

EADPH response to SCHER pre-consultation opinion

Critical Review of any new evidence on the hazard profile, health effects, and human exposure to fluoride and the fluoridating agents of drinking water

FINAL VERSION (SUBMITTED SEPT 22TH, 2010)

Global remarks

- This document presents a proposal of reply to the pre-consultation opinion adopted by SCHER (Scientific Committee on Health & Environmental Risks) at its 7th plenary on May 18th, 2010. Responses are due by Wednesday September 15th and should be delivered using a pre-determined questionnaire (on-line submission). For each question a level of agreement should be indicated (agree, mostly agree, mostly disagree, disagree, uncertain) and when the option 'disagree' or 'mostly disagree' is chosen, an explanation is compulsory.
- Although the timing of launching the consultation was unfortunate (summer period) and the period was limited in time, not allowing in depth analysis and discussion, EADPH wants to express its concern regarding several aspects of the document.
- The SCHER-document contains several inconsistencies, inaccuracies and even contradictions. The wording with respect to certain parts is unfortunate and not consistent, leading to confusion and possible misinterpretation. It is strongly felt that the document needs more work before a final version can be adopted.
- It is felt that the document would benefit from having more than one dental adviser on the committee. It is clear that the interface with dental issues can be improved considerably.

Answers to questions

QUESTION 1-A:

Critically review any information that is available in the public domain on the hazard profile and epidemiological evidence of adverse and/or beneficial health effects of fluoride.

= Do you agree with the observations made by the SCHER? mostly disagree,

= Explain: unsatisfactory conclusion from scientific point of view, relevant information missing

- It is well-known that fluoride can exert **effects** both locally (direct contact with oral environment, ie saliva, plaque and tooth surface) and systemically (distribution via blood stream). With regard to impact on dental health, both these pathways need to be distinguished. This should not be confused with the **route of administration**, which can be topical or by systemic route (ingestion). It should be made clear that either way of administration exerts both local and systemic effects. Fluoride containing water first passes the oral cavity before being ingested, therefore there will be both a local and systemic effect when using this source of fluoride. On the other hand, toothpaste containing fluoride will have a local effect when applied on the tooth surfaces, but a proportion of the paste will be swallowed and through this way also exert a systemic effect. In the proposed SCHER-document the terms 'local/topical' and 'systemic' do not take this into account and are used in a non-consistent way.
- A **distinction** needs to be made between health-threatening effects and effects that are more a cosmetic issue, as is the case for levels of dental fluorosis encountered in Europe.
- In addition, it should be highlighted that the clinical symptoms described as 'mild fluorosis' should be referred to as "**developmental defects of enamel (DDE)**". These symptoms are the result of factors impairing the mineralization of enamel that worked during the time-limited critical period of the enamel development and not afterwards. High fever infections, calcium and vitamin D intake deficiency, some antibiotics, inherited renal deficiency and also fluoride

intake belong to those factors working very often jointly. Since these symptoms can also be related to other causative agents or events (eg systemic disorders (Atar & Körperich, 2010); use of amoxicillin (Hong et al, 2005)), it is probable that **misclassification** of enamel developmental defects as (mild) dental fluorosis occurred in a number of surveys with inflation of prevalence data as a result.

- The SCHER-document states that 'fluoride cannot be classified as to its carcinogenicity'. This is rather suggestive and should be re-formulated as 'fluoride is not classified as carcinogenic'.
- The second part of question 1-a (and/or **beneficial health effects**) has not been answered in the SCHER-document, although a lot of evidence regarding this topic is available.

(References to be attached)

QUESTION 1-B

Conduct an integrated exposure assessment for fluoride covering all known possible sources (both anthropogenic and natural).

= Do you agree with the observations made by the SCHER? mostly disagree,

= Explain: unsatisfactory conclusion from scientific point of view

- The Council Directive 98/83/EC of 3 November 1998 on the quality of water for human consumption determines the maximum fluoride concentration of drinking water at 1.5 mg/L. Bottled waters containing more than 1.5 mg F/L must be labeled as not suitable for the preparation of infant formula (Commission Directive 2003/40/EC of 16 May 2003). The use of tap water is generally not recommended for this purpose. It is therefore highly unlikely that water with higher (than 1.5 mg/L) fluoride levels will be consumed in large quantities by young children. If so, the associated risk (developing mild dental fluorosis) is more a cosmetic issue and **needs to be balanced** against the health impact of developing (more) caries lesions (and associated need for dental treatment).
- The **worst case scenario** for fluoride intake (3 mg/l), while relevant for natural fluoridation is **not relevant** to water fluoridation at 1 mg/l, and that this should be clear in the text and summary. Using the normal level for artificial water fluoridation of 1 mg/l, the upper tolerable level will not be reached in any age group.
- Both the York review (Mc Donagh et al, 2000) and the Cochrane review of toothbrushing in adolescents (Marinho et al, 2003) show that water fluoridation is complementary to toothbrushing and can be safely carried out together.

(References mentioned already included in reference list)

QUESTION 1-C1

To evaluate the evidence of the role of fluoride in tooth decay prevention and rank the various exposure situations as to their effectiveness in offering a potential tooth decay preventive action.

= Do you agree with the observations made by the SCHER? mostly disagree,

= Explain: unsatisfactory conclusion from scientific point of view, relevant information missing

- See reply to question 1-a regarding differentiation of topical/local and systemic application and effect. It is clear that these terms were confused in the document and lead towards incomplete, even wrong conclusions.
- There is also the need to differentiate between those fluoride vehicles which **require no effort** of the part of the individual to benefit (water fluoridation) and those that require action or a behaviour change such as toothbrushing or attendance at a dentist.

- Misclassification of enamel developmental defects as mild dental fluorosis (see also reply to question 1-A) needs to be considered.
- The **impact of having dental caries** with regard to the individual affected (discomfort, impact on general health, costs, quality of life, ...) and society (economic impact,...) is important and should be mentioned in the document.
- The impact of population-based fluoride regimens (such as water fluoridation) on the reduction of **oral-health social disparities** is hardly mentioned in the document.
- **Benefits to adults** should be mentioned with the systematic review by Griffin et al (2007).
- The **graph on page 27** of the report (from the Cheng et al 2007 paper) originates from an opinion paper which has been widely criticized on the BMJ website.

The graph uses data for many countries from the WHO CAPP website which takes data from many sources. The inconsistency of the methods used to collect the data over time and over different countries needs to be taken into account, or at least mentioned.

The graph also seems to show only a best fit line for each country and not the actual data from the website. For instance Austria showed a rise in mean DMFT of 12-year-olds, between 1978 and 1988 which is not reproduced on the graph (see <http://www.whocollab.od.mah.se/euro/austria/data/austriacar.html>).

Also, some data is only for regions (Canton of Zurich instead of Switzerland, Flanders and not Belgium, England & Wales instead of UK data).

It should be mentioned that the footnote to the figure (Figure 2) is incomplete. The authors say correctly that the figure contains an error with regard to Germany. It is correct to say that water fluoridation was not practiced in West Germany and only in some regions in East Germany. But salt fluoridation was introduced in reunified Germany in 1991. Thus it is not correct to say "Germany should be placed under "no water fluoridation". Germany should be placed under "salt fluoridation". Also the footnote should add that Switzerland was not included in the Figure; Switzerland should be placed under "salt-fluoridation". Only the Swiss Canton Basle practiced water fluoridation between 1961 and 2003. In addition, it should be mentioned that the data presented on DMFT-values for Belgium refer to the northern part of the country (Flanders) and salt fluoridation has been available (in limited amounts) only in the southern part of the country; For this reason, Belgium should be mentioned as "no water fluoridation".

If SCHER want to use this data they should go to the original data from the WHO website to produce their own analysis instead of relying on an opinion piece with proven errors.

(References mentioned already included in reference list)

QUESTION 1-C2

To 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 particular population subgroup.

= Do you agree with the observations made by the SCHER? mostly disagree,

= Explain: unsatisfactory conclusion from scientific point of view

- We reiterate that a **distinction** needs to be made between health-threatening effects and effects that are more a cosmetic issue, as is the case for levels of dental fluorosis encountered in Europe.

- The statement on skeletal fluorosis is **irrelevant** since this disease entity does not occur in Europe. In addition, skeletal fluorosis is often caused by the combination of excessive fluoride intake and calcium/vitamin D intake deficiency, parathyroid hypofunction or plasma phosphate impaired regulations and this should be taken into account as well.

QUESTION 1-D

Identify any additional investigative work that needs to be done in order to fill data gaps in the hazard profile, the health effects and the exposure assessment of fluoride.

= Do you agree with the observations made by the SCHER? mostly agree,

Epidemiological studies investigating the oral health effects of fluoride (in water) in different population groups are needed (eg adults, elderly, special needs groups...), including risk-benefit analyses, and this against the background of the widespread availability of fluoridated toothpaste.

QUESTION 2

Assess the health and environmental risks that may be associated with the use of the most common drinking water fluoridation agents like silicofluorides (e.g. (hydro)fluorosilicic acid, sodium silicofluoride, disodium hexafluorosilicate or hexafluorosilicate or hexafluorosilicic acid) taking into account their hazard profiles, their mode of use in water fluoridation, their physical chemical behaviour when diluted in water, and the possible adverse effects they may have in exacerbating fluoride health effects as reported in some studies.

= Do you agree with the observations made by the SCHER? Agree.

SUMMARY

Fluoride, either naturally present or intentionally added to water, food and consumer products, e.g. toothpaste, is generally considered beneficial to prevent dental caries. Considering previous opinions from EFSA and SCCP, SCHER has reviewed the newest information in the area on risk and benefit of using fluoridated drinking water and intake of fluoride from all sources.

SCHER concludes:

- Hydrolysis of hexafluorosilicates used to drinking water fluoridation to fluoride was rapid and the release of fluoride ion was essentially complete. Therefore, the fluoride ion is considered the only relevant substance with respect to this opinion.
- There is a risk for dental fluorosis in children in EU countries with systemic fluoride exposure, but a threshold cannot be detected.
- The occurrence of endemic skeletal fluorosis has not been reported in EU.
- There is equivocal evidence linking fluoride in drinking to the development of osteosarcoma.
- Fluoride intake from drinking water does not hamper children's neurodevelopment and impairs IQ at the level occurring in EU.
- Human studies do not suggest adverse thyroid effects at realistic human exposures to fluoride.
- No new evidence from human studies indicating that fluoride in drinking water influences male and female reproductive capacity.
- The upper tolerable intake level (UL) is not exceeded for adults and children between 12 and 15 living in areas with fluoridated drinking water (<0.8 mg/L).
- The UL was exceeded in children between 6 and 12 years living in areas with fluoridated drinking water (<0.8 mg/L) when consuming up to 1 L water and using adult toothpaste (1.5%) unsupervised.
- The UL is exceeded in children between 1 and 6 years living in areas with fluoridated drinking water (<0.8 mg/L) when consuming up to 0.5 L water and using adult toothpaste (1.5%) unsupervised.

- Water fluoridation as well as topical fluoride treatments (e.g. fluoridated toothpaste or varnish) appears to prevent caries, primarily on permanent dentition, but topical application is the more efficient measure.
 - In children a very narrow margin exists between achieving the maximal beneficial effects of fluoride in caries prevention and the adverse effects of dental fluorosis.
 - Exposure of environmental organisms to levels of fluoride as used in fluoridation of drinking waters are not expected to lead to unacceptable risks to the environment.
- = Do you agree with the observations made by the SCHER? mostly disagree
- = Explain: unsatisfactory conclusion from scientific point of view

- Several inconsistencies are present in the conclusions. Following statements are incorrect and contradictory to those mentioned in the earlier paragraphs of the document:
 - Item 5: Fluoride intake from drinking water does not hamper children's neurodevelopment and DOES NOT impair IQ at the level occurring in the EU (words in capitals should be added).
 - Item 9: UL in children between 6 and 12 years: Is exactly the opposite of what was stated in the document on page 26.
 - Item 10: UL in children between 1 and 6 years: Is exactly the opposite of what was stated in the document on page 26.
- The contribution of fluoride exposure to mild fluorosis needs to be defined (see also reply to question 1-A).
- Toothpaste with fluoride levels of 1.5% should be labeled as not suitable for use in small children. In addition, the need for supervision by an adult while brushing should be mentioned.
- There needs to be separation of dental fluorosis and skeletal fluorosis. This is done in the text of the preliminary opinion, but the summary incorrectly links the two conditions.
- Benefits to deciduous teeth should be emphasised as the conclusion (number 10 on page 36) states the preventive benefit is primarily on the permanent dentition..

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