Benefit/Risk Assessment Today

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ABSTRACT

A systematic approach to benefit/risk assessment is presented which recognizes (a) the potentially broad exposure of humans and the environment to soap and detergent materials, (b) current regulatory requirements, and (c) the desirability for making these assessments at various stages of product development to minimize both unnecessary testing expense and the likelihood of an unacceptable risk in a product ready for market.

Each week, on the average, a homemaker in the U.S. does 8 loads of laundry, washes dishes 14 times, bathes herself 5 times, washes her hands an additional 45 times, her face 17 times, and performs 60 other household chores which involve soap and detergent products; such as cleaning windows, walls, floors, carpets, furniture, sinks, counters, etc. In doing this, she uses over three pounds of soap and detergent chemicals to which she and her family are exposed in a variety of ways. Much of the total product used eventually goes to the household sewer system and on into public or private sewage treatment facilities.

Although the frequency of these tasks and product usages or concentrations vary from country to country, exposures broadly of people and the environment to the chemicals in our industry's products are among the highest. It is not unexpected then that the soap and detergent industry has for many years, even before laws and regulations governing safety of products existed anywhere, made risk assessments when considering new product formulas.

Today we have the potential for even better benefit/risk assessments. More sophisticated analytical techniques permit determination of the detailed compositions of our materials and detection of traces of them and their residues in the environment. And more predictive toxicological and environmental testing techniques continue to be developed.

Risk assessments on new chemicals and on new applications of existing ones are now required by law in some countries. This is the case in the U.S. under the Toxic Substances Control Act. Thus, to wrap up this session on Health, Safety, and the Environment, I will outline an approach to safety testing and hazard assessment that is applicable to the full spectrum of types of materials that our industry considers for use. I will indicate how hazard assessment enables risks to man and the environment to be weighed relative to the benefits to be derived. Also, I will show how this assessment can be phased into the product development program to minimize unnecessary expenditures for testing on unsuccessful projects and to maximize the probability that a potential new product will not have unacceptable risks.

A few terms need to be defined, and the relations among them discussed. These include toxicity, hazard, safety, risks, and benefits.

Toxicity is the capacity of a substance to cause injury. It is an inherent, unalterable property of the substance itself.

Toxic effects, as determined in the laboratory, cannot be readily extrapolated to hazard to man. Unless man potentially can be exposed at levels that produce toxic effects, there can be no hazard. Thus, hazard is a function of toxicity and exposure. Normally, hazard will increase for higher exposure or for higher toxicity, but it is not necessarily proportional to either. In fact, more often than not, both factors show discontinuities, levels below which there are no significant toxic effects.

There is no common relationship between toxicity, as determined in the laboratory, and toxicity to man. Thus, extrapolation to man is often made using a safety factor. This method of expressing potential hazard compares man's potential exposure level to the maximum no-effect level in the laboratory toxicity test.

Risk goes one step beyond hazard. It measures the likelihood that hazardous exposures will actually occur, to how many individuals, and how often. To do this, a sound basis must be developed for projecting the frequency of different levels of exposure.

If risk is quite low, then a product is generally considered to be safe. Safety, therefore, is the converse or reciprocal function of risk. Recognize, however, that "zero risk," or complete safety, does not exist with any material.

Before getting into a discussion of benefit/risk assessment, benefit needs to be defined. Benefit to whom? Benefit to the consumer can be as improved performance, more convenience, lower cost, more acceptable aesthetics, improved safety for people, machines, or fabrics, etc. Benefit can also be to the company producing the product in terms of lower cost, higher volume resulting from better consumer acceptance, higher profit, or even lower possibility of potential regulatory action, and/or adverse public relations. Also, benefit can be to society in terms of better health and sanitation, lower impact on the environment, etc.

With such a broad spectrum of types of benefits and risks, let's consider an example to see how they fit into a benefit/risk assessment to reach a decision on a new ingredient or a new product. Assume that we plan to modify the formula of an existing laundry detergent, through the use of a new ingredient, to improve consumer benefit. This change might involve a new surfactant, a change in the builder system, or in other vital formula ingredients you heard about yesterday.

Before the change, our product is well established in the market, its benefits are perceived by a significant share of consumers, and its safety is well accepted, having been proven in the laboratory and in the marketplace. There is little doubt that the true benefit/risk balance is favorable.

Because the units of measure are different, the benefit/risk assessment on our new formula can be made with more confidence by extrapolation from that of the current product formula. As we look more closely at the benefits of the current formula, we see that the principal benefit is societal and is common to all laundry soap and detergent products. It is the tremendous contribution to general health and sanitation of cleaning and laundering processes that is recognized and accepted broadly.

Because our product is a synthetic detergent, the advent of which permitted the development of the automatic washer, another prime benefit is the convenience it pro-

vides. This benefit, too, is somewhat societal in today's social environment that demands convenience items.

Our current product has a number of other performance benefits, recognized and appreciated to varying degrees by various consumers. The significance of these will have been measured through performance testing and market research during the earlier development of the product and from its acceptance in the marketplace.

Benefits to the company are not shown separately in our balance because they are in great part a function of the benefits perceived by consumers and are, therefore, already being weighed in our balance.

Because the societal benefits of detergents are so large relative to the added consumer benefits of formula variations, any improvement in consumer benefits from our new formula will have relatively little influence on the total benefits. Thus, any potential risk added by a product change, which is even perceived to be at all serious – such as an adverse environmental effect – could readily upset the favorable balance.

Looking closer at the risk side of the balance on our current laundry detergent formula, we see a number of low order human and environmental safety risks. Before feeling comfortable that the risks are being weighed properly and can be used as a base for comparison, we need to decide whether the risk assessments are valid by today's standards and evaluation methods. If we have reviewed our safety support at regular intervals to assure its continuing validity, we will feel comfortable in using the existing benefit/risk balance as a stepping stone to that for the new formula.

Let's look now at the process to be used for developing benefit and risk information for the new formula.

Benefits for the new ingredient, and the new formula incorporating it, are established in the product development program – first as judged from laboratory measurements of the chemical's properties, then by small scale, followed by larger scale, laboratory testing of product, and finally by various stages and scales of market research. Ultimately, trial markets provide the final proof of benefit in a competitive environment before the decision for broad-scale expansion is considered. Stepwise, a solid case is built for the magnitude of the consumer benefit(s) provided by this ingredient.

Throughout the course of this product development, potential risks are also being assessed in parallel. Since the new ingredient potentially could present new risks, the risks must be identified, weighed for relative importance, and a determination made as to whether the risks can be controlled, before a sound business decision can be made on the new formula.

Safety testing for risk assessment, programmed in parallel with product development, affords three advantages. First, it provides early the safety support for the individuals involved in the development. Second, it can identify early the areas of potential consumer, environmental, or business risk. And third, if a serious safety concern is found, the project can be redirected early, just as it would if the benefits being sought were not forthcoming. This can save research and development time and dollars on unjustified project directions.

Looking at this process in some detail, it can be seen that for each go/no-go decision point along the path of the product development as shown by the star in Figure 1, potential human and environmental exposure information will have been developed for the next phase, appropriate safety testing will have been conducted to assess the potential hazards associated with those exposures, and the benefits will have been better assessed to help in the decision.

Whenever the toxicity, or environmental testing, indicates a potential concern about the ultimate broad-scale usage of the product, a business risk decision must be made

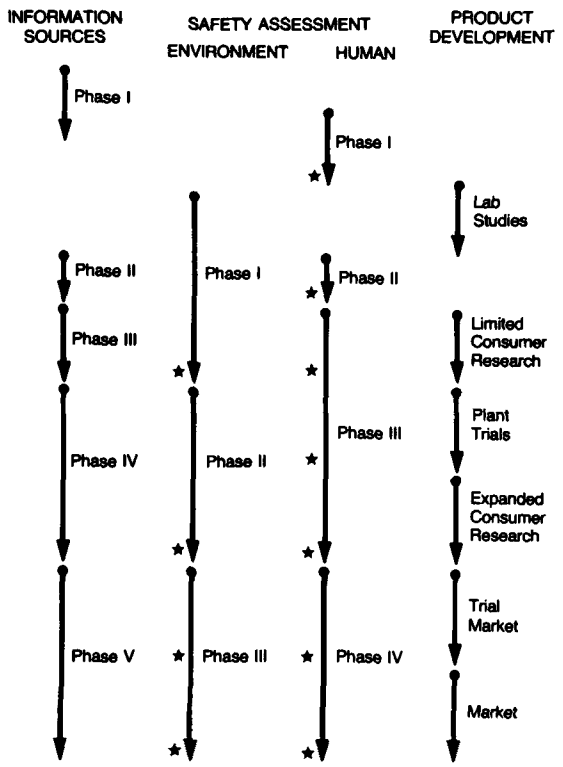

FIG. 1. Steps of human and environmental safety testing and of exposure determinations that are conducted in parallel with the product development steps.

around that concern. Those skilled in the particular toxicological or environmental area associated with the concern make the risk assessment. Management can then reach a decision regarding continuation of the development, taking into account the risk assessment and the potential benefits of the new development.

Let us return now to the benefit/risk assessment on our new formula involving a new ingredient. In general, new risks evaluated only on the basis of laboratory safety tests should be considered to weigh more heavily, until confirming safe experience under actual use conditions over extended periods is obtained. Until then, continuing consideration is given to which factors could cause the risks to grow – what concerns might be raised. This vigilance is essential because even concerns about a perceived risk could lead to regulatory action and adverse publicity for the product and the company. Sometimes a perceived safety risk can be more difficult to assess than a real one, and can be a real business risk.

Even the best risk assessment can change with time. New information can develop about the safety of a material. For this reason, environmental monitoring, plant worker and consumer epidemiological data, and periodic review of the safety support, gauged against current analytical methods, safety testing techniques, and societal concerns and standards, can be useful in updating the assessment of potential risks associated with a chemical. This will permit either a more solid base of support to be established for the material or will indicate that the support is eroding and that action may need to be taken either to strengthen the support or to curtail use of the chemical as appropriate.

A proposed thought process that one can go through to make the risk assessments for potential human hazards is charted in the next several figures. Although some of the questions are inspired by the U.S. Toxic Substances Control Act, they are worthwhile considerations for risk assessments in all countries. If, in answering these questions, we conclude we have a new chemical, a new use for an old

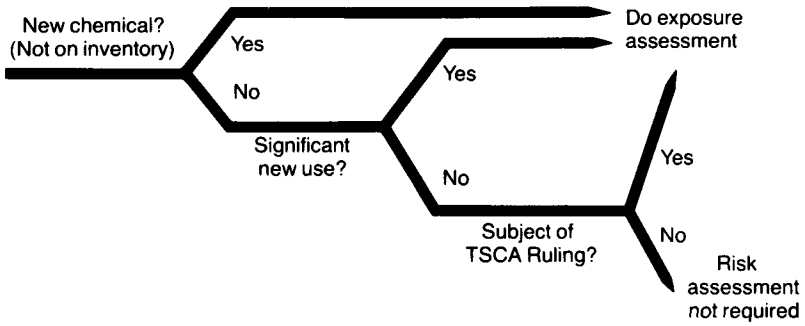

FIG. 2. Decision-tree type chart with decisions to be made on whether the chemical is new, whether it is a new use, and whether it is on a positive list.

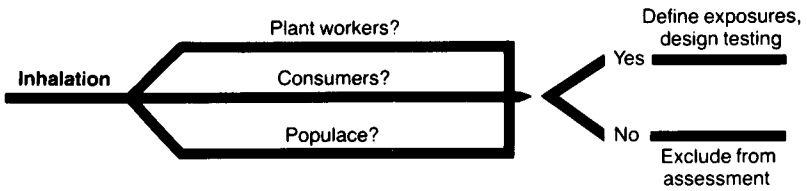

FIG. 3. Decision tree continued to determine who might be exposed to the chemical, via what routes, and at what levels.

chemical, or as a chemical not already on the TSCA Inventory List of old chemicals, then a risk assessment or analysis must be developed (Fig. 2) for submission to the Environmental Protection Agency. Although significant new use is defined by regulation in the U.S., the best general definition of new use is one where there is likely to be a significant increase in exposure level or a new route of exposure to man or the environment.

Consideration must be given to all groups of individuals who potentially might be exposed to the material under consideration (Fig. 3). Certainly in the case of soaps and detergent materials, laboratory and plant workers and consumers will be exposed. The population at large might be exposed if there is recycle from the environment in food, drinking water, or the atmosphere. One might also add small children as a separate group for accidental exposure.

Development of a flow chart (Fig. 4) to follow the material balance of a chemical to its ultimate fate can be useful to be certain that all possible human and environmental exposures are considered. I will not review this in detail, but it should cover manufacturing plant effluents, sewage treatment by-products, recycle through the aquatic food chain, etc. Detailed understanding of the physical and chemical properties of the new chemical, coupled with an understanding of sewage treatment and other environmental processes, permits a reasonably accurate approximation of the material balance, which can be verified and upgraded during the testing program.

Similarly, an intensive review of possible exposures in the home should be made. It should consider five different categories of reasons for exposures – intended uses, other known or probable uses, misuses, accidents, abuses. Much can be learned about the various ways products are handled in the home through market research. Development of sufficient understanding in this area, to be able to anticipate the exposures of a new product, is needed for the hazard assessment process.

The toxicological testing program is established to address each route of exposure. That testing needed to assess the potential hazards of the next product development phase is timed to have results for decision before that phase is started (Fig. 5).

How far the testing is carried in each area of exposure is primarily a function of the duration of exposure. Effects from a one-time or quite infrequent exposure might well be satisfied by acute testing; whereas repeated exposures over extended periods can dictate the need for longer term tests. When a test raises questions beyond that for which it was intended to answer, additional testing may be appropriate to answer the new questions. This means that there can be no standard testing program for all materials. Each must be tailored to the chemical, to its potential exposures, and to any legitimate questions or concerns raised about them.

Using the toxicological and exposure information, potential hazard and risk are assessed. If any risk appears to be substantial, steps are taken to minimize or avoid the exposure, as appropriate, or the application under consideration is dropped. With potential for repeated exposures over a significant period of time, appropriate screening tests for chronic effects are conducted and evaluated (Fig. 6).

Chronic tests (Fig. 7) are appropriate follow-up for potential adverse effects seen in the chronic screen. There

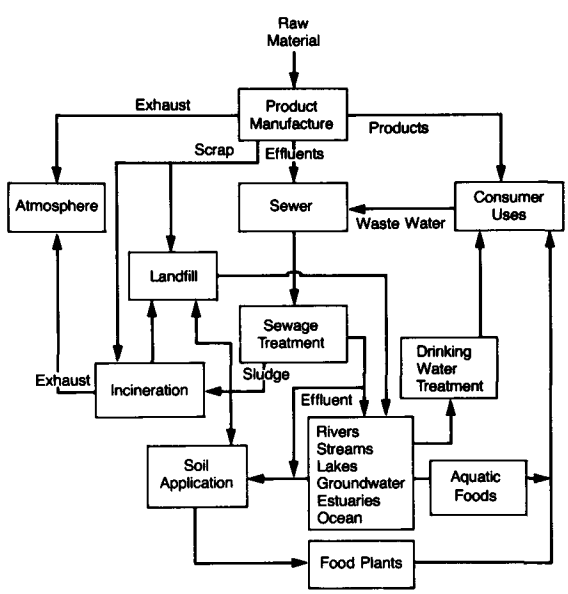

FIG. 4. Flow chart of detergent chemical from manufacture to its ultimate fate in the environment.

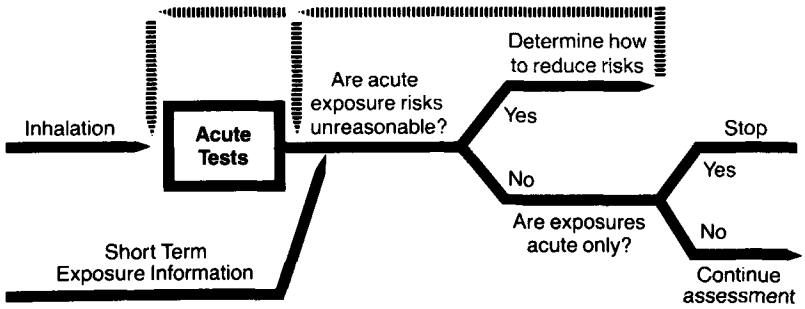

FIG. 5. Continuation of decision tree chart from Figures 2 and 3 to consider what human safety testing is appropriate.

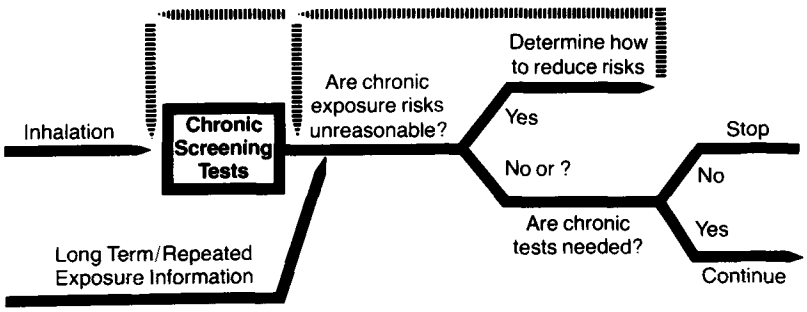

FIG. 6. Continuation of Figure 5 through chronic screening tests.

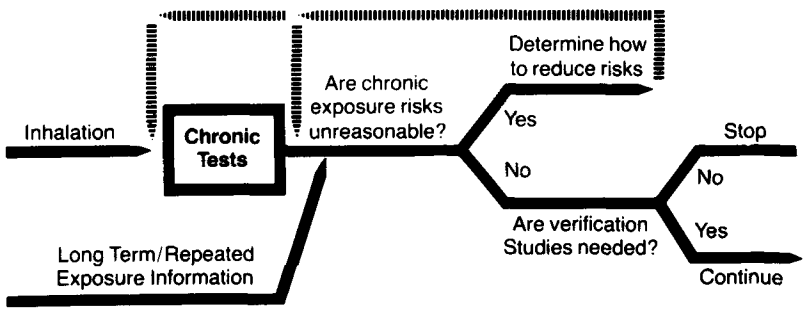

FIG. 7. Continuation of Figure 6 through chronic tests.

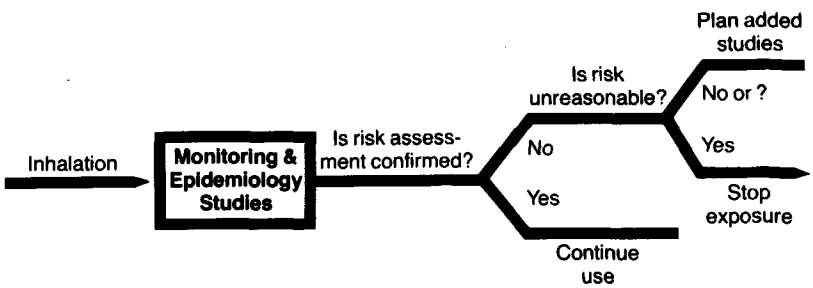

FIG. 8. Continuation of Figure 7 through monitoring, and consumer and plant epidemiology studies.

can be no hard and fast rules about how far the testing goes. Expert judgment must be used, based on needs of the individual case and the effects that are observed in the tests. And, at the end of each test or each phase of testing, a risk assessment is made.

Certainly any projections of potential human health effects from laboratory tests can be verified in many situations by appropriate epidemiological studies on plant and/or consumer populations after the chemical is in use, with risk assessments being made periodically on results of such studies (Fig. 8).

Time will not permit a review of the corresponding thought process for assessing potential environmental hazards. The types, levels, and duration of potential environmental exposures will determine the types of testing needed for risk assessment.

Before concluding I have a few final brief comments about risk assessment.

Normally, a toxic effect seen in a laboratory test should never in itself be the basis for decision about a chemical or a product, whether that decision is for safety, regulatory, or business purposes. Toxicity alone, as indicated early in the discussion, tells little about hazard or risk without exposure information being considered.

Toxicity test results often are more readily interpreted if the effects of new materials can be compared against standards, positive and negative controls, on which there is considerable human experience.

Tracking down the reasons for an adverse safety effect early in the research and development process can often lead to a modified molecule or the elimination of impurities that will avoid the undesirable toxicological or environmental property while maintaining those providing the benefits in the product.

Positive steps can be taken to reduce the high frequency of accidental exposure to our products which can add significantly to the potential risk.

A good example is the pamphlet "Home Safe Home," developed by the U.S. Soap and Detergent Association. Over three million copies of it have been distributed to parents of small children.

One last word about risk assessment. Consider in advance appropriate actions to be taken for the various alternative answers that might result from a testing program. Develop answers in areas of high apparent potential concern as early as possible to avoid surprises late in the product development process. The key points I have made are:

1. Chemicals in detergent products become somewhat ubiquitous and will, therefore, require careful safety screening.
2. Little recognition will be given by society to the added consumer benefits of product formula changes, which means that no additional risk of any significance will be acceptable.
3. Risk assessment must be based on hazard, not toxicity.
4. A decision-tree type approach provides an orderly thought process for assessing risk.
5. Safety assessment done in step with product development reduces the risk of throw-away money on unsafe developments, and can aid in directing the development to a safe efficacious answer.

Those who know the soap and detergent industry will recognize and applaud the efforts of the industry aimed at the development of products with minimal risk for health and the environment. By continuing to upgrade the benefit/risk assessments through approaches as have been outlined here, our industry can continue to merit and maintain this recognition for its commitment to safety.