

GLOBAL TRENDS IN CONSUMER PRODUCT SAFETY REFORM

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Product recalls, especially of imported products, skyrocketed throughout the developed world in 2007 and 2008. The acting chairman of the U.S. Consumer Product Safety Commission (“CPSC”), for example, dubbed the summer of 2007 the “summer of recalls.”¹ The spike in recalls created a perfect political storm—foreign goods posing actual or perceived safety risks to innocent domestic consumers, often children, against a backdrop of increasing skepticism toward free trade and, at least in the United States, the run-up to a presidential election.

For the first time in decades, consumer product safety was high on the political agenda, and governments seized the opportunity to adopt or propose significant legislative reforms. For instance, the United States enacted, on August 14, 2008, the Consumer Product Safety Improvement Act of 2008 (“CPSIA”); Canada is evaluating Bill C-6, the Canada Consumer Product Safety Act, first reading January 29, 2009²; and, while the European Union has not yet proposed far-reaching reforms of its General Product Safety Directive (“GPSD”),³



it is weighing significant reforms of Directives that cover specific industries, such as its new Toy Safety Directive, adopted on December 18, 2008.⁴

This article explores two broad issues. First, since most consumer products companies have a global reach, it is interesting to compare and contrast different facets of existing and proposed consumer product safety requirements:

1. Harmonization. To what extent do reform proposals serve the goal of increased harmonization of variegated consumer product safety standards?
2. Clarity. From a business perspective, increased clarity as to what is required, with respect to product features and performance as well as the procedures that apply to reporting and recalls, would be desirable. Do the various proposals offer clearer guidance?
3. Partnership. Historically, consumer product safety

efforts were a collaboration between business and industry. Do the recent legislative proposals enhance that partnership?

4. Enforcement. Are there trends with respect to enforcement, and if so, what do they augur?

Second, since businesses should at least start planning for how they can most effectively and efficiently comply with the new actual or proposed requirements, what practical suggestions might industry wish to consider?

HARMONIZATION

Increased harmonization of standards would be highly desirable from the perspective of global businesses. It is an explicit goal of the regulators themselves. See, e.g., "Memorandum of Understanding between the Healthy Environments and Consumer Safety Branch of the Department of Health of Canada and the Consumer

Product Safety Commission of the United States of America Regarding Cooperation Related to the Safety of Consumer Products,” June 22, 2005, at 1 (declaring as a purpose “to the greatest extent practicable, to make compatible their respective standards-related measures”). Nevertheless, the adopted and proposed reforms generally disserve the goal of increased global harmonization.

The new CPSIA in the United States, for example, adopted *total* lead standards for the surface coatings and substrates of children's products, eschewing the *soluble* lead standards which are favored throughout most of the developed world (EN 71 in the EU; ISO 8124 in most countries) and which are an attempt to limit exposure to safe levels using toxicologically derived health standards.

Likewise, the United States adopted limits on phthalates in children's products, even though risk assessments sponsored by U.S. government agencies had concluded that the substances posed little or no health risk as found in consumer products.⁵ And, while the newly adopted quantitative phthalate limits in the U.S. mirror those adopted in the EU and California, the standards apply inconsistently. In the EU, the standards for certain phthalates apply to those portions of toys and child-care articles, such as infant swings, that are capable of being mouthed by children aged three and under. Commission Decision 1999/815/EC (7 Dec. 1999). In the U.S., the new standards arguably apply to all parts of child-care articles, including inaccessible parts that pose no hazard. CPSIA, § 108(a), (b)(1).

CLARITY

From the perspective of business, clear safety standards and procedures would be preferable to ambiguous ones, particularly when violations can give rise to significant penalties.

With respect to safety standards, the CPSIA in the U.S. relies on them to a significantly greater degree, at least for products intended for children aged 12 and under. For example, under the CPSIA, the ASTM F963-07 voluntary standards will become mandatory.⁶ The vast majority of consumer products, however, remain subject to the U.S. catchall standard requiring recalls for products possessing a “defect” that creates “a substantial risk of injury to the public” (15 U.S.C. § 2064).

Products covered by specific directives in the EU are also subject to a range of specific, relatively clear standards. The GPSD generally requires all products to be “safe”; a “safe” product is defined as one that, under reasonably foreseeable conditions of use, presents no risk or only minimal risks compatible with the product's use. GPSD, Art. 5(3) and Annex 1(2).

Canada relies heavily on specific, relatively clear rules embodied in Schedules 1 and 2 to its statute. C-6 § 30(1) proposes, however, to adopt a U.S.-style general provision allowing the government to compel recalls where there are “reasonable grounds” to believe that “a consumer product is a danger to human health or safety.”

Application of these general criteria to specific circumstances may be ambiguous, particularly in the absence of well-developed case law such as that which informs common-law tort standards. The problem is compounded in two ways.

First, industry reporting obligations are triggered by the actual or constructive receipt of information that reasonably supports the conclusion that there has been a violation of these general, ambiguous standards. 15 U.S.C. § 2064(b), 16 C.F.R. § 1115.12; C-6 § 14(1); GPSD, Art. 5(3) and Annex 1(2). As the acting chairman of the U.S. Consumer Product Safety Commission candidly testified on June 6, 2007, before the U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Commerce, Trade, and Consumer Protection, the reporting obligation “is written in very broad and somewhat imprecise terms and requires... judgment calls about its applicability in specific cases.”

Second, these “judgment calls” will be examined by government authorities with the benefit of 20/20 hindsight to determine whether significant potential civil and criminal penalties should attach to the failure to timely report to government authorities as well as the marketing of products that violate these general standards. For example, the maximum civil penalty for violations in the U.S. has been increased to \$15 million, and the maximum criminal penalty includes up to five years' imprisonment. 15 U.S.C. §§ 2069 and 2070. See *also* C-6 §§ 46–48, 38–45; GPSD, Arts. 7 and 18(3).

PARTNERSHIP

Given scarce resources, government regulators the world over rely heavily on industry to report when products need to be recalled. Canada, for example, currently has no mandatory reporting obligation (unless a recall is required) or power to order recalls of consumer products. Most countries' regulators, moreover, have limited capacity to monitor the millions of consumer products on the market, and they only modestly supplement industry reporting, by collecting data on product-related hospital emergency visits and fielding consumer reports of unsafe products.

This system of industry reporting has worked well. Indeed, of the spate of recent recalls, the overwhelming majority were initiated as a result of industry reporting to authorities—not because of increased government surveillance, not because of inadequate safety standards, not because of manufacturers' exerting “undue influence” on proprietary testing laboratories to color their results, and not because of insufficient enforcement powers. Generalizations are difficult because the facts of individual recalls vary and the precise circumstances giving rise to a recall are often subject to salutary confidentiality protections, but it appears that the increased recall activity generally was due to inadequate design and/or inadequate control of the supply chain, particularly for goods manufactured in China.

A sensible legislative response would be to require technically competent design review and testing of representative samples of finished goods (or their components and raw-material inputs) for compliance with applicable safety standards and adherence to product safety design specifications. Recent legislative proposals generally do not do this. The CPSIA requires third-party testing for and certification of compliance only for “children's products” and only as to mandatory safety standards. CPSIA, § 102(a). The EU's GPSD only generally requires producers to adopt measures for becoming informed of risks their products might pose, including, “where appropriate,” sample testing. GPSD, Art. 5(1). And Canada neither has nor proposes a general system of design review or compliance testing and certification as to even mandatory standards, except by order of the Minister of Health in specific circumstances (C-6 § 12) and indirectly by

making “due diligence” a defense to potential criminal penalties (C-6 § 38(2)).

Instead of addressing what appear to be the root causes of the recent surge in consumer product recalls, reform proposals focus predominantly on other issues and suggest a disturbing distrust of industry. This trend is reflected through: (1) new mandatory standards (CPSIA, § 106) without any substantial evidence that voluntary standards have been ineffective and sometimes without adequate scientific support; (2) significantly increased civil and criminal penalties, including forfeiture (CPSIA, § 217), that, as the acting chairman of the U.S. CPSC has observed (June 6, 2007, testimony, *supra*), threaten to lead to less cooperation and more litigation between industry and regulators; (3) protections against potential “undue influence” by manufacturers or their third-party testing laboratories (CPSIA, § 102(b)) without evidence that this has been a problem; (4) “whistleblower” protections (CPSIA, § 219) that encourage employees to report perceived violations by their employers without evidence that employers significantly underreport violations; and (5) as discussed in the next section, stepped-up governmental enforcement. See, e.g., CPSIA, §§ 216, 217, 218, 222.

ENFORCEMENT

Most of the current reform proposals anticipate stepped-up enforcement. Canada, for example, proposes to designate “inspectors” with broad powers to prevent, punish, and remedy perceived violations. C-6 §§ 18–34. In addition to an expanded budget, an increased presence at U.S. ports, and the ability to impose new and stiffer penalties for an expanded array of violations, the CPSIA gives state attorneys general the authority to enjoin certain alleged violations and to retain private counsel to act on their behalf in exchange for statutorily permitted attorneys' fees. 15 U.S.C. § 2073(b).

Unlike the proposed Canadian inspectors, state attorneys general are political officers, they are not under the supervision of national regulators, and their decisions are not subject to review by national regulators.

In short, there is a real risk that product safety issues may become increasingly politicized and that different courts will

adopt different or even conflicting interpretations of what the law requires.

PREPAREDNESS

In light of the enacted and proposed reforms, are there steps that industry might take to minimize risk?

First, the adage that an ounce of prevention is worth a pound of cure seems apt. There are principally two areas on which industry might wish to focus: product design and manufacturing.

As to design, global consumer products companies should design their products to meet the most stringent mandatory safety standards that apply wherever their products are sold. To the extent that there are safety issues that are not addressed by mandatory standards, designs should be subjected to a safety review to avoid or minimize foreseeable risks.

As to manufacturing, manufacturers, particularly those that rely on third-party vendors in the developing world, should consider implementing quality assurance systems. The systems should test for conformity to all product safety requirements, not just mandatory standards, with adequate recordkeeping. To the extent that manufacturers rely on their vendors to perform the testing, they may wish to conduct process audits to ensure that the testing is performed.

Second, companies should attempt to minimize the threat, discussed earlier, of substantial penalties for a failure to timely report under “imprecise” standards that require “judgment calls” subject to Monday-morning quarterbacking by regulators. Companies should consider collecting and consolidating data from consumer reports and implementing periodic review for emerging safety issues by appropriately senior personnel. They might also want to consider whether it would be advisable to adopt or adapt the U.S. CPSC’s Retailer Reporting Model, whereby retailers are deemed to comply with their reporting obligations by automatically sending certain consumer report data to government regulators once thresholds, which are defined by the frequency and severity of the risk or injuries, are met. See, e.g., <http://www.cpsc.gov/BUSINFO/Retailreport3805.pdf> (last visited Feb. 2, 2009).

Third, companies should institute internal procedures that quickly elevate safety-related issues within the company to management for action.

Finally, companies should participate in the political and regulatory processes. Once established, government regulation of the kind evidenced in the current wave of reform proposals typically progresses incrementally over the long haul. In short, the recent reforms are unlikely to be the last and, once adopted, often will require administrative regulations to effect their implementation. It is important that industry members communicate to legislators and regulators their perspective on product safety issues and how problems can be most effectively and efficiently avoided or minimized. ■

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¹ Kevin Drawbaugh, “Toy Recalls Fuel Momentum Toward U.S. Safety Reforms,” Reuters, October 4, 2007.

² C-6 is available at: <http://www2.parl.gc.ca/HousePublications/Publication.aspx?Docid=3633883&File=14>.

³ Directive 2001/95/EC (15 Jan. 2002).

⁴ Directive 88/378/EEC (3 May 1988); new Directive, P6_TC1-COD(2008)0018 (18 Dec. 2008) at <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P6-TA-2008-0626>.

⁵ These include a number of risk assessments conducted under the U.S. National Toxicology Program, an interagency program involving the National Institutes of Health, the Centers for Disease Control, and the Food and Drug Administration, as well as a 2002 safety assessment by the Consumer Product Safety Commission. Based upon that assessment, the CPSC declined to take action on a petition to ban phthalates in children’s toys.

⁶ Some of these new standards may require further refinement through the regulatory process—e.g., what parts of children’s products are “inaccessible” and therefore exempt from the new lead standard for substrates?