

## **A Patent Attorney May Be a Good Source for Technical Expertise Associated with Product Compliance**

Consumer product labeling laws often raise technical issues similar to those that patent practitioners are trained in and deal with on a daily basis. In just one example, a company developing products containing certain chemicals and chemical compounds may seek patent protection for those products through a qualified patent attorney. At some point during the patent process, the company will also likely review those chemicals or chemical compounds, for example, to determine if any specific labeling is required for their associated products. Counsel with particular technical expertise may provide assistance both in the protection of such a company's intellectual property and in providing guidance as it relates to proper product labeling. For example, counsel may readily identify various chemicals for their potential reactions and recognize the potential that a finalized consumer product may be subject to labeling laws. The earlier this identification is made, the more cost effective the labeling compliance will be for the company.

Consumer products are regulated by the Consumer Product Safety Commission ("CPSC") in order to evaluate potential hazards that may be inherent to the consumer product in question. The CPSC was created by the Consumer Product Safety Act ("CPSA"), adopted in 1972 in an effort to be the gatekeeper in assessing consumer products that may pose a higher risk of personal injury to the consumer.<sup>1</sup> Regarding the above example related to products containing chemicals and chemical compounds, the CPSA also transferred authority to the CPSC to assess products under the prior Federal Hazardous Substances Act ("FHSA").<sup>2</sup> To maintain compliance with the FHSA, relevant consumer or household products should be evaluated to determine whether the chemical compound(s) in use should be classified as a hazardous substance. The FHSA<sup>3</sup> includes specific guidelines regarding the presence of a "hazardous substance" in a consumer product, which is defined as:

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 reasonable foreseeable ingestion by children.<sup>4</sup>

One method of determining whether a chemical or chemical compound(s) satisfies the definition of "hazardous substance," and thus requires compliance with proper labeling requirements, is the Hazardous Materials Identification System ("HMIS") provided by the National Institute for Health.<sup>5</sup> The HMIS assess three categories: health, flammability, and reactivity, each on rating scale 0 to 4, with 4 being the highest level of severity for each category.<sup>6</sup> Each of these categories correlates to criteria in the FHSA that are used to define a hazardous substance.

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<sup>1</sup> 15 U.S.C. § 2051-2084 (1972).

<sup>2</sup> 15 U.S.C. § 2079.

<sup>3</sup> 15 U.S.C. §§ 1261 et seq.

<sup>4</sup> FHSA, 15 U.S.C. § 1261(f)(A).

<sup>5</sup> See HAZARDOUS MATERIALS IDENTIFICATION SYSTEM, available at [https://tools.niehs.nih.gov/wetp/public/Course\\_download2.cfm?trandid=1483](https://tools.niehs.nih.gov/wetp/public/Course_download2.cfm?trandid=1483).

<sup>6</sup> *Id.*; For example, chemicals classified as a level 1 for flammability are those that "require considerable pre-heating under all ambient temperature conditions before ignition and combustion can occur. These chemicals include

If a chemical or chemical compound(s) contains a hazardous substance, then the FHSA requires that a “cautionary statement”<sup>7</sup> be written on the product containing the hazardous substance, such that the potential dangers associated with the product are conspicuous to the consumer.<sup>8</sup> For example, the warning must appear on the principal display of the packaging and be blocked together within a square or rectangular area.<sup>9</sup> This clear separation allows the consumer to easily identify and distinguish the warning and hazardous material from any surrounding instructions, general descriptions, and/or business information.

In addition to the concerns raised by products that may include a hazardous substance, the CPSC expanded on the protections of the FHSA to additional categories of “regulated products”. These “regulated products” are deemed to pose a higher risk of personal injury when compared to consumer products in general.<sup>10</sup> By way of example, some “regulated products” include infant bath seats, bicycle helmets, bunk beds, and caustic poisons. Products classified as a “regulated product” must comply with category-specific CPSC standards and include a General Certificate of Conformity (“GCC”)<sup>11</sup> to indicate compliance with those standards. Moreover, the CPSC has authority over additional federal safety regulations of consumer products to help classify regulated products.<sup>12</sup> As can be appreciated, many of the additional compliance issues raised by other regulated products are likely to involve technical information and analysis comparable to the information considered in the example of chemicals and chemical compounds.

While some hazardous substances are readily identifiable (e.g., poisons), determining whether other consumer products contain a hazardous substance may require in-depth investigation. Counsel with technical expertise may recognize or be able to evaluate particular substances, such as chemicals or chemical compound(s), for potential compliance issues and can provide helpful information for use in ensuring compliance and developing corresponding labeling. This technical expertise may also prove useful in assessing and maintaining compliance with applicable requirements for other regulated products. A patent attorney's involvement early in product development efforts, such as during patent drafting and prosecution, and/or trade secret discussions, puts them in close contact with the product's inventors, and accordingly, gives access to relevant technical information, at a particularly opportune time. Early involvement and identification helps to minimize, and likely prevent, costly redesigns of packaging or other labeling associated with the consumer product, or even of the product itself.

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materials that will burn in air when exposed to a temperature of 1500 degrees F for a period of 5 minutes or [sic] less; and liquids, solids, or semi-solids having a flashpoint at or above 200 degrees F.” *Id.*

<sup>7</sup> “These statements include: signal words; affirmative statements of the principal hazard(s) associated with a hazardous substance; the common or usual name, or chemical name, of the hazardous substance; the name and place of business of the manufacturer, packer, distributor, or seller; statements of precautionary measures to follow; instructions, when appropriate, for special handling and storage; the statement ‘Keep Out of Reach of Children’ or its practical equivalent; and, when appropriate, first-aid instructions.” 16 C.F.R. § 1500.121(a)(1).

<sup>8</sup> 16 C.F.R. § 1500.121(c).

<sup>9</sup> *Id.* at § 1500.121(b)(2)(i), (ii).

<sup>10</sup> See CONSUMER PROD. SAFETY COMM’N, REGULATIONS, MANDATORY STANDARDS AND BANS, available at <https://www.cpsc.gov/Regulations-Laws--Standards/Regulations-Mandatory-Standards-Bans>.

<sup>11</sup> See CONSUMER PROD. SAFETY COMM’N, SAMPLE GENERAL CERTIFICATE OF CONFORMITY (GCC), available at <https://www.cpsc.gov/Business--Manufacturing/Testing-Certification/General-Certificate-of-Conformity-GCC>.

<sup>12</sup> 15 U.S.C. § 2079.