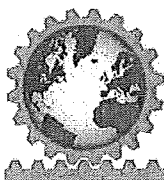


# **Presumption of Safety: Limits of Federal Policies on Toxic Substances in Consumer Products**



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## The Lowell Center for Sustainable Production at the University of Massachusetts Lowell

The Lowell Center for Sustainable Production uses rigorous science, collaborative research, and innovative strategies to promote communities, workplaces, and products that are healthy, humane, and respectful of natural systems. The Center is composed of faculty, staff, and graduate students at the University of Massachusetts Lowell who work collaboratively with citizen groups, workers, businesses, institutions, and government agencies to build healthy work environments, thriving communities, and viable businesses that support a more sustainable world.

This report was produced by the Lowell Center for Sustainable Production's Chemicals Policy Initiative, whose objectives are to significantly advance policy dialogue on reforming chemicals policy in the United States; assist in the development of sustainable chemicals management outside of the U.S.; encourage the development and use of safer alternatives by creating and promoting a comprehensive framework for alternatives assessment; and identify tools and appropriate ways of assisting green chemistry innovation and safer supply chain management of chemicals.

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## EXECUTIVE SUMMARY

### Presumption of Safety: Limits of Federal Policies on Toxic Substances in Consumer Products

The large number of recent consumer product recalls of toys, children's products, and other products containing dangerous chemicals, such as lead, has raised public concern about the safety of the products we use every day. Consumers are asking whether these products are safe for ourselves and our children. **Despite the fact that most consumers believe that everyday products are thoroughly tested for dangerous chemicals and determined to be safe by government authorities, the reality is that existing regulatory systems leave significant gaps in their capacity to adequately protect consumers from chemical hazards in these products.** Although issues of supply chain integrity and use of substandard raw materials are significant in ensuring safe products, a key element of the problem is inadequate federal regulation and policy to ensure that imported products are safe.

The Lowell Center for Sustainable Production at the University of Massachusetts Lowell conducted an analysis of current chemicals and product safety regulations in the United States as well as the agencies that implement these laws. Through literature review and consultation with key experts in government, academia, and the corporate and non-profit sectors, we identified several important limitations in the current regulatory system for ensuring the safety of chemicals used in everyday products, including:

- Voluntary Standards. Consumer product safety laws oblige the Consumer Product Safety Commission (CPSC) to rely largely on voluntary consumer product standards developed by industry groups, and leave the CPSC with limited capacity to ensure compliance with these voluntary standards and guidelines. Recent recalls suggest that voluntary assurances of product safety may not always work in practice, and that voluntary standards are not comprehensive.<sup>1</sup> Further, it is unclear whether product liability for uncertain chemical risks is a strong enough incentive for product safety.
- Limited Government Capacity. The Consumer Product Safety Commission is charged with assuring the safety of over 15,000 types of products; however it operates with half of its original budget and too limited a staff to cover areas such as toxic chemical hazards.
- Burdensome, Reactive Laws. Current laws and policies regulating toxic chemicals in toys and consumer products are burdensome and reactive in nature. The main federal law regulating the manufacture and use of chemicals, the Toxic Substances Control Act,

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<sup>1</sup> Recalls should be viewed as a safety net for design and manufacturing failures; policy should ensure that these failures do not occur in the first place.

requires companies to provide minimal data on chemical use, exposure and toxicity and provides limited authority for the Environmental Protection Agency to take swift action to address chemical hazards.

To regulate or restrict hazardous chemicals in toys or consumer products, the CPSC has to undergo a lengthy, costly, and time consuming process that must balance health protective actions with costs to industry. Thus, few chemicals are actually regulated in consumer products.

- Limited testing and safety requirements. Current laws do not require consumer product and toy manufacturers to test products for most chemical hazards. This problem is compounded by the fact that there is a significant lack of toxicity information available for many chemicals in commerce. *Currently, a lack of toxicity information for the chemicals used in consumer products and toys is effectively treated as evidence of safety.* Rather than ensuring the health and safety of consumers in the face of uncertainty by making precautionary decisions about chemicals for which there is some evidence of harm, manufacturers are given the benefit of the doubt. Further, there is no pre-market approval process for the use of chemicals in consumer products or toys which would ensure their safety.

This report focuses primarily on laws and agencies regulating toxic chemicals in consumer products, including toys. It spells out how the U.S. consumer product regulatory system functions and its limitations. The report examines two particular areas of consumer product safety:

- 1) The laws and regulations for toxic chemicals in consumer products and the agencies that regulate these products; and
- 2) The requirements and standards that exist for consumer product and toy safety and the process for issuing them.

We conclude that current regulatory and agency structures for protecting the public from chemical hazards in consumer products are inadequate and in need of reform. During the past year, Congress has initiated discussions of consumer product safety reforms with the Consumer Product Safety Modernization Act (HR 4040) and the Consumer Product Safety Reform Act of 2007 (S2045). These reforms include a full prohibition on lead, requiring some pre-market safety testing, strengthening recall procedures and enhancing the budget of the Consumer Product Safety Commission.

However, the minimal changes to consumer product safety laws currently being contemplated in these bills are insufficient to address the much larger structural problem of potentially dangerous chemicals in everyday products. A more comprehensive, long-term solution to the limitations of current policies is to fundamentally reform of the ways in which chemicals are designed and managed in commerce in a way that considers the inherent hazards of substances, as well as their use in all types of products, and the design and application of safer alternatives.

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## LAWS, REGULATIONS AND AGENCIES OVERSEEING TOXIC CHEMICALS IN CONSUMER PRODUCTS

The laws regulating toxic chemicals in toys and other consumer products are complicated and, in places, unclear as to requirements and responsibilities of government agencies and industry. In general toxic chemicals used in consumer products are regulated by three different agencies: the US Environmental Protection Agency (EPA), the Federal Food and Drug Administration (FDA), and the Consumer Product Safety Commission (CPSC). The EPA regulates the testing and manufacture of chemical substances and their risks in use and disposal; the FDA regulates chemical substances in food, cosmetics, and food contact materials (such as lunch boxes or ceramics); and the CPSC oversees chemical exposures from consumer products. Nonetheless, the lack of clarity regarding which agencies are in charge of which substances and products can lead to jurisdictional disagreements between agencies and hence slow health protective actions.

These overlapping responsibilities pose problems when a product crosses jurisdictional boundaries. For example, any consumer product or toy that involves contact with food would be regulated by the Federal Food and Drug Administration (FDA) under the Federal Food Drug and Cosmetics Act. But in the case of lead found in vinyl lunch boxes, the inside of the lunchbox would fall under the FDA's authority, while the outside of the lunchbox would be CPSC's responsibility.

Given concerns regarding chemical hazards in children's toys and other consumer products, this report focuses in particular on the Consumer Product Safety Commission and the laws it implements. It is instructive, however, to first provide some background on the regulations and roles of other laws and agencies involved in consumer product safety.

### **The Toxic Substances Control Act**

Toxic chemicals and their impacts through manufacture, use, and disposal are generally regulated under the Toxic Substances Control Act (or TSCA) of 1976. TSCA authorizes EPA to, under certain conditions, require testing of chemicals by manufacturers; to collect information on studies indicating human health risks or exposures of concern; to collect data on chemical use (including most recently information on chemical use in products for children); and to restrict chemicals of high concern. Despite these authorities, the limits of TSCA to enable EPA to protect the public from chemical hazards in products have been widely examined by federal government oversight agencies and, other experts.<sup>2</sup>

TSCA's Limited Requirements:

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<sup>2</sup> See Denison, Richard. 2007. Not That Innocent: A Comparative Analysis of Canadian, European, and U.S. Policies on Industrial Chemicals. Washington, DC: Environmental Defense; Government Accountability Office. 2007. Chemicals Regulation: Comparison of U.S. and Recently Enacted European Approaches to Protect Against the Risk of Toxic Chemicals. Washington, DC GAO-07-825.

- “Grandfathering” of most chemicals in commerce. When TSCA came into effect in 1977, all chemicals on the market at that time – 99% by volume of those on the market today – were assumed safe until proven dangerous and could be used with no limitations. To restrict a chemical, EPA has to undergo extensive procedures to demonstrate the harm from the chemical and to document that the benefits of regulation exceed the costs (meeting a standard of “presents or will present an unreasonable risk”). When EPA attempted to restrict uses of asbestos in the 1980s the agency was taken to court and the court ruled that the agency had not followed their own procedures. As a result EPA has restricted less than a dozen chemicals in 30 years, though it has used voluntary and negotiated measures to move industry away from certain chemicals, and integrate considerations of environment and health at the design stage of new chemicals.
- Lack of testing, use, and exposure data on most chemicals in commerce. While basic safety data is being collected on about 3,000 of the most widely used chemicals in commerce through a voluntary initiative between EPA and the chemical industry (called the High Production Volume Challenge), there is very little publicly available data on almost 10,000 other chemicals used extensively in commerce and even less on how these chemicals are used or how exposure may occur. To require testing data, EPA must demonstrate that the chemical may present an unreasonable risk or significant exposure, that there are insufficient data and experience to predict effects, and that testing is necessary to obtain such data. This has resulted in fewer than 250 chemicals undergoing mandatory testing since 1980, though a greater number have been subject to negotiated testing agreements.

With regard to chemicals in toys and consumer products that may adversely impact health, TSCA Section 9 states that when EPA concludes that when a chemical presents or will present an unreasonable risk of harm, and that the risk can be significantly reduced or eliminated through actions by another federal law not administered by EPA, EPA is required to send a report to that agency outlining the risk. If that agency determines that activity does not present a risk or initiates regulatory actions within 90 days then EPA is prohibited from regulating that substance. *In practice this means that EPA generally refers actions to protect children and consumers from chemical hazards in toys and other consumer products to the Consumer Product Safety Commission and the laws it implements.*

### **The Federal Food Drug and Cosmetics Act**

The FDA regulates chemicals in two consumer product categories: cosmetics and materials that have contact with food (such as water bottles, ceramics, or lunch boxes, and toys such as ovens). These product types are regulated in different ways by the agency.

*Cosmetics.* The FDA website succinctly summarizes the regulation of chemicals in cosmetics, stating, “FDA’s legal authority over cosmetics is different from other products regulated by the agency, such as drugs, biologics, and medical devices. Cosmetic products and ingredients are not

subject to FDA pre-market approval authority, with the exception of color additives...Cosmetic firms are responsible for substantiating the safety of their products and ingredients before marketing.”<sup>3</sup>

In general, except for color additives and those ingredients which are prohibited or restricted from use in cosmetics by regulation, a manufacturer may use any ingredient in the formulation of a cosmetic provided that the ingredient and the finished cosmetic are “safe”, the product is properly labeled, and the use of the ingredient does not otherwise cause the cosmetic to be adulterated or misbranded under the laws that FDA enforces.

*Food Contact Substances.* Also known as indirect food additives, Food Contact Materials are substances used in food-contact articles (such as packaging) but are not intended to be directly added to food, including adhesives and components of coatings, paper and paperboard components and polymers. Under the 1997 amendments to the Food Drug and Cosmetic Act, manufacturers are required to submit food contact notifications to the FDA for new uses of food contact substances (including new food contact substances). Notification is not required for food contact substances that have prior regulations related to their use in contact with food or are considered “Generally Recognized As Safe” (a designation made by FDA, and in some cases, by industry that applies to many food contact substances). These notifications are reviewed by FDA with the manufacturer, and FDA can issue limits on the use of those substances and on the degree that such substances can leach from contact surfaces to food.<sup>4</sup> FDA has expedited procedures for food contact substances that are of low exposure potential (below 1.5 micrograms per person per day).

Food items marketed with toys in them, such as cereals, are regulated by both the FDA and the CPSC. The FDA regulates the safety of the food, and the CPSC is responsible for the safety of the toy.

### **Consumer Product Safety Commission and Consumer Protection Laws Demystified**

The Consumer Product Safety Commission (CPSC) was created in 1972 by Congress as an independent agency under the Consumer Product Safety Act (P.L.92-573) and began operating in 1973. The Commission is currently directed by three Commissioners nominated by the President and approved by the Senate, who set the policy agenda for the Commission.<sup>5</sup> The Commission is charged with protecting the public from *unreasonable risks of serious injury or death* from more than 15,000 types of consumer products used in homes, schools, and recreation that pose a fire, electrical, chemical, or mechanical hazard, or can otherwise cause injury.

<sup>3</sup> <http://www.cfsan.fda.gov/~dms/cos-206.html>

<sup>4</sup> See <http://www.cfsan.fda.gov/~dms/opa-fcn.html> and <http://www.cfsan.fda.gov/~dms/opa-indt.html>

<sup>5</sup> The Chairman of the Commission has considerable power in setting the Commission's agenda. By statute there are five Commissioners, but since the 1980's only three positions have been funded. At least one of the Commissioners must be from either political party. Three commissioners constitute a quorum. If one of the funded positions is vacant or a member does not show up to vote mandatory regulations cannot be issued. For example, during the 1980's, the CPSC Chairman Scanlon vetoed numerous regulations simply by not showing up to vote.

To carry out its mission, CPSC administers several statutes passed by Congress, including two general laws— the Consumer Product Safety Act and the Federal Hazardous Substances Act — and two product specific laws — the Flammable Fabrics Act and the Poison Prevention Packaging Act.

(1) The Consumer Product Safety Act (CPSA) of 1972 is an umbrella statute that consolidated federal safety regulatory activity relating to consumer products within the CPSC. The law defines the authorities of the CPSC and authorizes the agency to develop standards to reduce or eliminate unreasonable risks of injury associated with consumer products, to ban products if there is no feasible safety standard, and to pursue recalls for products that present a substantial hazard.

(2) The Federal Hazardous Substances Act (FHSA) of 1960 requires the labeling of hazardous household products that are toxic, corrosive, combustible, or otherwise hazardous, and that have the potential to cause substantial personal injury or illness as a result of reasonably foreseeable handling, use, or ingestion. The Act also allows the CPSC to ban certain products (called “banned hazardous substances”) that are so dangerous that labeling is not adequate to protect consumers. For example, it specifically prohibits any toy or other article that is intended for use by children and that contains a hazardous substance if a child can gain access to the substance.

(3) The Flammable Fabrics Act of 1953, authorizes flammability standards for clothing, upholstery, and other fabrics.

(4) The Poison Prevention Packaging Act of 1970, authorizes requirements for child-resistant packaging for certain prescription and non-prescription drugs, cosmetics and other household substances.

Under the FHSA, a hazardous substance is: "Any substance or mixture of substances which (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable or combustible, or (vi) generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." This definition of a hazardous substance has been interpreted to include both acute and chronic toxicity.

*Thus, for a toxic substance to be considered hazardous under the FHSA, it must not only be toxic but people must also be exposed to the substance, it must be bioavailable (can enter the body) and there must be a significant risk of an adverse health effect associated with the customary handling and use of the substance. As such, the law requires that evidence that a substance may cause substantial illness be demonstrated before it is labeled as hazardous, although there is little guidance as to what is meant by "substantial" (i.e. of medical or toxicological significance). This strict risk-based definition means that many toxic chemicals that are components of consumer products, but may leach out during normal use, would be unlikely to meet the standard of a*



hazardous substance due to a lack of information demonstrating a substantial risk. Thus, the mere presence of a hazardous chemical in a product and the potential for leaching would not be sufficient to meet this standard. Indeed for many substances, as noted previously, very little toxicological data exists. If data do not exist to document a risk, then the substance is not considered hazardous.

*In general, companies make the determination as to whether their product contains a hazardous substance, though in some rare cases, the CPSC may issue a regulation defining a particular chemical or substance as hazardous. The CPSC has developed regulatory definitions of acute toxicity as well as voluntary guidelines to assist companies in determining the hazards of substances in their products (so as to comply with FHSA) including carcinogenicity, neurotoxicity, reproductive/ developmental toxicity, exposure, bioavailability, risk assessment, and acceptable risk. However, these guidelines are general and are interpreted on a case-by-case basis, meaning that they are not necessarily consistent from one toxicologist to another.<sup>6</sup> For example, in its guidance on lead in consumer products, the CPSC states "In evaluating the potential hazard associated with products that contain lead, the Commission staff considers these major factors on a case-by-case basis: that the total amount of lead contained in a product, the bioavailability of the lead, the accessibility of the lead to children, the age and foreseeable behavior of the children exposed to the product, the foreseeable duration of the exposure, and the marketing, patterns of use, and life cycle of the product."*

### **The Role of State Regulation of Consumer Products**

Potentially dangerous chemicals in products also may be regulated at the state level. The CPSA allows states to enact their own statutes and regulations regarding product safety as long as they meet the minimum standards set by the federal government (i.e. they can go beyond federal standards). For example, in 2002, the State of New York enacted General Business Law §391-b, effective March 16, 2003, restricting the retail sale of children's clothing with drawstrings. Massachusetts law allows the Massachusetts Department of Public Health to prohibit sales of products that can be hazardous to children, but are not prohibited nationally.

In the absence of changes to federal regulations with regard to lead and other problem chemicals in toys, several states are advancing proposals for regulation of toxic substances in toys and children's articles. A California law regulates lead in children's and adult jewelry, body piercing jewelry, and both metal and non-metallic jewelry components. The new law came into effect on September 1, 2007 for children's jewelry, and will come into effect on March 1, 2008, for all other jewelry. California Assembly Bill 1008 prohibits manufacture, sale, or distribution in commerce of certain toys and child care articles, if those products contain six types of phthalates in concentrations exceeding 0.1 percent. California's 2006 Safe Cosmetics bill, the nation's first state law on chemicals in cosmetics (including those directed to children), requires manufacturers to notify the state when they use chemicals linked to cancer and birth defects.

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<sup>6</sup> While the guidelines for defining hazard may not change from administration to administration, the more political responses to the risk assessments that the CPSC staff undertake, what to do under conditions of uncertainty but a threat of harm, as well as the speed of the response do change.

Michigan Senate Bill 174 of 2007 prohibits sales of any toy or child care item that contains more than 0.06 percent total lead content. An Illinois regulation of lead in consumer products, The Lead Poisoning Prevention Act, became effective June 20, 2006. This law relates to clothes, jewelry, candy, food, dietary supplements and items chewable by children. Bills and executive branch regulations to prohibit the use of lead, phthalates, and bisphenol-a in toys and child care items currently are being debated in at least 8 states. Bills have been introduced in the states of Maine and Washington which would require manufacturers to disclose all high priority hazardous chemicals in toys and restrict certain other high priority substances.

There is the possibility that some provisions in these laws could be preempted if the CPSC were to issue regulations in these areas.<sup>7</sup>

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## REQUIREMENTS AND STANDARDS FOR CONSUMER PRODUCT AND TOY SAFETY

*While CPSA and FHSA authorize the CPSC to take action to reduce or eliminate unreasonable risks of harm from toys and other consumer products, in practice, the agency's authority is limited. Rather than define specific safety standards for each of the consumer products which the CPSC regulates, the Consumer Product Safety Act delegated general authorities to the CPSC to investigate hazardous products, adopt safety standards, recall products, and require reporting of product hazards by manufacturers. The types of actions CPSC can take fall into several broad categories:*

A) Testing: *Contrary to public perception, the CPSA does not generally require any pre-market safety testing of consumer products or chemicals used in these products, including toys. It does not require specific testing for chronic hazards and it does not provide for pre-market approval of toys or other products containing hazardous chemicals. Rather, it requires manufacturers to ensure that their products are not hazardous or are properly labeled. A major problem, as noted above, is the lack of toxicity data on most chemicals in commerce. As such, if toxicity data are not available (particularly for chronic hazards such as the ability of a chemical to cause developmental disabilities) then it is impossible to ensure that a product is not hazardous or is properly labeled. Further, ensuring proper labeling is even more of a challenge as companies are not required to disclose the chemical constituents of their products to the CPSC (unless CPSC can show there is an unreasonable risk of serious injury or death). CPSC is thus responsible for ensuring the safety of hundreds of thousands of household products of generally unknown composition composed of ingredients whose health effects are often unknown. However, the EPA does have the authority to require testing of hazardous substances under TSCA (although, as noted above there are substantial limits on this authority) and CPSC does work with the EPA and other agencies to identify priorities for such testing.*

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<sup>7</sup> Preemption would only apply, however, under certain conditions. For example, the CPSC and state rule must address the same hazard, and they must be the same type of rule (for example labeling).

CPSC may selectively test certain product types for restricted or prohibited substances such as lead on a periodic basis. Also, when concerns are brought to the CPSC, such as lead in products or phthalates (softeners) in toys, the CPSC may initiate its own testing to determine whether reasonably foreseeable exposures may result in unreasonable risks to children. These initiatives are often driven by petitions from consumer groups

B) Safety Standards and Regulations: The CPSC has authority to promulgate mandatory federal safety standards for specific consumer products deemed to be unreasonably dangerous to the public. Most of the consumer product safety standards are set to avoid injury or acute hazards such as choking, burns, etc. Some standards are issued under the authority of the CPSA while others are issued under the FHSA. *There are less than 20 mandatory federal standards for toxic chemicals in toys and consumer products, the most notable being lead in paint.*<sup>8</sup> Safety standards and regulations can range from outright bans to restrictions to voluntary actions, and from written guidance to consumer information and outreach.

C) Labeling: Whether or not a product must be labeled under the FHSA depends on its contents (if it contains a hazardous substance as defined above) and the likelihood that consumers will be exposed to any hazards it presents. To require labeling, a product must meet the definition of a hazardous substance: toxicity, exposure, and potential for harm. Manufacturers, distributors, and /or importers make determinations on if and how to label their products in accordance with FHSA requirements (which requires that hazardous substances in products be labeled). It is the company's responsibility to comply with CPSC. This applies to both acute and chronic hazards. Companies are only required to list the hazardous ingredients in their products.

The FHSA lays out specific labeling requirements for hazardous products. If the CPSC finds that a given product is not properly labeled, it is considered "misbranded" and cannot be sold. However, enforcement is mostly limited to acute hazards, such as flammability or acute toxicity.

*In practice, few products containing toxic chemicals need to be labeled under the FHSA definitions. If data do not exist on a chemical's toxicity or a consumer/children's exposure to a substance, then it is impossible to determine whether it is "hazardous" and requires labeling.*

D) Bans: While CPSC has the ability to ban products where product labeling and safety standards will not adequately protect the public from a hazard, less than a dozen chemicals in products have actually been subject to outright bans.<sup>9</sup> In general CPSC bans or limits the use of a specific ingredient, not the products in which they are contained.

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<sup>8</sup> See <http://www.cpsc.gov/businfo/reg1.html> or [http://www.access.gpo.gov/nara/cfr/waisidx\\_04/16cfrv2\\_04.html](http://www.access.gpo.gov/nara/cfr/waisidx_04/16cfrv2_04.html) for a list of products for which safety standards have been developed.

<sup>9</sup> See [http://www.access.gpo.gov/nara/cfr/waisidx\\_04/16cfrv2\\_04.html](http://www.access.gpo.gov/nara/cfr/waisidx_04/16cfrv2_04.html)

- Under FSHA "banned hazardous substances" include: extremely flammable water repellents; carbon tetrachloride and mixtures in which it is an ingredient; certain fireworks devices; liquid drain cleaners that contain 10% or more by weight of sodium or potassium hydroxide, not packaged in child-resistant packaging; products containing soluble cyanide salts; general-use garments containing asbestos; and self-pressurized products that contain vinyl chloride monomer as an ingredient or in the propellant.. In addition, any toy or article designed for use by children that contains one of the substances listed above is banned if a child can gain access to it (e.g. it's not sold in a child-proof container).
- Under CPSA banned substances include: certain extremely flammable contact adhesives; paint and other surface coatings containing more than 0.06% lead, and furniture, toys, and other articles intended for use by children that are coated with such paint; and consumer patching compounds and artificial ashes or embers used in fireplaces containing inhalable free-form asbestos. Some bans, such as TRIS flame retardants in children's sleepwear and urea formaldehyde insulation were overturned in the courts, though these substances were eventually removed from the market.

E) Voluntary standards and actions: While the CPSC can adopt mandatory safety standards where such standards are necessary to reduce a significant risk associated with a consumer product, *the CPSA directs the CPSC to rely upon voluntary consumer product safety standards when compliance with them would eliminate or adequately reduce the risk of injury.* Beyond the federal and state statutes there are voluntary guidelines and standards for corporate product testing methods and the types of hazards to examine (for example, through the American National Standards Institute(ANSI), the American Society for Testing and Materials(ASTM), and the Underwriters Laboratory).The 1981 amendments to the Consumer Product Safety Act require CPSC to defer to a voluntary standard—rather than issue a mandatory regulation—if CPSC determines that the voluntary standard adequately addresses the hazard in question and where there is likely to be considerable compliance with the voluntary standard. These voluntary standards, such as those set by ASTM, do not have the force of law. However, many voluntary standards are widely accepted by industry and some are stricter than CPSC standards can be because they are not subject to economic balancing considerations (see below). The existence of a voluntary standard may also make it easier for CPSC to act when it finds a problem. Finally, CPSC sometimes issues product specific voluntary guidance documents outlining product testing, labeling, and design. Such guidance documents have been issued for baby rattles and metal jewelry for example.

The Toy Industry Association, a trade association for toy manufacturers, created a voluntary toy safety standard in 1971. In 1976, the standard was published by the National Bureau of Standards of the US Department of Commerce. The American Academy of Pediatrics, Consumers Union, the National Safety Council and several national retail organizations and toy industry safety experts were actively involved in developing this standard (later published as ASTM Standard F963-03, which has been updated at least twice). According to the Toy Industry Association, this voluntary standard includes specifications for toy safety and testing and takes into account US regulatory

requirements for toys. However, this standard focuses primarily on safety and injury issues rather than those of chronic toxicity. With regards to the latter in toys (art materials have stricter requirements), the only testing required is in compliance with section 4.3.5.2, which states that "surface-coating materials shall not contain compounds of antimony, arsenic, barium, cadmium, chromium, lead, mercury or selenium" and 4.3.8 which states that "pacifiers, rattles, and teethingers shall not intentionally contain di(2-ethylhexyl) phthalate".<sup>10</sup> Testing is also required to determine if labeling for content of a hazardous substance is required. *However, if a substance is not identified as a hazardous substance under the FHSA, there is no requirement to test. What to test for is generally left up to the manufacturer. Further, there is no requirement that manufacturers abide by these voluntary standards, nor is the standard enforced except when a particular manufacturer or retailer requires documentation of compliance.*

**F) Recalls:** The CPSC has authority to recall products either because they contain a defect, which makes them unsafe, or because they violate an existing consumer product safety rule. Voluntary recalls are the CPSC's preferred method of enforcement given the legal burdens of issuing

#### **An example: Lead in Toys**

Under the Consumer Product Safety Act, paint and similar surface-coating materials for consumer use that contain lead or lead compounds, and in which the lead content (calculated as lead metal) is in excess of 0.06 percent of the weight of the total nonvolatile content of the paint or the weight of the dried paint film, are considered banned hazardous products.

Toys and other articles intended for use by children that bear "lead-containing paint" are prohibited under this definition. However, to be a banned hazardous product it must generate levels of "accessible" lead that are enough to raise blood lead levels beyond 15 µg/dl. Toys containing lead as part of a metal or as a stabilizer in plastics – such as some vinyl toys and other products containing lead as a stabilizer, including miniblinds – are not included under this definition. Neither is lead in jewelry, which is subject to a voluntary guidance document on enforcement, and for which a notice of proposed rulemaking was issued to designate jewelry containing more than 0.06 percent by weight lead in metal components as a "banned hazardous substance".

Despite these efforts, in its 1998 voluntary guidance on lead in consumer products, the CPSC noted that: "To reduce the risk of hazardous exposure to lead, the Commission requests manufacturers to eliminate the use of lead that may be accessible to children from products used in or around households, schools, or in recreation." They further noted in response to several incidents of lead in consumer products (such as vinyl miniblinds) that: "the Commission believes that, had the manufacturers of these lead-containing products acted with prudence and foresight before introducing the products into commerce, they would not have used lead at all.

mandatory recall regulations, and the fact that many recalls are due to "technical violations" where, for example, limits are violated but there may be a minimal safety concern. When a product is recalled, the manufacturer and the CPSC negotiate a Corrective Action Plan which CPSC must approve. Publication of a joint press release, including which news stations and/or print media may report the story is a common element of such a plan. Manufacturers are required to notify retailers that the product has been recalled and should then be removed from store shelves. However, manufacturers are not required to retrieve the recalled products or to demonstrate that they have been returned to the company or otherwise taken out of use. In the case of a voluntary recall, there are no strict requirements as to the extent of outreach a company must undertake to consumers regarding recalls, and companies may even continue to sell a product subject to recall. In fact, recovery rates for recalled products hover around

15-20 percent, indicating that children may continue to be at risk even after recalls occur from inappropriate sales.

### **The Challenge of Issuing New Product Safety Standards**

While the FHSA and CPSA have specific requirements for labeling and safety and CPSC issues guidance to support industry compliance, CPSC can also take regulatory actions to ensure product

<sup>10</sup> See ASTM Designation: F 963-03, "Standard Consumer Safety Specification for Toy Safety."

safety. However, regulatory action occurs through a burdensome process and on a case by case, hazard by hazard basis. Below we present this process:

Deciding which hazards to investigate. In choosing which hazards to investigate, CPSC accepts petitions from any person asking CPSC to issue, amend, or revoke a regulation. To be docketed, a petition must contain data or analyses showing that a hazard exists and that the requested action must be within the Commission's authority. The Congress may also direct CPSC to study a product area for possible regulation or issue specific new legislation. CPSC commissioners and agency staff may also initiate projects or suggest areas to address based on individual concerns or referrals from other agencies or research organizations such as the National Toxicology Program. Most staff driven projects are based on information from the National Electronic Injury Surveillance System (NEISS) or National Fire Incident Reporting System (NFIRS). Since such surveillance databases do not exist for chronic chemical hazards, projects dealing with such hazards are generally a lower priority for the Commission.

Once a petition is received, the commissioners vote on whether the product hazard warrants further agency involvement and specific budget allocation.

CPSC has established criteria for setting agency priorities and for selecting potential hazards to address. These criteria include: the frequency of injuries and deaths resulting from the hazard; the severity of the injuries resulting from the hazard; the extent to which the hazard is likely to be reduced through CPSC action; the number of chronic illnesses and future injuries predicted to result from the hazard; preliminary estimates of the costs and benefits to society resulting from CPSC action; the degree to which consumers are aware of the hazard and its consequences; vulnerability of the population at risk; and probability of exposure to the product hazard.

Initiating regulation. Once the CPSC makes a decision to investigate a new chemical hazard and determine if regulation is necessary, a series of cumbersome procedures must be undertaken:

- 1) Before issuing a notice of intent to develop a regulation with regards to substances that may cause cancer, birth defects, or gene mutations, the CPSC must first appoint a Chronic Hazard Advisory Panel, consisting of independent scientists to determine whether the substance may cause cancer, birth defects or gene mutations and the potential risk from the substance. The panel is required to issue its report within 120 days after being appointed and the Commission is required to include the Panel's report in any rule making procedure.
- 2) Any regulation, ranging from naming a substance a hazardous or banned hazardous substance, to specific labeling requirements, to product bans, must fulfill several specific requirements, as well as public notice and comment, including:

- a. That the rule (including its effective date) is reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with such product; a voluntary approach must be attempted first.
- b. That the promulgation of the rule is in the public interest.
- c. In the case of a rule declaring the product a banned hazardous product, that no feasible consumer product safety standard under the CPSA would adequately protect the public from the unreasonable risk of injury associated with such product.
- d. That compliance with voluntary consumer product safety standards or other efforts is not likely to result in the elimination of adequate injury or that there will not be substantial compliance.
- e. That the benefits expected from the rule bear a reasonable relationship to its costs. In other words, the benefits of protecting health must be comparable to the costs to manufacturers of implementing product change. This is a difficult standard to achieve particularly when the health benefits of a standard may be hard to quantify (for example reducing developmental delays from IQ reductions due to lead exposure) and occur in the future while the costs to manufacturers are easier to quantify.
- f. That the rule imposes the least burdensome requirement, which prevents or adequately reduces the risk of injury for which the rule is being promulgated. This is also a challenging requirement to meet in that changes may not be burdensome for some manufacturers and that innovation in safer materials can occur as a result of regulation.

Determining if a regulation should be promulgated. If after following these procedures the Commission still believes that a regulation is necessary and the Commission has undertaken necessary studies to meet these burdens, the Commissioners vote on whether to issue the regulation. It is important to note that the Commissioners, who have significant powers in the agency, are politically appointed and these appointments can be influenced by regulated industries.

This process can take several years to complete and in several cases CPSC regulations have been overturned in the courts for failing to follow proper procedures or for not meeting the requirements to issue new regulations. Frequently while the rulemaking process occurs, no action is taken on a particular hazard.

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## CONCLUSION

### Presumption of Safety: Limits of Federal Policies on Toxic Substances in Consumer Products

*“Toys are one of the most heavily regulated products in our economy and by and large, toys are very very safe. Obviously we don’t like to see any recalls. A nine million piece recall, although it seems to be big, is certainly not the biggest recall that we have done, and when you put it in perspective of the hundreds of millions of toys that are sold in the US every year, frankly we want to be sure that the marketplace is safe, but consumers really shouldn’t be panicking and thinking that everything in their toy chest isn’t safe for the children.”*

*Nancy Nord, acting chairman of the U.S. Consumer Product Safety Commission, interview on National Public Radio, August 15, 2007, in response to a recall by Mattel.*

Contrary to Nancy Nord, acting chairman of the U.S. Consumer Product Safety Commission’s assertion, it is our conclusion that current regulations leave significant gaps in their capacity to adequately protect consumers from chemical hazards in consumer products, including toys.

#### **Safe Until Demonstrated Hazardous**

Manufacturers and importers of consumer products and toys operate in a landscape of “safe until proven dangerous,” where they have few requirements for testing or seeking approval for products that contain potentially harmful chemicals. In this context, chemicals in products are assumed safe until demonstrated to present an unreasonable risk, and lack of information on the toxicity of a chemical is implicitly considered evidence of safety. Our analysis has found that the consumer product safety statutes and regulations administered by the CPSC are not only burdensome, but have important gaps that leave them ineffective and potentially inadequate to protect the public from chemical hazards. Some of the key limitations in current product and toy safety regulations we identified include:

- **CPSC relies largely on voluntary consumer product standards as they have been directed; yet CPSC has little ability to ensure compliance with voluntary standards or guidelines.** While some industries, such as the toy industry, have developed their own voluntary safety standards, there is no requirement for companies to comply. Recent product recalls suggest that voluntary assurances of product safety may not work in practice.

One of the arguments for advocating voluntary product safety standards is the force of product liability in ensuring safe product design. However, such arguments are only partially correct. There is a general assumption that potential liability has a deterrent effect as firms consider the potential hazards of their product, potential losses, and the costs of



defending product liability claims. While this may be true for safety related hazards, where risks are relatively well established, it is likely less true for chemical (particularly chronic) hazards where manufacturers may not even have basic toxicity information on raw materials used in their products or risks are very uncertain and may occur far into the future. In fact, given the rapid life span of many consumer products, the time to adequately understand product risks may outweigh the need to get quickly to market, and possible harm may occur long after the product has been retired. Thus, legal scholar Michael Baram notes that the incentives to ensure safety at the design stage are limited (often being overwhelmed by other considerations). He concludes that: "the hypothesis that tort liability promotes safer design needs to be replaced with the more hesitant hypothesis that it promotes company deliberations about mitigating loss which may, under certain circumstances, lead to design of a safer product or process."<sup>11</sup>

- **Current laws and policies regulating toxic chemicals in toys and consumer products are reactive in nature.** While the CPSA and FHSA require manufacturers to ensure their products are not hazardous or improperly labeled, defining a substance as hazardous is difficult under current laws and in practice the initiation of preventive regulations for toxic chemicals in consumer products happens on a haphazard, case-by-case basis in response to petitions or other decisions of the CPSC.
- **To regulate or restrict hazardous chemicals in consumer products, the CPSC has to undergo a lengthy, costly, and time consuming process which requires balancing the costs of regulations to manufacturers with benefits to health and application of the least burdensome requirements for industry.** Given this process, it is virtually impossible for the CPSC to act rapidly (except through voluntary guidelines) to protect health. These high burdens also mean that few chemicals, consumer products or toys can be regulated in practice.
- **Current consumer product safety laws are inadequate to address chronic health concerns from chemicals in everyday products.** The FHSA was drafted in 1960 and the CPSA in 1972 during a period when the health hazards from exposure to small amounts of chemicals from a variety of products were not well understood. These laws were developed primarily for addressing well established acute hazards, injuries, and safety concerns, which have dominated most of the CPSC's work. While methods for defining and assessing chronic chemical hazards have improved over the years, federal laws are scientifically out of date. When exposures may be small (but could be combined from multiple sources resulting in larger exposures) or the types of health effects are hard to demonstrate scientifically, the current laws make it very difficult to label a toxic chemical as a hazardous substance or for CPSC to be able to undertake regulatory actions to protect the health of consumers.

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<sup>11</sup> Baram, Michael. 2007. Liability and its influence on designing for product and process safety. Safety Science 45: 11-30.

- **Consumer Product Safety Laws are administered by an agency that has very limited power and resources to develop new regulations or enforce existing requirements.** In 1973, when the CPSC began operating, it had approximately 1000 employees. In 1984, this number was reduced by half. There is now a staff of approximately 420. The largest number of employees work in the Compliance division with the remainder working in Hazard Identification and Reduction. Despite increasing workloads, there are less than fifteen health scientists, including toxicologists, pharmacologists, and physiologists. Further, the infrastructure and support at the Commission to study chronic chemical hazards is eroding.

There are currently two main proposals for reform of federal consumer product safety legislation in response to recent recalls. The Consumer Product Safety Modernization Act (HR 4040), and the Consumer Product Safety Reform Act of 2007 (S2045) are similar in that they would: expand funding for the Consumer Production Safety Commission (as well as minimal staffing); strengthen recall procedures; prohibit all lead in toys; and make the current ASTM standard F963 mandatory for toy manufacturers, thus requiring some premarket testing. HR 4040 has passed out of the House and will be discussed in the Senate in the Spring of 2008.

Our analysis indicates that the small, but important, changes to consumer product safety laws currently being contemplated in these bills are insufficient to address the problem of potentially dangerous chemicals in consumer products. As noted in our analysis, not only do laws implemented by the CPSC have serious limitations, but the key federal statute regulating chemicals in commerce – the Toxic Substances Control Act – is outdated and in need of reform as is the regulation concerning chemicals in cosmetics. The current structure of regulating toxic substances in consumer products is disjointed and fails to address the underlying problems posed by hazardous chemicals that end up in everyday products.

This troubling situation does not need to continue. A comprehensive solution to the limitations of current policies is to fundamentally reform the ways in which chemicals are designed and managed in commerce, which considers the inherent hazards of substances as well as their use in all types of products and their ultimate disposal. In the absence of federal leadership towards reforming chemicals management policies, several states have initiated their own reform discussions to address the intrinsic problem of toxic chemical hazards, not simply their use in specific product categories.

Despite the limitations of the current framework for regulating chemicals in consumer products, there is a growing recognition of the need for enhanced policies requiring safety data on chemicals in products, greater authority for agencies to act on uncertain chemical risks and incentives to design safer, more sustainable products that use safer chemistries.

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