RISK, RESPONSIBILITY AND RESEARCH

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ABSTRACT

Risks to safety and health are associated with the production, distribution and use of many chemicals. These risks are borne by different "targets" at different times during the life cycle of a given chemical, both voluntarily and involuntarily. By any criterion, it is upon the shoulders of the chemical professional that the responsibility for the discovery, evaluation and development of approaches for the control of these risks rests. The discharge of these responsibilities requires prediction of all the ways people can be harmed during the chemical's life cycle. Research into predictive methodologies is required to avoid discovery of these risks in accidental exposures. Such research must overcome the lack of theory explaining the harm-producing processes in accidents and severe semantic problems before "libraries" of harm-producing process descriptions can be developed. Research into control concepts for discovering conutermeasures, and into measurement methods for evaluating the degree of risk reduction are discussed.

The demands of professional responsibility and ethics for the adoption of efforts to organize and fund the needed research are described.

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PREFACE

This paper had its origins in personal reflections on widely scattered conversations expressing a common concern. Perplexity and increasing consternation about the future demands that will or should be placed on the chemical and allied industries by our "society" have been observed among a wide spectrum of interested persons over several years. The concerns seem to flow from the uncertainties about where the truth lies in some of the technological issues involving chemicals, and the threat they pose to the future health and safety of our population.

Examples of the uncertainties abound. The chlorinated fluorocarbon aerosol issue is probably one of the most vivid current examples. Recent controversy about vinyl chloride controls is another. Mention lead in paints, red food dye, cyclamates, DDT, or thalydamide and other controversies are quickly recalled.

The concern transcends products of the chemical industries. One has only to look to the nuclear energy, LNG importation and oil spill issues to recognize the breadth of the concern. Can it be laid solely in the laps of the consumerists, or the doomsayers? The durability of these issues suggests that the concern is not a passing phenomenon.

The roots of the concern, in the view of this author, seem to lie in the space program. As man traveled through space to stand on the moon, and shared his observations via television, a new and easily discernible perspective of our planet as "Spaceship Earth" began to seep into our daily thinking. The delicate dynamic balance of conditions that sustain life on our planet became visible and real to everyone watching--as a visible whole rather than abstract segments. With this new awareness, and against the backdrop of Hiroshima, concern about actions which might inadvertently upset this balance and threaten man's future well-being began to intensify. This concern is beginning to characterize our era. Is any reader personally oblivious of this concern today?

In this climate of concern for man's future well-being, rapid shifts in values are beginning to occur, and some difficult value conflicts are being addressed. I predict historians will record this change in social perspective rather than the technological advances as the most important legacy of our program to put man on the moon. For the first time, man can see with his own eyes why it is in his own best interests to prevent abuse of this planet which supports his existence as it hurtles through inhospitable space.

How do these changes relate to the risk, responsibility and research perspectives of the chemical professional? Primarily through the unmasking of the "externalities" not usually accounted for in our private or public economic "accounting" systems. These externalities are effects that spill over the third parties or the public at large from decisions made by private or public decisionmaking events.[1] The effects of your decisions as a chemical professional on my health and safety are being subjected to increasing scrutiny, as we learn of new ways harm has occurred. This scrutiny is

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*The views expressed are those of the author and do not necessarily reflect the positions of the National Transportation Safety Board.

disclosing unknowns of unsettling dimensions. The concern is for the possible harmful effects that will be discovered when the unknowns become known. It is a desire to try to assure the discovery of these unknowns, before investments and attendant risks escalate to irreversible levels, that propels controversy.

In this context, legislative actions such as the Delaney Amendment, the Environmental Protection legislation, the Occupational Safety and Health Act, and the Transportation Safety Act must be viewed by the chemical professional as a social "forcing function." What this legislation says is that society is willing to delay possible benefits until the potential harm has been assessed. The need to respond to these changing values is intensifying, affecting the ethics of the chemical professional.

Another forcing function is the public nature of regulatory rulemaking in the establishment of controls to achieve acceptable risk levels. No longer are the risk acceptance and control decisions made in relative privacy. Neither are they any longer solely the province of the chemical professional. His proposals are now subjected to increasing scrutiny by other parties, including an aroused segment of the public. Thus the need for technical excellence in his representations to governing agencies has never been greater. Allegations of inadequate concern for the possible future harmful effects of today's decisions must be disposed of with technically sound and readily understood arguments, rather than opinions clothed in secrecy or scientific jargon. This too affects the professional ethic.

This paper addresses these circumstances from the perspective of the risks to safety and health associated with chemicals, the responsibility of the chemical professional, and the resultant implications for research.

RISK

When one undertakes an activity, one recognizes that some unintended, undesired and unexpected harm may occur before the intended outcome of the activity is achieved. That possibility of harm is viewed as the "risk" associated with the activity. Risks to safety or health exist when the potential harm involves unintended temporary or permanent injury or illness of people, or damage to animate or inanimate objects.

The safety and health risks associated with the production, distribution and use of chemicals are diverse, by any measure. Thousands of chemicals are found in commerce. The persons exposed and their activities during exposure include almost the entire spectrum of activities of our population. The known ways chemicals are associated with harm over their life cycle is also accelerating. Because of this diversity of risks, and the wide variety of chemicals involved, the task of addressing the concerns described earlier seems, at first glance, overwhelming, and too complex to attack.

It may be. However, if the effort is not made, the public concerns will be resolved by the one certain way to remove the risk: prohibit or abandon the activity. To the chemical professional, who understands the benefits derived from chemicals, this is an unacceptable course of action. Therefore, these concerns must be addressed--deliberately, methodically, and objectively--if controversies about chemicals, such as those involving the SST, DDT, and other technological ventures, are to be constructively resolved in the future.

We speak of many persons being at risk, but who are these people? It is helpful to delineate who they are because their designation will help to identify the scope and nature of the technical effort required to resolve our concerns. It is from the perspective of these persons at risk that the risk must be discovered, evaluated and addressed by countermeasures if the concerns are to be allayed. A similar approach is necessary to address the concern about the risk to objects.

One approach by which these persons can be identified is to examine the life cycle of a chemical, and delineate those persons who could be within range of or exposed to possible harm during the activities involving the life cycle. Tracing a chemical from its inception in some laboratory through its life cycle to its ultimate disposal, conversion or decomposition facilitates discovery of the possible "targets" of this potential harm. These persons or objects are "targets" in both the negative and positive sense. In the negative sense, they are potential victims or targets of the harm associated with the chemical. In the positive sense, these targets become the focal points for the technical risk analysis efforts and precautionary measures addressing these concerns.

A chemical substance is involved in numerous activities during its life cycle. This involvement takes several forms. The one type of involvement is chemical-centered, where the chemical substance and behavior is the central outcome and concern of the activity. Examples are laboratory experimentation; process development; pilot plant production; chemical-specific plant start-up, construction, operation and maintenance; product storage, handling, and shipping; product transportation and distribution; product use or conversion, or disposal. These activities are generally conducted or controlled by chemical professionals.

A second general type of activity, for analytical purposes, is the chemical-convergent type of activity, where the intended outcome is not chemically centered, but the chemical is a transient factor during the conduct of the activity. For example, certain maintenance, transportation, selling, distribution, and use activities may involve the handling of a given chemical from time to time.

A third type of activity is the non-chemical type of activity, where the chemical plays no role, except to impinge on the activity during an emergency to produce harm. For example, a non-employee resident adjacent to a chemical plant, or a worker in an adjacent factory, or a resident along a pathway over which chemicals are transported engages in this type of activity, which is of interest because of exposure to chemical harm.

These activities can be visualized as shown in Figure 1.[2]

The degree of awareness of the risks and the willingness to accept them varies with the nature of an activity, and the view of the person engaging in these activities.

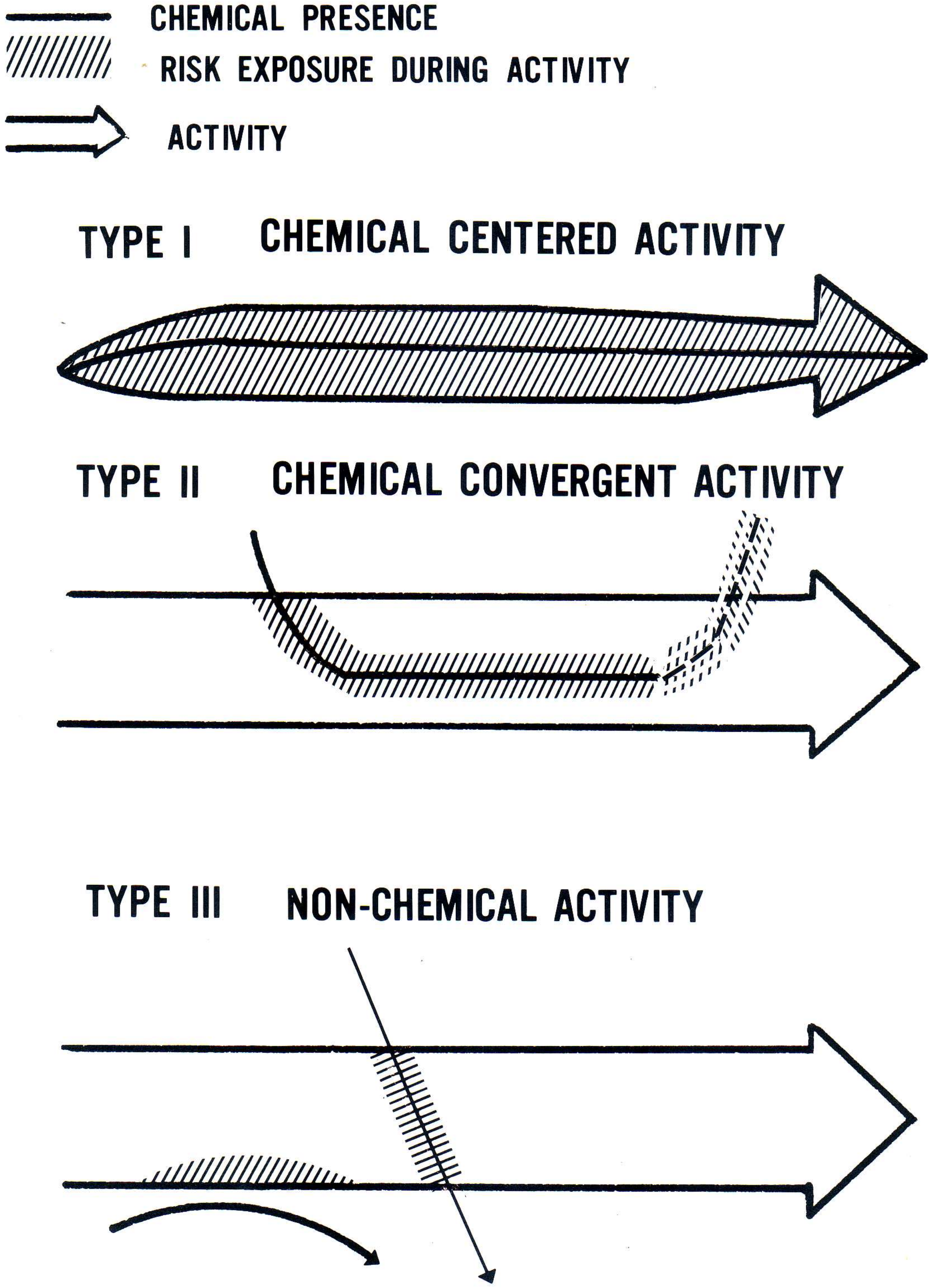
"Voluntary" and "involuntary" designations have been suggested to differentiate among persons at risk.[3] This classification, however, does not reflect risk control considerations for our purposes. A more appropriate differentiation might be:

1) voluntary and informed;
2) voluntary and uninformed;
3) uninformed and involuntary; and
4) informed and involuntary.

To illustrate in the first category we would find the knowledgable chemical professional engaged in Type I activities. The second category would embrace the carrier employee engaged in Type II activities; he is aware of some

FIGURE 1

ACTIVITIES AFFECTED BY CHEMICAL SAFETY AND HEALTH RISKS



risk, but not knowledgable about the specifics nor their control. The third category would embrace persons engaged in Type III activities. The last category can be related to Type I, II or III activities, but in a protestant or adversary role.

In each of these categories, specific persons at risk can be identified by "walking through" the physical handling of the chemical during its life cycle, and by considering potential exposures to the chemical during this review. In other words, who might come into contact with the chemical and become a "target" for harm? The targets vary with the chemical, the processes through which it moves during its life, and the ways harm can occur.

RESPONSIBILITY

Once the targets are identified, how can the risks to these targets be analyzed?

Might one expect each person at risk to identify these risks and look after his own safety? Possibly, if they are in the informed and voluntary risk taker category. Some chemical professionals are employed in activities in which they can discern and control the risks to which they are exposed. For the risk takers in other categories, this approach is not feasible, because they lack both the knowledge and the ability to discover the risks and to influence the activities, in most cases. The public, for example, can not reasonably be expected to identify the risks and assure its own safety directly.

Can government be expected to identify the risks and assure safety?[4] It has certain legislative mandates to do so. However its limited degree of involvement with chemical-centered activities in which risk is introduced raises difficulties. Risks are generated by actions of the chemical "doers"--those designing, supporting or engaging in such activities. The establishment of measures to control known or suspected risks occurs at several levels under our existing institutional structures. Governmental safety and health regulations establish "minimum" standards for some actions or decisions made by the doers. Additional "second level" requirements are prescribed in codes and standards established by non-governmental standards setting organizations, such as professional societies, trade associations, and insurance bureaus. Finally, for individual activities, the "doers" establish detailed "third level" controls and procedures governing most of the steps of their activities, which incorporate but go far beyond both the regulations and codes. These "third level" requirements are the most detailed and comprehensive, but it is this level at which the factors determining risk exist. Unless governmental regulations or codes specify this level of detail, government can not be expected to assure chemical safety through regulation for all parties at risk.

By any criterion--knowledge, span of control, incentive or ethics--it is upon the shoulders of the chemical professional that the responsibility for identifying the threat to the parties at risk must fall. It is the chemical professional who possesses the specialized knowledge and the ability to control such risks. It is the chemical professional who is one of the principal career and economic beneficiaries of the use of chemicals associated with potential harm. It is the chemical professional--whatever his position or activity, who must undertake the discovery of these risks, their evaluation, and the identification of available approaches for risk control methods to assure the safety of the parties at risk.

Note carefully one reservation: the chemical professional may or may not be required to establish what is an acceptable level of chemical risk. Societal mechanisms, including regulation, legislation, litigation, risk-pooling and others, are constantly grappling with this non-technical value decision. The chemical professional should be expected, however, to provide the technical inputs for this decisionmaking process.

What needs to be done to discharge these responsibilities?

RESEARCH

Both technical and non-technical difficulties exist. It is likely that resolution of the technical difficulties is necessary before the non-technical social and economic aspects can be addressed rationally. Therefore, the technical difficulties must be addressed first.

The principal technical difficulty involves identification of the ways chemicals can produce harm. Since harm is the concern being addressed, it would be useful for a risk analyst to be able to work from a "check list" of all ways people can be harmed. Regrettably, no such check list exists. The nearest approaches to such a list are the World Health Organization's International Classification of Diseases[5] and the ANSI Standards for recording facts of accidents.[6] Both fall far short of a complete checklist in the chemical field. In the absence of a check list, which would still not resolve all discovery problems, some method must be found to identify the full range of ways harm can occur. The method must 1) provide a high probability that risks will be discovered; and 2) assure that their discovery will be timely to permit corrective actions, to be credible and satisfy the concern about the unknown unknowns.

One approach that can be used to identify the harm-producing mechanisms for a risk analysis is to extrapolate data from accidents and illnesses which have occurred in the past, using a <u>persistence prediction approach</u>.[7] One of the difficulties with this approach is that someone must pay for the discovery with personal loss. In the accident field, where such harm has occurred to members of the general public, this approach might be viewed as "experimenting on the public."[8] When the person at risk is an informed voluntary risk taker, this method may be tolerable. However, it seems inadequate for other classes of risk takers. Furthermore, all the other pitfalls of persistence prediction methods are also applicable. Interestingly, this approach presently dominates the accident research field, and apparently[9] the health research field.

Another approach is to study the intrinsic properties of a substance on a laboratory scale, and attempt to identify properties which are related to harm-producing mechanisms empirically. The difficulties with "scaling up" using such an approach are well recognized and documented.[10] Nevertheless, it is widely relied on for tasks such as plant design and standards development. Great difficulties arise in relating these properties to behavior in "real life" situations such as transportation spills, leaks, prolonged exposures and accidents. This predictive approach, incidentally, predominates the regulatory field in transportation of chemicals, where measures of intrinsic properties govern the classification of materials considered hazardous under regulations.[11] It also seems prevalent in the health field.

This form of the <u>associative prediction</u> method suffers from the inadequacies of past efforts at establishing relationships between intrinsic properties of substances and actual injury mechanisms which exist with the various quantities and forms present during the various activities. An informative example is the irrelevance of "flash point" to the events sequences by which harm occurs, yet this intrinsic property is widely used to indicate "hazard." [12]

Another approach is full scale testing, in conditions approximating the conditions expected to be experienced during the activity.[13] The principal weakness of this approach is the limited number of conditions which can be simulated and studied, as compared with the large number of conditions which can prevail in different activities during the life cycle of the substance. A second weakness is the poor definition of conditions, such as stresses during accidents, which must be reflected by such tests. This and other forms of the prediction by analogy method, such as animal testing, have the inherent difficulty of verifying how accurately the test experience reflects, for predictive purposes, real world or human experience.

It appears that satisfaction of the risk concerns requires realistic prediction rather than post facto risk analysis. It further appears that presently used predictive methodologies do not provide the analyst with either a "check list" of harm-producing mechanisms, or a method for identifying such mechanisms.

Several forms of associative prediction methods employing "logic trees," and used in the system safety field, have been developed for "system" analysis.[14] This approach organizes informed speculations to develop predictive models of ways that assumed undesired events (accidents or harm) can occur within a system. The logic tree methods are not suited to the discovery of the harm which can occur with chemicals, because the analysis assumes the harm. Failure mode and effects analysis assume a failure and trace the harmful consequences in a well-defined system. If system is not well defined, the discovery of potential harm is inhibited. Both are primarily hardware system oriented, and do not lend themselves well to the display of parallel interdependent time relationships. However, they utilize two techniques of value. The first is events sequencing logic that structures the analysis effort. The second is charting or display techniques that facilitate communication, testing and refinement of the analysis.

In summary, there isn't any satisfactory predictive methodology available.

In the absence of satisfactory predictive methods for discovering chemical threats, it is clear that a high priority should be established for their development. Precautionary measures based on the existing approaches appear to have produced their maximum attainable level of discovery, as evidenced by the discoveries of the National Transportation Safety Board (NTSB) in chemical transportation accidents. In these investigations, despite traditional analysis efforts, a lack of understanding of the processes by which harm occurred (involving tank rocketing, explosion, and detonation) can be seen to have existed before the accident.[15,16,17] This appears to reflect a general lack of understanding of accidental harm-producing processes as a whole.

Based on limited observations, symptoms of the same difficulty appear in controversies about chemicals in the health and environmental field.[18] The symptoms are reflected in the widespread use of the term "hazards" and other "blanket words" which obscure the precise role of chemicals in the harm producing processes. Variant analysis methods are widely used in this field, but these methods deal largely with static variants, rather than dynamic process variants. For example, exposure precautions for "preventing" poliomyelitis were developed this way and widely disseminated, yet epidemics occurred. It was not until the role of viruses in the polio process was determined that polio was successfully controlled. Perhaps achievement of an understanding of the biological processes influencing cancerous cell growths will result in a dismissal of the alleged role of cigarettes and chemicals indicted by such methods.

In the transportation accident field, attention is being given to development of such process descriptions. For example, in 1971 the NTSB published a simplified accident process description in its report of an oxygen tank truck explosion.[19] That same year the NTSB suggested a framework for risk analysis that envisioned such descriptions.[20] In response to the NTSB recommendations the U.S. Coast Guard contracted for extensive research in which modeling of the harm producing mechanisms, among other tasks, is undertaken.[21] This research involves treating the evasive link between chemical dispersion and injury. An abbreviated process description for a certain type of hazardous materials emergency has also been published.[22]

As this work progresses, several new obstacles are appearing. One such obstacle in the transportation field is the lack of a theory for explaining the harm-producing processes. A second is the semantic difficulties related to recording and communicating injury process data. These difficulties seem to transcend the transportation field.

The theory problem can be discerned by its symptoms. The "blanket word" syndrome is one symptom of this problem. Another symptom is the diversity of types of "accident" data now accumulated. Another is the diversity of views about what an accident is, where it begins and ends, what losses are counted, and so forth. Still others include the reliance on variant analysis, the controversy about effectiveness of regulatory proposals, and a seeming public ambivalence about risk acceptance. This issue has been addressed but is as yet unresolved.[23]

The semantic problem is more obscure, but very real if the concerns about chemical risk are ever to be successfully resolved. "Blanket words" reflect poorly conceived abstractions; thus verbalizing the processes by which harm occurs has severe semantic limitations.[24] The description of the processes in the numeric or mathematical schema seems inappropriate because of the need to treat logical, temporal and spatial events relationships of different dimensions. Schema for chemical reaction notations seem inapplicable largely because they focus on matter rather than events. Graphic displays such as charting seem to hold promise. This technique is now employed to show process flows, but unintentional harm is not yet so treated.

I don't know what the answer is. I've been warned of failure because I'm dealing at the random noise level statistically. However, I'm still optimistic. A theory of harmful events outcomes has been proposed, based on principles of homeostasis, perturbation, adaptive learning or behavior, stress and injury.[25] It proposes that harmful outcomes involve several "actors," and parallel events sequences involving each actor. If this observation is valid, the development of process descriptions might look to a non-verbal, non-mathematical semantic approach used in another field. This approach

- identifies the actors required to produce the intended outcome;
- defines the events or actions required of each actor and the precise timing of the event in relation to every other event;
- incorporates the limitations in the capabilities of each actor;

. defines the duration and other specifications for the event; and
. displays the complete process from beginning to end.

The "language" is the orchestrated score of a musical melody. This example of a "multilinear events sequencing" method of communication suggests an approach that, in some combination with the events logic sequencing techniques of system safety, might be adapted to meet the needs for discovering, describing, and recording data about the harm-producing processes over the life cycle of a chemical substance. One line could be used for each of the "actors" and "targets" involved. Appropriate symbols might be developed to represent particular acts or injury mechanisms or classes of injury mechanisms. Process descriptions might be established by defining the performance levels or events required of each actor to produce "disharmony"--or injurious outcomes. A library of "orchestrations" could be accumulated. By structuring a symbolic language for the presentations, individual "scores" or contributions to the "library" from individual chemical professionals would be compatible. "Library loans" for risk analysis studies could be facilitated. National dialects need not be barriers to understanding with such a system.

Where events logic gaps occurred in the "orchestration," because of unknowns, these unknowns would become visible. Logic tree analysis methodologies could be applied to bridge these gaps. Thus the structuring of both the discovery of unknowns and their resolution might be achieved.

What can one do with these"orchestrations" (or harmful process "templates") once they are known? The first use is to provide hypotheses with which to identify possible harm-producing mechanisms for a specific chemical. New orchestrations could be developed by testing the "notes" of a new chemical with various segments of prior orchestrations and examining the likely effects.

With the identification of the events constituting the harm-producing processes, the probabilities of the occurrence of these events could be addressed. A variety of statistical and mathematical techniques for risk evaluations are available, and will be compended soon.[26] Using such techniques, the risk of harm attributable to a chemical at various stages in its life cycle might be described and displayed in a relevant, readily understood manner that facilitates review and constructive criticism, so essential for credibility of the technical decision inputs.

One final point. Once the possibility of harm has been identified, and its probability or risk established, precautionary countermeasures may be required to reduce the risk to acceptable levels. For example, if a chemical antidote for cancer is discovered, but it is potentially harmful if it escapes during transportation, what control measures would most efficiently reduce the risk to acceptable levels? This involves two problems:

1. What countermeasures are available?
2. Which of the countermeasures are the most efficient?

At the present time there exists no general method for discovering countermeasures. One approach, which assumes a linear "chain-of-events" sequence as the harm-producing mechanism, contemplates a "break-in-the-chain" approach.[27] Current "logic tree" approaches employ a related approach to frustrate progress along a "critical path." [28] If harm-producing processes are multilinear, "sneak circuits"[29] need to be considered. The use of events charting approaches for this purpose has been proposed. [30] Research into techniques for organizing the approach to risk-reducing countermeasures can also be seen to require research.

After the options for risk reduction have been developed, evaluation of their comparative effectiveness, or their safety efficiency, requires some method of measurement which permits economic values to be incorporated into the decision making.[31] This problem area is less the province of the chemical professional than the previous issues, but his interests as a citizen dictate a need to recognize its existence. The issues are still being defined [32] and are far from being resolved. However, until the technical risk inputs are available, these arguments are still in the philosophical realm.

CONCLUSION

In view of the technical needs confronting the chemical professional, some closing thoughts are indicated.

First, there is a professional responsibility to address the discovery of chemical risks, and to facilitate dissemination of knowledge of the ways chemical sutstances may inflict harm on members of our society.

Secondly, professional ethics require that this issue be treated objectively and to the best of our ability. This treatment requires the development of new methodologies for the discovery, evaluation and approaches to the control of safety and health risks.

Finally, the organization of the skills to produce the needed methods, and the organization of the funding of the research constitute two specific challenges to everyone with any role in the production, distribution and use of chemicals in our society.

These challenges must become a part of our everyday thinking if we are to responsibly address the societal concerns for a harmonious future on this Spaceship Earth. The fragmented approach of the past, where a "that part of the problem is not my responsibility" attitude prevails, is what has led us to present levels of disenchantment with chemical professionals in our society. As responsible citizens, we must adopt a broader view point.

And soon.

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