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April 26, 2011

To: The Director, Waste Reduction and Management Division, Department of the Environment, Gatineau, Quebec K1A 0H3.

Subject: Notice of objection, and request for board of review, respecting the notice published in Canada Gazette Part 1, volume 45, No. 9, dated February 26, 2011, regarding proposed *Regulations Respecting Products Containing Certain Substances Listed in Schedule 1 to the Canadian Environmental Protection Act, 1999*

Mr. Director:

The purpose of this Notice of Objection is to request that a board of review be established under section 333 of the Canadian Environmental Protection Act regarding the proposed *Regulations Respecting Products Containing Certain Substances Listed in Schedule 1 to the Canadian Environmental Protection Act, 1999* (hereinafter referred to as the proposed Regulations).

In particular, we object to the proposed exemption for dental amalgam. A board of review should be established to consider all of the current and relevant science and other information that is pertinent to this issue. The reasons for this objection are as follows:

1. The justification for exclusion of dental amalgam is unfounded.

   Dental amalgam is neither “essential”, nor is it without viable alternatives. Amalgam’s non-essential nature as a dental restorative material is made evident by the recent bans on amalgam use in Sweden (Sweden Ministry of Environment, 2009) and Norway (Norway Ministry of Environment, 2007), and the low rate of amalgam use in Japan (Nakata, 1997).

   Various surveys conducted in Canada and the US demonstrate the declining popularity of dental amalgam use and a significant proportion of the dental profession is now ‘amalgam free’. These surveys were reviewed by SNC-Lavalin Environment (SLE 2010) for consideration by a US FDA panel convened to review the issue of dental amalgam risks. Parts 1 and 2 of the SLE report are available from the IAOMT website (http://www.iaomt.org/articles/category_view.asp?catid=30) or from FDA’s website (http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/DentalProductsPanel/ucm235085.htm).

The majority of our Academy members who are dentists in Canada and the US are successfully amalgam-free and have been for 25 years or more.

Alternate restorative materials have been on the market in Canada for some time, the most common being composite resin. This material performs equally or superior to amalgam if placed correctly. This material has been evaluated for potential risks to dental patients, having been the subject of published risk assessments for exposures to components and degradation products, including bisphenol-a (Richardson 1997; 1999). Risk assessments for other common alternate restorative materials are currently being completed (GM Richardson, SNC-Lavalin Environment, personal communication).

2. Mercury is listed in Schedule 1 (List of Toxic Substances) to the Canadian Environmental Protection Act (CEPA).

   Mercury has been on CEPA's list of toxic substances (Schedule 1) since the introduction of CEPA in 1988. Mercury is persistent and bioaccumulative. Schedule 1 substances are intended for virtual elimination. Mercury from amalgam enters the environment in amounts that are or can be detrimental to the Canadian environment, detrimental the health of Canadians and/or detrimental to the environment upon which human health depends.

   A quantitative environmental emissions inventory of mercury from dental amalgam use in Canada was prepared on behalf of Environment Canada in 2000 (OAEI 2000; see also Van Boom et al. 2001). Total annual emissions, to the Canadian environment, of mercury from amalgam use were 685 kg/year. Dental amalgam, either through releases from dental clinics or from persons with amalgam fillings (via urine and feces), is now the primary source of mercury release to municipal wastewater collection systems and municipal wastewater treatment plants. The 3 fold increase in mercury importation associated with the importation of dental amalgam (see item 3 below), will have increased these amalgam-related environmental emissions by up to a comparable 3 fold.

3. The importation of mercury into Canada as a component of dental amalgam has increased by almost 3 times since 1999.

   In 1999, the quantity of mercury imported into Canada, as a component of prepared dental amalgam products, was 1,642 kg (OAEI, 2000; Van Boom et al. 2001). In 2008, total imports of mercury, as a component of dental amalgam, was some 4,700 kg (data detailed in the Canada Gazette notice for which this objection is being submitted). No other Schedule 1 substance has enjoyed a 3 fold increase in importation and use in Canada, in a manner that directly and intentionally exposes millions of Canadians.

4. Exemption of dental amalgam from regulation will omit regulatory consideration and control of the single largest source of mercury importation, use and population exposure in Canada.

   Dental amalgam is recognized by Health Canada as the single greatest source of mercury exposure in the Canadian population (Health Canada 1996). Although Health Canada has not assessed population exposure to all forms of mercury

since 1995 (Health Canada, 1995; see also Richardson and Allan 1996), this has been recently re-confirmed for the US population (Richardson 2010).

Therefore, if dental amalgam is exempted from any form of regulatory exposure control in the Canadian population, all other regulations will have no significant effect in reducing mercury exposure and risks in the Canadian population.

5. Some 18 million Canadians, greater than 50% of the Canadian population, are exposed to mercury vapour from amalgam in excess of the dose associated with Health Canada's reference exposure level that defines safe exposure to mercury vapour.

   Health Canada established a safe level of exposure to mercury vapour in 2008 (Health Canada, 2008; see also Richardson et al. 2009). In 2010 the US FDA considered a report that documented mercury exposure from dental amalgam in the US population (available on-line; see URLs under item 1, above). For the US population, some 181 million Americans exceeded the daily dose associated with Health Canada's reference exposure level of 0.06 μg mercury/m^3 of air. The Canadian population is approximately 1/10^{th} that of the US. Given similar standards of living and similar levels of dental care, it can therefore be expected that approximately 18 million Canadians (1/10^{th} the number in the US) will exceed the mercury dose associated with Health Canada's reference exposure level.

6. Dental amalgam is classified as a hazardous waste.

   Materials containing mercury are classified as hazardous materials, and wastes containing mercury are classified as hazardous wastes. The amalgam wastes collected by compliant dentists and dental clinics that have installed amalgam separators in their wastewater systems, must arrange for disposal of this amalgam waste with operators who are licensed to handle and transport this hazardous waste. Mercury emitted from crematoria as a result of the cremation of persons with amalgam fillings, has created environmental problems and crematoria must ensure they meet mercury emission standards. How can a material that is considered by the Canadian Dental Association for placement in pregnant women and young children possibly be a hazardous waste? Or alternately, how can a hazardous waste possibly be safe for placement into the mouths of pregnant women and young children?

7. Voluntary compliance with Health Canada's recommended codes of practice for the dental profession have been ineffective.

   The dental profession in Canada, as a whole, has not followed nor implemented Health Canada (1996) recommendations that were intended to reduce mercury exposure from dental amalgam. Those recommendations included: a) do not place or remove amalgam fillings in pregnant women; b) use non-amalgam alternatives in young children; c) do not place or remove amalgam fillings in individuals with impaired kidney function; d) employ techniques to reduce mercury exposure during procedures to place or remove amalgam fillings; e) advise individuals who may have allergic hypersensitivity to mercury to avoid the use of amalgam; f) new amalgam fillings should not be placed in contact with existing metal devices in the mouth such as braces.

   Of particular note has been the failure of general dentistry in Canada to implement Health Canada's recommendation respecting informed patient

consent. Specifically, Health Canada recommended that dentists provide their patients with sufficient information to make an informed choice regarding the material used to fill their teeth, including information on the risks and benefits of the material and suitable alternatives. We know that such informed patient consent is the exception, rather than the rule, for dentists in Canada.

In Quebec, for example, 376,879 amalgam restorations were placed in children and reimbursed by the Provincial Health Plan(RAMQ) to treating dentists in 2010; alternative restorative materials are not covered in back teeth. (https://www.prod.ramq.gouv.qc.ca/IST/CD/CDF_DifsnInfoStats/CDF1_CnsulInfoStatsCNC_iut/DifsnInfoStats.aspx?ETAPE_COUR=2&LANGUE=fr-CA)

8. Use of dental amalgam is disproportionately high in the poor, and in Canadian First Nations and Inuit populations.

   Canada's poor, and Canada's First Nations and Inuit populations, are generally reliant on socialized dental services that preferentially (perhaps exclusively) place amalgam for the repair of carious teeth. Refer to the Quebec Health Insurance Board (RAMQ) for details and examples. However, for people on welfare and children under 10, the lowest cost alternative (which is amalgam) is generally approved.

   According to Health Canada's First Nations, Inuit and Aboriginals Health Reports and Publications (http://www.hc-sc.gc.ca/fniah-spnia/pubs/nihb-ssna/_dent/2010-prov-fourn-guide/index-eng.php#a1.1): ''When both composite and amalgam procedure codes are billed on the same tooth, the system will pay at the cost of the lesser amount up to a maximum cost of an amalgam five surface restoration/complete tooth reconstruction (the lesser amount to be paid).''

   Further, in section 8.3.4 entitled CORES* AND POSTS" it stipulates that amalgam cores are reimbursed (' Bonded amalgam cores are covered at a rate of a non-bonded equivalent.''). A core is used to 'build a tooth up' before a gold or other metal alloy crown is placed over it. This practice is in direct contradiction of Health Canada's 1996 policy recommendation that amalgam fillings should not be placed in contact with other metal devices in the mouth. ''

   Therefore, patients and dentists are financially discouraged from using other safer materials, and Health Canada's own guidelines force dentists to contradict Health Canada's own policy statement regarding the need to avoid contact of amalgam with other metals.

   This all impacts the mercury exposure in population groups within Canada that are already exposed to excessive mercury and other environmental contaminants in their environment and foods.

9. Experts convened by the US FDA in December 2010 acknowledged many problems with dental amalgam.

   The transcripts of FDA's December 2010 meeting of an expert dental products panel that reviewed the issue of dental amalgam can be found on-line at: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/DentalProductsPanel/ucm235085.htm

Panel members made numerous statements and comments regarding dental amalgam, its safety or lack thereof, toxicity, etc. throughout the hearing. These comments highlight Panel members' concerns regarding the continued use of this dental material. Panel members included experts in toxicology, epidemiology, paediatrics and other relevant disciplines. Those comments included:

> DR. ZELIKOFF: "the FDA would be remiss in not looking into whether there is any long-term delayed effects in terms of disease manifestation from prenatal exposure."
>
> DR. KOTAGAL: [I] "really feel that we don't have any adequate neuropsychological information in preadolescent children there that we can rely on." AND "And I think that there really is perhaps no place for mercury in children."
>
> DR. RUE: "I feel that the safety issue from everything we've heard in the last 2 days still is in question. And especially when there are quite a few alternatives available."
>
> DR. BATES: "I think it's also important to … identify specifically particular endpoints and call for further studies to be done. And I would in that regard particularly like to mention the neurodegenerative diseases, MS, Alzheimer's and Parkinson's…. I can say that the data on these three outcomes are very inadequate and really one couldn't make any judgment whatsoever."
>
> DR. THOMPSON: "…I have serious concerns about this [amalgam] and think that really we have to look at informed consent; definitely not in pregnant women and definitely not in those below 6 years of age."
>
> DR. ISMAIL: "And children less than 6 years of age, I would restrict it [amalgam use] significantly"DR. BURBACHER: "So why put amalgams in children if we know they're going to live with that for the rest of their lives? And we don't know what that's going to do. So do we have to prove that before we stop doing it, is one question. I don't think we should."

10. The Precautionary Principal.

The Precautionary Principal, as published under the Canadian Environmental Protection Act, is explicit in the expectation of decisions that protect the Canadian population in the absence of absolute proof of safety or harm. With regard to the potential for harm associated with mercury exposure from dental amalgam, a substantive review of the evidence linking mercury exposure to Alzheimer's Disease and other degenerative neurological disorders was submitted to the FDA in 2009 and which contributed to the FDA's decision to convene its Expert Panel in December 2010. That review is available on-line at: http://www.regulations.gov/#!documentDetail;D=FDA-2008-N-0163-0291.

With respect to evidence of safety of dental amalgam, there is increasing reliance on a series of recent studies, collectively known as the Children's Amalgam Trials, as evidence for the safety of dental amalgam. Although these recent studies have evaluated the health significance of dental amalgam specifically in children receiving these fillings (Bellinger et al. 2006, 2007, 2008; DeRouen et al. 2006; Lauterbach et al. 2008), these studies represent sub-chronic exposure only. The follow-up period for the New England Children's Amalgam Trial has only been approximately 5 years to date. Follow-up on the Casa Pia Children's Amalgam Trial has been 7 to 8 years (depending on end point evaluated). However, Hg^0 accumulates with time in the body, and particularly in the brain (Mutter et al. 2007); the half life of Hg in the brain is on the order to decades, certainly much greater than 8 years. Also, the long latency for neurological effects of Hg exposure to arise (see Rice, 1996 with respect to methyl Hg, for example) further demonstrates the need for studies of greater duration upon which to establish the safety of this dental material. The Children's Amalgam Trial studies may eventually prove valuable in this regard, but only after repeated follow up for several additional years.

In these children's amalgam trials, the mercury level in urine was the primary measure of mercury exposure. Unfortunately, average urine Hg levels were equivalent in the control cohorts (receiving composite resin dental fillings) compared to the cohorts receiving amalgam (DeRouen et al. 2006; Bellinger et al. 2007). Any conclusion regarding safety of the mercury exposure associated with amalgam must be based on a comparison to a referent group with significantly less mercury exposure, not the same level of exposure. Therefore, the reported absence of statistical differences in the presence and frequency of effects between the exposed and control cohorts in these children's amalgam trials are neither scientifically defensible nor meaningful.

Contrary to the conclusion in one of the papers from the Casa Pia study (Woods et al., 2009) that there was no apparent relationship between amalgam load and alterations in urine chemistry (porphyrin levels), a more thorough analysis of that same data (Geier et al 2011) in fact revealed a dose-dependent relationship between urinary porphyrin levels and mercury exposure from amalgam. This indicates that the mercury exposure was affecting the heme synthesis pathway. Contrary to other claims of no effect of amalgam in the children of the Casa Pia study, additional re-evaluations currently in the publication process by these same authors (Geier et al.) further confirm dose-response relationships between amalgam-related mercury exposure and effects in the children who received amalgam fillings in this study.

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Yours truly,

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