Excerpts from the Report

By doing a "find" on "dental" and on "vaccinations".

Page 5:

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| **Objective** | |
| **Comment Summary** | **Response** |

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| The objective should be to prohibit and phase out all products containing mercury because the adverse impacts of mercury in products outweigh any benefits. | As stated in the Regulatory Impact Analysis Statement (RIAS), the objective is to reduce releases of mercury from products used in Canada to the lowest level possible. However, due to its unique properties, mercury continues to be required in certain products such as lamps and dental amalgam. The Government has determined that the benefits of continuing to use these products outweigh the costs. For example, mercury is required in lighting, which is an essential technology for Canadians. The Government will continue to assess available technologies and alternatives to mercury-containing products; and eventually, the Regulations could be amended to remove exempted products or lower content limits. |

Page 7:

**Drugs**

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| **Comment Summary** | **Response** |
| The rationale for excluding drugs from the Regulations was requested, as well as | The Government of Canada is using its authority under CEPA 1999 to control mercury releases to the environment from mercury-containing |
| information on the use of mercury in drugs.  The Regulations should apply to mercury-containing vaccines because they are dangerous to infants and pregnant women.  Canada needs stricter measures for testing and regulation of products such as antiseptic and antibacterial cream, skin lightening creams, antibiotics for the eye, some nasal preparations, and ear preparations. | products; however, it was recognized that certain products are already regulated under other legislation or are essential products which have no viable alternatives. Mercury-containing drugs, including vaccines, were proposed to be excluded from the regulations because they are an essential product with no viable alternative and are already regulated under the Food and Drugs Act.  The Food and Drugs Regulations prohibit the use of mercury or any of its salts or derivatives unless the drug is an ophthalmic drug or other drug used in the area of the eye, is a drug for nasal administration, is a drug for optic administration, or is a drug for parenteral administration that is packaged in a multi-dose container in which the mercury or the salt or the derivative thereof is present as a preservative and the manufacturer or importer has submitted evidence demonstrating that the only satisfactory way to maintain the sterility or stability of the drug is to use that preservative.10  Thimerosal is a preservative that contains mercury and it has been used in some vaccines and other products since the 1940's to prevent spoilage and contamination. Making vaccines safer and more effective is a constant goal for the federal government and vaccine manufacturers. But decisions must be based on weighing the risks and benefits of each vaccine. In some cases, mercury-free alternatives may not be available or may not be as suitable as the thimerosal formulations. Since thimerosal vaccines contain only minute levels of mercury, the benefits of vaccination with them far outweigh the minimal risks associated with thimerosal. Most vaccines licensed in Canada do not contain thimerosal. Since 1994, all routine childhood vaccines, with the exception of the flu vaccine, administered in Canada have not contained thimerosal. Thimerosal is not added to single dose vaccines.11 . . . |

Page 8:

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| **Waste** | |
| **Comment Summary** | **Response** |
| “Waste” should be defined since ambiguity could create compliance and enforcement issues. | The reference to waste is meant to apply to the notion as defined in its ordinary sense in dictionaries. The intention of making the regulations explicitly not applicable to waste is to be clear that the Regulations will apply to new products, not products at their end-of-life that are intended to be disposed. |

Page 10:

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| **Prohibitions Comment Summary** | **Response** |

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| Since lamps and dental amalgam make up almost three quarters of all uses of mercury in products, the Regulations should focus on these products. | The Government has determined that there are no viable alternatives to these products and that their use remains essential to Canadians. The Government will continue to assess available technologies and alternatives to mercury-containing products.  Dental amalgam waste is managed through the Pollution Prevention Notice for Dental Amalgam Waste17, and end-of-life mercury-containing lamps will be managed by the proposed Extended Producer Responsibility Regulations  that are currently being developed by Environment Canada. |

Pages 23 - 24:

**Dental Amalgam**

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| **Comment Summary** | **Response** |
| Dental amalgam should not be exempted from the Regulations. Banning amalgam would result in a cleaner environment by stopping mercury emissions and protecting human health. | The Government of Canada is using its authority under CEPA 1999 to regulate mercury releases to the environment from mercury-containing products. Dental amalgam was exempted because it is considered an essential product which has no viable alternative. Dental amalgam releases to the environment are controlled through the Pollution Prevention Planning Notice for Dental Amalgam Waste33.  The safety of dental amalgam has been evaluated by Health Canada.34 |
| Dental amalgam has viable alternatives. Resin and ART (atraumatic restorative treatment) are appropriate for most cavities.  The Government should have a time-limited exemption on dental amalgam in order to reassess the availability of alternatives later. | The Government will continue to monitor available alternatives and actions taken in other jurisdictions, including the global legally binding instrument on mercury pollution that is currently being negotiated under the United Nations. |
| Dental workers are exposed to mercury. | These Regulations under CEPA 1999 do not address occupational health and safety. |
| Voluntary measures for dental amalgam have failed, and the Pollution Prevention Notice for Dental Amalgam Waste35 is not enforceable. Dental amalgam accounts for half of the mercury currently entering the Canadian marketplace in products, and should be subject to regulatory measures. | Releases of mercury to the environment from dental amalgam waste are being managed using a pollution prevention notice, which is an enforceable instrument under CEPA 1999. |
| The Regulations should align with the US, which recently announced that they support a phase down of dental amalgam. | A phase down of dental amalgam use is expected in Canada due to the development of improved oral health promotion and disease prevention programs, research into alternative dental restorative materials and improved access to dental care. |
| There should be labelling of dental amalgam. | Dental amalgam products will require labelling under the Regulations. Dental amalgam products are already voluntarily labelled. |

Page 29

**End-of-Life Management of Mercury-containing Products**

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| The government should ensure the proper management of all mercury-containing products, including safe use, inventory reporting and appropriate disposal/recycling. Producers should be responsible for the collection and end-of-life management of their products.   1. What should companies do with excess mercury and products? 2. How mercury is collected and stored in Canada? 3. How do dentists dispose of dental amalgam waste? 4. How are old thermometers disposed of? | Environment Canada recognizes it is important that mercury-containing products are handled appropriately to prevent releases to the environment. Mercury-containing waste must be managed in accordance with all relevant governmental requirements and policies. To plan for the proper recycling of mercury-containing products, mercury recycling companies, hazardous waste management firms and/or certified carriers should be contacted and products should be properly packaged prior to transport to help prevent breaks or leaks.  Furthermore, the control of hazardous waste and hazardous recyclable material within Canada is a shared responsibility between the federal, provincial/territorial and municipal governments. Since the provinces/territories are responsible for establishing controls for licensing hazardous waste generators, carriers and treatment facilities within their jurisdiction, provincial/territorial government’s may also be contacted for guidance. Mercury-containing products may also be collected as part of municipal household hazardous waste collection programs and many companies will take back mercury-containing products.  At the federal level Environment Canada has taken action to ensure the proper management of various mercury-containing products at their end-of-life. For example, under the Pollution Prevention Planning Notice for Dental Amalgam Waste, dentists should contact an authorized carrier to dispose of their dental amalgam waste. Environment Canada is also in the process of developing an Extended Producer Responsibility regulation for the collection and recycling of mercury-containing lamps. By prohibiting most mercury-containing products, these Regulations will mean there will be far fewer mercury-containing products to manage at their end-of-life. |

Page 30:

**Education**

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| Health Canada should implement an education and outreach campaign within the dental industry to educate Canadians about the health impacts of mercury-containing dental amalgam and to raise awareness of the non-mercury options available. | Health Canada has reviewed the safety of dental amalgam and provided advice. |

**Regulatory Impact Analysis Statement (RIAS) General Comments**

Page 32:

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| Various information and analysis was requested, including:   1. The quantity mercury in products over a number of years 2. The cumulative quantity of mercury used in dental amalgam and lamps in Canada over time 3. A list of all mercury-containing products imported into Canada 4. An example of the mass balance framework, including the assumptions used to determine the baseline scenarios and releases to each media (air, land and water) | These points will be considered in the development of the final RIAS.  Regarding the list of mercury-containing products imported into Canada, Environment Canada gathered data from the Canadian Border Services Agency, industry associations, and other sources. However, since importers of mercury-containing products do not currently have to report to any government department or agency, it is possible that some minor sources could have been missed. It is for that reason that Environment Canada has consulted broadly and repeatedly regarding these Regulations  The mass balance framework and assumptions regarding the various product streams are available in the 2009 report prepared by ToxEcology for Environment Canada entitled “Socio-Economic and Mass Balance Study for Mercury-Containing Products”. Part of the report is available on-line through the United Nations website at: http://www.unep.org/hazardoussubstances/Portals/9/Mercury/Documents/INC2/Canada%20information.pdf  Note that certain parts are blacked out in order to protect Confidential Business Information. |

**References**

Page 33

11 Health Canada Mercury Issues Task Group. 2004. Mercury: Your Health and the Environment: Exposure from Dental Amalgam and Thimerosal Vaccines.

Available online at: www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/mercur/q28-q34-eng.php#q-30.

Takes you to this statement from Health Canada:

**Mercury  
Your Health and the Environment**

[Next](http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/mercur/q35-q42-eng.php)

[Previous](http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/mercur/q18-q27-eng.php)

[Table of Contents](http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/mercur/index-eng.php)

**Exposure from Dental Amalgam and Thimerosal Vaccines**

***Q28. Should I avoid mercury amalgam dental fillings?***  
Current evidence does not indicate that dental amalgam is causing illness in the general population. However, it is generally a good idea to reduce exposure to mercury if this can be achieved at a reasonable cost and without other adverse effects. Health Canada recommends non-mercury filling materials be considered for restoring the primary teeth of children where the mechanical properties of the material are suitable. Pregnant women and people who may have allergic hypersensitivity to mercury or who have impaired kidney function should avoid the use of dental fillings containing mercury amalgam.

***Q29. Should I have my existing mercury amalgam dental fillings replaced?***  
Health Canada does not support removal of sound amalgam fillings in patients who have no indication of related adverse health effects. Individuals who have developed hypersensitivity to amalgam should replace existing mercury amalgam fillings with another material if their physician recommends this. Amalgam fillings should not be removed while a woman is pregnant because she might be exposed to mercury vapour during removal.

***Q30. What is thimerosal and why is it used in vaccines?***  
Thimerosal is a preservative that contains mercury and it has been used in some vaccines and other products since the 1940's to prevent spoilage and contamination. Efforts are under way to eliminate thimerosal from product formulations, where possible.

***Q31. If patients have a choice of vaccines, one with mercury or one without, which should they choose?***  
They should choose mercury-free vaccines, if they are available and if they are just as suitable as thimerosal vaccines. Patients should discuss this with their doctor and follow his/her advice. The most important consideration is that parents should not miss an opportunity to have their children immunized. Currently, the only thimerosal-containing vaccine in routine use in the infant immunization schedules of some Canadian jurisdictions is the hepatitis B vaccine.  
(See  
Next link will take you to another Web site[http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/ccdr-rmtc/02vol28/dr2809ea.html](http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/02vol28/dr2809ea.html)  
Next link will take you to another Web site[http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/ccdr-rmtc/03vol29/acs-dcc-1/index.html](http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/03vol29/acs-dcc-1/index.html))

***Q32. Why is the federal government not recommending removal of thimerosal vaccines from use if there is a concern?***   
Making vaccines safer and more effective is a constant goal for the federal government and vaccine manufacturers. But decisions must be based on weighing the risks and benefits of each vaccine. In some cases, mercury-free alternatives may not be available or may not be as suitable as the thimerosal formulations. Missing vaccinations would put children at risk from disease. Since thimerosal vaccines contain only minute levels of mercury, the benefits of vaccination with them far outweigh the minimal risks associated with thimerosal.

***Q33. What degree of mercury exposure has my six-month-old baby encountered from vaccines? Is there a health risk associated with this level of exposure?***  
There is little chance for a six month old to be exposed to mercury through vaccination. Most vaccines licensed in Canada do not contain thimerosal. Since 1994, all routine childhood vaccines, with the exception of the flu vaccine, administered in Canada have not contained thimerosal. Thimerosal is not added to single dose vaccines.

In Canada, vaccines to prevent the following diseases are used for routine immunization of children and do not contain thimerosal:

* diphtheria
* tetanus (lockjaw)
* pertussis (whooping cough)
* polio
* rubella (German measles)
* measles (red measles)
* mumps
* hepatitis B (available free to children only in some provinces and territories)
* Haemophilus influenzae type b disease

For immunization of infants against hepatitis B, parents or guardians in some provinces and territories have the choice of a thimerosal-free vaccine.

***Q34. Do children receive toxic levels of mercury from vaccines?***  
No. Children who receive vaccines containing thimerosal may be exposed to minute levels of mercury, but these are very far below any toxic level.

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**References**

continued

17 Environment Canada. 2010. Notice Regarding Pollution Prevention Planning in Respect of Mercury Releases from Dental Amalgam Waste.

Available online at: <http://www.ec.gc.ca/planp2-p2plan/default.asp?lang=En&n=EB42EEDF-1>

**Dental Amalgam Waste**

**Pollution Prevention Planning Notices**

**Notice Regarding Pollution Prevention Planning in Respect of Mercury Releases from Dental Amalgam Waste**

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34 Health Canada. 1996. The Safety of Dental Amalgam.

(NOTE (Nov 19, 2011) this is actually an invalid link.)

Available online at: [www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/pubs/dent\_amalgam-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/pubs/dent_amalgam-eng.php).

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<http://www.ec.gc.ca/mercure-mercury/default.asp?lang=En&n=B0BF94F2-1>

Mercury – Spills and Disposal (Environment Canada)

Municipal Collection Plans

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Mercury and the Environment (Environment Canada)

<http://www.ec.gc.ca/mercure-mercury/default.asp?lang=En&n=71347F83-1>

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