



205 / 07-PA25

February 28, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. 2005D-0481

Dear Sir/Madam:

This letter is in response to FDA's request for comments on the draft Guidance to Industry on *Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy*. The Toxics in Packaging Clearinghouse would like to advise the FDA of state laws prohibiting the use of lead in the manufacture and distribution of packaging, including candy wrappers, and request that FDA include a reference to these state laws in its Guidance for Industry, Section II C.

A total of nineteen US states have Toxics in Packaging legislation that prohibits the intentional use of heavy metals, including lead, in packaging or packaging components, such as candy wrappers. The Toxics in Packaging Clearinghouse, on behalf of its nine member states (California, Connecticut, Iowa, Maine Minnesota, New Hampshire, New Jersey, New York, and Rhode Island), request that FDA include the following in its guidance, Section II.C:

The use of lead or lead-based inks in or on packaging, including candy wrappers, is prohibited by state Toxics in Packaging legislation, which has been enacted in nineteen US states. The state laws also prohibit the use of cadmium, mercury and hexavalent chromium in packaging.

For your further information, below is a brief summary of the Model legislation that is the basis for state laws. Copies of the Model legislation and a Fact Sheet are also enclosed. The Toxics in Packaging Clearinghouse (TPCH) coordinates implementation of the legislation on behalf of member states, and serves as a single point of contact for organizations and companies seeking further information and clarifications.

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The Toxics in Packaging legislation:

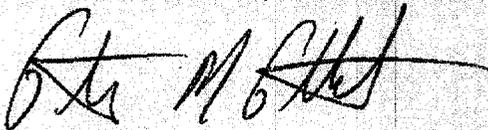
- **prohibits the intentional use** of any amount of the lead, mercury, cadmium or hexavalent chromium into any packaging or individual packaging components;
- limits the sum of the concentrations of the incidental presence of the specified metals to below 100 ppm in any package or individual packaging component;
- provides for limited exemptions as specified;
- requires self certification by the affected company (kept in company files); and
- requires the affected company to produce a Certificate of Compliance upon request.

These requirements apply to any and all packaging and packaging components offered for sale or for promotional purposes by the manufacturer or distributor (including importers) in states with Toxics in Packaging legislation. Member states have included in their laws the ability to levy substantial monetary penalties for non-compliance.

Thank you for taking into consideration the request of TPCH member states to include a reference to state Toxic in Packaging legislation in the final FDA Guidance for Industry pertaining to lead in candy and associated wrappers.

If you have any questions or comments, please contact me at (518) 402 8794 or pmpettit@gw.dec.state.ny.us, or Patricia Dillon, TPCH Program Manager at (802) 254 8911 or info@toxicsinpackaging.org

Sincerely,



Peter Pettit
Chair, Toxics in Packaging Clearinghouse
NY Department of Environmental Conservation

Enclosures:
Model Legislation
Fact Sheet – Toxics in Packaging Clearinghouse

Cc:
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FACT SHEET

Introduction

The Model Toxics in Packaging Legislation was developed in 1989 to reduce the amount of four heavy metals in packaging and packaging components sold or distributed throughout the states. As of July 2004, legislation based on this model has been adopted by nineteen states:

- California
- Connecticut
- Florida
- Georgia
- Illinois
- Iowa
- Maine
- Maryland
- Minnesota
- Missouri
- New Hampshire
- New Jersey
- New York
- Pennsylvania
- Rhode Island
- Vermont
- Virginia
- Washington
- Wisconsin

The influence of the Model Legislation extends beyond US borders. The European Union, for example, used the Model as the basis of its packaging requirements (94/62/EC).

Incidental Presence Concentration Limits

No intentional introduction of any amount of the four metals is allowed. The sum of the concentration levels of incidentally introduced lead, mercury, cadmium, and hexavalent chromium present in any package or packaging component shall not exceed the following:

- 600 parts per million, two years after enactment
- 250 parts per million, three years after enactment
- 100 parts per million, four years after enactment

Who is Responsible?

- Manufacturers of packaging and packaging components
- Suppliers of packaging and packaging components
- Product manufacturers or distributors who use packaging

How to Comply

The manufacturer or supplier to the purchaser must submit a certificate of compliance stating that a package or packaging component is in compliance with the requirements of the law. (This provision does not apply to the individual making retail purchases or to retail storeowners.) The purchaser, manufacturer and supplier should keep a copy of the signed certificate of compliance on file as long as that package is in use. The certificate of compliance can be subject to state and public review upon request.

Enforcement

Enforcement of the Model Toxics in Packaging Legislation is at the discretion of each individual state. However, violation information will be shared among the Clearinghouse member states, and will be pursued in a consistent manner, to the extent possible.

Exemptions

Details of these exemptions can be found in the individual state laws, and specific exemptions may vary by state. All packages and packaging components are subject to the law except:

- Packages and packaging components with a code indicating that the date of manufacture was prior to the effective date of the law.
- Packages and packaging components to which heavy metals have been added in order to comply with health and safety requirements specified by federal law. (*2-year exemption—requires approval*)
- Packages and packaging components that would not exceed the maximum contaminant levels, but for the addition of recycled materials. This exemption does not apply to use of the metals when they have already been recovered and separated for use as a metal or metallic compound. (*Expires Jan. 1, 2010*)
- Packages and packaging components to which heavy metals have been added in the manufacturing process for which there is no feasible or technical alternative. (*2-year exemption—requires approval*)
- Packages and packaging components that exceed the contaminant levels, but are reused; and the enclosed product, its transportation and disposal are regulated by federal health and safety requirements. (*Expires Jan. 1, 2010*)
- Packages and packaging components that exceed the contaminant levels but have a controlled distribution and are reused. (*Expires Jan. 1, 2010—requires approval*)
- A glass package or packaging component that has a vitrified label.

More Information Online

See www.toxicsinpackaging.org, which includes:

- 2004 revised model legislation
- Q&A document, which lists the most commonly asked questions regarding the toxics in packaging legislation
- Sample certificate of compliance and certificate of exemption
- Comparative Analysis, presenting a side-by-side comparison of the model legislation and existing state laws.

Interested in Joining?

Membership categories include:

- States that have enacted toxics in packaging legislation
- States considering adoption of the legislation
- Industry/Trade Associations
- Non-Profit Organizations

Revised January, 2005



Model Toxics in Packaging Legislation

Summary

The legislation calls for the reduction of lead, mercury, cadmium and hexavalent chromium in packaging or packaging materials used or sold within the state.

Manufacturers and distributors have two years from the effective date of the law to clear inventory and make necessary adjustments to their operations in order to comply with the law.

Manufacturers and distributors of packaging or packaging materials would be required to reduce the sum of the concentration levels of incidentally introduced lead, cadmium, mercury and hexavalent chromium to 600 parts per million two (2) years after the legislation is signed into law; 250 parts per million 3 years after it is signed into law; and 100 parts per million 4 years after it is signed into law. The legislation prohibits the intentional introduction of the four heavy metals during manufacturing or distribution.

The legislation provides an exemption for packaging made from recycled materials; packages and packaging components manufactured prior to the effective date of the legislation; packaging that is essential to the protection, safe handling or function of the package's contents - for example, medical products related to radiation therapy, x-rays, etc.; packages and packaging components for which there is no feasible alternative; reusable packaging for products that are subject to other federal or state health, safety, transportation, or disposal requirements (i.e., hazardous waste); packaging having a controlled distribution and reuse (i.e., beverage containers subject to mandatory deposit requirements); and packaging or packaging component that is glass or ceramic where the decoration has been vitrified and when tested, meets specific requirements.

Manufacturers and suppliers of packaging and packaging components are required to furnish a certificate of compliance to the purchasers of packaging. (This applies to companies who actually put their products in the package and does not apply to the retailer or the individual consumer). The public and the state have access to these certificates.

The legislation also provides for a review process by the state to determine the effectiveness of the Act. More specifically, that review will address the need to continue the recycling exemption and will determine if other toxic substances contained in packaging should be subject to reduction.

Model Legislation

Section 1. (Title)

Section 2. The legislature finds and declares that:

- a. The management of solid waste can pose a wide range of hazards to public health and safety and to the environment;
- b. Packaging comprises a significant percentage of the overall solid waste stream;
- c. The presence of heavy metals in packaging is a part of the total concern in light of their likely presence in emissions or ash when packaging is incinerated, or in leachate when packaging is landfilled;
- d. Lead, mercury, cadmium and hexavalent chromium, on the basis of available scientific and medical evidence, are of particular concern;
- e. It is desirable, as a first step in reducing the toxicity of packaging waste, to eliminate the addition of these heavy metals to packaging; and
- f. The intent of this Act is to achieve this reduction in toxicity without impeding or discouraging the expanded use of recycled materials in the production of packaging and its components.

Section 3. Definitions:

"Package" means: any container, produced either domestically or in a foreign country, providing a means of marketing, protecting or handling a product and shall include a unity package, an intermediate package or a shipping container as defined in American Society of Testing and Materials (ASTM) specification D 996. "Package" shall also mean and include such unsealed receptacles as carrying cases, crates, cups, pails, rigid foil and other trays, wrappers and wrapping films, bags and tubs.

"Distributor" means: any person, firm or corporation who takes title to goods, produced either domestically or in a foreign country, purchased for resale or promotional purposes.

"Packaging Component" means: any individual assembled part of a package which is produced either domestically or in a foreign country, such as, but not limited to, any interior or exterior blocking, bracing, cushioning, weatherproofing, exterior strapping, coatings, closures, inks and labels. Tin-plated steel that meets the American Society for Testing and Materials (ASTM) specification A 623 shall be considered as a single package component. Electro-galvanized coated steel and hot dipped coated galvanized steel that meets the American Society for Testing and Materials (ASTM) specifications A653, A924, A879 and A591 shall be treated in the same manner as tin-plated steel.

"Manufacturing" means: Physical or chemical modification of (a) material(s) to produce packaging or packaging components.

"Distribution" means: The practice of taking title to (a) package(s) or packaging component(s) for promotional purposes or resale. Persons involved solely in delivering (a) package(s) or packaging component(s) on behalf of third parties are not considered distributors.

"Manufacturer" means: Any person, firm, association, partnership, or corporation producing (a) package(s) or packaging component(s) as defined in this Act.

"Supplier" means: Any person, firm, association, partnership, or corporation who sells, offers for sale, or offers for promotional purposes packages or packaging components which shall be used by any other person, firm, association, partnership, or corporation to package (a) product(s).

"Intentional Introduction" means: The act of deliberately utilizing a regulated metal in the formation of a package or packaging component where its continued presence is desired in the final package or packaging component to provide a specific characteristic, appearance, or quality.

The use of a regulated metal as a processing agent or intermediate to impart certain chemical or physical changes during manufacturing, whereupon the incidental retention of a residue of said metal in the final package or packaging component is neither desired nor deliberate, is not considered intentional introduction for the purposes of this Act where said final package or packaging component is in compliance with subsection c of Section 4 of this Act.

The use of recycled materials as feedstock for the manufacture of new packaging materials, where some portion of the recycled materials may contain amounts of the regulated metals, is not considered intentional introduction for the purposes of this Act where the new package or packaging component is in compliance with subsection c of Section 4 of this Act.

"Incidental Presence" means: The presence of a regulated metal as an unintended or undesired ingredient of a package or packaging component.

Section 4. Prohibition/Schedule for Removal of Incidental Amounts:

a. As soon as feasible but not later than two years after the adoption of this Act, no package or packaging component shall be offered for sale or for promotional purposes by its manufacturer or distributor in the state of _____, which includes, in the package itself or in any packaging component, inks, dyes, pigments, adhesives, stabilizers or any other additives, any lead, cadmium, mercury or hexavalent chromium which has been intentionally introduced as an element during manufacturing or distribution as opposed to the incidental presence of any of these elements.

b. As soon as feasible, but not later than two years after the adoption of this Act, no product shall be offered for sale or for promotional purposes by its manufacturer or distributor in the state of _____ in a package which includes, in the package itself or in any of its packaging components, inks, dyes, pigments, adhesives, stabilizers or any other additives, any lead, cadmium, mercury or hexavalent chromium which has been intentionally introduced as an element during manufacturing or distribution as opposed to the incidental presence of any of these elements.

c. The sum of the concentration levels of lead, cadmium, mercury and hexavalent chromium present in any package or packaging component shall not exceed the following:

600 parts per million by weight (0.06%) effective two (2) years after adoption of this statute;

250 parts per million by weight (0.025%) effective three (3) years after adoption of this statute;
and

100 parts per million by weight (0.01%) effective four (4) years after adoption of this statute.

Section 5. Exemptions:

All packages and packaging components shall be subject to this Act except the following:

- a. those packages or package components with a code indicating date of manufacture that were manufactured prior to the effective date of this statute; or
- b. those packages or packaging components to which lead, cadmium, mercury or hexavalent chromium have been added in the manufacturing, forming, printing or distribution process in order to comply with health or safety requirements of Federal law, provided that the manufacturer of a package or packaging component must petition the [State administrative agency] for any exemption from the provisions of this subsection for a particular package or packaging component based upon either criterion; and provided further that the [State administrative agency] may grant an exemption for up to two years if warranted by the circumstances; and provided further that such an exemption may, upon reapplication for exemption and meeting the criteria of this subsection, be renewed at two-year intervals; or
- c. packages and packaging components that would not exceed the maximum contaminant levels set forth in subsection c of Section 4 of this Act but for the addition of recycled materials; and provided that the exemption for this subparagraph shall expire January 1, 2010; and shall not apply to any cadmium, lead, mercury or hexavalent chromium that has been recovered and/or separated from other materials for use as a metal or metallic compound; or
- d. those packages or packaging components to which lead, cadmium, mercury or hexavalent chromium have been added in the manufacturing, forming, printing or distribution process for which there is no feasible alternative, provided that the manufacturer of a package or packaging component must petition the [State administrative agency] for any exemption from the provisions of this subsection for a particular package or packaging component based upon the criterion and submit such documentation as necessary to support the request for the exemption; and provided further that the [State administrative agency] may grant an exemption for up to two years if warranted by the circumstances; and provided further that such an exemption may, upon reapplication for exemption and meeting the criterion of this subsection, be renewed at two-year intervals. For purposes of this subsection, a use for which there is no feasible alternative is one in which the petitioner conclusively demonstrates that the regulated substance is essential to the protection, safe handling, or function of the package's contents and that technical constraints preclude the substitution of other materials. "No feasible alternative" does not include use of any of the regulated metals for the purposes of marketing; or
- e. packages and packaging components that are reused but exceed contaminant levels set forth in subsection c of Section 4 of this Act, provided that the product being conveyed by such package and/or the package/packaging component is (are) regulated under Federal and/or State health or safety requirements; and provided that transportation of such packaged product is regulated under Federal and/or State transportation requirements, and provided that disposal of such package is performed according to Federal and/or State radioactive or hazardous waste disposal requirements, and provided that an exemption under this subparagraph shall expire on January 1, 2010; or
- f. packages and packaging components having a controlled distribution and reuse that exceed the contaminant levels set forth in subsection c of Section 4 of this Act, provided that the manufacturer or distributor of such packages or packaging components must petition the (State administrative agency) for exemption and receive approval from the (State administrative agency, working with the CONEG Toxics in Packaging Clearinghouse) according to standards in subsection f.1 below set by such agency and based upon satisfactory demonstrations that the environmental benefit of the controlled distribution and reuse is significantly greater as compared

to the same package manufactured in compliance with the contaminant levels set forth in subsection c of Section 4; and provided that an exemption under this subparagraph shall expire on January 1, 2010; and

f1. Standards - A plan, to be proposed by the manufacturer seeking the exemption of his designee, shall include each of the following elements:

i. a means of identifying in a permanent and visible manner those reusable entities containing regulated metals for which an exemption is sought;

ii. a method of regulatory and financial accountability so that a specified percentage of such reusable entities manufactured and distributed to other persons are not discarded by those persons after use, but are returned to the manufacturer or his/her designee;

iii. a system of inventory and record maintenance to account for reusable entities placed in, and removed from, service;

iv. a means of transforming returned entities that are no longer reusable into recycled materials for manufacturing or into manufacturing wastes which are subject to existing Federal and/or State laws or regulations governing such manufacturing wastes to ensure that these wastes do not enter the commercial or municipal waste stream; and

v. a system of annually reporting to the [appropriate State administrative agency] changes to the system and changes in designees.

g. A glass or ceramic package or packaging component which has a vitrified label when sample is prepared according to ASTM C1606-04 and tested in accordance with the Toxicity Characteristic Leaching Procedures of US EPA Test Method and publication SW 846, 3rd edition, Test Methods for Evaluating Solid Waste, does not exceed 1.0 ppm for cadmium, 5.0 ppm for hexavalent chromium and 5.0 ppm for lead. Mercury shall not be exempted by this provision.

Section 6. Certificate of Compliance:

As soon as feasible, but not later than two years after the adoption of this Act, a Certificate of Compliance stating that a package or packaging component is in compliance with the requirements of this Act shall be furnished by its manufacturer or supplier to its purchaser provided, however, that where compliance is achieved under the exemption(s) provided in subsection 5, the Certificate shall state the specific basis upon which the exemption is claimed. The Certificate of Compliance shall be signed by an authorized official of the manufacturing or supplying company. The purchaser shall retain the Certificate of Compliance for as long as the package or packaging component is in use. A copy of the Certificate of Compliance shall be kept on file by the manufacturer or supplier of the package or packaging component. Certificates of Compliance, or copies thereof, shall be furnished to the [state administrative agency] upon its request and to members of the public in accordance with section 9.

If the manufacturer or supplier of the package or packaging component reformulates or creates a new package or packaging component, the manufacturer or supplier shall provide an amended or new Certificate of Compliance for the reformulated or new package or packaging component.

Section 7. Enforcement:

[Each state to add its own enforcement provisions]

Section 8. State Review:

[The state administrative agency] shall, in consultation with the Toxics in Packaging Clearinghouse (TPCH), review the effectiveness of this Act within five years of its adoption and every 5 years thereafter. The agency shall provide a report based upon that review to the Governor and Legislature. The report may contain recommendations to add other toxic substances contained in packaging to the list set forth in this Act in order to further reduce the toxicity of packaging waste, and a description of the nature of the substitutes used in lieu of lead, mercury, cadmium, and hexavalent chromium.

[The State administrative agency] shall, in consultation with the TPCH, review the extension of any exemption as it is provided for in Section 5 of this Act. This review shall commence no later than January 1, two years prior to the expiration of the exemption. A report based upon that review shall be provided to the Governor and Legislature by January 1 of the year prior to the expiration of the exemption.

Section 9. Public Access:

Any request from a member of the public for any Certificate of Compliance from the manufacturer or supplier of a package or packaging component shall be:

- a. Made in writing with a copy provided to the [state administrative agency];
- b. Made specific as to package or packaging component information requested; and
- c. Responded to by the manufacturer or supplier within 60 days.

Section 10. Effective Date:

This Act shall become effective immediately upon adoption.

Section 11. Severability and Construction:

The provisions of this Act shall be severable, and if any court declares any phase, clause, sentence, or provision of this Act to be invalid, or its applicability to any government, agency, person, or circumstance is declared invalid, the remainder of the Act and its relevant applicability shall not be affected. The provisions of this Act shall be liberally construed to give effect to the purposes thereof.

As revised, December 1998 and October 2004.