T R E N D S • I N

Risk & Remediation

Spring 2000

Overview: Product Stewardship

Product stewardship programs use the underlying tenets of risk characterization and risk management to direct the responsible development and application of chemicals in commerce.

Product stewardship is the process whereby a company involved in the manufacture of a product (*e.g.*, a particular chemical) takes responsibility for the product's possible health and environmental impacts throughout its life cycle. Impacts can potentially occur at several stages in the history of a product. For example, impacts could occur through environmental releases or occupational exposures during manufacture of the chemical; releases and exposures may occur when the chemical is used in the manufacture of another product; or, exposures may occur with consumer use of the manufactured product, or with disposal of the final product (see Figure 1). Product stewardship is, in general, not regulatory-driven. Nonetheless, product stewardship places weight on the manufacturer to consider possible adverse impacts associated with production, use, and disposal of a product. Such considerations can, in turn, affect corporate decisions on a range of issues from product design and market selection, to decisions on whether or not to continue manufacturing a particular product.

Perhaps most importantly, the risk management aspects of product stewardship must ensure that the product's ultimate uses are protective of the end users and the environment.

The analytical tools used with product stewardship overlap, but are distinguished from, Life Cycle Analysis (LCA). Both product stewardship and LCA analyze the health and environmental burdens associated with the manufacture and use of a product; however, LCA also includes the associated resource depletion and energy impacts. LCA is frequently used to compare two or more processes or products (*e.g.*, electric cars *vs.* gasoline-powered cars, or disposable *vs.* cloth diapers) in terms of their overall health and environmental impacts.

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I N S I D E

Letter to our Readers

May 2000

Dear Colleague,

In this issue of *Trends*, we explore the concept of product risk. Society is becoming more aware that no consumer product is risk-free, and consumers themselves are impacting companies' decisions to more thoroughly understand the risks their products may pose throughout the product's life cycle. Here we examine product stewardship, product testing requirements, and consumer product risk assessment. This issue describes how progressive companies like Kodak and Exxon are using product stewardship programs to enhance product offerings.

Contributors to this issue include Dr. Barbara Beck, Gradient Principal and nationally recognized expert in toxicology and health risk assessment. Joining her are Dr. Lorenz Rhomberg, Principal Scientist and expert in quantitative risk assessment, and Dr. Teresa Bowers, Principal and expert in exposure modeling. We are pleased to welcome to this issue Dr. Hugh Campbell, Vice President of the Alliance for Chemical Awareness (ACA), a non-profit organization dedicated to a proper understanding of the risks of chemicals in commerce, and an Environmental Manager at DuPont. We thank him for his thoughts on product stewardship as a good business practice.

We hope this issue of *Trends* provides you with new insights on the role of and need for consumer product risk assessment.

Yours truly,

Neil Shifrin
President

Trends in Risk & Remediation is a publication of Gradient Corporation. As a national leader in risk assessment and negotiation of risk-based remediation, Gradient offers this publication free of charge to interested groups and individuals. If you have a colleague who would benefit from this publication – or if you have comments or suggestions – please contact Susan Hew at (617) 395-5000 or email us at *trends@gradientcorp.com.*

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Overview: Product Stewardship

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The two components of product stewardship are evaluation and management, which are essentially risk characterization and risk management activities. The evaluation (risk characterization) phase is usually broader in scope than a typical risk characterization that would focus on a single chemical or class of chemicals released into the environment during a single process, *e.g.*, manufacture or disposal. But the evaluation phase in product stewardship still involves the two fundamental risk characterization steps: hazard analysis and exposure assessment. All hazards associated with the product are considered, including toxicity to humans or ecological receptors, physical hazards such as flammability, and contribution to pollution, such as ground level ozone formation or stratospheric ozone depletion. In the case of new chemicals under development, new hazard assessment tools may be required. For example, to address the challenges of understanding the toxicity of new materials, Kodak has worked with the EPA to implement a test method to evaluate the chemical hazard of photographic chemicals based on molecular structure.

The exposure assessment component of product stewardship is similarly broad, and involves tracking the product from manufacture, through use, to eventual disposal. The exposure assessment describes the populations that may be exposed, under what conditions, through what environmental media, and the potential magnitude of the exposure, and considers not only permitted uses, but also plausible misuses and accidents that could lead to exposures. Combining information derived from the hazard analysis and the exposure assessment forms the basis of the product risk characterization. Oftentimes, this risk characterization provides a basis for understanding where, in the life cycle of a product, there is the greatest potential for adverse impacts, as well as the nature and magnitude of those impacts. As such, risk characterization forms a basis for subsequent product risk management activities.

Risk management under product stewardship can encompass a broad array of management practices. First, effective risk management will include systems that accurately track hazards and exposures from a product throughout its history, and that can be updated as new information becomes available. Product risk management also entails informing and ensuring the protection of workers involved in the manufacture of the raw materials, intermediates, and final products. Perhaps most importantly, the risk management aspects of product stewardship must ensure that the product's ultimate uses are protective of the end users and the environment. This includes fostering proper downstream use and eventual disposal of the product.

In cases where there are continued concerns over potential risks from a given product, a company may decide to provide additional risk management support to the customer, to redesign the product, to modify its packaging, or to develop other ways to mitigate the risks. For example, Exxon worked with one of their customers, the offset printing industry, to encourage a switch from more volatile to less volatile hydrocarbons, thus reducing emissions of these materials. In some cases, responsible product stewardship may involve a company deciding not to sell the product to certain customers or in certain markets, or to discontinue manufacturing altogether.

Product stewardship represents an important, primarily non-regulatory, mechanism for minimizing the potential impacts of a product. As described in the Chemical Manufacturers Association Product Stewardship Code of Management Practices, the aim for the chemical industry is to "make health, safety and environmental protection an integral part of designing, manufacturing, marketing, distribution, using, recycling, and disposing of our products." The fundamental elements of risk science underpin this worthy goal.

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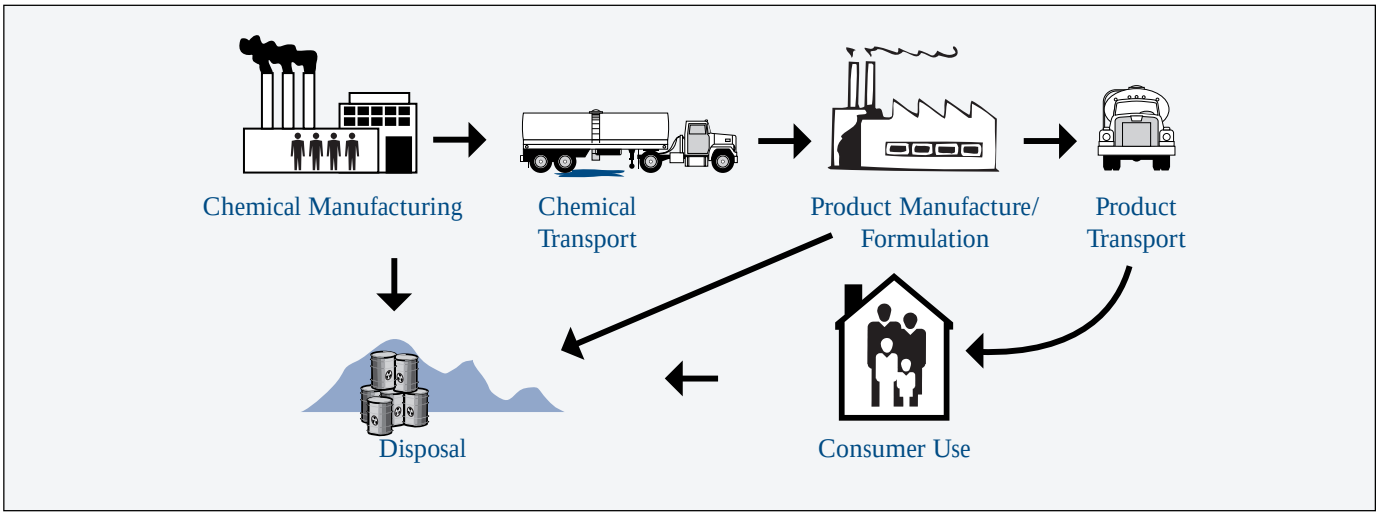

Figure 1. Product stewardship evaluates the potential for release and exposure throughout a product's life cycle.

Structured Approach is Best for Product and Chemical Testing

Recent efforts to screen a vast number of chemicals for health effects point to the limitations of these testing approaches.

The prosperity of our modern society has been brought about by the development of many new and more efficient technologies using an array of novel materials. Modern life involves living side-by-side with a wide variety of chemical substances, both naturally-occurring and man-made. Some of these, by virtue of their exposure levels and their ability to interact with living systems, present the potential to affect human and environmental health.

It is important to ensure that these are wise uses of resources, and that the results provide the most useful information toward achieving the goal of public health protection.

Toxicity testing is necessary to identify these potential causes of concern, to develop knowledge of the adverse effects compounds may have, and to determine the doses at which they may occur. Such testing lies at the base of product stewardship programs in industry and supports an array of government regulatory programs aimed at ensuring the protection of workers, the public, and the environment.

Increasingly, emerging issues in environmental health are being met with comprehensive screening programs aimed at subjecting a broad spectrum of compounds to specialized tests designed to identify the "bad actors" with respect to a particular toxic endpoint. In recent years, these screening programs have arisen on several fronts. Under the High Production Volume Challenge, industry is voluntarily subjecting approximately 2,800 compounds to a battery of standardized toxicity tests. Similarly, a screening program mandated by federal law will examine more than 10,000 compounds in an attempt to identify potentially hormonally active agents. Most recently, programs are being designed to screen for chemicals that may affect children in particular.

Information on a material's toxicity always has value, but the large effort involved in such programs, in terms of expenditure of public and private dollars and the use of experimental animals, dictates that such programs be undertaken thoughtfully. It is important to ensure that these are wise uses of resources, and that the results provide the most useful information toward achieving the goal of public health protection.

There are some pitfalls to be avoided. First, when a health concern is new, such as with endocrine disruption, there may be little in the way of established, validated methodologies to use in screening tests. Implementing immature test methods runs the risk of producing faulty, ultimately misleading information (Rhomberg, 1997). Even well-established test methods do not give definitive information. When many otherwise unsuspected compounds are put through a screen, there will be few true positives to find, and a high proportion, perhaps a large majority, of "positives" will be false. Even if extensive follow-up investigation eventually establishes that initial results are misleading, there will have already been considerable efforts wasted and unwarranted fears engendered.

Secondly, the screening tests typically provide little information about how high the levels of exposure must be before the interactions they identify actually lead to harmful effects in humans. Among the many chemical compounds in our modern world, only a relatively few pose much opportunity for other than trace human exposures. Most non-food consumer formulations maintain their integrity during use, and do not substantially release their constituents. A screening program that does not consider exposure puts unnecessary effort into examining chemicals that are unlikely to pose health threats, since people do not encounter them in significant quantities.

Screening tests should be reserved for their proper purpose, namely to bring those particular chemical exposures that warrant deeper investigation to our attention. It is important to follow up on positive screening results, but such findings should not be misconstrued as definitive indications of hazard. Proper hazard identification entails integration of screening results with more definitive follow-up studies (Rhomberg, 1998).

A rigorous program of toxicological testing is key to an

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By The Way...

Companies respond to consumer concerns. In February, Frito-Lay announced that it was asking farmers who supply the company with corn not to use genetically modified crops.

Source: "Genes With Your Salsa? Public Pushes for Labeling of Genetically Modified Foods," by Robin Eisner, ABCNEWS.com, 3/8/00. http://abcnews.go.com/sections/living/dailynews/gmolabel000308.htm.

Measuring and Modeling Household Exposures

Understanding household exposures draws on basic elements of exposure assessment.

Assessment of risk arising from consumer products in the home has the appearance of being the most difficult aspect of product stewardship. However, an examination of requirements for this assessment suggests ways in which to proceed. First, it is clear that a product containing a toxic chemical does not necessarily pose risk to the consumer, unless there is a pathway by which exposure occurs. So, the real challenge in consumer product risk assessment lies in understanding the ways in which an individual can become exposed, either by inhalation or direct contact, including dermal and ingestion exposures.

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Household exposures are specific to the product, and products can include such diverse articles as carpeting, insulation, paint, aerosol cans, soaps, drain decloggers, degreasers, *etc.* (see Figure 2). The same chemical may be found in a variety of products, to which exposure may be occurring *via* different pathways. For example, coal tars are used in products as diverse as dandruff shampoos and driveway sealants. However, this apparently complicated situation can be unraveled for assessment purposes by thinking in standard risk assessment terms of the mass, volume, or concentration of a chemical, and the frequency of contact.

Pesticide exposure assessment currently operates at the forefront of consumer product risk assessment in the home. This is largely a consequence of the requirements of the 1996 Food Quality Protection Act and its predecessors to assess exposure to adults and children resulting from contact with pesticides over all exposure pathways, including diet. Pesticides can be encountered in numerous ways in the home, including outdoor applications to lawns and gardens, indoor applications to houseplants for insect control, and pet care including collars and sprays for fleas. Such a consideration of multiple products and pathways of exposure provides a framework for evaluating other chemicals that may be found in a variety of household products.

Assessing exposures requires knowledge of how individuals spend time in their home environments. One interesting study in this regard uses the Jazzercise® scenario, where the amount of pesticide residue on carpeting transferred to an adult performing a prescribed exercise routine on the carpeting was measured (Ross *et al.*, 1990). Another such experiment measured the amount of pesticide residue found on children's toys following

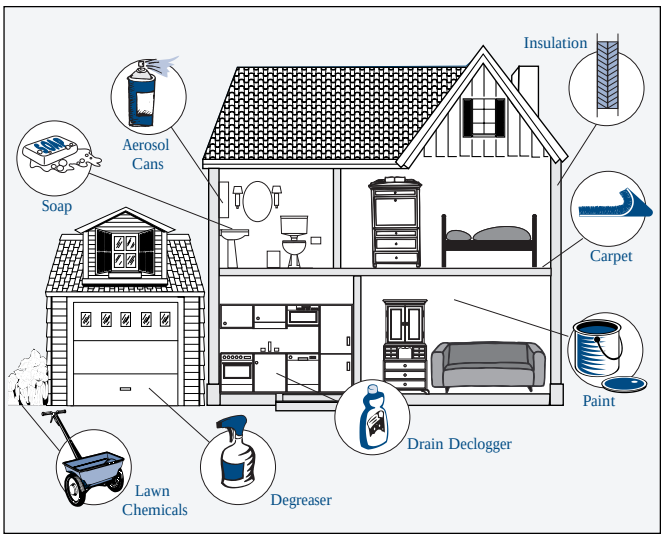

Figure 2. The opportunity for chemical exposure exists throughout the household environment.

indoor pesticide application (Gurunathan *et al.*, 1998). These experiments were aimed at understanding the dermal and ingestion exposure pathways, and can potentially provide a guide to assessing household exposures to other non-pesticide consumer products. Recent concerns over children's exposure to phthalates in pacifiers provide an indication of just how seriously some consumer-level exposures are being considered.

An interesting, but not unexpected, outcome of the work to characterize household exposures to pesticides is that modeling predictions do not always match biomonitoring results (ILSI, 1998). This observation serves as a reminder as scientists move forward in measuring exposures to consumer products to also develop methods of monitoring actual exposures as a ground-truth for developing models.

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Gurunathan, S., M. Robson, N. Freeman, B. Buckley, A. Roy, R. Meyer, J. Bukowski, and P.J. Lioy. 1998. Accumulation of chlorpyrifos on residential surfaces and toys accessible to children. *Environ. Health Perspect.* 106: 9-16.

International Life Sciences Institute (ILSI). 1998. Aggregate Exposure Assessment, Workshop Report.

Ross, J., T. Thongsinthusak, H.R. Fong, S. Margetich, and R. Krieger. 1990. Measuring potential dermal transfer of surface pesticide residue generated from indoor fogger use: An interim report. *Chemosphere* 20:349-360.

What's New at Gradient

Bureau of National Affairs Reports Views of Gradient Scientists

The *BNA Environment Reporter* (Vol. 31, No. 10) quotes Dr. Lorenz Rhomberg describing the value of the U.S. EPA's process for revising the risk characterization for trichloroethylene (TCE). In his interview, Dr. Rhomberg emphasizes that the EPA's decisions will have a better scientific basis when the biological mode of toxic action is considered. The same issue quotes Dr. Teresa Bowers from her presentation on behalf of the Association of Battery Recyclers and the Lead Industries Association at the U.S. EPA Science Advisory Board meeting on the EPA's residual risk assessment for the secondary lead smelter source category, where she described flaws in the modeling methodology.

Dr. A. Dallas Wait Joins Advisory Board

Gradient Principal Dr. A. Dallas Wait was recently invited to join the Scientific Advisory Board (SAB) for the International Conference on Contaminated Soils, Sediments, and Water.

Recent and Upcoming Presentations

Cambridge, MA. March 21, 2000. Neil S. Shifrin. "Innovation and Entrepreneurship," presentation at MIT's colloquium on The Future of Civil Engineering in the 21st Century.

Memphis, TN. March 24, 2000. A. Dallas Wait. "Environmental Forensic Chemistry and Quality Science in the Courtroom," presentation to the Memphis Bar Association.

Kings Island, OH. April 10-13, 2000. Barbara D. Beck. "Development of a Stochastic Physiologically-based Pharmacokinetic Model for Lead," presentation at the Toxicology and Risk Assessment Approaches for the 21st Century conference.

Nutley, NJ. May 3-4, 2000. Barbara D. Beck. Invited participant/speaker to The Fourth Annual Workshop on Evaluation of Uncertainty/Safety Factors in Health Risk Assessment.

Recent Publications

Rhomberg, L.R. 2000. Strategies to Protect the Health of Deployed U.S. Forces: Analytical Framework for Assessing Risks. Board on Environmental Studies and Toxicology, Commission on Life Sciences, National Research Council. National Academy Press, Washington, D.C.

Rhomberg, L.R. (ed.) 2000. Strategies to Protect the Health of Deployed U.S. Forces: Assessing Health Risk to Deployed U.S. Forces: Workshop Proceedings. Board on Environmental Studies and Toxicology, Commission on Life Sciences, National Research Council. National Academy Press, Washington, D.C.

Wait, A.D. 2000. Evolution of Organic Analytical Methods in Environmental Forensic Chemistry. *Journal of Environmental Forensics* 1:41-51.

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Structured Approach is Best for Product and Chemical Testing

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effective product stewardship program and to the protection of public health and the environment in today's technological world. The most effective testing program is one that targets its efforts so as to most reliably and efficiently discover those exposures to potentially toxic materials that need to be controlled and avoided. A rational approach considers existing information on compound toxicity and the potential for exposure to these materials under real-world applications. Using such an approach as the basis for the program's design will be more effective than blanket screening.

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Rhomberg, L. 1997. Beyond screening: problems and prospects for risk characterization of endocrine disruptors. *Regulatory Toxicology and Pharmacology* 26:74-79.

Rhomberg, L. 1998. Risk characterization for human health effects from potential environmental endocrine disruptors. In *Human Diet and Endocrine Modulation: Estrogenic and Androgenic Effects* (Eds: G.E. Dunaif, S.S. Olin, J.A. Scimeca, and J.A. Thomas). ILSI Press.

Guest Editorial: Product Stewardship is Good Business

The recent High Production Volume Chemical Testing Program could represent an opportunity to enhance a manufacturer's offering through demonstrated product stewardship programs.

Product stewardship is a business process for identifying the hazards and risks of a material throughout its product life cycle and then assessing if appropriate risk management systems are in place. For many years, product stewardship was viewed as an option – a nicety that a company could either choose to embrace or ignore, depending on the views of management.

More recently, however, responsible manufacturers are coming to recognize that a well-implemented product stewardship program can represent a competitive advantage. While it may not be intuitively obvious how this could be, consider for a moment the nature of a well-developed product stewardship program. In such a program, a supplier understands where the chemical is going in commerce, how it is used, and the risks associated with these uses. In the course of developing this understanding, a supplier gets to know the needs of every customer in the supply chain, right down to the final consumer. Thus, product stewardship ultimately enhances the quality of the supplier's offering by getting them closer to the customer, and driving an understanding of the needs of the customer back up the supply chain.

...responsible manufacturers are coming to recognize that a well-implemented product stewardship program can represent a competitive advantage.

Someone once said that there are no problems, only opportunities. Throughout the years, pressures exerted by regulatory programs and the court of public opinion have created numerous "opportunities" for manufacturing companies to improve the efficiency of their processes, enhance the quality of their products, and reduce the environmental impact of their operations. Perhaps the most recent such opportunity lies in the High Production Volume (HPV) Chemical Testing Program, which will require several thousand HPV chemicals to undergo a series of toxicity tests to determine potential health effects that might be associated with exposure to these compounds. Some members of the chemical and manufacturing industries are viewing the upcoming release of these data with considerable angst. The reality is that the release of these data, when interpreted in the context of exposure, represents an enormous opportunity for these industries. Just as a product stewardship program is driven by an understanding of the risks of a material in commerce, the HPV testing initiative will provide the hazard data necessary to make these types of risk judgments. This hazard information, when coupled with information on exposure, will provide the basis for a better understanding of the potential risks posed by these chemicals, and a chance to put any risks into their proper context.

Through the initiation of the voluntary HPV testing program, additional information will now be available to enhance product stewardship programs. With this supplemental information, the business benefit of a product stewardship program can be more fully realized. Manufacturers, distributors, processors, and retailers will be in a position to better understand the risks associated with their products, and consumers will have the necessary information to make informed decisions about the use of chemicals and the products that contain them.

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In the next issue:

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