

Scientific Committee on Human and Environmental Risks

Request for a scientific opinion

on the environmental risks and indirect health effects of mercury in dental amalgam

1. Background

Dental amalgam and its substitutes are regulated under Council Directive 93/42/EEC¹ concerning medical devices, according to which they must comply with the essential requirements laid out in the directive, in particular in relation to the health and safety of patients.

Dental amalgam has been used for over 150 years for the treatment of dental cavities and is still used, in particular in large cavities due to its excellent mechanical properties and durability. Dental amalgam is a combination of alloy particles and mercury that contains about 50% of mercury in the elemental form. Overall, the use of alternative materials such as composite resins, glass ionomer cements, ceramics and gold alloys, is increasing, either due to their aesthetic properties or alleged health concerns in relation to the use of dental amalgam.

On 28 January 2005, the Commission adopted the Communication to the Council and the European Parliament on a Community Strategy Concerning Mercury². The Strategy addresses most aspects of the mercury life cycle. Its key aim is to reduce mercury levels both in relation to human exposure and the environment. It identifies twenty priority actions to be undertaken, both within the EU and internationally. The Strategy was welcomed by Council Conclusions on 24 June 2005 as well as by a European Parliament Resolution on 14 March 2006. 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 services consulted two Scientific Committees on the use of dental amalgam, the Committee for Environmental and Health Risks (SCHER) and the Committee for Emerging and Newly Identified Health Risks (SCENIHR). The opinions^{3,4} of both Committees were not conclusive regarding the appropriateness of additional regulatory measures to restrict the use of dental amalgam.

Concerning the environmental aspects, the SCHER opinion concluded that on the basis of the information available, it was not possible to "comprehensively assess the environmental risks and indirect health effects from use of dental amalgam in the Member States of the EU 25/27", and identified a number of gaps that would have to be addressed.

¹ OJL169, 12.7.1993, p.1

² COM(2005)20 final

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

⁴ http://ec.europa.eu/health/archive/ph_risk/committees/04_scenihhr/docs/scenihhr_o_016.pdf

In the 2005 communication, the Commission had already expressed its intention to undertake a review of the Mercury Strategy by the end of 2010. To this effect, the Commission requested an external contractor, Bio Intelligence Service, to prepare a study, examining the progress of its implementation, assessing the success of the policies and corresponding measures, and proposing additional actions, if needed. The report produced, "Review of the Community Strategy Concerning Mercury"⁵, identified Actions 4 and 6 of the Mercury Strategy, both linked to dental amalgam, as areas where substantial improvement could still be achieved.

The Commission issued a new Communication⁶ to the European Parliament and the Council on the review of the Community Strategy Concerning Mercury on 7.12.2010. Given that some Member States have already substantially restricted the use of dental amalgam in their national health care systems and given that dental amalgam represents the second largest use of mercury in the EU, the Commission expressed its intention to further assess the use of mercury in dental amalgam with due consideration to all aspects of its lifecycle.

This assessment has now been concluded under a contract with Bio Intelligence Service, including a stakeholder consultation in March 2012. The final report⁷ focuses mainly on the environmental impacts of dental amalgam use and seeks also to address to the extent possible the gaps identified in the SCHER 2008 opinion.

There is an international dimension that needs to be considered too. The Governing Council of the United Nations Environment Programme (UNEP) established in 2009 an intergovernmental negotiating committee (INC) with the mandate to prepare a global legally binding instrument on mercury. The Committee has started its work in 2010 with the goal of completing it, prior to the 27th regular session of the UNEP Governing Council in 2013. The Commission represents the European Union in these negotiations and strives for a comprehensive multilateral environmental agreement. Dental amalgam is among the products that are likely to be regulated under the Convention. The last negotiation round (INC5) is scheduled for mid-January 2013. Following discussions in the Council Working Party on International Environmental Issues, the Commission has undertaken the coordination of work on this issue in cooperation with experts of the Member States with a view to assessing the feasibility of a phase down of the use of dental amalgam and identifying the required conditions such as a clear timeline and well-defined exceptions. Timely input from SCHER would be very important to help inform these discussions in view of establishing a common EU position for INC5.

In light of the above we would like to ask the Scientific Committee on Health and Environmental Risks (SCHER) to update, if appropriate, the opinion adopted in 2008. We are well aware of the volume of work entrusted to SCHER and of the complexity of the analysis needed to provide a scientifically valid opinion. Nevertheless, given the need for the EU to form a common position in view of the international negotiations mentioned above, we would like to kindly ask you to deliver an opinion (or at least a preliminary one) no later than the end of November 2012.

⁵ http://ec.europa.eu/environment/chemicals/mercurv/pdiyreview_mercurv_strategv2010.pdf

⁶ Communication from the Commission to the European Parliament and the Council on the review of the Community Strategy Concerning Mercury, COM(2010)723final

⁷ http://ec.europa.eu/environment/chemicals/mercurv/pdiyFmal_report_11.07.12.pdf

2. Terms of reference

Taking into consideration recent developments, the SCHER is requested to review and update, if appropriate, the scientific opinion adopted in May 2008 on "The environmental risks and indirect health effects of mercury in dental amalgam ".

In particular, the Scientific Committee is requested to consider the following questions:

- Are mercury releases caused by the use of dental amalgam a risk to the environment? The fate of mercury released from dental clinics as well as the fate of mercury released to air, water and soil from fillings placed in patients should be taken into account.
- Is it scientifically justified to conclude that mercury in dental amalgam could cause serious effects on human health due to mercury releases into the environment?
- Comparison of environmental risk from the use of mercury in dental amalgam and the use of alternatives without mercury

3. Deadline

November 2012