

RISK ASSESSMENT AND LEGISLATION

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SUMMARY

The use of risk analysis and risk assessment in the legislative process is a recent phenomenon. Both risk assessment and the legislative process are uncertain, seemingly irrational, unpredictable and generally to be avoided. The use of risk analysis has been found useful in improving the management of risk in society and in particular improving the framework for discussion and decision-making.

The paper reviews the characteristics of both risk and legislation and provides some guidelines for incorporating risk assessment in an efficient and effective way.

INTRODUCTION

In Canada, since the turn of the century, life expectancy has been increasing at about 1/4 year per year. At the same time there has been increasing concern about risk. This paradox is indicative of the complicated and seemingly chaotic state of risk assessment and the associated legislation to manage risks we face.

The situation is complicated by the fact that people are increasingly less confident that governments and industry are acting in the interests of the public (ref. 1,2).

"Annual surveys since 1966 by Louis Harris ... show a steady decline in public confidence for leaders of some nine major social institutions--television news, medicine, the military, the press, organized religion, major companies, Congress, the Executive branch, and organized labour ... business leaders (went) from 55% public confidence in 1966 to 19% in 1980 " (ref. 1).

A recent poll by the Canadian Chemical Producers Association of Canada found similar results with public confidence in their industry.

In response to these trends, governments have turned to risk analysis and risk assessment to assist them in managing risks for society. The use of risk

analysis techniques started with the nuclear industry and has been applied to regulation of toxic substances, transport and the chemical industry. For example, in 1981 risk analysis was used for the first time in Canada to inform on a regulatory decision for transport (ref 3.)

The purpose of this paper is to review the basics of risk assessment and to explore how risk assessment can be used by government to:

"aid the societal judgement based on our legislative authority. The techniques are valuable and will certainly be refined and strengthened. Risk analysis is a powerful tool for categorizing and assessing risks but its role in decision -making is, as yet, limited. Whether or not greater scientific knowledge will radically alter this situation is debatable, but that should not detract, to the smallest extent, from our pursuit of a better understanding of the risk assessment process" (ref. 4).

The paper is organized into the following sections;

- 1) Risk Assessment - a definition of terms
- 2) Risk Characteristics
- 3) Legislative Issues
- 4) Successful Approaches to Risk Analysis
- 5) Legislation and Risk Assessment

RISK ASSESSMENT

The term "risk management" is used to represent the activity of identifying and reducing risks to acceptable levels within the context of a particular society. The dominant characteristic is the mixture of technical and scientific aspects with political and decision making aspects. For example, in Canada the provinces regulate the acceptable levels of asbestos in the work place; levels of 2 fibres/cm³, and 5 fibres/cm³ are found in different provinces as well as the possibility of different levels of enforcement (ref. 5).

The usual definition of risk is "the possibility of loss". While this is not a very useful operational definition it may be the best available. Often people have more disagreement about what risk is than they do about the differences between alternative risk management plans (ref. 2). It should be noted that a loss need not actually occur, only the possibility of loss.

Figure 1 illustrates the topology of risk in society (ref.6). The existence of hazards, both natural and man made, can expose people to the consequences of loss of health, life and property. The hazards can be managed by regulating standards and levels of prevention, by limiting the population exposed to the hazard and by providing mitigating safety services to reduce the consequences if they should occur. Safety services include fire services, hospitals, evacuation plans etc.

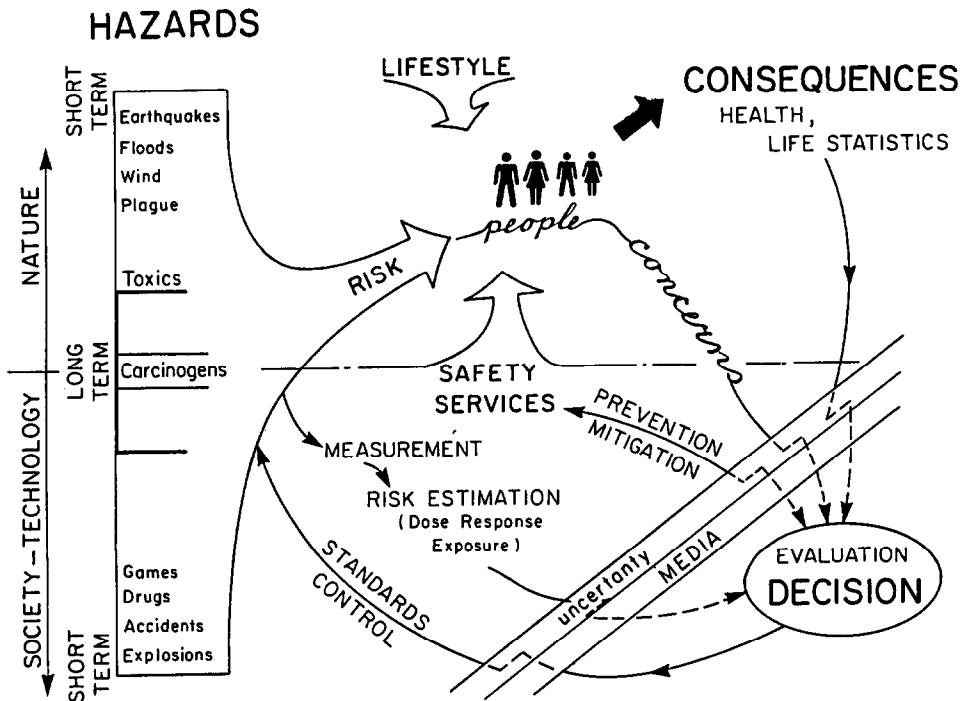


Fig. 1 Risk in Society (ref. 6)

For a man-made risk to exist a human activity and thus the benefits of that activity must exist. If there are no benefits then the risk management task is easy -- the activity is banned. However, most risk management tasks involve the trade-offs among the benefits of the activity, the risks, the costs of risk management and the availability of substitutes for the activity. This is clearly more difficult than the usual economic optimization where only costs and benefits are involved.

It is helpful to identify four steps in the risk management process (ref. 6). These are: risk selection, risk analysis, risk assessment and implementation.

Risk Selection

The selection of risks to manage initiates the risk management process. This is both a technical and a political activity. In the technical mode,

- 3) accepted risk - the estimate of the risks that are accepted or tolerated by people in similar circumstances

For all these estimates a range of values was given to explicitly express the uncertainty (ref. 10).

In some cases, such as the assessment of acceptable standards for chemicals in the air, the assessment process may be a technical activity with the general assessment procedure approved in a political process. Generally in the area of environmental standards for toxic substances the term risk assessment means both risk analysis and risk assessment as defined here.

TABLE 1

Recommended performance factors for assessing risk management for the movement of dangerous goods (ref. 10)

A RISK ESTIMATES	- Objective risk
	- Perceive risk
	- Acceptable risk
B COST FACTORS	- Estimated net costs
	- Organizational and compatibility costs
C PRACTICALITY	- Implementation time
	- Compliance level
D FAIRNESS	- Responsibility for safety
	- Incidence of risk
	- Mode competition impacts

Implementation

The last step is the implementation of the risk management alternative selected. If this is not done according to the estimated risk analysis as evaluated in the risk assessment then the whole risk management process is called into question. For example, a study of the reasons for Seveso, Pemex Mexico and Bhopal concluded that (ref. 11):

"the causes of catastrophic accidents ... a combination of design deficiencies, operating errors, managerial mistakes ... In all the cases we have examined, plant management deficiencies had an important effect ... which suggests the necessity of surveillance actions by institutional bodies that are properly safety oriented and have adequate enforcement powers."

This problem is rooted in the fact that for most catastrophic situations

the initiating events and the required human response are expected to occur only every 10th or 100th worker's lifetime.

RISK CHARACTERISTICS

Risk as the possibility of loss can be measured as the expected number of lives, the expected dollars lost, the largest loss that is possible, the anxiety associated with a particular possibility of loss (e.g. leukemia in your child), etc. There is not, nor will there likely be, universally accepted measures of risk. This immediately complicates the risk assessment.

There are two ways in which this difficulty is resolved. Either the process becomes a decision-making process of society and thus a legislative function rather than a technical function, or classes of risk problems are dealt with in a technical way given a legislative mandate.

Classification of Risks

The groupings of risk problems could be defined by an allocation to a specific government department, for example, transport, labour, health and welfare, environment, etc., although the allocation does vary from jurisdiction to jurisdiction (ref. 5). There is also the problem of consistency of treatment between departments and there are indications that this is a growing concern.

The most useful grouping of risk problems is to explicitly recognize the multidimensional nature of risks and the basic political classification of risk management. For example, in the United States Clark University and Decision Research Inc. have done a number of studies on the way people classify risk, especially in terms of the relationship between observed and perceived risk levels. They have identified five major descriptors of risks: biocidal, delay, catastrophic, mortality and global. Based on these descriptors, they studied 93 technological risks and suggest the following classification of risk (ref. 1);

<u>Multiple Extreme Hazards</u>	nuclear war, recombinant DNA pesticides, dam failure
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Extreme Hazards

- | | |
|--------------------------|--------------------------------------|
| a) Intentional Biocides | chain saws, antibiotics, vaccines |
| b) Persistent Teratogens | uranium mining, rubber manufacturing |
| c) Rare Catastrophes | LNG explosions, air crashes |
| d) Common Killers | auto crashes, coal mining |
| e) Global Threats | greenhouse effect, ozone depletion |

Hazards

saccharin, appliances, aspirin, skateboards,
power mowers

While between classifications the treatment of risks might be expected to be different, within a classification the objective should be for equal treatment of risks in terms of cost/benefit/risk trade-offs.

Uncertainty

As noted by the U.S. National Academy of Sciences, "The basic problem in risk assessment is the sparseness and uncertainty of scientific knowledge ... and this problem has no ready solution." Even for risk analysis of well-behaved industrial plants, (plants with good data and a reasonably predictable operating environment), there is an uncertainty of 2 or 3 orders of magnitude (ref. 7,12).

The uncertainty is not only due to the lack of data or knowledge but is inherent in the low probabilities involved. For example, with over 140 years of operation of nuclear reactors in Canada it is now possible to review failure probabilities in light of experience. However, even for fairly high failure rates for individual components the possible range given operating experience could be from .03 to .00003, or three orders of magnitude (ref. 13).

It is necessary to explicitly consider uncertainty in risk analysis and assessment and methods for doing this for even complicated fault trees have been developed (ref. 10).

There is a tendency for people analyzing risk to take a conservative position and thus the analysis tends to underestimate risks. There is also a body of theory that suggests that as systems operate, experience is gained, corrective measures are taken and the failure probabilities for components decreases with time (ref. 13).

On the other hand data from the chemical industry indicates that about 20% of all actual failures were not considered in the risk analysis (ref. 7).

Control

There are some risks which are specific to the individual and directly under their control. These include mountain climbing, smoking in the outdoors, etc. Observed accepted risk levels in these areas are about .001-somewhat easier.

However, government decisions such as permitting the location of a LNG storage tank or a nuclear power plant impose risks which are beyond the control of the individual. The acceptability of these risks are perceived to

be two to three orders of magnitude greater than risks under individual control. Moreover, there are theories of government which indicate that these perceptions are reasonable and that risks must be controlled to levels of

LEGISLATIVE ISSUES

Risk decisions have the following attributes:

- 1) The "risk" means different things to different people.
- 2) There are benefits attached to man-made risks but generally the people who benefit are different from those who bear the risks. The benefits are often diffusely distributed while the risks are acutely focussed.
- 3) The levels of uncertainty generally preclude a consensus on the appropriate course of action.
- 4) Risk decisions typically are taken over time through a number of evolutionary decisions and precedence and risk and benefit ownership are very much a part of the power structure of the society.
- 5) Besides the benefits of the activity and the risks created by the activity there are the additional complications of the cost of the risk management and the possibility of not having a substitute (e.g., lost jobs).
- 6) It is important that risk decisions are perceived as being reached fairly and rationally.

These attributes lead to the classical problem that only has a political solution and thus requires close examination of the requirements for "good" political solutions.

"Risk handling may vary with "the temper of the people," that is it is not a "single answer" approach. In the LNG siting example, California passed an LNG Terminal Siting Act (ie the site must have a population density of <10 persons/square mile in the first surrounding mile and <60 persons/square mile within 4 miles of the site). This also applies to tankers which transport the LNG. However, in Scotland the chosen site is in the most densely populated area and tankers will pass within a mile of an industrial town and within 4 miles of Edinburgh." (ref. 20)

Figure 2 (ref. 15) illustrates the general approach to risk management in Canada. There are separate estimates of benefits and risks, then a comparative analysis and a decision, followed by two opportunities for comment.

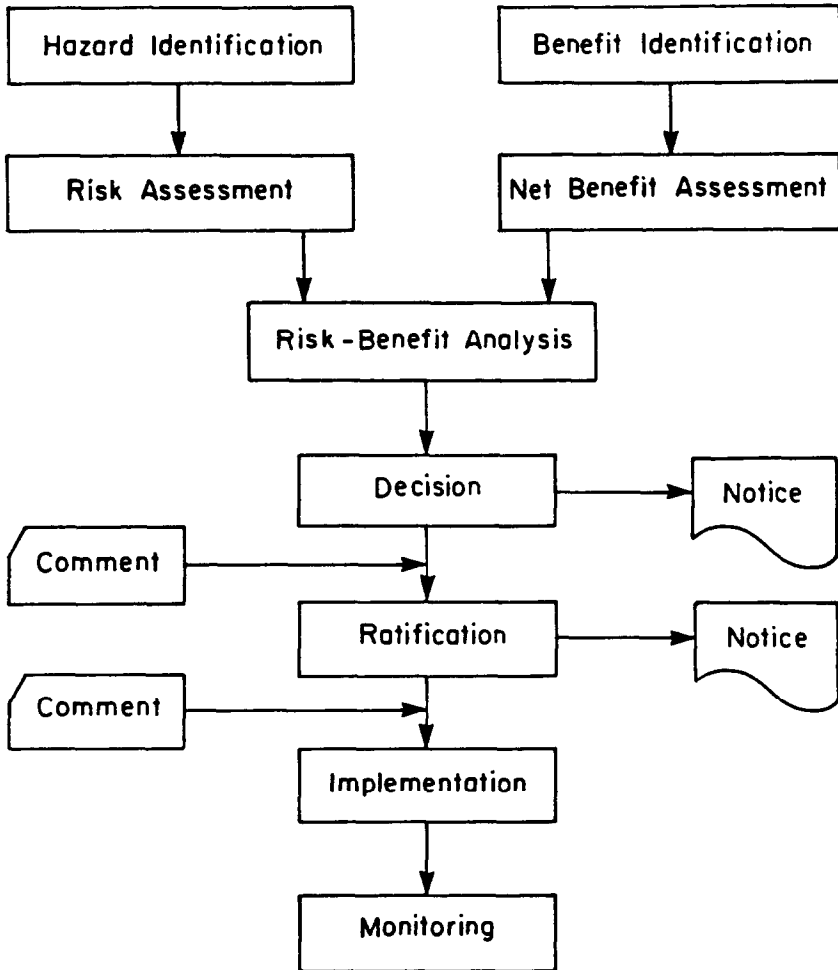


Fig. 2 The general legislative approach to risk management in Canada.

The process illustrated in Figure 2 can take considerable time. For instance, in 1972 a review of transport regulation concluded that dangerous goods were a problem and that lack of regulation was compromising public safety. In 1975 a Dangerous Goods Secretariat was established. In 1976 it was decided to use a federal act to regulate the problem. A bill was introduced in 1978 and in 1980 it was passed. Finally the regulations under the act were introduced and, subject to the notice and comment process, the regulations were enforceable on July 1, 1985. By the end of 1986 most provinces had put the regulations in place for transport modes under their control. (ref. 16)

For the 1980 Dangerous Goods Act risk analysis and assessment were not used as they were not available. However subsequently steps have been taken to introduce risk assessment into the ongoing regulation of transport. (ref. 10)

Legislative Options

In Canada "there appear to be few limitations on what the Parliament can do under the criminal law power and it can legitimately be applied to the regulation of the production and distribution of hazardous substances" (ref. 4)

While there is no limit to government power it is clear that there are a variety of regulatory tools available and a variety of delivery vehicles. These must be applied carefully both to insure fairness and to ensure efficiency.

The governmental structure may also limit the legislative options. In Canada the "traditions of ministerial responsibility and civil service anonymity make it difficult to hold anyone below the ministerial level accountable ... there is no way to separate scientific reasoning from political negotiation" (ref.17).

In broad terms governments can implement policy in four ways (ref. 5):

- 1) Spending - grants, subsidies, transfer payments, etc.
- 2) Regulating - imprisonment, fines, revocation of licences, stop orders, reporting requirements
- 3) Exhortation - information programs, research, consultative and advisory committees and processes
- 4) Bill of Rights - worker right to refuse unsafe task, seek redress for rights violation in courts.

All methods are used for risk from the spending on air traffic control systems to advertizing programs to promote better health through participation. In many cases regulation is used only after a spending or exhortation program has made the heavy-handed legislative approach more

acceptable.

The legislative vehicles available include:

- 1) Direct action by the legislature
- 2) Government departments providing for programs under approved programs
- 3) Commissions established as independent special purpose bodies
- 4) Special inquiries to investigate and recommend on risk issues

For example, Workman Compensation Boards exist as independent commissions to both develop safety standards and to provide financial incentives for reducing risks.

There are a number of other dimensions for describing legislative options including: open consultation or closed consultation, risk specific solutions or general solutions applied universally.

Credibility

Governments exist in democratic societies only with the general support of the population. Thus governments must maintain credibility as an effective and fair manager of the society. For example, in regulating traffic speed limits there is a rule of thumb that for a "good" speed limit, at least 85% of drivers should obey the limit and that less than 15% of drivers would perceive the limit to be unreasonable.

Because of the lack of consensus and the high media profile, risk decisions are difficult from a credibility point of view. At the same time there are often issues which require action by government and can not be set aside. The use of risk assessment techniques may provide an additional method to successfully resolve risk management issues and maintain credibility.

There are a number of theoretical and equity issues which can be raised and used as a basis for estimating the credibility of a legislative solution to risk management. Issues include equity, paternalism, responsibility, values, compensation, consent, etc. (ref.1).

Technical information provided to the legislative process to be credible must be available for review and independent assessment.

"Risk analyses have multiple purposes and can be used for multiple audiences. Initially they can be used to advise council members and eventually, justify decisions to their constituents. Risk analyses is almost always intended to persuade those responsible for setting the policy ... there may be little motivation for the authorities to take an independent and critical look at the plans ... none of the four countries had adequate review procedures of the risk analysis done for LNG siting. However, all of the analyses were reviewed. In the US the review was redundant; in Germany the government agencies that commissioned the reports carried out the reviews; and in the Netherlands all interested parties reviewed the report. In all cases it was possible that no one was qualified to judge the technical merits of the analyses." (ref. 20)

Complications

Legislation for risk is complicated by the usual factors which make any government activity difficult. A recent study on regulations identified 17 obstacles to new regulatory strategies in Canada. The first three give the flavour of the complications which are very real and constrain legislative effectiveness.

- 1) "The difficulty of communication and diversity of interests due to the size and regional differences of the country.
- 2) The powerful economic incentive for industrialized nations to seek and exploit technological innovation, even in the face of recognized scientific uncertainties and ethical dilemmas.
- 3) Many governments, which results in overlapping responsibility in some cases and neglect in others" (ref. 17).

In Ontario it is estimated that persons dealing with hazardous substances are governed by 31 Ontario statutes and 31 Federal statutes.

SUCCESSFUL APPROACHES TO RISK ASSESSMENT

In spite of the difficulties inherent both in the nature of risk and in the legislative process it is possible to do risk assessments successfully. Success is measured by the fact that the risk assessment has an impact on the risk management decision and that the the decision or decision process is judged to be improved. The use of risk assessment was implemented first in areas which are considered highly technical and amenable to the use of quantitative methods to assess and design for risk. The explosives, nuclear, chemical and toxic substances industries all contain examples of successful risk analysis.

For illustrative purposes the approach used by a Swiss consulting engineering firm will be described (ref. 18) but it is not very different from standard approaches in the chemical industry (ref. 7). The process is developed as two separate activities: risk analysis to quantify the risk and risk assessment or appraisal to determine acceptable standards for risk management (ref. 18).

Risk assessment is considered at three levels (ref. 18):

- 1) Individual Risk - the annual probability of death or injury as a result of an accident. (Figure 3 gives a proposed set of criteria for different risks primarily recognizing the degree of individual control involved and the observed acceptability of risks in society.)
- 2) Collective Risk - the total losses from a hazardous activity

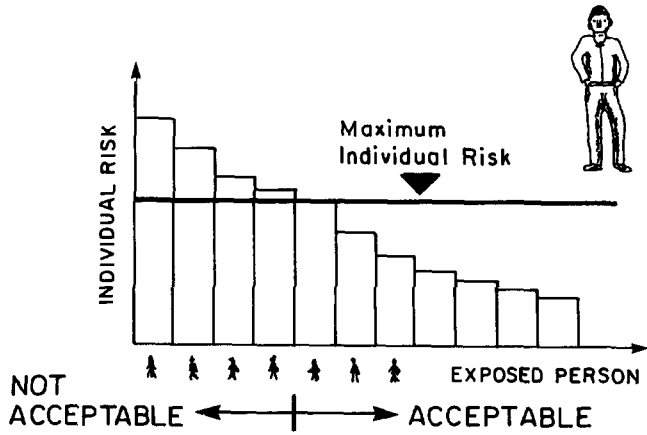
expressed in terms of the expected annual accident statistics or the sum of the individual risks. (Figure 4 suggests proposed criteria and illustrates the trade-off analysis used to establish the economic criteria for collective risk.)

- 3) Institutional Risk - the perceived collective risk associated with catastrophic accidents which governments and other institutions desire to avoid; this is calculated as a multiplication factor applied to the collective risk. The factor increases with the category of risk and the potential number of fatalities and is set by the decision makers, e.g., 100 deaths in a train accident (factor=3), 1000 deaths in an explosion (factor=16).

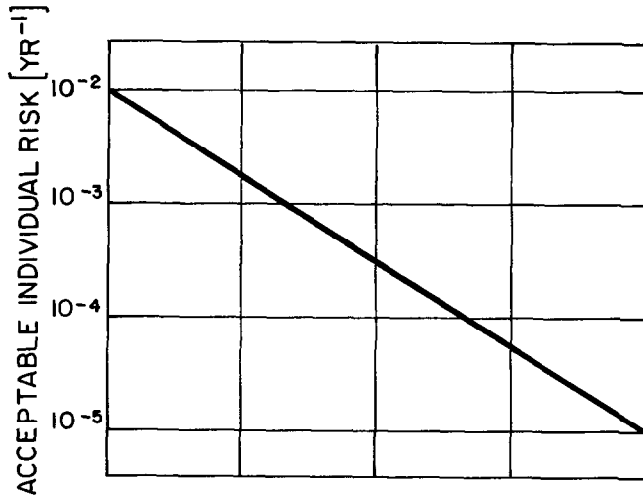
This procedure for quantifying the risk assessment has been applied successfully for two cases of explosive storage facilities, transportation of dangerous goods, two cases of railway safety, road safety and for natural hazards (ref. 18). It is clear that not everyone would agree with the approach and that it will not work for every risk situation, however, it is an example of a working approach to the problem which corresponds to the conceptual approach outlined in this paper.

The area of risk analysis has a relatively standard approach. Recent trends are to update existing procedures to incorporate uncertainty in all the numerical and estimation methods (ref.10). The analysis of risks associated with the movement of dangerous goods provides a typical example of risk analysis (ref.10):

- 1) The accidents and events which lead to the loss of containment of a hazardous material are identified and modeled. The initiating events are either an accident or a leak due to corrosion, valve defect, product instability, etc. From this initiating event fault trees are used to model the probable release of the product and also to allow for modeling of proposed improvements. The accident rates and the fault tree parameters are calibrated to the available data.
- 2) Given the release of a hazardous product an estimate is made of the possible rates of release and the total quantity released. Then an event tree is used to model the creation of hazards and the area which is hazardous. The event tree considers the existence of an ignition source, the likely atmospheric conditions, wind direction and speed, different threshold concentrations for injury, death, property, etc.



RISK CATEGORIES			
Category 1	Category 2	Category 3	Category 4
"Voluntary"	Large Degree of Self-Control	Small Degree of Self-Control	"Involuntary"



Examples

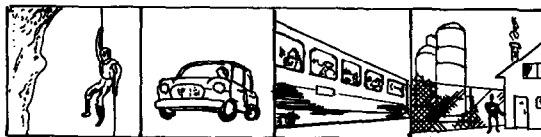


Fig. 3 Risk categories and individual risk assessment criteria in use in Europe (ref. 18)

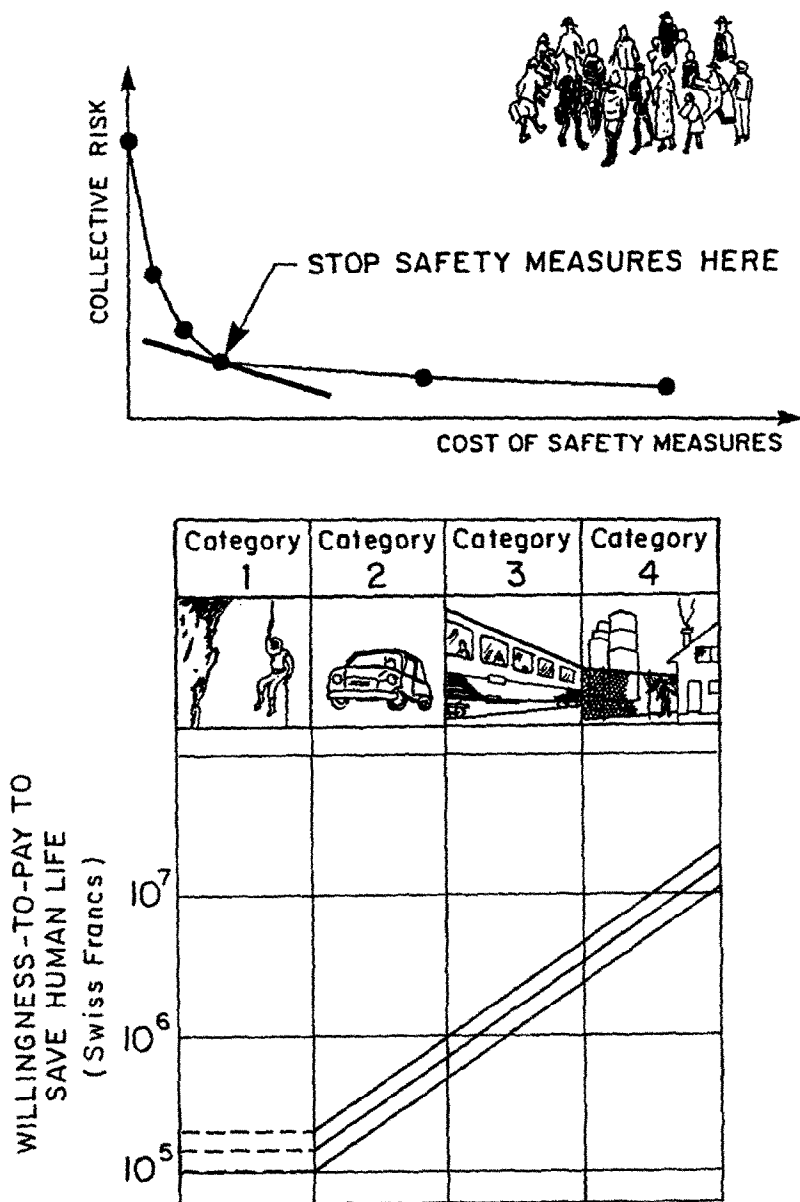


Fig. 4 Society risk assessment criteria in use in Europe

- 3) Given the hazard areas the population and property exposed can be calculated and estimates made of both the individual risk and total society risk in terms of lives, injuries, clean up costs, evacuation costs, etc. At this stage the analysis can evaluate the type of emergency response and containment capability available which will act to reduce the population exposed to hazards.
- 4) The design phase then allows for the estimation of risk reduction in response to rerouting of traffic, mode shifts, changes in equipment standards, improved emergency response, and better information.

The main difference in types of risk analyses is the inclusion or exclusion of probabilities. Some risk analyses simply model a number of the worst possible situations that could occur and then use these in the risk assessment to determine if the risk is acceptable or not. These analyses tend to be quite conservative since there is no explicit consideration of how low the probability of the event might be. Risk analyses which incorporate the probabilities of events give a more accurate picture but can be more expensive to carry out since many more possibilities than just the most critical situations, must be considered. These analyses often do not analyze events with probabilities less than 1 in 10 million and can be criticized as not including some catastrophic events.

LEGISLATION AND RISK ASSESSMENT

Two topics will be discussed:

- 1) What is the recommended approach in legislating risk?
- 2) What should be the role of risk assessment?

The multidimensional nature of risk and the complexities of the legislative process make risk assessment difficult and almost impossible. However, it must be done and judicious use of risk assessment can make resolution of some risk issues more tractable. It is similar in this respect to "systems approach", with an indirect contribution of structuring the problem and providing a framework for discussion and negotiation, even when on the surface it does not seem to provide resolution of the issues. Similar to any systematic approach there are organizational benefits.

Care must be taken to ensure that the objective is safety. For instance, the author heard about two approaches to safety investigations that exist

within one department. In the first approach the objective was safety and investigations were carried out to identify risky activities so they might be addressed. This approach is well known and there is good cooperation by all those involved in the accident. In the second approach the investigations are very formal and involve attaching responsibility and blame for the accident. Cooperation of those involved is obtained only with difficulty and usually in an adversarial approach.

Regulations should encourage fundamental changes rather than band-aid solutions. Reductions in the quantity of dangerous goods are preferable to better ways of shipping dangerous goods.

The time taken to introduce or to change legislation is a major factor in limiting effectiveness of risk management. This can impact the choice between the direct provision by government of specific and detailed recommendations, versus the legislation by government of a process or performance standard with industry required to meet the performance levels. Unions and workers tend to prefer direct, legally-enforceable government regulation and standards since the basis for compliance is clear (ref. 5).

The "Seveso Directive" is a good example of legislation which sets performance levels and then leaves it to industry to meet them (ref.7). Following the Seveso incident in 1976 and other concerns about hazardous materials, the Council of the European Communities passed a directive in 1982 which required compliance by the member states by January 8, 1985. The directive is only a few pages long and requires each industry containing dangerous substances to file a "safety case" outlining measures taken to reduce risks through both preventive and response measures. These plans are submitted to authorities to be audited and approved. Both the industries involved and the approving bodies have used extensive risk analyses done by industry, government and consultants. The process involves relatively little time and improvements can be made as quickly as a new plan can be audited and approved.

In contrast, the Canadian regulations for the handling and movement of dangerous goods contain over 500 pages, are fairly difficult to work with, and appear to require about three years to make modifications to incorporate safety improvements. It should be noted that these regulations are working quite smoothly and are improving safety levels.

Because of the importance of values in risk assessment and the differential incidence of risks and benefits there must be a mechanism in any risk assessment process for discussion and possibly for negotiations with those involved (ref. 19). This is clearly present in the process shown in Figure 2 which involves major legislation. There should also be room for

discussion and comment even for routine changes in minor regulations. Since risk is so uncertain, there are usually opposing opinions about the need for and the effectiveness of many safety regulations. The discussion and negotiation may not change anyone's mind, but it will clarify the uncertainty, and make the process more acceptable and improve risk management.

Risk assessment in a legislative process should be separated from risk analysis by different stages in the process, separate reporting, etc. It is also important that there be agreement on the interpretation and content of the risk analysis, before proceeding to the assessment phase. There should also be agreement on the risks considered and the alternative risk management policies that have been analysed.

Because of the uncertainty, the expected lack of consensus, and the need for discussion and negotiation, it is advisable to have a timetable for completing the risk assessment and a means to amend the timetable. If possible, a facilitator or non-adversarial process should be used.

The role of risk assessment and the extent of quantitative analysis is largely a function of the type of risk problem. No risk assessment will ever be completely comprehensive and defensible. Its value is to organize the discussion and assist in understanding the risks involved and the way in which different groups value those risks. Thus, the extent of risk assessment is a function of the degree to which it will help people understand the risk management problem. For detailed technical problems with restricted interface with population, quantitative risk assessment can form the greater part of the legislative activity. For problems such as the impacts of electromagnetic fields on school children where there is little scientific information and a very emotional risk, risk assessment is useful as a framework for the discussions but will represent only a minor part of the effort in the legislative process.

Since risk analysis is numeric and can appear to be highly technical and scientific there is always the temptation to spend more time and effort doing more analysis, especially to attempt to remove uncertainty. Risk analysis is currently much better understood than other elements of the risk assessment process such as evaluating risks, conflict resolution and risk communication. A chain is only as strong as its weakest link. The design of legislative processes which are comprehensive and balanced is itself an area that is not well understood. Fortunately, research is ongoing in risk communication, conflict analysis, etc., that promise a more effective basis for risk assessment.

The legislative risk assessment process must explicitly consider other risks faced by people, the cost of risk management, the possibility of

failure of the risk management implementation, and the benefits of the activity. If this is not done then the problem is isolated and there is a tendency to deal with risks that really do not matter in the total picture and thereby preclude the management of more critical risks.

CONCLUSIONS

Risk assessment is necessary for risk management within a legislative process. Its use will continue to grow as techniques for conflict analysis, risk communications, and comparison of risks, are further developed. For many highly technical problems risk assessment is currently being used successfully to improve the management of risk by governments and their agents.

Risk assessment is confounded by the uncertainty of risk, the risk communication difficulty, the multidimensional risk value system, the lack of consensus, and the realities of the political process. Its main benefit is to provide a framework for discussion and negotiations and to help people better understand risk so risks are dealt with in a more balanced way.

Continued success in reducing actual risks will make the results of risk analysis even more uncertain than they are to-day. Thus, even greater demands will be placed on risk assessment in the future.

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