



Safety First

by Eric Stone

Improved Consumer Protection Presents Corporate Challenges

In 2007, public outrage following the high-profile recalls of children's toys containing lead, hazardous cribs and many other products forced Congress to act. Voices far and wide spoke out against the regulatory failures that allowed dangerous goods to hit the shelves, and the U.S. Consumer Product Safety Commission's (CPSC) was the obvious target of scorn. The media questioned CPSC's commitment to protecting the public. Legislators bemoaned the watchdog's lack of authority and resources. Consumer groups assailed its effectiveness.

After months of constant criticism and deliberation, Congress passed the Consumer Product Safety Improvement Act of 2008 (CPSIA), amending the various statutes administered by the commission, broadening the agency's authority and granting greater resources for it to carry out its mission.

New legislation often creates new obligations and risks for the regulated. CPSIA is no exception. And the stream of regulations and interpretations that have followed over the past 18 months have left many companies unsure whether or not their compliance efforts are still up to par.

It is hard to fault them for their uncertainty. This still-evolving regulatory scheme creates an array of new—and, at times, ambiguous—obligations for consumer product firms, raising the stakes for those who fail to meet the stronger stipulations put into place after "The Year of the Recall" (2007).

Of course, ignorance is not an excuse. Every risk manager in the retail, manufacturing or shipping industries must now be aware of these requirements, understand the magnitude of noncompliance and have systems in place to minimize that risk.

Back in 2007, the CPSC was a lilliputian outpost with fewer than 400 employees. But despite its tiny size, the CPSC had broad authority over approximately 15,000 products for sale to consumers. CPSC could recall hazardous products; penalize those who violated CPSC laws, bans, standards or orders; seize noncomplying products distributed in commerce; and refuse admission to—or even seize—hazardous products at the port of entry, with the assistance of Customs and Border Protection. The commission also required manufacturers to certify that their products complied with its standards.

But when the CPSIA was passed in 2008, it not only allocated more resources for the commission but also greatly extended its authority. The effect was that much of the compliance burden shifted onto the backs of the regulated. Product manufacturers

rules under any of the CPSC's acts. Domestic manufacturers (for U.S.-made products) or importers (for foreign-made products) must now certify their products based on either a test of the individual product or based upon a "reasonable testing program."

By separate rule, the commission has determined that importers must certify any products based on testing conducted before importation of the product. Certification must be in English, accompany the product (or be available electronically) and be available to the commission at the time the product enters the country. (CPSC has posted the format and content for a certificate of compliance their website at www.cpsc.gov.) In implementing regulation for product certification, the CPSC also "recommended" that records supporting the certificate be maintained for three years and be available for inspection.

old for selling products in the United States. Failure to certify and test allows Customs and the CPSC to allow entry of an imported product into the country, which can also mean injunctions against sale, or seizure of, a product in cases where there are severe penalties for violating the certification and testing requirements. Providing a false certification or attempting to unduly influence a third party conformity assessment firm can also lead to civil penalties—or even criminal prosecution. The CPSC has been working on the process of establishing standards for such conformity assessment bodies and certifying labs to test products for each standard, ban and similar rule.

Because testing to support certification must be done on either each individual product or based on a "reasonable testing" program, and be done before the product arrives in the United States (or is distributed in domestic com-

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and importers, for example, must now test and—most importantly—certify product compliance before a violation is recorded.

Previously, this certification requirement did not apply to many of CPSC's bans. Nor did it apply to many standards, bans and other requirements under the other laws that Congress transferred to the CPSC with the passage of CPSIA, including the FHSA, FFA, PPPA or RSA. Known collectively as the "transferred acts," these other laws included requirements for children's products, fireworks, hazardous chemicals, flammability of clothing/textiles, hazard labeling and child-resistant packaging. All of these areas were now fully under the authority of the CPSC.

The CPSIA also extended the certification requirement to manufacturers and importers of products subject to any of the standards, bans and similar

At the time of this writing, the CPSC was in the process of developing a series of guidance documents and rules to define what kind of testing is necessary for a "reasonable testing program." The staff's position was that, at a minimum, such a program include the following elements: development of product specifications; certification testing to prove the product, as designed, complies; a plan for testing of the product during production; a system for remedying problems; and full documentation of all these efforts.

In addition to this certification scheme, Congress imposed additional testing requirements on manufacturers of children's products. New rules require manufacturers or importers to obtain third party testing by a CPSC-accredited conformity assessment body to back up their certification efforts.

The certification and third party testing requirements set a thresh-

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Ramping Up Child Safety

In drafting the CPSIA, no area received more attention from Congress than children's products. Although the CPSC already had authority to ban certain chemicals in children's products if they presented an unreasonable risk of injury, legislators intervened to require the CPSC to take action against previously unregulated compounds that Congress perceived to present a risk.

By definition, a "children's product" is any consumer product designed or intended primarily for the use of children 12 and under. A "children's toy" is any item designed or intended for use in play by a child 12 and under. And a "child care item" is anything designed or intended to facilitate sleep or feeding

for, or used for sucking or teething by, a child three-years-old and under.

Congress imposed a ban on “children’s products” with more than 600 parts per million lead, which went into effect on February 11, 2009. (That amount decreased to 300 parts per million by August 14, 2009, and will be reduced to 100 parts per million by August 14, 2011, if such levels prove “technologically feasible.”)

CPSC has listed some materials that

Hazard Reporting and Recalls

In the CPSIA, Congress broadened the reporting requirement beyond CPSA standards and bans. Now firms must report violations of any CPSC standard, or ban or “similar rule,” under any of CPSC’s statutes. The CPSC expects prompt reporting and is prone to exercising “20/20 hindsight” in second-guessing a firm’s processing of safety information and decision making about reporting. This means that firms must

tribution of, certain hazardous products. Under this provision, CPSC may identify “substantial hazards” based on observable product characteristics, where the risk has been addressed by a voluntary standard, and where such voluntary standards have been effective at reducing injury and there is substantial compliance with such voluntary standards. The CPSC has already discussed using this new authority for voluntary standards that apply to drawstrings in children’s garments and hair dryers with immersion protection devices that prevent electrocution. And this may be just the start of things to come. The CPSC now has its choice of possibly hundreds of voluntary standards it could make mandatory via this process in the future.

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it believes do not contain significant levels of lead, and it has devised exclusions for some other components permitted to contain lead or those only showing safe levels (for example, certain electrical products). But CPSC has refused to exclude many children’s products that probably cause little risk because Congress only allows exclusions if there is no absorption of “any” lead.

The CPSC has chosen to read the word “any” literally—despite arguments from industry—as opposed to interpreting it as “enough lead to cause health effects.” Due to this, many children’s products that contain brass or other materials that contain lead are now banned.

In further efforts to “get the lead out,” Congress decreased the legal limit for lead in paint and surface coatings in an existing CPSC ban from 600 ppm to 90 ppm as of August 14, 2009. But lead was not the only major compound that legislators sought to outlaw.

Congress also imposed a ban (which also went into effect on February 11, 2009) on “children’s toys” or “child care items” that contain certain phthalates, which are plasticizers used most commonly in PVC plastic. This provision prohibits more than 0.1% of certain phthalates in children’s toys or child care items.

have good systems for channeling all product safety information to an individual or group that can evaluate the information in light of the reporting obligation. Further, firms must maintain good records of such consideration to show that careful consideration of the statutory factors took place.

Congress also enhanced the CPSC’s recall authority to include all the products regulated under the CPSC’s various laws. To address past disputes with firms over remedies, Congress eliminated a provision that allowed firms to unilaterally elect to repair or replace a

New Import Provisions

The original CPSA import provisions required the refusal of admission for noncomplying products. Under the CPSIA, Congress now expresses a preference for the destruction of noncomplying products. While Customs may decide to allow the re-export of products that are refused admission into the United States, if those products are not re-exported within 90 days, they must be destroyed.

The CPSC now also works with Customs and Border Patrol to set higher bonds to insure that the cost of

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product, or to provide a refund. Now, the CPSC has the final say on what an acceptable remedy must be. The CPSIA also broadens the public hazard notification requirements and provides for the enforcement of even voluntary recalls.

Congress created an innovative new tool to enhance the CPSC’s ability to prevent entry into commerce, or dis-

destruction is provided for. The law also requires companies to at least consider using a bond or insurance to cover the costs of potential product recalls.

Under the CPSIA, CPSC must work with CBP on risk assessment techniques to target hazardous imports. To this end, CPSC and Customs have increased their information sharing capabilities, most noticeably by placing

CPSC personnel in Custom and Border Patrol's National Targeting Center. The CPSC has already created a new Import Surveillance Division within its Office of Compliance and Field Operations and placed investigators at ports of entry, and CPSC may now refuse entry to products of firms that have not cooperated with inspections.

Heightened Enforcement

Along with strengthening child safety, CPSC has also bolstered its bottom line—through increased enforcement and fines. It raised the ceiling on civil penalties from a maximum of \$1.825 million to \$15 million for any related series of violations. It also created a much more onerous criminal penalty scheme under the various statutes. Violations of CPSC rules that were previously misdemeanors have been converted to felonies.

Even more significantly, Congress lowered the standard to obtain criminal penalties. CPSC can now seek forfeiture of assets “associated with the violation.” In the past, Congress has typically only

applied asset forfeiture to more nefarious criminal enterprises such as drug trafficking.

Congress also granted individual state attorneys general authority to enjoin violations of CPSC's laws. State attorneys general must first notify the CPSC

the CPSC has been given the authority to become a much more vigilant—and aggressive—watchdog. Although the CPSIA has not been fully interpreted or implemented, it is evident that the law dramatically broadens the CPSC's authority and creates many new obliga-

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at least 30 days in advance, except in the case of substantial hazards, from which they can file a case immediately. The CPSC may intervene in such cases but is not required to do so. Such attorney general actions are only restricted if the United States has already filed a civil or criminal action regarding the same violation.

Committing to Compliance

In the wake of “The Year of the Recall,”

tions for the regulated.

Firms not only must comply with new rules but also certify that they are doing so. Congress has provided for a rapid implementation scheme that requires CPSC to write many new rules over the next several years. This means that companies must keep track of new developments to ensure that they have sufficient time to adjust to new requirements and changes in enforcement.

At a minimum, risk managers must

ALL MY CHILDREN

As with most things involving safety, much of the momentum that gave the Consumer Product Safety Commission (CPSC) broader authority and stronger enforcement backing was created by kids getting hurt. Children's toys and babies' cribs were found to contain lead, and parents and consumer groups decided that it was time to ramp up protection. Now, according to one group of doctors, there is another menace threatening the nation's offspring: food.

In February, the American Academy of Pediatrics (AAP) released a policy statement on choking prevention for children that highlighted hot dogs, carrots and hard candy as major dangers to the youth of America. According to the statement's lead author, Dr. Gary Smith, a child dies from choking on food every five days in the United States, and 17% of the kids under 10-years-old who die are killed by hot dogs being lodged in their throats.

In an interview with *Time*, Dr. Smith broke down exactly why the hot dog is such threat. “If you were to take the best engineers in the world, and you said to them, ‘design for me the perfect plug for a child's airway,’ you couldn't do better than a hot dog,” he said. “Unfortunately, it's exactly the right shape of the airway, it's the right diameter—it forms a plug, completely sealing off the upper airway...It's almost impos-

sible to dislodge. Then it's only a matter of minutes before there is irreparable brain damage and even death.”

In addition to “redesigning” man-made foods such as hot dogs, marshmallows and candy, the AAP cites the CPSC's National Electronic Injury Surveillance System (NEISS), which monitors emergency rooms visits caused by consumer products, as an example of how choking hazards can be better managed. By analyzing NEISS data, regulators are able to determine which consumer products are truly dangerous. Injury and death records are highly detailed and tell officials whether or not a boy was hurt by a Tonka dump truck or a hula hoop made by Mattel. Through its database, any trends are easily noticed and action can be taken.

By contrast, the FDA and the Department of Agriculture, which regulates meat products, including hot dogs, does not maintain such thorough data. According to Smith, the most they usually ever find out on a systematic basis is that a child died of “choking on food.”

Without better information, it will be hard to determine if hot dogs and other inconveniently shaped foods are a true threat to our nation's children or if learning to swallow properly is just an inevitable hazard of youth. You gotta eat, right?

—Jared Wade

evaluate their systems to ensure all of the companies processes are in compliance. An ideal system starts with a high level of corporate commitment to compliance. Within any organization, a person or group should become familiar with the CPSIA and be responsible for compliance activities. Training programs for employees who participate in product development, purchasing, packaging or marketing processes will be crucial, as will careful selection of reputable suppliers that have demonstrated the ability to comply with all requirements.

Supplier agreements must build in safeguards to ensure a high compliance level is maintained, products are tested as required, adequate records are maintained, complaints are handled and reviewed to insure that problems and supplier manufacturing practices are monitored properly. Further provisions may also be in order, including those limiting the liability of the firm, providing for insurance and building in other safeguards.

Finally, firms must ensure that they have a system in place to properly evaluate safety information and, as necessary, elevate it to those with the authority to cut through red tape and fix problems promptly. Such safety information must not only be evaluated with an eye toward reducing overall liability but also with a focus on the reporting requirements.

Generally speaking, firms should also have procedures to consider whether a product recall or other corrective action is necessary. Ideally, a firm would have a “recall contingency plan,” or, at least, access to experienced legal, technical, logistics and public relations professionals who can work with the firm to rapidly assess a product hazard and develop a corrective action plan.

If one thing has become clear during this wave of products recalls in recent years, it is that Congress and the CPSC are now taking product safety more seriously. Now, companies must as well. ■

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