

Product Responsibility Best Practices	SUBJECT Food Contact Items and the FDA		LAST UPDATE July 2018
	APPLIES TO • Suppliers • Distributors	FOCUS ON Federal regulations for products that come into contact with food.	
	QUICK LINKS • PPAI Corporate Responsibility: http://ppai.org/corporate-responsibility • UL: industries.ul.com/premiums-promotional-and-licensed-goods • Consumer Product Safety Commission: www.cpsc.gov		Intended for beginner compliance programs

Italic grey text indicates a hyperlink listed in the Online Resources section of this document.

The **U.S. Food and Drug Administration (FDA)** began regulating food contact substances in 1958. Since then the FDA has developed a wide-ranging set of regulations covering most classes of food packaging materials. The FDA refers to these materials as **food contact substances (FCS)**.

FDA Requirements for Items in Contact with Food

- Some substances are *Generally Recognized As Safe (GRAS)*. A food substance may be deemed GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food. The FDA has a page listing GRAS substances.
- Non GRAS materials must be tested. Extraction tests must be performed on all substances not on the GRAS list to determine if any harmful chemicals present in the materials will leach into the food.

Promotional Products Most Affected

- Drinkware and glassware including water bottles
- Food cutlery items
- Food containers and food contact items such as metal gift tins or cooler bags

In Addition to FDA Requirements, Children's Drinkware is Regulated by Many Other Federal and State Regulations:

- **CPSIA Ban on Lead-containing Paint:** The Consumer Product Safety Improvement Act (CPSIA) limits the amount of lead that can be present in all inks, paints and surface coatings used on children's products to 90 ppm
- **CPSIA Lead Content in Substrate Materials:** The CPSIA limits the amount of lead that can be present in any substrate materials of children's products to 100 ppm.
- **CPSIA Phthalates Ban:** A CPSIA regulation that regulates the amount of phthalates that can be in any children's toy or child-care article.

Children's toys or child-care articles cannot have more than 0.1 percent of di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP) or benzyl butyl phthalate (BBP).

A second group of phthalates (DINP, DIDP, DnOP) cannot be in any mouth-able toy or part of a toy or child-care article in amounts exceeding 0.1 percent. The second three phthalates are under an interim ban, while a Chronic Health Advisory Panel is convened and study done. This phthalate ban applies only to children's toys and child-care articles, and does not apply to all children's products.

- **CPSIA Tracking Label Requirements:** A CPSIA regulation that requires all children's products manufactured as of August 14, 2009 to have tracking labels. This includes children's drinkware.
- **Federal Hazardous Substances Act:** Requires that certain hazardous household products bear cautionary labeling to alert consumers to the potential hazards that those products present and guidance on protecting themselves from those hazards; including
 - Physical and mechanical testing (use and abuse tests)
 - Choking
 - Laceration
 - Toxicity
- **California Proposition 65:** Proposition 65, essentially a labeling requirement, requires a warning prior to exposing consumers to any one of the 900+ chemicals known to the state of California to cause cancer or birth defects.
- **Massachusetts Lead Poisoning Prevention and Control:** Massachusetts has a lead prevention and control regulation that requires total immersion of the decorated glassware of ceramic drinkware, with a lead limit of 2 ppm. The FDA test is performed on the interior only, so this is a more stringent test.

- Lip and Rim Test: Industry-wide leaching test, established by the Society of Glass & Ceramic Decorators in 1978, to assess chemical leaching from decoration within top 20 mm of the outside rim of glass tumblers and ceramic drinkware.

<i>Bisphenol (BPA) for various states</i>	
California	any drink/food containers
Connecticut	any reusable food or beverage container
Delaware	BPA is banned from children's bottles, cups, and other food and beverage containers.
Illinois	children's drink/food containers
Maine	banned from baby bottles, sippy cups, water bottles and reusable food storage containers
Maryland	drink/food containers, toys, child-care items
Minnesota	children's beverage containers for children less than three years old
New Jersey	any drink/food containers and toys
New York	children's beverage containers for children less than three years old
Vermont	any drink/food containers
Washington	children's drink/food containers
Wisconsin	requires "BPA-free" label

Online Resources:

PPAI Webinar: Focus on Drinkware, Tableware & Kitchenware: <https://onlineeducation.ppai.org/products/focus-on-drinkware-tableware-and-kitchenware>

PPAI Responsible Sourcing FAQs: <http://ppai.org/corporate-responsibility/product-responsibility/product-responsibility-faqs/>

PPAI Guide to Navigating the Consumer Product Safety Improvement Act <http://www.ppai.org/media/1839/pr-guide-navigating-the-cpsia.pdf>

PPAI California Prop 65 Best Practices: <http://www.ppai.org/media/1814/pr-bp-proposition-65.pdf>

FDA Guidance On Food Contact Substances:

www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm081807.htm

UL-STR Food Safety: industries.ul.com/management-systems/food-safety-management-systems

FDA regulations related to food contact items and substance and regulations: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

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