

105 CMR 650.000: HAZARDOUS SUBSTANCES

Section

- 650.001: Purpose
- 650.002: Authority
- 650.003: Scope
- 650.004: Statutory Definitions
- 650.005: Supplemental Definitions
- 650.006: Incorporation of Findings Made Pursuant to the Federal Hazardous Substances Act, 15 USC § 1261 *et seq.* (FHSA)
- 650.010: Hazardous Mixtures
- 650.015: Listing of Toxic Substances
- 650.016: Listing of Irritants
- 650.017: Listing of Hazardous Substances
- 650.020: Listing of Banned Hazardous Substances
- 650.100: Substances Determined to be Special Hazards
- 650.105: Labeling of Tobacco Snuff
- 650.220: Repurchase of Banned Hazardous Substances
- 650.221: Modification or Replacement of Banned Hazardous Substances in Lieu of Repurchase
- 650.990: Severability

650.001: Purpose

To establish the administration and enforcement of regulations concerning hazardous substances.

650.002: Authority

105 CMR 650.000 is adopted under the authority of M.G.L. c. 94B and 111, §§ 3, 5 and 6.

650.003: Scope

105 CMR 650.000 shall apply throughout the Commonwealth.

650.004: Statutory Definitions

Banned hazardous substance, any toy, or other article intended for use by children, which is a hazardous substance, or which bears, contains a hazardous substance susceptible of access to a child, or is otherwise hazardous because it presents electrical, mechanical or thermal hazards; or any hazardous substance intended or packaged in a form suitable for use in households, which the commissioner by regulation classifies as a "banned hazardous substance" on the basis of a finding that notwithstanding cautionary labeling required under 105 CMR 650.000, the degree or nature of the hazard involved in the presence or use of the substance in households is such that the protection of the public health and safety can be adequately served only by keeping the

substance out of the channels of commerce. The commissioner, by regulation, shall, however, exempt articles, such as chemical sets, which by reason of their functional purpose, require the inclusion of the hazardous substance involved or necessarily present an electrical, mechanical, or thermal hazard, and which bear labeling giving adequate direction and warnings for safe use and are intended for use by children who have attained sufficient maturity and who may reasonably be expected to read and heed these warnings.

Children's Reusable Food Or Beverage Containers Containing Bisphenol-A means reusable bottles or cups that contain bisphenol-A and that are designed and intended by a manufacturer to be filled with food or liquid and used by children age three or younger.

Combustible, any substance or mixture of substances which has a flash point from 80° to and including 150°F, as determined by the Tagliabue Open Cup Tester.

Commerce, any and all commerce within the commonwealth, including the operation of any business or service establishment.

Commissioner, the Commissioner of Public Health.

Corrosive, any substance which when in contact with living tissue will cause destruction of such tissue by chemical action.

Department, the Department of Public Health.

Electrical hazard, an article which in normal use, or when subjected to reasonably foreseeable damage or abuse by its design or manufacture, may cause personal injury or illness by electrical shock.

Extremely flammable, when used with respect to a substance, any substance which has a flash point at or below 20° as determined by the Tagliabue Open Cup Tester.

Flammable, when used with respect to a substance, any substance which has a flash point of above 20° to and including 80°F, as determined by the Tagliabue Open Cup Tester; when used with respect to all items of wearing apparel in sizes 0 through 6X intended to be worn primarily for sleeping or activities related to sleeping and for fabric or related material intended or promoted for use in such wearing apparel, which exceeds the acceptance criteria specified in the federal children's sleepwear standard, DOC FF 3-71, and determined by an appropriate test performed in accordance with said standard; or when used with respect to all items of wearing apparel in sizes seven through 14 intended to be worn primarily for sleeping or activities related to sleeping and for fabric or related material intended or promoted for use in such wearing apparel, which exceeds the acceptance criteria specified in the federal children's sleepwear standard, FF 5-74, and determined by an appropriate test performed in accordance with said standard; provided, that the flammability of solids and of the contents of self-pressurized containers shall be determined by methods generally recognized as applicable to such containers and established by regulations issued by the commissioner.

Hazardous substance, any substance or mixture of substances which is toxic, corrosive, an irritant, a

strong sensitizer, flammable or which 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, or any toy or other article intended for use by children which presents an electrical, mechanical or thermal hazard. It shall include any radioactive substance if, with respect to such substance as used in a particular class of article or as packaged, the commissioner determines by regulation that the substance is sufficiently hazardous to require labeling in accordance with 105 CMR 650.000 in order to protect the public health. It shall not include economic poisons subject to the Federal Insecticide, Fungicide and Rodenticide Act, unless the Commissioner finds that such economic poison is not adequately labeled for the protection of the public health, nor foods, drugs and cosmetics subject to the Federal Drug and Cosmetic Act or M.G.L. c. 94 nor substances intended for use as fuels when stored in containers and used in heating, cooking, or refrigeration systems. It shall include any article which is not itself an economic poison within the meaning of the Federal Insecticide, Fungicide and Rodenticide Act but which is a hazardous substance within the meaning of this definition by reason of bearing or containing such economic poison.

Hazardous substances intended or packaged in a form suitable for use in the household, means any hazardous substance, whether or not packaged, that under any customary or reasonably foreseeable condition of purchase, storage, or use may be brought into or around a house, apartment, or other place where people dwell, or in or around any related building or shed including, but not limited to, a garage, carport, barn, or storage shed.

Highly toxic, when used with respect to a substance, any substance which:

- (a) produces death within 14 days in half or more than half of a group of ten or more laboratory white rats each weighing between 200 and 300 grams, at a single dose of 50 milligrams or less per kilogram of body weight, when orally administered; or
- (b) produces death within 14 days in half or more than half of a group of ten or more laboratory white rats each weighing between 200 and 300 grams, when inhaled continuously for a period of one hour or less at an atmospheric concentration of two hundred parts per million by volume or less of gas or vapor or two milligrams per liter or less of mist or dust, provided such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner; or
- (c) produces death within 14 days in half or more than half of a group of ten or more rabbits tests in a dosage of 200 milligrams or less per kilogram of body weight, when administered by continuous contact with the bare skin for 24 hours or less; provided that if the commissioner finds that available data on human experience with any substance indicate results different from those obtained on animals with the aforesaid dosages or concentrations, the human data shall take precedence.

Immediate container, excludes a package liner.

Irritant, any substance not corrosive which on immediate, prolonged or repeated contact with

normal living tissue will induce a local inflammatory reaction. "Irritant" includes "primary irritant to the skin" as well as substances irritant to the eye or to mucous membranes. "Primary irritant" means a substance that is not corrosive and that human experience data indicate is a primary irritant. "Eye irritant" means a substance that human experience data indicate is an irritant to the eye.

Label, a display of written, printed or graphic matter upon the immediate container of any substance, or in the case of an article which is unpackaged or is not packaged in an immediate container intended or suitable for delivery to the ultimate consumer, a display of such matter directly on the article involved or on a tag or other suitable material affixed thereto. A requirement made by or under the authority of 105 CMR 650.000 that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement or other information also appears on the outside container or wrapper, if any there be, unless it is easily legible through the outside container or wrapper and on all accompanying literature where there are directions for use, written or otherwise.

Mechanical hazard, an article which, in normal use or when subjected to reasonable foreseeable damage or abuse, by its design or manufacturer presents an unreasonable risk of personal injury or illness from fracture, fragmentation or disassembly of the article, from propulsion of the article or any part or accessory thereof, from points or other protrusions, surfaces, edges, openings or closures, from moving parts, from lack or insufficiency of controls to reduce or stop motion, as a result of self-adhering characteristics of the article, because the article or any part or accessory thereof may be aspirated or ingested, because of instability, or any other aspect of the article's design or manufacture.

Misbranded package or misbranded package of a hazardous substance, a hazardous substance in a container, or not in a container if the substance can be handled or transported without one, which is intended or suitable for household use or personal use and which, except as otherwise provided by or pursuant to 105 CMR 650.002, fails to bear a label which states prominently in the English language, in conspicuous and legible type in contrast by typography, layout or color with other printed matter on the label,

- (a) the name and place of business of the manufacturer, packer, distributor or seller;
- (b) the common or usual name or the chemical name, if there be no common or usual name, of the hazardous substance or of each component which contributes substantially to its hazard, unless the commissioner by regulation permits or requires the use of a recognized generic name;
- (c) the signal word "DANGER" on substances which are corrosive, extremely flammable or highly toxic;
- (d) the signal word "WARNING" or "CAUTION" on all other hazardous substances;
- (e) an affirmative statement of the principal hazard or hazards, such as "FLAMMABLE", "VAPOR HARMFUL", "CAUSES BURNS", "ABSORBED THROUGH SKIN", or similar wording descriptive of the hazard;
- (f) precautionary measures describing the action to be followed or avoided; except when modified by regulations of the commissioner pursuant to 105 CMR 650.002;
- (g) instructions, when necessary or appropriate, for first-aid treatment;
- (h) the word "POISON" for any hazardous substance which is defined as "HIGHLY TOXIC" by 105 CMR 650.004;

- (i) instructions for handling and storage of packages which require special care in handling or storage; and
- (j) the statement "KEEP OUT OF THE REACH OF CHILDREN", or its practical equivalent.

Person, includes an individual, partnership, corporation, association, or legal representative or agent.

Proximate result means a result that follows in the course of events without an unforeseeable, intervening, independent cause.

Radioactive substance, a substance which emits ionizing radiation.

Reasonably foreseeable handling or use includes the reasonably foreseeable accidental handling or use, not only by the purchaser or intended user of the product, by all others in a household, specially children.

Snuff, is a form of smokeless tobacco, often referred to as such, which is a finely ground or cut tobacco mixture that is intended to be placed in the oral cavity.

Strong sensitizer, a substance which will cause on normal living tissue, through an allergic or photodynamic process, a hypersensitivity which becomes evident on reapplication of the same substance and which is designated as such by the commissioner. Before designating any substance as a strong sensitizer, the commissioner, upon consideration of the frequency of occurrence and severity of the reaction, shall find that the substance has a significant potential for causing hypersensitivity.

(a) Strong allergic sensitizer, is a substance that produces an allergenic sensitization in a substantial number of persons who come into contact with it. An allergic sensitization develops by means of an "antibody mechanism" in contradistinction to a primary irritant reaction which does not arise because of the participation of an "antibody mechanism". An allergic reaction ordinarily does not develop on first contact because of necessity or prior exposure to the substance in question. The sensitized tissue exhibits a greatly increased capacity to react to subsequent exposures of the offending agent. Subsequent exposures may therefore produce severe reactions with little correlation to the amount of excitant involved.

(b) Photodynamic sensitizer, is a substance that causes an alteration in the skin or mucous membranes in general or to the skin or mucous membrane at the site of contact so that when these areas are subsequently exposed to ordinary sunlight (or equivalent radiant energy) an inflammatory reaction will develop.

Substantial personal injury or illness means any injury or illness of a significant nature. It need not be severe or serious. What is excluded by the word "substantial" is a wholly insignificant or negligible injury or illness.

Thermal hazard, an article which, in normal use or when subjected to reasonably foreseeable damage or abuse, by its design or manufacture presents an unreasonable risk of personal injury or illness because of heat as from heated parts, substances or surfaces.

Toxic, when used with respect to a substance, any substance, other than a radioactive substance, which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface.

650.005: Supplemental Definitions

(1) Toxic. To give specificity to the definition of "toxic" in 105 CMR 650.004(28), the following supplements that definition:

(a) Acute Toxicity. Toxic means any substance that produces death within 14 days in half or more than half of a group of:

1. White rats (each weighing between 200 and 300 grams) when a single dose of from 50 milligrams to five grams per kilogram of body weight is administered orally.
2. White rats (each weighing between 200 to 300 grams) when an atmospheric concentration of more than 200 parts per million but not more than 20,000 parts per million by volume of gas or vapor, or more than two but not more than 200 milligrams per liter by volume of mist or dust is inhaled continuously for one hour or less, if such concentration is likely to be encountered by humans when the substance is used in any reasonably foreseeable manner; and/or
3. Rabbits (each weighing between 2.3 and 3.0 kilograms) when a dosage of more than 200 milligrams but not more than two grams per kilogram of body weight is administered by continuous contact with the bare skin for 24 hours by the method described in 16 CFR § 1500.40 which is incorporated herein by reference.

The number of animals tested shall be sufficient to give a statistically significant result and shall be in conformity with good pharmacological practices.

(b) Chronic Toxicity. Toxic also means any substance that presents a chronic hazard if it falls into one of the following categories.

1. For Carcinogens. A substance is toxic if it is or contains a known or probable human carcinogen.
2. For Neurotoxicological Toxicants. A substance is toxic if it is or contains a known or probable human neurotoxin.
3. For Developmental or Reproductive Toxicants. A substance is toxic if it is or contains a known or probable human developmental or reproductive toxicant.

(c) Toxic also applies to any substance that is TOXIC (but not HIGHLY TOXIC) on the basis of human experience.

(2) Irritant. The definition of "irritant" in 105 CMR 650.004(17) is supplemented by the following: "Irritant" includes "primary irritant to the skin" as well as substances irritant to the eye or to mucous membranes. "Primary irritant" means a substance that is not corrosive and that human experience data indicate is a primary irritant and/or means a substance that results in an empirical score of five or more when tested by the method described in 16 CFR § 1500.41 which is incorporated herein by reference. "Eye irritant" means a substance that human experience data indicates is an irritant to the eye and/or means a substance for which a positive test is obtained

when tested by the method described in 16 CFR § 1500.42 which is incorporated herein by reference.

650.006: Incorporation of Findings Made Pursuant to the Federal Hazardous Substances Act, 15 USC

§ 1261 et seq. (FHSA)

(1) Hazardous and Banned Hazardous Substances. Any substance, mixture, or article found to be a hazardous substance or a banned hazardous substance pursuant to the FHSA is deemed such for all purposes under M.G.L. c. 94B and regulations promulgated there under.

(2) Toxic, Highly Toxic, Irritant, Strong Sensitizer and other Substances. Any substance, mixture, or article found to be toxic, highly toxic, an irritant, a strong sensitizer, corrosive, flammable or pressure generating pursuant to the FHSA is deemed such for all purposes under M.G.L. c. 94B.

650.010: Hazardous Mixtures

For a mixture of substances, the determination of whether the mixture is a "hazardous substance" should be based on the physical, chemical, and pharmacological characteristics of the mixture. A mixture of substances may therefore be less hazardous or more hazardous than its components because of synergistic or antagonistic reactions. It may not be possible to reach a fully satisfactory decision concerning the toxic, irritant, corrosive, flammable, sensitizing, or pressure-generating properties or a substance from what is known about its components or ingredients. The mixture itself should be tested.

650.015: Listing of Toxic Substances

The commissioner finds the following substances to be toxic:

- (1) Formaldehyde.
- (2) Urea-formaldehyde foamed-in-place insulation.
- (3) Snuff.
- (4) Children's reusable food or beverage containers containing bisphenol-A that are manufactured on or after January 7, 2011, or sold at retail on or after July 1, 2011.

650.016: Listing of Irritants

The Commissioner finds the following substances to be irritants:

- (1) Formaldehyde.

105 CMR: DEPARTMENT OF PUBLIC HEALTH

- (2) Urea-formaldehyde foamed-in-place insulation.
- (3) Snuff.

650.017: Listing of Hazardous Substances

The commissioner declares the following substances to be hazardous substances:

- (1) Formaldehyde.
- (2) Urea-formaldehyde foamed-in-place insulation.
- (3) Snuff.
- (4) Children's reusable food or beverage containers containing bisphenol-A that are manufactured on or after January 7, 2011, or sold at retail on or after July 1, 2011.

650.020: Listing of Banned Hazardous Substances

The commissioner declares the following articles to be banned hazardous substances and requires their removal from commerce:

- (1) Urea-formaldehyde foamed-in-place insulation.
- (2) Children's reusable food or beverage containers containing bisphenol-A that are manufactured on or after January 7, 2011, or sold at retail on or after July 1, 2011.

650.100: Substances Determined to be Special Hazards

If the Commissioner finds that the requirements of M.G.L. c. 94B, § 1, as to labeling of a "misbranded hazardous substance" are not adequate for the protection of the public health and safety in view of the special hazard presented by any particular hazardous substance, he may by regulation establish such reasonable variations or additional label requirements as he finds necessary for the protection of the public health and safety; and any hazardous substance intended, or packaged in a form suitable, for use in the household or by children which fails to bear a label in accordance with 105 CMR 650.000 shall be deemed to be a misbranded hazardous substance.

650.105: Labeling of Tobacco Snuff

Any container or package of tobacco snuff shall be deemed to be misbranded unless it bears the warning statements required pursuant to the Comprehensive Smokeless Tobacco Health Education Act of 1986. Any container or package of tobacco snuff so labeled shall not be deemed misbranded for failure to comply with the requirements of 105 CMR 650.004(20).

650.220: Repurchase of Banned Hazardous Substances

- (1) Definitions used for the purposes of 105 CMR 650.000.
 - (a) manufacturer includes any person who manufactures or imports an article or substance for distribution or sale, including importers for resale, except that in the case of an article or substance distributed or sold under a name other than that of the actual manufacturer of the article or substance, the term "manufacturer" includes any person under whose name the article or substance is distributed or sold.
 - (b) distributor includes any person, including any person who would otherwise be considered a dealer, who sells an article or substance at wholesale.
 - (c) dealer includes any person who sells an article or substance at retail.
 - (d) purchase price means the amount of money paid to acquire an article or substance, including all taxes, but excluding transportation or shipping costs and finance, interest, or service charges.
 - (e) reasonable and necessary transportation charges, when used in connection with the return of an article or substance to a dealer, means:
 1. the actual costs incurred in returning the product in any manner reasonably specified by the dealer, including personal conveyance; or
 2. the actual costs incurred in returning the products by mail, commercial carrier, or any other manner, including personal conveyance, reasonably utilized in the absence of specific instructions by the dealer.
 - (f) reasonable and necessary expense when used in connection with the return of an article or substance to a distributor or manufacturer shall include the cost of labor, administration and transportation in the handling, processing, and shipping of that product.
- (2) Repurchase. In the case of any article or substance sold by its manufacturer, distributor, or dealer which is a banned hazardous substance, whether or not it was such at the time of its sale, such article or substance shall be repurchased as follows:
 - (a) The manufacturer of any such article or substance shall repurchase it from the person to whom he sold it, and shall refund to that person the purchase price paid for such article or substance. If that person repurchased such article or substance pursuant to the provisions of 105 CMR 650.220, the manufacturer shall reimburse him for any amounts paid in connection with its repurchase, and reimburse such person for any reasonable and necessary expenses incurred in returning it to the manufacturer.
 - (b) The distributor of any such article or substance shall repurchase it from the person to whom he sold it, and shall refund to that person the purchase price paid for such article or substance. If that person has repurchased such article or substance pursuant to the provisions of 105 CMR 650.220, the distributor shall reimburse him for any amounts paid for the return of such article or substance in connection with its repurchase and reimburse that person for any reasonable and necessary expenses incurred in returning it to the distributor.
 - (c) In the case of any such article or substance sold at retail by a dealer, if the

105 CMR: DEPARTMENT OF PUBLIC HEALTH

person who purchased it from the dealer returns it to him, the dealer shall refund the purchase price paid for it and reimburse him for any reasonable and necessary transportation charges incurred in its return.

650.221: Modification or Replacement of Banned Hazardous Substances in Lieu of Repurchase

- (1) Scope. 105 CMR 650.221 clarifies and sets forth the conditions whereby repurchase of an banned hazardous article or substance will not be required under 105 CMR 650.220. Generally, repurchase will not be required whenever, with the consent of the owner, the banned hazardous article or substance is replaced or modified so that it no longer meets the definition of a banned hazardous article or substance.
- (2) Modification. Any article or substance which is a "banned hazardous substance" (including any article or substance which became a banned hazardous substance because of some alteration which occurred after its introduction into interstate commerce and before its sale to an ultimate consumer) but which is thereafter modified so that it is no longer a banned hazardous substance shall not be subject to repurchase. Provided, however, that if the owner of a particular product which is a banned hazardous substance (for reason other than an alteration by the owner) will not consent to modification of the product as an alternative to repurchase, the obligation of the party shall not be affected by the provisions of 105 CMR 650.221.
- (3) Replacement. Any party who is obligated to repurchase an article which is a banned hazardous substance may replace it with an equivalent product which is not a banned hazardous substance. Provided, however, that if the owner of the particular product which is a banned hazardous substance (for reason other than an alteration by the owner) will not consent to replacement with an equivalent product which is not a banned hazardous substance, the obligation of the party who sold the banned hazardous substance to repurchase that product and refund the purchase price shall not be affected by the provisions of 105 CMR 650.221.
- (4) Expenses. In any case where a manufacturer, distributor, or dealer elects to offer to modify a banned hazardous substance or to replace it with an equivalent product which is not a banned hazardous substance as an alternative to repurchase, all expenses incurred in connection with the modification or replacement shall be borne by the party originally offering the modification or replacement.

650.990: Severability

Any section, subsection, paragraph or provision of 105 CMR 650.000 declared illegal or unconstitutional by a court of competent jurisdiction is severable from 105 CMR 650.000.

REGULATORY AUTHORITY

105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 650.000: M.G.L. c. 94B; c. 111; St. 1985, c. 728.

NON-TEXT PAGE

(PAGES 3009 THROUGH 3020 ARE RESERVED FOR FUTURE USE.)