

To Test or Not to Test: *Managing Increasing Toxic Substance Regulations*

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In an effort to protect consumers from toxic chemicals, legislators, scientists, environmental advocates, and businesses have been making great strides in identifying harmful ingredients and enforcing regulations to limit exposure. As children are most vulnerable to the effects of toxic chemicals, it is no wonder that toys fall under particular scrutiny.

Toy manufacturers, along with importers, distributors, and retailers, have been operating in an uncertain regulatory environment. New chemicals are continually added to the lists of harmful substances, and, in addition to the federal laws regulating their use, many states are adding their own rules, affecting all businesses that manufacture or sell within the state.

Federal Regulations

A number of federal laws regulate toxic substances in consumer products, including toys. The Toxic Substances Control Act of 1979 provides the Environmental Protection Agency with authority to require reporting, record-keeping, testing requirements, and restrictions relating to chemical substances and/or mixtures, such as polychlorinated biphenyls, asbestos, radon, and lead-based paint.

Passed by Congress in July 2008, the Consumer Product Safety Improvement Act limits the amount of lead and phthalates allowed in children's toys and child care articles.

The American Society for Testing and Materials International F963 Standard regulates eight heavy metals found in toys: antimony, arsenic, barium, cadmium, chromium, lead, mercury, and selenium.

State-Specific Regulations

In addition to federal laws, many states are pioneering their own toxic substances legislation. This year, proposed

legislation agendas include classification of chemicals harmful to children in 13 states and a ban on cadmium in children's products in four states.

California's Proposition 65

In toxic substance regulations, California leads the way with its Proposition 65. In effect since 1986, it now lists more than 850 chemicals considered cancerous or responsible for causing reproductive harm. Companies may not expose Californians to these chemicals without providing a "clear and reasonable warning." Companies that fail to provide notices face civil penalties as high as \$2,500 per violation per day.

Prop 65 is enforced when legal action is brought against a business that has allegedly discharged a listed chemical into a source of drinking water. The state government office, as well as private individuals acting in public interest, can serve a 60-day notice of violation to any business suspected of breaking the law. Many retailers now require their suppliers to be compliant with listed Prop 65 settlement limits. However, testing a product to an existing settlement will not grant businesses immunity from potential notices; it only reduces the risk.

California's Green Chemistry Program

In addition to Prop 65, the California Department of Toxic Substances Control is putting finishing touches on its Green Chemistry Program. The DTSC released the informal draft for public comment last October and plans to finalize the regulation later this year. Manufacturers, importers, and retailers will all be responsible under the proposed law.

The initiative expands the list of Chemicals of Concern to roughly 3,000 and imposes extensive risk and life-cycle

analyses for prioritized products. The required analyses may lead to limitations on the use of certain chemicals, reformulation requirements to eliminate targeted chemicals, or the outright ban on sales of certain products in California.

The alternative assessment process, intended to promote the development of safer, alternative products, will require manufacturers to select an alternative chemical to replace a hazardous one. As another option, they can decide to discontinue distribution of the product within the state.

Washington's Children's Safe Products Act

The first deadline to report harmful chemicals in children's products is this August for the Children's Safe Products Act, a law imposed by the Department of Ecology of the State of Washington. Established in 2009, it lists 66 substances as Chemicals of High Concern to Children. Similar to the Green Chemistry initiative, it holds importers and distributors of toys just as responsible as manufacturers.

A responsible party is required to notify the state if a compound is intentionally added with a concentration greater than the Practical Quantitation Limit. Likewise, if the manufacturer uses a quality control program designed to minimize the presence of contaminants related to these chemicals, it need not test its finished products. It will need to present the quality control information if the government tests the products and finds a chemical on the CHCC list at a level higher than 100 ppm. Recently introduced legislation will also prohibit toys from containing more than 100 ppm TRIS (Tri[2,3-dichloropropyl phosphate]).

The reporting deadlines are tiered according to the type of products and amount of sales. The largest manufacturers of products likely to be placed in a child's mouth or on their skin, or products for children ages 3 and under, must report first.

To Test or Not to Test?

It is not cost-effective or practical to test every product for all of the chemicals in an effort to comply with each state's specific regulations. Toy manufacturers need to determine which regulated chemicals are likely to be present in their products and test for the ones that pose the highest compliance risk. Partnering with a reliable testing laboratory will help determine the substances of high concern for

a particular toy product and distribution market.

Toxic chemicals most often found in toys include lead, cadmium, and phthalates. Therefore, toy manufacturers are well advised to test for them. It is also helpful to keep the following in mind:

- Metals do not need to be tested for phthalates;
- Cotton fabric does not need to be tested for lead;
- Nylon does not contain BPA;
- Chlorine-free products do not need to be tested for vinyl chloride, methylene chloride, pentachlorobenzene, or hexachlorobutadiene.

Manufacturers are responsible for maintaining a database for all their products and should track all ingredients and raw materials used in the production process via detailed records, including Material Safety Data Sheets.

It can be beneficial to monitor recent trends of settlements, notices, and recalls to identify areas of concern, collect information on individual formulation constituents, and create a risk matrix of chemicals for each product type.

To keep up with the ever-changing regulations, manufacturers, importers, distributors, and retailers need to have an in-house regulatory or product safety/quality team, or work with an independent laboratory, consultant, or agency that monitors regulations and standards updates. This is especially true when toys are imported to or exported from the U.S., as international product safety regulations and standards change daily.

As state legislators address their constituents' requests to reduce the use of hazardous substances in products, toy businesses need to comply with increasingly complex and fragmented regulations. Tracking ingredients used in toys, testing for the most frequently found hazardous ingredients, keeping up with the industry developments, and working with a knowledgeable compliance partner can ease the compliance journey significantly. ■

Cheryl Rieser, director of global business development for TÜV Rheinland, has 15 years of experience in consumer products, quality assurance, technical support, and global key account management. She is experienced in international consumer product safety regulations and standards, as well as how they influence product design and manufacturing.