

EMPOWERING THE SECRETARY OF HEALTH TO REGULATE THE LABELING, SALE AND DISTRIBUTION OF HAZARDOUS SUBSTANCES.

PRESIDENTIAL DECREE NO. 881, January 30, 1976

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WHEREAS, the Food, Drug and Cosmetics Act (Republic Act No. 3720) establishes standards and quality measures for food, drugs and cosmetics;

WHEREAS, there are substances other than food, drugs and cosmetics that are hazardous to the health and safety of the public;

WHEREAS, there is no law at present that regulates the labeling, sale and distribution of hazardous substances;

WHEREAS, there is an urgent need to adopt appropriate measures designed to protect the people against other hazards to their health and safety;

NOW, THEREFORE, I, FERDINAND E. MARCOS, President of the Philippines, by virtue of the powers vested in me by the Constitution, do hereby order and decree, as part of the law of the land, the following:

SECTION 1. Definitions.—For purposes of this Decree, the following terms are defined as follows:

- "Secretary" means the Secretary of Health.
- "Administrator" means the Food and Drug Administrator.
- "Person" means any individual, partnership, corporation or association, trust, government or governmental subdivision or any other legal entity other than the consumer.
- "Hazardous substance" means:
 - (A) 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 injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable ingestion by children.
 - (B) Any substance which the Secretary by regulation finds pursuant to the provision of this Decree, to be under the categories enumerated in sub-paragraph (1) (A) of this paragraph.
 - (C) Any radioactive substance, if, with respect to such substance as used in a particular class of article or as packaged, the Secretary determines by regulation that the substance is sufficiently hazardous to require labeling in accordance with this Section in order to protect the public health.
- This term shall not apply to foods, drugs, and cosmetics nor to substances intended for use as fuels when stored in containers and used in the heating, cooking or refrigeration system of a house, but such term shall apply to any article which is not in itself a pesticide but which is a hazardous substance, as construed in paragraph (1) of this sub-section, by reason of bearing or containing such harmful substances described therein.
- "Toxic" means any substance (other than a radioactive substance) which can cause injury or illness or death to

man through ingestion, inhalation, or absorption through any body surface.

- "Highly Toxic" means any substance which has any of the following effects: (1) produces death within four teen days to one half or more than one half of a group of ten or more laboratory white rats each weighing between two hundred and three hundred grams, at a single dose of fifty milligrams or less per kilogram of body weight, when orally administered; or (2) produces death within fourteen days to one half or more of a group of ten or more laboratory white rats each weighing between two hundred and three hundred 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 by volume 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 (3) produces death within fourteen days to one half or more of a group of ten or more rabbits, when tested in a dosage of two hundred milligrams or less per kilogram of body weight, or when administered through continuous contact with the bare skin for twenty-four hours or less.

- "Corrosive" means any substance which on contact with living tissue will cause destruction of tissue by chemical action, but shall not refer to action on inanimate surfaces.

- "Irritant" means any substance not corrosive within the meaning of subparagraph (g) of this section which, on immediate, prolonged, or repeated contact with normal living tissue will induce a local inflammatory reaction.

- "Strong sensitizer" means any substance which will cause on normal living tissue, allergy or photodynamic quality of hypersensitivity which becomes evident on re-application of the same substance, to be designated as such by the Secretary. Before designating any substance as a strong sensitizer the Secretary upon consideration of the frequency of occurrence and severity of the reaction shall find that the substance has a significant capacity to cause hypersensitivity.

- "Extremely flammable" means any substance which has a flash point at or below twenty degrees Fahrenheit as determined by the Tagliabue Open Cup Tester; the term "flammable" shall apply to any substance which has a flash point of above twenty degrees to and including eighty degrees Fahrenheit as determined by the Tagliabue Open Cup Tester; and the term "combustible" shall apply to any substance which has a flash point above eighty degrees Fahrenheit to and including one hundred and fifty degrees as determined by the Tagliabue Open Cup Tester; Provided, that the flammability or combustibility of solids and of the contents of self-pressurized containers shall be determined through methods found by the Secretary to be generally applicable to such materials or containers, respectively, and established by regulations issued by him Such regulations shall also define the terms "Flammable" "Combustible" and "Extremely Flammable" in accordance with acceptable methods.

- "Radioactive substance" means any substance which emits ionizing radiation.

- "Label" means a display of written, printed or graphic matter upon the immediate container of any substance, or in the case of an article which is not packaged in an immediate container but suitable for delivery to the consumer in such condition, a display of such matter directly upon the article involved or upon a tag or other suitable material affixed thereto. A requirement made by or under authority of this Section that certain words, statements, or other information appear on the label shall not be considered to have been sufficiently complied with unless such words, statements, or other information also appear (1) on the outside container or wrapper, if any there be, unless they are readable through the outside container or wrapper, and (2) on all accompanying literature where there are directions for use, written or otherwise.

- "Immediate container" refers to the container or package which is immediately after or near the substance

excluding package liners.

- "Misbranded hazardous substance" means any hazardous substance intended, or packaged in a form suitable, for use in households, especially by children, the packaging or labeling of which is in violation of the special packaging regulation issued by the Secretary or if such substance fails to bear a label—

- which states conspicuously (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 the harmfulness of the substance, unless the Secretary by regulation permits or requires the use of the recognized generic name; (C) the signal word "DANGER" on substances which are extremely flammable, corrosive, or highly toxic; (D) the signal word "WARNING" or "CAUTION" on all other hazardous substances; (E) a frank statement of the principal hazard or hazards involved, 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 regulation by the Secretary pursuant to Section 2 of this decree; (G) instructions, when necessary or appropriate, for first-aid treatment; (H) the word "poison" for any hazardous substance which is defined as highly toxic; (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, if the article is intended for use by children and is not a banned hazardous substance, with adequate directions for the protection of children, from the hazard involved. The aforementioned signal words, affirmative statements, description of precautionary measures, necessary instructions or other words or statements may be in the English language or its equivalent in Pilipino, and

- on which any statement required under sub-paragraph (1) of this paragraph are located prominently and in conspicuous and legible type in contrast by typography, layout, or color with other printed matters on the label.

- "Banned hazardous substance" means (1) any toy or other articles intended for use by children, which are hazardous per se, or which bear or contain substances harmful to human beings; or (2) any hazardous substance intended, or packed in a form suitable, for use in the household, which the Secretary by regulation classifies as a "banned hazardous substance" notwithstanding the existence of cautionary labels, to safeguard public health and safety; Provided, That the Secretary, by regulation, shall exempt from this Section articles, which by reason of their functional purpose require the inclusion of the hazardous substance involved and which bear appropriate labels giving adequate directions and warnings for their safe use.

Procedures for the issuance, amendment or repeal of regulations pursuant to paragraph (2) of this subsection shall be governed by the rules and regulations promulgated by the Secretary: Provided, That if the Secretary finds that the distribution for household use of the hazardous substance involved presents an imminent hazard to the public health, he may publish in a newspaper of general circulation a notice of such finding, and such substance shall be deemed to be a "banned hazardous substance" pending the issuance of regulation formally banning such substance.

SEC. 2. Regulations declaring hazardous substances and establishing variations and exemptions.—

The Administrator, upon approval by the Secretary, shall promulgate the rules and regulations governing the implementation of this decree.

To resolve uncertainty as to the coverage of this decree, the Secretary may by regulation declare as hazardous any substance or mixture of substances which he finds meets the requirements of paragraph (1) (A) of Section 1 (d).

If the Secretary finds that for good and sufficient reasons, full compliance with the labeling requirements otherwise applicable under this Decree is impracticable or is not necessary for the adequate protection of the

public health and safety, he shall promulgate regulations exempting such substances from these requirements to the extent he deems consistent with the objective of adequately safeguarding public health and safety, and any hazardous substance which does not bear a label in accordance with such regulations shall be deemed to be a misbranded hazardous substance.

SEC. 3. Grounds for seizure and condemnation of misbranded hazardous substances.—

- Any misbranded hazardous substance or banned hazardous substance when introduced into commerce or while held for sale shall be liable to be proceeded against while in commerce or at any time thereafter and condemned upon order of the Administrator in accordance with existing procedure for seizure and condemnation of articles in commerce: Provided, That this Section shall not apply to a hazardous substance intended for export to any foreign country if it (1) is in a package branded in accordance with the specifications of the foreign purchaser, (2) is labeled in accordance with the laws of the foreign country, (3) is labeled on the outside of the shipping package to show that it is intended for export, and (4) is so exported.

- Any hazardous substance condemned under this Section shall, after entry of the order be disposed of by destruction or sale as the Administrator may direct and the proceeds thereof, if sold, less the legal costs and charges shall be paid into the Treasury of the Philippines; but such hazardous substance shall not be sold under any order which is contrary to the provisions of this Decree: Provided, That, after entry of the order and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such hazardous substance shall not be sold or disposed of contrary to the provisions of this Decree, the Administrator may direct that such hazardous substance be delivered to the owner thereof for destruction or for alteration to comply with the provisions of this Decree under the supervision of an officer or employee duly designated by the Administrator. The expenses for such supervision shall be paid by the person obtaining release of the hazardous substance under bond.

- All expenses in connection with the destruction provided for in subsection (a) of this Section and all expenses in connection with the storage and labor with respect to such hazardous substance shall be paid by the owner or consignee, and default in such payment, shall constitute a lien against any importation by such owner or consignee.

SEC. 4. Imports: regulations on imported hazardous substances.—

- The Commissioner of Customs shall deliver to the Administrator, upon his request, samples of hazardous substances being imported or offered for export to the Philippines, giving notice thereof to the owner or consignee who may appear before the Administrator and exercise the right to make testimony. If it appears from the examination of such samples that such hazardous substance is a misbranded hazardous substance or banned hazardous substance, then such hazardous substance shall be refused admission except as may be provided in an order issued by the Administrator authorizing delivery of the refused articles under the requirements imposed therein. The Commissioner of Customs shall cause the destruction of any hazardous substance refused admission unless such hazardous substance is exported, under regulations issued by the Commissioner within ninety days from the date of notice of such refusal or within such additional time as may be fixed by him.

- Pending decision on the admissibility of a hazardous substance being imported or offered for import, the Commissioner of Customs may authorize delivery of such hazardous substance to the owner or consignee upon execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default. If it appears to the Administrator that the hazardous substance can, by relabeling or other action, be made to comply with the requirements of this Decree, final determination as to the admission of such hazardous substance may be deferred, and upon filing of a timely written application by the owner or consignee and the

execution by him of a bond as provided in the provisions of this subsection. The Administrator, may in accordance with regulations, authorize the applicant to perform such relabeling or other action specified in such authorization (including destruction or export of such rejected hazardous substance). All such relabeling or other action pursuant to such authorization shall be in accordance with regulations and shall be under the supervision of an officer or employee of the Bureau of Customs and the Food and Drug Administration.

SEC. 5. Examination and investigation for purposes of enforcement of this Decree.—Officers or employees duly designated by the Administrator upon presenting appropriate credentials to the owner, operator, or agent in charge are authorized (1) to enter at reasonable hours, any establishment or warehouse in which hazardous substances are manufactured, labeled, packed or held for introduction into domestic commerce or are held after such introduction, or to enter any vehicle being used to transport or hold such hazardous substance in domestic commerce; (2) to inspect, in a reasonable manner, such establishment or vehicle, warehouse and all pertinent equipment, finished or unfinished, materials and labeling therein; and (3) to obtain samples of such materials or packages therein or of such labeling, issuing proper receipts for them.

SEC. 6. Prohibited acts and penalties.—

- Prohibited acts.—The following acts and the causing thereof are prohibited:

- The introduction or delivery for introduction into commerce of any misbranded hazardous substance or banned hazardous substance.
- The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the label of a misbranded hazardous substance or banned hazardous substance, if such act is done while the substance is in commerce or while the substance is held for sale (whether or not it is the first sale)
- The receipt in commerce of any misbranded hazardous substance or banned hazardous substance and the delivery or proffered delivery thereof at cost or other wise.
- The giving of a guarantee or undertaking referred to in Section 3(b) and Section 4(b) if such guarantee or undertaking is false, except by a person who relied upon a guarantee or undertaking which he received in good faith.
- The introduction or delivery for introduction into commerce, or the receipt in commerce and subsequent delivery or proffered delivery at cost or otherwise, of a hazardous substance in a reused food, drug, or cosmetic container or in a container which, though not a reused container, is identifiable as a food, drug, or cosmetic container by its labeling or by other identification. The use of a used food, drug, or cosmetic container as a container for a hazardous substance does not diminish the danger posed by the hazardous substance involved, therefore such substance shall be deemed a misbranded hazardous substance. As used in this paragraph, the terms "food," "drug," and "cosmetic" shall have the same meaning as in the Food, Drug and Cosmetic Act (Republic Act No. 3720).

- Penalties, exception.—(1) Any person who violates any of the provisions of subsection (a) shall, upon conviction, be subject to imprisonment of not less than six months and one day, but not more than five years, or a fine of not less than one thousand pesos, or both, such fine and imprisonment to be at the discretion of the court; (2) no person shall be subject to the penalties of paragraph (1) of this subsection, (i) for having violated subsection (a) (3) of this Section unless he refuses to furnish upon request by the Administrator or his representative the name and address of the person from whom he purchased or received such hazardous substance, (ii) for having violated subsection (a) (1) of this Section, if he establishes a guarantee or undertaking signed by, and containing the name and address of, the person from whom he received in good faith, the hazardous substance to the effect that the hazardous substance is not a misbranded hazardous substance or banned hazardous substance within the meaning

of that term in this Decree.

SEC. 7. Effectivity.—This Decree shall take effect immediately.

Done in the City of Manila this 30th day of January in the year of Our Lord nineteen hundred and seventy-six.

(Sgd.)

FERDINAND E. MARCOS

President

Republic of the Philippines

By the President:

(Sgd.)

JUAN C. TUVERA

Presidential Assistant

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