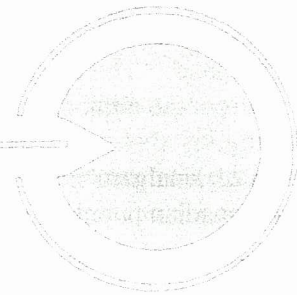


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HEALTH CANADA

DENTAL AMALGAM RISK ASSESSMENT

The long awaited Health Canada report entitled "Assessment of Mercury Exposure and Risks from Dental Amalgam" was made public on 27 November 1995 in conjunction with the first "Amalgam Stakeholder Meeting" in Toronto. Although the report does not represent official policy of the Canadian Government, it has been suggested that an official position will be taken after the second Stakeholder Meeting, which will be held in February of 1996.

The Risk Assessment report recommends the establishment of a "Tolerable Daily Intake (TDI)" for mercury vapor and suggests the number of dental amalgam fillings for various age groups that will not compromise the TDI. The synopsis of the report follows:

EXECUTIVE SUMMARY

"For Canadians with amalgam-filled teeth, it was estimated that total mercury (Hg) exposure averages: 3.3 Hg

mcg/day in toddlers (aged 3 to 4 years); 5.6 mcg Hg/day in children (aged 5 to 11 years); 6.7 mcg Hg/day in teens (aged 12 to 19 years); 9.4 mcg Hg/day in adults (aged 20 to 59 years); and 6.8 mcg Hg/day in seniors (aged 60+ years). Of this exposure, amalgam was estimated to contribute 50% to total Hg exposure in adults, and 32 to 42% for other age groups. Estimates, based on two independent models, of exposure from amalgam alone were: 0.8-1.4 mcg Hg/day in toddlers; 1.1-1.7 mcg Hg/day in children; 1.9-2.5 mcg Hg/day in teens; 3.4-3.7 mcg Hg/day in adults; and 2.1-2.8 mcg Hg/day in seniors.

There are insufficient published data on the potential health effects of dental amalgam specifically to support or refute the diverse variety of health effects attributed to it. Numerous studies constantly report effects on the central nervous system (CNS) in persons occupationally exposed to Hg. Virtually all studies failed to detect a threshold for the effects CNS measured. A tolerable daily intake (TDI) of 0.014 mcg Hg/kg body weight/day was proposed for mercury vapour, the principal form of mercury to which bearers of amalgam fillings are exposed. This TDI was based on a published account of sub-clinical (i.e. not resulting in overt symptoms or medical care) CNS effects in occupationally exposed men, expressed as slight tremor of the forearm. An uncertainty factor of 100 was applied to these data, to derive a reference dose (TDI) which should, in all probability, prevent the occurrence of CNS effects in non-occupationally-exposed individuals bearing amalgam fillings.

The number of amalgam-filled teeth, for each age group, estimated to cause exposure equivalent to the TDI were: 1 filling in toddlers; 1 filling in children; 3 fillings in teens; and 4 fillings in adults and seniors. It was recognized that filling size and location (occlusal versus lingual or buccal) may also contribute to exposure.

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However, data suggest that no improvement in prediction of exposure is offered by any particular measure of amalgam load. Therefore, the estimates of exposure derived from the number of filled teeth were considered as reliable as those that might be based on size and position of amalgam fillings, were such data available for the Canadian population.

Effects caused by allergic hypersensitivity to amalgam or mercury, including possible auto-immune reactions, can not be adequately addressed by any proposed tolerable daily intake. Individuals suspecting possible allergic or auto-immune reactions should avoid the use of amalgam by selecting suitable alternate materials in consultation with dental care (and possibly health care) professionals."

BIO-PROBE COMMENT: There are several dramatic features of this report. First and foremost, Dr. Richardson concludes that the daily exposure to mercury from amalgam fillings is not without possible health risk to patients. This is the same conclusion that was presented by the United States Public Health Service in 1994, which stated: "Thus, both MRLs are below estimated exposure levels from dental amalgam [USPHS. ATSDR. Toxicological Profile for Mercury (Update), TP-93/10, page 125]." The USPHS statement referred to its Minimal Risk Level (MRL) Standards for chronic and acute exposure to mercury vapor for the general population.

Dr. Richardson recommends a Tolerable Daily Intake (TDI) of 0.014 mcg Hg/kg body weight/day. This would translate to a daily intake of 0.98 micrograms of mercury/day for the average 70 kilogram (154 pound) adult. The USPHS established mercury vapor exposure MRLs and computed them to intake levels of 0.28 and 0.4 micrograms of mercury/day for chronic and acute exposure to mercury vapor. Most importantly, the USPHS MRLs are already a formal Standard of the United States Government, and therefore not subject to interpretation or dismissal.

The agreement between the USPHS and the Health Canada report is significant and dramatic; both determinations are well below the estimations of daily intake of mercury vapor from dental amalgam derived by both spokespersons of the dental profession (1.2-3.0 micrograms Hg/day) and medical scientific experts (mean of 10 micrograms Hg/day). Further, it should be pointed out the unknown levels of mucosal absorption of amalgam mercury are not considered in these conclusions. Of primary importance is the fact that these standards of the

governments of the United States and Canada are for the general population, not for just otherwise healthy adult workers limited to a maximum of forty hours per week of mercury vapor exposure. The dental profession continues to compare the continuous daily amalgam mercury exposure to "occupational" workroom standards (where, by the way, the mercury source is not implanted directly into the body), such as that of the United States OSHA (50 mcg Hg/m³ of air). This position of the dental profession is inexcusable!

The second dramatic feature of the Health Canada report is the calculation of mercury vapor intake related to age (i.e. average body weight) and the conversion of this to the maximum number of amalgam dental fillings in each age group that will not compromise the TDI. This factor has already received widespread attention in the Canadian media and has even been reported in the United States. Few reasonably prudent parents will believe that one mercury filling is totally harmless for their child, while two mercury fillings presents a possible health risk.

Another important feature of the Health Canada report is that it was peer-reviewed by a large international panel of experts before submission. Naturally, defenders of dental amalgam are attempting to undermine the report by claiming that it was not subject to peer-review; a spin that is patently false. Further, any person that reads the report in its entirety must be impressed by the monumental effort and documentation supporting Dr. Richardson's conclusions.

Finally, the Health Canada report concisely summarizes the weak foundation for the safety of dental amalgam. In the Introduction, the report states: "There is considerable debate and controversy as to the validity of reports of illness associated with dental amalgam (Weiner et al. 1990; Molin 1992; Eley and Cox 1993; Berry et al. 1994; and others). Their onset has been attributed to psychosomatic factors (Swedish National Board of Health, 1994), and the remission or elimination of effects following amalgam removal has been attributed to placebo effect (Englund et al. 1994). However, there have been no properly controlled and conducted clinical investigations that provide unequivocal data to support or refute health hazards attributed to this dental material. Despite the recognition of the lack of adequate clinical studies as early as 1931 (Souder and Sweeney 1931), again in 1987 (Enwonwu 1987), and in 1990 (Weiner et al. 1990), appropriate studies have not been initiated by