks to precautionary actions.

VII. Version 3: Shifting the Burden of Proof

What emerges most clearly from the preceding discussion is that, in spite of being a precautionary strategy, clean production must still address the problem of countervailing risk. Clean production interventions, just like any other technological interventions, need to be able to demonstrate that any associated risks are acceptable. In particular, if clean production must accept the burden of proof in demonstrating the risk superiority of its intervention. In other words, clean production is not simply a strategy which is motivated by the precautionary principle; it is also a strategy which requires the continuous application of precaution in its operation. Specifically, Version 3 of the precautionary principle is absolutely vital to clean production. In fact, Version 3 of the precautionary principle has a long pedigree. For example, it is encoded into the 1973

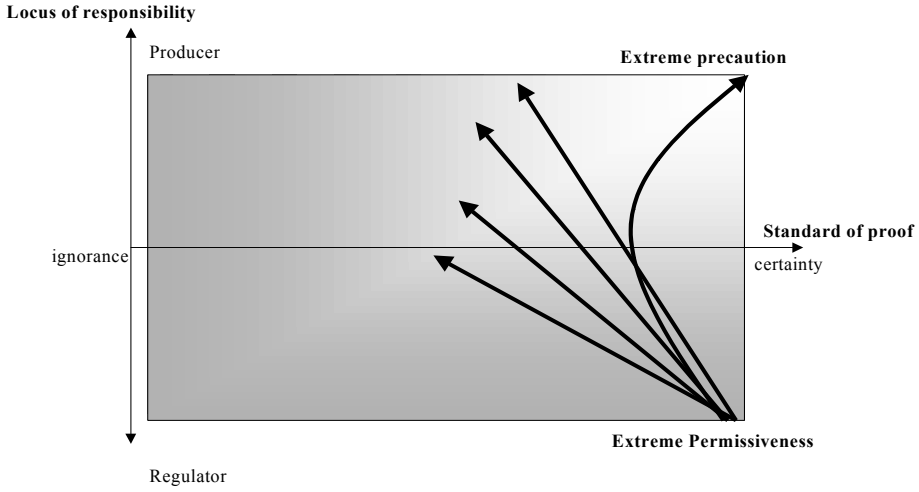
Swedish Act on Products Hazardous to Human Health and the Environment, which stated (Wahlström 1999) that:

> *'where there is a scientifically-based suspicion of risk, the producer must show, beyond reasonable doubt, based on existing scientific knowledge and principles, that the suspicion is unfounded.'*

In other words, Version 3 represents a 'shift in the burden of proof' in the sense that, prior to the introduction of the precautionary approach, it was largely the responsibility of regulators to show that particular processes, products and activities were unsafe. There was a presumption in favour of continuation. Potentially dangerous activities were considered 'innocent until proven guilty'; and moreover proven guilty, as we have seen, according to rather exacting standards of proof, namely scientific certainty of a causal link. The basic thrust of Version 3 is to overturn this assumption and to place certain new responsibilities on the instigators of new (or existing) activities.

Wiener argues that Version 3 'swallows itself' in the following sense: if all risky activities are to be banned until they can demonstrate safety, then this must also apply to precautionary actions. In other words, we must apply precaution to precaution, and thence end up paralysed by inaction. Once again, Wiener's argument contains a grain of truth. It falls however, once we distinguish between two distinct factors involved in 'shifting the burden of proof'. The first is concerned with the 'locus of responsibility' – ie the question of who bears the burden of demonstrating safety or harm. The second relates to the 'standard of proof' required of those with whom responsibility rests.

Figure 1: Shifting the Burden of Proof



A narrow interpretation of Version 3 would have us shift from a situation in which the regulator (or environmental objector) is required to demonstrate 'full scientific certainty of a causal link' between a particular activity and a harmful effect before that action is stopped (extreme permissiveness) to a situation in which the instigator of the activity is required to produce 'full scientific certainty of absence of harm' before being allowed to proceed (extreme precaution). But as Figure 1 illustrates, this interpretation by no means exhausts the possibilities for shifting the burden of proof. In fact, we can conceive of a variety of different kinds of shifts which involve both the locus of responsibility (who bears the burden of demonstrating safety or harm) and the standard of proof required before taking action. Amongst the most obvious shifts would be to require producers of new materials or products to take responsibility for the provision of health and safety information relating to their products, as envisaged (for certain kinds of products) within the Chemicals Policy White Paper (EC 2000).

VIII. Conclusions

I have argued in this paper that preventive clean production offers a 'risk superior' way of reducing multiple risks in concert. The concept of clean production emerged as a specific response to the emergence of the precautionary principle in the context of marine pollution. The pursuit of clean production – defined as a progressive incremental search for safer, and less materials-intensive ways of meeting human needs - can be thought of as the precautionary action mandated by the precautionary principle. At the same time, clean production must remain wise to the possibility of countervailing risks – risks arising from clean production interventions themselves. In addressing these risks, I have argued specifically that the precautionary principle is as relevant to clean production interventions as it is to any other intervention. Thus, the precautionary principle both motivates clean production and guides its search for acceptable alternatives.

In the latter part of this paper I have addressed the importance of a shift in the burden of proof, as suggested by Version 3 of the precautionary principle. I have highlighted the fact that a strict reversal from extreme permissiveness to extreme precaution is only one of a number of possible ways of shifting the locus of responsibility for determining hazard or safety. In particular, it is clearly possible to increase the role of producer responsibility (for the safety of products, for the quality of information regarding products, for the ultimate fate of products) in guiding clean production towards its goal.

REFERENCES

Baas, L., H. Hofman, D. Huisingh, J. Huisingh, P. Koppert and F. Neumann, 1990. Protection of the North Sea: Time for Clean Production, Erasmus Centre for Environmental Studies, Erasmus University, Rotterdam.

Boehmer-Christiansen, S 1994. The Precautionary Principle in Germany – Enabling Government, in O'Riordan and Cameron (1994).

CIA 2002. 'Chlorine – life depends on it' http://www.chlorine.org.uk/morechlorine.htm. (Jan 24th 2002).

Dethlefsen, V., T. Jackson and P. Taylor 1993. The Precautionary Principle – towards anticipatory environmental management, Chapter 3 in Jackson (1993).

Dorfman, M., A.White, M.Becker and T. Jackson, 1993. Profiting from Pollution Prevention – better environmental protection; improved economic competitiveness, Chapter 10 in Jackson (1993)

EC 2000. Strategy for a future Chemicals Policy, White Paper, 13/2/01, Commission of the European Communities, Brussels.

ENDS 2001. Strong EU Chemicals Policy Gets Green Light, Ends Daily, Issue 1005, 18th June.

Geiser 1999. Cleaner Production and the Precautionary Principle, Chapter 20 in Raffensberger and Tickner (1999).

Geiser 2001, Materials Matter: toward a sustainable materials policy, MIT Press, Boston.

GESAMP 1990. The State of the Marine Environment, UNEP Regional Seas Reports and Studies, No 115. UNEP, Nairobi.

Hirschhorn, J., T. Jackson, and L. Baas, 1993. Towards Prevention – the emerging environmental management paradigm, Chapter 7 in Jackson (1993).

Hirschhorn, J. and K. Oldenburg 1991. Prosperity without Pollution – the prevention strategy for industry and consumers, Van Nostrand Reinhold, New York.

ICES 1987. Overview of Contaminants in the Marine Environment, Report of the 1986 ICES/ACMP meeting, International Commission for the Exploration of the Seas, International Maritime Organisation, London.

Jackson, T 1993. Clean Production Strategies – developing preventive environmental management in the industrial economy, CRC Press, Boca Raton, Florida.

Jackson, T 1996. Material Concerns – pollution, profit and quality of life, Routledge, London.

Jackson, T and N Marks 1999. Consumption, Sustainable Welfare and Human Needs - with reference to UK expenditure patterns 1954 - 1994, Ecological Economics, 28(3), pp421-442.

MacGarvin, M 1994. Precaution, Science and the Sin of Hubris, in O'Riordan and Cameron (1994).

MacGarvin, M 1989. The Future: Clean Production, Paper 30 to the 3rd North Sea Conference, Greenpeace International, Amsterdam.

Misra, K.B. (ed), 1995. Clean Production, Springer Verlag, Berlin and Heidelberg.

O'Riordan T and J Cameron (eds) 1994. Interpreting the Precautionary Principle, Earthscan, London.

PIU 2001, Resource Productivity – making more with less, Performance and Innovation Unit, Cabinet Office, London

Raffensberger, C and J Tickner (eds) 1999. Protecting Public Health and the Environment: implementing the precautionary principle, Island Press, Washington DC.

Schmidt-Bleek, F 1993. MIPS – a universal ecological measure, Fresenius Environmental Bulletin, vol 2, pp306-311.

Thornton, J 1991. The Product is the Poison – the case for a chlorine phaseout, Greenpeace, Washington, DC.

UNEP 2000. CP Declaration Update, Cleaner Production Newsletter, No 17, UNEP Industry and Environment Office, Paris.

UNEP 1992. Cleaner Production Programme, Industry and Environment Office, United Nations Environment Programme, Paris.
Verschoor, A.H. and L. Reijnders, 2000. Toxics reduction in ten large companies, why and how, Journal of Cleaner Production, vol 8(1), pp69-78.
von Weizsäcker, E., A.B.Lovins and H.L. Lovins, 1997. Factor Four – Doubling Wealth, Halving Resource Use, Earthscan, London.
Wahlström, B 1993. Risk Reduction and Chemicals Control – lessons from the Swedish Chemicals Action Programme, Chapter 13 in Jackson (1993).
Wahlström, B 1999. The Precautionary Approach to Chemicals Management: a Swedish Perspective, Chapter 3 in Raffensberger and Tickner (1999)
Wiener, J 2001. Precaution in a Multi-Risk World, in Paustenbach, D (ed) The Risk Assessment of Environmental and Human Health Hazards (2nd edition), John Wiley, New York.

PRECAUTIONARY DECISION MAKING IN PRODUCT DEVELOPMENT AND MARKETING

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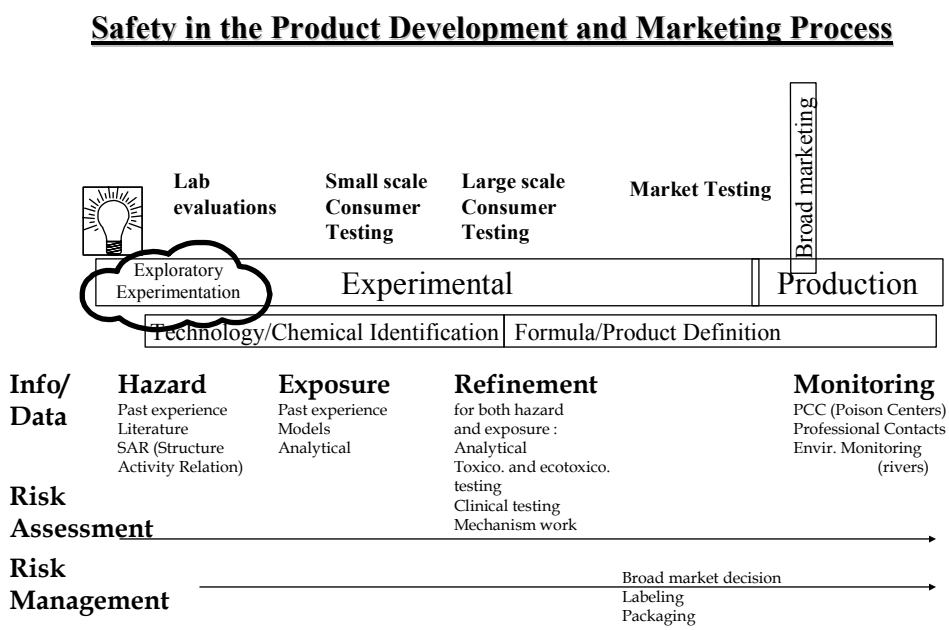
I. Introduction

Many types of chemical based consumer products entail frequent general public exposure and wide disposal after use. This is certainly the case for the types of products sold by Procter & Gamble like detergents, cosmetics, health care and hygiene products. The Company purpose is : "To provide products of superior quality and value that improve the lives of the world's consumers." Quality and value encompass the beneficial attributes for the consumer, the monetary value but also the human and environmental safety and impact profiles. This is rooted in P&G policy : "Our products shall be safe for humans and environment when used as intended and under reasonably foreseeable use." Establishing product safety starts with an assessment of risks for human health and the environment as well as a verification of applicable regulations in the many countries where we operate. This is the responsibility of dedicated regulatory and safety departments. Risk management, where needed, is a business decision taken on the basis of the scientific risk assessment as well as other economical and societal considerations. Safety itself covers those working in laboratories and factories, the public at large (consumers and communities), and the environment.

II. Integrating safety in the product development and marketing thinking.

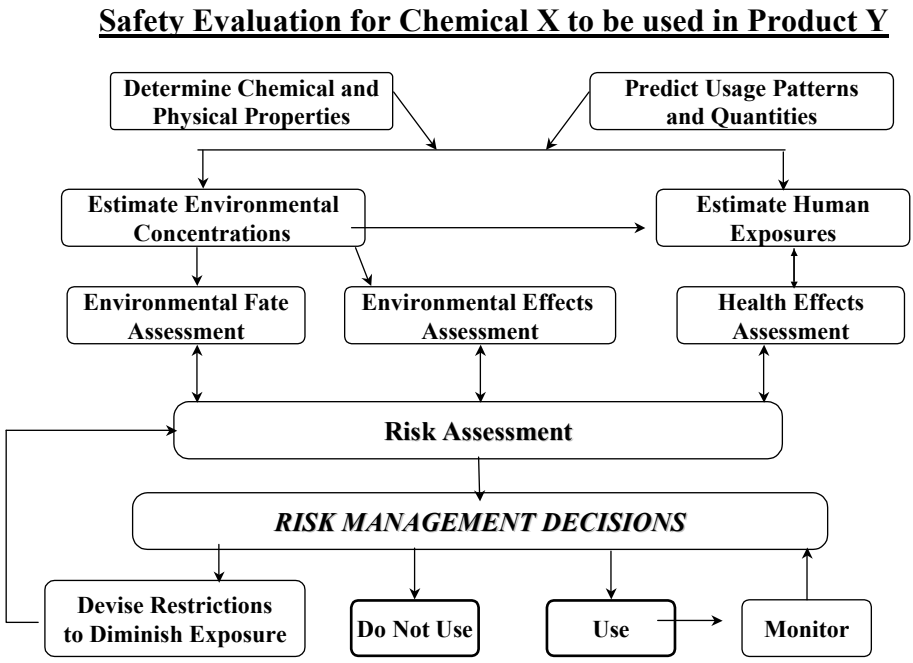
The principle is one of parallel paths with safety information always one small step ahead. (Fig. 1). From the first idea about a new technology or a new application to broad marketing, we look at hazard and exposure information, refining it as we go along, drawing risk assessment(s) on the basis of which risk management decisions including due precaution can be taken. These management decisions range from using or not a particular chemical, postponing its use on a large scale till more objective information or further data are available to indicating warnings, devising special packaging etc… (Fig. 2) The principle of parallel paths allows to address safety at every point while making most efficient use of economical, personnel and animal resources. It goes from the simplest to the most complex evaluations with a possibility to stop or modify the product development and marketing process if and when needed.

Figure 1



Risk management may require intervention at any part of the product life cycle. A few examples among many: At the manufacturing phase, it may be decided to establish an air limit value in factories; at the transport and distribution phase, to design special containers; at the product use phase, to label on pack; at the disposal phase, to choose a chemical presenting a faster biodegradability profile. Furthermore, in order to provide the product benefit and to ensure safety at the same time, one can act on any component of the risk assessment procedure (hazard, exposure and uncertainty) at any of the life cycle phases described above. Reducing hazard is normally achieved through reformulation of the product, avoiding the chemical of concern all together or replacing it by a substitute or mitigating its hazard by changing another chemical it is associated with in the product. Reducing exposure may mean reformulation or entail personal protection equipment, warnings, packaging restraints, education material and others. Reducing uncertainty usually comes from doing further research, supplementing in vitro or animal studies with clinical work, installing human health surveillance or environmental monitoring programs.

Figure 2



III. Examples of chemical risk management decisions at the use (consumer) phase.

Focussing on consumer use and discharge, here are concrete examples of real chemicals which led to various types and levels of precaution, which we judged to be proportionate with the risk.

1. *Reducing toxicity (hazard)*

A new chemical was developed for hair conditioning products. On two occasions the chemical behaved unexpectedly in acute oral toxicity studies with nine perfectly healthy animals and one very ill. Were these results relevant for possible cases of accidental ingestion by children? Trying to answer this question in order to assess the risk would have been very costly in animals and in time with a rather uncertain outcome. Risk management was therefore to abandon the substance and reformulate the product.

2. *Reducing (consumer) exposure*

The example of enzymes in laundry detergents is illustrative. Enzymes are very efficient chemicals offering remarkable cleaning performance at extremely low levels. From a risk assessment viewpoint, enzymes are respiratory allergens (hazard) but consumer exposure through use of laundry products for machine or for hand washing presents a negligible risk. Safe handling in factories is however submitted to strict exposure control measures and adequate surveillance (risk management).
The prospect of a new market expansion confronted us with a potentially different consumer exposure situation and the risk assessment thus needed to be carried out again. In rural Egypt and Yemen it is not unusual to use laundry powder product for body and hair washing, something we would consider a ”misuse” in the western world but which for some people is a ”use”. The precautionary approach consisted of postponing the broad marketing decision till exposure would be sufficiently characterised. Through simulation studies in laboratories we could eventually establish that even under such consumer practice, the respiratory exposure was so low it would not entail a higher level of risk than under western habits. The decision was thus to market and start an education campaign on best use of laundry products.

Another example on how to reduce (consumer) exposure came when we considered a new form of machine dishwashing products offering increased convenience. Going from the same product (same chemical composition) in powder form to tablets required a new risk assessment. Evidently the exposure under normal conditions of use would, if anything, be lower than with the powder. However the exposure under accidental conditions was difficult to estimate and led to questions like: ”Would potential oral irritation (hazard) be increased with the tablet product in case of accidental licking or ingestion? Could choking occur?” In this case the precautionary attitude was to turn to the toy regulations and see if it could offer applicable risk management tools. We applied the same types of size and strength considerations as prescribed for toys to avoid that young children could bite a piece and choke. In addition packaging restraints were decided upon. We have since monitored the market with the help of Poison Control Centres (PCC’s) in Europe and have ascertained that the few accidents which did occur produced no or minimal reversible irritation.

3. *Reducing (environmental) exposure*

An interesting example relates to a known antibacterial chemical widely used in cosmetic products (dentifrices, soaps, etc.). Risk assessment shows that although this compound is toxic to aquatic life (hazard), the environmental risk is negligible based on

the predicted, and in some cases measured, river exposure. Here too, a new risk assessment had to be performed when we considered using the same chemical for its biocidal properties in household cleaning products. The risk assessment based on a very significant tonnage increase and a much higher predicted river concentration, led to a conclusion of possible concern. Discussing the assessment with others concerned with this substance, the precautionary approach consisted of a voluntary decision by the whole European detergent and cleaning Industry not to increase above what was at the time ”current” (1997) usage.

4. *Reducing uncertainty*

Let’s examine the example of d-limonene broadly used as perfume and flavour ingredient since the last century. When a long term animal toxicity study showed a few years ago that d-limonene is clearly carcinogenic (hazard), concern with broad public exposure and potential cancer risk was expressed and made worse by the fact it is an important component of oranges…. Further research allowed to determine that the mechanism responsible for d- limonene cancer is related to a protein, which is present in the male rat, but absent in man! Evidently this discovery reduced drastically the uncertainty and allowed to return to a ”no risk management measure” situation for this particular health effect.

IV. Conclusion

A good risk management framework for consumer products along the product development and marketing timeline is comprised of several aspects. This paper focuses on the first aspect, the assessment of risks for human health and the environment, a process requiring iteration as knowledge and circumstances evolve. Where the risk is judged to be unacceptable or insufficiently characterized, provisional precautionary measures may be necessary till the situation changes. Other aspects involve regulatory compliance, efficient use of resources, waste management strategy, consideration of societal concerns. Finally, going from theory to practice, a risk management framework in Industry must be supplemented with verification means like a quality assurance program ensuring that the products are of the quality required for the use and that swift corrective action is taken where needed.

PRECAUTION IN THE FUTURE EUROPEAN CHEMICALS POLICY

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I. Introduction

- The Precautionary Principle is a fundamental principle in Community Environment policy. The Amsterdam Treaty on the European Union states that the policy on the environment shall (...) be based on the Precautionary Principle and on the Principles that preventive actions should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.
- As has been discussed at this Conference, Precaution is also increasingly being relied on in global and regional environmental instruments and is being referred to expressly in an ever-growing number of international agreements and domestic statutes, e.g. most recently in the IMO Convention on the control of harmful anti-fouling systems, the Stockholm Convention on Persistent Organic Pollutants and the Cartagena Protocol on Biosafety.

II. Where are we on precaution in the EU in general and more specificly in the context of chemicals?

II.1. The Commission Communication on the Precautionary Principle

- In its Communication of February 2000, the Commission underlines that
  - the Precautionary Principle forms part of a structured approach to the analysis of risk, as well as being relevant to risk management.
  - it covers cases where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU.
  - where action is deemed necessary, measures should be proportionate to the chosen level of protection, non-discriminatory in their application and consistent with similar measures already taken. They should also be based on an examination of the potential benefits and costs of action or lack of action and subject to review in the light of new scientific data. Measures

should thus be maintained as long as the scientific data remain incomplete, imprecise or inconclusive and as long as the risk is considered too high to be imposed on society.

- it may assign responsibility or the burden of proof - for producing the scientific evidence necessary for a comprehensive risk assessment.

- These "guidelines" in the Communication guard against unwarranted recourse to the Precautionary Principle as a disguised form of protectionism.
- The Communication makes it clear that application of the Precautionary Principle is neither a politicisation of science or the acceptance of zero-risk but that it provides a basis for action when science is unable to give a clear answer. In those cases, we should err on the side of caution and – for instance in the case of chemicals- limit or ban use until such time as our scientific knowledge improves.
- What is very important to note in this respect, is that there can be no question of inconsistency between the need for a scientific basis and the use of the precautionary principle. The implementation of the principle starts with as complete a scientific evaluation as possible.
- Science cannot and should not be seen as something separated from precaution. The scientific view of the risk is essential to evaluate risk. Therefore, the application of the precautionary principle will not undermine the scientific process. On the contrary, it will enhance it by providing greater public confidence in this process.
- The Council of Ministers endorsed the orientations of the Commission in its Conclusions of December 2000 and also the European Parliament has given its opinion on this issue.

II.2. The Chemicals White Paper

- In its White Paper on a Strategy for a future Chemicals Policy of February 2001, the Commission has given its views on how the EU should manage the risks posed by chemicals.
- The Precautionary Principle is only mentioned a few times in the Paper, but runs through the whole policy concept. It is clearly stated that whenever reliable scientific evidence is available that a chemical substance may have an adverse impact on human health and the environment but there is still scientific uncertainty about the precise nature or the magnitude of the potential damage, decision-making must be based on precaution in order to prevent damage to human health and the environment.

What is the current situation on chemicals?

- Firstly, there are potentially 100,000 chemicals produced and used in the EU on the market before new assessment procedures came into force in 1981. For the large majority of these substances we have no information about the risks they pose to human health and the environment. Despite this scant amount of information, these substances have remained on the market.
- Secondly, the current assessment procedures for existing chemicals have proved to be too cumbersome and slow. This is due to the fact that authorities have to prove that a certain chemical or some of its uses are not safe. Therefore, to be absolutely sure, comprehensive risk assessments are being prepared by Member State authorities and the Commission.
- Finally, because the "existing" chemicals may be produced and marketed without further testing efforts, the current system has unintentionally discouraged innovation and hampered the production of substitutes for harmful chemicals.
- With this share out of responsibilities between authorities and industry there is no scope for applying the precautionary principle!

Which elements of the new system (REACH: Registration, Evaluation, Authorisation of Chemicals) facilitate the application of precaution?

- First of all, the ”burden of proof” will be reversed. Producers, manufacturers and downstream users should be responsible for proving the safety of the chemicals they (want to) place on the market and thus be more careful before they do so.
- The inclusion of downstream users in the chain of responsibility will have many positive effects. Firstly, they will more than today think about the substances they use and therefore will put more pressure on producers and importers to provide them with safe substances with adequate information on their properties. Further, it will be much more easy to trace a substance from cradle to grave in case there are problems.
- Where possible, we should go for targeted risk assessments and not to try to cover all possible options and wait with management action until all information is on the table. This makes sure that regulatory action does not come too late.
- All substances will be introduced in a database, not only the ones which are dangerous. This allows for better information to downstream users and the public. It also allows for quicker action in future, when a problem arises.
- As far as possible, computer models should be developed and used to avoid time-consuming and costly scientific studies. These models will facilitate the screening of potential problematic substances and hence prioritisation of substances to be tackled first.

- The White Paper includes an accelerated risk management system, based on preliminary - in many cases targeted - risk assessments to be prepared by industry. The precautionary principle will be invoked whenever the risk assessment process is unduly delayed and where there is an indication of unacceptable risk. In particular, should a producer of a given substance delay the filing of information or test results, authorities would be entitled to conclude the assessment. The assessment would then be passed to the Commission with a recommendation to apply the precautionary principle and to proceed to risk management measures to the possible extent of a total ban.
- Last but not least, the new REACH system includes an authorisation mechanism for the substances of very high concern. These are substances with carcinogenic, mutagenic properties and toxic effects on our reproduction system (categories 1 and 2), but also substances with POPs characteristics as defined in the Stockholm Convention. The Commission is considering to also add substances which are persistent, bio-accumulative and toxic and which are very persistent and very bio-accumulative.
- In principle, those substances should not be produced or used unless there is a clear societal need for them and less dangerous alternatives do not (yet) exist. Industry has to prove the safety of the uses it proposes and indicate the risk management measures it will take.

III. Final remarks

- The Commission has set up a number of Technical Working Groups with experts from the Member States, industry, NGOs and the Commission to advice on issues such as the mimimum requirements for registration, what computer models can be used, what criteria should be applied for PBT and VPVB substances and should thay qualify for the authorisation mechanism. Results are expected in February 2002. The outcome of the Working Groups is one of the major inputs into the Commission proposals for legislation.
- At this stage, I cannot predict the timing of the Commission proposals. My best estimate, if everything goes smoothly, would be April/May 2002, but in any case the aim should be to present proposals to the Parliament and Council before Summer-2002.
- I will be happy to discuss at that stage whether the draft legislation will pass the precautionary test!

THE NEW EU CHEMICALS STRATEGY AND THE PRECAUTIONARY PRINCIPLE: HOW PRECAUTIONARY IS THE WHITE PAPER AND WHAT COULD BE IMPROVED?

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"We change what we say
and yet remain prisoners
of what we have been"

(Anon.)

I. Introduction

The White Paper published by the European Commission in February 2001 (CEC 2001) proposes a number of fundamental changes to the management of chemical manufacture, use and exposure within the European Union. That the strategy sets out to provide a single system of regulation for chemicals, to replace the current outdated and ineffective system, is laudable in itself. Moreover, specific provisions such as a presumption against the continued use of the most hazardous substances, requirements to address chemicals in consumer products and measures to reduce reliance on animal testing, illustrate a desire to move towards more sustainable use of chemicals in the service of society. At least in principle, the strategy recognises at the outset the need for a high level of protection for the environment and human health and the role of precaution in delivering this. But is the strategy truly precautionary in its formulation? How far will it contribute to delivery of truly sustainable exploitation of chemicals and what more will need to be done?

II. Goals of the strategy and the role of precaution

In setting out its aims and objectives, the White Paper stresses that the new strategy "*must ensure a high level of protection of human health and the environment*", consistent with obligations under the Treaty itself. At the same time, strong emphasis is placed on ensuring "*the efficient functioning of the internal market and the competitiveness of the chemical industry*" in Europe. While it is clear that an effective strategy on chemical production and use must take account of socio-economic

conditions and drivers, the search for a ”balance” between protective goals and economic development has in the past all too frequently resulted in the compromise of those desired levels of protection. It remains unclear whether the new strategy will really provide for effective controls on the use and release of hazardous chemicals or if issues of trade will once again remain paramount.

The White Paper goes on to stress that, central to achieving the objectives of the new chemicals strategy will be the application of the *precautionary principle*. Fundamentally, precaution is about acting with foresight, taking steps on the basis of early indications of harm (or the potential for harm) to the environment or human health in order, as far as possible, to avoid that harm being realised. In order to facilitate such action, a common element of definitions of the precautionary principle is an acceptance that protective decisions may need to be taken in the absence of scientific certainty regarding the magnitude or likelihood of the identified threats.

Definitions of the principle differ markedly, however, both in the extent of the conditions which must be fulfilled before ”precautionary” action is deemed to be justified and in the degree to which preventative action in such cases is required. For example, the definition adopted at the World Summit in Rio (UNCED 1992) implies merely that that action to prevent serious or irreversible effects should not be excluded by lack of certainty. Other interpretations envisage a more active role for precaution in mandating such protective action (FRG 1986) and providing a framework for decision-making which, though fundamentally rooted in scientific knowledge, is nevertheless more sensitive to the inherent limitations to that knowledge (Stirling 1999).

Within the White Paper, the precautionary principle is only briefly elaborated, with reference primarily made to the European Commission’s earlier communication on precaution (CEC 2000). This communication, presented in February 2000, represented an attempt by the Commission to outline the manner in which it intended to apply the principle in the context of community law. In general terms, the communication defined precaution in highly restrictive and procedural terms, with one of the key objectives being the avoidance of ”inappropriate recourse” to the precautionary principle. This concern appeared to arise from the fear that precaution would be misused as a justification for disguised trade restrictions. In trying to provide such a prescriptive and, in many ways, legal interpretation, however, the Commission effectively removed some of the fundamental elements which make the application of precaution both necessary and effective for responsible governance[1].

In particular, the communication envisaged that the application of precaution would remain restricted to cases in which every attempt to complete a standard risk assessment had failed to provide the degree of certainty required for decision-making. In the case of chemical regulation, this approach appeared remarkably similar to the existing, discredited assessment system which has contributed so much to the delay of protective measures, even for some of the most hazardous substances. In a similar manner, the chemicals White Paper itself stresses that "*precise knowledge on the intrinsic properties as well as on the exposure arising as a result of a particular use and of the disposal is an indispensable prerequisite for decision making...*". It is difficult to reconcile such requirements against the stated aim for a more precautionary system.

III. A precautionary strategy?

Definitions aside, however, the real test of the new strategy will be in its ability to provide the high level of protection from the harmful effects of chemicals to which it aspires. In turn, this will depend on the strength of the specific elements of the strategy and the practical measures which will result from their implementation. A brief assessment of these key elements is presented below[2].

1. The REACH (Registration, Evaluation, Authorisation of Chemicals) system

Many aspects of the strategy set out in the White Paper are, at least in principle, laudable and progressive. For example, initiatives such as the authorization procedure (under the REACH system) acknowledge that there are certain intrinsic properties of chemicals which render them undesirable for continued use other than in limited, justified and essential applications. This certainly introduces elements of precaution by indicating that action may be taken to avoid exposure to such chemicals without requirements for proof of harm. Furthermore, the continued use of a chemical of high concern will ultimately depend on justification presented by the proponents of that chemical, suggesting a shift in the burden of proof towards a more precautionary regime.

In application, however, the success of the REACH procedure in preventing the ongoing widespread contamination of both urban and natural environments will depend greatly on the properties deemed to render chemicals to be of sufficient concern to warrant the exclusion of unauthorised uses. The original proposal is that authorisation should apply only to chemicals with POP-like properties and to so-called CMR chemicals[3], both classes which are, to a large extent, already subject to the development of relatively

tight controls. Unless criteria for selection of chemicals to be subject to authorisation are sufficiently broad to capture a diversity of mechanisms of toxicity and to ensure avoidance of systematic build-up of synthetic chemicals in the environment, the protection afforded by the prevention of unauthorised uses will remain very limited. In this regard, proposals made by Environment Council in June 2001[4] to make a broader range of persistent, bioacumulative and toxic chemicals (*i.a.* PBT, VPVB[5], endocrine disruptors) subject to authorisation, would substantially strengthen the strategy.

2. No data, no market?

Substantial questions also remain with respect to other elements of the strategy. How comprehensive will the coverage of chemicals in consumer products be, and how capable will the system be at ensuring delivery of adequate data for those substances falling outside of REACH? The concept that the marketing of a chemical should not be permitted unless certain basic data are supplied (”no data, no market”) has received considerable discussion and support, but it remains difficult to see whether the strategy will insist on such restrictions. Certainly deadlines are set for data delivery, but the consequences of not meeting these timelines remain to be seen.

3. Exclusion of intermediates?

Furthermore, how will the strategy ensure an equivalent level of protection from chemicals used in open applications such as pesticides and biocides, and releases of those used as intermediates or generated as unintentional by-products of chemical processes and waste disposal technologies? It is a common assumption that chemicals used as intermediates in production processes are not released to the environment, despite evidence that such chemicals can be emitted as significant components of liquid, solid or gaseous waste streams. Fugitive emissions can also result during storage, transport and transfer of chemicals, leading to further releases despite the fact that the chemicals are not marketed for general sale or open applications. The potential for bulk releases arising from accidents is ever present, of course. In short, there is no such thing as a truly ”closed system” and generic exclusions from registration and authorisation of hazardous chemicals on the basis of assumed zero releases from restricted use patterns would be ill-founded.

4. Substitution in principle or practice?

Other fora, in particular the OSPAR Convention (for the protection of the North East Atlantic) have recognised the central role to be played by the principle of substitution in

reducing exposure to hazardous chemicals, i.e. the replacement of hazardous substances with less hazardous, or preferably non-hazardous, alternatives. Indeed, substitution is one of the guiding principles of OSPAR's Hazardous Substances Strategy (OSPAR 1998a), and the practical application of the principle as a tool contributing to OSPAR's target for the cessation of releases of hazardous substances by 2020 is currently being elaborated. In the context of the offshore oil and gas industry, the practice of substitution is mandatory under the system for drilling and production chemical selection (ref).

Within the proposed EC chemicals strategy, the concept of substitution appears to be viewed rather as something to be "encouraged" than as a general obligation. It is clear that, for those uses of substances of very high concern which are not considered acceptable for authorisation, alternatives will need to be found. Beyond this, however, the White Paper misses the opportunity to introduce broader requirements for ongoing evaluation of chemicals and selection of the least hazardous effective alternative available in each case.

The concept of substitution has received substantial criticism in recent years, the common barriers raised being the absence of suitable alternatives and the dangers of substituting a known hazardous substance with a less well characterised alternative. Although these are, at least fundamentally, reasonable concerns, these barriers are often theoretical in nature. In some cases, for example, the argument that there are no alternatives has been readily countered in practice by demonstration within industry or the retail sector that effective alternatives are already in use. The phase out of all applications of brominated fire retardants in furnishing and textiles by certain retailers is a case in point[6].

It is clear, of course, that for some hazardous chemicals, effective alternatives might not be immediately available (at an achievable cost) for all applications. It is very much a policy decision, however, as to whether this presents a fundamental barrier to progress (and is justification, therefore, for continued indefinite use of the hazardous substance) or is seen rather as a stimulus for innovation and investment to identify or develop more sustainable solutions. It might not always be possible to substitute a hazardous substance immediately, but this should not be seen as a reason to ignore the obligation to do so as soon as possible, nor to reduce the protection and environmental quality goals to which we ultimately strive.

The second issue, that of the potential replacement of one problem chemical with another ("out of the frying pan, into the fire") is also a legitimate concern, but is a

barrier only if substitution is considered in restrictive ”chemical-for-chemical” terms. Rather than looking always to replace one chemical with another (often chemically similar), there is a need to explore opportunities to solve the problem in other ways (e.g. alternative materials, chemical processes, even other strategies to provide the same service to society). The simple replacement of phthalate plasticisers in PVC toys with other chemical groups whose toxicities are perhaps even less well described, for example, completely misses the opportunity to avoid the use of leachable additives altogether through the use of alternative polymers or other non-hazardous materials.

5. Informing the public?

The strategy goes on to acknowledge the need to provide information on hazardous substances to the public. In envisaging the provision of access the databases of chemical hazard information, however, the Commission addresses only one of the issues with respect to information provision, that of the greater transparency of the system. What appears to be missing at present is a commitment to provide the public with concise but informative information on the chemical constituents of consumer products (articles). Ministers of OSPAR contracting parties (representing 12 EU Member States) made the commitment to provide this in 1998 (OSPAR 1998b). On a more practical level, such information will be a prerequisite for the concerned consumer to make informed decisions, and a stimulus to manufacturers and retailers to avoid hazardous ingredients, thereby further contributing to the overall objective of the chemicals strategy.

IV. Beyond the chemicals strategy

The discussion presented above highlights a number of areas in which, with further development, the degree of environment and human health protection afforded by the chemicals strategy proposed in the Commission’s White Paper of February 2001 could be strengthened. In order to deliver truly precautionary management of chemicals, however, the new strategy will need to provide some surety that the lessons of the past have really been learned. In part, this will entail a recognition that current exposure to chemicals is not just a ”burden of the past”, but one to which our current misuse and over-reliance on chemicals continues to contribute.

Fundamental to approaching a ”non-toxic environment” will be the recognition that cessation of production and release of hazardous substances through all stages of chemical lifecycles is the only truly sustainable option, even if this entails substitution not just at chemical, but at material or product level, or even changes in common

practice, expectations and behaviour. The 2020 cessation target agreed under the OSPAR Convention (OSPAR 1998a) should provide the final deadline for all releases of, and exposures to, hazardous substances, with well-defined and challenging interim timelines to address specific chemicals or modes of use (i.e. early phase out of substances of highest concern, and of hazardous chemicals in consumer products).

Integral to such an approach should be requirements not to introduce any new substances with hazardous properties, to label products with sufficient chemical content information to enable informed purchasing and a general obligation to implement the principle of substitution on a continuous basis. Such an approach would be consistent with the goal identified by the European Environment Agency (EEA 1998) of achieving an overall reduction in the chemical burden of society. A similar concept was captured within the early formulations of the precautionary principle. In providing the impetus for the development of more sustainable alternatives, precaution should do more to stimulate than stifle innovation.

Ultimately, therefore, precautionary chemicals management will require a more fundamental rethink of the manner in which we employ chemicals in the service of society than that promised under the new strategy, as far reaching as the proposed reforms undeniably are. In order to approach true sustainability, man's exploitation of chemical technologies must necessarily avoid the systematic accumulation of chemicals in the environment and depletion of the fundamental bases of productivity. How far the new chemicals strategy will contribute to this broader goal remains to be seen.

V. Conclusions

1. The Commission's White Paper begins to outline a new way of thinking with regard to our use and management of chemicals, but there are many elements in the detail which imply that, in practice, we will remain tied to the past.

2. Precaution will always be more effective in practice than in principle. Acknowledging the principle at the outset is welcome, but few of the practical measures in the strategy look to be consistent with this.

3. In seeking a balance between the protection of our environment and health and the competitiveness of the European chemical industry in a global market place, the danger remains that the protection goals enshrined within the Treaty will continue to be compromised. That we may not yet be able to reach the overarching goal of

true sustainability is not a justification to lower our aspirations and accept a lower level of protection indefinitely.

4. Substitution provides a central mechanism to reduce and ultimately eliminate our exposure to hazardous substances, but must operate in a broad manner such that opportunities to replace a hazardous substance with another chemical must also be complemented with consideration of alternative materials, products, industrial processes, even the provision of services. We should be ready to accept that some changes in consumer/public behaviour or expectations may be unavoidable, and to communicate this.

5. In order to cast the consideration of alternatives as broadly as possible, it will be essential to engage broader representation from industry and the retail sector than is currently the norm. Experience has shown that, in this way, some assumed barriers to substitution have been readily resolved through demonstration that effective alternatives are already in use.

6. Additional to measures to address substances with specific hazardous properties, we should strive to avoid chemical release and exposure wherever possible. A general and progressive reduction in the overall chemical burden on society, though perhaps not deemed necessary through the application of the traditional risk assessment paradigm, would nevertheless be a desirable goal in the context of a sustainable chemicals strategy.

REFERENCES

CEC (2000) Communication from the Commission on the precautionary principle, (COM(2000) 1 final), Commission of the European Communities, Brussels, 2.2.2000: 28 pp.

CEC (2001) Commission White Paper: Strategy for a future Chemicals Policy (COM(2001) 88 final), Commission of the European Communities, Brussels, 27.2.2001: 32 pp.

EEA (1998) Chemicals in the European Environment: Low Doses, High Stakes? The EEA and UNEP Annual Message 2 on the State of Europe's Environment. European Environment Agency, Copenhagen: 32 pp.

FRG (1986) Umweltpolitik: Guidelines on Anticipatory Environmental Protection. Federal Ministry for the Environment, Nature Conservation and Nuclear Safety: 43 pp.

OSPAR (1998a). The Sintra Statement (Final Declaration of the Ministerial Meeting of the OSPAR Commission, Sintra 20-24th July 1998). OSPAR 98/14/1 Annex 45. OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic.

OSPAR (1998b) OSPAR Strategy with Regard to Hazardous Substances. OSPAR 98/14/1 Annex 34. OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic.

OSPAR (2000) OSPAR Decision 2000/2 on a Harmonised Mandatory Control System for the Use and Reduction of the Discharge of Offshore Chemicals, OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic

Santillo, D. & Johnston, P. (2000) A Precautionary Tale: Report back from the Precautionary Principle Debate held at the Third SETAC World Congress, Brighton, May 21-25, 2000, Environmental Science and Pollution Research 7(3): 144-146

Stirling, A. (1999) On science and precaution in the management of technological risk. Synthesis report of studies conducted by O. Renn, A. Klinke, A. Rip, A. Salo & A. Stirling, EC Forward Studies Unit/ESTO Network, European Commission, May 1999.

UNCED (1992) Rio Declaration on Environment

NOTES

[1] An overview of the Commission's communication, and a critique of the approach, is provided by Santillo & Johnston (2000), summarising a debate on this issue which took place at the 3rd World Congress of the Society of Environmental Toxicology and Chemistry (SETAC).

[2] A more detailed evaluation is available at http://www.greenpeace.to/pdfs/white paper critique.PDF

[3] CMR, Carcinogenic, Mutagenic or toxic to Reproduction

[4] 2355th Council Meeting, Luxembourg, 7th June 2001

[5] VPVB, very persistent and very bioaccumulative chemicals, for which demonstration of toxicity is considered not to be an additional prerequisite for concern

[6] In addition, a very recent report from the Danish Ecological Council lists sources of electronic goods which do not incorporate these toxic and persistent compounds:- http://www.greeninfo.dk/artikel.asp?artikelID=4150&kategoriID=86

PRECAUTION AND THE STOCKHOLM CONVENTION

JIM WILLIS
UNEP Chemicals, Geneva

The Stockholm Convention

- **Adopted in Stockholm in May, 2001**
- **Seeks to reduce or eliminate releases of Persistent Organic Pollutants (POPs)**
- **Resolutions in "Final Act" also adopted**
- **Signed by 104 countries and one REIO**
- **Open for signature until 22 May 2002**

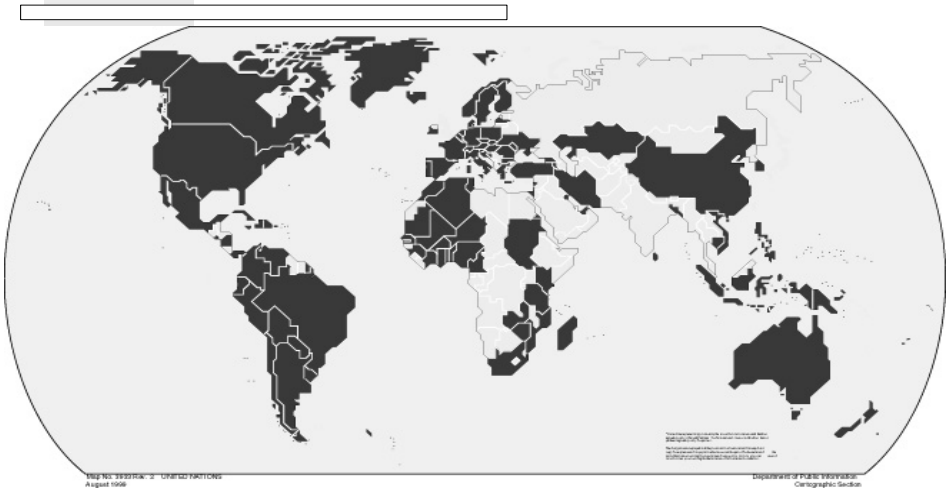
What are POPs?

- **POPs are organic compounds (*i.e.*, carbon-based)**
  - **natural or anthropogenic origin**
- **unique combination of physical & chemical properties:**
  - **resist degradation in environment (*i.e.*, persistent)**
  - **low, but significant, vapor pressure ("semi-volatile") leads to distribution in all environmental media**
  - **low water solubility + high fat solubility**
- **regional and global distribution by air, water, wildlife**
- **long-term exposure to humans and wildlife**
- **bioaccumulation in fatty tissues of living organisms**
- **acute and chronic toxic effects on humans & wildlife**

What does the Convention Do?

- **Objective = protection of health and environment**
  - **acknowledges *precaution* as an important element**
- **Main provisions:**
  - **control measures**
    - **intentionally produced POPs (Article 3/Annex A, B)**
    - **unintentionally produced POPs (Article 5/Annex C)**
    - **stockpiles and wastes (Article 6)**
  - **addition of new chemicals (Article 8/Annex D)**
  - **general obligations**
  - **financial and technical assistance**
  - **implementation aspects**

Who has Signed?



How is Precaution captured

- **Four explicit references to Precaution**
- **The spirit of Precaution flows through the treaty**

Explicit References to "Precaution" (1)

- **Preamble:**
- **"Acknowledging that precaution underlies the concerns of all the Parties and is embedded within this Convention,"**

Explicit References to "Precaution" (2)

- **Article 1 – Objective**
- **"Mindful of the precautionary approach as set forth in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Convention is to protect human health and the environment from persistent organic pollutants."**

Explicit References to "Precaution" (3)

- **Article 8 - <u>Listing of chemicals in Annexes A, B and C (paragraph 9)</u>**
- **"The Conference of the Parties, taking due account of the recommendations of the Committee, including any scientific uncertainty, shall decide, in a precautionary manner, whether to list the chemical, and specify its related control measures, in Annexes A, B and/or C."**

Explicit References to "Precaution" (4)

- **Annex C (Article 5)**
- **"In determining best available techniques, special consideration should be given, generally or in specific cases, to the following factors, bearing in mind the likely costs and benefits of a measure and consideration of precaution and prevention…"**

The spirit of Precaution (1)

- **Preventing "new POPs" (Article 3)**
- **"Each Party that has one or more regulatory and assessment schemes for new pesticides or new industrial chemicals shall take measures to regulate with the aim of preventing the production and use of new pesticides or new industrial chemicals which, taking into consideration the criteria in paragraph 1 of Annex D, exhibit the characteristics of persistent organic pollutants."**

The spirit of Precaution (2)

- **Preventing "future POPs" (Article 3)**
- **"Each Party that has one or more regulatory and assessment schemes for pesticides or industrial chemicals shall, where appropriate, take into consideration within these schemes the criteria in paragraph 1 of Annex D when conducting assessments of pesticides or industrial chemicals currently in use."**

The spirit of Precaution (3)

- **Circumscribing exemptions and acceptable purposes (Article 3)**
- **"Any Party that has a specific exemption in accordance with Annex A or a specific exemption or an acceptable purpose in accordance with Annex B shall take appropriate measures to ensure that any production or use under such exemption or purpose is carried out in a manner that prevents or minimizes human exposure and release into the environment."**

The spirit of Precaution (4)

- **Byproducts (Article 5 and Annex C)**
- **Establishes a "pollution prevention hierarchy"**
  - **Article 5 – "Promote the development and, where it deems appropriate, require the use of substitute or modified materials, products and processes to prevent the formation and release of the chemicals listed in Annex C, taking into consideration the general guidance on prevention and release reduction measures in Annex C and guidelines to be adopted by decision of the Conference of the Parties;"**
  - **Annex C – "Priority should be given to the consideration of approaches to prevent the formation and release of the chemicals listed in Part I."**

The spirit of Precaution (5)

- **Adding New POPs (Article 8 and Annex D)**
- **Precaution will be incorporated in a number of ways to ensure that all proposed candidates are thoroughly considered on the basis of available data to see if they possess POPs properties**

Summary Thoughts

- **Highly charged environment at final POPs negotiating session in Johannesburg**
- **Some parties nervous about ultimate objectives of precaution proponents**
- **Is this a "North-North" issue?**
- **Some aspects of the debate have focused on semantics rather than substance**
- **Is incrementalism the objective or a means to an end?**

WRITTEN INTERVENTIONS

FIRST SESSION: THE PRECAUTIONARY PRINCIPLE IN EXISTING LAW

FRANZ XAVER PERREZ, Swiss Agency for the Environment, Forests and Landscape:

"It is often argued that the precautionary principle does mandate measures in situations of lack of (full) scientific evidence in order to prevent possible environmental harm, be it serious or be it irreversible.

This interpretation however does not find any bases in the language in international declarations and treaties: These always indicate that according to the precautionary principle, lack of full scientific certainty shall not be used as a reason to postpone measures to prevent harm. In short. the precautionary principle does not mandate but allow precautionary measures.

As such, the precautionary principle stands not in conflict with sound science or risk assessment: It is only relevant in law as science and risk assessment are not able to provide an answer whether a measure is necessary or not. It therefore does not contradict but complements sound science and evidence-based policies in situations where not evidence exists.

The precautionary principle allows to adopt a measure but does not provide for the criteria indicating when such a measure must be or must not be taken. Therefore, the precautionary principle has to be complemented by a rule providing criteria in order to decide whether a precautionary measure should be adopted or not.

However, by allowing the adoption of measures, the precautionary principle pierces the traditional WTO approach according to which trade restrictive measures must always be based on scientific evidence and proof.

Art. 5.7 of the SPS-agreement fully reflects this situations, but in areas, where the SPS-agreement does not apply, there might be a tension between WTO-rules and the precautionary principle.

ERWIN TOMSCHIK, Federation of Austrian Chemical Industry FCIO:
(re: JAN VAN DER KOLK'S presentation)

"The Austrian chemical industry has concluded a self obligation provided for existing substances produced in Austria above 1 ton/year to establish base data on toxic, ecotoxic and physico chemical properties.

Since we believe we must strive for the safe use of chemicals for which the well drafted safety data sheet is a prerequisite.
We asked our Austrian EPA to establish a guide for drafting SDS's which has received general acceptance in Austria. This is in the process of being updated.
We also made this guide well known in several conferences and organised seminars for users of chemicals how to transpose the contents of SDS's into practice."

WERNER PFANNHAUSER, Institute of Food Chemistry and –technology, Graz University of Technology:

"I am disappointed to hear that Precautionary Principle versus Risk Assessment not both need to be based on sound scientific basis. I feel it is necessary to apply scientific principles to both, Precautionary Principle and Risk Assessment.
If Precautionary Principle uses vague definition someone can take out what he wants because of lack of certainty."

SECOND SESSION: THE RATIONALITY OF PRECAUTION

Dr. MICHAEL D. ROGERS, Group of Policy Advisors, European Commission:

"The use of the precautionary principle also involves risks – the risks of acting against a product or process on the basis of faulty evidence – a false positive situation – the regulation decided to ban or limit something when the uncertain information was pointing in the wrong direction (Type 1 and 2 error situation). Furthermore, there are always countervailing risks and in deciding to ban something, consideration should always be given to the risk-risk tradeoff. In the case of the flame retardant chemical, which was mentioned, consideration should be give to all the alternatives including the risks involved in banning flame retardants (deaths in the home from fires etc.)."

JAN VAN DER KOLK, Ministry VROM, Netherlands:

"Rather than putting lots of efforts in further developing further codification of the Precautionary Principle or elaborating processes, it is important to come to clear implementation systems, where room for dispute is reduced to a limited area or number of chemicals.

Chemicals policy should be as generic as possible and aim at focussing on individual chemical on an exception.
Clarification on substitution:
When addressing the issue of substitution, it is necessary to clearly distinguish between substitution as a guiding principle for all actors, in particular industry, to continuously improve and substitution as a formal obligation for regulators, requiring them to demonstrate the availability of sound, safe and cost-effective alternatives before a chemical on a specific use can be restricted."

THIRD SESSION:
THE FUTURE OF PRECAUTION IN CHEMICALS POLICY

WYART REMY MICHELLE, Industrial Minerals Association – Europe (IMA-Europe):

"Mr Verstrynge highlighted that risk assessment and precautionary principle are not contradictory, but complementary and that zero risk situation doesn't exist. Isn't it absent from our current thought a debate on the acceptable risk level. In this respect, could the precautionary principle prevent regulatory bodies to provide a transparent access to the grounds of their own interpretation of the acceptable risk?
The Netherlands already started a discussion on acceptable risk definition, I am wondering which could be the future of such a debate in the EU."

ARNO DERMUTZ, VKI Austrian Consumer Association – Dep. Ecolabel:

"Fast and strong implementation of the precautionary principle in policy is more necessary than endless discussions about the theory of it. Thus discussions putting the precautionary principle into practise are helpful rather than debates about scientific evidence of risk. Acceptable risk is always a term of policy decision. Moreover there is no necessity to think additionally about different standards of protection of food, health or environment – in "ecosystem earth" all these things are linked together. However – in the workshop the variation of all of these discussions were presented and it was very informative especially with respect to proactive strategies for management of chemicals by some national governments.
Regarding the Commissions White Paper for a new chemicals strategy it is a first approach to implement the precaution but in the view of consumers improvements and some completion are essential and policy has to be more consequently.

The evaluation of substances has to be based on dangerous effects rather than the amount of production. Some chemicals have negative impact on environment although they are produced in small quantities (e. g. the gas SF6 - used in tires or windows - has a global warming potential which is 23.900 times higher than that of CO2. Brominated flame retardants are persistent, bio-accumulative and toxic. The hormonal effect is especially worrying and BDEs have been found widely in the environment, in human blood and in mother's milk. Nitro musk perfumes can be found in mothers milk too and some of them are suspect of being carcinogenic.)

”No data (by industry), no market” for all new substances and – with the mandatory dates of the EU-White-Paper – as well for existing substances. Unauthorized marketing of dangerous substances has to be imposed with similar rigorous fines like cartelisation.

Clear instruction for the use of chemicals depending on the category of danger and definition of these categories: substances of ”very high concern” --> no use in consumer products, ”high concern” or ”concern” --> ”no, unless …”, … (for example see Dutch proposals: http://www.vrom.nl/pagina.html?id=1&goto=1540).

Requirement for active searching for chemical or non-chemical substitutes of substances with unacceptable risks (e.g. PTB, CMR, POP) including all relevant stakeholders (e. g. the Swedish Government is looking for alternatives of certain flame retardants with members of the fire department).

Consumers have the right to know. Therefore the ingredients of consumer-products should be indicated on the packaging like the INCI-declaration for cosmetics. Transparent information and databases about the risk and properties of chemicals used in consumer products shall be available.

VKI hopes that all national governments support the implementation of the precautionary principle. If there is a clear and suitable political framework for a sustainable economy by national and by EU-legislation European industry has not to fear competition with USA or Asia. ”Innovation is the lifeblood of chemical industry (CEFIC)”.

FRANZ XAVER PERREZ, Swiss Agency for the Environment, Forests and Landscape:

”During the whole conference, numerous references were made to the clash between the US and Europe on the precautionary principle and the question was raised whether the precautionary principle is only a ”North-North” issue or whether it is also a ”North-South” issue. Several speakers have also made clear that the real problem between the US, the developing countries and Europe is not the precautionary principle as such, or the precautionary approach, the principle of precautionary approach or however you want to label it. The real problem relates to the fear that the

operationalization of the precautionary principle will lead to the application of different standards. In other words: not the use of precaution as such but the possibility of differing uses of precaution is the real problem. Similarly, industry is not per se against rules and regulations, but it is afraid that the rules will be different from country to country. Indeed, often coherence between rules and principle is as important if not more important than details of their content.

However, the problem of coherence arises not only between states, but also between different interrelated regimes and institutions. At the global level, there are at least four institutions dealing with chemicals and the environment: UNEP chemicals, the Basel Convention, the PIC-convention and the POPs-convention. Obviously, a coherent approach to precaution is desirable not only between the different countries, but also between these four institutions. The fact that these four institutions have been working in the same building – UNEP Chemicals administers the Interim Secretariat of the PIC and of the POPs-Convention and the secretariat of the Basel Convention has its offices next to UNEP Chemicals – has clearly facilitated cooperation and coherence. Cooperation and coherence would certainly not be as easy if the four institutions would be scattered all over the world. In order to address the real reasons underlying the clash on the precautionary principle, it is crucial to pay attention to mechanisms and arrangements ensuring coherence between different regimes. Therefore, institutional and geographic clustering of the relevant institutions and multilateral environmental agreement should be an important element of the future chemicals policy on precaution."

JAN VAN DER KOLK, Ministry VROM, Netherlands:

"The ongoing discussion on the application of a precautionary approach should both keep in mind long term visions related to sustainable development and propose clear and practical solutions for implementation of the approach in current and future policy, measures and instruments."

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