

## Scientific Committee on Health and Environmental Risks (SCHER)

**Request for a scientific opinion on: Critical review of any new (after 2005) evidence on the hazard profile, health effects, and human exposure to fluoride, and assessment of the risks that may be associated with the use of most common drinking water fluoridation agents like silicofluorides (e.g. (hydro)fluorosilicic acid, sodium silicofluoride)**

### 1. Background

Fluoride is not considered to be essential for human growth and development but it is beneficial in the prevention of dental caries (tooth decay). As a result, intentional fluoridation of drinking water and the development of fluoride containing oral care products (toothpastes and mouth rinses), foods (fluoridated salt) and supplements (fluoride tablets) have been employed since the early 20th century in several parts of the world as a public health protective measure against tooth decay. Additional exposure to fluoride comes from naturally occurring fluoridated water (tap and mineral) beverages, food, and to a lesser extent from other environmental sources (e.g. air).

While no one doubts the beneficial effects of fluoride, a body of scientific literature seems to suggest that excessive intake of fluoride may be associated with a number of negative health effects. Dental fluorosis and effects on bones (increased fragility and skeletal fluorosis) are two well documented adverse effects of excessive intake of fluoride. Systemic effects following prolonged or high exposure to fluoride have also been reported and more recently effects on the thyroid and an association with certain types of osteosarcoma (bone cancer) have been reported more recently but have not been properly documented.

Individual and population exposures to fluoride vary considerably and depend on the high variability in the levels of fluoride found in tap (be it natural or the result of intentional fluoridation of drinking water) and mineral waters, and on individual dietary and oral hygiene habits and practices. Hence an exposure assessment of humans to fluoride taking into account all possible sources carries a high level of uncertainty and compromised by the sheer number of exposure scenario permutations that are possible given the multitude of exposures. Hence a scenario driven sensitivity analysis exposure assessment was conducted in the most recent (2005) evaluations by the European Food Safety Authority (EFSA) (setting Tolerable Upper Intake Levels and related to concentration limits for fluoride in natural mineral waters), and the Commission Scientific Committee on Consumer Products (fluoride in oral care products). A similar approach was taken by the National Research Council of the United States National Academies of Science in its 2006 review of the United States Environmental Protection Agency's water standards for fluoride.

The emerging picture from all risk assessments conducted on fluoride is that there 'exists a narrow margin between the recommended intakes for the prevention of dental carries and the upper limits of exposure and invariably all assessments to date call for continued monitoring of the exposure of humans to fluoride from all sources and an evaluation of new scientific developments on its hazard profile.

The potential for negative health effects that may result from excessive intake, have put in question the practice of intentional water fluoridation and in some parts of the European Union and elsewhere (USA). Besides questioning the practice of water fluoridation itself as being unnecessary or superfluous in light of the high relative exposure from other sources, opponents of water fluoridation, have pointed to scientific evidence showing one of the most

common fluoridating agents, hydrofluorosilic acid has not been properly assessed for safety and point to evidence that it may exacerbate fluoride bone metabolism and toxicity.

The debate over water fluoridation has prompted several questions from the European Parliament from Ireland and the United Kingdom where intentional water fluoridation is still practiced.

In order to obtain an updated advice on the issue, the Commission considers it necessary to seek the advice of its Scientific Committee on Health and Environment Risks who should work in close collaboration with the Scientific Committee on Consumer Safety (SCCS) and the EFSA NDA and CONTAM panels who have previously delivered opinions on fluoride.

## **2. Terms of reference**

Taking as the basis the SCCP opinion of 20.09.05<sup>1</sup> on the safety of fluorine compounds in oral hygiene products, the EFSA NDA opinion of 22.02.2005<sup>2</sup> on the Tolerable Upper Intake Level of Fluoride, and the EFSA CONTAM panel opinion of 22.06.05<sup>3</sup>, the Scientific Committee on Health and Environment Risks (SCHER) is requested to:

- (1) Critically review any information that has become available in the public domain since 2005 on the hazard profile and epidemiological evidence of adverse and/or beneficial health effects of fluoride.
- (2) If supported by information that has become available in the public domain since 2005 concerning the exposure of humans to fluoride from all sources, conduct an integrated exposure assessment for fluoride covering all known possible sources (both anthropogenic and natural). In doing so and in the case of uncertainties or lack of actual exposure data, the SCHER is requested to include a sensitivity analysis that includes a range of possible exposure scenarios (e.g. sources, age groups), and describe using appropriate quantitative or qualitative means the weight of the evidence behind each scenario, the uncertainties surrounding each scenario, and the probability of it occurring in real life.
- (3) On the basis of its answers to (1) and (2) above, pronounce itself as to whether there may be reasons for concern arising from the exposure of humans to fluoride and if so identify particular exposure scenarios that may give rise to concern in particular for any particularly sensitive population subgroups. In doing so the SCHER is asked to take into account the potential benefits of fluoride in tooth decay prevention.
- (4) Identify any additional investigative work that need to be done in order to fill data gaps in the hazard profile, the health effects and the exposure assessment of fluoride.
- (5) Assess the risks that may be associated with the use of hydrofluorosilic acid in the fluoridation of drinking water taking into account its hazard profile, its mode of use in water fluoridation, its physical chemical behaviour when diluted in water, and the possible effects it may have in exacerbating fluoride health affects as reported in some studies.

## **3. Deadlines**

-----

---

<sup>1</sup> [http://ec.europa.eu/health/ph\\_risk/committees/04\\_sccp/docs/sccp\\_o\\_024.pdf](http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_024.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620766918.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620766918.htm)

<sup>3</sup> [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620762415.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620762415.htm)