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Commentary

Opinion on environmental risks and indirect health effects of mercury from dental amalgam



Regulatory Toxicology and Pharmacology

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Dental amalgam has been used for over 150 years for the treatment of dental cavities and is still used, in particular, for the treatment of large cavities due to its excellent mechanical properties and durability. Dental amalgam is a combination of alloy particles and mercury and contains about 50% of mercury in the elemental form.

Most aspects of the mercury life cycle are addressed in the Community Strategy Concerning Mercury which key aim is to reduce mercury levels both in relation to human exposure and the environment. Pursuant to Action 6 of the Strategy, the use of dental amalgam should be evaluated with a view to considering whether additional regulatory measures are appropriate. The Commission consulted the independent Scientific Committee on Health and Environmental Risks (SCHER) on the environmental risks and indirect health effects of mercury from dental amalgam (see http://ec.europa.eu/health/scientific_committees/environmental_risks/).

In the 2008 Opinion on the environmental risks and indirect health effects of mercury from dental amalgam, the SCHER concluded that only a preliminary screening risk assessment was possible, based on existing knowledge at the time³. As new evidence has become available, this has been evaluated to determine whether the risk assessment provided in the 2008 opinion needed updating. In particular, the SCHER was requested to assess (i) the risk to the environment of mercury releases caused by the use of dental amalgam, (ii) whether it is scientifically justified to conclude that mercury in dental amalgam could cause serious effects on human health due to mercury releases into the environment, and (iii) the environmental risk caused by the use of mercury in dental amalgam compared to that of the use of alternatives without mercury⁴.

The concentration of mercury in surface water was estimated considering three possible scenarios. The Predicted Environmental Concentrations (PECs) calculated in the three scenarios have been compared with the Water Framework Directive

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³ http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_089.pdf

⁴ http://qec.europa.eu/health/scientific_committees/environmental_risks/docs/ scher_o_165.pdf

(WFD) Environmental Quality Standards (Annual Average (AA) EQS and Maximum Allowable Concentration (MAC) EQS) that have been set for mercury. The comparison enables the conclusions stated below:

- best case scenario: the PEC is negligible in comparison to both EQS;
- average case scenario: the PEC is one order of magnitude below the AA EQS;
- worst case scenario: the PEC is substantially above both AA and MAC EQS.

Methylation in the aquatic ecosystem and mercury accumulation in fish have also been estimated. According to the three proposed scenarios and based on five hypothetical values for the methylation rate (between 0.0001% and 1%), the following conclusions are derived:

- best case scenario: all the calculated concentrations are far below the acceptable level in fish as well as the WFD threshold for secondary poisoning;
- average case scenario: all the calculated concentrations are far below the acceptable level in fish, however, the WFD proposed threshold for secondary poisoning is exceeded at methylation rates higher than 0.05%;
- worst case scenario: the acceptable level in fish is exceeded (or at least approached) at methylation rates higher than 0.1%, while the WFD threshold for secondary poisoning is also exceeded at methylation rates higher than approximately 0.005% (see http://ec.europa.eu/health/ph_risk/committees/ 04_scher/docs/scher_o_089.pdf).

The SCHER concluded that, in the worst case scenario, under extreme local conditions, a risk of secondary poisoning due to methylation cannot be excluded. These risks depend on the methylation rate of inorganic mercury which may differ with exposure conditions. For the soil and air compartment a quantitative PEC cannot be estimated and an assessment of local risk is not possible due to insufficient relevant exposure data.

Regarding the risk for human health due to environmental mercury in soil and air originating from dental amalgam use, it can be concluded that this emission fraction of Hg represents a very minor contribution to total human exposure from soil and through inhalation.

Regarding the contribution of amalgam use to the concentrations of methyl mercury in fish, any calculation is affected by a high degree of uncertainty and based on a number of assumptions. However, a screening assessment was undertaken using a provisional risk assessment for surface water based on five hypothetical values for the methylation rate in three possible scenarios (worst, average and best case). In the best and the average cases, the expected methyl mercury concentrations in fish related to contributions of dental amalgam uses are well below maximum tolerable content of methyl mercury in fish. In the worst case scenario, the values obtained with the two highest methylation rates exceeded the threshold. Thus, in the worst case, mitigation measures are expected to be needed to reduce the risk. Further, the WFD's threshold for secondary poisoning is exceeded at methylation rates higher than 0.005%. Therefore, compliance with the WFD threshold would contribute to the prevention of human health effects (see http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_165.pdf).

With regard to human health, the SCHER is of the opinion that the conclusions of the 2008-opinion are still valid. For health effects due to alternative materials particularly the potential leakage of bisphenol A (Bis-DMA), the SCHER recommends referring to the SCENIHR opinion on the use of bisphenol A in medical devices⁵.

For the environment, considering the probably low level of emissions and the relatively low toxicity of the chemicals involved, it is reasonable to assume that the ecological risk is low. However, it is the opinion of the SCHER that, at present, there is no scientific evidence for supporting and endorsing these statements. Therefore, more research on alternative materials is recommended.

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⁵ http://ec.europa.eu/health/scientific_committees/emerging/opinions/index_en. htm