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PROBABILISTIC RISK ANALYSIS AND SAFETY REGULATION IN THE CHEMICAL INDUSTRY

ELISABETH PATÉ-CORNELL

Department of Industrial Engineering and Engineering Management, Stanford University, Stanford, CA 94305 (U.S.A.)

and RAYMOND BOYKIN

California State University, Chico, CA (U.S.A.)

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Summary

The recent evolution of risk regulations in general is discussed. The state-of-the-art probabilistic risk assessment (PRA) in the chemical industry and the current use of the results by the industry and the regulatory agencies are examined. The methodology of chemical risk assessment for routine as well as catastrophic release is discussed. More specifically are examined the questions of how to assess and report the uncertainties involved in the risk analysis, and where to include conservativeness. As an illustration, the problem of uncertainties in the dose–response relationships for carcinogens is considered. The adequacy and feasibility of safety goals such as those proposed in the nuclear industry as a basis for regulatory standards are discussed. The notion of coherence of standards is explored and a proposal is made to treat explicitly the analytical uncertainties both in the assessment of the risk and in the safety goals.

1. New perception of chemical risks

Historically, the chemical industry has been one of the safest in the United States. Yet, in recent years, it has faced increased scrutiny in the wake of several accidents and close calls. The tragic release of methylisocyanate in Bhopal, India, and a release of aldicarb oxide at a similar plant in Institute, West Virginia, has created a deep concern in the public, the chemical industry, the insurance industry, and the regulatory agencies. Chemical companies are increasing their efforts to assess and, if necessary, to increase their safety level. They are also trying to improve their public image. New chemical risk regulations have been passed at local and state levels. Others are being considered at the federal level. Given the diversity and the complexity of the chemical industry, these decisions require setting priorities which involves identifying and quantifying both the initial risks and the effects of potential risk reduction measures.

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2. Risk and regulation in the chemical industry

2.1 Evolution of the U.S. regulatory climate

The prospect of new chemical regulations happens at a time of considerable change in the U.S. regulatory climate [1]. Risk regulation has evolved in recent years from the goal of absolute safety, to the concept of "best available technology" (regardless of costs), to the notion of balancing risks and benefits, recognizing that under other philosophies this balancing is often done implicitly for practical reasons [2,3]. Today, the agencies are pressed to reach reasonable decisions that on one hand, provide adequate levels of public safety and environmental protection, and on the other hand, preserve the economic interests of the industries, their workers, their owners, and their customers. This requires that risks, costs, and benefits be assessed in a coherent way to allow comparisons and establish priorities.

The language of the law, however, is often ambiguous. For example, the Toxic Substance Control Act (TSCA) requires balancing the beneficial and adverse consequences of chemical use and therefore balancing the actual risks and the potential loss of benefits that might be lost due to regulation of a chemical. It does not specify, however, what role risk analysis and cost-benefit analysis should play under TSCA [4]. Yet, knowing what the stakes are and what safety levels are actually achieved, is, in the end, in the best interest of the public, the industry, and the consumers. Formal risk analysis helps to communicate this information. Recent state regulations, for example, in New Jersey, may require a formal probabilistic risk assessment for chemical facilities. The state of California is currently drafting a similar regulation.

There is presently a movement to establish a federal chemical regulatory agency similar to the Nuclear Regulatory Commission. The public and the legislators are searching for a way to control an industry which, in their opinion, has been operating almost unregulated. Determining if and how much regulation is needed is a problem facing the chemical industry and government officials.

2.2 The chemical industry

The chemical industry involves both the major producers, such as Union Carbide, Monsanto or Dow Chemical, and the companies dealing with specific commodities and specialty chemicals. Commodity manufacturers includes the petrochemical industries, and the companies that produce basic inputs (e.g., methanol or styrene) often produced and stored in very large quantities. Specialty chemicals are produced by a large number of companies, and include, for example, food additives, agricultural chemicals such as fertilizers, pesticides, and herbicides, or consumer products such as soaps and detergents. Facing similar problems but not directly included in the chemical industry, are the oil

and gas companies, the companies that process radioactive material for the nuclear industry, and the electronics industry.

2.3 Chemical hazards and safety decisions

The hazards from the operation of the chemical industry include on-site and off-site events: accidental spills and dispersion of a toxic substance, routine exposure of the workers, low level pollution and its effects on the population and the environment, and physical hazards such as fires and explosions. Safety decisions for the management of these hazards involve:

- siting and design
- retrofitting of existing facilities
- operation and maintenance procedures
- transportation: mode, routes, and procedures
- storage: raw material, intermediate products, and final product
- response to minor incidents
- monitoring system: design, operation, and procedures
- response to emergencies and crisis situations
- waste disposal

In addition, the chemical firms must decide upon an insurance level (or possibly, to rely on self insurance), given their financial risk attitude and the situation of the insurance market.

For these types of decisions, probabilistic analysis is a way to quantify risks and uncertainties in order to establish priorities [5]. The different steps of risk assessment have been described in a study for the Office of Management and Budget [6] as risk-source characterization, dose–response assessment, exposure assessment, and risk estimation. Risk analysis for the chemical industry is currently a topic of interest and a focus of active research [7]. An important part of the exposure assessment is the analysis of the mechanisms and the probability of accidental release of a toxic substance. A major problem is to describe adequately the uncertainties in the risk analysis models, for example, the uncertainties about the toxicity or the physical properties of different chemicals.

2.4 Risks and uncertainties

Uncertainty about a variable, or about the correctness of the alternatives in an exhaustive set of possible hypotheses, is represented by a probability distribution according to the Bayesian definition [8]. The analysis of the risks leads to a probability distribution of the different magnitudes of losses that might potentially occur every year. In this distribution, two types of uncertainties are blended: analytical uncertainties about the adequate model and the range of parameter values, and observational uncertainties (or randomness) that would remain even if the risks were exactly known.

Separating these two types of uncertainties is unnecessary in the classical

framework of decision analysis where the goal is to maximize an expected utility [9,10]. Yet, it is sometimes desirable, for example, when one safety objective is to put an upper bound on a probability (for example, an annual probability of accident, or an individual probability of death) which is one of the concerns of the regulators. The analytical uncertainties must then be assessed and reported separately if the administrator wants to know the probability that his objective is reached. One of the ways of conducting this assessment is to define the future frequency of events (e.g., accidents) as a random variable and to describe the analytical uncertainties as the probability distribution of this random variable [11]. In this paper, however, we refer to analytical uncertainties as the uncertainties about models and parameter values. The question is to know how they affect the risk assessment results, both in terms of probability of accident and in terms of distribution of losses.

One classical form of the results called "risk profile" is the future frequency (number of events per year) of accidents involving x or more fatalities as a function of x. To reflect the analytical uncertainties as defined above, one needs a family of curves, representing the characteristics (mean, standard deviation, fractiles, etc.) of the distribution of the frequency of accidents of different magnitudes. Other relevant results are the individual probability of death or injury in each human group and the annual probability of different types of accidents. In all cases, a mere point estimate such as an expected value may be insufficient to represent the analytical uncertainties in the results and to allow the administrator to account for these uncertainties in the decision framework of his choice. Property losses, environmental damage, and human health effects can be assessed separately in the analysis, then combined in the decision itself.

2.5 Risk assessment and risk management: conservativeness

Although the situation is evolving, there are mixed feelings in the industry as well as the regulatory agencies regarding probabilistic risk assessment. The opinion is sometimes expressed that assessing the risks implies "unconservative" decisions, which may or may not be the case. The industry's claim that its risk management decisions have been made in the past by "thoughtful persons who had the sensitivity to do the right thing" [12] without the support of quantified risk information is probably correct most of the time. It is clear, however, that implicit assessment of the residual risk has been less than adequate in some instances, resulting in accidents whose possibility may or may not have been perceived *a priori*.

In the regulatory process, PRA can help improve communications, the choice of priorities, and the coherence of decisions in the absence of perfect information. The agencies, however, have been hesitant to use PRA because of the range of probability estimates that are sometimes obtained by different groups supporting different interests. Yet, it is from this process of exchange of view points that the administrator can obtain a complete spectrum of information

for regulatory decisions. The Nuclear Regulatory Commission (NRC), for example, having rejected probabilistic analysis as imperfect, found itself with no better alternative when trying to decide how to manage the retrofitting of existing nuclear reactors in the wake of the 1979 accident at Three Mile Island.

Risk assessment, obviously, is only part of the task. Actual risk management decisions require, in addition, that trade-offs be examined in the light of chosen decision criteria [13–15]. This is a task that legislators and managers would generally prefer to avoid because it involves deciding upon an acceptable level of risk or an acceptable cost of safety which are politically sensitive issues. Indeed, there is no such thing as a universally "acceptable risk" but there are acceptable decision processes. Risk analysis results are necessary inputs into such processes in spite of the institutional and practical problems posed by the introduction of probability notions in regulation [16].

Conducting a risk assessment in itself does not presume the conservativeness of safety decisions. The results of the analysis, however, can be biased by the choice of a particular model and of a set of parameter values when several scenarios are possible. The conservativeness of the final decision is often impossible to judge because one effect of these biases may be to reverse regulatory priorities. This is why the assessment procedure itself must be specified to disclose and if possible eliminate fundamental biases, even well-intentioned ones. On the basis of the results, the administrator can make the standards as stringent as he wants. Risk assessment only helps a decision maker to use the best available information. Conservativeness belongs in the decision criteria, not in the risk assessment process [17], and much less in deliberately ignoring the levels of risk involved.

Risk assessment also allows for coherent regulations provided that there is some consistency in the regulatory process and in the decision criteria. Even though it is not an obvious goal of the legislation, the coherence of risk regulations, and in particular, of standards within the chemical industry, is desirable for two reasons: equity and economic efficiency [3]. Neither may be perfectly achievable in practice, but both are desirable and should be sought when writing laws and regulations. The objective is to avoid that one chemical be regulated at an extremely stringent level and a very high cost while another one, possibly more hazardous, is treated more laxly [18]. If there are valid causes for doing so, they have to be discussed explicitly. Most of the time, however, these inconsistencies in regulations happen for short-term political reasons that are likely to evolve quickly, leading to abrupt changes in regulatory focus and to a waste of resources.

2.6 The experience of the nuclear industry

The experience acquired in the regulation of the nuclear industry can be fruitfully transferred to the regulation of the chemical industry, both for its positive and its negative aspects. The chemical industry and its regulators have

the opportunity to start fresh. On one hand, their problem is simpler than the regulation of the risks posed by the operation of nuclear power plants because the regulation of chemical risks seems less politically charged. On the other hand, it is more complicated because of the diversity of industrial chemicals.

Probabilistic risk assessment (PRA) has been used extensively in the nuclear industry and has reached a high level of sophistication [19]. This effort started with the Reactor Safety Study [20]. This work was reviewed by the Lewis Committee [21] whose goal was to evaluate the study and the method and to advise the NRC as to the use of such a methodology in the regulatory and licensing process. Although the report called the study "a substantial advance over previous attempts to estimate the risks of the nuclear option", it also pointed to some of its weaknesses. As far as the use of PRA in setting regulations, the recommendations can be extended to the chemical sector:

> In general, avoid use of the probablistic risk analysis methodology for the determination of absolute risk probabilities for subsystems unless an adequate data base exists and it is possible to quantify the uncertainties. However, the methodology can also be used for cases in which the data base will only support a bounding analysis, and for other cases in the absence of any better information if the results are properly qualified.

The Reactor Safety Study was followed by several extensive PRAs for specific reactors, for example the Zion nuclear power plant [22]. The results of these analyses have been used by the industry as well as the NRC to make safety decisions [23,24]. Bernero, from NRC, states clearly, however, that "for the foreseeable future, PRA must be used as a supplement to the regulatory process, not as the sole basis of regulatory decisions." Recently, the NRC has proposed a set of qualitative and quantitative guidelines for regulatory decisions [25]. The numerical criteria, useful as they may become as the PRA methodology develops further, must be used prudently in addition to other types of guidelines in order to avoid dangerous "number games", Yet, they may help to improve reactor safety at the same time as the cost-effectiveness of regulation. As stated by Bernero [24], PRA can be most useful in "the development of general licensing criteria and the evaluation of system or subsystem reliability within plants." With appropriate transformations, the risk assessment general methodology [26] and the risk management guidelines of the nuclear industry can be useful starting points to approach the problem of designing a coherent regulatory framework for the chemical industry.

The chemical industry can also benefit from the negative aspects of the nuclear regulation experience. It is clear, for example, that more stability and consistency in the regulatory process is desirable. The incoherence and at times, the apparent contradictions of successive decisions have been very costly to the industry, to the public, and to the NRC. As far as risk assessment methods

are concerned, the chemical industry can avoid some of the early mistakes of nuclear PRA. These include, for example, the treatment of analytical uncertainties by "conservative estimates" which made it impossible to judge the conservativeness of the final results [21]. Also, the presentation of risk results by comparison with other risks can help put risks in perspective, but it must be made clear that this comparison does not imply that the rational decision maker must accept equally risks of the same magnitude regardless of the circumstances [20].

2.7 The experience of the offshore platforms sector

The safety history of offshore platforms also presents interesting similarities with the current situation of the chemical industry. In the mid-seventies, the safety of offshore platforms was unregulated. Yet, after a certain number of accidents, it appeared that federal regulation was going to occur in order to protect the safety of the workers and the quality of the environment threatened by oil spills. Like the chemical industry today, the oil industry was secretive about its procedures for reasons of business protection and anti trust concerns. Although there were variations in safety practices, the industry generally considered itself advanced in the domain of structural reliability.

The sharing of the information occurred promptly when the American Bureau of Shipping and the United States Geological Survey began to develop their own methods of probabilistic risk assessment for regulatory purpose. The industry, which had much more experience in that field, reacted quickly by spreading the technical knowledge through the published literature and professional committees. An American Petroleum Institute (API) structural code was developed with a few probabilistic elements, followed by the current development of the API 2 code, explicitly based on probability (Load and Resistance Factor Design). The federal government has for the moment accepted the industry-sponsored code and considers that it provides acceptable safety norms.

In this particular case, the industry and its workers found themselves in a better position sharing the information and participating in the code design than simply responding to government initiatives. This corporatist approach to regulation [27] can sometimes be more successful than the adversarial approach, given the delays and the resistance that the latter involves.

3. Examples of chemical PRAs

The probabilistic methods used for complete risk analyses in the chemical industry (as opposed to toxicity studies for specific chemicals) are very similar to those generally used in the nuclear industry. As with nuclear risk assessment, chemical PRA involves system reliability [58,59] and exposure analysis [28]. In addition, chemical risk assessment poses particular problems due to

the variety of chemical products and to uncertainties in the pathways, the dispersion, the transformation, and the toxicity of some substances. Some of the risk assessment work done in the industry remains proprietary. What follows represents only selected examples of the published studies.

One of the most extensive and most comprehensive chemical PRAs is the study of the hazards from petrochemical operations in the Canvey Island in England [29]. Several methane terminals, petroleum refineries, and chemical plants are situated in an area of a population of about 33,000 people. "Attention was focused primarily on those events where a failure of containment could result in the speedy generation of a substantial quantity of flammable, explosive, or toxic vapour". The main products involved were toxic liquefied gases (ammonia and hydrogen fluoride) and flammable liquefied natural and petroleum gases (methane, propane, butane). The study involves an analysis of the reliability of equipment and operations (including the performance of storage tanks), of the toxicology of the substances involved, and of the possibilities of evacuation. The results include an assessment of the societal and individual risks and also the risk reduction effects of suggested improvements.

Several PRA studies involve the risks associated with handling and transporting liquefied natural gas (LNG). Drake [30] studied the risk involved in LNG systems using a classical method of fault tree and event tree analysis. Keeney et al. [31] studied the risk at the potential site of an LNG terminal. They also used a method based on event trees including different accident mechanisms, the probability of release of different quantities, meteorological conditions, dispersion, and number of people present at the site at the time of an accident.

Meslin [32] uses a method directly based on the model of the Nuclear Reactor Safety Study [20] to study the risk of chlorine transport in France. His analysis involves four steps: transportation system analysis, determination of accident rate, package behavior analysis, and environmental impact assessment. He presents his results in the form of a risk profile that allows comparison of this risk to that of airplane crashes or fires. The relevance of such comparison is to put the results in perspective. The comparative acceptability of the risk, however, does not follow and has to be examined in the light of specific decisions.

Boykin et al. [33] present a similar method of risk assessment for a chemical storage facility. In addition to risk assessment results for the system as it is, they consider two improvement alternatives and compute the corresponding costs and risk reduction benefits. In another paper, Boykin [34] presents a general method of PRA, based on functional analysis, fault tree analysis (see Fig. 1), event trees and probabilities (see Fig. 2), consequence analysis and risk profiles.

Another type of method is needed to study the risks of fires as opposed to toxic chemicals. An analysis of fire risks in oil refineries was conducted to

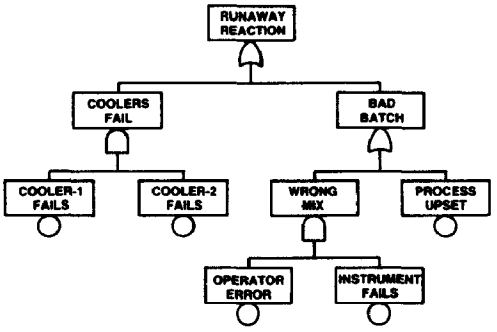

Fig. 1. Fault tree for a chemical reaction (from Boykin [34]).

compute the costs and benefits of camera monitoring [35]. This kind of analysis involves the mathematical modelling of the physical evolution of the fire (in this case by Markov model with different parameters for the different phases of fire growth) and an economic analysis of fire losses reduction. This model allows linking the fire losses to the detection time and thus evaluating the benefits of early fire detection.

Glickman and Rosenfield [36] present a method of analysis of the risks involved in the transportation of hazardous chemicals by railroads, linking the different forms of hazards (e.g., fire effects, toxic effects, and blast effects) in an impact model tree. Like Meslin, they present their results in the form of a cumulative risk profile curve (see Fig. 3).

Campbell et al. [37] present an application of decision analysis to the regulation of perchloroethylene under TSCA. They use probabilistic methods to address the different parts of the analytical model. In particular, they put a probability distribution on the different possible models for the dose–response relationship and show how their results differ from those obtained by the use of upper bounds.

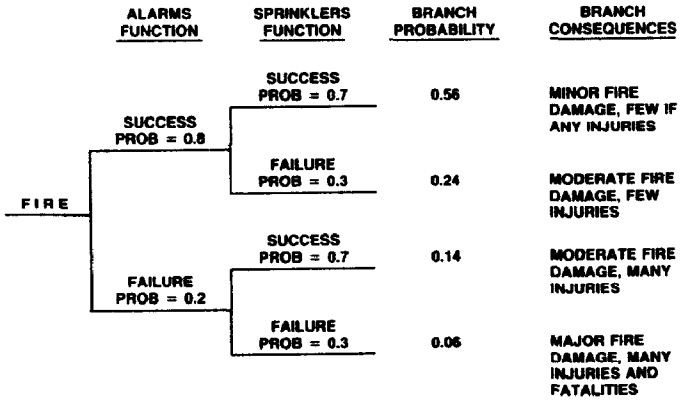

Fig. 2. Event tree for building fire (from Boykin [34]).

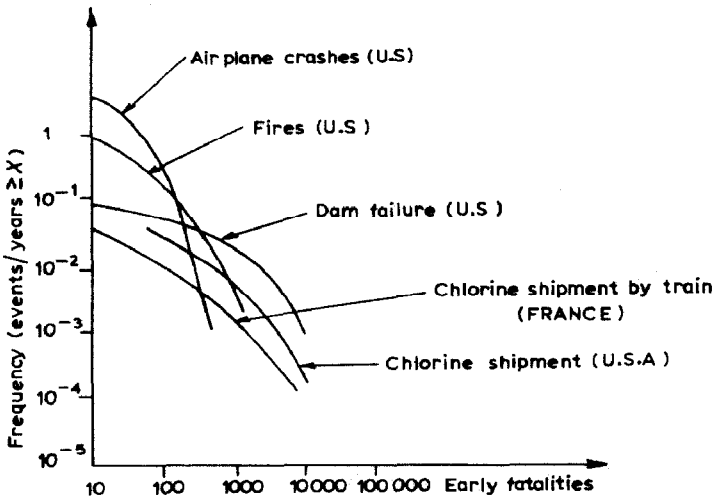

Fig. 3. Frequency of different types of accidents involving fatalities (from Meslin [32]).

Other types of relevant studies include the large body of work done in academia, the industry, and the regulatory agencies to address different aspects of the toxic risk assessment problem, mainly toxicity and exposure. The toxicity of specific chemicals is evaluated on the basis of epidemiological data, animal studies, and pharmacokinetics. Exposure models such as the one described by Travis [38] involve pathway analysis, transport, transformation, and intermedia transfer. The different aspects of risk analysis in general and toxic risk in particular have been studied in recent comprehensive studies of the state-of-the-art in risk assessment [5] and in a recent survey of the field of environmental health risk analysis [39].

4. Risk management in the chemical industry

Risk management decisions in the chemical industry are made most of the time on the basis of experience and intuitions as a result of management concerns or in response to regulations [12]. The use of PRA in the industry itself has been very limited. Some companies have performed deterministic studies, such as "failure modes and effects analysis" which focuses on the failure mechanisms but provides no information about uncertainties and, therefore, about priorities. The industry has generally relied on experience and on accepted rules. For example, a general rule for siting is to look for an isolated area remote from population zones. In this case, the remaining questions are: what level of isolation is sufficient, and what is the probability that an area which is now isolated will become populated in the future?

4.1 Emission modelling and monitoring

Currently, the modelling and monitoring of chemical plants' emission are the focus of particular attention. Emission modelling and monitoring can take several forms: from simple atmospheric monitoring based on measures of emission out of the plant, to real time computer simulation of plume dispersion or continuous dispersion model of fugitive emissions. Systems such as MIDAS (Meteorological Information and Dispersion Assessment System) use computer simulation to predict the dispersion of released material [40]. These systems, however, are far from perfect and their predictions are not always reliable.

4.2 Maintenance and operation

A majority of the risk management programs currently depend on safety systems and procedures that address specific hazards. Risk management for the operation and maintenance of chemical plants relies on the availability of these safety systems and on the observance of the procedures by the plant personnel. The use of PRA techniques allows analytical evaluation of the effect of these various safety systems and procedures and provides chemical plant management with a clearer understanding of plant hazards and their control. In this respect, the application of PRA techniques are a complement of the current chemical plant risk management programs.

4.3 Transportation risk management

The decision of a railroad transportation route is made by the railroad companies whereas the chemical company often owns the rail cars and is legally responsible for the consequences of accidents. PRA has sometimes been performed to guide the choice of a route [36]. This type of analysis is promising because it is relatively straightforward and the transportation risks involve high potential losses.

4.4 Waste disposal

Probabilistic risk assessment has been more frequently used in recent years for decisions concerning waste disposal, for example, for the choice of a general strategy such as incineration, solidification, bacterial disposal, or modification by processing. Risk assessment methods for waste disposal, however, still need a great deal of improvement, both in the understanding of the physical mechanisms and in the gathering of the different pieces of information into one relevant and complete model.

4.5 Insurance

When making insurance decisions, the chemical industry like many others is currently in a difficult position as more and more uncertainties have clouded decisions regarding financial risks, adequate levels of coverage, and reasonable

premiums. The insurance industry itself relies essentially on actuarial data and very little on probabilistic risk assessment, even for rare events for which there is almost no statistical information. At this time, the insurance market is in disarray. The insurers are facing the possibility of enormous and unpredictable liability losses in catastrophic accidents such as a massive toxic release. Their response has been to withdraw some types of policies from the market. As insurance becomes unavailable, the chemical industry must rely on self insurance, often without a clear idea of the risks that it is facing.

5. Safety regulation of the chemical industry

In this climate, safety regulation appears to the industry as a mixed perspective. On one hand, there are some concerns about additional government requests and interference. On the other hand, the insurance market is of little help and the court system seems to produce unpredictable results. Without shifting the burden of liability that remains, as it should, on the companies, regulation provides guidance, norms, and standards, and also promotes the sharing of risk information within the industry.

Regulations are issued by federal agencies, state legislatures, and local governments. The federal agencies regulate (1) the safety of products through the Consumer Product Safety Commission (CPSC), (2) the safety of the industry workers through the Occupational Safety and Health Agency (OSHA), and (3) the safety of the public off-site through the Environmental Protection Agency (EPA). In addition, the Department of Transportation and the United States Coast Guard regulate the transportation of hazardous substances. The EPA regulates the risks associated with hazardous materials under the Comprehensive Environmental Response, Compensation and Liability Act of 1980, the Resource Conservation and Recovery Act, the Toxic Substances Control Act, the Clean Air Act, and the Clean Water Act. However, the regulation of the chemical industry under these laws, for example TSCA, leaves many questions unanswered. The use of probabilistic risk analysis if it is required at all needs to be specified further.

For a long time, the EPA has focused on carcinogens and has given little attention to acute toxics. Carcinogens, however, do not seem to be a main source of hazard in cases of accidental release. After the Bhopal accident, the EPA published a Chemical Emergency Preparedness Program "to help communities become aware of any acutely toxic chemicals in their area and prepare to respond to any accidental release of such chemical into the air" [41]. The EPA document includes a long list of acute toxics such as methylisocyanate and acrolein, used in the production of agricultural chemicals, and hydrogen cyanide, a by-product in the manufacturing of a nylon intermediate. To identify acutely toxic chemicals, the EPA has used median lethal doses (LD_{50}) or median lethal concentrations (LC_{50}) that will result in the death of 50% of exposed

test animals. As a crude measure of toxicity for emergency action, the EPA defines the level that is Immediately Dangerous to Life and Health (IDLH) as the maximum level to which a healthy worker can be exposed for 30 minutes without suffering irreversible health effects. In addition, explosive, flammable and corrosive chemicals were listed separately. These measures, however, are only screening devices. They represent useful information as a first step to establish crude priorities for emergency actions and for further research. They are not sufficient to do the kind of probabilistic risk analysis that is needed for longer term risk regulation. To do so will require the design of standard procedures that allow quantification of uncertainties and, in any case, avoid some of the current confusions among upper bounds, best estimates, etc.

At the state level, new efforts are made to prevent catastrophic accidents and to reduce chronic exposure to routine emission. The State of New Jersey, for example, passed in January 1986 the Toxic Catastrophe Prevention Act giving the New Jersey Department of Environmental Protection (DEP) clear authority to regulate chemical manufacturing operations [42]. The understanding is that if a chemical facility has no adequate preventive plan, DEP requires an accident risk assessment. How the risk is to be assessed, however, is still unclear.

State legislations have also recently focused on the problem of waste disposal. The concern is to ensure the safety for the public of the operation of the industry, to prepare for emergencies, and to regulate the long-term effects of waste disposal. Probabilistic risk assessment is now required by several states, but because of the lack of experience with this type of method, the meaning of PRA is often unclear to the regulators themselves. Much work is needed to improve communications, to standardize the procedures while leaving some flexibility, and to provide specific information as to what is actually required.

PRA can be a costly exercise, but by developing the method and providing a coherent framework of analysis the regulators can obtain comparable information from the different branches of the industry and the different companies. This consistency of data is critical to equitable and efficient regulatory decisions.

6. PRA: the analytical framework

6.1 The chemical PRA technique

The PRA method is based on the construction of a set of scenarios and on the quantification of their probabilities and their consequences. PRA for the chemical industry involves the combination of different probabilistic models as shown in Fig. 4. One difficulty is that these models come from different fields of expertise and need to be formulated and assembled in a coherent manner. They include:

- Initiating event model

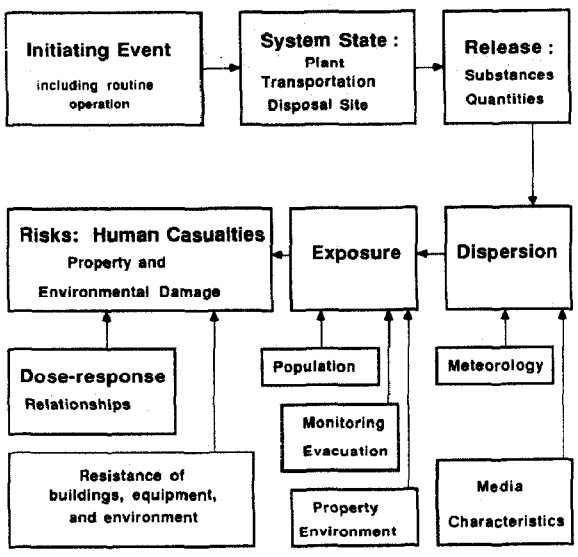

Fig. 4. Chemical PRA. The different models.

- Plant (site) state model
- Release model
- Dispersion model
- Exposure model
- Dose–response model
- Fire and blast model
- Individual and societal risk models.

The *initiating event* model describes the mechanism and the probability of unusual occurrences that may start an accidental release. These events can be internal to the plant (e.g., a pipe rupture) or external (e.g., a flood). An initiating event can be characterized by its level of severity and its probability of occurrence.

The *plant (or site) state* model describes the failure of a plant or transportation system, or the physical characteristics of their routine operation, or the characteristics of a waste disposal site. The result of this model is a probability distribution for the different possible states given the occurrence of an initiating event.

For each of these states, the *release* model characterizes the different levels of emission, routine or catastrophic, per type and quantity of chemical or mixture released. For each of these situations, the *dispersion* model incorporates the different possible meteorological situations, the characteristics of the media, and the chemical reactions to assess the concentrations at different points in the air, the water, or the ground.

The *exposure* model is then used to obtain the number of people potentially

exposed to a given dose or mixture under all forseeable circumstances. Inputs to this model involve the different levels of human occupancy as a function, for example, of the season or the time of the day. The *dose–response* relationships then allow the analyst to assess the forseeable effects on humans of different levels of exposure.

Other hazards, such as *fires and blasts*, must be analyzed separately. They also involve a probabilistic study of initiating events, plant states, release of a flammable material, dispersion and ignition of this material, and human exposure analysis.

This analysis is relevant to the problems of continuous exposure to low doses of chemicals as well as catastrophic release situations. The results can be presented under different forms, including individual risk (probability of death or injury per year and per person in different groups), societal risk (probability distribution of the number of casualties per year), breakdown of probability of accidents of different categories per type of initiating event and mechanism, description of analytical uncertainties, and effects of possible risk reduction measures.

6.2 Difficulties and limitations

Producing meaningful and relevant risk assessment figures for regulatory decisions is difficult for theoretical as well as practical reasons.

Theoretically, the value of the analysis of risks is based on the improvement of the decision to be made. The classical framework of decision making under uncertainty relies on the notion of rationality as defined by the von Neuman axioms of economic choices [43]. The theory of decision analysis that was derived from these axioms, however, is designed to guide only individual decisions [9,10]. Several fundamental problems arise in the transfer of these concepts to regulation; mainly that Bayesian probability [8] as well as utility are individual notions. Regulatory decisions are essentially collective, even though, in the end one administrator must set a standard [1,44,45].

The practical difficulties in the use of probabilistic techniques for industrial risk analysis have been emphasized in many places, particularly in the nuclear literature [21,46]. They include the weakness of some data bases for component failures and human errors, the difficulty to accurately propagate and represent the analytical uncertainties, and the choice of adequate models during the analysis. Another problem, often called the completeness issue, is that, although the construction of fault trees and event trees is a logical step-by-step procedure [3], it is impossible to be certain that no scenario has been left out, in particular those that might involve unknown physical or chemical properties of the substance of interest. There are, for instance, serious questions concerning the behavior and the ignition of LNG clouds following a liquid spill.

The analysis of human intervention and human error requires another type of expertise. The question is two-fold: what is the possibility of gross error as

an initiating event, and what is the ability of an operator to diagnose and correct a plant problem, for example by closing a valve in time to avoid further toxic spill. Although the data are scarce, there has been some marked progress in recent years in the understanding of cognitive and behavioral problems leading to human errors. Some specific studies focused on the implications of human errors in fields such as the aeronautic or the nuclear industry [47]. The chemical industry, which has undoubtedly accumulated knowledge in this domain, can also benefit from cross-industrial experience.

In addition to the general problems of industrial PRA, one of the major difficulties of performing chemical risk assessment is the weakness of the data base concerning chemicals' toxicity. To interpret the information from toxicological studies conducted on animals, the use of experts' opinions is indispensable. Bayesian techniques, including calibration and aggregation, allow the analyst to treat this information along with other types of data in a coherent and logical manner [48].

Experts, however, often disagree. They disagree, for instance, about the adequacy of the different possible dose–response models. The resulting uncertainties need to be reported in the results. The results unfortunately can be biased and misleading when experts mix public policy advocacy with objective scientific expertise [49]. Careful assessment of the basis of their opinions and openness of the scientific debate can attenuate the effects of experts' biases which still remain one of the major difficulties in some domains of risk analysis.

The difficulties of forming collective opinions and making collective decisions are inherent to risk management in the public sector. They do not imply that the risk analysis and decision analysis methods are inadequate. The PRA techniques and the quality of the data bases are still improving and further progress is certainly needed. The probabilistic approach has the advantage of making the administrator's thought process explicit and more scrutable. It ensures that logic is preserved in the information gathering process and that equity and efficiency are considered – if not fully satisfied – in regulatory decisions.

7. Safety goals in regulatory decisions

7.1 Overall objectives

The objectives of cost-effective safety standards are three-fold:

- to ensure that the individuals are adequately protected;
- to ensure that the residual societal risk is acceptable;
- to ensure that the benefits of a regulation outweigh the costs involved.

Individual risk is defined as the probability that an individual becomes sick or is killed by potential exposure to a given chemical each year or in his life time. *Societal risk* is defined by the probability distribution of the total number of people that may be affected every year at different levels of severity. *Cost-*

effectiveness of safety regulation means that the costs invested in human safety at a low probability of exposure would not be better used elsewhere by society or by the individual himself in alternative methods of protection, additional consumption, or productive investments.

These three types of safety constraints are not independent. Obviously, the societal risk is directly linked to the different levels of individual risk and to the number of people exposed. This relation, however, varies from site to site. One may require that all three objectives be satisfied, and thus that the most stringent constraint be the binding one. This approach implies that the cost-effectiveness objective apply only beyond the safety levels required be the other two.

7.2 Safety goals in the nuclear industry

After years of hesitation and recognizing the problems of both insufficient and excessive regulation, the Nuclear Regulatory Commission proposed a set of qualitative and quantitative safety goals [25]. The intention is that these goals be used as a complement to other types of procedures. The idea is to improve both the effectiveness and the efficiency of the regulatory process. In June 1986, the NRC voted to adopt a policy statement on nuclear power plant safety goals containing several revisions to the original draft [50].

The applicability of these goals to risk regulation in other industrial sectors has been discussed elsewhere [51]. One major advantage is that they can help to translate the language of the law into workable design guidelines. This approach, appropriately adapted and used as a complement to classical regulatory procedures, can be helpful to set coherent standards for the chemical industry and to make the regulatory process more consistent and more predictable. The framework should be designed, however, so as to leave some flexibility to the regulator to take into account special circumstances.

The qualitative goals are based on comparison of societal risk from industrial plants (1) to other risks to life, and (2) to risks from alternative methods of producing an equivalent service. For nuclear plants, it is the risk of producing electricity by other means such as coal burning. The first safety goal is the following:

Individual members of the public should be provided a level of protection from the consequences of nuclear power plant operation such that individuals bear no significant additional risk to life and health.

This goal, if one wants to transfer it to chemical risk management must be extended to include also the hazards of chemical transportation and waste disposal. The second safety goal is the following:

Societal risk to life and health from nuclear power plant operation should be comparable to or less than the risk of generating electricity by viable competing technologies and should not be a significant addition to other societal risks.

This goal reflects the administration's concern with risk transfer and with consistency of standards across the electric power industry. The equivalent in the chemical industry would be to ensure that a particular regulation in one segment of the industry does not create elsewhere another risk of greater magnitude. This might be the case, for example, of the production and the use of a particular pesticide or a given raw material, whose price may be driven to uncompetitive levels by regulation, thus leaving the public exposed to a higher risk of another type, or to a more toxic substitution product. The third safety qualitative safety goal concerns the performance of the technical system:

Severe core damage accidents can lead to more serious accidents with the potential for life threatening off-site releases of radiation, for evacuation of the public, and for contamination of public property. Apart from their health and safety consequences, such accidents can erode public confidence in the safety of nuclear power and can lead to further instability and unpredictability for the industry. In order to avoid such adverse consequences, the Commission intends to pursue a regulatory program that has as its objective providing reasonable assurance, giving appropriate consideration to the uncertainties involved, that a severe core damage will not occur at a U.S. nuclear power plant.

This safety goal addresses some of the political as well as technical aspects of nuclear power. It allows the NRC to focus on the probability of radioactive release which is easier to quantify than the risk to human health. For this reason, it can be transferred to the chemical industry and to the reliability of chemical plants or transportation systems.

The quantitative objectives involve numerical constraints that allow the actual testing of design and procedures on the basis of PRA. The first one is the individual safety objective (immediate accidental deaths):

The risk of an average individual in the vicinity of a nuclear plant of prompt fatality that might result from reactor accidents should not exceed one-tenth of one percent (0.1%) of the sum of prompt fatality risks resulting from other accidents to which members of the U.S. population are generally exposed.

For the chemical industry, this goal should be extended to include not only death but also lower level and routine effects (e.g., respiratory problems) of chemical plants operation. The second goal concerns cancer risks:

The risk to the population in the area near a nuclear power plant of cancer fatalities that may result from nuclear power plant operation should not exceed one-tenth of one percent (0.1%) of the sum of cancer fatality risks resulting from all other causes,

The difficulty in transferring this goal to the chemical industry is to obtain

consistent, acceptable assessments of the carcinogenicity of the multitude of chemical substances produced in this country, particularly in the low dose range. The current EPA assessment procedure is inadequate in this respect because it produces upper bound estimates whose conservativeness is impossible to evaluate in their current form.

Other quantitative guidelines are still under consideration by the NRC. In an earlier draft of the safety goals, a cost-benefit guideline was proposed in addition to the basic objectives to evaluate additional safety measures:

The benefits on an incremental reduction of societal mortality risks should be compared with the associated costs on the basis of $1,000 per man-rem averted.

This goal defines the acceptability of additional costs of human safety in the range in which the risks themselves are considered acceptable. The objective, as mentioned earlier is to ensure optimality of capital spending for safety in society at large. This objective can be transferred to other industries on the basis of an acceptable cost per life saved (e.g., $2 Million) beyond the requirements of the first two numerical goals. The use of such a number, however, is appropriate only for small probabilities of death [52].

Finally, the NRC is still considering a numerical design objective of the following form:

The likelihood of a nuclear reactor accident that results in a large scale core melt should normally be less than one in 10,000 per year of reactor operation.

This objective was introduced because of the large uncertainties involved in the exposure part of the analysis beyond the source term evaluation, i.e., in the dispersion, exposure, and dose–response models for radioactive material. It was felt that such a goal was easier to translate into design characteristics than the other ones. The same problem arises in the chemical industry, but it is difficult to conceive a similar goal that would be consistent across the industry. Setting a limit to the probability of accidental release would have to be done plant by plant on the basis of the nature, the quantities, and the toxicity of the substances involved.

8. Analytical uncertainties

8.1 Assessment of analytical uncertainties

One of the conceptual difficulties in the application of these goals to standard setting is to show that the objectives are reached "with reasonable certainty". The administrator faces two types of uncertainties, analytical and observational. As we discussed earlier, analytical uncertainties refer to the incompleteness of the information about the fundamental mechanisms that actually underly the phenomenon of interest, the appropriate models, or the parameter values. The observational uncertainties (sometimes called random-

ness) are those that would remain even if the models, the parameters, and therefore the risks were perfectly known. There is no uncertainty, however, about the probabilistic method itself whose goal is to be precise about the state of knowledge. PRA is designed to adequately represent uncertainties through correct logical and probabilistic treatment of the information.

The main concern is to ensure that the range of possible models and possible parameters is accurately represented, and that the corresponding spectrum of possible effects on the individual and the social risk is presented to the administrator in charge of the regulatory decision.

Consider the problems of toxicity assessment for substances whose effect on humans are poorly known. Although carcinogens are not the main source of hazards in case of accidental chemical release, they provide an illustration of the problems of analytical uncertainties because they are sometimes involved in pollution control and because they have been the focus of many studies. Yet fundamental problems remain in the current use of the information. The issue is to know (1) what is the shape of this function (and in particular, if it is linear in the low-dose range) and (2) what are the parameters corresponding to each of these models (for example, the threshold point and the slope of the curve if one considers a linear threshold model). The model as well as the parameter values are linked to fundamental mechanisms of carcinogenicity that are poorly known at this time. The available evidence comes from epidemiological studies and from animal studies. The use of animal bioassays introduces large uncertainties in the analysis because it requires a double extrapolation: extrapolation from high doses to low doses, and from animals to humans.

In the general case where the risk analysis involves the possibility of different mechanisms and for each of them, a spectrum of possible parameters, the correct probabilistic procedure is (1) to identify the possible underlying mechanisms and assess a probability distribution to the corresponding set of models (probabilistic or deterministic) and (2) for each model to assess a probability distribution to the set of possible values of the parameters. Each combination {model, parameter value} leads to an estimate of consequences to the public, and therefore of the risk reduction associated to a given regulatory standard. The joint probability of the set {model, parameter} associated with the corresponding level of consequences gives the probability distribution of the effects of exposure to a toxic chemical.

This Bayesian procedure is not the one that is used today by agencies such as EPA. Instead, the EPA Carcinogen Assessment Group (CAG) routinely uses toxicity assessment methods that lead to quasi-upper bound estimates without giving appropriate measures of the modelling uncertainties [53,54]. This upper bound method can be acceptable as a first cut to risk assessment, for example, for screening purposes. When used as a method for risk management, however, this method is insufficient because it makes it difficult to cor-

rectly judge the validity of the results and the overall impact of overestimations on the final risk estimates. This approach leads to distorted figures that do not even ensure the correct ranking of risks by order of severity. It is then quite possible to reach suboptimal decisions, defeating the purpose of conservativeness itself.

North [4] describes the EPA upper bound method in the particular case of perchloroethylene (PCE), and its effect on the risk assessment results. He shows that (1) the results are misleading and (2) it is not possible to estimate the effects of these built-in "conservatisms" without a more complete and more sophisticated treatment of the uncertainties, i.e., one that involves the spectrum of possible models. As an illustration, he examines a set of eight (2^3) possible scenarios of the form: choice of species, scaling of dose from animal to human, and low-dose extrapolation. The species can be mouse or rat, the scaling can be based on surface area or on body weight, and the response to low doses can be represented as a linear or nonlinear function. For one particular scenario, the life time probability of cancer for a machine operator under present conditions of exposure is estimated at 3×10^{-5}, five orders of magnitude below the 0.23 EPA upper bound estimate. Indeed, EPA uses standard language to indicate that the lower bound may be zero, but a mere statement of upper and lower bounds without further definition does not provide sufficient information for risk management decisions. A probability distribution of the risk for different scenarios would give the administrator a clearer idea of the effects of a spectrum of possible models on the results.

The complete treatment of uncertainties includes the description and propagation through the analysis and in the risk assessment results of all the uncertainties involved: failure of the basic elements, human errors, occurrence of initating events, human exposure, dose–response functions, etc. Confronted with the same problem the analysts of the nuclear industry either compute error factors (ratio of the 95th upper fractile to the mean) and propagate these factors in the results, or combine all analytical uncertainties (on models and parameters) in the probability distribution of the final result [55]. The latter is far superior in its information content. This method has been succesfully used for the seismic risk analysis of nuclear power plants such as the Limmerick power station [56] for which several alternative seismic mechanisms could be envisioned, given existing evidence.

A similar procedure can be developed for the effect of human exposure to accidents from chemical plants [57]. The complete results of this method include a probability distribution of the future frequency of incidence of toxic effects for given human groups as well as a risk profile describing the potential impact on society. If one chooses the safety goal approach to regulation, the definition of "reasonable certainty" combined with probabilistic results of this type allows the administrator to make more informed and consistent decisions as far as individual and societal risks are concerned.

8.2 Treatment of uncertainties in the safety objectives

The treatment of analytical uncertainties and the use of the analytical results therefore depends on the type of objective that one is trying to achieve. When making a decision about an optimal allocation of safety funds, it is the mean value of the future frequency of mortality or disease that should be considered if the goal is to protect the maximum number of people. Consider, as an illustration, the choice to eliminate either risk A or risk B for which analytical uncertainties remain in the assessment of the individual risk. For one million dollars, we can eliminate either risk A or risk B for one million people. For risk A, the mean of the individual risk with respect to the spectrum of models and parameter values if 10^{-5}, the 95th upper fractile is 1.5×10^{-5}, and the EPA-style upper bound estimate is 2×10^{-5}. For risk B, the mean of the individual risk is 0.1×10^{-5}, the 95th upper fractile is 10×10^{-5}, and the upper bound estimate is 20×10^{-5}. Note that the probability of exceeding the upper bound is unknown, but has no reason to be the same for risk A and risk B. If the decision to spend the funds is made on the basis of the upper bound or of the upper 95th percentile of the risk estimate, the choice will be to eliminate risk B, whereas in fact the expected value of the number of people saved would be ten times higher if the funds were spent towards the elimination of risk A. In general, the use of an upper bound or of a given fractile of the distribution (e.g., 95%) can lead to suboptimal allocation of safety funds.

When deciding on a maximum acceptable level of societal risk, individual risk, or annual probability of accident, the mean value of future frequencies with respect to the range of models and parameter values is only one of the possible options. The use of the mean or of a fractile has to be specified at the same time as the objective (e.g., 10^{-4} per year, with probability 0.95, or 10^{-5} per year on the basis of the mean). The definition of such a "reasonable degree of certainty" is not more arbitrary than setting the safety goal itself. For reasons of practicality and consistency, the use of the mean and of corresponding numerical guidelines is a logical one for all safety goals.

9. Conclusion

Regulation may not be the best way of ensuring the safe operation of the chemical industry. If the chemical companies received better and more predictable guidance from the legal court system and from the insurance industry, they could be in a better position to make safety decisions for themselves. In the present situation, however, regulation is one possible solution and the question is to know on what basis to establish a workable, coherent, and reasonable system of safety standards. In this perspective, it is important for the regulator to design a regulatory framework involving consistent information gathering procedures and consistent safety criteria.

The chemical companies have a unique opportunity to participate in the

shaping of regulation provided that they accept the principle of sharing information and knowledge at the cost of revealing some of the methods of operation. The chemical sector can benefit from the experience of the nuclear power industry in the development of risk assessment methods and in the use of PRA along with other types of conventional procedures for regulatory decisions. Probabilistic methods offer a practical way of making balanced and informed safety decisions. PRA for the chemical industry is complicated by the variety of the substances involved and the lack of information concerning the toxicity of a large number of chemical products. Current methods of toxicity assessment such as those used by EPA for carcinogens need to be improved: they are insufficient in that they fail to include adequately the spectrum of possible models and parameter values. Instead, they try to include conservativeness in the computation of the risk, possibly leading to unconservative decisions. Keeping risk assessment and risk management separated allows the decision maker to interpret the results and to know what decision criteria are used. Fully assessing and reporting the analytical uncertainties is crucial not only to the understanding of the results, but also to ensuring that the safety objectives are reached with reasonable certainty.

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