

CLIENT ALERT

Navigating the U.S. Market for Children's Products: Guidance for Manufacturers of Infant and Toddler Products

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Products designed and manufactured for use by infants, toddlers and children must comply with legal requirements at both the federal and state level in order to be sold in the United States. Manufacturers can successfully enter the U.S. children's product market if they identify what regulations apply to their products, what testing and certification and labeling requirements exist, and what record keeping requirements must be followed. This guide helps manufacturers spot the issues they must know about when deciding to enter the U.S. market.ⁱ

Identifying Applicable Mandatory Legal Requirements

As an initial matter, a manufacturer must identify what mandatory legal requirements apply to the products it makes. At the federal level, several agencies oversee the safety of products for infants, toddlers and children.

- The Consumer Product Safety Commission (CPSC) regulates the chemical content of toys and children's products and sets performance requirements for durable infant and toddler products. CPSC also has specific regulations on products ranging from bicycle helmets to youth-sized ATVs.
- The National Highway Traffic Safety Administration (NHTSA) has specific requirements for car seats, though the CPSC also regulates car seats where they are used outside the car, such as with strollers.
- The Food and Drug Administration (FDA) regulates certain children's products that qualify as food, drugs, cosmetics or medical devices.
- The Federal Trade Commission (FTC) regulates the labeling of certain products, and polices marketing statements that are considered deceptive or misleading to consumers.

In addition, many states have specific labeling requirements that apply to children's products, and manufacturers must ensure that their products have the right labels. For example:

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- [FTC Updates Guidance to Search Engine Industry on the Need to Distinguish Between Advertisements and Search Results](#)
- [Navigating the U.S. Market for Children's Products: Guidance for Manufacturers of Infant and Toddler Products](#)
- [What Does *FTC V. ACTAVIS INC.* Mean for Hatch-Waxman Litigation?](#)
- [Supreme Court Again Finds Federal Preemption of Liability for Generic Drug Manufacturers: Will the FDA Finally Step In?](#)
- [NHTSA Punts Again On Requiring Rearview Cameras](#)
- [The Latest In Advertising Class Action Lawsuits](#)
- [Food Safety Regulation Deadline: Court Orders FDA to Propose Regulations by November 30](#)

- Illinois requires products to bear a label if they contain more than 40 ppm lead.
- California's Proposition 65 requires manufacturers to provide a clear and reasonable warning label if a product contains one of the listed chemicals California has determined are known to cause cancer or birth defects.

Requirements for Children's Products

A "children's product" is a consumer product designed or intended primarily for children 12 years of age or younger. Manufacturers of children's products are subject to laws and regulations enforced by the CPSC and other agencies, including the following:

- **Children's Product Certification:** All children's products must be accompanied by a Children's Product Certificate (CPC), stating that the product complies with any mandatory standards that apply to the product. The CPC must be based on passing test results from a CPSC-accepted laboratory.
- **Chemical Content Limits:**
 - **Lead:** Children's products must not contain more than 100 ppm of total lead content in accessible parts or more than 90 ppm lead in paint or similar surface coatings.
 - **Phthalates:** Children's toys and certain child care articles must not contain more than 0.1% of any of 6 types of phthalates (DEHP, DBP, BBP, DINP, DIDP, and DnOP) (computed for each phthalate, individually, and each component part of the product). Child care articles are consumer products that are designed or intended by the manufacturer for a child who is 3 years old or younger, to facilitate sleeping or feeding, or to help a child who is sucking or teething.
 - **Other hazardous substances:** The Federal Hazardous Substances Act (FHSA) also bans hazardous substances in children's products and should be consulted prior to launching products in the U.S. market. For example, there are non-toxicity requirements for children's art materials, felt tip markers, crafting kits for children and the like.
- **Durable Infant Products:** Durable infant and toddler products are those intended or expected for use by children under the age of 5 years. The CPSC has issued mandatory consumer product safety rules for eight durable infant and toddler products:
 - bath seats
 - portable bed rails
 - full-size cribs
 - non-full-size cribs
 - infant swings
 - infant walkers
 - play yards
 - toddler beds

These products cannot be imported into or distributed in the U.S. without a CPC (see above).

The CPSC will continue to issue new rules adopting the current voluntary industry standards for the following durable infant and toddler products:

- high chairs, booster seats, and hook-on chairs
- gates and other enclosures for confining a child
- stationary activity centers
- infant carriers
- strollers
- bassinets and cradles
- children's folding chairs
- changing tables
- infant bouncers
- infant bathtubs
- infant slings

In the interim, manufacturers should comply with the existing voluntary standards, as the CPSC may view products that do not comply with those standards as presenting unreasonable risks of injury to children.

- **Small Parts:** Nursery equipment and infant furniture, toys and other products intended for use by children under 3, with limited exceptions, must not have small parts or produce small parts when broken. The CPSC's regulations contain a test to identify noncompliant small parts.
- **Toys:** All toys intended for use by children under 14 years of age must comply with ASTM F963-11. That standard contains safety requirements on a wide range of issues ranging from the materials used and the stability and cleanliness of toys to their hazardous substance content. Toys cannot have hazardous sharp points or edges or exceed certain flammability limits. The ASTM standard provides a detailed description of what products are considered toys. There are also specific requirements for electrically operated toys and toys that create sounds.
- **Additional Product-Specific Regulations:** There are other laws and regulations enforced by CPSC and other federal agencies that may cover children's products:
 - CPSC has product-specific requirements for pacifiers, rattles, small balls, infant pillows and cushions, children's clothing, children's sleepwear, kites, crib mattresses, bicycles and bicycle helmets, and carpets designed for use in a nursery or children's room, among others. Product-specific regulations should be consulted before those products are introduced into the U.S. market.
 - FDA has specific requirements for children's products that may be used in eating and drinking, including infant bottles and sippy cups. FDA also regulates where medical claims are made about a product, such as an infant sleep positioner that is marketed as preventing sudden infant death syndrome, reflux issues, or flat head syndrome.ⁱⁱ

- NHTSA has specific mandatory requirements that must be met for car seats used in motor vehicles. NHTSA requires car seats to undergo specific testing procedures and achieve specified results. NHTSA mandates test procedures for car seat belts, buckles, seat bottoms, armrests, and headrests. Car seat manufacturers must report to NHTSA failures to satisfy the testing requirements, as well as any other safety-related defects concerning their car seats. NHTSA has the authority to conduct recalls of products that fail to meet the testing regulations or that contain safety-related defects. Regardless of whether there is a defect or failure to satisfy testing requirements, car seat manufacturers must also provide the following information to NHTSA on a quarterly basis: 1) production information, 2) information on incidents involving death or injury, 3) number of consumer complaints and warranty claims, and 4) copies of field reports.
- EPA may require labeling for children's products that contain an anti-microbial that qualifies as a pesticide.

Labeling Requirements for Products

- **Durable Infant Products:** The various mandatory standards for durable infant products contain various requirements for label products to inform users about their safe use. Voluntary standards for children's products contain similar labeling requirements, and manufacturers are well advised to include such warnings on their products.
 - **Registration Cards:** The CPSC requires that consumers be provided with a postage-paid registration card for the following durable infant products:

<ul style="list-style-type: none"> ○ full-size cribs and non-full-size cribs ○ toddler beds ○ high chairs, booster chairs, and hook-on chairs ○ bath seats ○ gates and other enclosures for confining a child ○ play yards ○ stationary activity centers ○ infant carriers 	<ul style="list-style-type: none"> ○ strollers ○ walkers ○ swings ○ bassinets and cradles ○ children's folding chairs ○ changing tables ○ infant bouncers ○ infant bathtubs ○ portable toddler bed rails ○ infant slings
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The manufacturer must follow record keeping requirements based on the use of these consumer registration cards.

- **Tracking Labels for Children's Products:** Tracking labels are required for all children's products, including, but not limited to, toys and durable infant products such as cribs, high chairs, play yards and strollers. A tracking label must contain certain basic information, including:
 1. the name of the manufacturer or private labeler;

- 2.** the location and date of production of the product;
- 3.** detailed information on the manufacturing process, such as a batch or run number, or other identifying characteristics; and
- 4.** any other information to facilitate ascertaining the specific source of the product.

- **Small Parts Labeling:** Toys that contain small parts that are intended for use by children from 3 to 6 years old must be labeled to warn purchasers not to buy them for children under 3 years old. There are also specific labeling requirements for toys that contain small balls and balloons.

Other Labeling Requirements:

- NHTSA has regulations for labeling on car seats similar to the requirements on other durable infant products, including the need for model number and manufacturing date.
- FTC requires textiles to be labeled with different information, including the generic name and amount (in percentage terms) of constituent fibers contained therein and name of the manufacturer and country where the textile fiber produce was processed or manufactured. The information must all appear on the front side of the label.
- FTC's Green Guides provide manufacturers with guidelines for making environmental claims on packaging and marketing products. Manufacturers must be able to substantiate claims that their products "environmentally-friendly" or "eco-friendly." Other terms such as "free-of" or "non-toxic" must also be used with caution to avoid claims that labeling is misleading or deceptive.

Avoiding Design and Manufacturing Defects

Design and manufacturing defects may emerge even when products comply with the law. Manufacturers may take preventative steps to minimize defects:

- Meeting or exceeding voluntary industry standards and testing products to assess potential failure modes and misuse patterns can help to avoid surprises down the road. Even a product that fails to comply with a voluntary standard can be recalled if such failure presents a substantial product hazard, such as strangulation and entrapment hazards from drawstrings on children's upper outerwear.
- Manufacturers should engage in rigorous testing to ensure products do not present a design or manufacturing defect. To determine what testing may be required, manufacturers should rely on the judgment of internal and external expert engineers, collect and incorporate all relevant mandatory and voluntary standards into the testing protocols, engage in real-world testing that accounts for reasonably foreseeable product use and misuse, and consider testing to failure.

- Finally, manufacturers should be vigilant once their products are on the marketplace to watch for indications of design or manufacturing defects that may present product hazards. Evaluation of consumer complaints, inquiries, injuries, and warranty data can help quickly identify problems if they arise.

ⁱ This document is a high-level overview of the requirements for children's products with a particular emphasis on the CPSC's requirements and is not a comprehensive list of all applicable requirements for all children's products. It has been prepared for informational purposes only and does not, and is not intended to, constitute legal advice. Given the complexity of the regulations applicable to children's products in the United States, and pending regulatory proposals to revise these regulatory requirements, we recommend that you consult with legal counsel to ensure compliance with all applicable laws.

ⁱⁱ In this example, if no medical claims are made about the sleep positioner, the CPSC has jurisdiction over the product.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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