SAFETY EVALUATION UNDER THE TOXIC SUBSTANCES CONTROL ACT

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I would like to thank the Organizing Committee and especially Dr. Tati and Professor Ikeda for their kind invitation to speak at this symposium. Judging from the list of speakers and topics, this meeting will provide a valuable opportunity to exchange the knowledge and experience gained from assessing the risks posed by industrial chemicals and further the mutual understanding among countries who are either conducting or plan to conduct chemical risk assessments.

Today I would like to present an overview of chemical assessment activities under the Toxic Substances Control Act (TSCA). In particular I will be focusing on our new and existing chemical control programs. First, however, I would like to provide some background for those of you who are not familiar with the overall structure and goals of the Toxic Substances Control Act.

BACKGROUND

The Toxic Substances Control Act passed in 1976 charged EPA with protecting human health and the environment from unreasonable risks of injury from toxic chemicals. This Act was passed in response to a growing awareness that humans and the environment are being exposed each year to a large number of chemical substances, some of which may pose an unreasonable risk, and for which sufficient data do not exist to evaluate that risk.

TSCA is only one of several pieces of legislation in the U.S. that addresses toxic chemicals. Although several of these predate TSCA, experience had shown that regulatory gaps existed in these other authorities. For example, prior to the passage of TSCA the burden for testing industrial chemicals of concern had to be borne by the regulatory authority. Now, under TSCA, those responsible for producing or processing the chemical are also responsible for assuring that the chemical is safe.

TSCA is a risk/benefit statute, i.e., EPA is charged with the task of carefully balancing the potential health and environmental impacts of chemicals against the benefits they bring to society. Risk assessment, as carried out in the Office of Toxic
Substances, is a multidisciplinary activity based on the concept that risk is a function of both hazard\(^1\) and exposure.

Since TSCA is a risk/benefit statute and encompasses the entire life-cycle of the chemical, it provides EPA with a broad range of authorities. The Act gives EPA authority to gather information from manufacturers, importers, and processors. This information may either be exposure related data (e.g. production volume, number of workers exposed, quantities released to the environment and the extent of such exposure) or it may be the results of toxicity tests conducted by industry as a normal part of business. The Act also provides EPA with the authority to require companies to test chemicals where necessary to obtain data needed to evaluate risk. Again the data may be either exposure related (e.g. environmental partitioning, persistence, and bioavailability) or related to human and non-human toxicity. In addition the Act requires manufacturers and importers to notify EPA 90 days prior to introduction of a new chemical into commerce. This provides EPA with an opportunity to review and evaluate information with respect to a substance to determine if additional testing is necessary or if exposure should be controlled.

**EVALUATION ACTIVITIES**

Having touched on the general background and uniqueness of TSCA, I would like now to focus on two major sections of the Act which involve chemical testing and our experience in conducting chemical assessments under these provisions.

*Section 4 :*

Under this section of TSCA, EPA has authority to require manufacturers or processors to test chemicals that are currently in commercial production. To require testing, EPA must find that the chemical may present an unreasonable risk, that there are insufficient data available with which to reasonably determine or predict the effects of the chemical, and that testing is necessary to generate such data. Alternatively, EPA must find that there may be substantial production and exposure to humans or the environment, in addition to insufficient data and the need for testing.

Under section 4 an Interagency Testing Committee (ITC) was established to recommend chemicals to EPA for priority testing consideration. In addition to recommending, the ITC can “designate” chemicals. EPA must respond to the designation within 12 months by starting rule making under section 4 or giving reasons for not so doing. The total number of designated chemicals and mixtures under consideration by EPA may not, at any time, exceed 50. The Committee is required to make any revisions that it considers necessary to this section 4 priority list at least every six months.

To carry out its responsibilities, the ITC performs two principal types of activities

\(^1\): Hazard refers to inherent properties such as toxicity, flammability, and explosibility.
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(1) chemical scoring or selection exercises to screen large numbers of chemicals and identify candidates for detailed review by the Committee and (2) in-depth review of the "candidates" to select chemicals for addition to the priority list, i.e., the list to which EPA must give priority consideration in the promulgation of test rules. At least every six months, the ITC submits a report to EPA revising the list of priority chemicals.

Of particular importance has been the experience with the lack of exposure information on chemicals under review by the Committee. This lack of information has been a significant factor in the decreasing effectiveness of the scoring exercise as those chemicals obviously in need of testing have been identified. For example, the fourth and fifth scoring exercises, which started out with over 5000 chemicals under consideration, have only produced 15 additions to the ITC priority list.

Several steps are being taken to help alleviate this problem. OTS has been active in developing predictive methodologies covering environmental, consumer, and occupational exposure (EPAa-e, 1985) and these are being computerized to support the ITC exposure scoring. The ITC uses exposure scoring to eliminate chemicals with low exposure potential prior to the biological effects scoring step. The objective of exposure scoring is to eliminate, on the basis of low exposure potential, approximately 2/3 of the chemicals. The basic exposure scoring methodology used by the ITC has been to assign scores to a number of exposure factors (e.g., number of workers exposed, and frequency of exposure). The score for these factors are then weighted and combined into several exposure indices that serve as measures of the different kinds of exposure of interest (e.g., occupational, consumer, and environmental exposure). The chemicals are then ranked according to the exposure indices for each exposure pathway and the chemicals with the highest exposure rankings are selected for biological effects scoring. In an effort to improve the exposure scoring effectiveness, OTS is developing a personal computer based exposure scoring system which will incorporate information on frequency, duration, intensity, and populations to arrive at an exposure score and a population score which are then combined in an overall score. The level of effort to score a chemical for exposure is intended to be approximately 2-person-hours.

OTS is also beginning to make use of its human monitoring surveys to identify substances of potential concern. Data from the National Human Adipose Tissue Survey (NHATS) was recently used to produce the first human exposure-based chemical list for OTS review and plans are being finalized to establish a national blood network. The presence of chemicals in human tissue and fluids provides evidence of exposure and can minimize the problem of "false positives" when surrogate measures (e.g., production volume) are utilized.

The need for section 4 testing authority and the magnitude of the problem are illustrated by a recent report by the National Academy of Sciences (NRC, 1984) where a study group was assembled to characterize the toxicity testing needs for substances
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to which there is known or anticipated human exposure.

The NAS committee began with a selected universe of 53,500 substances including pesticides, prescription and non-prescription drugs, food additives, cosmetic ingredients, and chemicals in commerce. From this list a random sample of 675 substances was selected and from these a subsample of 100 was selected for detailed analysis. The committee estimated based on this sample that between 25-82% of the original 53,500 chemicals had no toxicity information, on the basis of what the panel was able to discover from published and available unpublished data. It was evident from the results that the amount of testing information available on any category of substance is related to the regulatory history of that category. The panel concluded that only about 20% of the industrial chemicals have a prescribed minimal toxicity data set as compared to 39% for drugs. In the data set testing for acute, subchronic, and mutagenic effects was present more frequently than testing for chronic or reproductive/developmental effects. Although the analysis was limited by the availability of studies and did not include those contained in confidential files, it does point out the paucity of data on chemicals currently in commerce.

Section 5

Section 5 is the other section of TSCA which involves chemical testing issues. Under section 5 EPA reviews new chemicals prior to manufacture or import into the U.S. New chemicals are defined as those that are not listed on the TSCA Chemical Substances Inventory. This inventory is EPA’s comprehensive list of chemical substances in commerce. Under section 5, EPA reviews and evaluates the potential risk posed by the substance and makes a determination whether controls are appropriate, whether additional data are needed, or whether production and/or use should be prohibited.

TSCA does not require that submitters conduct testing prior to submission of the notice, however, any health or environmental test data which are available to them must be submitted at the time of submission. Since the establishment of TSCA, EPA has received an increasing number of notices to review. In FY 1985, EPA received 1,478 notices, bringing the total received since the inception of the program to 5,679 (EPA, 1985).

Presently, EPA receives test data on less than 50% of the submissions. When provided, the data most commonly consist of acute lethality (about 40% of the time) and local irritation studies (about 38% of the time). Environmental fate and effects data are submitted only about 10% of the time.

When concerns arise during the review of a new chemical, either because of toxicity or exposure, EPA asks for testing before production begins if the testing can be done quickly and without unreasonable expense. EPA also asks for preproduction testing if the potential risk cannot be adequately controlled pending availability of the data. However, if the potential risk can be controlled (e.g., by restricting use of the
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chemical, or by requiring protective equipment for workers handling the chemical), EPA issues "delayed trigger" testing orders. Such orders require submission of test data only when total production of the chemical reaches a predetermined volume.

Because of this lack of data on the submitted substance, EPA has had to develop and rely on a variety of predictive methods for both exposure and hazard assessment. This involves using data on structurally analogous substances, the professional judgements of experts, and the use of quantitative prediction methods where available.

In the exposure assessment area, OTS has developed several unique tools for use in the presence of limited data. These include a manual for estimating occupational exposure based on limited physical/chemical properties and simplified process and use descriptions, an interactive computer system (GEMS) for environmental fate and exposure modeling and physical/chemical property estimation, and a personal computer system (PC-EASY) which contains modules dealing with consumer, environmental, and drinking water exposure.

As mentioned earlier, these predictive exposure assessment tools, originally developed for new chemical assessments, are now being employed in the early screening and priority setting for existing chemicals. Also as a result of our participation in various new and existing chemical activities of the OECD, many of these tools have been made available to other countries for the purpose of developing harmonized approaches to the review, evaluation, and control of toxic substances.

CONCLUSION

Again I would like to thank the members of the Organizing Committee for the opportunity to participate in this symposium. Certainly, chemical risk assessment is a rapidly developing science where necessity has truly been the mother of invention and it can only benefit from the kind of exchange of ideas that will take place at this meeting.

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