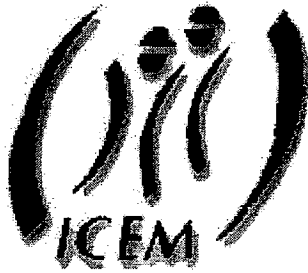


February 7, 2002 - Version 8.0

# JUDGING THE DANGER - CITIZENS AND CONTROL

## Risk Assessment and the Precautionary Principle



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## **JUDGING THE DANGER - CITIZENS AND CONTROL**

### **Risk Assessment and the Precautionary Principle**

#### **ABSTRACT**

Decision-making systems that allow society to deal with hazardous substances or dangerous processes have several dimensions. Characterizing them as 'precautionary' or 'risk based' is unhelpful unless a careful examination is made of where, along each dimension, the particular system lies.

At the outset, consider the dimension of **purpose or intent**. Are the decision-makers attempting to use good science, in an open and transparent manner, to develop sound policies to prevent harm? Or are they hoping to create the impression of scientific certainty where none exists, seeking to argue cost versus benefit, avoid legal responsibilities, or justify a previous decision to take no action at all?

A second dimension to be considered is whether the nature of the **input data** is predominately objective, or subjective. At one extreme, only hard, measurable data, related to the intrinsic hazard properties of the substance or situation would be used. At the other extreme are decision making systems that use a great deal of soft, assumption-based or derived data such as outcomes, or cost.

A third dimension concerns the **error sensitivity** of the overall system. Decision making systems that allow the public to deal with hazardous products or dangerous activities in an inclusive and transparent manner, utilizing the collective wisdom and judgement of appropriate stakeholders, will be relatively insensitive to error in a single piece of data. On the other hand, decision making that attempts to be very mathematical and quantitative, that is done in private by 'professionals', and that uses complex formulae to bridge data gaps with estimates and assumptions can be very sensitive to errors in the individual pieces of data which form the basis of those estimates and assumptions.

A final dimension might be considered to be the **response** dimension. At one extreme, the proposed response to a hazard will be based on the need to prevent the perceived potential negative outcome, by eliminating hazards or controlling hazards at the source. At the other extreme, decisions will be based on the desire to minimize the effects, or costs, of the potential negative outcome.

-Depending upon where, on each of the above dimensions, a particular decision making system lies it will tend to be described as 'precautionary' or 'risk based'. Few decision-making systems are pure examples of one, or the other. More frequently, 'risk assessment' and 'risk management' methodologies attempt to incorporate at least some of the philosophy of the precautionary principle in different ways and to varying degrees. However, building conservative assumptions into a risk assessment process does not make it a precautionary approach.

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## JUDGING THE DANGER - CITIZENS AND CONTROL

### Risk Assessment and the Precautionary Principle

#### 1 Introduction

In the highly developed democratic countries - typically those within the OECD - citizens assume that their interests, particularly those basic to their health and well-being, are the first priority of their governments. They even, optimistically, assume that it is at least a high priority for the corporations they deal with. On the surface, their faith would appear to be justified. There exists a range of laws, regulations, codes of practice, voluntary initiatives, etc. whose aim is to protect workers, the general public and the environment from the known or reasonably foreseeable harmful effects of industrial activity.

Despite this, it would be almost impossible to find anyone who would agree that such protection can, in any way, be perfect. This is principally because there is no common agreement on what constitutes a risk or a hazard in any particular set of circumstances. This problem is, in turn, compounded by the fact that 'risk' is a comparative term and what for one person - or in one set of circumstances - might seem acceptable would for another person - or in differing circumstances - be deemed unacceptable.

Thus, in examining how we deal with a particular danger, a crucial set of questions could be:

- i) who judges it, the judges' level of tolerance for danger, and whether they themselves believe they will face it;
- ii) the quantity and quality of data available to the judges, the circumstances in which they envision the danger arising (assumptions) and the analytical methodology used; and
- iii) the possible control alternatives, perceived cost of controlling - or not controlling - the danger, and how the controls are implemented.

Our lives and our well-being, not to mention the lives of countless other living things, depend on the decision-making and control methods selected, and the wisdom, honesty and integrity of those charged with making them work.

To judge dangers, governments - and in some cases industries - hire individuals, qualified by education and experience, to design decision-making systems and to evaluate the hazards and risks of new technologies, hazardous substances, and dangerous activities. The effective application of any laws, regulations, code, or voluntary initiative depends on their judgements.

Several methodologies for judging dangers exist; some more appropriate for certain situations than others. Frequent examples exist where bad methodology, questionable legal advice, conflicting priorities, and a simple lack of data have resulted in a flawed decision - making process. In other cases, the circumstances of exposure to the hazard change from those predicted. Our health, and the protection of the environment, can be compromised as a result.

Although there is a widespread belief that those creating the hazards are the ones that need to address them, it is probably equally true to say that most people accept that nothing in life is perfect and that perfect protection is equally unlikely - especially in the face of the need to innovate and respond to changing circumstances and demands. In short, most people understand that there is no such thing as certainty in any aspect of life - except the leaving of it. Increasingly, people are coming to realize that there is no such thing as a 'free lunch'; for every action there will be consequences.

In short, most people recognize that there is generally likely to be a trade-off between maximum protection on the one hand and maximum freedom to act (or not act) on the other. Establishing a balance between these competing forces whilst garnering widespread public acceptance is becoming increasingly important.

Nor is the process static; a practice considered acceptable yesterday may well not be acceptable today, or vice-versa. This is not solely due to the continuous emergence of new knowledge about dangers and how to prevent or control them. People's expectations change in the light of improved education, higher standards of living and experience.

## **2 Purpose or objectives of this paper**

The focus of this paper is upon 'risk assessment', the 'precautionary principle' and the relationship between the two. An initial discussion of these two terms and some of their variants is, therefore, important.

The 'precautionary principle' first became a subject of public debate following the first United Nations Conference on the Environment and Development, which took place in Rio de Janeiro, Brazil, in 1992. Principle 15 of the Rio Declaration, and Chapter 19 of Agenda 21, endorsed the precautionary principle even though specifics were generally lacking. This was followed by a general tendency to re-define various risk-assessment methodologies as 'precautionary' when in fact the authors had simply built somewhat wider safety margins into a risk management process.

Most versions of the precautionary principle embody (i) preventative action without waiting for incontrovertible proof of causality; (ii) the placement of the burden of proof on the proponent of the activity, not the public; (iii) the contemplation of various alternative courses of action, including no action, in decision-making; and (iv) open, transparent and multi-stakeholder, consensus-based, decision making involving all of the affected parties.

The formulation of the precautionary principle in the Rio Declaration has a 'cost-effectiveness' qualification, raising the possibility that economic considerations may trump precaution at any time. Furthermore, it suggests that the precautionary principle is of greatest value when there is scientific uncertainty; implying that other approaches may be used when the science is quite certain.

This latter point agrees with the stance taken by the authors of this paper. We believe that there are appropriate uses for risk assessment and precaution; and that decision-making systems exist on a

continuum in several dimensions, some of which would be described as risk based, and others of which would be described as precautionary.

Moreover, it should be noted that the precautionary approach is consistent with most definitions of sustainability; in that it admits a discussion of social values. Most proponents of risk-based approaches, on the other hand, claim that their procedures are purely 'scientific' and value-free. This, in part, explains why there are those who maintain that the precautionary principle is diametrically opposed to risk assessment with little, if any, common ground. The choice between them then becomes a contest of political strength between the true believers of one approach or the other.

There are myriad decision-making systems used to deal with dangers of various sorts. Some of the areas of variation include:

- The purpose and social context of the exercise
- The degree of exclusivity of the decision-making (whether other points of view or methodologies are considered)
- Whether the approach is very formal or more informal; entirely quantitative, semi-quantitative, or qualitative
- Whether the decision-making considers cost-benefit or risk management as part of its process
- The premises, assumptions and operational variable used
- The choice of models, paradigms, and methodology
- The degree of incompleteness, arbitrariness, and uncertainty in the selection of the information base and exposure data
- The quality of the inferences used
- The scope of the effects considered
- The degree to which the decision-making considers additive, cumulative, synergistic and ecosystem effects
- The assumptions made about dose, exposure, and uptake
- The role of assumed thresholds; e.g. safe limits, insignificant harm, acceptable risk.

In all of these, there are both comparisons and contrasts between decision-making systems that might be characterised as risk based, or precautionary.

The role of uncertainty is crucial to understanding the distinction between risk and precaution. Much of the rivalry between the two concepts hinges on arguments as to whether certainty is ever adequate to justify the use of risk assessment over precautionary decision-making. For example, the more an assessment relies on calculation rather than observation, the less reliable it is likely to be.

The objectives of this paper are to review the overall philosophy and structure of decision-making processes related to public health and environmental hazards, including some of the dominant perceptions involved in the use of concepts such as 'risk', 'precaution', 'safety', 'protection', etc. The underlying - and differing - perceptions, philosophies and political, social and economic agendas of those using these terms have, to a large degree prevented the necessary open discussion upon

which decisions can be based. This paper does not pretend to provide any 'answers'. However, it is hoped that it may provoke a wider discussion such that approaches if not answers - can be identified.

In attempting to do this, some assumptions need to be clearly stated at the beginning. The first of these is that the discussion in this paper is located in what might be termed a liberal Western democratic tradition with its historical commitment to checks and balances, the rule of law and political enfranchisement. To be sure there are still many countries that do not accept, or adhere only very imperfectly to, these principles.

The paper explores the general structure of a decision-making system for managing the use of hazardous substances or dangerous processes, including the questions of 'why', 'who', 'what', 'when', and of course 'how'. 'How' to make decisions is further broken down into defining the problem, gathering information, analysing the information, looking at alternatives, and finally making decisions benefiting society while controlling potentially detrimental effects. .

In this context, some of the differences between 'precautionary' or 'risk based' systems will be discussed. Decision-making systems that allow society to deal with hazardous substances or dangerous processes have several dimensions. Characterizing them as 'precautionary' or 'risk based' is unhelpful unless a careful examination of where, along each dimension, the particular system lies.

At the outset, consider the dimension of purpose or intent. Are the decision-makers attempting to use good science, in an open and transparent manner, to develop sound policies to prevent harm? Or are they hoping to create the impression of scientific certainty where none exists, argue cost versus benefit, avoid legal responsibilities, or justify a previous decision to take no action at all?

A second dimension to be considered is whether the nature of the input data is predominately objective, or subjective. At one extreme, only hard, measurable data, related to the intrinsically hazardous properties of the substance or situation would be used. At the other extreme are decision making systems which use a great deal of soft, assumption- based or derived data such as outcomes, or cost.

A third dimension concerns the error sensitivity of the overall system. Decision making systems that allow the public to deal with hazardous products or dangerous activities in an inclusive and transparent manner, utilizing the collective wisdom and judgement of appropriate stakeholders, will be relatively insensitive to error in a single piece of data. On the other hand, decision-making that attempts to be very mathematical and quantitative, that is done in private by 'professionals', and that uses complex formulae to bridge data gaps with estimates and assumptions, can be very sensitive to errors in the individual pieces of data which form the basis of those estimates and assumptions.

A final dimension might be considered to be the response dimension. At one extreme, the proposed response to a hazard will be based on the need to prevent the perceived potentially negative outcome, by eliminating hazards or controlling hazards at the source. At the other extreme, decisions will be based on the desire to minimize the effects, or costs, of the potentially negative outcome.



Based on where, on each of the above axes, a particular decision-making system lies it will tend to be described as 'precautionary' or 'risk based'. Few decision-making systems are pure examples of one, or the other. More frequently, 'risk assessment' and 'risk management' methodologies attempt to incorporate at least some of the philosophy of the precautionary principle in different ways and to varying degrees. However, building conservative assumptions into a risk assessment process does not make it a precautionary approach.

The authors hope that this paper will lead to a better understanding of the debate between 'precautionary' and 'risk based' decision-making systems.

### 3 Preparing to judge the danger –Why?, Who?, What?, When?

History teaches us - if nothing else - that human activities do not typically, if ever, confer unalloyed blessings on society. Greater personal freedom of movement has been accompanied by loss of habitat, serious congestion and pollution from the private motor car. Increasing access to time- and labour saving technologies have undoubtedly removed much of the drudgery of yesteryear; but at a cost. The world is increasingly facing major disposal and resource limitations, as well as the widely accepted threat of serious climate change and global warming. Moreover, time and labour-saving technologies may be a mixed blessing in another sense; they may lead to de-skilling and loss of employment - at least in the short- and medium terms. (It is not even clear how much time and labour these technologies have actually saved e.g. middle-class households!)

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#### DEFINITION

*"Cost-benefit analysis is based on the premise that a balance should be struck between the costs involved in reducing risks and benefits stemming from risk reductions. It provides a framework for examining the trade-offs involved in [chemical] regulations where these include the impacts on industry, consumers, society more generally, and the environment."*<sup>1</sup>

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Cost-benefit analysis is the direct ancestor of most risk analysis and risk management processes in use today. It has been one of the main techniques used to determine whether a particular process or product is desirable or not. However, in a globalised and highly interdependent world, those who pay the 'costs' in any given instance may well not be those who stand to benefit. Moreover, there is a very complicated cost/benefit matrix that applies: each individual in a given system may perceive a wide variety of 'costs' and 'benefits' associated with a particular activity, material, or thing; and there may be thousands of individuals who could be considered 'affected stakeholders'. A worker employed producing automobiles benefits from the financial security of a wage and, more subjectively, from the knowledge that he or she is 'contributing' to society. However, the same worker is increasingly obliged to pay the costs of the down side of the private automobile in terms

of pollution (chemical, noise, light), vehicle- related death and injury, serious congestion, major infrastructural investment, etc., with a wide range of unwanted knock-on effects including delays, stress, etc.

The utility of cost/benefit analysis may well be reduced the more general the issue to which it is applied. At the individual and local levels it may have some utility. However, even here it is important to understand its limitations. Suppose that the introduction of private automobiles, and the subsequent commitment of considerable public resources to the construction of the infrastructure to support them, such as roads, bridges, parking areas, police services, etc. had been subject to a cost-benefit analysis at an early stage, when the private automobile was still seen as a product of limited utility. An agglomeration of individual decisions (such as the decisions by huge numbers of people to own automobiles) greatly affect both the cost and benefit side of the equation, and might have resulted in a very different cost-benefit analysis result had they been anticipated and considered.

**...3A WHY make a judgement, why must society decide?**

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**DEFINITION**

*In this document, the term "society" is used to refer to any and all systems of collective decision-making used by democratic nations.*

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By 'societal decision-making' is meant primarily decision-making by our governments, but not solely by our governments. Indeed, it has been argued that at the beginning of the twenty-first century, the defining structure of society is not the government, but the corporation. Thus, societal decision-making refers to governmental decision making, i.e. legislation and regulation along with the administrative and enforcement activities they entail; but it also includes corporate decision-making including such systems as industry voluntary initiatives.

When private business judges, the results are often very different from the judgements of governments.

In the increasingly globalised economy, societal decision-making is, of necessity, beginning more frequently to be characterised by decision-making systems at the international level through institutions such as the United Nations (e.g. the International Labour Organization, the World Health Organization) and others such as the Organization for Economic Cooperation and Development, the European Union, etc.

It is because there are conflicting wishes and demands - at both the individual and the group levels - that society needs credible and widely supported principles for making decisions. The alternative is conflict and ultimately anarchy with the strong prevailing, and the devil-take-the-hindmost.

It is a fundamental responsibility of governments to protect the health of their citizens. In an unfettered free market, decisions about new processes and products would be based solely upon the potential to generate wealth for those who have control over them. Recognizing that these interests might sometimes conflict with societal protection, we have enacted laws and written regulations.

It must be understood that there is nothing inherent about a free market that would ensure the protection of human health, let alone the environment. Proposals to make the free market more responsive to these factors, such as voluntary initiatives and full-cost accounting will never entirely replace the need to regulate. Indeed, in their application they can better be described as complementary approaches to regulation, rather than substitutes for regulation.

Questions of sustainability are ultimately questions of how society makes decisions in all of its institutions and structures. In effect, they are questions of democracy. Exactly what kind of a society do we want? Who benefits, and who pays the price, for the introduction of new processes, products and technologies? Can the costs and benefits be measured accurately and shared fairly?

### **...3B WHO should judge? The professional versus lay stakeholder.**

In any democracy, those who take decisions must expect to be subject to scrutiny and criticism by those who perceive themselves as being affected by such decisions. This is as it should be.

It has been well said that one person's rights end where another's begin. However, this truism provides only a guiding principle - there is all too often disagreement about where the 'boundary fence' lies between, for instance, individual and collective rights..

A side effect of the evolution of ever more complex and sophisticated decision-making systems has been the creation of an elite group of decision-makers, largely divorced from those whose lives are affected by their decisions. The more the technical complexity of both the science and the regulations has tended to become, the more we have placed the responsibility for judging dangers and their management in the hands of this small group. They have become, in effect, professionals in that field.

It has also been said - with some justification - that at some level, every profession is a conspiracy against the laity. 'Ordinary' or 'lay' persons rely on the expertise of various professions. However, professionals rely on the trust and support they receive from the laity. Physicians, in response to this problem, developed the 'Hippocratic Oath' as a public commitment to their patients. This has evolved into a code of medical ethics that usually includes such concepts as (i) above all do no harm; and (ii) informed consent, (amongst other principles).

A similar problem faces all of those charged with the protection of human health, and the environment. Do scientists and other professionals, educated and employed from the public coffers, have a responsibility to use their knowledge in the public interest? Whose trust must they maintain? Are they guided by codes of ethics similar to physicians? Are present decision-making processes based on ensuring that no harm is done, and that citizens make informed consent?

Faith in public decision-making is further eroded by the way some regulatory authorities inconsistently mix quantitative- and qualitative- risk-based, and precautionary, approaches.

A further issue faced by those who make decisions on behalf of the public is whether, at this time in the history of many western democracies, there is any real commitment to public policy, including regulation, in the public interest. There are increasing efforts by 'experts' to persuade us, (sometimes by haranguing, bullying and blackmailing us) - that economic competitiveness is the most important, or perhaps even the sole, criteria by which public policy decisions should be judged. Globalisation, trade, restructuring and downsizing, and technological change have thrown into stark relief some of the basic precepts upon which democratic society is based.

The problem of globalisation, with its ever-present implied threat of the flight of capital to countries with lower standards, is one which cannot be dealt with here. Suffice to say that citizens are increasingly demanding that their governments work towards some kind of meaningful international regulatory regime, rather than abandon the notion of effective regulation.

In this environment, there have even been calls to re-define regulators as 'service providers' and those who are the targets of regulation as 'clients'. This is fundamentally wrong. The relationship between regulator and regulated is not the same as service provider to client. Business models that work well for service providers are quite inappropriate for government agencies that, at least part of the time, must enforce regulations governing the behaviour of individuals and corporations. For example, the 'customer is always right' may be a useful guide to behaviour if one is in the business of selling a service, but is disastrous when the 'customer' may be engaging in harmful activities that the public, quite rightly, want controlled.

No reasonable person can be opposed to the development of systems and processes by which government agencies, even regulatory ones, do what they must do in the most efficient, fair, and open manner possible. In this way the credibility of the regulators, and the regulatory system, can be maintained.

As for the actual regulatory decision-making processes, there must be recognition that technical expertise is necessary, but not sufficient, for sound public policy. Stakeholders must be involved.

Experience has shown that risk assessments tend to differ depending on who is doing the assessment, and who is facing the risk. At all times, the stakeholder whose input must be given the most weight, is the one who is involuntarily put at risk. This is particularly apparent in the case of decisions

having to do with the introduction of new processes and products, where we have by definition successfully lived without them up until the present.

**...3C WHAT kinds of dangers do we need to decide about?**

*"But a kingdom that has once been destroyed can never come again into being; nor can the dead ever be brought back to life. Hence the enlightened ruler is heedful, and the good general full of caution." - Sun Tzu<sup>2</sup>*

Sun Tzu, who wrote his still-studied treatise on the Art of War about 500 years before Christ, defined the areas in which a ruler (government) should exercise the greatest caution as those that may destroy a kingdom (country or, one might reasonably argue, and by extension, the environment) or cause death. His definition remains valid today.

Although Sun Tzu was no doubt primarily considering military advantage, he may have recognized that a kingdom can be 'destroyed' socially, economically, and politically. He may even have recognized that environmental destruction (at least as a consequence of war) could spell the end of a kingdom.

We, of course, are primarily interested in the question of environmental destruction and threats to human health in this paper. As a consequence of new technologies, hazardous substances, and dangerous activities, human health and environmental sustainability are potentially threatened. This means more than a statistical increase in cancer rates, or species loss. They can indeed mean the destruction of our country, our society, our 'kingdom'. How enlightened are our rulers? How cautious our generals?

Each of us makes risk-based decisions on a daily basis. Most of us do it on the basis of a mixture of experience, enlightened self-interest and common sense. Very few of us refuse to acknowledge risk or deal with it. However, it is one thing to accept a risk on one's own behalf, and an entirely different thing to have to accept a risk imposed from without. The difference can be summed up in one word, 'choice'. However, it has still to be recognised that the choice exercised by one person may well be the imposition suffered by another. The slipstream smoke from a smoker's cigarette might be a good example of this. One also has to recognize that an improvement in one area may lead to degeneration in another especially where decision-making is based on the assessment of only one or a very limited number of parameters.

In general, society-based decisions are probably best restricted to those risks and hazards that cannot be described in any reasonable understanding of the term as either within the control of individuals and/or freely chosen. Thus an individual may have a perfect right to smoke cigarettes. However, it is perfectly acceptable for society to determine the limits of that right with regard to the rights of non-smokers.

When the dangers of asbestos became well known, there was a strong movement for banning all uses of the product. As the medical aspects of exposure to asbestos became more widely discussed it became clear that exposure to asbestos fibres combined with cigarette smoking resulted in a synergistic increase in risk of the order of 10 times. The asbestos apologists quickly seized on this truth to blame the victim; i.e. if s/he had not smoked s/he would not have suffered the disease. Apart from the fact that exposure to asbestos fibres in the absence of any other confounding factor – including smoking - has been well demonstrated to give rise to a very significant risk of serious health problems, this argument clearly confuses a freely chosen risk with an imposed hazard.

On the other hand, that these kinds of judgements are complex can be illustrated by the relationship between driving a vehicle and alcohol consumption. In developed countries, many situations virtually demand the use of an automobile. Driving a car is inherently risky but those risks leap enormously when the driver consumes what would otherwise be a trivial amount of alcohol. Yet we do, and probably rationally, blame the alcohol drinker for drinking and driving accidents on the grounds that they have needlessly added to their own risk. In this case the freely chosen risk of drinking is given more weight than the socially-imposed risk of driving; perhaps because of the potential for this behaviour to injure and kill others.

There are still numerous and widespread occupational health and safety problems around the world, but we are now also faced with major new challenges in the way we, as human beings, interact with our fellow creatures and our broader environment. This is an issue whose importance is growing rapidly. Perhaps the most well known of the many aspects of the human/environment relationship is that concerning climate change and global warming resulting, principally, from the anthropomorphic emissions of so-called 'greenhouse gases' (GHGs). Evidence is mounting that GHG emissions pose a serious threat to the quality of life on earth and may even threaten life itself. The issue provides a good case study of many aspects of the risk vs. precautionary approaches to problem solving and decision making. Huge vested interests spend equally huge resources in denying the problem. Other interests take every opportunity to paint the worst possible picture in the hope that this will trigger what are believed to be the necessary radical measures to address climate change. The former typically take the view that a modified 'business as usual' scenario based on risk assessment is the correct approach, whilst the latter tend to the view that the possible dangers are so great that only the most assiduous application of the 'precautionary principle' will suffice. Both approaches are accompanied by major and far-reaching implications for the economy, the environment, and the society we share.

### **...3D WHEN should we make judgements/decisions?**

The best possible time to make judgements about any kind of hazard is when: (i) they have not become entrenched as 'necessary' to the economy; (ii) new information becomes available; (iii) significant changes in use, quantity, or distribution of the hazard occur;

The process of licensing or approving new products and processes, in particular, provides us with a unique opportunity to do the right thing, at the right time. Existing substances, substances whose

use is already integrated into the economy, are much harder to deal with. Even noting that at the point of requesting licensing or approval, a chemical company may have already incurred significant research and development costs, it is better to require hazard information then, than earlier (when a large number of new substances that will never be mass produced would require testing) or later (when the substance has already become entrenched in the economy and when many people may have already been exposed to it).

In any discussion regarding judgement and decision-making it is important to understand that we rarely have the luxury of starting with a blank sheet. Past decisions have implications for future decision-making. Nor do we live in a static world. Yesterday's well considered decision may prove to be less than perfect in the light of experience and in the face of new knowledge and subsequent technological progress. However, yesterday's decision may, nevertheless, have been made in good faith and have involved considerable capital expenditure. A major question is then, at what point is it reasonable to demand that the process and the investment be repeated?

Against this background, it makes sense to make the best possible decision as early as possible if unwanted consequences are to be avoided. In the past, companies have tended to base their decision-making on the philosophy that 'the business of business is business', and the responsibility of industry is first and foremost to its shareholders. Both approaches have been narrowly interpreted - and still are by many companies. All the signs are, however, that the growth of vocal, well informed, well organized citizens and interest groups is changing the criteria on which business decisions and shareholder value will in future be made and the criteria on which companies will be judged.

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A paper from 'The Industrial Society' a UK-based organization representing some leading thinkers and advisors on the world of work, contained the following observation:

*"The new centrality of business in contemporary life means that business must acknowledge that it too has citizenship responsibilities. Victory in the ideological battle means that paradoxically it has never had greater obligations to act with integrity and wider social purpose."*

The paper went on to say that:

*"The successful business must increasingly be able to demonstrate to customers, workers and shareholders that it possesses an integrity of purpose and that its practices respect individual and human rights. In this sense, a business franchise can no longer be considered as the creation of brand loyalty earned by a sustained capacity to deliver consumer satisfaction; brand loyalty also requires that a business earns a reputation for business conduct that has integrity and solid ethical compass."*

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**Conclusion to Section 3: Preparing to judge the danger**

Thus, there are three essential points to be made about the social context of decision-making.

The first is that communities have an outlook on what sorts of society they value. For instance, they may have a preference to live in a non-toxic economy or an economy, which is the least toxic feasible. Or they may accept the "toxic economy" as a given and seek to limit it only at the margins or when it may get out of hand.

Second, they choose the degree to which they call on science to inform decision-making. For instance, a community may broadly reject food adulterated with chemical additives. Or it may broadly accept that chemical additives are tolerable unless there is scientific evidence of detriment.

Third, a community has choices about what sorts of science it will utilize and how it uses science in the decision-making process.

Many present-day governments have chosen a policy of limiting or restricting the social choices available to communities. They have done this by restricting access to information, and limiting both the interpretation and the degree to which communities can utilize both risk assessment and precautionary decision-making systems.

For instance, the World Trade Organisation's (WTO) Agreement of 1994 very broadly requires that:

- (i) there be no programmatic attacks on the toxic economy and even piecemeal attacks are to be severely limited;
- (ii) science and science alone is to be the criterion for restricting the toxic economy;
- (iii) by "good" science is meant risk assessment and risk assessment alone; and
- (iv) risk assessment is given a particular interpretation; i.e. it is to be as defined by the WTO.

Trade unions reject this. Economic considerations on their own are important; but must not be given precedence over environmental and social ones.

#### **4. Making the judgement**

Recent history suggests that a growing number of people are unwilling to stand meekly by as decisions with potentially significant impacts on their lives are taken (or not taken). Although speculative, it seems reasonable to expect that this unwillingness is likely to manifest itself more frequently, especially in light of the growing distance between decision-maker and impacted citizen that is all too often a feature in this rapidly globalising world.

In light of the above general introduction to the issue, and discussion of the why?, who?, what? and when? of danger assessment and decision-making, the specifics of how such judgements are made can now be discussed. There are two broad philosophical approaches to such judgement making. For discussion, they can be labelled the 'risk assessment' and the 'precautionary principle' camps. These are not pure polar opposites as will be seen later, and there is a range of interpretation and differences



of methodology in each camp. There are also appropriate uses for each; and there are good and bad examples of the application of each. Even when a particular approach can be agreed upon, there are often quite serious errors made in application.

However, risk-based approaches are by definition based on an evaluation of risks, whereas precautionary approaches generally consider hazards (see definitions section below).

In either case, normal good decision-making must be followed: define the problem; gather information, analyse the information, consider alternatives, and decide upon a course of action.

Here are a couple of simple grids; one representing a hazard based approach and one representing a risk based approach as follows (numbers in the 2x2 grid represent priority):

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**RISK BASED** (assumes accidents are exceptional events)

increasing 2 | 1  
severity ---+--  
of outcome 3 | 2

^  
>increasing frequency/likelihood>

---

**HAZARD BASED** (assumes accidents inevitably will happen)

increasing 2 | 1  
severity ---+--  
of hazard 3 | 2

^  
>increasing quantity/frequency of use/action>

---

As can be seen, a hazard-based approach avoids the need to estimate exposure and outcome and is thus more precautionary.

In both of the above diagrams, the number indicates the priority of action. The highest priority, (1), would be high severity, high likelihood/quantity/frequency situations

The intermediate priority, (2), would be those situations where the likelihood was high but the severity was low, OR where the severity was high but the likelihood was low.

The lowest priority, (3), would be those situations where both the severity was low AND the likelihood/quantity/frequency was low as well.

Many people would accept the logic of the above grids. Disagreement would probably arise over the location of a particular hazard or risk on the grid. Within that disagreement lies part of the distinction between risk assessment and a precautionary approach. Another point of disagreement between 'risk assessment' and a 'precautionary approach' lies in the choice of 'outcome' (consequence) versus 'hazard' (intrinsic properties) as the basis for decision making in general. Although there is some overlap in the two approaches, risk assessors prefer to analyse potential consequences while advocates of a precautionary approach prefer to base their decisions on the intrinsic properties of a substance or process.

#### **...4A Defining the problem**

The first step in any decision-making system is to define the problem. Immediately, those who would judge dangers on behalf of the rest of us are faced with a question of intent: is the problem to determine what hazards should be tolerated, or is it to minimize the risk of such hazards? Within the answer to this question lies the question of choice between a risk assessment approach, and a precautionary approach or a mixture of both.

The dimension of intent can be thought of as a continuum, with one extreme being 'prevent harm' and the other being 'avoid responsibilities'. If we define the problem as being one of preventing harm, then we would try to use good science in an open and transparent manner to develop sound policy. That approach would represent one end of the continuum. If, on the other hand, the intent is to avoid the need to take action and/or to avoid legal responsibilities, we would design a decision making system that creates the impression of scientific certainty where none exists, argue cost/benefit of protecting human life, etc.

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#### **DEFINITION:**

*"Risk assessment is a conceptual framework that provides the mechanism for a structured review of information relevant to estimating health or environmental outcomes. In conducting risk*

*assessments, the National Academy of Sciences risk assessment paradigm has proven a useful tool (US NAS, 1983). This paradigm divides the risk assessment process into four distinct steps: hazard identification, dose-response assessment, exposure assessment and risk characterization."*<sup>3</sup>

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Risk assessment demands evidence of likely and unacceptable consequences before action is taken, whereas the precautionary principle generally demands action where there is a perceived risk of serious and unacceptable consequences despite the absence of any direct and/or incontrovertible evidence of harm. Risk assessment is most appropriate when there is considerable data available, and when selecting between different known alternatives, or control options of proven effectiveness. Precaution is most appropriate when there is an absence or severe shortage of data, the safety of alternatives and/or the effectiveness of control options are questionable or unknown, and the consequences may be serious. Both philosophies incorporate a number of assumptions. Risk assessors often claim that theirs is the more scientific approach, while precautionary principle advocates usually claim moral or ethical superiority. However, the precautionary principle is not anti-scientific, nor are risk assessors all amoral people bent on the destruction of the planet. The real question, of course, is not whether risk assessors are amoral but whether they are truly scientific. Because 'risk' implies a greater use of estimated, derived or inferred data than 'hazard' it can be argued that risk assessment is actually a less scientific approach than precautionary ones (that prefer to use hazard data rather than risk data).

In general, many of the assumptions built into risk assessment are based on terminology and the definition of the problem. 'May pose a risk' has a very different meaning, and implies a very different regulatory approach, than, for example, the phrase 'is a risk'. 'May pose a risk' implies the same meaning as 'hazard'. However if something 'is a risk' then there must already be exposure or even harm.

A widely accepted definition of the word 'risk' is the 'probability and magnitude of harm'. In the case of chemical exposures, for example, risk is normally presented as a function of both exposure and toxicity. Contrast this with the definition of 'hazard', which is the 'source of risk'. Put another way, 'hazard' has something to do with the intrinsic properties of a substance, technology, or process. However, 'risk' addresses the consequences, in terms of both the likelihood and nature of the outcome, of an exposure to a hazard. 'Toxic', another word frequently used in any discussion of chemical regulations, describes the specific hazard of a substance (i.e. the intrinsic property of being potentially or actually poisonous) just as 'flammable', for example, describes another specific hazard.

A sealed vial of poison, buried twenty miles underground or launched into space, with virtually no chance of an exposure to it, is nevertheless 'toxic' and a 'hazard' despite there being virtually no 'risk' associated with it.

Note that a reverse search from the definition phrase 'may pose a risk' would produce the word 'hazard', or in the case of a chemical, 'toxic'; and NOT the word 'risk' by itself. It is a hazard that may pose a 'risk', not a risk that may pose a 'risk'.

### **Example #1 -the Importance of Using Clear, Standard Definitions**

To illustrate the importance of clear definitions, the above definitions of 'risk' and 'hazard' are not the same ones as used by Health Canada and Environment Canada in the administration of the Canadian Environmental Protection Act. For the purpose of determining whether a substance is a candidate for prevention and control measures, (and for reasons best known to themselves), they have re-defined something that 'may pose a risk' as something that 'is a risk'. They have done this, not by explicitly using the words 'risk' or 'hazard', but by insisting that a substance, in order to be considered 'toxic' (the hazard) must also be one to which there is exposure (thus, risk). Using this erroneous and somewhat self-cancelling (like a double negative) definition, the definition of a toxic substance under the Canadian Environmental Protection Act (CEPA) is one that poses (not 'may pose') a risk. The semantic equivalent of CEPA's definition of 'toxic' is a 'risk', when it should be 'hazard'. Semantics become important in regulations, especially those that attempt to translate something technical into something comprehensible and enforceable. Consider that both Environment Canada and Health Canada subsequently do risk assessments on substances that initially pass the threshold of meeting this flawed definition of 'toxic'.

Therefore the two agencies charged with protecting human health, and the Canadian environment, are reduced to considering only those substances that can be described by the recursive, confusing and grammatically challenging phrase 'risky risks'.

To add a further measure of confusion and ambiguity, the same Act is forced to use the phrase "inherent toxicity" (which should be redundant, toxicity referring by definition to the inherent properties of a substance) in the section on determination of Priority Substances, because of the flawed definition of "toxic" adopted in other sections!

### **...4B Gathering information**

Another dimension of any decision making system to deal with dangerous products or activities is the data dimension. Here, too, there is a continuum of choices, with most practical decision-making schemes lying between the extremities. At one extreme, we would only use hard, measurable, objective data, mostly related to the intrinsic hazard properties (e.g. toxicity, potential for bio-accumulation and bio-concentration, persistence and mobility in the environment) of the substance or situation. At the other extreme, we would plug in a great deal of soft, assumption-based derived data such as outcome and cost (e.g. anticipated levels of human exposure, health impacts). This is the end of the continuum that assigns a monetary value to human life, or the odds of killing x number of people per hundred thousand per year, and at a later stage, a cost-benefit analysis on the merits of controlling the hazard. In rare cases, environmental and occupational health 'costs' are also considered. Still rarer are instances in

which social costs are considered. At an intermediary stage along the data continuum, between 'hard' and 'soft' data, lie information about usage patterns, estimates of exposure, and in some cases alternative products and/or uses.

Decision-making, if it is to be effective and credible has, as far as possible, to lie towards the objective end of this continuum. This means, amongst other things, that it has to be based on best available evidence and information. Ideally, such evidence and information should be available before a decision is taken. However, even then, there will be a need to monitor and update decisions on the basis of latest evidence and information; the better the initial data (evidence, information, etc.), the better the initial decision and the less the likelihood of costly mistakes.

Where it is not possible to be 100% objective (the 'normal' case) the basis and the assumptions upon which subjective criteria are used must be made clear. Part of the increasing citizen dissatisfaction with appeals to 'sound science' is due to the fact that science and scientists have not been sufficiently humble and open regarding the limits of their knowledge.

What data is needed, and how do we ensure its quality?

Some of the desirable pieces of information to judge, for example, a chemical hazard would include:

(1) toxicity:

- (i) basic toxicity data, e.g. LD50/LC50, aquatic toxicity, target organ and systemic characteristics (carcinogenicity, mutagenicity, reproductive toxicity, endocrine disruption, etc.)
- (ii) dose-response relationship, especially the dose below which no detectable harm occurs, if such exists/is known; or whether the substance exhibits any non-threshold effects, e.g. a genotoxic carcinogen
- (iii) any synergistic effects, or combination effects with other chemicals.

(2) environmental fate

(3) any tendency for the substance to bioaccumulate or bioconcentrate

(4) other environmental effects; e.g. ozone depletion, greenhouse gas, etc.

(5) persistence in the environment

(6) nature of use and potential alternatives and options

(7) anticipated quantities of use

(8) anticipated nature and distribution of use

(9) social consequences of use/non-use

(10) economic consequences of use/non-use

The choice of what data to look at, and what to ignore, is not a trivial question. For example, those citizens whose health is most at risk if bad decisions are made about a chemical substance, are the workers who will handle it directly. And yet occupational data is very often unavailable. This is particularly true in the case of licensing of new substances. In other cases, occupational data may exist, but is deliberately ignored.

It can immediately be seen that some of the data points mentioned above are much more easily and objectively determined than others. For example, those relating to environmental, social, and economic consequences have a history of being found to be in error, after the fact. Sometimes this is because of the unfortunate choice of an inappropriate or misleading indicator. The Atlantic cod fishery on the Grand Banks of Newfoundland is a classic example, where stocks were estimated in part on the basis of the previous season's catch. When technological change caused an upwards trend in the catch, scientists were misled into believing that there were a lot of cod when in fact the cod were being efficiently strip-mined from the ocean.

It is important to understand that all of these pieces of data are interrelated, and it is impossible to understand the complete picture in the absence of certain pieces. For example, persistence in the environment is commonly understood to be a problem; yet if the substance is non-toxic and does not bioaccumulate, evidence of persistence may simply be confirmation that it is quite an inert substance.

All data must be scrutinized to determine its quality, or more precisely, its credibility. Many of the data points will never be more than an estimate, at best, or perhaps little more than an educated guess. For example, information on anticipated quantities, nature, and distribution of use for a new substance can only rely on the expectations of the manufacturer or supplier. Frequently, these expectations have proven to be dramatically wrong. Where real harm and real benefit cannot be accurately determined, potential harm and potential benefit must be considered. It is important to keep in mind the quality of the available data during the analysis step.

#### **...4C Analysing the information**

How we treat, or analyse the information that is available, is to some extent connected with the issue of sensitivity to errors in the data set. Again, a continuum of choices can be used to design a decision making system that is very sensitive, or quite insensitive, to individual errors or gaps in the data set. On the one hand, decision making systems that are inclusive, public, transparent - in other words that try to make use of the collective wisdom and judgement of appropriate stakeholders - and that bridge the inevitable gaps in data with 'worst case scenarios' will be relatively insensitive to error in a particular piece of data. However, such systems will generally only be able to produce estimates or rankings that are qualitative, rather than quantitative. On the other hand, decision making that attempts to be very mathematical and quantitative tends to be done by 'professionals' and (usually) very quickly becomes a private and elitist system. These formulaic approaches tend to bridge data gaps with estimates and assumptions. While useful in some instances, decision making systems that lie towards this extreme are very sensitive to errors

in individual pieces of data which may form the basis for several of the estimates and assumptions built into them.

When the pesticide DDT (dichloro diphenyl trichloroethane) was first introduced it was very effective in dealing with the vectors against which it was employed. There is no doubt that many cases of malaria in all parts of the world have been prevented through the use of DDT. However, we now know that not only are mosquitoes becoming resistant to DDT, but also that DDT is one of the persistent organic pollutants that are increasingly implicated as the cause of a wide range of health and environmental damage. DDT is a relatively straight forward case, and even here it has taken decades for the world to wake up to the unacceptable downside of DDT use. The more complicated the world has become the more difficult it has become to be sure of the likely consequences of any particular course of action (or inaction).

The case of DDT also throws into stark relief the rather sobering point that for every solution there is often a problem. This should not stop us looking for improvements, but it most certainly should act to keep us humble about our scientific, economic and social certainties.

In either risk based or precautionary approaches, the goal is to identify real and potential hazards. Precaution tends towards the extreme of demanding from the proponents of a technology at least some 'evidence of no harm' while risk assessment is often content to work with 'no evidence of harm'. Both decision making processes must use models and assumptions, but the more transparent precautionary approach tends to be better at acknowledging what those models and assumptions are.

Of course, 'evidence of no harm' is impossible in an absolute sense, but striving towards that goal would mean that we should give serious consideration to, for example, the development and implementation of tests for endocrine disruption. As risk assessment is currently practised, unfortunately, we are often content to make decisions based on 'no evidence of harm'. In these systems, unless through serendipity we find some evidence of e.g. endocrine disruption, we will not consider it. There is no such thing as zero risk, but the objective of a good decision making system ought to be to impose much less severe risks to the environment and human health than we have done in the past.

#### **An Example of an Analysis Process, #1** **-New Substances Notification in Canada**

According to their own presentations, Health Canada and Environment Canada engage in separate risk analyses for new substances.

The three key pieces of data used are:

- ( x ) the anticipated final concentration in the environment, based on manufacturer's or importer's proposed pattern, extent, and quantity of use;
- ( y <sup>1</sup> ) a fixed fraction (essentially a built-in safety factor to take into account margins of error) of the predicted concentration at which harmful effects upon the environment (in the case of Environment Canada) would occur; based on environmental, toxicological, and chemical data.
- ( y <sup>11</sup> ) a fixed fraction (essentially a built-in safety factor to take into account margins of error) of the predicted concentration at which harmful effects upon human health (in the case of Health Canada) would occur; based on toxicological, chemical, and environmental data.

While the concentration determined as x is common to both Environment Canada and Health Canada, concentrations y <sup>1</sup> and y <sup>11</sup> differ based on whether primarily environmental effects or primarily human health effects are being considered.

In both Health Canada's and Environment Canada's risk assessment, cause for action is determined by whether  $x/y > 1$  (that is, whether the anticipated concentration in the environment will exceed the specified fraction of what is believed to be the "harm" level).

It should be immediately obvious that x is by far the least reliable piece of data, based as it is upon guesses and predictions about usage. While y <sup>1</sup> and y <sup>11</sup> are also problematic, most frequently due to a simple lack of information, they are at least based on measurable indicators.

The unreliability of estimates of the eventual environmental concentration of chemicals whose ultimate use patterns are unknowable, has consequences for what are known as 'exemption triggers' as well as for regulatory decision making for non-exempt chemicals. Some chemicals are not required to be reviewed prior to use, if their quantities of use are very low; others are subject to less stringent testing requirements based on low levels of usage.

Leaving aside the question of the arbitrary selection of these exemption levels and the effects of an error in quantity x upon their triggering, a serious methodological problem exists with Health Canada's and Environment Canada's risk assessment process even for chemicals that are subject to the full notification requirements.

By their common use of estimated concentration x, the anticipated final concentration in the environment, Health Canada and Environment Canada have constructed a system in which the least reliable piece of data can trump all other data. This can be understood from the following logic.

x is estimated as part of NSN process based on manufacturer's predictions about use.

y <sup>1</sup> is calculated by Environment Canada.

y <sup>11</sup> is calculated by Health Canada.



Regulatory action will be taken IF AND ONLY IF either  $x/y^I$  or  $x/y^{II} > 1$ .

If  $y^I$  is in error, then  $x/y^{II}$  may nevertheless trigger some action.

If  $y^{II}$  is in error, then  $x/y^I$  may nevertheless trigger some action.

However

If  $x$  is in error, then all subsequent work by both Environment Canada and Health Canada will be in error and regulatory action will be either wrongly applied or wrongly determined to be unnecessary.

This is more than a problem of insufficient quantity and quality of data. It betrays a fundamental failure to understand the very risk assessment process itself. Advocates of the precautionary principle would argue that in this situation (decision making about chemicals whose use is not yet entrenched in the economy) a precautionary approach is more appropriate than a risk-based one. However, even defenders of a risk-based approach must be concerned by the illogicality of the above system.

It would not be difficult to construct an alternative system, even one based on risk assessment. For example,  $x$ ,  $y^I$  and  $y^{II}$  might each be assigned a certain number of points, the total of which, exceeding a threshold, would trigger regulatory action. Better still, the individual pieces of data used to calculate  $x$ ,  $y^I$  and  $y^{II}$  could be assigned their own points, weighted if necessary, to contribute to a total which would trigger regulatory action. In this way, an error in any one or even a few piece(s) of data would not be absolutely fatal to the decision making, and hence regulatory process.

As previously alluded to, however, a more fundamental question, however, is whether the quantity and quality of information available for new substances is more appropriate to a precautionary approach, or a risk assessment approach.

### **An Example of an Analysis Process #2**

-the Precautionary Principle and the European Union

The precautionary principle is often portrayed by its opponents as ill-defined, anti-technology, and anti-scientific. In fact, precaution is neither anti-technology nor anti-scientific, and is at least as well defined as risk assessment - a term which is itself used to describe a wide variety of assessment and management approaches.

The February 2, 2000 European Commission Communication on the Precautionary Principle notes:

*"The precautionary principle applies 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."*

Other conferences and organisations have adopted similar definitions. The principle seeks to place responsibility for demonstrating the safety of a technology upon its proponents, and to encourage the investigation and consideration of alternative technologies. In addition, a precautionary approach would explicitly acknowledge the limitations in available knowledge, and allow for public policy decision-making to be done in as transparent and democratic a fashion as possible.

As has been demonstrated in example #1 above, where the data available to a decision making process is highly questionable, the decision making systems generally described as 'risk assessment' do in fact tend to create a false aura of authority or certainty where in reality there is only insufficient data. It would be better in such circumstances to continue to utilize all the available data, but to acknowledge its limitations, and take a precautionary approach.

As has been previously stated, in both risk-based and precautionary approaches, the goal is to identify real and potential hazards. Precaution tends towards the extreme of demanding from the proponents of a technology at least some 'evidence of no harm' (remembering the difficulty in proving a negative), while risk assessment is often content to work with 'no evidence of harm'. Both decision-making processes must use models and assumptions, but the more transparent precautionary approach tends to be better at acknowledging what those models and assumptions are.

One aspect of the precautionary principle that has been less widely discussed is the extent to which it has generally been used in a rather narrow form. Risk assessment in international trade regimes and in some national legislation is used to limit restrictions to what is necessary; while the precautionary principle identifies action which is desirable or opportunities to make society safer rather than the minimum action required. Peter Colley, in the book *Reforming Energy: Sustainable Futures and Global Labour* has commented:

*"The precautionary principle broadly requires that where actions carry a significant risk then they should not be proceeded with. Often this is used only with regard to environmental risk that if some economic activity has a risk of significant environmental impact then it should be avoided or minimised. It is implied that environmental impacts are irreversible and economic risks are not. Neither is true. Environmental impacts are usually reversible, but often only over a very long time frame. Similarly, economic decisions and risks are not easily reversible. It was the wrong decisions made by many of the socialist economies that brought them to collapse, and the people of such nations are still paying a high price. The capitalist world is paying the price of its rapid deregulation of financial markets in the 1980's and again such policy decisions cannot be easily reversed."*

An interesting aspect of the above commentary is the absence of any serious consideration of the social dimension of sustainability. A balancing of economic and environmental imperatives, while necessary, is insufficient without consideration of the social impacts to achieve sustainability.

Another interesting aspect of the above paragraph is the number of times the word 'risk' is used. This illustrates that precaution and risk based approaches are not mutually exclusive alternatives but points on a continuum.

The linkage between the Precautionary Principle and Risk has been acknowledged even more explicitly by the Commission of the European Communities:

*"The precautionary principle should be considered within a structured approach to the analysis of risk which comprises three elements: risk assessment, risk management, risk communication. The precautionary principle is particularly relevant to the management of risk"*

*"The precautionary principle, which is essentially used by decision-makers in the management of risk, should not be confused with the element of caution that scientists apply in their assessment of scientific data"*

*"Recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty"*

*"The implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty." (emphasis added)*

It is clear from the above that many are unable to separate the concept of risk from that of the precautionary principle

The precautionary principle and risk assessment are, therefore, not necessarily mutually exclusive. In fact, many advocates of the precautionary principle would agree that risk assessments are appropriate where there is sufficient credible information to evaluate alternatives. Where the two approaches depart is over the false sense of certainty that either of them can create out of uncertain data.

Given this, how unambiguous are the benefits to be expected from either the Risk Assessment or Precautionary Principle approach? It is the view of the authors that neither approach can be considered unambiguously beneficial on all occasions or in all circumstances. Some illustrations might help to demonstrate the nature of the problem.

For the purposes of these illustrations, it is assumed that the precautionary principle and the risk assessment approach are not necessarily limited to health, safety and environmental issues per se. We believe that it is crucially important to make this point, since decisions about health, safety and environmental protection are never taken in isolation. They are always, in practice, taken against a background of economic, social and political considerations.

**Illustration 1. One person's 'precaution' is another person's 'risk'**

A worker is offered increased money for being prepared to undertake dangerous, dirty or unpleasant work. The risk to the worker of increased health and safety harm is understood by her/him. However, s/he may perceive that a prudent health and safety precautionary approach (i.e. not accepting the work) would increase the risk to the family (in terms of reduced wages and reduced life opportunities for children, dependents, etc.). Which course of action is 'right' and who has the right to make that determination for the worker?, the worker's family?, the State?, the employer?, the health and safety specialist?, the economist?, all of them?

**Illustration 2. One person's 'risk' is another person's 'precaution'**

A pressure group succeeds in closing a polluting plant down. There is no doubt that the plant is causing pollution, but there are differences of opinion about the extent and effect of the pollution and the acceptability/effectiveness of proposed mitigation measures. The pressure group admits that there are a number of unknowns but insists that for this very reason the plant should close - on the basis of the precautionary principle'. The upshot is that the plant closes and a significant number of jobs are lost. Which course of action is 'right', and who has the right to make the determination the environmental pressure group?, the workers?, the employer?, the State?, local citizens?, the economist?, all of them?

These two Illustrations can be considered extreme cases (though by no means so extreme as to be unheard of). However, they should serve to demonstrate that when the precautionary principle and the risk assessment approach are understood and applied more broadly, they can rapidly lead to a complicated matrix of considerations. Moreover, it is not just the matrix of considerations that becomes complex. There is likely to be a complex matrix of interested parties.

From this one can reasonably expect that the combination of interests and the interrelation of measures and their effects will require a process of negotiation. For that process to be broadly acceptable, it will have to be as inclusive as possible of all relevant stakeholders. **In short, there is nothing inherent in either the precautionary principle or the risk assessment approach that relieves their various protagonists of the responsibility of thinking through the consequences of their positions.**

**An Example of an Analysis Process #3**  
- the World Bank

Several of the commonly used risk analysis methods are essentially attempts to apply cost-benefit analysis to risk-based decision making. In order to use the principles of cost-benefit analysis, of course, it is necessary to determine what the costs are, and what the benefits are. One of the most problematic aspects is how to assign a value to human life. This is commonly done in one of two ways:

1. an extrapolation from the principles applied in civil court cases (e.g. damages awards for injury);
2. an examination of existing wage rates for various occupations, based on the assumption that the marketplace already sets a value on human life through the wage differential for 'safe' or 'clean' jobs versus 'dangerous' or 'dirty' jobs.

The World Bank apparently uses the first of the two principles above (some would argue it simply asserts the "natural justice of the market"). Several years ago, the chief economist of the World Bank argued that the export of toxic wastes and dirty, dangerous industries to the developing world made perfect sense. The argument can only be understood if the principles used in civil court cases to determine the level of damages awards are understood.

In many developed countries, but particularly in the United States, damages awards are calculated using a formula that attempts to evaluate (1) lost earning potential; (2) reduced life expectancy; and (3) reduced quality of life.

If the worth of human life is set according to these indicators, then a cost benefit analysis of the proposal to ship toxic wastes or dirty, dangerous industries to the third world does indeed make perfect (economic) sense to someone who sees only monetary values, rather than human beings.

Citizens in developing countries tend to have much lower incomes than their counterparts in OECD countries. Therefore, by that indication, their lives are worth 'less'.

Citizens in developing countries tend to have a much lower life expectancy than their counterparts in OECD countries. By this indicator their lives are again worth 'less'.

Finally, from the perspective of a very well paid economist living in a highly developed country and working for a major international institution, the quality of life experienced by someone in the third world must appear abysmally low. By this indicator, therefore, the life of a citizen of a developing country is also worth much 'less'.

If the potential cost or liability of dangerous industries or toxic waste dumps is measured in these terms, then it would indeed appear that such costs must be lower in developing countries than in OECD countries. On the benefit side, there may even be some economic activity and job creation as a result of the industry or waste disposal.

The flaw in this argument is, of course, that the assumptions are biased towards producing this very outcome. It is no surprise that the rich would define the value of human life in a way that favours those who are rich. The surprise is that so many accept this definition as impartial or scientific.

#### **An Example of an Analysis Process #4** **-the Canadian Regulatory Review Process**

As discussed in the previous example, several of the commonly used risk analysis methods are essentially attempts to apply cost-benefit analysis to risk-based decision making. The World Bank attempts to assign a value to human life based on an extrapolation from the principles applied in civil court cases (e.g. damages awards for injury). The other method of determining the value of human life (that was mentioned earlier) is an examination of existing wage rates for various occupations, based on the assumption that the marketplace already sets a value on human life through the wage differential for 'safe' or 'clean' jobs versus 'dangerous' or 'dirty' jobs. This is the method used for several purposes by the government of Canada in the business impact analyses and statements appended to the Regulatory Review process.

In at least some of these, the government surveys incomes in several different occupations, defined as 'safe' or 'dangerous' based upon WCB accepted fatality rates. The differential between the average incomes of the two categories of occupation is determined to be the value society places upon the relative 'safety' or 'danger' of these occupations. Thus, if the average income of a coal miner (a dangerous job) is \$50,000 per year, and the average income of a bank clerk (a relatively safe job, in Canada, at least from the point of view of the chance of sudden death on the job) is \$30,000 then the value society places upon the increased risk of death is the difference between the two. Conveniently, the chance of dying on the job can be easily transferred to other risks. If a coal miner has a one in one hundred thousand increased chance of death due to occupation and the government believes that that increased risk is worth \$20,000 in additional annual pay, then the additional risk of cancer in the same order of magnitude from the use of, say, a toxic pesticide must also represent a 'cost' to society of \$20,000 per year per individual at risk.

This analysis, while no doubt appealing to the 'bean counter' mentality, is clearly ridiculous. It makes a number of unsupportable assumptions, for example that every individual, when seeking work, has complete information about the relative risks of those occupations, that the labour market is totally free, and that the primary consideration in choosing an occupation is some sort of individual cost-benefit analysis in which one weighs the chance of being killed as a result of one's work against the rate of pay.

Once the differential in pay per incremental increase in the risk of being killed on the job has been determined using this formula, it is then extrapolated to life-time earning potential based on average ages and multiplied by an arbitrary factor to allow for 'errors'. Based on this analysis, the Canadian government has determined that the value of a human life is approximately (Canadian dollars) \$7 million.

Once this has been determined, it is a relatively simple matter to use this in decision-making. In other words, if controlling a hazard is considered to have the likelihood of saving only one life, and the cost is greater than \$7 million, then it would not make sense to control it. The cost would outweigh the benefit.

Needless to say, the practitioners of this particular analysis are far removed from the occupations they feel competent to analyse.

#### **...4D Looking at the alternatives**

Looking at alternatives is a part of the decision making process that is usually applied at the point of determining what response, if any, should be made to a real or perceived danger. Responses can be related to a dimension or continuum, the extremities of which are 'proactive' and 'reactive'. At one extreme, decisions will be based on the need to prevent the perceived negative outcome; will tend to control hazards at the source, and will most frequently be described as 'precautionary'. At the other extreme, decisions are based on the desire to minimize the effects, or costs, of the potential outcome, or mitigate the outcome at the point or person(s) impacted. These decision making systems are most frequently described as 'risk management'.

In any situation where there are alternative courses of action available, there will inevitably be protagonists and antagonists. People may be driven by beliefs ranging from genuine conviction that their assessment is 'objective' all the way to an admission that the driving force is economic or political in nature.

This is why it is extremely important to undertake this examination of two of the most hotly disputed approaches to decision-making; the one based on 'risk assessment' and the other on the basis of the 'precautionary' principle. These two approaches are often presented by their supporters as polar opposites. They also tend to promote evangelistic fervour amongst their respective protagonists and antagonists. Lastly, they are not infrequently used as weapons in a broader ideological battle.

Yet from an individual perspective, even the most unreconstructed supporter of one or other of the 'schools' would quickly have to admit that they do not always practice what they preach in their day-to-day existence. The risk assessment supporter might well be the most assiduous person when it comes to balancing 'cost' against 'benefit', but he or she almost certainly also has to make decisions where information is not available to allow such an assessment. In such instances, self-preservation alone may require that the approach be precautionary (e.g. do I cross a busy road on a blind corner). Conversely, the adherent of the 'precautionary school' - unless he or she is a very exceptional person - is equally unlikely to ignore good cost/benefit evidence that suggests one course of action over another, even in the face of some residual risk.

It is important to understand why there should be this apparent contradiction between private action and public pronouncement.

For the decision makers to retain their credibility, and for the public to have trust in them, the options and alternatives considered during the decision making process must be clear to all stakeholders. What were the available courses of action considered? What were believed to be the consequences of doing 'X' versus 'Y'? What were believed to be the consequences of doing nothing?

This is a transparency issue. It must be clear to everyone in society with an interest in the issue:

- (1) what data was available and credible, and what was missing or questionable;
- (2) what policies, assumptions, and estimates were used to fill gaps in the data set;
- (3) what alternatives were examined;
- (4) the rationale for the decision that was made.

#### **Conclusion to Section 4: Making the judgement**

In any decision-making system, it is important to clearly define the problem, gather sufficient reliable information, and analyse the information before deciding what to do about it. This is true no matter where, on each of the dimensions discussed, a decision-making system lies; no matter whether it is characterized as 'risk based' or 'precautionary'.

In judging dangers, then, we should ask:

1. How has the problem been defined, and by whom? Who was not consulted?
2. What information is available, and what is its source? What information is missing?
3. What is the information telling us? What are the gaps in information telling us?
4. What are the alternative courses of action available, including taking no action? What are the likely consequences of each course of action? What is the worst-case scenario?
5. Based on the information, what would a reasonable, informed, member of the public without any vested interests, do?

Much of the debate about which process is the more scientific and credible can be settled by referring to this simple test.

#### **5 Benefiting society -while controlling the adverse effects**

It is not only the choice of decision making system that is important; the uses to which it will be put are important as well. In other words, the recommendations and ultimately actions that result from the decision making system need to part of the societal consensus on dangerous activities and things.

The concept of 'societal benefit' is a thorny one, and impossible to resolve in this paper given the differing views of the world's major philosophers in this regard. At the risk of gross



over-simplification, the definition of 'benefit' is more often than not dependent upon one's personal perspective; where one stands at any particular time and place.

Perhaps a more important concept relates to what might be described as a 'balance of benefits'. It might be acceptable to some people that they enjoy reduced benefits or protection in a particular respect or at a particular time as long as they can be reasonably sure that the same principle applies to their fellow human beings. This concept is closely related to the principle of the 'greatest good of the greatest number'. It does not require, and is not predicated upon the idea, that all will be satisfied at all times and in the same manner. However, there is explicit recognition that permanent and serious inequities between one individual or one group and another are not commensurate with the principle of the greatest good of the greatest number.

Thus, one of the important questions in science policy is who benefits, and who will pay the price, for e.g. the implementation of a new technology, or the introduction of a new substance, or the introduction of some other hazard into society. Clearly, the owners of industrial processes and technologies hope to be beneficiaries or they would not attempt to exploit them. Society or at least significant parts of it - may be either beneficiary, or victim, depending on the nature of the process, product or technology. The most easily definable group of potential victims are workers in the relevant industry.

The capacity of many countries to regulate industrial activities for the benefit of their citizens has been put to the test in recent years. Our capacity to produce independent scientific data has been eroded almost to the vanishing point. Nevertheless, we continue to expect our governments to enact laws to preserve the environment and protect human health, while allowing some measure of innovation and progress.

The credibility of governments has been somewhat compromised of late in the eyes of many citizens by governments' image as cheerleaders for industry. However, if our governments are serious about taking an active role, then perhaps they should be asking proponents of risky technologies to provide estimates of investment, job creation or other social or economic goods resulting from their introduction. Hypothetically, if a complete assessment based on sustainability (environmental, economic, and social) were to take place, a whole new set of indicators and appropriate data sets would need to be developed.

Not only are there clearly alternative approaches in methodology in judging a hazard, there are also clear alternatives in the available courses of action to control or eliminate/prohibit it. One of the tests of any decision-making system is whether the resulting decisions can be implemented or not. Decisions made should not merely address the management of the risk, they should prevent it where possible. Control at the source, or prior to widespread use in the economy, is far simpler to ensure than regulation and/or remediation after the fact.

## **6 Danger judgements in the context of regulation**

We are everywhere constantly reminded that we live in a globalised economy. In the new global economy, the capacity of national governments to regulate the behaviour of multinational corporations is being severely tested. There is little doubt that a new international regulatory structure must evolve. It will consist of cooperative agreements between national regulatory and quasi-regulatory bodies as well as traditional (or perhaps even some new) international bodies such as the ILO (International Labour Organisation) and the WHO (World Health Organisation). Standard setting and voluntary initiatives are also likely to play an increasing role, especially if they are credible.

Unfortunately, these international agreements and institutions have not caught up to the present day reality of globalisation, much less its rapid evolution. In this international regulatory vacuum, national governments must continue to assert their right to regulate on behalf of and for the benefit of their citizens.

It is well known that if the way in which decisions are made is changed, the resulting decisions will change. For example, very frequently, hazardous substances are introduced - by multinational corporations - as products or into production processes of one country that are already being used by the same corporations in other jurisdictions. All developed countries have regulations governing these types of introductions, yet it is clearly an area where some sort of international regulation or standard would be beneficial. The process by which these types of regulations and standards are written, even at a national level, is complex in the extreme and nearly impossible for labour, let alone NGOs, to have an effective voice in. When this is subsequently translated to the international level, it becomes even more problematic. This is not to say that labour has never been invited to participate. We have been, and we do. But the effectiveness of that participation, the opportunity to influence the outcome, is very limited indeed.

Multinational corporations, the beneficiaries of globalisation, should share in the responsibility to achieve sound decision making at the international level by promoting transparent and democratic processes and helping NGOs and labour to build capacity at the national and international level. It is in their interests to do so, for the alternative is to allow public opinion, and public policy, to head in opposite directions. This is a recipe for confrontation, and possibly violent confrontation, in society at some point in the future. It would certainly make for a less than stable basis on which to ensure long term capital investment.

## 7 Conclusion

Risk Assessment and the Precautionary Principle are not absolutes of good or evil.

- They each have their uses
- They each have their positive and negative aspects
- They can each be used to support a particular philosophical point of view
- They can each be used to support or undermine the status quo

- More humility and honesty is required of the proponents of both 'risk assessment' and the 'precautionary principle'
- 'Risk assessment' and the 'precautionary principle' have become to a large extent the insignia of one or other political or philosophical view of the world

An honest recognition of the strengths and weaknesses of each would permit decision-making to be supported by the strengths and to avoid, as far as possible, the weaknesses of each.

Risk Assessment and the Precautionary Principle do not exist in a political, social or economic vacuum.

If neither Risk Assessment nor the Precautionary Principle can be expected at all times and in all respects to give the 'right' answer or to command universal support, a number of consequences follow. These include:

- The need for consensus-building;
- The need for stakeholder involvement;
- The need for honesty, openness and transparency (including the mechanisms and structures for ensuring this).

Coda

If we fail to protect the environment, we will eventually face certain economic catastrophe and social disintegration. On the other hand, if we consider only narrowly defined environmental issues in isolation from their economic and social impact, we may destroy communities, enterprises, and individual working peoples' lives and have nothing to offer them in return. Somehow, society must be able to make the right decisions about what needs to be done, and at the same time there must be a sense of fairness about who will bear the costs of those decisions, and who will reap the benefits.

Systems that allow us to judge dangers and make appropriate decisions regarding them are a crucial component in building a sustainable society. They are not the whole answer. They may not even be the biggest piece. But it is a necessary one, and one which we must do better. That is what this paper was all about, and the authors hope that we have provided some fresh thinking on this topic.

February 7, 2002

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### Some Definitions

**ACCEPTABLE RISK** - A level of risk that those making a decision believe to be acceptable to society as a whole. Frequently, the opinion of those actually facing the danger are ignored in deciding what is "acceptable".

**ASSUMPTION OF RISK** - The doctrine that individuals and groups, by making certain choices (e.g. what type of occupation or recreational activity to pursue), have "assumed" the risks associated with that choice. This assumes that full comparative information is available to the individual or group, and that risk is the only criteria used to make their choice.

**BURDEN OF PROOF** - the individual or party at whose expense or effort data supporting claims of safety or acceptable risk must be provided.

**COST EFFECTIVE** - the point at which expense and benefit balance. If, for example, a human life is determined to be worth \$7 million, then spending more than \$7 million to protect that life from a given hazard would not be cost effective.

**COST BENEFIT** - an analysis to determine the point of cost effectiveness, for the purpose of decision-making.

**DANGER** - for the purposes of this document; a general term that encompasses the concepts of both 'risk' and 'hazard', both of which have more specific definitions.

**EXPOSURE ASSESSMENT** - An analysis based on measured data of present exposure to a hazard.

**EXPOSURE ESTIMATES** - An analysis based on a mixture of data and assumptions of future exposure to a hazard.

**HARM** - The negative consequences of exposure to a hazard, e.g. injury, disease, environmental degradation, resource depletion.

**HAZARD** - The intrinsic properties of an activity, substance or thing that have the potential to cause harm.

**HAZARD ASSESSMENT** - An analysis based on measured data of the potential (both type and extent) of an activity, substance, or thing to cause harm.

**IMPACT ANALYSIS** - An analysis of the consequences of a particular decision or course of action upon any thing or any person.

**INTRINSIC TOXICITY** - See Toxicity.

**PRECAUTIONARY PRINCIPLE** - Actually a set of principles intended to guide decision-making about dangers. These are: (i) that preventative action need not await scientific proof of causality; (ii) that the burden of proof rests on the proponent of an activity, substance, or thing; (iii) that all alternative courses of action (including taking no action) must be considered in decision-making; and (iv) that decision-making should be open, transparent, inclusive of all affected stakeholder, and consensual.

**PRECAUTIONARY APPROACH** - decision making that attempts to follow the precautionary principle, characterized by the intent of preventing harm, the avoidance of excessive reliance upon subjective data, relatively insensitivity to individual errors in the data set, A precautionary approach is inclusive and respectful of those facing the danger and strives to eliminate hazards or control them at the source rather than manage the effects.

**PRECAUTIONARY MEASURES** - Measures taken as the result of decisions made in a precautionary manner.

**QUALITATIVE RISK ASSESSMENT** - An analysis of potential risks that does not attempt to estimate the level of risk, only identify them.

**QUANTITATIVE RISK ASSESSMENT** - An analysis of potential risks that attempts to estimate the actual level of risk, either in absolute terms or relative terms.

**RELATIVE RISK** - Level of risk in one circumstance compared to the level in some other.

**RISK** - The probability of, and magnitude of, harm. In the case of chemical exposures, for example, risk is a function of both exposure (level, duration, and extent) and toxicity.

**RISK ASSESSMENT** - An attempt to identify the level of risk associated with an, activity, material or thing. In classical risk assessment for e.g. an occupation chemical hazard, an identification of the hazards(s) is followed by a quantification of the hazard(s), then a quantification or estimate of the extent and duration of exposure to the hazard.

**RISK COMMUNICATION** - Informing exposed individuals and the public about the results of a risk assessment.

**RISK ANALYSIS** - A risk assessment followed by an attempt to characterization of the risk as to importance and the urgency of taking action.

**RISK MANAGEMENT** - Decision-making that is guided by the principle of reducing liability, rather than harm.

**RISK-BENEFIT** - An analysis that attempts to weigh the potential negative consequences of certain risks with the perceived benefits of the action, material or thing that produces the risk.

**STUDY** - Epidemiological research or a series of related laboratory tests designed to provide evidence.

**TESTS** - laboratory tests, e.g. tests performed on animals or cell cultures to estimate toxicity.

**TOXICITY** - The inherent properties of a substance related to its ability to harm health.

**WEIGHT OF EVIDENCE** - One method of dealing with conflicting data. For example if three of four studies indicate that exposure to a substance causes a slight increase in lymphoma, but one does not, on the weight of evidence the substance could be treated as having the potential to cause lymphoma. This is not the same thing as absolute scientific proof of causation.



## Supplement - Human Made Disasters

In some of the disasters recounted below, a risk assessment had actually been done, but the wrong conclusions were reached. In other cases, there is no evidence that a risk assessment or any other attempt to judge the danger was made. In any case they all stand as examples of the general insufficiency of information before the fact; and the fallibility of humans in understanding and utilizing even that information which is available.

The Iron Ring and Engineering History -Poor design and careless use of human-made products is the cause of many accidents and quite a few spectacular disasters. In every case, the risk was believed to be low. It is a tradition in Canada for many engineers to wear an iron ring. The iron ring was intended to be a symbol of the engineers' pride in their profession as well as a reminder of their fallibility, and the consequences of their failures. The first iron rings were supposedly handed out in a ceremony at the University of Toronto in 1925. It was rumoured that the rings were made of iron from the remains of the Quebec Bridge, above Quebec City. One of the spans fell into the St. Lawrence river in 1907 killing 75 workers. The span had been lengthened without allowing for the increased strain. Then, in 1916 the centre span fell killing another 13 people. Here are some other notorious engineering failures and human-made disasters, in alphabetical order:

Bhopal, India, 1984. Over 2,000 deaths and thousands more injured, many permanently, when piping systems failed at a pesticides plant. Methyl isocyanate was released when water was added to a storage tank. Among the safety systems that were under-engineered or out of service at the time were a refrigeration system (shut down for cost reasons), a high temperature alarm (set too high), a scrubber system (undersized and under repair) and the flare system (disconnected). Plant under-staffing was also implicated. The company suggested that the water may have been deliberately added by a disgruntled employee. However, low pay may also have contributed to the scale of the disaster in another way, by encouraging the establishment of a densely populated shanty town adjacent to the plant.

The space shuttle Challenger blew up on January 28, 1986 when 'O'-rings failed. Seven astronauts were killed. Design problems with the 'O'-rings had been identified prior to the disaster but had not been corrected. A risk assessment had concluded that the margin of safety was sufficient.

Chernobyl - in history's worst nuclear accident, the Number 4 reactor in this aging nuclear complex near Kiev, Ukraine, exploded on April 26, 1986 at 1:21 AM. Staff had been conducting tests on the reactor's safety systems at the time of the explosion. The reactor design had been criticized by nuclear experts from around the world. About thirty to forty times the radioactivity of the bombs dropped on Hiroshima and Nagasaki at the end of the second world war was released. The Soviet government did not at first admit to a problem, and local residents first heard of a problem in news broadcast from Sweden. Thirty-one people died immediately, hundreds of thousands of people were relocated, entire cities were abandoned. Ten thousand people still live in Chernobyl and 3 million people still live in zones considered contaminated. Unknown numbers

of people will eventually die of cancer as a result of Chernobyl; possibly numbering into the hundreds of thousands. Several reactors of the Chernobyl design are still in operation.

Egypt leptophos disaster - Many farmers and more than a thousand farm animals died of leptophos poisoning in Egypt. This chemical, manufactured in the United States by Velsicol and exported to about 30 countries between 1971 and 1976, had never been registered for domestic use in the U.S.A.

Exxon Valdez - On March 24, 1989 at four minutes past midnight, the Exxon Valdez ran aground in one of the most famous (although not the biggest) oil disasters in history. Almost 11,000,000 gallons of oil was spilled. The U.S. National Transportation Safety Board cited the probable causes of the grounding of the Exxon Valdez as: the failure of the third mate to properly manoeuvre the vessel because of fatigue and excessive workload; the failure of the master to provide a proper navigation watch because of impairment from alcohol; the failure of Exxon to provide a fit master and a rested and sufficient crew for the Exxon Valdez; the lack of an effective vessel traffic service because of inadequate equipment and manning levels, inadequate personnel training, and deficient management oversight; and the lack of effective pilotage services. However, many scientists and environmentalists had predicted this disaster since the large-scale shipping of oil in tankers up and down the coast of Alaska and British Columbia began in the 1970s. Because of the very narrow and changeable nature of the shipping channels, frequent severe weather conditions, difficult and often unguided navigation - they had demanded that the large Alaska oil tankers be designed with 'double bottoms' - a design in use in some other parts of the world. Their recommendation was rejected, in part due to risk assessments. Results: financial costs in the billions of dollars; incalculable environmental costs; and a captain made scapegoat. Exxon continues to deny liability and fight civil lawsuits totalling billions, but has become fanatically obsessed with drug- and alcohol- testing of its employees. Meanwhile, oil continues to be shipped up and down this treacherous coast in an aging fleet of single-bottom tankers.

Hyatt Regency skywalk, Kansas City, Missouri, USA. When this two-level catwalk at the Hyatt Regency hotel collapsed in 1981, 111 fatalities resulted and several engineers lost their professional licenses. The designers intended certain nuts to support the weight of only one floor, but the design was faulty because it turned out to be impossible to install them where specified. The nuts as actually installed bore the weight of both floors. The nuts eventually tore through when there were many people dancing on the catwalk.

Iraq mercury disaster - In 1972, at least 459 people were killed (estimates are over 500) and over 6,500 were hospitalised in Iraq after 8,000 tonnes of wheat and barley, intended as seed for planting only, was instead distributed to villagers and ground for flour. Warning labels on the bags of grain were in English only. Methyl mercury concentrations in the bread baked from the flour were estimated to average approximately 9 milligrams per kilogram (mg/kg) or 9 ppm. The mercury based fungicide which had been used to treat the seed grain, had already been banned in the U.S. at the time of the disaster.

In 1966 the Silver Bridge across the Ohio river in Gallipolis, Ohio, USA collapsed during rush hour traffic when a support failed. Forty-six motorists died.

Tacoma Narrows Bridge, Tacoma Washington, USA. Faulty design failed to take into account the effect of wind. The bridge crossed the Puget Sound inlet, which with its mountainous sides, acts as a wind tunnel. The bridge began to oscillate or 'gallop' in the wind until it eventually tore itself apart and collapsed, only a few months after it was built, on November 7, 1940.

Thalidomide -This drug, prescribed to pregnant women to combat 'morning sickness' was introduced in 1957 and used until it was banned in the early 1960s. It produced "an estimated 10,000 children - but probably many more - born throughout the world as phocomelics, deformed, some with fin-like hands grown directly on the shoulders; with stunted or missing limbs; deformed eyes and ears; ingrown genitals; absence of a lung; a great many of them still-born or dying shortly after birth; parents under shock, mothers gone insane, some driven to infanticide" according to Hans Ruesch, medical historian. Inadequate pre-release safety testing and a tendency to ignore warning signs contributed to the scale of the tragedy. In the 1990s, thalidomide's reputation has undergone something of a rehabilitation and many researchers believe that it may be valuable in the treatment of some disabling diseases. The U.S. Food and Drug Administration (FDA) has recently approved its use for research purposes. The fear of many is that if thalidomide is re- allowed for even these diseases, despite precautions, it is only a matter of time until a pregnant woman is given thalidomide. According to the Thalidomide Victims Association of Canada, "The thalidomide history is unique and ironic. No longer do we have an assumption of safety regarding new drugs, safety must be proven before licensing. The very reputation of the FDA was built on preventing a thalidomide tragedy in the United States in 1961, and now they have approved this drug ..."

The 'Therac-25', a Canadian designed and manufactured medical device used to deliver radiation for cancer therapy. Poor software design and an absence of safety alarms allowed several people to be overdosed with radiation, some fatally, between 1985 and 1987.

Titanic. At 2.20 am on Monday April the 15th 1912, Titanic disappeared under the Atlantic, just off the Grand Banks, not to be seen again by human eyes for another 73 years. Perhaps the most famous, although not the most deadly, human-made disaster of all time. Excessive pride in the 'unsinkable' design prompted the owners and crew to race the Titanic, on her maiden voyage, at high speeds across the North Atlantic in iceberg season. When the Titanic struck a 'berg, substandard steel plates and rivets buckled and shattered, breaching more watertight compartments than the designers had ever considered a possibility. Insufficient numbers of lifeboats, (after all, who would need them on an unsinkable ship?) incompletely loaded, resulted in the deaths of about two-thirds of the approximately 2,200 people on board, a total of 1,500 people.

West Gate Bridge, Melbourne Australia, 1970. When construction crews had difficulty connecting two poorly fitted sections, the bolts at the ends of the bridge were loosened in the hopes of allowing enough 'give' for the sections to be joined. It was felt that the risk of this procedure was

low. The idea was a bad one: the end bolts failed and one section fell to the ground, killing 35 workers.

**Yangtze Dam Bursts** -On August 7, 1975, following heavy typhoon rains, a series of 62 dams on the Yangtze River burst in sequence, initiated by the failure of two major dams. Weather conditions (which might have been anticipated), difficult geology, poor engineering (there were insufficient means to release excess water) and poor maintenance (a large dam requires constant care and repair) contributed to the disaster. Within the few hours tens of thousands of people died. Hundreds of thousands more died in the following months due to disease and starvation. This may have been the greatest human-made disaster in history. Today, China plans to build a new megadam called 'Three Gorges' on the Yangtze river. Besides the environmental disruption it will cause, Three Gorges has been criticized as badly underfunded and situated on a fault line.

**Yusho Poisoning** - In 1968, more than one thousand people in western Japan became seriously ill after eating food that was cooked in rice oil, contaminated with polychlorinated biphenyls (PCBs). The source of the PCBs had been leaking PCB containing equipment in the factory where the rice oil was produced, so that it mixed with the rice oil during the manufacturing process. Their symptoms included fatigue, headache, cough, numbness in the arms and legs, and unusual skin sores. Pregnant women later delivered babies with birth defects. Another similar incident of massive human exposure to PCBs occurred in Taiwan in 1979.

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