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TRENDS
Risk Science & Application

Spring 2008

Compromised Products: An Overview

By Kim Reynolds Reid, B.A.

A rash of recent concerns over contaminated and adulterated products is driving manufacturers and regulators to take action.

Today's news reports regularly include headlines about recalls of compromised (chemically contaminated) products. The issue of compromised products is certainly not new. Some might remember the 1982 Tylenol© recall, when 31 million bottles were withdrawn from the market after a few were deliberately tampered with and filled with cyanide-laced capsules. In 1990, Perrier® recalled millions of bottles of water worldwide due to benzene contamination. Recently, the culprit has been lead in toys and children's products. In fact, since September 2007, over 85 products, mostly manufactured in China, have been recalled due to violation of the Consumer Product Safety Commission's (CPSC) lead paint regulation.

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Compromised products are either inadvertently contaminated with a chemical, *i.e.*, lead in painted toys or toy jewelry, or are "adulterated" by a chemical. Although the Food and Drug Administration (FDA) defines adulterated products specifically in the context of food, drugs, and cosmetics, here the definition includes any products that have been intentionally modified with a chemical, *i.e.*, anabolic steroids in dietary supplements, melamine in pet food, or diethylene glycol in counterfeit toothpaste.

Why do compromised products seem to be much more prevalent in today's marketplace? For one thing, we are living in a global economy so more products

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I N S I D E

Letter to our Readers

May 2008

Dear Colleague,

In this issue of *Trends,* we examine the timely topic of compromised products, whether unintentionally contaminated or purposefully adulterated. News reports of recalls stimulate our fears, while the extent of actual exposure that can, or has occurred, is rarely discussed – with some notable exceptions. Here, we survey analytical testing methodologies designed to assess exposure instead of concentration only, and we consider the aggressive environment in which communication of potential exposures must be conveyed.

Contributors to this issue include Ms. Kim Reid, a Gradient analytical chemist who is currently advising several clients on product testing needs, and Dr. Teresa Bowers and Dr. Peter Valberg, Gradient Principals with specialties in exposure analysis and risk communication. Joining them with our guest editorial is Mr. William J. Walsh, Esq., an attorney with the law firm of Pepper Hamilton, who shares his thoughts on how the regulatory landscape will change in response to the public's growing awareness of contaminated products.

We hope this issue of *Trends* will provide you new ways to think about exposure to contaminated products.

Yours truly,

Neil Shifrin, Ph.D.
President and Founder

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Compromised Products: An Overview

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are available to the consumer than ever before. And because a high demand exists for cheaper products, many companies are outsourcing production to non-U.S. countries to reduce labor and manufacturing costs. China, for example, manufactures approximately 80% of the toys sold in the U.S. Thus, as the number of products manufactured overseas and exported to the U.S. increases, it becomes more difficult for companies to perform adequate oversight and testing of their products throughout the supply chain. Several companies have been surprised to learn that the paint used on their toy cars contained lead, or that their flashing eyeball toys contained kerosene instead of a non-toxic liquid.

Given the many recent toy recalls and rising concerns for toy safety, it is clear that more rigorous manufacturer oversight and testing is warranted. However, one of the greatest challenges confronting U.S. toy companies is deciding what should be tested and how often. It would be impossible, and impractical, to test for absolutely everything. It seems, with the exception of the standard testing for lead and other toxic metals, testing for chemicals in products is generally dealt with in a reactive manner, in that product crises and recalls dictate what is tested. So, what is a company to do?

Proactive testing measures and a well-defined testing protocol are some ways that companies can combat this issue. To comply with CPSC requirements, many U.S. toy companies already voluntarily test their products for lead and other metals using standard procedures. Some companies also test their products at various stages during the manufacturing process. But given the recent spate of recalls, this has clearly not been enough. Companies must be even more proactive to ensure that their products are not compromised. This begins with better oversight of the manufacturing process. Random testing of raw materials, review of product specifications, factory audits, and increased frequency of finished product testing are other ways that companies can reduce their likelihood of problems.

In response to the recent toy recalls and the associated issues confronting toy companies, the Toy Industry Association (TIA) partnered with the American National Standards Institute (ANSI) to develop technical and international policy guidance to address toy safety. The draft guidance, *Toy Safety Coordination Initiative Draft Program Recommendations,* includes procedures for product hazard analysis and/or risk assessment evaluation, process control audits at the manufacturing level, testing and reporting at various manufacturing stages, and product certification. The objective "is to develop a sustainable system to enhance the reality and public's confidence that toys sold in the U.S. market are safe." If/when the guidance is implemented, it may help manufacturers identify contamination issues before their products reach the market, thus significantly reducing product recalls.

On March 11, 2008, the Senate passed the CPSC Reform Bill, which will ban lead in children's products, require third-party safety certification of children's products, and mandate toy safety standards. In the meantime, some retailers are already requiring that manufacturers meet more stringent standards and participate in testing programs to make sure that the products on their shelves are safe. This legislation, and the regulations and guidelines that will ensue, may become a model for similar programs aimed at enhancing product safety.

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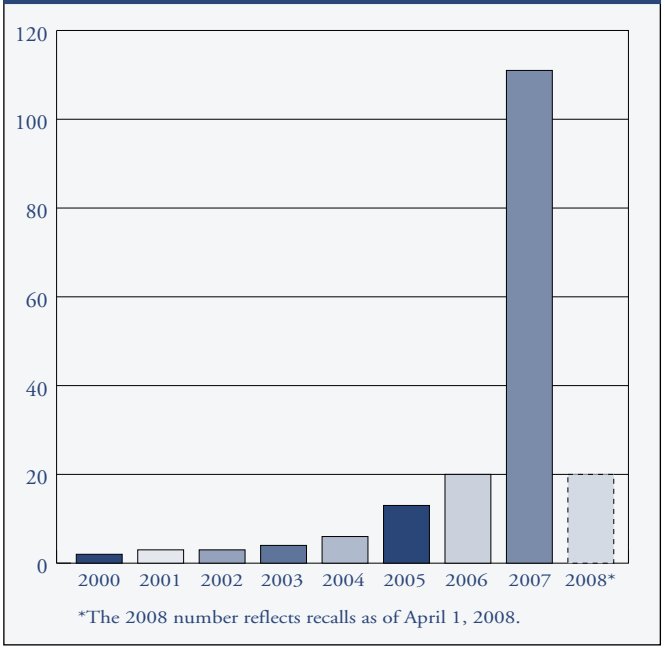
Number of U.S. Recalls of Products Containing Lead



Modified from: National Economic Research Associates. "China Product Recalls: What's at Stake and What's Next." Accessed at http://www.nera.com/image/PUB_ChinaProductRecalls_2.08_FINAL.pdf. February.

For Additional Information:

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Product Testing Protocols

By Kim Reynolds Reid, B.A. and Teresa S. Bowers, Ph.D.

Exposure potential, not merely the presence of a contaminant in a product, is driving the development of a suite of new product testing protocols.

It's easy to agree that the primary focus of product testing should be based on exposure. Contaminants should not be present in a product in a form where unacceptable exposure can occur. However, while some exposures can be anticipated, such as small toys that are attractive for mouthing by young children, other exposures may be less foreseeable. Furthermore, translating the concept of unacceptable exposure into a regulation broad enough to cover many types of products can be difficult. As a result, current regulations, such as the Consumer Product Safety Commission's (CPSC) regulation for unacceptable levels of lead in paints and coatings on toys, often target a concentration threshold for a limited subset of materials, rather than considering the total amount of exposure that may occur.

Many responsible companies are already voluntarily engaging in such broader testing programs as a reaction to consumer concerns over product safety.

Exposure of children to contaminants in products or toys most often occurs as a result of mouthing behavior, possibly leading to ingestion of the contaminant. However, the concentration of the contaminant in the product is only one piece of information relevant to exposure. More important to assessing exposure is the extent to which a contaminant will be released during mouthing behavior or, if a part of the toy is swallowed, will be released from the product while in the digestive tract. Analytical protocols have been designed to assess these exposure pathways, and they may form a better guide to the likelihood of unacceptable exposure than focusing on concentration alone.

ASTM Standard F963 specifies testing procedures that will soon become mandatory for U.S. companies producing children's toys and products. The tests determine total lead (currently regulated by the CPSC) and solubility of eight metals, including lead, in a solution that mimics the digestive tract. Products must pass both the total lead concentration threshold test, as well as the solubility test that is more focused on the potential for the product to release the contaminants. If a product fails either test, a recall may ensue.

Other children's products, such as pacifiers, are unlikely to be ingested but may represent potential exposure if contaminants leach from the product as a result of contact with saliva. A migration test was developed by the CPSC to assess this exposure scenario when concern arose over the presence of phthalates in pacifiers and metals in plastic and vinyl products. The test procedure involves extraction of the product as it is agitated in an artificial saliva solution to mimic the mechanics that occur during mouthing or sucking. Aliquots of the solution are sampled at specified time intervals and analyzed for contaminants of concern. If nothing is detected in the solution, exposure to the contaminant *via* mouthing of the product can be considered unlikely. Although selectively used to date, this test procedure could be modified to consider a broader range of products and contaminants where dissolution in saliva is expected to be a primary exposure route.

GradJinks

"We couldn't have seen THAT one coming."

Other analytical protocols have broadened the types of products that can be addressed. In contrast to ASTM Standard F963, which addresses metals only in paints and surface coatings on a product, the European Union (EU) Method EN71 Part 3 specifies soluble metals testing of all accessible substrate material as well. This includes polymers, paper and board, natural/synthetic textiles, glass/ceramic/metallic materials, pliable molding materials, and surface coatings.

Such an expanded scope of testing is aimed at assessing a broader category of potential exposures, and it may provide a glimpse of the type of future testing that could be mandated in the U.S. Many responsible companies are already voluntarily engaging in such broader testing programs as a reaction to consumer concerns over product safety.

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Risk Communication on Adulterated Products

By Peter A. Valberg, Ph.D.

Because potential health concerns with contaminated or adulterated products can arise quickly, having a well-prepared risk communication strategy in place can be critical to a successful outcome.

In the Superfund era, human health risk assessments were typically applied to assessing low (but non-zero) health risks from environmental contaminants. In most cases, the actual doses of chemicals of concern, even for the "maximally affected" individual, were small, and the health risks often hypothetical. Risk communication often had to address overreaction to perceived, but not actual, dangers to populations. However, for directly ingested products (*e.g.*, supplements, over-the-counter drugs, vitamins, herbal cures), doses of both active ingredients and potential adulterants can be large, because of the undiluted and purposeful intake. Consequently, the possibility of health endangerment from contamination can be imminent and substantial, and the situation can quickly reach crisis proportions.

…an intense crisis can develop in a short space of time, and a prompt, decisive response can help to minimize impacts on public trust.

The best approach to dealing with the risk communication challenge presented by such a situation is to be open, forthright, and prompt. A classic historical example of a crisis related to product adulteration is the 1982 tampering (by persons unknown) with containers of Tylenol© pain-relief medicine, wherein some capsules had been deliberately laced with cyanide. Several deaths from poisoning occurred in the Chicago area, and the deaths were quickly linked to Tylenol©, a product of Johnson & Johnson (J&J). Rather than contesting the existence of a link, J&J promptly distributed warnings to pharmacies, hospitals, and distributors, and cooperated with media warnings to the public. When the problem was determined to be with capsules, J&J offered to exchange all Tylenol© capsules already purchased with new Tylenol© tablets. Although the adulterated containers had come from different manufacturing locations, and the adulteration was almost certainly not related to a problem at the factory, J&J issued a nationwide recall of Tylenol© products, and halted Tylenol© production and advertising.

Because of this up-front, aggressive, and highly public approach, J&J was praised for its handling of the incident, and Tylenol© products and stock recovered within a year from an initial nosedive. Public trust was restored by the development and use of tamper-resistant seals on containers for consumer products designed for oral intake.

The lessons here are that an intense crisis can develop in a short space of time, and a prompt, decisive response can help to minimize impacts on public trust. A crisis management strategy to address such a situation needs to be worked out in advance, and it needs to incorporate both a technical and a communications component. For example, such a strategy might include an ongoing sampling program that monitors for contamination. It is far preferable to be in a position to say: "We have thought about this and already have data!" than to be in a position of relying on *post-hoc* analysis: "We'll check into it!"

Furthermore, it should be recognized that the specter of consuming an adulterated product provokes a series of viscerally negative responses based on risk perceptions alone. The perceived risks will be driven by such factors when the situation: a) is involuntary, unfamiliar, or unexpected; b) has an unpleasant or loathsome outcome (*e.g.*, death or cancer); c) affects vulnerable people (*e.g.*, children); d) is imposed by mistrusted sources; or, e) arises from a synthetic, poisonous, and polysyllabic constituent. Conversely, trust can be preserved when companies work openly, promptly, and sincerely to address adulteration questions with reliable facts and understandable solutions.

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By The Way...

The Consumer Product Safety Commission has about 400 staff, approximately half what it had in the 1980s. Fifteen inspectors monitor all consumer product imports that are under CPSC supervision. Last year this market was valued at $614 billion.

Source: *New York Times*, March 7, 2008 (http://www.nytimes.com/2008/03/07/business/07consumer.html).

What's New at Gradient

Recent Awards and Appointments

Barbara Beck was elected President of the Academy of Toxicological Sciences, in addition to being reappointed a member of the Watertown (Massachusetts) Board of Health.

Julie Goodman has been elected to the Canton (Massachusetts) Board of Health.

Kurt Herman is now a Registered Geologist in the state of Oregon.

Recent Articles

Grasso, N.C. 2008. Multi-sector approach to climate change: Cap-and-trade may need help. *Environ. Managers Compl. Advisor* 703:5-6.

Langseth, D.E. 2008. Valuing environmental remediation liability transfers. *Environ. Claims J.* 20(1):2-22.

Rhomberg, L.R., T.S. Bowers, L.A. Beyer, and **J.E. Goodman.** 2008. Comment on "Residential and biological exposure assessment of chemicals from a wood treatment plant" by James Dahlgren *et al.* *Chemosphere* 70(9):1730-1733.

Upcoming Presentations

Naples, FL. May 16, 2008. **Teresa S. Bowers.** Association of Battery Recyclers Annual Meeting: "An Update on the Lead NAAQS Rulemaking."

Sacramento, CA. May 20, 2008. **Lorenz Rhomberg**. Characterizing Dose Response & Hazard (California Mode of Action Workshop): "Proposed Weight of Evidence Scheme for Applying MOA Frameworks."

Boston, MA. June 1-5, 2008. **Christopher M. Long.** 2008 NSTI Nanotechnology Conference and Trade Show: "Development and Application of an Exposure-based Framework for Assessing Nanomaterial Safety."

Boston, MA. June 23-27, 2008. **Peter Valberg.** Comprehensive Industrial Hygiene: Practical Applications of Basic Principles, Harvard School of Public Health: "Portals of entry: Pulmonary deposition and clearance of particles."

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Product Testing Protocols

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For Additional Information:

American Society for Testing and Materials (ASTM) International. 2007. F963-07. Standard Consumer Safety Specification for Toy Safety.

Chen, S.B. 1998. Appendix A: Migration of DINP from Polyvinyl Chloride (PVC) Children's Products. Consumer Product Safety Commission (CPSC). December.

Deutsches Institut für Normung (DIN). 2002. European Standard EN 71-3. Safety of Toys, Part 3: Migration of Certain Elements. November.

Guest Editorial: Product Regulations Are Blowin' in the Wind

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Ban Asbestos in America Act S-742, available at http://thomas.loc.gov/cgi-bin/query/D?c110:3:./temp/~c1106Bg2pZ::.

U.S. EPA Consumer Products Environmental Partnerships Program – Public Meeting. 73 Fed. Reg. 11,112 (Feb. 29, 2008).

U.S. EPA Voluntary Labeling Program, available at http://epa.gov/oppt/labeling/.

Guest Editorial: Product Regulations Are Blowin' in the Wind

By William J. Walsh, Esq.

Multiple forces are at work to shape the future landscape of product safety.

Just as the title of Bob Dylan's 1963 song, "Blowin' in the Wind," suggests, future changes can come from many directions. Such is the case with emerging efforts to remove "toxic" chemicals from products. Such changes are mounting in many quarters, including consumer and market forces supplementing traditional government regulations. Chief among these forces are:

Unlike the Alice-in-Wonderland world where the "fair trial" follows a guilty verdict, the rule of law dictates that a case-by-case evaluation be performed.

Regulation by ban: Some regulations explicitly ban a substance in a product (*e.g.*, the proposed Ban Asbestos in America Act). Such bans, besides being difficult to implement, also run contrary to the long-standing U.S. risk management policies that accept low-level risks. Furthermore, bans can lead to unintended, if not absurd, consequences, such as where the "toxic" substances occur naturally. Thus, science and scientifically sound risk assessments remain essential.

Regulation by information: Some programs encourage removal of "toxic" constituents by providing information to consumers on their presence in a product. Examples include California's Proposition 65 and the U.S. EPA's Voluntary Labeling Program. Most recently, the EPA's Consumer Products Environmental Partnerships Program was created to provide consumers with "reliable information concerning the degree of environmental stewardship exhibited by consumer products and coatings manufacturers" so that this information plays "a role in consumers' purchasing decisions."

Regulation by press release: Advocacy groups sometimes assert that a constituent in a product, whether a familiar organic chemical, an exotic-sounding substance, a common trace metal, or a new nano-particle, presents a significant risk even though it is below a regulatory limit or there is no duly promulgated limit. However, scientific facts must be reviewed by neutral experts in these situations. Unlike the Alice-in-Wonderland world where the "fair trial" follows a guilty verdict, the rule of law dictates that a case-by-case evaluation be performed.

Regulation by purchasing power: Federal and state governments are increasingly using their enormous purchasing power to create a market for "green" products. Distributors such as Wal-Mart are turning "green" themselves and becoming private sector enforcers by requiring their suppliers to be "green" as well. There are benefits to a "green" classification for one's products, but such classification must be based on facts and administered with impartiality.

Each of these forces (as well as measures directed towards stabilizing climate change) are likely to provide incentives for companies to adopt more sustainable products. Historically, environmental groups and state regulators have dominated regulatory agency interactions with stakeholders. It is important to ensure that all regulatory and "green" programs are scientifically sound, and do not advance one set of stakeholder interests over others without any meaningful environmental benefit.

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For Additional Information:

Grist, A. Don't Discount Him, An interview with Wal-Mart CEO H. Lee Scott (April 6, 2006), available at http://grist.org/news/main-dish/2006/04/12/griscom-little.

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In the next issue:

Impacts of Mass Agriculture: Livestock

Mass Farming vs. Local Food

Who is Regulating Farm Emissions?

Guest Editorial: Feeding the World

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