

Mercury Law Requirements

This is not a Medical Device Directive/Regulation.
This Regulation applies to Medical Devices

Vinay Goyal
February 24, 2009



Mercury Awareness Logo



Agenda

- Key definitions
- IMERC form
 - Notification
 - Exemption
- VT Form
 - Certified labeling plan and alternate labeling plan

Key definitions

- What is IMERC?
- What is intentionally added mercury?
- Is there any de-minimis (threshold) limit?

Why Mercury?

- It is a Persistent, Bioaccumulative Toxin (PBT)
 - Long-lasting substances that can build up in the food chain to levels that are harmful to human and ecosystem health
 - Because of their persistence and bioaccumulative properties, they do not break down easily and are particularly difficult to clean up
 - These contaminants can be transported long distances and move readily from land to air and water

The Truth About Mercury Poisoning

- How does mercury occur in the environment?
 - Mercury is a naturally occurring element that can be found throughout the environment.
 - Human activities such as burning coal and using mercury to manufacture certain products, have increased the amount of mercury that is currently cycling in the atmosphere, in soils, and in lakes, streams and the oceans.

The Truth About Mercury Poisoning

- What are the biggest sources of mercury air emissions?
 - Coal-fired electric power plants are the largest source of human-caused mercury air emissions in the U.S (40%)
 - According to EPA's 1999 National Emissions Inventory.
 - Industrial boilers (about 10% of U.S. mercury emissions),
 - Burning hazardous waste (about 5%), and
 - Chlorine production (also about 5%).

Truth About Mercury Poisoning

- How do people and wildlife become exposed to mercury?
 - Mercury that is emitted to the air falls to the ground either very close to the source or many miles away.
 - Mercury deposited into the water, or runs off the ground into the water, microorganisms convert some portion to methylmercury, a highly toxic form of mercury.

Truth About Mercury Poisoning

- How do people and wildlife become exposed to mercury?contd
 - Small organisms take this up as they feed. As animals higher up the food chain eat those small organisms, they also take in methylmercury. The process, known as bioaccumulation, continues with levels of mercury increasing as it moves up the food chain.
 - Fish that are higher in the food chain, such as sharks and swordfish, have much higher mercury concentration than fish that are lower on the food chain.

Truth About Mercury Poisoning

- Humans become exposed when they eat fish that are contaminated with mercury and methylmercury
 - Methylmercury cannot be removed by cooking or cleaning the fish.
 - Mercury cannot be detected in fish by its smell or appearance.

Truth About Mercury Poisoning

- Mercury is a powerful neurotoxin that affects every aspect of brain and nerve function. It can cause
 - Tremors,
 - Memory loss,
 - Mental impairment and
 - Many other complications in the nervous system.
- Pregnant women who eat contaminated fish can pass mercury to their unborn children, who are very sensitive to its toxic effects.
 - Mercury is especially dangerous to the developing fetus as it impairs brain development, resulting in lowered intelligence and other brain deficits.

What household products contain Mercury

Batteries	Mercuric oxide and pre-1996 alkaline batteries	Look for labeling that says mercury reduced or eliminated. Avoid mercury zinc button batteries
Fluorescent light bulbs	Compact and tubes	Buy low-mercury fluorescent light bulbs
Gauges	Including barometers, manometers, blood pressure, and vacuum gauges with a silver-colored liquid	Alternatives include digital and needle or bourdon gauges
Mercury vapor lights	High intensity discharge (HID), metal halide, and high pressure sodium and neon bulbs	Alternatives are not available, use low-mercury brands if available
Paint	Pre-1990 latex and some oil-based paint (check the label)	Buy new latex paints and avoid oil-based paints containing mercury

What household products contain Mercury

Thimerosal and Merbromin	In some antibacterial products such as mercurochrome	Read labels on medicines, ointments and creams
Pilot light sensors	Some gas appliances such as stoves, ovens, clothes dryers, water heaters, furnaces, and space heaters	Newer models have electronic sensors
Switches and relays	Some freezer chests and clothes irons, pre-1972 washers, sump and bilge pumps, electric space heaters, silent light switches, farm equipment and vehicles	Ball-type switches becoming more available in car hoods and trunks
Thermometers	Containing a silver-colored liquid	Use red-bulb (alcohol) or electronic digital thermometers instead
Thermostats	Non-electric	Switch to electronic models and snap switches, esp. when remodeling
Vintage Toys	Toy drawing screens and mercury maze games	Electronic devices and other liquids are used in newer toys

What is IMERC?

- The Interstate Mercury Education and Reduction Clearinghouse (IMERC) was established by state environmental officials from
 - Connecticut
 - Maine
 - Massachusetts
 - New Hampshire
 - New Jersey
 - New York
 - Rhode Island
 - Vermont

In 2001 to help them implement laws and programs aimed at getting mercury out of consumer products, the waste stream, and the environment.

Current IMERC – Member States

- California
- Connecticut
- Illinois
- Maine
- Massachusetts
- Minnesota
- New Hampshire
- New Jersey
- New York
- North Carolina
- Rhode Island
- Vermont
- Washington
- Louisiana

IMERC – Member States

- The participating states are coordinating these mercury reduction initiatives through the Interstate Mercury Education and Reduction Clearinghouse (IMERC) in order to:
 - Promote consistency among the states in implementing labeling and notification requirements; and
 - Provide a single point of contact for manufacturers

Other States Labeling Laws

- Maryland and Oregon also have mercury-added product labeling laws. These states are not members of IMERC.
- Most of the US states have some sort of mercury laws

State by State Comparison

<u>Alabama</u>	<u>Guam</u>	<u>Montana</u>	<u>South Dakota</u>
<u>Alaska</u>	<u>Hawaii</u>	<u>Nebraska</u>	<u>Tennessee</u>
<u>American Samoa</u>	<u>Maine</u>	<u>Nevada</u>	<u>Texas</u>
<u>Arizona</u>	<u>Illinois</u>	<u>New Hampshire</u>	<u>United States Virgin Islands</u>
<u>Arkansas</u>	<u>Indiana</u>	<u>New Jersey</u>	<u>Vermont</u>
<u>California</u>	<u>Iowa</u>	<u>New Mexico</u>	<u>Utah</u>
<u>Colorado</u>	<u>Kansas</u>	<u>New York</u>	<u>Vermont</u>
<u>Confederation of the Northern Mariana Islands</u>	<u>Kentucky</u>	<u>North Carolina</u>	<u>Virginia</u>
<u>Connecticut</u>	<u>Louisiana</u>	<u>North Dakota</u>	<u>Washington</u>
<u>Delaware</u>	<u>Maine</u>	<u>Ohio</u>	<u>West Virginia</u>
<u>District of Columbia</u>	<u>Maryland</u>	<u>Oklahoma</u>	<u>Wisconsin</u>
<u>Florida</u>	<u>Massachusetts</u>	<u>Oregon</u>	<u>Wyoming</u>
<u>Georgia</u>	<u>Michigan</u>	<u>Pennsylvania</u>	
	<u>Minnesota</u>	<u>Rhode Island</u>	
	<u>Mississippi</u>	<u>South Carolina</u>	
	<u>Missouri</u>		

Among all, it appears the most “Stringent” requirements are from Interstate Mercury Education and Reduction Clearing House (IMERC)

Key IMERC Member States Requirements

- Notification
- Ban
 - If a product/part is banned
- Exemption
 - If a product is listed on phase out list.
 - State authorities have to be convinced that use of mercury is essential based on some solid reasoning
 - Exemption could be time limited
- Certified Labeling Plan (State of Vermont)
 - Alternate labeling plan if unable to meet Certified labeling plan requirements

Notification

Purpose of Mercury-added Product Notification?

- "Product Notification" requirements are intended to inform consumers, recyclers, policy makers, and others about:
 - Products that contain intentionally-added mercury;
 - The amount of mercury in a specific product; and
 - The total amount of mercury in the specific products that were sold in the US in a given year.

What is intentionally added Mercury

Where mercury or a mercury compound was added with the intent of providing or contributing a specific characteristic, appearance, quality, or any other specified / intended function in the end product

Is there any de minimis level?

If a Product Contains Only Trace Levels of Mercury Do I Need to Notify?

There is no de minimis level of mercury in the definition of a mercury-added product. The critical question for compliance with IMERC-member state requirements is whether the mercury is *intentionally added* to the product.

This is a critical difference between states' regulations in the U.S. and the regulations established by the European Union.

What are the Deadlines for Notification?

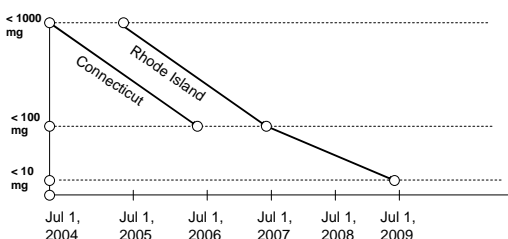
Companies must provide a complete update of their Notification Form, including product information and total mercury use based on U.S. sales of mercury-added products at least once every three years.

The triennial notification schedule is shown in the table below:

Reporting Year	Notification Deadline
2001	April 1, 2002
2004	April 1, 2005
2007	April 1, 2008
2010	April 1, 2011
2013	April 1, 2014

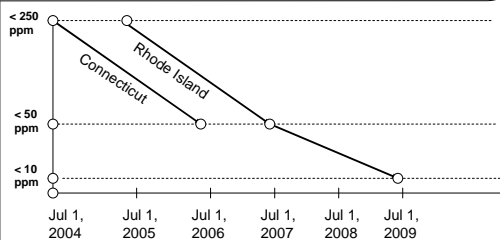
Mercury Ban and Phase Out requirement

Mercury Phase-out requirement and time-line¹ (Fabricated Hg added product)



¹Unless exemption is granted by the Commissioner of the State Department of Environmental Protection <http://www.newmoa.org/prevention/mercury/imerc/Phase-outForm.pdf>

Mercury Phase-out requirement and time-line¹ (Formulated Hg added product)



¹Unless exemption is granted by the Commissioner of the State Department of Environmental Protection <http://www.newmoa.org/prevention/mercury/imerc/Phase-outForm.pdf>

Mercury Phase Out requirement

Products	Effective dates
Thermostats	Jan 1, 2006 ME; May 1, 2008 MA; Jan 1, 2008 NH
Barometers, esophageal dilators, bougie tubes, gastrointestinal tubes, flow meters, hygrometers, psychrometers & pyrometers	Jan 1, 2006 NY; July 1, 2006 ME; Jan 1, 2007 VT; Jan 1, 2008 NH; May 1, 2008 MA
Sphygmomanometers	Jul 1, 2006 CA; Jan 1, 2007 VT; Jan 1, 2008 NH; May 1, 2008 MA
Diostats	Jan 1, 2008 CA
Hydrometers & manometers	Jul 1, 2006 ME; Jan 1, 2007 NY; VT; May 1, 2008 MA
Neon signs	Jan 1, 2007 VT;
Switches & relays	Jul 1, 2006 CA, ME; Jan 1, 2007 VT; Jul 1, 2007 IL; Jan 1, 2008 NY; May 1, 2009 MA; Jan 1 2008 NH

Who requires Exemption Application

- IMERC
- Connecticut
- Rhode Island
- Illinois

Ban versus Phase-out

- The difference between a mercury-added product sales ban and a mercury-added product sales phase-out is that some exemptions are allowed under a product phase-out.

Exemption Justifications

- Exemption is granted based on the following sound reasons as listed below
 - Why the product or component must use mercury
 - The potential non-mercury alternative products or components and why they are not technically feasible;
 - Current status of the industry efforts to find a non-mercury substitution;
 - The process by which company researched available non-mercury alternative products or components and made a determination that they are not feasible, including discussions with outside unbiased experts;
 - There are technically feasible non-mercury alternatives but you are claiming that their costs are unreasonable, include data documenting your claim.

Certified Labeling Plan Alternate Labeling Plan

Products Subject to Vermont's Labeling Law

(Vermont has the most stringent law related to mercury labeling and notification)

Items that must be labeled:

The products covered under Vermont's labeling law are the following: (individually or as a part of another product)

- Thermostat
- Thermometer
- Switch
- Medical instrument
- Scientific instrument
- Electric relay
- Electrical device
- Lamp
- Battery (other than button battery)
- Formulated products

Vermont's Labeling Requirements

- Certified labeling Plan
 - 10 font size
 - The (part) in this product contains mercury. Do not put in the trash. Recycle or Dispose of as per the local, state and Federal requirements – on the
 - Product
 - User instructions
 - Packaging
 - Prior-to-purchase notification
 - Visible
- Alternate labeling Plan
 - If unable to meet certified labeling plan
 - Good for 2 years, renewal required

Standard Labeling Requirements

- Is visible to the product user;
- Is printed in English using 10 point font or larger;
- Is mounted, engraved, molded, embossed, or otherwise affixed to the product using materials that are sufficiently durable to remain legible throughout the life of the product;
- Bears the wording "contains mercury" or equivalent wording;
- Label should state that the product cannot be placed in trash and must be recycled or disposed of as a hazardous waste.

Examples:

"Contains Mercury, Don't Put In Trash. Recycle or Dispose as Hazardous Waste"

"Contains Mercury, Dispose According to Local, State or Federal Laws"

"Contains Mercury, Dispose of Properly "

Product Catalog

- Sales literature
 - Connecticut, Louisiana and Mass require “prior-to-purchase” visibility
 - Which means you would need to ask yourself “what does my customer see prior to purchasing this product”
 - If the product is purchased off the internet you could put information there
 - If it is sold by sales people using catalogues then you may need to put something there.
 - If you want to comply with these states for these requirements you may wish to include that information in your labeling plan so that you will have your bases covered should they check for compliance.

One form for all member states

Question:

Does it require an approval from IMERC. If yes, what is a typical approval time?

IMERC Response

Yes, once the Form is submitted it will be reviewed by the participating states and they may approve it or not. The approval time varies a lot depending on the quality and thoroughness of the Form that is submitted.

Standard Labeling Requirements

If the product incorporates a mercury-added component that is not visibly labeled in accordance with this standard, the label on the larger product must clearly identify the internal component, e.g.,

“(describe component) in this product contains mercury, dispose according to local, state, or federal law or some equivalent language indicated in sample wording above”.

What are IMERC Product Labeling & Notification Requirements?

Labeling Products and Packaging

Connecticut, Maine, Massachusetts, Minnesota, New York, Rhode Island, Vermont, and Washington State prohibit the sale of mercury-added products unless they have a label to:

- Inform consumers at the point of purchase that the product contains mercury and may require special handling at end of life; and
- Identify the products at the point of disposal so that they can be kept out of the trash and recycled.

Producer’s responsibility

Question:

Any producer’s responsibility for collection/recycling fee?

IMERC Response:

Yes, there is producer responsibility for product collection of certain products in Connecticut and Rhode Island -- see the guidance at the following url -

<http://www.newmoa.org/prevention/mercury/imerc/collectioninfo.cfm>

Where Can I Get More Information?

For more information on state specific Mercury-added Product Bans, including how to apply for exemptions, visit the following websites:

California - <http://www.dtsc.ca.gov/HazardousWaste/Mercury/>
Connecticut - http://www.ct.gov/deep/cwp/view.asp?a=2708&q=324018&depNav_GID=1638
Illinois - <http://www.epa.state.il.us/mercury/mercury-illinois.html>
Louisiana - <http://www.deq.louisiana.gov/portal/tabid/287/Default.aspx>
Maine - <http://www.maine.gov/deep/mercury>
Massachusetts - <http://www.mass.gov/dep/toxics/stypes/hgres.htm>
Minnesota - <http://www.pca.state.mn.us/air/mercury.html>
New Hampshire - <http://www.des.state.nh.us/nhapp/Mercury/index.asp?link=leg>
New Jersey - http://www.nj.gov/dep/dsr/mercury_task_force.htm
New York - <http://www.dec.ny.gov/chemical/8853.html>
North Carolina - <http://www.enr.state.nc.us/html/technicalassist.html>
Rhode Island - <http://www.dem.ri.gov/topics/mercury.htm>
Vermont - <http://www.mercvt.org/manreq/bans.htm>
Washington - <http://www.ecy.wa.gov/mercury/>

Comparison between US and EU laws

- EU laws have threshold limits
 - RoHS 2002/95/EC
 - Part should not have mercury greater than 1000 parts per million (ppm) at homogenous material level (unless exempted by the European Commission)
 - 2006/66/EC
 - .0005% weight by weight should be marked accordingly
- IMERC (US) has no threshold limit
 - If it is considered intentionally added mercury in any amount then it must meet the requirements

Minimum detection limit of Hg is .2 parts per billion

Questions?



- Questions or comments:

Vinay Goyal

vinaygoyal@sbcglobal.net

(714)-876-3927

