Scientific Committee on Emerging and Newly Identified Health Risks

Request for a scientific opinion

on the safety of dental amalgam and alternative dental restoration materials for patients and users

1. Background

Dental amalgam and its substitutes are regulated under Council Directive 93/42/EEC 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 the 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 related to the use of dental amalgam.

In January 2005, the Commission adopted a proposal for a Community Strategy concerning Mercury[2] in order to reduce mercury levels in the environment and human exposure. 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.

In view of the above, the Commission requested the opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on the safety of dental amalgam and alternative dental restoration materials. According to the SCENIHR opinion adopted in May 2008, dental amalgam is a safe material to use in restorative dentistry for patients. No health risk other than allergic reaction in certain individuals can be associated with the use of dental amalgam. The alternatives are not without clinical limitations and toxicological hazards and less is known about these alternatives for which available scientific data are more limited.

In 2010 a report of the meeting convened by WHO on "Future Use of Materials for Dental Restoration" was published, in which a 'phase-down' of the use of dental amalgam at the global level was suggested. According to the report this may be achieved effectively by strengthening the prevention of dental caries and by encouraging better use of quality alternatives to dental amalgam. More quality studies and systematic reviews are needed in the case of dental materials alternatives to amalgam.
A recent "Study on potential for reducing mercury pollution from dental amalgam and batteries" (May 2012) addresses the environmental impacts of dental amalgam use (http://ec.europa.eu/environment/chemicals/mercury/pdf/BIO_Draft%20final%20report.pdf). The study is not conclusive on the health aspects.

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11.
Office: DM24 2/82. Telephone: direct line (32-2) 295 57 38 Fax: (32-2) 296.64.67.

2. Terms of reference

In the light of recent developments and studies on dental amalgam we would like to ask the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to update, if appropriate, the opinion adopted in 2008. In view of possible safety concerns linked to the use of dental amalgam and its substitutes, it is essential to review and evaluate available scientific data related to the safety of these substances for patients and in particular for high risk groups.

In particular, the SCENIHR is asked the following questions:

1. Is there any new scientific evidence that justify reasons for concern from the health point of view in the use of dental amalgam as dental restoration material?

2. In view of the above, is the use of dental amalgam safe for patients and users, i.e. dental health professionals? Are certain populations particularly at risk, e.g. pregnant women or children? Is it possible to recommend certain practices to minimize patient's and user's exposure to dental amalgam?

3. Is there new scientific evidence on the safety and performance of alternative materials?

4. Is it possible to recommend alternative materials and certain practices related to these materials to reduce potential risks for patients and users?

5. In case there is not enough scientific data to answer these questions, the SCENIHR is asked to formulate recommendations for research that could help to provide the necessary data.

3. Deadline

February 2013.