

## Product Safety in a Global Market

By James M. Meister and Mark A. Kinzie

Compliance with governing regulations is but one aspect of the overall product safety regimen. This becomes more difficult when a product is sold in several countries, particularly when coordinating the overlapping requirements of performance testing, use of hazardous substances, and assessing health and safety risks. Below are a few international regulations to evaluate in the schedule of regulatory compliance.

### Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH)

The EU's new regulatory framework for chemical substances, Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) (Regulation EC No. 1907/2006) is governed by the European Chemicals Agency (ECHA). Under REACH, an industry must register with ECHA a broad scope of chemical "substances" that are either manufactured in or imported into the EU. (REACH, Title II.) Although manufacturers and importers have an obligation to register substances, REACH treats "articles," i.e., finished goods, differently. Registration of articles and their substances is required where the article releases substances that present risks to human health or the environment. (REACH, Article 7.) Because the test is a "release," the regulation impacts everything from a pen to textile fragrances to an aerosol deodorizer. (Id.)

REACH also controls the risks presented by Substances of Very High Concern (SVHCs). Substances are listed as SVHCs where scientific evidence demonstrates that they cause

probable, serious effects to humans or the environment. SVHCs may present as carcinogens, mutagens, reproductive toxins, and endocrine disrupters. (REACH Article 57.) Ultimately, SVHCs will be replaced with safer, feasible alternative substances. (REACH Articles 55 to 59.) Approximately 20 substances are currently listed by ECHA as SVHCs.

### Canada Hazardous Products Act (HPA)

The Canadian Hazardous Products Act (HPA) governs both general and specific product safety provisions. (R.S., 1985, c. H-3 (2000)). HPA creates 3 classes of products: (1) Prohibited products, which are expressly excluded from advertisement, import, or sale; (2) Controlled products, which are not prohibited but are inherently dangerous products generally identified in the HPA and specifically identified in Canadian regulations; and (3) Restricted products, which are not inherently dangerous but may pose a risk of harm to consumers who warrant additional protections. (id.; Schedules I-II.)

Canadian law is changing. This year, the Canadian Parliament is considering the Canada Consumer Product Safety Act, Bill C-6 (similar to the 2008 Bill C-53). This legislation proposes to modernize Canada's product safety laws through stronger oversight, compliance, and enforcement actions. Health Canada will have new authority to order the recall of unsafe products and to stop importation of production at the border via the Canada Border Service Agency. (s. 33(2) (a).) Other regulations, including new classifications

of hazardous products, including lead and BPA, are also controlled by the proposed Safety Act. The Safety Act passed the House of Commons on June 12, 2009, and awaits consideration by the Canadian Senate.

### General Product Safety Directive (GPS)

The EU's General Product Safety (GPS) Directive is an EU New Approach Directive that requires "producers" place only "safe" consumer products on the market in the EU. (92/59/EEC; Article 1.1.) The GPS Directive defines a "safe product" as "any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, . . . does not present any risk or only the minimum risks compatible with the products use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons..."

(Article 2(b).) A product that does not meet this definition is a "dangerous product." (Article 2(c).) The GPS Directive sets general standards for "safe" and "dangerous" products, based upon reasonable expectations of safety and risks presented by the use of the products. The GPS Directive covers risks related to human health and safety, including chemical, mechanical, thermal, electrical, noise and flammability risks. It does not govern health risks to the environment, animals, or plants.

The GPS Directive applies only to "consumer products," i.e., products intended for consumers, as well as those products that, "under reasonably foreseeable conditions," are likely to be used by consumers, even

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if not intended for them. (Article 2(a).) Although there is no definition of “consumer” in the GPS Directive, the Directive’s Guidance explains that consumers are persons acting in their personal capacity in the market, and not individuals or legal persons acting in a professional capacity. (See Guidance Document, Section 2.2 (November 2003).)

### Low Voltage Directive (LVD)

The Low Voltage Directive (“LVD”) is an EU New Approach Directives that provides EU health and safety requirements covering all risks in ensuring in certain electrical equipment designed for use with a voltage rating of between 50 and 1000 V for alternating current and 75 to 1500 V for direct current based upon rated input or output voltage. (2006/95/EC) These risks address electrical mechanical, chemical, and other risks directly associated with the product and include risks to persons, domestic animals, and property. Generally, the LVD covers consumer and capital goods, including electrical appliances, lighting equipment, switch gear and control gear, electric motors, electrical wiring, appliance couplers, cord sets, and electrical installation equipment. The health aspects of emissions of most electromagnetic fields are also under the domain of the LVD. Compliance with the LVD allows sale in the EU and proper application of the EU’s “CE” mark.

### Restrictions of Hazardous Substances Directive (ROHS)

The EU Directive on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (EU RoHS) applies to

“electrical and electronic equipment” which is “equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields. . .” (2002/95/EC) (Article 3(a)).

EH RoHS restricts the use of six hazardous materials in the manufacture of various types of electronic and electrical equipment, which are lead, mercury, cadmium, hexavalent chromium (Cr6+), polybrominated biphenyls (PBB), and polybrominated diphenyl ether (PBDE). Maximum allowable concentrations for these substances are 0.1%, except for cadmium, which is more tightly limited to 0.01%, by weight of homogeneous material. The “homogenous material” measurement in the Directive means that the concentration limits do not apply to the overall weight of the finished product. Instead, allowable concentration limit apply to any single substance that may be separated from the finished product. All items identified as a homogeneous material must meet the allowable Directive limits.

Several RoHS Directives exist, but no two are the same. A few of these Directives are: California RoHS, Cal. Health & Safety Code. §§ 25214.9–25214.10.2.; China RoHS (1-Mar-07); Japan RoHS, Notification No. 1, Law No. 48 of 1991, (01 April 2001); Korea RoHS, Bill Nr. 6319 (02 April 2007); EU Proposed Directive, RoHS2, Decision 768/2008/EC, 2009 New Legislative Framework.

### Waste Electrical and Electronic Equipment (WEEE)

Waste Electrical and Electronic Equipment (WEEE) began on February, 2003 to facilitate the proper disposal, collection, reuse, recovery, treatment, and recycling of electrical and electronic equipment. (2002/96/EC) (WEEE, Article 5). The Directive requires EU Member States to adopt laws to ensure that producers and distributors of WEEE products are responsible for the product as waste and that it can be returned to a distributor or collection facility. (Id.)

WEEE covers all electrical and electronic equipment used by consumers and intended for professional use. (WEEE, Article 2.) WEEE covers equipment under 1000 Volts AC that is “dependent on electric current or electromagnetic fields in order to work properly, and equipment for the generation, transfer and measurement of such currents and fields.” (WEEE, Article 3(a).) Products properly within the WEEE scope must be labeled with a crossed-out wheeled bin.

RoHS Directives differ from the WEEE Directive. WEEE set targets for collecting, recycling, and recovering electrical and electronic goods to reduce toxic waste. RoHS Directives restrict the use of six hazardous materials manufactured into electrical and electronic equipment.

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