

E-6715/08EN  
Answer given by Mr Verheugen  
on behalf of the Commission  
(11.2.2009)

According to the opinion of the Scientific Committee on Emerging and Newly identified Health Risks (SCENIHR) adopted in May 2008<sup>1</sup>, dental amalgam is an effective restorative material which may be considered as the material of choice for some restorations.

The SCENIHR opinion is limited to the safety of mercury when used in dental amalgam. As indicated in the opinion, mercury in general does constitute a toxicological hazard with reasonably well defined characteristics for the major forms of exposure and it is accepted that the reduction in use of mercury in human activity would be beneficial, both for the decrease in indirect human exposure and environmental considerations.

There have been claims of causation with respect to a variety of systemic conditions, particularly neurological and psychological/psychiatric effects, including Alzheimer's, Parkinson Disease, Multiple Sclerosis and also kidney disease. However, the available academic studies on human population, including some very recent epidemiological studies, did not confirm a causal link with respect to a variety of systemic conditions, or an association between the use of amalgam and neuropsychological development in children. It is recognized that some local adverse effects are occasionally seen with dental amalgam fillings, including allergic reactions, but the incidence is low and normally readily managed. Therefore, SCENIHR does not consider that the current use of dental amalgam poses a risk of systemic disease.

Denmark has notified its intent to prohibit, with certain specified exceptions, the use of mercury, including dental amalgam, on the basis of environmental considerations. The Commission did not oppose the Danish previous measures against mercury which were strictly based on environmental considerations under specific environmental circumstances. The most recently notified amendments are currently under the Commission's examination.

As regards Sweden, the compatibility of the ban on mercury, including dental amalgam, with Community law is under scrutiny by the European Court of Justice (C-288/08), following a Swedish court's request for a preliminary ruling under Article 234 EC of the Treaty. The Commission is also handling a complaint introduced by an economic operator against the Swedish ban on export of dental amalgam.

Concerning Norway, the **European Free Trade Association (EFTA)** Surveillance Authority and the Commission on behalf of the European Community have provided detailed comments on the Norwegian notification concerning the general ban on mercury that includes dental amalgam. However, it is a responsibility of the EFTA Surveillance Authority to ensure that the European Economic Agreement is properly enacted and applied by the EFTA countries. The Commission has not been informed of any infringement or court procedures against the Norwegian ban on mercury.

The United States (US) Food and Drug Administration (FDA) has introduced modifications in the "Questions and Answers on Dental Amalgam" posted on its website. The revised version indicates that mercury may have neurotoxic effects on the nervous systems of sensitive populations and that when amalgam fillings are placed or removed, they release mercury vapour. However, FDA does not conclude that mercury-containing dental amalgams are unsafe. FDA indicates that they will re-examine this specific concern.

Based on the SCENIHR recent opinion, which took into consideration the academic and scientific literature available during the time of the development of the opinion, as well as the contributions received through the call for information and public consultation published on the website of the

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<sup>1</sup> For further information, see weblink:  
[http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihhr/scenihhr\\_opinions\\_en.htm](http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/scenihhr_opinions_en.htm)

Directorate-General for Health and Consumers (DG SANCO), the Commission does not consider that regulatory measures to limit the use of mercury-containing dental amalgams are justified, on the basis of current science and knowledge. The Commission will monitor scientific developments in these fields and will re-examine the need to take appropriate measures if and when further scientific evidence on the potential health risks of dental amalgam becomes available.